



eHealth Standards and Profiles in **Action** for Europe and Beyond

## Deliverable 3.1

# The case for formal standardization in large-scale eHealth deployment

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## Deliverable description

Deliverable:	D3.1: The case for formal standardization in large-scale eHealth deployment
Publishable executive summary:	<p>The case for formal standardization to support large-scale deployment of eHealth is asserted in this paper from four distinct perspectives that entail a balance of roles with different interests, costs, and benefits. Each perspective reveals a compelling case for formal standardization that can be empowered by collaboration and coordination among standards development and profiling organizations and their constituencies at all levels. It is the resulting trusted dialogs that will lead to co-creation in interoperability and nurture large-scale eHealth deployment.</p> <p>The four perspectives are:</p> <ol style="list-style-type: none"> <li>1. Citizens (as consumers of health services) <ul style="list-style-type: none"> <li>- Navigating the health system (or systems) for prevention, care, and wellness</li> <li>- Seeking active involvement and engagement in health maintenance and decisions on their care</li> </ul> </li> <li>2. Workforce (in the delivery and administration of health services) <ul style="list-style-type: none"> <li>- Communication and coordination of care by sharing relevant and trusted information within and across health systems</li> <li>- Dissemination and availability of knowledge for better decisions at the point of care</li> <li>- Workforce training in making the most of new technologies</li> </ul> </li> <li>3. eHealth Market (where eHealth solutions and services are traded) <ul style="list-style-type: none"> <li>- Creation of markets for new health and IT services</li> <li>- Expanding the choices for providers and consumers in existing markets</li> </ul> </li> <li>4. Health System (where care is delivered and cost, quality, and access decisions are made): <ul style="list-style-type: none"> <li>- Evidence-based rules and guidance for sustaining and innovating the health system</li> <li>- Public health reporting, surveillance, and analysis</li> <li>- Communication and coordination across health systems</li> </ul> </li> </ol> <p>The report concludes with a number of implications at the policy level for both the direct users and stakeholders of standards, as well as the standards development and profiling organizations, highlighting the need for collaboration and coordination at all levels. Notably, it concludes that actions need to be taken to promote the development of standards sets and tools to support them throughout the standards life cycle for development, deployment, testing, certification, as well as monitoring adoption and eventual revision.</p>
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# 1 Introduction

## 1.1 Scope

The case for formal standardization sets the stage for a policy dialog on the roadmap for standardization for large-scale eHealth deployment. The target audience are the policy makers in eHealth from a global to a local level, with particular emphasis on the standards development and profiling organisations (SDOs) and the eHealth stakeholders directly or indirectly involved in and/or impacted by the sustainable deployment of eHealth within and across health systems.

Focusing on health systems, and in particular the industry, professionals and citizens, the case for formal standardization applies to all geographical levels, providing for localization of global standards, in accordance with national, regional or local practices whenever possible. Ideally, the common and repeated use of standards to advance interoperability will take place at:

- The global level, for global travellers and global stakeholders in eHealth development and deployment;
- The pan-European level, in support of the Directive on Patients' Rights in Cross-Border Healthcare and the realization of a Digital Single Market for consumer health services;
- The multinational level, where public health and other specific common interests drive cross-border collaboration beyond the pan-European objectives;
- The national level, where each government strives for high quality, accessibility, and efficiency of health care delivery throughout the country;
- The regional level, where (sometimes similar to the multinational level) specific interests and needs drive developments that go beyond the national eHealth agenda;
- The local level, where individual provider organizations need to organize and monitor their health care delivery processes and deploy eHealth solutions and services as part of these processes.

There is an urgent need for standards and profiles to support large-scale eHealth deployment in a way that balances cost, quality, and access. The cost of inaction consists of a loss of trust, a diminished uptake of eHealth solutions and services, and only partial achievement of the objectives at all levels. Policy makers should therefore make firm commitment to:

- *Standards sets*, being the outcome of the collaboration among SDOs to produce coherent standards, profiles, and related standards artefacts, fit for the purpose of supporting specific use cases in eHealth deployment;
- *Tooling* for the specification, distribution, understanding, deployment, testing, and certification of standard sets and their implementations, encouraging their broad, accelerated, and consistent adoption to benefit large-scale deployment of eHealth services at low cost.

For that reason, the processes of formal standardization proposed in this document need to encompass the coordinated selection, development, use, and maintenance of standards, profiles, and related standards artefacts from multiple sources, and the use of these standards sets in the development and deployment of eHealth solutions, as well as the development and maintenance of individual standards and profiles that address specific aspects of eHealth solutions and services, where required.

## 1.2 Key concepts

- **Large-scale eHealth deployment:** the process to deliver eHealth solutions and services for large-scale adoption by individuals and organizations as an embedded part of their health management and health care delivery processes; as such processes typically span multiple organizations and can cross multiple health systems, the eHealth solutions and services involved need to support this type of networked deployment.
- **Formal standardization:** The formulation, maintenance and support of (a set of) standards, profiles, and standards artefacts that can be referenced by contracting parties and/or regulatory bodies, delivered through an open consensus-based process that engages all relevant stakeholders.
- **Case:** reasoning, arguments and supporting facts that intend to convince policy makers to support a particular course of action that furthers and sustains their objectives and the long-term interests of their constituents.
- **Standards Set:** a collection of standards and standards artefacts that support a specific use case<sup>1</sup>.

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<sup>1</sup> This definition stems from a work-in-progress of the Joint Initiative Council; this is a refinement of the term profile as used by IHE, Continua and other SDOs, and may change over time. (See: A JIC Foundation and Scope Report for Patient Summary Standards Set, 1 October 2015, draft 3.4; [www.jointinitiativecouncil.org](http://www.jointinitiativecouncil.org))

## 2 Background: eStandards Project

The eStandards project has been initiated by HL7, CEN/TC 251, and IHE, leading SDOs in the field of health informatics, and is supported by the eHealth Network, ISO/TC 215, GS1, IHTSDO, IEEE11073, EFMI and IMIA, to advance eHealth interoperability and global alignment of standards. To this end, eStandards pursues seven objectives:

- Join up with stakeholders in Europe and globally to build consensus on eHealth standards by accelerating knowledge-sharing, and promoting their wide adoption.
- Deliver an evidence-based roadmap for alignment, iterative consolidation, and broad acceptance of standards sets that is endorsed by SDOs, recognized in the European eHealth Interoperability Framework, adopted by the European eHealth Network, deployed by the providers and the workforce, and implemented by the industry.
- Contribute to the refinement and extension of the use cases in the European eHealth Interoperability Framework, focusing on clinical content modelling for different paradigms and embedding a quality management system for interoperability testing and certification of eHealth systems.
- Collect evidence and provide guidance on the coexistence of competing or overlapping standards in large-scale eHealth deployment nationally and cross-border.
- Participate in EU/US roadmap actions, such as the international patient summaries standard, which emanate from the EU/US memorandum of understanding on cooperation surrounding health related information and communication technologies.
- Explore socio-economic aspects of eHealth interoperability, revisiting the language for user-vendor interaction that embodies 'co-making' in trust, collaboration, and long-term engagement.
- Align across the Assess CT, openMedicine and ValueHealth projects to nurture innovation, sustainability and growth under the Connected Europe Facility and beyond, contributing to key European policy actions through cooperation with the Joint Action supporting the eHealth Network (JAseHN).

The proposal's ambition is to strengthen Europe's voice and impact, while reinforcing the bridges established with the European Patient Summary guideline across the Atlantic in Trillium Bridge and among member states with epSOS, e-SENS, Antilope, and EXPAND. The eStandards Roadmap and associated evidence base, this white paper on the case for formal standardization, and two guidelines addressing how to work with clinical content in profiles and competing standards in large-scale eHealth deployments, will be pragmatic steps toward alignment and convergence.

The project consists of mutually complementary lines of work that feed into the roadmap activities evidence, processes, use cases, and background information bringing together the activities under the EU/US Memorandum of Understanding, large-scale eHealth deployment, the evidence from the coexistence of standards, the socioeconomic aspects surrounding eHealth, and the refinement of the European Interoperability framework. The list of participating organizations can be found in Annex III.

This white paper prepares the ground to developing the first iteration of the roadmap for sustainable and collaborative standards sets. Building the case for formal standardization from the perspective of the health system, the eHealth market, the workforce and the citizen, it provides recommendations to facilitate large-scale eHealth deployment for a globally competitive Europe through global SDO collaboration on standard sets and supporting tools across the standards development lifecycle.

### 3 Building the Case

#### 3.1 Overview

The costs and benefits of large-scale eHealth deployment are distributed across a long list of stakeholders. A well-known problem in analysing the impact of innovations in healthcare is the fact that the short, medium and long term costs and associated benefits are often not aligned across stakeholders. The cost of health care hardly plays a role with the direct users of eHealth (patients and professionals), even in the unlikely event that these costs are actually known at that level of detail. Then again, the cost of healthcare is almost a constant across quite a few of the other stakeholders. The direct users of eHealth operate within the patient-provider-payer triangle, in which the responsibility for cost containment is imposed upon the payer through the health system. The health system itself is set up to balance three competing objectives: quality, accessibility, and affordability. Therefore, the cost of health care by itself provides a limited perspective to address the case for formal standardization.

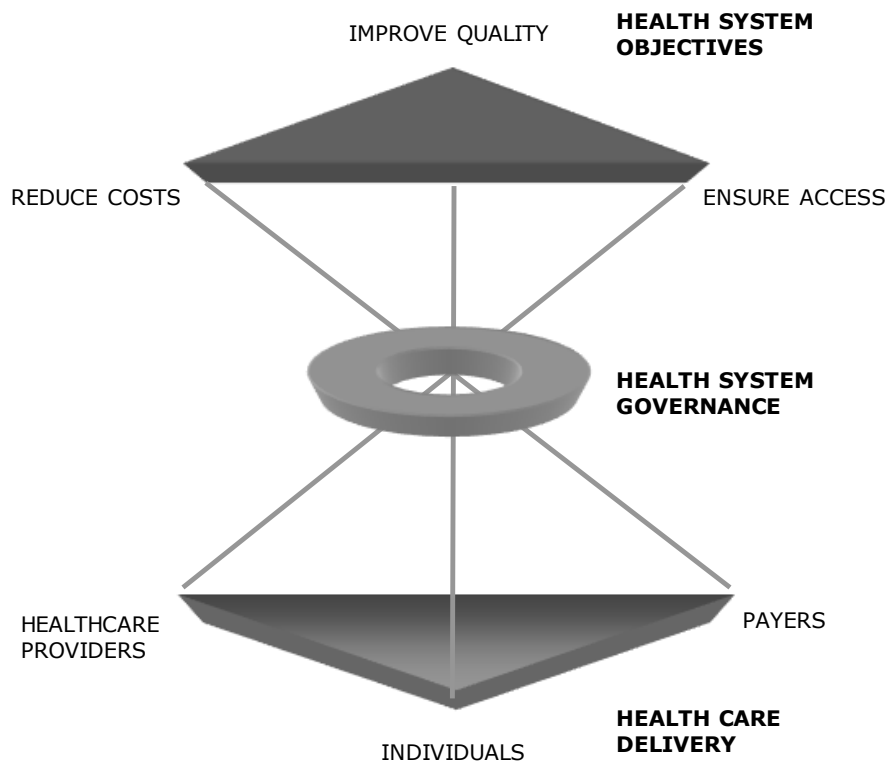


Figure 1: The two triangles of healthcare that formal standardization is challenged to balance leveraging data science and technology<sup>2</sup>.

When considering the large-scale deployment of eHealth from the perspective of availability of and access to health information, the objectives across stakeholders seem to be much more aligned, although from quite different backgrounds. Taking the perspective of direct patient care, including the inherent administrative activities, allows for a stable alignment of objectives across most stakeholders. This starts with tangible improvements in direct care and extends to secondary use of health information for health system governance.

<sup>2</sup> Graphic adapted from Arnold Moerkamp, National Healthcare Institute, the Netherlands.



As a result, the case is presented from four perspectives that balance the interests, costs, and benefits of eHealth stakeholders in different ways<sup>3</sup>. The four perspectives are:

- Citizens (as consumers of health services)
- Workforce (in the delivery of health services)
- eHealth Market (where eHealth solutions and services are traded)
- Health System (where care is delivered and cost and access decisions are made)

Each will be detailed below<sup>4</sup>. In each of the areas we also provide a few examples to illustrate the potential of eHealth deployment, supported by formal standardization. In general, a number of studies confirm that large-scale deployment of eHealth is hindered by a lack of commonly agreed standards. Therefore, when formal standardization takes form in a coordinated and accessible way, it would be easier to deploy each of the illustrations provided at scale, ranging from a local to a global level. We will further detail the contribution of formal standardization to each of the areas mentioned.

## 3.2 Citizens

Citizens, and their circle of informal care givers, play an increasingly important role in the maintenance of their own health. Teaming up with them is supported through formal standardization, because it enables:

- **Navigating the health system (or systems) for prevention, care, and wellness**

*Driver:* A well-documented trend among patients is the wish for more control over their health and the care they need, for more independence in managing the health care process, and for respect of their personal lifestyle and choices.

*Examples:* Control starts with proper insight into their health and the options available to improve it. In terms of choices, citizens want to be informed of the availability of health care services, their quality, and the associated costs.

*Standardization:* Appropriately deployed standards can help replicate services across organizations and health systems, match citizens' expectations to available services, provide guidance on how and what to choose, and eventually what it will cost.

- **Seeking active involvement and engagement in health maintenance and decisions on their care**

*Driver:* Once patients have made their choice, possibly in close collaboration with a primary care provider, they want to meet with a professional team that is well informed about their particular situation and any relevant history they bring. It needs to be noted, however, that patients and perhaps also their caregivers may wish to withhold information that will get in the way of their preferred life or treatment choices. Therefore, control of the information being shared is crucial. Once the patient is part of a trusted health care process, ease of access and arrangement of services with the health team, is key.

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<sup>3</sup> A similar differentiation of perspectives has been proposed by the ValueHealth project, when addressing the delivery of value in business models for sustainable eHealth services ([www.valuehealth.eu](http://www.valuehealth.eu)).

<sup>4</sup> Please note that for the sake of easy reading all supporting references and evidence are presented in Annex I.

*Examples:* Common examples of eHealth solutions and services that can help achieve this level of engagement are personal health records that provide a detailed patient history, online scheduling services, video consultation, self-monitoring and self-medication. In order for these activities to have an impact on the daily delivery of care by health care professionals, the eHealth services employed by the citizens need to be able to integrate or exchange information with the electronic health record or practice management systems that the professionals on their health team use.

*Standardization:* Patient information that is recorded using professional standards can be easily filtered, presented, and communicated in a way that is both safe and understandable for patients and professionals alike. Protection of personal information and patient consent require standardization to be effective across different platforms, when sharing information with different professionals and providers. Standards for self-services in the area of eHealth will enable citizens to engage with different healthcare providers across the health system without having to constantly adapt to local systems and practices.

### 3.3 Workforce

The reasons for adopting eHealth by health professionals and other personnel engaged in the delivery of health care and wellness services has been studied to some extent. The professionals' practice has changed profoundly over the years, due to sub-specialization, rapid pace of innovation, availability of immense amounts of information, relevant or not, and the changing practice of (medical) care in relation to other professionals and patients. Their main driver is to provide safe and high quality healthcare services, i.e. to do their job well and to do good to their clients, patients, and customers. High quality targeted information and decision support at their fingertips, enabled by standards, provides direct relevance to health professionals in their day-to-day activities. To gain a professional's trust, such tailored eHealth solutions do not dictate a preconceived process, but rather grant the users a great amount of control over the way they work with the system.

Formal standardization can contribute to those goals in distinct ways:

- **Communication and coordination of care by sharing relevant and trusted information within and across health systems**

*Driver:* Numerous studies have found that the objectives of professionals are quite different from what provider organizations expect. "Just being a good doctor" is more important than time saved, or having access to more detailed and timely information. Of course, spending less time on documentation or finding information is definitely a benefit. However, in the changing world of health care, being a good professional means collaboration across the health team, in order to coordinate activities, share essential information, and protect patients from preventable errors. A well-known goal is to provide continuity of care for the patient across care settings and provider organizations.

*Examples:* Especially within multidisciplinary teams, sharing information in coordination of care is key. Knowing the relevant facts about your patient is important, as is the fact that your patient knows what is going on, to the best of his or her ability. Alerts and reminders, when properly directed at situations that otherwise would go wrong, will certainly be appreciated as contributing to taking good care of a patient.

*Standardization:* The use of standards in making targeted information available is at least as significant for the workforce as it is for the citizens. Additionally, standards-based interoperability needs to be established across the diversity of eHealth systems involved, in order for information to be truly actionable by these systems, such as providing alerts and reminders. This is especially important when alerts need to be generated based on self-monitoring data provided by patients and their sensor devices. Moreover, when the continuity of care is at stake, for instance when a patient is referred to another professional in a different organization, sharing and using the information needed in different systems requires a high degree of standardization of health information exchange.

- **Dissemination and availability of knowledge for better decisions at the point of care**

*Driver:* The explosion of knowledge about support or treatment options and their effectiveness is a major challenge to all people engaged in health care. Online communities of both patients and professionals have helped, but it is still a struggle to present the right knowledge at the right time in such a way that it can be used in a safe and effective manner.

*Examples:* Especially in the area of cancer care, systems are available to help combine knowledge with individual patient characteristics, leading to precision medicine, rather than standard care plans for a standard patient. In addition, feedback loops within care teams and among professional groups, based on their actual daily practice, have shown to be a very effective and inspirational form of knowledge dissemination and even knowledge creation.

*Standardization:* Linking patient characteristics to the expected effects of treatments relies on formal standards for capturing these distinguishing characteristics. In addition, the logic of care plans that links characteristics to expected outcomes requires some form of computable standardization.

- **Workforce training in making the most of new technologies**

*Driver:* Educational and training support to complement evidence-based practice with practice-based medicine needs to scale beyond the local care team level, to contribute to a health system that is able to learn and adapt.

*Examples:* Extending the feedback loops to wider professional and expert communities has helped in the quick dissemination of knowledge and education of the less experienced colleagues, and continuous professional growth for all. In addition, professionals engage in serious gaming exercises to train their skills based on actual experience from their peers.

*Standardization:* Codifying the actual cases for use in learning communities and applications requires a solid set of formal standards, guided and supported by the experts in the community. Standards also help in the offering of free or competitive seminars through technology, such as massively open online courses (MOOCs). Learning about the impact of standards for interoperability on their professional life, will help in the adoption and the productive use of new and interoperable technologies, as well as the generation of new ideas for technology application.

### **3.4 eHealth Market**

The main players in this market have been vendors (suppliers) of health IT solutions and services, on the one hand, and health care provider organizations (customers) that commission these services, on the other. Increasingly, we see the rise of a strong consumer market, where mHealth, personal health,

wellness and fitness services are involved. The citizens will be a formidable force in the eHealth market for such personal applications of eHealth as they embrace their new role of the empowered health consumers.

The chief benefits of formal standardization supporting eHealth deployment is:

- **Creation of markets for new health and IT services**

*Driver:* The creation of markets benefits all, as it provides new opportunities for vendors, while it provides choice for commissioners and health consumers. Conditions of increased competition among new eHealth solution and service providers, will provide for a marketplace that is not limited by historic choices on the core health IT systems deployed already.

*Examples:* Current developments around well-established IHE profiles and open interfaces fit for use in personal health and mobile apps, such as the Continua profiles and new HL7 FHIR specifications, open up the market to new players. Proactive eHealth vendors, both incumbents and new entrants in the eHealth market, will see a potential rise in their revenues when formal standardization opens up markets across Europe and beyond, liberating the data with limited and clear localization requirements.

*Standardization:* The focus of formal standardization for eHealth deployment should be aimed at conditions for certain types of eHealth solutions and services to flourish in the larger ecosystem, not on the detailed description and regulation of the requirements of such services. Formal standardization, defined as an open consensus based process, aims to reach a level of agreement across a wide variety of stakeholders.

There are concerns that the interface development part of the market is adversely affected by standards deployment. Plug-and-play interoperability will no doubt alleviate or reduce the cost of developing and maintaining integrated systems. However the shift of focus to big data, including collection, extraction, and clean up, calls for standards. Combined with an emerging strong data culture / hunger new opportunities for integrators will no doubt emerge.

- **Expanding the choices for providers and consumers in existing markets**

*Driver:* Provider organizations, in their role as customers of eHealth systems and services, have their own strategic objectives, which may be quite different from one organization to the other. In general, three types of objectives can be discerned from a strategic perspective:

- Being the preferred provider organization for patients and referring professionals, by virtue of the personal attention and “client intimacy”;
- Being the best provider in a particular area of health care, by virtue of high levels of training, innovation and research;
- Being the most efficient provider in terms of cost, operational excellence and guaranteed levels of quality.

*Examples:* All of these objectives can be served by eHealth deployment, but the types of eHealth solutions and services that contribute to each of these objectives are quite different. Client intimacy is served by a rich variety of patient engagement tools, as well as support for easy assessment and referral by professionals. Engaging eHealth for enhanced monitoring and data capture, including the analytics capabilities to turn the data into new knowledge and practice, will foster a culture of excellence across the organization. Self-service tools and adaptive planning techniques, taking the characteristics

of patients and professionals into account, will suit provider organizations striving for efficiency and operational excellence.

*Standardization:* The variety of services needed makes it hard to agree on a common eHealth deployment strategy for a single vendor that serves multiple provider organizations. Formal standards enable the deployment of specialized eHealth services on top of a variety of core systems. Already core systems vendors are being pushed into working together to provide a suite of standardized interfaces for advanced eHealth services from other vendors. Explicit and consistent reference to standards sets in the procurement of eHealth systems and services across the provider community will help shape the supply side of the market. In order for this to happen, however, it is crucial that standards sets are the result of a trusted dialog on interoperability across the provider and vendor communities.

### 3.5 Health System

The health system perspective relates to governments and regulators that have responsibility for the operation of services and outcomes of health for the population that relies upon the particular health system. In that sense, the health system is the provider of services, while the health workforce and citizens are the co-producers of health and the customers or beneficiaries, respectively. Policy makers need to make sure the system is sustainable and the customers are happy. Extensive research indicates that eHealth deployment can contribute to the overarching objectives of each health system, simply formulated here as:

“ Improving the overall health of the population at an acceptable cost, whilst ensuring the quality, accessibility, and affordability of health care for all. ”

The examples we provide below will have profound implications for health systems deployment of eHealth systems and services in support of the policy objectives often found across the western world, such as more emphasis on community care, staying at home longer, self-management of chronic conditions, dependence on informal care givers, etcetera. eHealth standards add to the predictability of costs, the agility of the health system and its ability to capitalize on the results and best practices of other health systems.

Large-scale deployment of eHealth systems and services, conforming to standards sets, is deemed to be an essential ingredient of a number of these policy objectives, all under the umbrella of collecting evidence as we understand and continually improve health care practices. Transparency of health care delivery, through readily available health care data for secondary use, will drive the decisions to move the provision of care away from the more costly specialized centres and more into the home and under the personal responsibility of the patient and his or her informal caregivers, if the outcomes are similar or at least acceptable. Formal standards and profiles in eHealth are positioned to help achieve and build upon this degree of transparency and performance within and across health systems.

The contribution of formal standardization is most obvious in three areas:

- Use of evidence-based rules and guidance for sustaining and innovating the health system.

*Drivers:* Regulators of the health system have a growing need to promote the use of cost effective measures in the maintenance of health across the population. Insights in the relationship between prevention and treatment options, on the one hand, and health outcomes to be obtained, on the

other, is increasingly important. This understanding lies at the heart of a Learning Health System, a notion that is quickly gaining momentum across the world.

*Examples:* Evidence suggests that eHealth services for personal learning in the management of one's health, including prevention, is very effective in certain areas, such as mental health. Supporting rules and guidance to employ these services lead to lower costs and higher availability, trust, and impact than having health system personnel provide face-to-face coaching to each person individually. In addition, eHealth has been proven to be very effective in reaching remote communities at an affordable cost. Innovative eHealth systems also facilitate the use and enhancement of professional best practices. This has an impact on the workforce itself, as discussed above, but will also result in higher quality outcomes and more effective use of resources at the health system level.

*Standardization:* eHealth standards sets build confidence in eHealth by shaping expectations on the interconnectedness of services, able to share and use essential information. Standards sets also help smooth the transition from data to actionable information in knowledge based decision support systems, thus strengthening the impact and uptake of evidence-based guidelines.

- **Public health reporting, surveillance, and analysis**

*Drivers:* The governance of the health system relies in part on public health reporting and the analysis of the information reported. Differences in the prevalence and incidence of specific health issues across geographic or demographic populations may lead to targeted investigations and interventions. For instance, education, prevention, or treatment options made available or promoted to these groups can be appropriately tailored.

*Examples:* Large-scale eHealth deployment for the maintenance of personal and professional health records will facilitate and improve the secondary use of health care data, resulting in more timely and more targeted decisions on organizing health and health care delivery. Also, when using eHealth systems, the quality of the health care services provided through these systems can be monitored easily through the addition of both process and outcome measurements, including patient-reported outcome measures, as eHealth enables the automatic capture of such information.

*Standardization:* Common definitions of data elements help lower the cost to populate and maintain population health data repositories that are built upon clinical data from health record systems. This includes the selection and assessment of patient cohorts for further analysis of differences in health outcomes. eHealth standards also help shape quality indicators, data extraction, preparation, and delivery in formats independent of particular vendors and systems. However, in order for such standards to be used in key decision making at a health system level, it is crucial that they are the result of trusted dialogues that are involved in the co-making of standards with professionals in areas such as epidemiology, health care delivery, and technology.

- **Communication and coordination across health systems.**

*Drivers:* Individual health systems will often share resources with other health systems in order to provide cost-effective access to high quality care for their population. Expensive and specialized health technology, expertise in the treatment of rare diseases, temporary shortage of personnel and convenience to travellers, including medical tourism, are all reasons to exchange resources and services.

*Examples:* For health systems to collaborate effectively, communication and coordination of care across health systems has proven to be very relevant. Projects like epSOS, Semantic HealthNet, Tril-

lium Bridge, and e-SENS to name a few, but also the experience of patients and professionals in teleconsultation and telemedicine, show the necessity and feasibility of eHealth services for cross-border care.

*Standardization:* eHealth standards sets are essential for the transfer, sharing, and common understanding of the provided information in a cross border setting. They enable structural arrangements in the safe and cost-effective delivery of cross-border care. In addition, such eHealth standards sets also facilitate a more detailed comparison of health information across health systems.

## 4 Implications

Health and health care are universal human rights that need and deserve strengthening. With the information revolution, health information technology (in the form of eHealth solutions and services) becomes essential to the fabric of health and health care. This is true for the health of citizens, as well as for the care provided by professionals, and for the sustainability of health systems. This novel combination of perspectives raises the bar for standards-based interoperability considerably. Interoperability is no longer just a nice-to-have, nor just a lever for productivity or cost control. It is quickly becoming a prerequisite for safe, high quality, affordable, and accessible health care across our health systems. At the same time, it fuels our eHealth market with a global demand for eHealth systems and services, supporting our workforce at the point of care, and providing security, comfort, and choice to our citizens.

We have argued that formal standardization supports the large-scale deployment of eHealth solutions and services. In most cases, standards sets are a precondition to achieving the objectives set forward in each of the perspectives covered. To this end, formal standardization needs to be more than an exercise in appropriate use case and information modelling limited to specifying the technical artefacts and infrastructure. As detailed in both the Calliope and Antilope projects, formal standardization for interoperability needs embedding in a solid combination of policy, professional and legal frameworks and ambitions. However, SDOs and their key stakeholders have yet to successfully establish their role in and contribution to such broad and inclusive collaborative efforts.

There is an acute need for trusted dialogues among stakeholders, leading to common understanding of means and objectives, followed by focused and balanced collaboration among SDOs, in turn leading to high quality standards sets that can be directly and consistently deployed by industry, with support through appropriate tools.

In recent years the SDO community has come to recognize that coordination and collaboration across the standards development life-cycle is a crucial precondition for increased success in formal standardization. An example of such close collaboration is the development of standards for the identification of medicinal products (IDMP) as a project through the Joint Initiative Council (JIC) on SDO global health informatics standardization. Over the next two years, this standard will be deployed to serve as the backbone of a pan-European medicines database at the European Medicines Agency. Similar implementation of IDMP is taking place through the US Food and Drug Administration. Connecting IDMP to other standards projects and initiatives, such as cross-border patient summaries and ePrescription, strengthens the notion of coordinated standards sets and resonates with the decision to form a European SDO platform for eHealth, as adopted by the European eHealth Network.

The picture below identifies the five key phases in the life-cycle of formal standardization in support of large-scale deployment of eHealth. Coordination and collaboration, facilitated with trusted dialogs and well recognized synergies, need to address and link all of these phases.



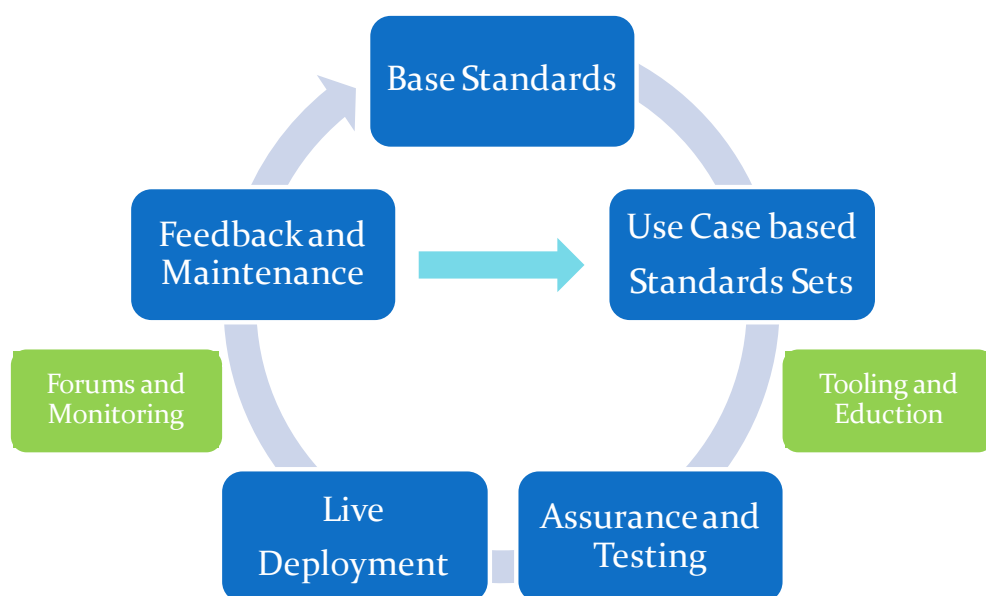


Figure 2: Standards Development lifecycle, adapted from "Tools for interoperability - Time for eStandards" Workshop at MedInfo 2015

Policy makers, that recognize the key role of formal standardization in supporting the innovation necessary to enable large-scale eHealth deployment, can strengthen the collaborative efforts striving toward:

- Achieving easy interoperability across eHealth applications
- Increasing accessibility and usability of eHealth standards and specifications
- Reusing knowledge through tooling for eHealth deployment

Provided with appropriate support, SDOs can collaborate on the development of resilient standard sets that are fit for the purpose of large-scale eHealth deployment, whilst:

- Achieving consistency across the different phases of standards development and deployment
- Enlarging the pool of contributors to eHealth within an interoperable eHealth ecosystem.

To this end, tooling and education are identified as important instruments to support the ease of implementation, especially when integrated well in the assurance and testing phase. In addition, forums and monitoring will help in systematically providing guidance and collecting feedback on the real-life experience in working with the standards sets developed. This will help maintain a consistently high level of relevance of the standards sets for large-scale eHealth deployment.

The eStandards project, together with a large number of other ongoing initiatives at a European and global level, will outline a roadmap for standardization in support of large-scale eHealth deployment. The purpose of this roadmap is to identify key activities that will help answer to the needs of the stakeholders that are directly involved in the deployment of eHealth. It will help achieve the objectives of such large-scale eHealth deployment, balancing the interests of stakeholders from the perspectives covered in this paper.

## Annex I – Annotated references supporting the case

In this annex we provide the supporting literature references that have helped build the case for formal standardization supporting large-scale eHealth deployment, as described in this document. More background information and the highlights of some of the references are provided in Annex II.

### 1. Introduction

The scope that is being addressed by this document includes the pan-European level, in support of the Directive on Patients' Rights in Cross-Border Healthcare and the realization of a Digital Single Market, also for consumer health services.

- [Dir2011-24] Directive 2011/24/EU of the European Parliament and of The Council on the application of patients' rights in cross-border healthcare, <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=URISERV:sp0002>, 2012.
- [DSM2015] European Commission, Digital Single Market Roadmap, [http://ec.europa.eu/priorities/digital-single-market/docs/roadmap\\_en.pdf](http://ec.europa.eu/priorities/digital-single-market/docs/roadmap_en.pdf), 2015.
- [DSM2015a] European Commission, Digital Single Market, <http://ec.europa.eu/priorities/digital-single-market/>, 2015.

### 2. Building the Case

In general, cases for formal standardization have been discussed and documented at length. They lie, for instance, at the heart of the International Standards Organization.

- [ISObenefits] Benefits of standards: the ISO materials:  
[http://www.iso.org/iso/home/standards/benefitsofstandards/benefits\\_of\\_standards.htm](http://www.iso.org/iso/home/standards/benefitsofstandards/benefits_of_standards.htm)
- Economic Benefits of standards: Fact Sheets: International case studies Vol 1:  
<http://www.iso.org/iso/pub100288.pdf>
- Economic Benefits of standards: Fact Sheets: International case studies:, Vol 2:  
<http://www.iso.org/iso/pub100311.pdf>

The case for formal standardization starts out with the notion that there is an urgent need for standards and profiles to support large-scale eHealth deployment. A number of studies confirm that large-scale deployment of eHealth is hindered by a lack of commonly agreed standards.

- [Nictiz2015] eHealth Monitor 2015 (in Dutch), eHealth competence centre Nictiz, <https://www.nictiz.nl/SiteCollectionDocuments/Rapporten/eHealth%20monitor%202015.pdf>, 2015.
- [eHSG2014] Widespread Deployment of Telemedicine Services in Europe, eHealth Stakeholder Group, [http://ec.europa.eu/newsroom/dae/document.cfm?doc\\_id=5167](http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5167), 2014.
- [eEIF2013] eHealth European Interoperability Framework Study, 2013, <https://ec.europa.eu/digital-agenda/en/news/ehealth-interoperability-framework-study-0>
- [Calliope2010] Calliope Project, eHealth Interoperability Roadmap, <http://tinyurl.com/kctzsl2>, 2010.
- [M4032006] Mandate to the European Standardisation Organisations CEN, CENELEC and ETSI in the field of Information and Communication Technologies, applied to the domain of eHealth, <http://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=search.detail&id=363#>, 2006

We dismiss the perspective of a simple return on investment business case, as analysing the impact of innovations in healthcare is hindered by the fact that the short, medium and long term costs and associated benefits are often not aligned across stakeholders. The direct users of eHealth operate within the patient-provider-payer triangle, in which the responsibility for cost containment is not felt by patients and providers, as it is imposed upon the payer through the health system. The health system

itself is set up to balance three competing objectives: quality, accessibility, and affordability.

[PorterLee2013] The Strategy That Will Fix Health Care, Michael E. Porter & Thomas H. Lee, <https://hbr.org/2013/10/the-strategy-that-will-fix-health-care> 2013.

[Kongstvedt2013] Essentials of Managed Health Care, Peter R. Kongstvedt, Jones & Bartlett Learning, 2011.

[PorterTeisberg2016] Redefining Health Care, Michael Porter & Elizabeth Teisberg, Harvard Business Review Press, 2006

We therefore take the perspective of availability of and access to health and patient information, through health information technology, in which the objectives across stakeholders seem to be much more aligned, although from quite different backgrounds.

[Buntin2011] The Benefits Of Health Information Technology: A Review Of The Recent Literature Shows Predominantly Positive Results, Melinda Beeuwkes Buntin et al. <http://content.healthaffairs.org/content/30/3/464.full>, 2011.

## 2.1. Citizens

In analyzing the added value of availability of and access to health information, we start out with the trend among patients to wish for more control over their health and the care they need, as well as for more independence in managing the health care process, and for respect of their personal lifestyle and choices.

[Empathie2014] EMPATHiE: Empowering patients in the management of chronic diseases, [http://ec.europa.eu/health/patient\\_safety/docs/empathie\\_frep\\_en.pdf](http://ec.europa.eu/health/patient_safety/docs/empathie_frep_en.pdf), 2014.

[Aujoulat2008] Reconsidering patient empowerment in chronic illness: A critique of models of self-efficacy and bodily control, Isabelle Aujoulat, et al. <http://www.sciencedirect.com/science/article/pii/S0277953607006223>, 2008.

[Segal1998] The importance of patient empowerment in health system reform, Leonie Segal. <http://www.sciencedirect.com/science/article/pii/S0168851098000074>, 1998.

In addition, citizens want to be informed of the availability of health care services, their quality, and the associated costs.

[EPF2014] Patient Safety and Quality of Care: examples of transparency and accountability, presentation at Rome Conference, [http://ec.europa.eu/chafea/documents/health/rome-0203122014-immonen\\_en.pdf](http://ec.europa.eu/chafea/documents/health/rome-0203122014-immonen_en.pdf), 2014.

[Coulter2005] European patients' views on the responsiveness of health systems and healthcare providers, Angela Coulter & Crispin Jenkinson, <http://eurpub.oxfordjournals.org/content/15/4/355.short>, 2005.

[Magee2003] Public views on healthcare performance indicators and patient choice, Helen Magee, et al. <http://jrs.sagepub.com/content/96/7/338.short>, 2003.

When they have made their choice, they want to meet with a professional team that is well informed about their particular situation and any relevant history they bring.

[NPCF2015] Personal Health Record : Experience and needs (in Dutch), Patient federation NPCF, <https://www.npcf.nl/Documenten/PGD/ADpgd.pdf>, 2015.

[CFAH`2013] Sharing Medical Information with Multiple Doctors: Your Medical Records, Center for Advancing Health, <http://www.cfah.org/prepared-patient/organize-your-health-care/sharing-medical-information-with-multiple-doctors-your-medical-records>, 2013.

Last but definitely not least, control of the information being shared is crucial.

[COM2012] Safeguarding Privacy in a Connected World A European Data Protection Framework for the 21st Century COMMUNICATION FROM THE COMMISSION [http://ec.europa.eu/justice/data-protection/reform/index\\_en.htm](http://ec.europa.eu/justice/data-protection/reform/index_en.htm), 2012.

[Whiddett2006] Patients' attitudes towards sharing their health information, Richard Whiddett, et al. <http://www.sciencedirect.com/science/article/pii/S1386505605001735>, 2006.

## 2.2. Workforce

The professionals' practice has changed profoundly over the years, due to sub-specialization, rapid pace of innovation, availability of immense amounts of information, relevant or not, and the changing practice of (medical) care in relation to other professionals and patients.

[Christensen2009] The Innovator's Prescription: A Disruptive Solution for Health Care, Christensen CM et al., McGraw-Hill Professional 2009.

When discussing the added value of eHealth for professionals, we turn to the reasons for adopting eHealth by health professionals and other personnel engaged in the delivery of health care and wellness services. Numerous studies have found that the objectives and motives of professionals are quite different from what provider organizations expect.

[Villalba2015] Adoption of health information technologies by physicians for clinical practice: The Andalusian case, Elena Villalba-Mora, et al. [http://www.ijmijournal.com/article/S1386-5056\(15\)00062-3/abstract?cc=y](http://www.ijmijournal.com/article/S1386-5056(15)00062-3/abstract?cc=y), 2015.

[Michel2013] Electronic patient record: what makes care providers use it? Margreet Michel-Verkerke, <http://doc.utwente.nl/84625/>, 2013.

[Smith1996] What clinical information do doctors need? Richard Smith BMJ, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2352351/pdf/bmj00565-0044.pdf> 1996.

A well-known goal is to provide continuity of care for the patient across care settings and provider organizations. When the continuity of care is at stake, for instance when a patient is referred to another professional in a different organization, sharing and using the information needed in different systems requires a high degree of standardization of health information exchange

[ContSys2015] System of concepts to support continuity of care, ISO standard under publication, [http://www.iso.org/iso/home/store/catalogue\\_tc/catalogue\\_detail.htm?csnumber=58102](http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=58102), 2015.

[Kripalani2007] Deficits in Communication and Information Transfer Between Hospital-Based and Primary Care Physicians : Implications for Patient Safety and Continuity of Care, Sunil Kripalani et al., <http://jama.jamanetwork.com/article.aspx?articleid=205790>, 2007

The explosion of knowledge about support or treatment options and their effectiveness is a major challenge to all people engaged in health care. Important progress is shown when treatment decisions combine knowledge with individual patient characteristics, leading to precision medicine, rather than standard care plans for a standard patient.

[Collin2015] A New Initiative on Precision Medicine, Francis S. Collin, et al, <http://www.nejm.org/doi/full/10.1056/nejmp1500523>, 2015.

[Chen2012] Promise of personalized omics to precision medicine, Rui Chen and Michael Snyder, <http://onlinelibrary.wiley.com/doi/10.1002/wsbm.1198/abstract>, 2012.

Establishment of feedback loops within care teams and among professional groups, based on their actual daily practice, has shown to be a very effective and inspirational form of knowledge dissemination and even knowledge creation.

[Jamtvedt2003] Audit and feedback: effects on professional practice and health care outcomes, G Jamtvedt, et al. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000259/abstract>, 2003.

[Clercq1999] A Strategy for Developing Practice Guidelines for the ICU Using Automated Knowledge Acquisition Techniques, Paul A. de Clercq, <http://link.springer.com/article/10.1023/A:1009911121207>, 1999.

[Rubinstein1995] Improving patient quality of life with feedback to physicians about functional status, Lisa V. Rubenstein, et al., <http://link.springer.com/article/10.1007/BF02602744>, 1995.

Extending the feedback loops to wider professional and expert communities has helped in the quick dissemination of knowledge and education of the less experienced colleagues, and continuous professional growth for all.

[Cunningham2012] Health professional networks as a vector for improving healthcare quality and safety: a systematic review, Frances C Cunningham, et al. <http://qualitysafety.bmj.com/content/21/3/239.short>, 2012.

[Wensing2011] Connectedness of healthcare professionals involved in the treatment of patients with Parkinson's disease: a social networks study, Michel Wensing, et al. <http://www.biomedcentral.com/content/pdf/1748-5908-6-67.pdf>, 2011.

Learning about the impact of standards for interoperability on their professional life, will help in the adoption and the productive use of new and interoperable technologies, as well as the generation of new ideas for technology application.

[Hersh2014] Beyond information retrieval and electronic health record use: competencies in clinical informatics for medical education, William R Hersh, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4085140/>, 2014.

[Watson2013] The future of Australian medical education: a focus on technology, Marcus O Watson & Brian C Jolly, <https://www.mja.com.au/journal/2013/199/5/future-australian-medical-education-focus-technology>, 2013.

### 2.3. eHealth Market

We see the rise of a strong consumer market, where mHealth, personal health, wellness and fitness services are involved.

[RockHealth2015] Digital Health Consumer Adoption: 2015, Rock Health, <http://rockhealth.com/reports/digital-health-consumer-adoption-2015/>, 2015.

[GrandView2015] mHealth Market Analysis, Grand View Research, <http://www.grandviewresearch.com/industry-analysis/mhealth-market>, 2015.

[E&Y2012] Mobile Technology poised to enable a new Era in Health Care, Ernst & Young, [http://www.ey.com/Publication/vwLUAssets/mHealth/\\$FILE/mHealth%20Report\\_Final\\_19%20Nov%2012.pdf](http://www.ey.com/Publication/vwLUAssets/mHealth/$FILE/mHealth%20Report_Final_19%20Nov%2012.pdf), 2012.

[PWC2012] Touching lives through mobile health : Assessment of the global market opportunity, PWC, [http://www.pwc.in/assets/pdfs/telecom/gsma-pwc\\_mhealth\\_report.pdf](http://www.pwc.in/assets/pdfs/telecom/gsma-pwc_mhealth_report.pdf), 2012

Current developments around well-established IHE profiles and open interfaces fit for use in personal health and mobile apps, such as the Continua profiles and new HL7 FHIR specifications, open up the market to new players.

[JASON2014] A Robust Health Data Infrastructure, JASON taskforce report, [http://healthit.gov/sites/default/files/ptp13-700hhs\\_white.pdf](http://healthit.gov/sites/default/files/ptp13-700hhs_white.pdf), 2014.

[Argonaut] HL7 Argonaut Project – Argonaut Project Testing Community, [http://argonautwiki.hl7.org/index.php?title=Main\\_Page/Implementation](http://argonautwiki.hl7.org/index.php?title=Main_Page/Implementation)

[ContinuaAlliance] Member Company Showcase, <http://www.continuaalliance.org/about-the-alliance/company-showcase>

[IHE] Integrating the Healthcare Enterprise – Member Organizations, [http://ihe.net/Member\\_Organizations/](http://ihe.net/Member_Organizations/)

There are concerns that the interface development part of the market is adversely affected by standards deployment.

[Tassey2000] Standardization in technology-based markets, Gregory Tassey, <http://www.sciencedirect.com/science/article/pii/S0048733399000918>, 2000.

When looking at the market from a procurement perspective, we discern three types of objectives for healthcare provider organizations from a strategic perspective.

[Hillestad2013] Health care market strategy: from planning to action, Steven G. Hillestad & Eric N Berkowitz, Fourth Edition, Jones & Bartlett Learning, 2013.

[Treacy1993] Customer intimacy and other value disciplines, Michael Treacy & Fred Wiersema, <https://hbr.org/1993/01/customer-intimacy-and-other-value-disciplines>, 1993.

Formal standards enable the deployment of specialized eHealth services on top of a variety of core systems.

[HL72015] Koppeltaal on HL7® FHIR® : A New Behavioral Health Platform for Information Exchange in the Netherlands, HL7 Newsletter September [http://www.hl7.org/documentcenter/public/newsletters/HL7\\_NEWS\\_20150910.pdf](http://www.hl7.org/documentcenter/public/newsletters/HL7_NEWS_20150910.pdf), 2015

[SMART2014] Something New and Powerful: SMART on FHIR®, <http://smarthealthit.org/smart-on-fhir/>, 2014.

## 2.4. Health System

In general, eHealth deployment can contribute to the overarching objectives of health systems.

[Nictiz2015] eHealth Monitor 2015 (in Dutch), eHealth competence centre Nictiz, <https://www.nictiz.nl/SiteCollectionDocuments/Rapporten/eHealth%20monitor%202015.pdf>, 2015

[RAND2010] Business Models for eHealth, report for the European Commission, RAND corporation, [http://ec.europa.eu/newsroom/dae/document.cfm?doc\\_id=2891](http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=2891), 2010

[eHealthTF2012] eHealth Task Force Report – Redesigning health in Europe for 2020, [http://ec.europa.eu/newsroom/dae/document.cfm?doc\\_id=2650](http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=2650), 2012

Specifically, insights in the relationship between prevention and treatment options, on the one hand, and health outcomes to be obtained, on the other, lies at the heart of a Learning Health System, a notion that is quickly gaining momentum across the world.

[ONC2015] Connecting Health and Care for the Nation : A Shared Nationwide Interoperability Roadmap, Final Version 1.0, ONC report, <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>, 2015.

[SHN2015] SemanticHealthNet Deliverable 6.1: Recommendations, to, industry, and, to, health, ministries: on the scaling up and widespread deployment of semantic interoperability solutions. [http://www.semantichealthnet.eu/SemanticHealthNet/assets/File/SHN%20288408%20D6\\_1%20Recommendations%20to%20industry%20and%20to%20health%20ministries.pdf](http://www.semantichealthnet.eu/SemanticHealthNet/assets/File/SHN%20288408%20D6_1%20Recommendations%20to%20industry%20and%20to%20health%20ministries.pdf), 2015.

[IOM2006] The learning Healthcare System: Workshop Summary, IOM Roadmap on evidence-base medicine. <http://www.nap.edu/catalog/11903/the-learning-healthcare-system-workshop-summary-iom-roundtable-on-evidence-2005>

Evidence suggests, also, that eHealth services for personal learning in the management of one's health, including prevention, is cost effective in certain areas, such as mental health.

- [Jordan2015] Supported self-management for patients with moderate to severe chronic obstructive pulmonary disease (COPD): an evidence synthesis and economic analysis, Rachel E. Jordan, et al. [http://www.journalslibrary.nihr.ac.uk/\\_data/assets/pdf\\_file/0004/144850/ScientificSummary-hta19360.pdf](http://www.journalslibrary.nihr.ac.uk/_data/assets/pdf_file/0004/144850/ScientificSummary-hta19360.pdf), 2015.
- [Craske2009] Computer-assisted delivery of cognitive behavioral therapy for anxiety disorders in primary-care settings, Michelle G. Craske, et al., <http://onlinelibrary.wiley.com/doi/10.1002/da.20542/abstract>, 2009.
- [Caroll2008] Computer-Assisted Delivery of Cognitive-Behavioral Therapy for Addiction: A Randomized Trial of CBT4CBT, Kathleen M. Caroll, et al., <http://ajp.psychiatryonline.org/doi/abs/10.1176/appi.ajp.2008.07111835>, 2008.
- [Lorig2001] Effect of a self-management program on patients with chronic disease, K.R. Lorig, et al., <http://europepmc.org/abstract/med/11769298>, 2001.

In addition, eHealth has been proven to be very effective in reaching remote communities at an affordable cost.

- [Adler2015] Bridging the Distance in the Caribbean: Telemedicine as a means to build capacity for care in paediatric cancer and blood disorders, Ellie Adler, et al., <http://ebooks.iospress.nl/volumearticle/39204>, 2015.
- [Olson2014] Telemedicine Versus Emergency Transfer of Trauma Patients: A Systematic Review, Jason Olson, <http://commons.pacificu.edu/pa/488/>, 2014.
- [Lokkerbol2014] Improving the Cost-Effectiveness of a Healthcare System for Depressive Disorders by Implementing Telemedicine: A Health Economic Modeling Study, Joran Lokkerbol, et al., <http://www.sciencedirect.com/science/article/pii/S1064748113000638>, 2014.

In cross-border care, projects like epSOS, SemanticHealthNet, Trillium Bridge, and e-SENS to name a few, but also the experience of patients and professionals in teleconsultation and telemedicine, show the necessity and feasibility of cross-border deployment of eHealth services.

- [eSens] eSens and eHealth – real life piloting, <http://www.esens.eu/real-life-piloting/e-health/>
- [TrilliumBridge2015] Trillium Bridge Recommendations for transatlantic policy convergence, D5.2, [www.trilliumbridge.eu](http://www.trilliumbridge.eu), 2015.
- [SHN2015] SemanticHealthNet Deliverable 6.1: Recommendations, to, industry, and, to, health, ministries: on the scaling up and widespread deployment of semantic interoperability solutions, [http://www.semantichealthnet.eu/SemanticHealthNet/assets/File/SHN%20288408%20D6\\_1%20Recommendations%20to%20industry%20and%20to%20health%20ministries.pdf](http://www.semantichealthnet.eu/SemanticHealthNet/assets/File/SHN%20288408%20D6_1%20Recommendations%20to%20industry%20and%20to%20health%20ministries.pdf), 2015.
- [EHRImpact2009] The socio-economic impact of interoperable electronic health record (EHR) and ePrescribing systems in Europe and beyond, [http://www.ehr-impact.eu/downloads/documents/EHRI\\_final\\_report\\_2009.pdf](http://www.ehr-impact.eu/downloads/documents/EHRI_final_report_2009.pdf), 2009.

### 3. Implications

Standards sets are a precondition to achieving the objectives of large-scale eHealth deployment. The term “standards set” stems from a work-in-progress of the Joint Initiative Council; this is a refinement of the term profile as used by IHE, Continua and other SDOs, and may change over time.

- [JIC2015] A JIC Foundation and Scope Report for Patient Summary Standards Set, draft 3.4, [www.jointinitiativecouncil.org](http://www.jointinitiativecouncil.org), 2015.

In recent years the SDO community has come to recognize that coordination and collaboration across the standards development life-cycle is a crucial precondition for increased success in formal standardization.

[Antilope2015] Adoption and take up of standards and profiles for eHealth Interoperability - Refinement of the eHealth Interoperability Framework (WP1), [http://www.antilope-project.eu/wp-content/uploads/2013/05/D1.2b\\_Executive\\_Summary\\_V1\\_0.pdf](http://www.antilope-project.eu/wp-content/uploads/2013/05/D1.2b_Executive_Summary_V1_0.pdf), 2015.

[CEN2015] CEN/TC 251 Health Informatics Business Plan 2015-2018, [http://www.ehealth-interop.nen.nl/dynamics/modules/SFIL0100/view.php?fil\\_id=1333](http://www.ehealth-interop.nen.nl/dynamics/modules/SFIL0100/view.php?fil_id=1333), 2015.

[JIC2015] San Francisco Declaration of the Joint Initiative Council on Global Health Informatics Standardization, <http://www.jointinitiativecouncil.org/declaration.asp>, 2015.

[eHN2014] eHealth Network – Multi-Annual Work Plan 2015-2018, [http://ec.europa.eu/health/ehealth/docs/ev\\_20140513\\_mwp\\_en.pdf](http://ec.europa.eu/health/ehealth/docs/ev_20140513_mwp_en.pdf), 2014.

[eHealthInterop2009] eHealth-INTEROP Report in response to eHealth Interoperability Standards Mandate, <http://www.ihe-europe.net/drupal/sites/default/files/final%20report%20eHealth.pdf>, 2009.

For coordination and collaboration to work, we identify five key phases in the life-cycle of formal standardization in support of large-scale deployment of eHealth.

[Stegwee2015] Tools for Interoperability: Time for eStandards?, Robert Stegwee, Catherine Chronaki, Giorgio Cangiolli, Amnon Shabo (Shvo), Morten Bruun-Rasmussen, Kai Heitmann, Charles Jaffe, Workshop at MedInfo 2015, Sao Paulo, Brasil, Aug 19-22, 2015 (available at [www.estandards-project.eu/index.cfm/download](http://www.estandards-project.eu/index.cfm/download)).

The eStandards project, together with a large number of other ongoing initiatives at a European and global level, will outline a roadmap for standardization in support of large-scale eHealth deployment.

[RollingPlan2015] European Commission, Rolling Plan for ICT standardization 2015, [http://ec.europa.eu/newsroom/dae/document.cfm?doc\\_id=9137](http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=9137) 2014.

[WHO2012] World Health Organization, National eHealth Strategies Toolkit, [https://www.itu.int/dms\\_pub/itu-d/opb/str/D-STR-E\\_HEALTH.05-2012-PDF-E.pdf](https://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf), 2012.

The purpose of this roadmap is to identify key activities that will help answer to the needs of the stakeholders that are directly involved in the deployment of eHealth. It will help achieve the objectives of such large-scale eHealth deployment, balancing the interests of stakeholders from the perspectives covered in this paper.



## Annex II – Background Material

[JAS2014] A Robust Health Data Infrastructure, JASON taskforce report, [http://healthit.gov/sites/default/files/ptp13-700hhs\\_white.pdf](http://healthit.gov/sites/default/files/ptp13-700hhs_white.pdf), 2014

The JASON report was produced by MITRE foundation for the Health IT Agency for Healthcare Research and Quality. It starts from the premise that the two overarching goals of moving to the electronic exchange of health information are improved health care and lower health care costs.

The JASON report highlights the need for high quality records, urgency to communicate information of relevance to the party involved, and the importance of dealing with legacy. In this spirit, it promotes a culture of open standards and interfaces that will enable to share information advocating for robust communication: send conservatively, receive liberally. It also estimates the economic benefit of swift response to 50-100B from predictive analytics. A number of benefits that the combination of electronic health records (EHRs) and improved health information exchange could serve:

- Satisfy the growing demand of patients for flexible access to their own health information
- Offer faster, interoperable access to patient records by health care providers
- Reduce errors within individual records and across records
- Reduce redundant testing and diagnostic procedures
- Produce more complete health records and more accurate health data
- Promote better longitudinal tracking of patients and patient groups
- Promote improved standards of care and reduce the incidence of errors in clinical practice
- Provide research data to inform clinical care, public health, and biomedical research
- Facilitate better communication among health care providers and patients
- Enable electronic detection of health care fraud
- Improve tracking of health care costs and benefits, thereby enhancing understanding of the economics of health care delivery.

The evidence for modest, but consistent, improvements in health care quality and safety is growing, especially over the last few years with the adoption of EHRs and health information exchange. A meaningful exchange of information, electronic or otherwise, can take place between two parties only when the data are expressed in a mutually comprehensible format and include the information that both parties deem important.

The JASON report outlines the characteristics of a possible software architecture for the exchange of health information based on the following principles:

- Be agnostic as to the type, scale, platform, and storage location of the data
- Use public APIs and open standards, interfaces, and protocols
- Encrypt data at rest and in transit
- Separate key management from data management
- Include with the data the corresponding metadata, context, and provenance information
- Represent the data as atomic data with associated metadata
- Follow the “robustness principle”: be liberal in what you accept and conservative in what you send
- Provide a migration pathway from legacy EHR systems.

The JASON report supports the arguments of urgency, and highlights the need for action without explicitly mentioning SDOs. It does not address the need for sustaining and maintain-

ing standards and specifications in the long term. The report highlights that frequently health informatics tend to invent their own solution to problems that have been tackled effectively elsewhere. This advice has in some way been incorporated in the development of HL7 FHIR.

[CALL2012] Calliope Project, Standardization, eHealth Interoperability Roadmap, <http://tinyurl.com/kctzsl2>, 2012

The ultimate goal of the eHealth Interoperability Roadmap delivered by the Calliope project in 2010 has been “Sustainable Healthcare: Sharing Information and knowledge for better health. It does so by bringing together visions, concepts, principles and emerging findings from collaborative European cross-border initiatives. This vision relates to the individual EU citizen in all his/her potential roles whether as a patient, a healthcare professional, a decision maker, or an eHealth entrepreneur. Interoperability is both a pre-requisite and a facilitator for eHealth deployment as it requires crossing boundaries – professional, cultural, organizational and technical and thus stimulates profound changes in the way we understand partnerships to realize this vision. The roadmap draws attention to the challenges in the four pillars of interoperability: Electronic identification; Technical interoperability; Semantic interoperability, and Legal and Regulatory interoperability that need to be organized both at the national and EU levels.

However, the The EU eHealth Interoperability Roadmap as such *focuses on cross-border interoperability* and aims to describe an approach to overcoming any current barriers that fail to enable EU citizens to fully enjoy the potential of travel with all their rights as foreseen in the Treaty. For example, with respect to eID It recommends: (a) a common European framework for eID management, enabling cross-border recognition of eIDs for health purposes, and European governance for eID management. A key figure from the roadmap that graphically shows the relation between the different levels is presented blow, showing how the policy interact with operational activities across national, EU, and global levels in multiple iterations to achieve alignment.

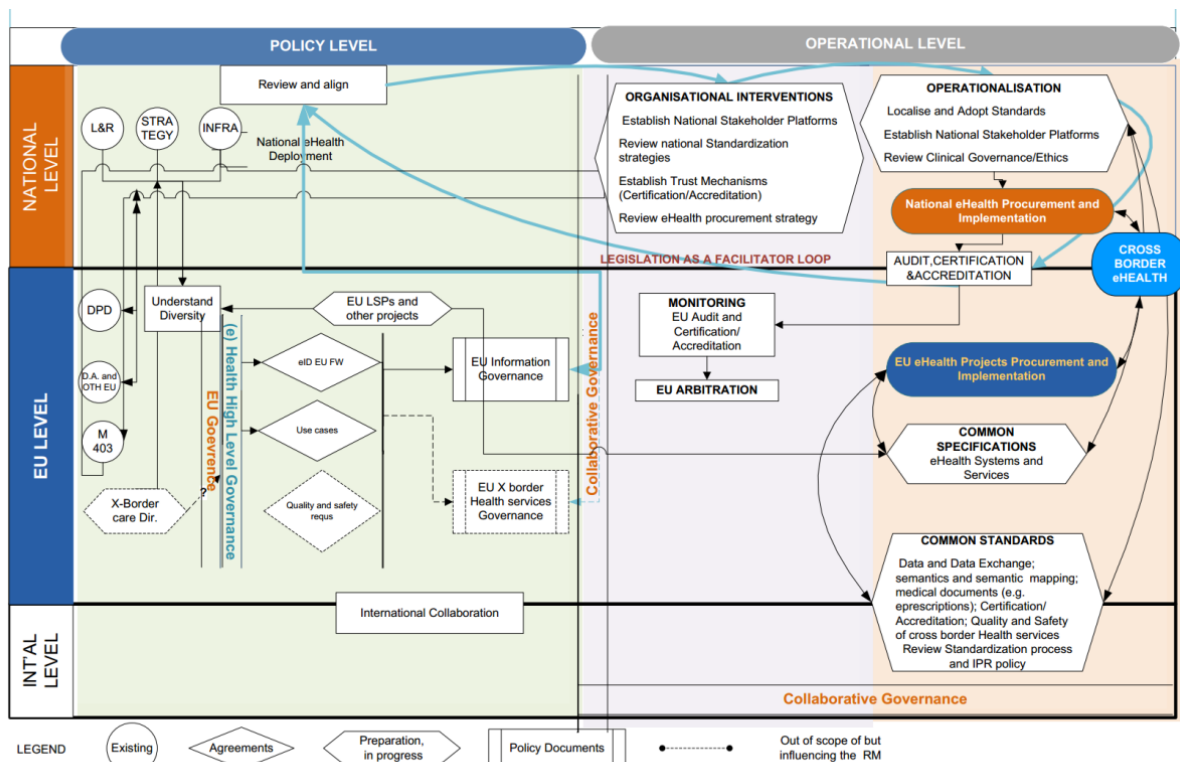


Figure 3: The Main Highways of the EU eHealth Interoperability Roadmap: figure from [CALIO2012]

Common specifications and standards interacting with EU eHealth procurement (as shown in the lower-right part of the figure from the Calliope Roadmap) is to be refined by the eStandards roadmap building on policy actions and international collaboration to deliver the tools required for large-scale eHealth deployment at lower cost and higher quality.

[Christ2009] Christensen CM et al. *The Innovator's Prescription: A Disruptive Solution for Health Care*, 2009, McGraw-Hill Professional, 0071592083

The innovator's prescription presents health care as a business no different from others that have been transformed from expensive, centralized offerings to affordable, localized through disruptive innovation that drives costs down increasing accessibility. According to Christensen, there are three predominant business models, the problem solving model (traditional medicine) addressed by traditional medicine, the specialized health services model (where specialty providers offer single procedures at highly competitive prices), and the network services model to support chronic diseases. Meanwhile, specialty providers will themselves be disrupted by general practitioners, general practitioners will be disrupted in turn by nurse practitioners and doctors in the box type services, and nurse practitioners and doctors in the box services will be disrupted by online communities of care and automated self-service tools.

The underlying business models are shown in the figure below: 1) Solution shops fee-for-service basis. 2) Value-adding process businesses fee-for-outcome basis. 3) Facilitated networks fee-for-membership basis (keep people well).

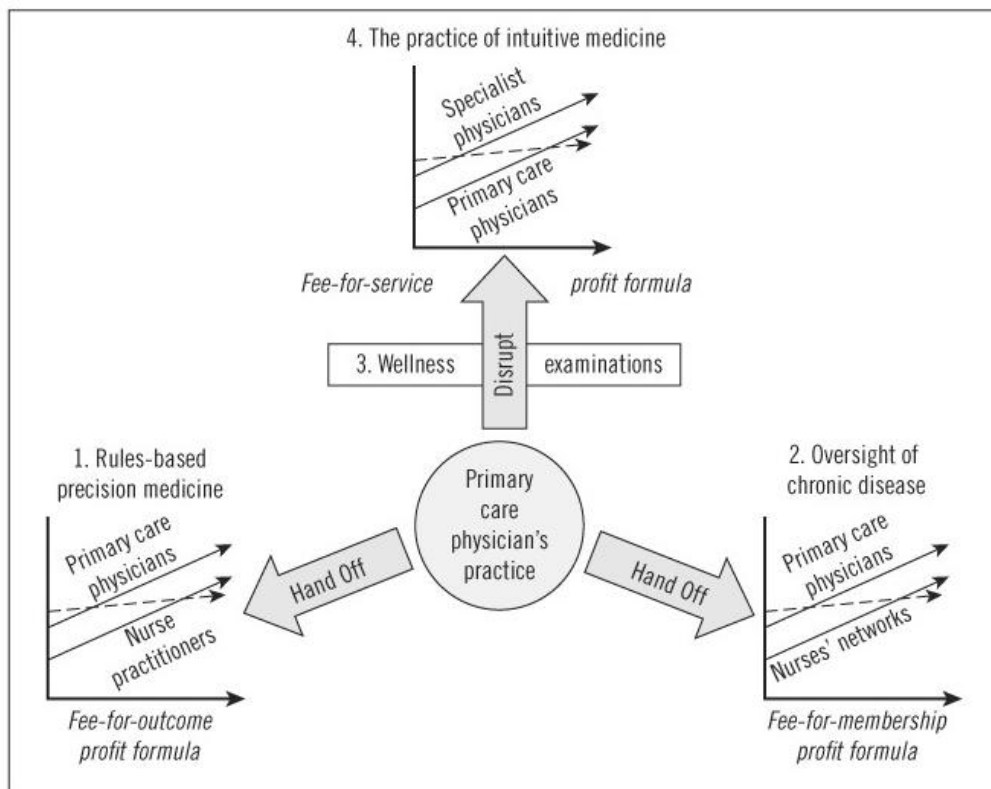


Figure 4: Emerging Business Models in the eve of healthcare disruption. Original in [Christ2009]

This gives rise to an acute need for standard-based eHealth applications that enable these new types of medical practices/business models, helps the workforce adapt to new ways of work, and supports health systems in smoothly adjusting their practice to benefit from the disruption brought by the digital revolution.

[ONC2015] Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Final Version 1.0, ONC report, <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>, 2015.

The ONC Interoperability Roadmap proposes timed actions to improve interoperability nationwide in the United States in the near term while working toward a learning health system in the long term. A call to action for eHealth stakeholders to come together to establish a coordinated governance process for nationwide interoperability.

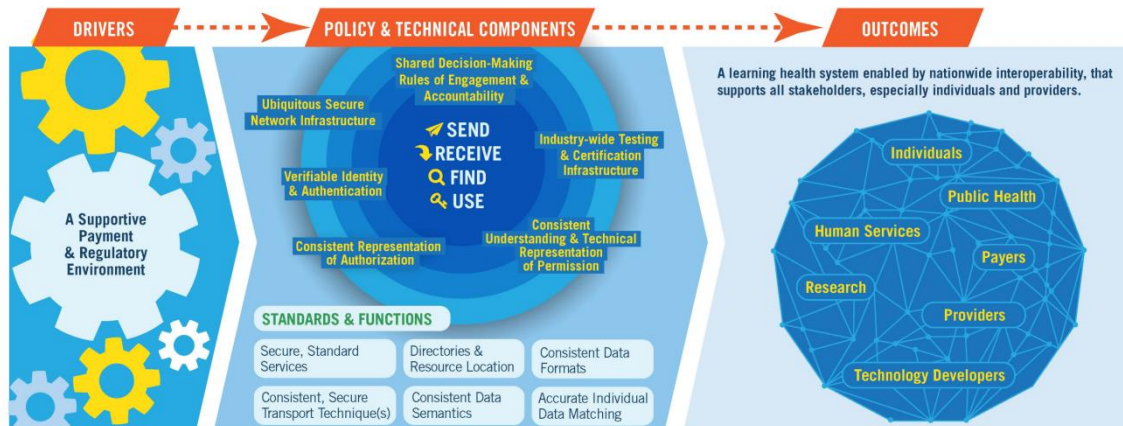
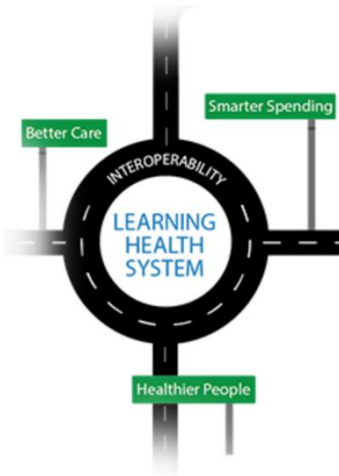


Figure 5: How the ONC Roadmap is organized – captured from [ONC2015]

[LHS22006] The learning Healthcare System: Workshop Summary, IOM Roadmap on evidence-base medicine. <http://www.nap.edu/catalog/11903/the-learning-healthcare-system-workshop-summary-iom-roundtable-on-evidence> 2005



The vision of a learning health system is that of healthcare system that draws on the best evidence to provide the care most appropriate to each patient, Emphasizes prevention and health promotion, delivers the most value, adds to learning throughout the delivery of care and leads to improvements in health.

The vision of the learning health system targets that by 2020, 90 % of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, to reflect best available evidence.

The Learning health system has to solve a number of problems: (a) the failure to apply the evidence we have about the medical care that is most effective (b) the shortfalls in provider knowledge and accountability, (c) the inadequate care coordination and support, (d) the poorly aligned payment incentives, and (e) the misplaced patient expectations.

[KLAS2015] Healthcare vendors agree to interoperability metric during KLAS keystone Summit. <http://tinyurl.com/q58etup>

This important agreement signifies that interoperability is taking shape, and adoption of standards can no longer be general, it has to become measurable and specific. ““On October 2, 2015, a broad group of EHR stakeholders, including vendor CEOs and provider CIOs, agreed by consensus to objective measures of interoperability and ongoing reporting. Leaders of 12 different EHR vendor companies proactively stepped forward to have an independent entity publish transparent measures of health information exchange that can serve as the basis for understanding our current position and trajectory.”

[Trill2015] Trillium Bridge recommendations, D5.2, August 2015, [www.trilliumbridge.eu](http://www.trilliumbridge.eu)

**Key Recommendation**

Advance an International Patient Summary (IPS) standard to enable people to **access and share their health information** for emergency or unplanned care anywhere and as needed. At minimum the IPS should include **immunizations, allergies, medications, clinical problems, past operations and implants**.

Trillium Bridge compared patient summary specifications from epSOS/ EU patient summary guideline and EU MU2, carried out a gap analysis, developed proof of concept demonstrations and collected evidence that led to the recommendations summarized in the figure below.



The actual 20 recommendations organized by theme are as follows:

**Future standardization.** Standards and profile development organizations and eHealth/health IT stakeholders should by 2020:

- collaborate on developing and adopting an IPS standard to enable the interoperable representation and communication of information about a patient’s immunizations, allergies, medications, clinical problems, past operations and implants, building on reusable interoperability assets and tools;
- work closely with clinician and patient associations in the EU, US, and globally to define, refine, and validate the IPS standard, and establish with them a standing governance process under the Joint Initiative Council of SDO Global Health Informatics Standardization to maintain it in the light of updated requirements, legislation and learning from use of the IPS;
- target the IPS standard as the means for sharing a core set of clinical data for the purpose of emergency or unplanned patient care, aligning it with other relevant existing standards, and incorporating where possible the needs of public health and other secondary uses of aggregated health summary data;
- work with producers of multi-national terminology systems to publish reliable and quality assured translations of patient summary value sets between relevant languages and of cross-mappings between terminology systems;
- work with EU and US policymakers to secure funding for governance processes to validate and endorse the accuracy of cross-border clinical information structures and associated terminology value sets.

**Cross-vendor integration.** EU and US policy makers in collaboration with competence centres and other relevant stakeholders should:

- promote the capability to generate and export patient summaries in the IPS standard, as well as import and integrate patient summaries in the IPS standard with locally-held EHR data;
- advance conformity assessment methods and tools that verify the robustness and quality of vendor implementations of the IPS standard, including the ability to generate and exchange

patient summaries conforming to the IPS standard from/between EHR systems.

**Innovation.** EU and US policy makers, and eHealth/health IT purchasers and providers, with support from relevant stakeholders, should:

8. stimulate the market for the adoption of the IPS standard by lowering trade barriers and supporting entrepreneurs working with eHealth/health IT systems and mHealth applications to capture and deliver patient summaries in the IPS standard, and by encouraging novel business models;
9. make a joint transatlantic commitment to demonstrate the value of sharing patient summaries in the IPS standard internationally, potentially leveraging events of high visibility such as international sporting championships;
10. refine, test, and evaluate multiple models of comprehensive person-centred health information stewardship, supporting the IPS standard.

**Incentives.** Healthcare payers and insurers should consider:

11. rewards and incentives for health care providers to maintain complete, up-to-date health records that enable the generation and sharing of accurate patient summaries in the IPS standard.
12. Healthcare professional associations should consider licensing and accreditation schemes that demonstrate competence and commitment to accurate and complete clinical documentation that enables the creation, maintenance, and communication of patient summaries in the IPS standard.
13. Health providers should consider quality criteria on maintaining accurate health records in the appraisal of healthcare professional staff and other relevant care givers to support effective exchange of patient summaries in the IPS standard.

**Privacy and security.** EU and US policy makers should:

14. develop and adopt a legal framework enabling the safe and secure global exchange of patient summaries in the IPS standard;
15. develop and enact legal agreements to enforce and assure the implementation of organisational and security safeguards needed to underpin global exchange of patient summaries in the IPS standard between providers;
16. define policies specifying the safeguards and measures needed to protect citizens in the cross-border exchange of patient summaries in the IPS standard including, but not limited to, identity management, access controls and audit trails.

**Education:** EU and US policy makers with support from eHealth/health IT stakeholders, in particular educators, health professional and provider associations, patient advocacy groups and developers of eHealth/health IT solutions should:

17. promote the development of guidance and training for all healthcare professional disciplines and specialties, and patients, about creating, maintaining and using high quality health records, including the appropriate use of patient summaries in the IPS standard to inform clinical decision-making;
18. foster initiatives that motivate and equip patients to maintain and harness their own health summary information in the IPS standard for better health and the self-management of health conditions.

**Research:** EU and US policy makers should promote:

19. joint research on metrics for assessing the quality of patient summaries in the IPS standard;
20. allocation of resources to monitoring the implementation of the IPS standard and its impact on improving patient safety and effective continuity of care, such as more efficient emergency diagnosis, reduced adverse drug events and reduced duplicate investigations.

[SHN2015] Semantic Healthnet Deliverable 6.1: Recommendations, to, industry, and, to, health, ministries: on the scaling up and widespread deployment of semantic interoperability solutions, May 29, 2015.  
<http://tinyurl.com/p9xwtgq>

The report includes

- Recommendations from panel from **Clinician and Patient Perspectives** highlighting their perspective on standards noting that Standards should not impose an unreal precision on the interpretation of clinical statements: they need to cater for uncertainty and excluded findings. At the same time, high quality documentation is key: applications and medical terminologies must reflect the words and phrases of the clinicians, and the patients. Additional statements discuss terminologies and vocabularies, design systems, incentives, procurement, platforms, and ease of use. There is even reference to the collection of too much data. Notably they mention that eHealth interoperability needs to be simple - learn from the supermarkets that are now offering simple healthcare services to their customers; (but note that making things simple is often far from easy).
- Recommendations from panel on: **Healthcare Purchaser Perspectives** highlight the role of health ministries and authorities in promoting eHealth, investing in clinical content standards, and promote interoperability jointly with the Finance ministers. Regarding semantic interoperability they note that it should be perceived as the business model for the eHealth infostructure.
- Recommendations from the panel on: **Clinical Research and Learning Healthcare Perspectives** raised that a clinical trial is a nice picture of a dirty world: we need to complement this with data from real world use of medicines. There are huge opportunities for insight from re-used patient data, but can we create a continuously tracking & learning world? The objective of giving value back to healthcare from clinical trials was highlighted and that can be supported by an open data access mentality. The recommendations note that semantic disharmony is a major obstacle to scaling up data on a global level. It is also noted that the industry seems risk averse and that results in localized innovations that do not make good use of standards. Governments can promote standards adoption by mandating the use of standards – but they also need to reduce the costs of standards adoption, especially for SMEs.
- Recommendations and insights from panel on: **Standards Development Organisations Perspectives** highlight that SDOs want to collaborate towards interoperability - the brand wars are over, the community know each other and want to work together - yet the list of currently available and overlapping standards relating to EHR data is huge!
  - Standards have to be accessible financially and intellectually, and a “delight to use” – this includes providing clarity about which ones to use, and when.
  - The value of using a forthcoming standard must be defined prospectively, used to justify its adoption, and then evaluated. We have especially to show the benefits to clinicians e.g. avoid duplicate data entry.
  - Mappings between different, non-interoperable standards introduce patient safety risks and have huge maintenance issues. In addition the need for mapping must not be left to each vendor to work out - these are real costs incurred today.
  - Quality assured multi-lingual assets should be shared including guidance, education and mappings.
  - The current standards development process (necessary) takes time to gain community engagement and consensus - SDOs must be honest about what can be delivered, and by when.

## Annex III – Project Partners

Partners			
1	RAMIT	Research in Advanced Medical Information and Telematics vzw ( <i>Coordinator</i> )	BE
2	HL7 International	HL7 International Foundation ( <i>Scientific Coordinator</i> )	BE/EU
3	NEN	Stichting Nederlands Normalisatie-Instituut ( <i>for CENTC/251</i> )	NL/EU
4	IHE-EUR	Integrating the Healthcare Enterprise-Europe aisbl	BE/EU
5	EuroRec	European Institute for Health Records	FR/EU
6	MEDIQ	Mediq AS	DK
7	OFFIS	OFFIS EV	DE
8	Lombardy	Regione Lombardia	IT
9	Nictiz	Nictiz, centre of expertise for standardisation and eHealth	NL
10	HOPE	The EU hospital association	BE/EU
11	COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry	BE/EU
12	SPMS	Serviços Partilhados do Ministério da Saúde, E.P.E.	PT



## Annex IV – Abbreviations and Acronyms

Antilope	Advancing eHealth Interoperability – European project to drive eHealth interoperability in Europe and beyond [ <a href="http://www.antilope-project.eu">http://www.antilope-project.eu</a> ]
Assess CT	European project to contribute to better semantic interoperability of eHealth services in Europe [ <a href="http://assess-ct.eu">http://assess-ct.eu</a> ]
CALLIOPE	CALL for InterOPERability – a European thematic network for implementation of Interoperable eHealth solutions (ended 2010)
CEF	Connecting Europe Facility – finances projects which fill the missing links in Europe's energy, transport and digital backbone [ <a href="https://ec.europa.eu/inea/en/connecting-europe-facility">https://ec.europa.eu/inea/en/connecting-europe-facility</a> ]
CEN/TC 251	European Committee for Standardization, Technical Committee 251 Health Informatics (an SDO and member of JIC) [ <a href="http://www.cen.eu">http://www.cen.eu</a> ; <a href="http://www.ehealth-interop.nen.nl">http://www.ehealth-interop.nen.nl</a> ]
Continua	Organization to develop standards-based guidelines for end-to-end, plug-and-play connectivity for personal connected health (an SDO) [ <a href="http://www.continuaalliance.org">http://www.continuaalliance.org</a> ]
EFMI	European Federation for Medical Informatics [ <a href="http://www.efmi.org">http://www.efmi.org</a> ]
eHN	European eHealth Network – a voluntary network of national responsible authorities on eHealth, as provided for by Article 14(1) of Directive 2011/24/EU [ <a href="http://ec.europa.eu/health/ehealth/policy/network">http://ec.europa.eu/health/ehealth/policy/network</a> ]
epSOS	Smart Online Services for European Patients – European large-scale pilot to improve the quality and safety of healthcare for citizens when travelling to another European country [ <a href="http://www.epsos.eu">http://www.epsos.eu</a> ]
e-SENS	Electronic Simple European Networked Services – European large-scale project to consolidate, improve, and extend technical solutions to foster electronic interaction with public administrations across the EU [ <a href="http://www.esens.eu">http://www.esens.eu</a> ]
EXPAND	Expanding Health Data Interoperability – a European thematic network to progress towards an environment of sustainable cross border eHealth services [ <a href="http://www.expandproject.eu">http://www.expandproject.eu</a> ]
GS1	Organization to develop the standards to identify, capture and share information across the supply chain (an SDO and member of JIC) [ <a href="http://www.gs1.org">http://www.gs1.org</a> ]

HL7	Health Level Seven (an SDO and member of JIC) [ <a href="http://www.hl7.org">http://www.hl7.org</a> ]
IDMP	IDentification of Medicinal Products –set of common global ISO/CEN standards for data elements, formats and terminologies for the unique identification of and the exchange of information on medicines
IEEE 11073	IEEE Standards Association, Healthcare IT Standards [ <a href="http://standards.ieee.org">http://standards.ieee.org</a> ]
IHE	Integrating the Healthcare Enterprise (an SDO and member of JIC) [ <a href="http://www.ihe.net">http://www.ihe.net</a> ]
IHTSDO	International Health Terminology Standards Development Organisation (an SDO and member of JIC) [ <a href="http://www.ihtsdo.org">http://www.ihtsdo.org</a> ]
IMIA	International Medical Informatics Association [ <a href="http://www.imia-medinfo.org">http://www.imia-medinfo.org</a> ]
ISO/TC 215	International Organization for Standardization, Technical Committee 215 Health Informatics (an SDO and member of JIC) [ <a href="http://www.iso.org">http://www.iso.org</a> ; <a href="http://www.iso.org/tc215">http://www.iso.org/tc215</a> ]
JAsEHN	Joint Action supporting the eHealth Network
JIC	Joint Initiative Council for Global Health Informatics Standardization [ <a href="http://www.jointinitiativecouncil.org">http://www.jointinitiativecouncil.org</a> ]
OpenMedicine	Global initiative to better enable the cross-border exchange of ePrescriptions and safe dispensation of prescribed medicinal products [ <a href="http://www.open-medicine.eu">http://www.open-medicine.eu</a> ]
SDOs	Standards development and profiling organizations
SemanticHealthNet	European project to develop a scalable and sustainable pan-European organisational and governance process for the semantic interoperability of clinical and biomedical knowledge
Trillium Bridge	Project to extend the European Patient Summaries and Meaningful Use II, Transitions of Care in the United States to establish an interoperability bridge that will benefit EU and US citizens alike [ <a href="http://www.trilliumbridge.eu">http://www.trilliumbridge.eu</a> ]
VALUEHEALTH	European project to establish how eHealth interoperability can create, deliver, and capture value for all stakeholders [ <a href="http://www.valuehealth.eu">http://www.valuehealth.eu</a> ]

## **Annex V – Contributors**

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