TRILLIUM II

Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary

WP5

D5.2 Towards an international patient summary standards Governance Framework: managing requirements, intelligence gathering, and updates-WP5-CEN

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Deliverable description

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Change History

Version	Date	Author	Organisation	Description
0.1	20-06-2017	Robert Stegwee	CEN	First outline of content to be filled by partners
0.2	23-06-2017	Shirin Golyardi	CEN	Added ethical considerations
0.3	29-06-2017	Stephen Kay	CEN	Added perspectives on governance
0.4	30-06-2017	Robert Stegwee	CEN	Final review and edits for interim version
0.5	12-02-2019	Robert Stegwee	CEN	Draft description of framework and findings from interviews
0.6	19-02-2019	Robert Stegwee	CEN	Incorporated WP5 member comments and suggestions
0.7	25-02-2019	Robert Stegwee	CEN	Incorporated PEC comments and suggestion; completed Appendix I
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0.9	06-03-2019	Robert Stegwee	CEN	Incorporated final detailed comments from scientific coordinator
0.9.1	13-03-2019	Robert Stegwee	CEN	Incorporated recommendations from review on clarity and conciseness of descriptions and recommendations
1.0	15-03-2019	Janne Rasmussen	MEDCOM	Final QA and submission

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Deliverable overview

Objectives

The objective of the deliverable as set out in DoA is to outline the road towards an international patient summary standards Governance Framework, incl. managing requirements, intelligence gathering, and updates, which is sustainable.

The deliverable builds on 'Task 5.3: Promote sustainable governance for the IPS engaging SDOs through the JIC' and 'Task 5.4 Contribute feedback from implementation to align Patient Summary Standards sets in SDOs'.

Content

Deliverable 5.2 Towards an international patient summary standards Governance Framework fulfils the objective by presenting:

- The IPS and governance background (chapter 1), incl. methodology (chapter 2);
- The need for governance (chapter 3) and the interlinked life cycle models of both generic standards and the IPS (chapter 4);
- The stakeholder landscape (chapter 5);
- The IPS Governance Framework (chapter 6);
- Recommendations based on the knowledge and analysis of the tasks (chapter 7).

Deviations

The deadline of delivery of Deliverable 5.2 Towards an international patient summary standards Governance Framework was surpassed by 2 weeks. This was due to needing to perform an in-depth review of input from key contributors that were of significance to the content and recommendations of the deliverable.

Executive summary

The objective of this deliverable is to promote sustainable governance for the International Patient Summary (IPS). It takes the global collaboration of Standards Developing Organisations (SDOs) in the Joint Initiative Council (JIC) on Global Health Informatics Standardization as a starting point. Through the Health Informatics Standards Life Cycle, as adopted by the JIC, in combination with the IPS Life Cycle, we develop the notion of interlinked governance of IPS specifications. This notion reinforces the reality that patient summaries are based on real data on real patients residing in various Electronic Health Record (EHR) systems. Any patient summary initiative will strive to extract that data from these systems and present them to other users using possibly different systems, whether in a local, regional, national, or cross-border setting. A coherent set of IPS standards and specifications will help to improve the quality of the patient summary and to prevent conflict in patient summary requirements across different initiatives.

Good governance starts by supporting the work being done in real-life patient summary initiatives. A study of 14 patient summary initiatives (listed in Appendix I) provides guidance and leading practices on how to engage SDOs and collaborating initiatives in the governance of patient summary specifications. The identification of shortcomings and the coordinated propagation of change requests and approved changes throughout the network of interlinked initiatives are highlighted as the core of effective governance.

The insights are presented in the form of a governance framework. This framework is established to guide individual patient summary initiatives in setting up their own governance. The process of collaboration between initiatives and SDOs at different levels is inferred from the actions that individual initiatives bring forward. The use of this governance framework is recommended, in order to provide a solid foundation for collaboration throughout the interlinked network of initiatives, focusing on the following key areas:

1. Clearly identifying standards and specifications that are used, included or referenced in the patient summary specification of the initiative;
2. Creating processes to be responsive to change, by engaging the user and stakeholder community of the initiative and through participation in the communities managing the standards and specifications as mentioned in point 1;
3. Engaging in implementation, monitoring and auditing activities, to gather real-life experience and feedback to be used in the processes mentioned in point 2. Special attention should be attributed to building on leading practices and on addressing up-front sustainability and continuity of the effort beyond the initial stages of the project or initiative;
4. Refining governance structures over time, reflecting both a long-term and a short-term view, in flexible structures that facilitate alignment and incentivises feedback to standards bodies.

In order to take full advantage of the real-life experience that European, national and local patient summary initiatives bring, we also recommend a community of experts from participating SDOs, fully engaged with these initiatives, to be formed as a single point of contact for questions about and suggested changes to the IPS standards. Apart from a global IPS community, similar communities can provide guidance at a national and regional scale, with an important role for National eHealth Competence Centres (NCCs). Their involvement can drive the adoption of consistent IPS standards from the global community all the way down to the local implementation in Electronic Health Record (EHR) systems. Consistent local implementation is crucial for the effective exchange of patient summary data, whether in a local format on a local level or in IPS format for a national or cross-border scenario, for improved data quality and ultimately patient safety.

1. The International Patient Summary and the need for governance

An Electronic Patient Summary is defined by EN-ISO 13940:2016 as an "electronic health record extract containing essential healthcare information intended for specific uses" (EN-ISO 13940, 2016). The International Patient Summary (IPS) was initially developed specifically for use in unplanned care in cross-border settings. It will critically rely upon international agreements (e.g. policies, standards) for such use concerning the access and legitimate use of an individual's health data extracted from records held by local healthcare organisations. However, experience shows that local healthcare (provider) organisations are not keen to invest in an IPS for just the initial scenario of unplanned care in cross-border settings, unless it builds upon or enables the sharing of patient summary data from the individual local healthcare setting to a broader healthcare (provider) community. The IPS was intended to support continuity and coordination of care, and consequently other scenarios involving local and scheduled care are also within the standards remit.

In addition, it is anticipated that controlled extensions to the IPS dataset, which is presently required to be minimal but not exhaustive, will widen the applicability of the IPS to other scenarios, beyond the initial one, to address specific needs or patient groups. Any further developments, however, will amplify rather than diminish the need to satisfy the governance requirements that pertain to the individual and organisations from the local, national, regional and international stakeholders' perspectives.

Therefore, there is a need to construct a governance framework, which informs all parties concerned with a minimum of governance activity to effectively engage SDOs and other "authors" of patient summary specifications. The framework provides the linkage of the different governance processes and illustrates how they may impact each other. This document describes the need for governance (chapter 3) and links it with the standards life cycle and the IPS life cycle models developed in earlier projects (chapter 4). Chapter 5 then goes on to describe the various organisations that currently play a role in some form of patient summary governance.

The governance framework itself is described in chapter 6, where it is interlaced with experience we collected through interviews with the 14 patient summary initiatives described in Appendix I. The methodology used to identify and carry out the interviews is described in the next chapter. The final chapter provides recommendations on how to achieve aligned governance of patient summary standards and initiatives in view of the interdependencies at the different levels.

2. Methodology

The need for governance (chapter 3) and the interlinked life cycle models of both generic standards and the IPS, specifically, (chapter 4) have guided the initial construction of an interview guide on the topic of IPS governance. The participants in the Trillium II consortium contributed to the description of the stakeholder landscape (chapter 5). In addition, their knowledge and experience helped to detail the options and suggestions in the final interview guide, included in Appendix II.

The methodology used to compile an inventory of patient summary governance practices consists of five steps described below. These are focussed on various aspects of Patient Summary governance and aimed to identify best practices, problems and issues:

1. Identify key IPS related initiatives (in collaboration with WP2 / Task 2.1);
2. Assess the goals, objectives, and activities related to governance within the initiative;
3. Assess the initiative's current linkage with standards governance;
4. Inventory the initiative's needs for standards updates and version management of the specifications in use;
5. Compare results, identify best practices and provide a summary.

These five steps were operationalized by the means of a questionnaire, a so-called Topic Matrix, and various interviews. Whereas the Topic Matrix focused on ticked boxes which indicated an inclusion of data (e.g. allergies, medications), the Questionnaire covered the process surrounding the collection, use and management of data. By conducting the interviews, we aimed to gather information regarding the usage of (inter)national standards as stepping stones for national initiatives as well as governance regarding the implementation of updates and version management of the specifications developed and used by the initiative.

The consortium managed to conduct interviews with fourteen Patient Summary Initiatives throughout Europe and the United States, listed in Appendix I. Two of these initiatives are standards developing initiatives, one in Europe and one at a global level. The other twelve initiatives are aimed at the implementation and operation of patient summaries at various levels.

After obtaining and processing the information collected in the interviews, the findings were summarized in an overview document, which focused on best practices, problems and issues. The findings from these interviews and the subsequent processing formed the essential input for this deliverable. The resulting Governance Framework for International Patient Summary standards is described in chapter 6, mixed with key findings from the interviews that demonstrate the value and use of the framework.

3. What type of Governance Framework is appropriate?

Governance frameworks are typically aimed at three types of entity:

1. Enterprises of various types; different examples include private corporations, commercial and public sectors and even countries or regions covering several countries;
2. Sensitive activities; examples include clinical trials or people-centric research with associated data protection concerns;
3. Individual projects; examples include IT projects, finance projects and building constructions;

What is meant by 'an international patient summary standards governance framework'? Who and/or what is to be governed? Arguably all three types are applicable but, if so, the construction of an inclusive framework will be challenging for the following main reasons:

1. The IPS, by definition, will span multiple types of enterprise and these will be based in different jurisdictions as the intention is that it will serve the 'cross-border scenario' and therefore has international if not global aspirations. All countries will have their own unique take on governance, reflecting cultural, professional, economic and legal perspectives. Differences in organisational culture and working practices with respect to enterprises within a country will also be diverse and non-standard.
2. The IPS can certainly be regarded as a sensitive activity; it is person-centric, and will no doubt be used both for service and research activities in healthcare. Confidentiality and privacy will tax the data protection regulations and IPS sits firmly in the healthcare domain and so emphasizes the problem of global perspectives and jurisdictional incompatibilities.
3. The IPS as an implementation project has an IT component. Types 1 and 2 both share the same problem of multiple stakeholders and gaining accountability, whereas the IPS as a project mitigates the problem to some extent. "The only proven mechanism for ensuring projects meet customer and stakeholder needs, while optimising value for money, is to allocate Project ownership to specialist party, that otherwise would not be a stakeholder to the project." (Wikipedia) This seems to have some merit, but the problem is that the 'specialist party' does not presently exist in a form that can mandate a governance framework that the international community will sign up to.

Even so, there are some positives from the above to be considered. For example, there are business drivers for international harmonisation; as disease knows no barrier nor should healthcare be constrained by an irrelevant scope. Such drivers encourage consistent practice across borders and the European Commission, in this regard, demonstrates leading practice through its directives and regulation.

External to the EU, but also internally, appropriate balances will need to be struck between regulation and voluntary action in determining the nature of any governance framework so as to promote adoption, acceptance, and sustainability.

Furthermore the 'standards governance framework' postfix may imply that the Governance Framework is exclusively aimed at the IPS standard; if so this is a relatively trivial exercise, for all the IPS project has to do is to create the formal ISO standard and then rely upon the existing Governance arrangements of ISO to do their job. This is simplistic and likely to fail; the IPS relies on activities of multiple standards developing organisations (SDOs) and a 'standards governance framework' is still a challenge but, more importantly, it is

also insufficient as the IPS governance includes other considerations that are not just the development of formal standards.

The SDOs, however, do have an important role to play with their consensus processes and their developmental approach. Furthermore, agencies such as ISO and WHO, offer substantive authority and credibility for a global framework to be established and complied to. Moreover, standards are part of the digital health ecosystem and linking the governance of IPS specifications, as localized in specific initiatives, to the governance of global standards is essential for continuity and sustainability of the patient summary initiative.

4. The Life Cycle of an International Patient Summary

In order to understand the different governance activities needed to support the successful adoption and continued sustainable use of the IPS, we examine two different life cycle models, both taken from the *e*Standards project work.

4.1. The Generic Standards Life Cycle applied to eHealth

The truism that 'change is a constant' is formerly acknowledged by the Health Informatics Standards Life Cycle, as illustrated in Figure 1, developed by the *e*Standards Project (Stegwee & Chronaki, 2015). Standardisation, however, offers some respite and some stability for the stakeholders by providing a consensus process and a development cycle that formalises how the changes to standards and specifications can be managed.

The International Patient Summary has a broad and diverse history, not only within the EU-US cooperation on eHealth, but also within organisations, states, and networks that have implemented and used patient summaries within their own domain. The specification of the IPS standards has taken advantage of experience and will continue to appraise current developments and insights from practical implementations with the intention to achieve future alignment. Figure 1 illustrates a series of activities that are explained in the following paragraphs.

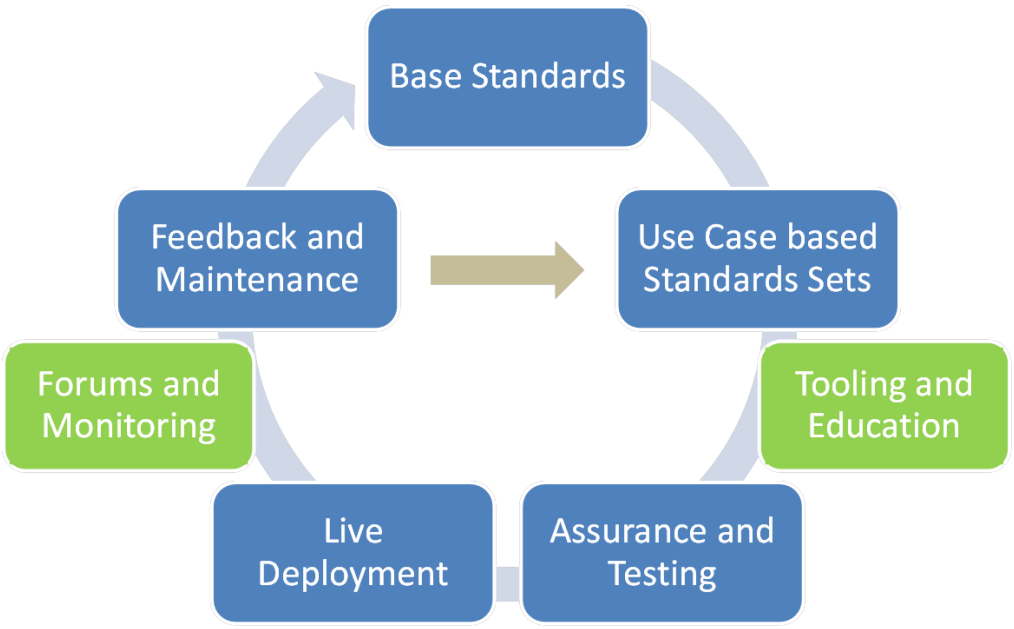

Figure 1: Health Informatics Standards Life Cycle

The development of base standards forms the foundation of any (standards based) specification. Centred around a well-described use case specification, the necessary base standards are brought together and profiled[1] to form a coherent standards set[2], fit for purpose to meet the needs of the identified use case. In order to guide the deployment of these standards sets, tooling and education are provided for implementers to use the specifications in their software products. After these products have gone through assurance and testing, to make sure they conform to the standards sets and provide the required interoperability with other products, they are ready for live deployment in the delivery of health care and secondary uses of health IT. In order to systematically gather the real-life experience in deploying standards-based software products, one or more forums are made available to share experiences regarding solutions or workarounds for identified problems. Monitoring the use of standards sets, ideally enabled and fully automated by the tooling and libraries deployed in the standards-based software products, provides another key input to the feedback and maintenance activities. Depending on the issues identified, such maintenance may lead to a revision of one or more of the underlying base standards or to new versions of the standards set developed for the particular use case. Of course, the use case description itself may be augmented with further details, depending on the feedback received, leading to a new version of the standards set. This starts the next iteration of the life cycle. Taking the IPS as a case study, the Joint Initiative Council on Global Health Informatics Standardisation developed a patient summary standards set (PSSS), which fed into the work of the *e*Standards roadmap, which addresses the impact of digitization on standards, shifting the focus from use cases to user needs.

Even though different implementations of a patient summary may build upon the same base standards, each implementation will have to orchestrate its own activities across the life cycle, which may or may not be interlinked to activities at other levels or in other jurisdictions. The envisioned IPS Governance Framework aims to take in the experiences across different implementations in the digital health ecosystem and discuss to what extent streamlining of these activities along a common framework with reuse of resources and tooling will help sustain and improve the necessary governance.

4.2. The Patient Summary Life Cycle

The Health Informatics Standards Life Cycle is intended to be generic for all eHealth Standards and not just specific to the IPS. Viewed from a different perspective, the explicit 'Standardisation' activities can be seen as being one particular aspect of the real-world concept 'Patient Summary'; this entity has its own life cycle and activities, much of which are not explicitly related to, or directly impacted by the formal SDO standardisation processes[3].

[1] Profiling is used to collectively reference activities such as constraining the standard specification, removal of optionality, providing clear terminology bindings and specifying the value sets to be used from such terminology. The IHE global standards adoption approach, as documented in ISO Technical Report 28380, provides a methodology to develop and deploy integration and content profiles.

[2] The term 'standards set' here is used to describe the actual specifications selected for use. It is likely that these might be suggested by the broad guidance document of the same name from the international collaboration of health informatics SDOs (known as the JIC). This guidance document provides a range of possible choices (some alternatives too) that might be used for a specific use case. The JIC Standards Sets is informative only and should be positioned within the 'Tooling and Education' part of the standards life cycle.

[3] It could be argued that the Standards Life Cycle should cover everything, but this is not feasible, not least because SDOs are not constituted/empowered or have the capacity/bandwidth to manage it all. Ideally, one could argue that the monitoring and feedback from an artefacts' live deployment should be passive activities for an SDO, with data

Figure 2 shows a representation of the Business Process IPS Lifecycle, as presented in the *e*Standards project (Cangioli, 2017).

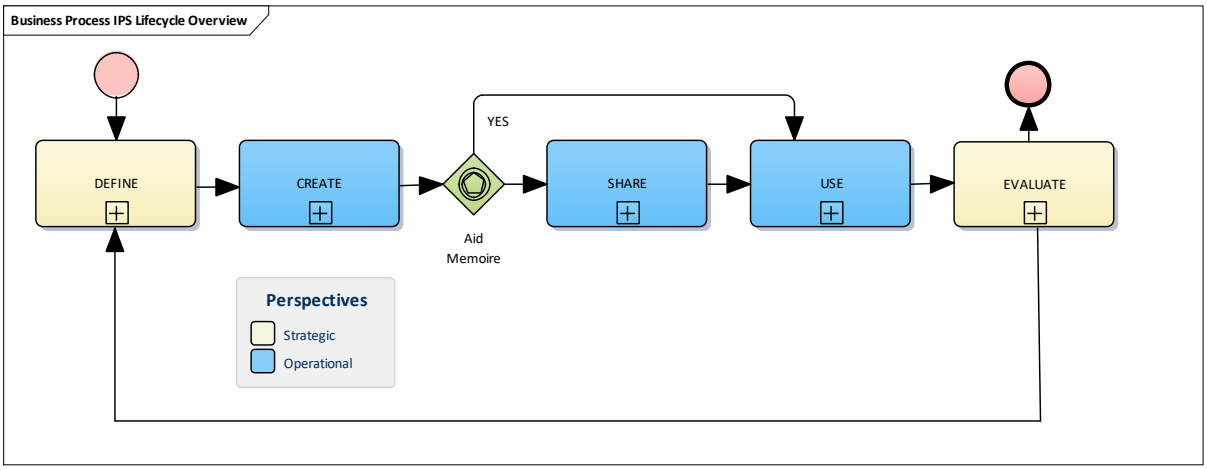

Figure 2 : Five phases in Business Process IPS Life Cycle

Patient Summaries can be created as aide memoirs to simplify a complex case. However, they are usually created with the intent to share, and this is clearly the overarching use case for the IPS.

Today the Formal Standardisation activity would typically be consigned to the 'DEFINE' activity with aspirations to be present in the 'EVALUATE' phase. It was noted in *e*Standards that the IPS in comparison to other patient summaries, "has distinct, qualitative differences at the strategic levels. In particular, DEFINE and EVALUATE will be subject to significant stakeholder scrutiny given the intent to standardise the products and to make them suitable for cross-border application, whilst enabling and supporting national and local use."

Each phase is described in greater detail within the *e*Standards project work, and Governance relates to each one. Stakeholder involvement (who and extent) may vary from phase to phase.

'Governance' as a concept, however, can be applicable to both life cycles because it is a concept which directly addresses both 'control' and 'use', and can be comprehensive by taking the form of regulation that applies to a single realm or set of realms. As such, the Governance Framework envisaged for the IPS spans both the strategic and operational dimensions of the IPS. Figure 3 from *e*Standards deliverable D5.3 shows a high-level, abstract model of the Patient Summary Life Cycle condensing the operational activities under a single USE* designation (Cangioli, 2017).

An important issue for sustainability of IPS deployment efforts is that the two cycles are frequently disconnected in the global digital health ecosystem.

*collection and requests for change coming from the standards consumer communities that have incentives to share their experience with the SDOs. At the same time, digitization has the potential to accelerate the life cycle.

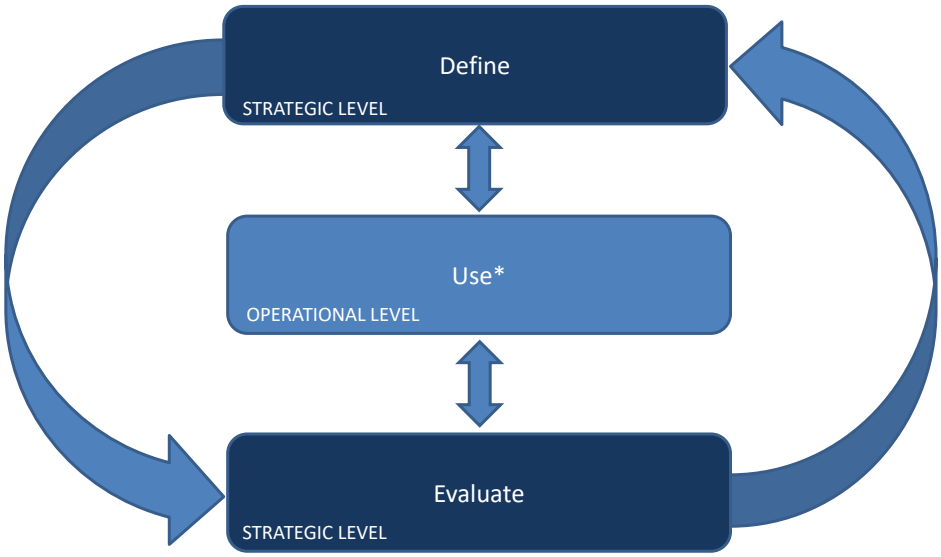

Figure 3: Abstract model separating the strategic from the operational activities of the life cycle

4.3. Linkage of Life Cycles

It is important to note that standardisation and implementation of IPS can take place at different levels. At a global level, we have the Patient Summary Standards Set (PSSS), a guidance document, published by the Joint Initiative Council on Global Health Informatics Standardisation, which catalogues several base standards from the participating standards developing organisations. It is expected that the reference will give rise to feedback and maintenance activities that can influence both the base standards it refers to and the PSSS itself. Meanwhile, EU/US collaboration has provided a global specification in the form of the CEN International Patient Summary Standards[4] and the HL7 International Patient Summary, with implementation guides for both the HL7 CDA and the HL7 FHIR standard format. Both the CEN and HL7 IPS standards take the notion of the informative guidance provided by the PSSS to a whole new level, providing a coordinated and fully specified set of normative standards and implementation guides for the patient summary. They build upon prior specifications of a C-CDA patient summary adopted by the Meaningful Use (MU Summary of Care) program in the US and a CDA patient summary used in the cross-border exchange in Europe, using the eHealth Digital Service Infrastructure (eHDSI CDA Implementation Guide). Recently, SNOMED International has made available a free set of SNOMED CT terms to use in conjunction with the IPS. This provides a set of four closely linked normative standards, as depicted in figure 4.

In the context of Europe, the focal point for the CEN standards for the International Patient Summary is a policy document from the European Commission, called the Patient Summary (PS) Guideline. The companion implementation guideline references the HL7 IPS specifications to show how the conceptual specification of the IPS can be implemented in such a way that it is truly interoperable. By means of the European Standards, it is expected that individual member states within the European Union will adopt patient summary standards that are compatible and will drive the cross-border exchange of patient summary data.

[4] Strictly speaking the CEN IPS Standards are not global, as is discussed in the next paragraph, but the aim of the collaboration was global from the outset. Discussion of this work within ISO has already set the adoption at a global level in motion.

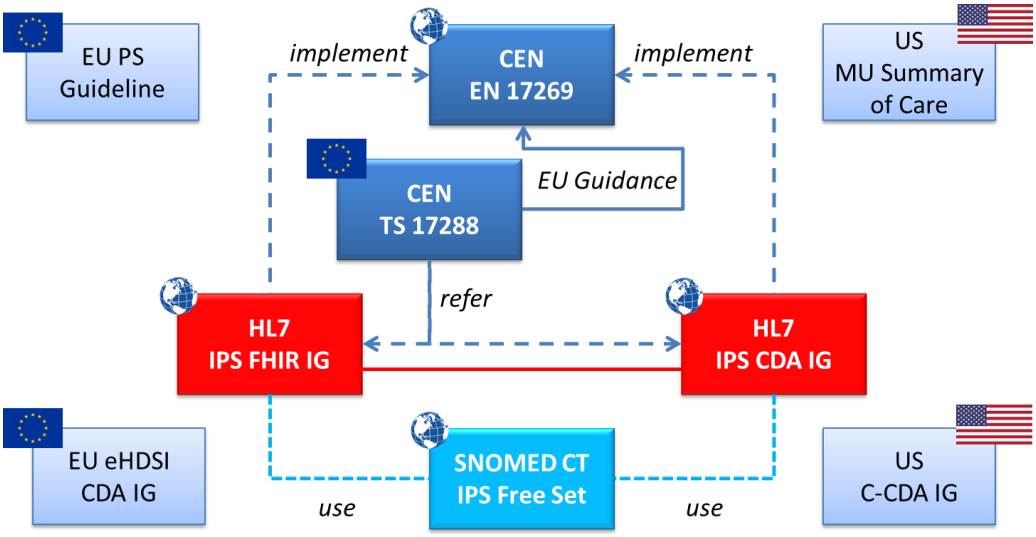

Figure 4: Four closely linked global IPS standards with EU Implementation Guidance

In the US, formal reference to the HL7 IPS specifications is expected to be established in the upcoming months. In this case, linkage to the formal governance of the national IPS standards was not part of the HL7 IPS project, even though one of the important governing bodies, ONC, funded part of the work.

This goes to show that, already at the level of setting standards, there is an intricate dependency on various, otherwise autonomous governance processes. Different instances of the Health Informatics Standards Life Cycle need to be linked together. Matters become even more complicated when we move to the actual application of the IPS, where the five phases of the IPS life cycle come into play. Somehow, the defining phases of each of these initiatives need to be aligned with the standards, and the evaluation needs to surpass the IPS Life Cycle when it becomes clear that changes need to be made to the IPS standards in order to respond to issues brought up in the evaluation. We also see implementation efforts being nested, for instance when a national IPS project in Europe links to the cross-border exchange through a National Contact Point for eHealth (NCPeH), or when innovative use of patient data hitches onto the implementation of the Promoting Interoperability Program of the Centers for Medicare & Medicaid Services in the US (e.g. Substitutable Medical Applications, Reusable Technologies on Fast Healthcare Interoperability Resource, SMART on FHIR)

Awareness of and incentivising these interlinked life cycles is a prerequisite for taking appropriately sustainable governance actions. To this end, we provide an illustration of how the different life cycles can be positioned in relation to each other. Please note that the phases “Assurance and Testing” and “Live Deployment” in the Health Informatics Standards Life Cycle (top of the picture) have been substituted by the actual IPS Life Cycle stages for the implementation efforts taking place. The experience at the local level of implementation needs to be able to find its way up to the highest level of global standards specification, when necessary.

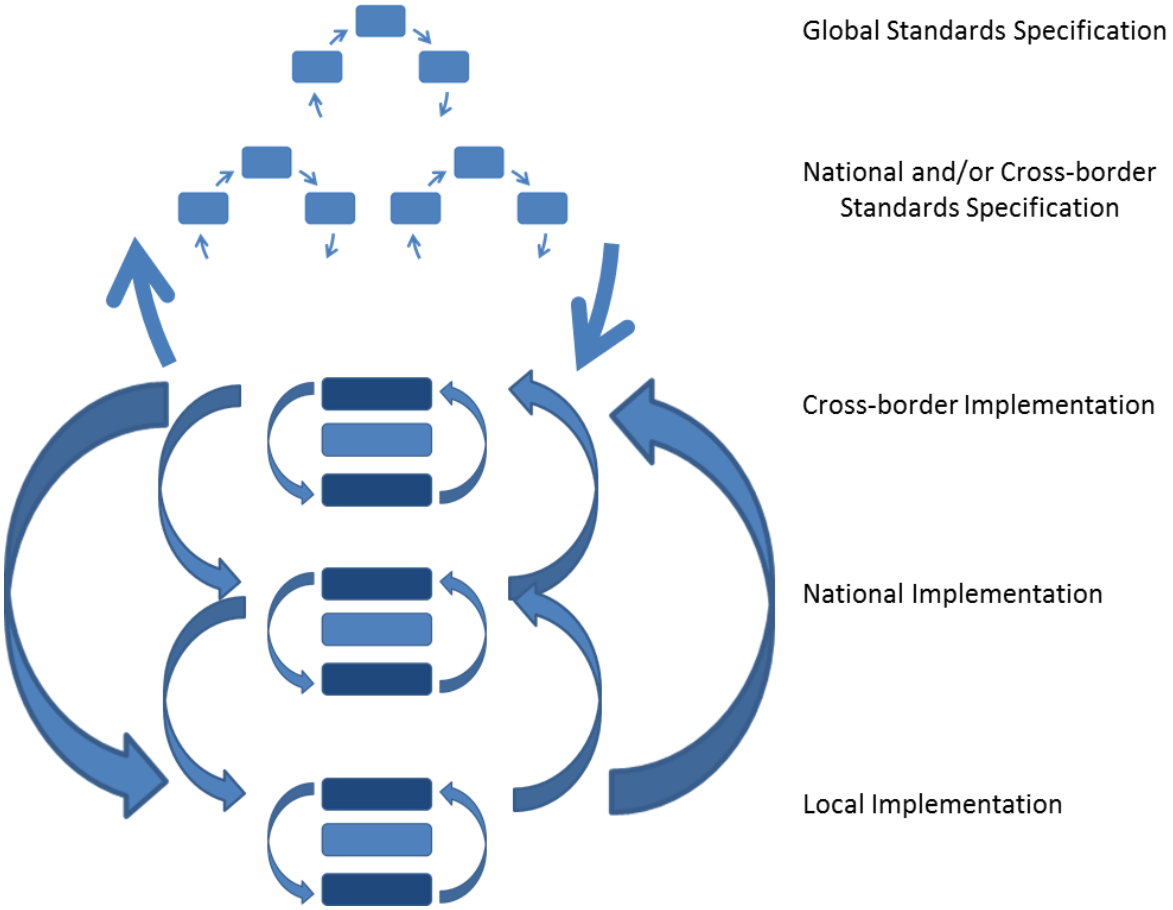

Figure 5: Linkage of Standards Life Cycles and IPS Life Cycles for global interoperability

The next chapter identifies some of the different governance bodies already in place that may or may not be aware of the dependencies they have in terms of linkage of life cycles.

5. Identified governance bodies

This chapter provides an overview of the different stakeholders involved in the governance of patient summaries and patient summary standards. The overview will build upon the activities described in the previous chapter. We begin our overview at a global level. Next, we provide some detail for both Europe and the US and for their respective states or regions. Similar insights might be produced for other countries, regions or continents across the globe, but these are out of scope for this deliverable.

5.1. Global

On a global scale, the SDOs are playing an active role, not only in the development of base standards and profiles, but also on the specific topic of the patient summary. In January 2018, the Joint Initiative on SDO Global Health Informatics Standardisation, led by the Joint Initiative Council (JIC), published a joint informative document, called the Patient Summary Standards Set. It is currently uncertain how the governance of this document is to be organised, as the patient summary document serves as the first of its kind and has piloted a JIC process for standards set development. The governance is likely to be the next JIC process that will be piloted, using the patient summary exemplar in an effort to maintain the relevance of the standard set.

It is important to understand that there is close linkage between the JIC and the SDOs contributing to the standards set, in particular, CEN, GS1, HL7, IHE, ISO, and SNOMED International. Hence, the governance process will most likely include these SDOs.

In October 2018, the HL7 CDA® R2 Implementation Guide International Patient Summary has been published as a Standard for Trial Use. Publication of the companion HL7 FHIR® Implementation Guide is scheduled for February 2019, also as a Standard for Trial Use. These two standards have been developed in close collaboration with the CEN IPS project, that aimed at providing a European Standard (EN 17269) and Technical Specification (TS 17288) based on global IPS standards and specifications. The International Organization for Standardization (ISO) is considering the adoption of the standards developed within the CEN IPS project as well. Early 2019, HL7 International and SNOMED International announced their agreement to provide a free set of SNOMED CT terms for use in the HL7 International Patient Summary implementations. Together, this provides a coordinated set of five normative standards for the implementation of a Patient Summary that are governed in close collaboration between the respective SDOs.

What is still unclear, however, is the type of governance that would incentivise local, regional and national initiatives to actually use and localise these standards as needed and to share their experience with implementation of the standards set with the SDOs.

5.2. European Union (EU)

5.2.1. Connecting Europe Facility – eHealth Digital Service Infrastructure (CEF eHDSI)

The European Union is in the process of realizing a cross-border infrastructure for, among others, sharing of patient summaries in the case of emergency and unplanned care. There are several organisations involved in the operational governance of this eHealth Digital Service Infrastructure (eHDSI):

- eHealth DSI Operational Management Board (eHOMB), under the directorate general (DG) Santé of the European Commission and with representation of DG CONNECT, DG DIGIT and Member States;
- Under the eHOMB, the CEF eHDSI Solution Provider from DG Santé is responsible for maintaining CEF eHDSI assets, such as the NCPeH reference implementation (see below);

- eHealth DSI Member State Expert Group (eHMSEG), composed of participating member states that have joined the eHealth DSI for the exchange of patient summaries;
- Under eHMSEG, the eHMSEG Semantic Task Force is responsible for managing semantically related aspects of the Patient Summary and ePrescription services;
- National Contact Points for eHealth (NCPeHs), within each participating member state, serve as the entry point into the national infrastructure for the exchange of patient summaries;
- National eHealth Competence Centres (NCCs) support the implementation of eHealth and underlying infrastructures within their country;
- European branches of global SDOs, in particular, HL7 Europe and IHE Europe, and the European standards organisation CEN, which works closely together with ISO.

Change management in the eHealth DSI is complicated as it is linked to elaborate governance structures and processes.

The development of the eHealth DSI is coordinated by the European eHealth Network, which is a voluntary network identified in Article 14 of the European Directive on the application of patients' rights in cross-border healthcare (European Union, 2011). It is a political and strategic body composed of national authorities responsible for eHealth, designated by the Member States. The eHealth Network has published, among others, a guideline for cross-border exchange of patient summary for unscheduled care (eHealth Network, 2016). This document serves as the core policy document to guide the implementation of the patient summary exchange using the eHealth DSI, using the standards provided by the SDOs.

The VALUeHEALTH project has identified a number of alternatives for the governance of the eHealth DSI in a sustainable manner beyond its initial financing (VALUeHEALTH, 2017). These approaches need to be evaluated in the context of the new financial cycle of the EU and, in particular, in relation to the European Digital Innovation Hubs and the EC position on digital transformation of health and care.

5.2.2. European Member States

Looking at the different member states, a multitude of patient summary specifications using different standards and profiles, can be found. Often, they are localisations of well-known (global) standards, but cases of fully locally developed standards are also known. In some countries, often depending on the type of health system they have, the exchange of patient summaries has been an initiative led and controlled by a central government agency. In other countries there are huge regional differences, when the regions are the responsible bodies for organizing healthcare. It is expected that the role of NCPeHs and NCCs will also turn out differently across member states, which will lead to complex governance issues around the national patient summary specification. Not all global SDOs have local branches, or representation in all member states, but their number is steadily growing. Some countries have local/national organisations that develop and maintain their own country-specific standards, such as MedCom in Denmark and the Belgian eHealth Platform in Belgium. In all cases we expect the governance processes in place between users and the maintenance organisation for the standards to be (by necessity) quite varied.

5.3. United States of America (US)

The use of patient summary standards in the US is mandated through the Meaningful Use (MU) measures put in place by the Centres for Medicare & Medicaid Services (CMS) as part of their Promoting Interoperability program (formerly known as the EHR Incentive Program). They reference the certification criteria published by the Office of the National Coordinator (ONC), which in turn reference standards produced by global SDOs, including ISO, HL7, and SNOMED International. In certain cases, also national

specifications, for instance form the National Council for Prescription Drug Programs (NCPDP) are referenced. Even though the formal governance of the patient summary specifications is with CMS, the ONC plays an important role through its annual publication of the Interoperability Standards Advisory (ONC, 2019). A number of private initiatives also aim for interoperability of patient summary data across the US, such as the Sequoia Project, the Argonaut Project, SMART on FHIR, and Carequality.

5.3.1. Individual American states and local regions

Health Information Exchanges (HIEs), established or expanded across the US under the ONC HITECH program from 2010 onwards, operate in state and local regions. The variety in organisational set-up, architecture and services they provide is extensive and may or may not include patient summary exchange. They often depend or rely on private initiatives from the individual health systems, integrated delivery networks and EHR developers to provide the mechanisms to actually exchange data. Hence, we decided not to study the HIEs in more detail for the purpose of IPS Governance, as we expect most governance issues to be tackled across the various national initiatives.

6. The IPS Governance Framework

As described in the previous chapters, governance of the International Patient Summary (IPS) will need to take into account a number of initiatives at different levels, ranging from global specification to local implementation. Rather than trying to establish elaborate governance processes across all these initiatives, our aim is to provide a governance framework that can be employed by each of these initiatives individually, clarifying the linkage with related patient summary initiatives as well as with standards developing organisations.

In this context**, a patient summary initiative is any specification, implementation, or operational effort that uses the exchange of patient summary data as the basis for adding value to their particular care setting**. This includes the original focus on cross-border unplanned care for the international patient summary, as well as part of a targeted effort for specific patient groups (chronic diseases, rare diseases) or for general patient empowerment initiatives using personal health record exchange. The list of existing and foreseeable patient summary initiatives is extensive (Chronaki, 2018).

Governance of the patient summary in this context is focused on the Information layer of the Refined eHealth European Interoperability Framework (ReEIF) (eHealth Network, 2015). However, this focus does not isolate the governance processes from the other layers in the ReEIF, with specific attention to the way the patient summary is implemented in both the Care Process and Applications layers. The CEN TS 17288 Patient Summary Guideline for European Implementation includes a section on governance that covers both the process and product aspect of governance. It also points to guidance on GDPR compliance and considerations for the patient summary.

The governance framework we propose for the patient summary initiatives consists of five major categories:

1. **Initiative** – a clear description of the aim of the patient summary initiative and the stakeholders that are directly involved in the exchange of the patient summary;
2. **Specification and Standards** – an overview of the patient summary specification developed or used within the patient summary initiative and the extent to which standards are used or referenced, either in the specification itself or as part of the underlying infrastructure for the exchange of patient summaries;
3. **Governance Scope and Objectives** – a description of the governance in place for the initiative, including the responsible parties, the embedding of patient governance in a broader governance structure, and the current and future scope and objectives of the governance including sustainability considerations;
4. **Stakeholder Involvement** – apart from the stakeholders directly involved in the exchange of a patient summary and the responsible parties for patient summary governance, other parties are often included in the governance processes, with a particular purpose or indirect role;
5. **Update and Version Management** – for any specification to remain relevant in the world of health care and health informatics, updates to the specification need to be taken care of and version management may be called for, in full alignment with the maintenance of the underlying standards.

We will describe each of these categories in more detail in the next sections, including the lessons learned from our interviews.

6.1. Initiative

In order to provide proper governance, it is essential to understand the overall aim of the initiative and to engage (representatives of) the key stakeholders involved in the actual exchange of the patient summary data. The aim of the initiative may be as simple as a legal or regulatory requirement, such as the obligation of a General Practitioner (GP) or other healthcare provider to regularly submit a patient summary to a local, state wide or national repository. Alternatively, it may be a specific care setting, such as an out-of-hours GP office needing to retrieve an up-to-date patient summary from the Electronic Medical Record (EMR) of the patient's regular GP. In some cases, the aim is quite generic, to provide an up to date patient summary at the point of care throughout a single health system. This may or may not include access by patients and relatives. As a general checklist for stakeholders that are directly involved in the exchange of patient summary data, we advise the following:

- Patients and relatives;
- Healthcare professionals;
- Healthcare provider organisations;
- Payer organisations;
- Patient data registries;
- Research institutions.

6.2. Specification and Standards

It is assumed that any **patient summary initiative will deploy some form of specification of the patient summary data to be exchanged**. This was confirmed by all initiatives that we studied. However, not all initiatives develop their own specifications; six of the twelve implementations and operation initiatives rely on specifications developed on a national scale or are conformant to the eHDSI and NCPeH Patient Summary specifications. This reinforces the notion of interdependence between specifications and the need for a coherent set of normative standards at the global level.

The particular patient summary specification can reference and make use of several standards in the following domains:

- Function of the patient summary exchange:
    - The HL7/ISO EHR-S and PHR-S functional models may be referenced, but IHE use-case and workflow definitions also provide a basic functional description;
- Content of the patient summary itself:
    - Reference to ASTM CCR, HL7 CCD, or the European Guideline on the patient summary data set;
- Structure of the document or message to be exchanged:
    - HL7 v3, CDA R2, C-CDA and FHIR, as well as ISO 13606 are common global standards for structuring;
- Terminology and/or value sets used for the elements of the document or message;
    - SNOMED CT, LOINC, ATC, ICD and ICPC are often mentioned, but so are national terminologies and value sets.

A more extensive overview of relevant standards is presented in the Patient Summary Standards Set, as published by the Joint Initiative Council on Global Health Informatics Standardization (JIC, 2017).

Please note that legal and organisational standards are not mentioned as part of our framework, even though they are part of the ReEIF. These were not mentioned by the initiatives studied and often these fall

outside the scope of Health Informatics standards. However, considerable work has been done in these areas by a number of the initiatives studied, so they do form an important part of the overall specification delivered.

For the underlying infrastructure, necessary to achieve secure exchange of the patient summary at the application and IT infrastructure layers, a number of alternatives are available, including:

- Messaging infrastructure;
- Dedicated registries;
- Dedicated repositories;
- IHE XDS (and XCA) infrastructure;
- Secure e-mail.

Six out of the twelve implementation and operation initiatives studied employ some form of repository to physically store the patient summary for access by professionals and/or patients. As expected, the initiatives referencing national or European patient summary specifications also make use of the infrastructure already made available for the exchange of such patient summaries. In addition, some other initiatives also mentioned the use of a generic national health information exchange infrastructure.

6.3. Governance Scope and Objectives

Good governance requires a responsible party or combination of parties to organise the processes that make up the governance of the initiative. One would expect that (representatives of) the key stakeholders involved in the patient summary exchange are in control, but often the governance is either organised by an independent party, set up for health information exchange in general, or by the initiative's own leadership. The key stakeholders are involved, but sometimes at a distance and without perception of control over the specifications. The same is true of the SDO-led initiatives, where the SDO itself is in control of the governance and assumed representation of key stakeholders is not always obvious. See also the next section on stakeholder involvement.

The aim of the governance varies greatly, depending on the type and maturity of the initiative, and is almost certain to evolve over time. The different aspirations for which governance of a patient summary initiative is created may include:

- Maintaining and updating the specification guiding the patient summary implementation;
- Managing the requirements on data content, data quality and data protection as agreed by the parties exchanging patient summaries;
- The involvement of the patient in the exchange of patient summaries e.g. informing patients and asking permission;
- The infrastructure of the patient summary exchange;
- The implementation of a patient summary specification;
- Testing existing implementations of a patient summary specification.

It may help to formulate concrete objectives for the governance of the patient summary initiative, such as:

- Maintaining a stable specification of a fixed (minimal) dataset;
- Enabling the growth of topics and applications of patient summary exchange;
- Ensuring the data, data quality and data protection of the patient summary exchange;
- (improved) Alignment with international patient summary specifications;

- Correct implementation of the patient summary specification at new affiliated parties;
- Ensuring correct use of the patient summary specification at existing affiliated parties.

Especially when a patient summary initiative references specifications that are governed by other bodies, for instance national or European programs, the influence on those specifications becomes blurred and it is hard to meet some of the concrete objectives listed. From an (inter)national alignment perspective, such dependencies are of course welcomed, but these need to be well understood and well managed. For this purpose, the notion of an open governance framework is an idea worth elaborating further.

6.4. Stakeholder Involvement

As mentioned in the previous section, one would expect the direct users of the patient summary exchange to be recognised as key stakeholders in the initiative. Recall from section 6.1 the list of possible users:

- Patients and relatives;
- Healthcare professionals;
- Healthcare provider organisations;
- Payer organisations;
- Patient data registries;
- Research institutions.

Depending on the type of patient summary initiative, one may also want to include (representatives) of the following stakeholders:

- The organisation managing the PS specifications;
- Health Authorities;
- Clinical Societies;
- Professional Societies;
- Patient Organisations;
- Vendor Associations;
- Payer Associations;
- Investment Partners;
- National eHealth Competence Centres;
- Standards Developing Organisations;
- Individual Experts.

It is important to note that some of the initiatives studied, explicitly mention that input is provided by users or expert groups from different stakeholder communities. Whether these users or experts express their individual opinions or represent the views of the specific stakeholder community they are part of, is not always clear.

For each of the stakeholders involved, it is helpful to recognize their key role in the governance of the patient summary initiative, such as:

- Gathering requirements for draft specifications, including revisions;
- Providing stakeholder input on draft specifications;
- Aligning specifications with external organisations;
- Deciding upon final specifications;
- Publication and dissemination of final specifications;

- Establishing and running incentive schemes for adoption and maintenance of specifications;
- Monitoring the adoption of specifications (users/vendors/regions);
- Monitoring the use of specifications (numbers of PS created or exchanged);

From the above, the most mentioned tasks are on the topic of specifications, from requirements through to publication, very few initiatives mention monitoring of adoption or use of the patient initiative.

6.5. Update and Version Management

Updating the patient summary specification is core to the governance process, unless the specifications rely on specifications managed elsewhere. In both cases, formal or informal communication is established with each of the stakeholder groups, including implementation experience and feedback. This will be used in the update process, usually followed by a testing period and final adoption of a new version. Regarding the specifications, it is important to keep a number of key questions in mind:

- How are the adjustments brought to the attention of the people maintaining the specifications?
- Is there a process for capturing user feedback as input for adjustments to the specification?
- How is decision-making carried out upon desired adjustments to the specification?
- How are the adjustments implemented in the patient summary specification?

Sometimes the intended adjustments also require changes to the standards used or referenced in the patient summary specification, including the terminologies and value sets employed or simply limitation of the standard that need to be overcome. As most initiatives have a direct linkage to standards developing organisations, they will propose these changes as part of the standards life cycle. Meanwhile, they may also adopt a practical approach toward solving such issues, depending on complexity and cost.

In addition, changes to related standards and specifications are also used as a source for adjustments, as some initiatives are committed to stay aligned to national or European specifications. One of the initiatives mentions conformance to the future International Patient Summary standards as an important objective.

Implementation support for both vendors and user organisations is a definite part of patient summary initiatives and is often a rich source of feedback on issues with the current specifications and requirements for future versions. In addition, formal auditing of implementations may be established in order to ensure compliance to the specifications. Especially for the larger initiatives with a national or international scope, such audit processes are in place (seven out of twelve implementation and operation initiatives).

When looking at version management, the more mature initiatives face, among others, the following questions:

- Are multiple versions of the same specification supported in parallel?
- What flexibility/autonomy do stakeholders have in selecting a version?
- Is backward compatibility required for new versions of the specification?
- When to react to new versions of the underlying standards, profiles, etc.?

Only one of the fourteen initiatives have a set cycle for publishing updates, most mention a dynamic process based on the needs expressed by the stakeholders. In some cases, only the most recent version of the specification is supported. This enforces uniformity among health professionals. In one case, a transition phase is offered to protect those health professionals against "being out of support/service" due to delayed implementation of providers of the software used.

7. Recommendations

The complexity of interlinked governance processes around the patient summary at local, regional, national and international levels is such that it is impossible to establish a single overarching governance for all aspects of the international patient summary. Instead, we propose a framework to inform the governance of each of the individual patient summary initiatives. Key features of the framework are:

1. Clearly identifying standards and specifications that are used, included or referenced in the patient summary specification of the initiative;
2. Creating processes to be responsive to change,
    a. by engaging the user and stakeholder community right from the inception of the initiative;
    b. through active participation in and from the communities managing the standards and specifications as mentioned in the previous point;
3. Engaging in implementation, monitoring and auditing activities, to gather real-life experience and feedback to be used in the processes mentioned in the previous point. Special attention should be attributed to building on best practices and on addressing up-front sustainability and continuity of the effort beyond the initial life cycle of the project or initiative;
4. Refining governance structures over time, reflecting both a long-term and a short-term view, in flexible structures that facilitate alignment and incentivises feedback to standards bodies.

From the perspective of the standards developing organisations, it is recommended to establish a joint governance of the patient summary standards, as a single community or an open governance framework for the patient summary initiatives to turn to with questions and feedback. At the global level, the standards developing organisations have pulled together, initially under the JIC in establishing an informative Patient Summary Standards Set. At almost the same time CEN and HL7 entered into a collaborative agreement to create a set of consistent normative IPS specifications. SNOMED International has now joined these two organisations to provide a free set of concepts from the SNOMED CT terminology to be used in the value sets of the IPS. ISO has indicated an interest in joining the agreement as well. Given the reach and richness of the World Health Organization (WHO), especially around the International Classification of Diseases (ICD) and International Classification of Functioning, Disability and Health (ICF), as well as their international certificate of vaccination (also known as the Yellow Card), their participation in the International Patient Summary governance could be extremely valuable. Furthermore, it is essential that key user representatives are added to this governance community, in order to safeguard the relevance of the IPS standards and specifications in their daily use.

For patient summary governance to be manageable and responsive to the needs of a varied set of stakeholders, it is strongly argued to keep the governance processes as simple as possible. That is why we favour community collaboration over formal bodies of stakeholder representation. The formal processes within the participating SDOs are usually sufficient to ensure a balance of interest and to provide an opportunity for broad participation. These need not be duplicated in patient summary governance across SDOs at a global level.

In addition to the global governance community, similar collaborations are necessary at a national level. These could be coordinated by the National eHealth Competence Centres. The role of national patient summary governance is to ensure that localisations of the combined patient summary standards and specifications are carried out in a coordinated way and any required changes make their way up into the global standards collaborative. The key role of the European National eHealth Competence Centres is crucial in this respect, as they provide the linking pin between the EU Guidelines and the eHealth DSI

specifications for cross-border care, on the European level, and the actual implementation within EHR systems in the national healthcare domain. Moreover, they can create synergies with start-up and innovation hubs within the (inter)national digital health innovation ecosystem to take full advantage of the standards-based availability of pertinent personal health data. The active involvement of these NCCs could drive adoption of the standards locally, as well as provide a channel for suggested changes at a European and global level, provided they coordinate well with the respective (branches of the) SDOs who provide the expert consensus process for standards governance. This linkage between local IPS implementation and global standards governance provides for a collaborative environment for sustainable standards-based innovation.

8. Ethical aspects

An International Patient Summary (IPS) can document sensitive information that patients might not want others to know. Medical choices may reflect personal or religious values, such as decisions concerning reproductive medicine, organ donation or life support. Other information on health records may be seen as embarrassing or stigmatizing, including decisions concerning cosmetic surgery or psychiatric services. Finally, an IPS may contain information, such as descriptions of psychiatric or substance abuse treatment, chronic debilitating illness, reproductive decisions or elective surgery, that could be used to discriminate against persons.

The right to privacy protects persons from unwanted intrusions into their personal life. For this reason, during any action where an IPS is shared between different actors (clinicians, nurses, patients, administrative staff), this action must include all the security actions to ensure patient data confidentiality (Porsdam Mann, Savulescu, & Sahakian, 2016). The role of the General Data Protection Regulation (GDPR) deserves special attention in the context of an IPS (Kay, 2018).

9. Appendixes

9.1. Appendix I: List of initiatives interviewed

In the table below, an overview of the interviewed initiatives is provided including its country of origin. For means of clarification, the names of some of the initiatives are translated into English and put down in italics after the original name.

Number	***Name***	***Country of origin***
1	CEF eHDSI Solution Provider	European Union
2	CEN/TC 251 International Patient Summary	Europe
3	Historia Clínica Compartida de Catalunya *(Shared Catalan Clinical History)*	Catalonia, Spain
4	HL7 International Patient Summary	EU/US – Global
5	Huisartswaarneming *(Out-of-hours General Practitioner Summary)*	The Netherlands
6	Intermountain Clinical Health Data Exchange	United States
7	KANTA Patient Summary	Finland
8	Médecin Référent (*Patient summary for adults and children*)	Luxembourg
9	MedMij PGO *(Personal Health Environment)*	The Netherlands
10	PIEZO, Programma Implementatie Europese Zorgdiensten *(Program implementation European Healthcare Services)*	The Netherlands
11	Profilo Sanitario Sintetico. *(Health Profile* – Italian Patient Summary). Fascicolo Sanitario Elettronico. (*Electronic Health Record* – National EHR-System via which the PS is shared)	Italy
12	RCU2 – Resumo Clínico Único do Utente (*Clinical summary of the patient)*	Portugal
13	Sundhedsjournalen *(Health record)*	Denmark
14	Synthèse médicale *(Medical Summary)*	France

9.2. Appendix II: Interview scheme and possible answers

This interview scheme is created within the Trillium II project, that aims at further advancing global Electronic Health Record interoperability. As part of this interoperability, the International Patient Summary is a minimal and non-exhaustive Patient Summary usable for cross-border exchange in case of unplanned care. The Trillium II project also investigates other use-cases for the Patient Summary, beyond unplanned care. The International Patient Summary consists of general information about the patient (e.g. name, birth date, gender), a medical summary of the most important clinical patient data and a list of current medication of the patient. The aim of this interview is to understand how existing patient summary initiatives across the globe are managing the use of patient summaries and (changes to) the underlying specifications, standards and interchange technology, including the processing of feedback and suggested modifications to each of these aspects of patient summary implementation. However, this interview does not only aim at the current situation but also investigates the desired future situation of governance within the different initiatives. We use the term Patient Summary Governance to collectively identify all activities that aim at the introduction, use and ongoing development of patient summaries as part of the regular delivery of healthcare.
Our aim is to provide guidance for all current and future patient summary initiatives and the supporting Standards Developing Organisations on governance mechanisms that will sustain the successful use of patient summaries and promote future alignment of specifications with the International Patient Summary toward a stable basis for digital health innovation based on global access to patient summary data.

0: Patient Summary Initiative Characteristics		
0.1	What is the name of the patient summary initiative?	
0.2	What is the scope of the patient summary initiative?	**Depth:** ○ What is the content of the patient summaries that are exchanged? **Width:** ○ Which use-cases are supported in the exchange of patient summaries?
0.3	What is the stated purpose of the patient summary initiative?	
0.4	Which stakeholders are involved in the actual exchange of patient summary data?	**Possible stakeholders** ○ Patients and relatives ○ Healthcare professionals ○ Healthcare provider organisations ○ Payer organisations ○ Patient data registries ○ Research institutions

1: Patient Summary Specification and Use of Standards		
1.1	Is there a common specification for the Patient Summary?	
1.2	Are chosen standards in place for the use of patient summaries?	**Standards regarding:** ○ Patient summary content ○ Structure ○ Terminology
1.3	Are agreements made about a underlying infrastructure for the exchange of patients summaries?	**Possible forms of infrastructure:** ○ Dedicated repository ○ Dedicated registry ○ IHE XDS ○ Secure e-mail

2. Patient Summary Governance Scope and Objectives		
2.1	Which party (or parties) is (are) responsible for the patient summary specification?	
2.2	Is patient summary governance part of a bigger governance process or is it dedicated?	
2.3	Where is the patient summary governance aimed at currently?	**Possible aims:** o Maintaining and updating specification of the patient summary o The data, data quality and data protection regarding the parties exchanging patient summaries o The involvement of the patient in the exchange of patient summaries e.g. informing patients and asking permission o The infrastructure of the patient summary exchange o The implementation of a patient summary specification o Testing existing implementations of a patient summary specification
2.4	What are the current objectives of patient summary governance?	**Possible objectives** o Maintaining a stable specification of a fixed (minimal) dataset o Enabling the growth of topics and applications of patient summary exchange o Ensuring the data, data quality and data protection of the patient summary exchange. o (improved) Alignment with international patient summary specifications o Correct implementation of the patient summary specification at new affiliated parties o Ensuring correct use of the patient summary specification at existing affiliated parties.
2.5	What are the future aims and objectives of patient summary governance?	*Possible aims and objectives- as described above - can be selected.*

3: Stakeholders involved in the Patient Summary Governance		
3.1	Which stakeholders are currently involved in the patient summary governance?	**Two sorts of stakeholders:** 1. Stakeholders that are directly involved in the exchange of patient summaries (see 0.4) 2. Stakeholders which are not directly involved in the exchange of patient summaries but are involved in the patient summary governance: o The organisation managing the PS specifications o Health Authorities o Clinical Societies o Professional Societies o Patient Organisations o Vendor Associations o Payer Associations o Investment Partners o National eHealth Competency Centers o Standards Developing Organisations o Individual Experts
3.2	What role does each stakeholder currently have in the patient summary governance process?	**Possible roles for stakeholders:** o Gathering requirements for draft specifications, including revisions o Providing stakeholder input on draft specifications o Deciding upon final specifications o Publication and dissemination of final specifications o Establishing and running incentive schemes for adoption of specifications o Monitoring the adoption of specifications (users/vendors/regions) o Monitoring the use of specifications (numbers of PS created or exchanged)
3.3	To what extent are changes desired in stakeholders and their roles for the future?	*Possible stakeholders and roles as described above can be selected.*

4: Specification Update Process and Version Management		
4.1	Is updating of the patient summary specification part of the patient summary governance?	**Main Answer:** **Follow-up questions:** o How are the adjustments brought to the attention? o Is there a process for capturing user feedback as input for adjustments to the specification? o How is decision-making carried out upon desired adjustments to the specification? o How are the adjustments implemented in the patient summary specification?

4: Specification Update Process and Version Management		
4.2	How frequent are adjustments made to the patient summary specification	**Main Answer:** **Possible options:** o Dynamic adjusting the specification, on demand o Periodically adjusting the specification
4.3	Do adjustments of the patient summary specification require adjustments to be made in the used standards?	**Main Answer:** **Follow-up questions:** o Do you wait for the adjustments to be addressed in a new publication of the corresponding standard or do you include the adjustment directly in the specification? o How are the required changes adopted by the standard developing organisation? o How are those changes of the standards adopted in the patient summary specifications?
4.4	Are there other (patient summary) specifications that need to be taken into account in the patient summary governance?	**Main Answer:** **Follow-up questions:** o Which specifications are these? o How are those specifications addressed in the patient summary governance? o Is there a leading specification?
4.5	Is the implementation of the patient summary specification addressed in the governance process?	**Main Answer:** **Follow-up question:** o How is this implementation performed? o Knowledge exchange o Guidance of the implementation
4.6	Is there an audit process in place for testing existing implementations of the patient summary specification?	**Main Answer:** **Follow-up question:** o Who performs this audit process?
4.7	How is version management addressed when the patient summary specification is updated?	**Main Answer:** **Follow-up questions:** o Are multiple versions of the same specification supported in parallel? o What flexibility/autonomy do stakeholders have in selecting a version? o Is backward compatibility required for new versions of the specification? o When to react to new versions of the underlying standards, profiles, etc.?

9.3. Appendix III: Abbreviations List

In the table below are listed all the abbreviations used in this document.

Term	***Description***
C-CDA	Consolidated CDA
CCD	Continuity of Care Document
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CEF	Connecting Europe Facility
CEN	European Committee for Standardization
DG CONNECT	Directorate General Communications, Networks, Content and Technology (EC)
DG DIGIT	Directorate General for Informatics (EC)
DG Santé	Directorate General Health and Food Safety (EC)
EC	European Commission
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth DSI Member State Expert Group
eHOMB	eHealth DSI Operational Management Board
EHR	Electronic Health Record
EHR-S	Electronic Health Record-System
EMR	Electronic Medical Record
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation (EC)
HIE	Health Information Exchange
HL7	Health Level Seven
IG	Implementation Guide
IHE	Integrating the Healthcare Enterprise
IHE XCA	IHE Cross-Community Access
IHE XDS	IHE Cross-Enterprise Document Sharing
IPS	International Patient Summary
ISO	International Organization for Standardization
JIC	Joint Initiative Council for Global Health Informatics Standardization
LOINC	Logical Observation Identifiers Names and Codes
MU	Meaningful Use (US)
NCC	National eHealth Competence Centre
NCPeH	National Contact Point for eHealth
ONC	Office of the National Coordinator for Health Information Technology (US)
PHR-S	Personal Health Record System

PSSS	Patient Summary Standards Set
ReEIF	Refined eHealth European Interoperability Framework
SDO	Standards Developing Organisation
SMART on FHIR	Substitutable Medical Applications, Reusable Technologies on FHIR
SNOMED	Systematic Nomenclature of Medicine
US	United States of America
WHO	World Health Organization

References

Cangioli, G. (2017). *Deliverable 5.3 Final Activity Report relevant to Global Standards and the EU/US MoU*. Retrieved from eStandards Project: http://www.estandards-project.eu/eSTANDARDS/assets/File/deliverables/eStandards_D5_3_Final_Activity_Report_Global_Standards_and_EU_US_MoU.pdf

Chronaki, C. (2018). *Deliverable 3.1 Use case Selection and Analysis of Patient Summary Use Cases.* Retrieved from Trillium II: https://trillium2.files.wordpress.com/2018/08/d3-1-v2018-06-01-use-case-selection-and-analysis-of-patient-summary-use-cases-beyond-emergency-or-unplanned-care-wp2-hl7.pdf

eHealth Network. (2015). *Refined eHealth European Interoperability Framework.* Retrieved from https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

eHealth Network. (2016, November 21). *Guideline on the electronic exchange of health data : Patient Summary for unscheduled care.* Retrieved from European Commission - eHealth : Digital health and care: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf

EN-ISO 13940. (2016). *System of concepts to support continuity of care.* Brussels: CEN.

European Union. (2011, March 9). *Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.* Retrieved from EUR-Lex - Access to European Law: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

JIC. (2017). *Patient Summary Standards Set*. Retrieved from Joint Initiative Council: http://www.jointinitiativecouncil.org/registry/standards.set.patient.summary.asp

Kay, S. (2018, September 13). *GDPR Compliance and the International Patient Summary (IPS).* Retrieved from Eureopean eHealth Standards: http://www.ehealth-standards.eu/wp-content/uploads/2019/01/Final-report-Workshop-IPS-GDPR_13-September-2018_incl-attendance-list.pdf

ONC. (2019, January). *2019 Interoperability Standards Advisory.* Retrieved from The Office of the National Coordinator for Health Information Technology: https://www.healthit.gov/isa/sites/isa/files/inline-files/2019ISAReferenceEdition.pdf

Porsdam Mann, S., Savulescu, J., & Sahakian, B. (2016). Facilitating the ethical use of health data for the benefit of society: electronic health records, consent and the duty of easy rescue. *Philos Trans A Math Phys Eng Sci.*

Stegwee, R. A., & Chronaki, C. (2015). *Deliverable 3.1 The Case for Formal Standardization in Large-Scale eHealth Deployment.* Retrieved from eStandards Project: http://www.estandards-project.eu/eSTANDARDS/assets/File/deliverables/eStandards_D3_1CaseforFormalStandardization(1).pdf

VALUeHEALTH. (2017). *Establishing the value and business model for sustainable eHealth services in Europe*. Retrieved from http://www.valuehealth.eu/

Wikipedia. (n.d.). *Project Governance*. Retrieved June 30, 2017, from https://en.wikipedia.org/wiki/Project_governance