Joint Initiative Council

Patient Summary Standards Set

GUIDANCE DOCUMENT

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Acknowledgements

Whilst work to produce this first draft of the Patient Summary standards set has been coordinated through the JIC, members have been responsible for heading up Task Forces to deliver each of the sections of this Standards Set working with Subject Matter experts from across the world

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Welcome from the Joint Initiative Council Chair

In October 2015 in San Francisco the Joint Initiative Council (Joint Initiative on SDO Global Health Informatics Standardization) worked on an overall strategy to enhance the role of the Council and provide more benefits to global users of international standards. The first order of business was to define something that the Council could develop and offer globally that would make a fundamental difference in how international standards are implemented.

The Council decided that given the diversity of standards and opinions on how to deploy standards, a Standards Set should be developed and offered freely globally. This Standards Set serves the purpose to inform users and experts on a process that would allow them to consistently implement international standards in a health setting.

This also marked the first time that all Council members agreed to come together and commit resources jointly to an initiative. I would like to thank all of those organisations and individuals that freely put in many many hours of work to create this document. What started as perhaps an onerous work project has turned into a labour of love for all who have been involved.

In today's world we have seen rapid developments in health and more notably in the movement of people around the globe. Perhaps the most important gap in health today is the need to have the patient record move with the patient as they travel. Having this capability allows clinicians to have the right information at hand as they make crucial decisions to provide care.

The Standards Set itself is not a set of standards, but as stated above, a process to be followed to allow an informed and consistent approach to identifying, selecting and deploying standards and related artefacts. The first step in this process is to define a Use Case. Given the gap identified, the cross organisational teams agreed that a Patient Summary use case was the top priority to address both the gap in health information but to also inform other projects and initiatives that are currently underway.

The Standards Set guidance document you are about to read is meant for a wide audience. It is meant for clinicians who wish to understand, implementers who deploy, software developers who build the tools and systems, experts who work in the fields that touch health and standards, and most importantly those governance bodies that make decisions to fund new digital deployments.

In fact this guidance document is for everyone who touches health and by definition needs a process to implement or use international standards.

The Patient Summary Standards Set guidance document is free and is meant to be informative, and not normative. The guidance document and the work itself will always be open to the changing landscape in health and will be updated based on the feedback from users. The current guidance document is based on today's standards, artefacts and profiles. Thus in an ever changing world this document will be maintained and updated, as any living document should be, by the Joint Initiative Council.

In closing, I wish to thank the global group of experts who contributed to the task groups, the chairs of the task groups who pulled the work together, the members of the Joint Initiative Council for believing in this work and lastly to all who take the time to read this guidance document.

Respectfully submitted,

Don Sweete

Chair, Joint Initiative Council

1.0 Introduction to the Patient Summary Standards Set

This document is a guide to a set of health informatics standards and related materials that can be used to support the implementation of a Patient Summary. Its value is for use in electronic information systems to produce a Patient Summary that can be used across borders and different providers. This guide provides a broad perspective on the different types of standards and related materials necessary for this purpose, explains how to assess the conformance of products that claim to use them, and highlights current and emerging practice.

This information pack, termed a Standards Set, is the first of its kind and signals a different, more overt and customer-facing way of working for the *Joint Initiative on SDO Global Health Informatics Standardization* (JIC). The focus in this guidance document is on a specific Use Case, with the aim that the methodology can be applied to other Use Cases over time. It is a 'live' document and will be updated based on feedback, standards being developed, updated or deprecated and knowledge and experience evolving. At time of publishing (January 2018), a feedback form is available through the JIC website http://jointinitiativecouncil.org/registry/standards.set.patient.summary.asp along with other related materials. The feedback will be collated over a year and the document updated to a new version early 2019.

This document is NOT A STANDARD but is an informative and supportive tool for the use of national and international digital health and health care stakeholders at all levels. It i provided cost-free.

1.1 What is the JIC?

The JIC is a federation of standards and profiling development organizations (SDOs) that operate in Health Informatics (see the JIC website for details of its membership – www.jointinitiativecouncil.org/). The JIC was formed to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counterproductive standardization efforts. To date, the focus of the JIC has been on harmonization and strategic matters of standardization and consequently JIC has been working invisibly, but openly, behind the scenes within and across their organizations and with members of their communities. This activity is removed, however, from the end user communities that JIC ultimately aim to serve.

1.2 What is a Standards Set?

The JIC discussed at its meeting in April 2015 its strategic direction and agreed the following statement:

The JIC will contribute to better global patient health outcomes by providing strategic leadership in the specification of sets of implementable standards for health information sharing.

The JIC agreed to operationalize this goal by developing a number of relevant Use Case focused standards sets with recommendations for national and international use. The working definition for a Standards Set is a *"coherent collection of standards and standards artefacts that support a specific use case"*. At the June 2015 JIC meeting it was agreed that work should be started on developing the first 'Standards set'. The first high-level topic agreed for a Standards Set was the Patient Summary.

The intent of a Standards Set is to provide guidance about health informatics standards, standards artefacts and profiles that meet agreed criteria, to meet a specific Use Case. It does not recommend a single, specific implementation for a particular topic. Rather the intent is to provide sufficient detail to enable the different stakeholders to choose the standards, standards artefacts and profiles most suited to satisfying their requirements/Use Case. This first Standards Set is focused on the 'Patient Summary' and the long term aim is to take this exemplar and lessons learned to develop generic guidance which can be applied to other Use Cases.

1.3 Why the 'Patient Summary'?

The 'Patient Summary' is a concise document that can inform clinicians at the point of care. It is applicable to planned care but is particularly important in cases when an unscheduled or unplanned health event occurs and the patient's clinical history is unknown to the attending clinician(s). In such cases it may be the only source of information available to support the clinical process and decision making, and its absence can create safety issues, with possible life changing or life threatening consequences for the patient. A Patient Summary provides information needed for healthcare coordination and for the continuity of care.

There are considerable benefits to the patient if an accurate and up to date Patient Summary is available at the point of care and conversely there are the associated high risks and costs for that person if it is unavailable. In addition to the patient safety aspects, for an organization the absence of this document can be costly and wasteful of both clinical and administrative resources. The attending clinician, for example, with no prior knowledge of the patient must use precious time and expend unnecessary effort to become informed and in the worst case be forced to act without any specific details being available. In the organizational context, the discovery and matching of a person's identity, the probable duplicate procedures and the avoidable repeated tests ordered by the clinician will consume scarce resources; furthermore, the inevitable delay this activity will cause may introduce more risk with associated consequences, costs and potential liability.

In planned care situations, a Patient Summary may be readily available but in unplanned care situations it is often more challenging to access. The Patient Summary, or different versions of it, might pre-exist and be collected or conversely it may be possible for the system at the point of care to generate a summary on the fly from the patient's electronic health record. To further complicate matters, the patient's previous history may reside or be distributed across different organizations, and the information may even be stored in a different country to the one in which the incident occurs.

The Patient Summary is not the same as a patient's full electronic health record; it is often an extract or precis of the full record, so it does not include the detailed previous history, extensive historic detail about medication or comprehensive detail on each health condition that a person may have had. The objective of the Summary is to provide sufficient, relevant and usable information, fit for purpose at the point of care.

The importance of the Patient Summary is clear. However, even if a Patient Summary is relatively concise and is made available at the point of care there is still no guarantee that the content will be relevant, up to date or of sufficient quality to be understandable. The usability and usefulness of any Summary is dependent upon a number of different solutions such as datasets, interoperability standards and profiles, compatible formats, terminologies, semantics, and certainties around differing levels of maturity and diverse technologies. These challenges need to be met, if the Patient Summary is to have value.

The JIC have chosen this as the first Use Case for a Standards Set because there are efforts across the globe at all levels to develop Patient Summaries which is leading to duplication and potential lack of interoperability. Aligned with this, members of the SDOs are themselves involved in the different efforts and therefore are keen to provide guidance based on existing standards rather than developing new. The JIC has adopted the following definition for the Patient Summary, as used in the Patient Summary Standards Set:

"the minimum set of information needed to assure healthcare coordination and the continuity of care"

1.4 Users of the JIC Patient Summary Standards Set

The ultimate beneficiaries of the Standards Set content will be the patient, possibly the carer in some settings, and the healthcare professionals involved in the care of the individual. Before such benefit accrues however, a significant number of the challenges have to be addressed by intermediaries who require, and who can make use of, the information provided in the Standards.

This guide provides detail of work that has been undertaken to define a Patient Summary Standards Set, using a specific Use Case and defining a draft dataset. This has involved clinicians to ensure that the proposed content is a sound basis for such a Use Case. This Use Case requirement is then aligned with a set of standards and standards artefacts to enable the technical

instantiation of the Use Case, work which involved standards experts from multiple SDO communities. Such solutions are a part of the whole complex ecosystem that involves choice, decisions, agreements and factors that are necessary and have to be in place if lasting value is to be achieved.

This Standards Set has been developed with a number of stakeholders in mind, including:

- Governments/Government agencies/Ministries of Health
- Clinicians/Clinical bodies – nationally and internationally
- Vendors/Suppliers
- Healthcare organizations
- Regulators
- Insurance companies/purchasers/commissioners
- Information specialists
- Information governance bodies
- Patient organizations
- Patients
- Carers
- Standards Bodies

We do not assume that the Standards Set will be used in the same way by all. Some might wish to read the contents serially from start to finish, whereas others might wish to dip in and out, treating it as a reference to answer a specific question. The objective is to brief the stakeholders about the landscape, informing them of the current status and choices.

Table 1 suggests how different readers might approach/make use of the Patient Summary Standards Set:

	Decision Makers	Developers/ Implementer/ Integrators	Vendors/ Vendor Groups	Individual Stakeholders
Provide Overview and reassurance (e.g. JIC, Context, Guidance)	X			
Raise awareness of the current landscape, activity and available resources (e.g. Use Case Descriptions, Standards Categorization and Selection)	X	X	X	X
Assist with procurement decisions (e.g. Standards Categorization and Selection, Conformance Assessment Framework)	X			
Show leading practice/ highlight known pitfalls (e.g. Guidance materials throughout and Guidance Fact Sheets)	X	X	X	X
Provide knowledge of gaps and existing work (e.g. Guidance and Guidance fact Sheets, what is present/ absent, Conformity Assessment)		X	X	
Enable informed choice about assessment (e.g. Conformance Assessment Framework, Guidance Fact Sheet on 'Readiness assessment and peer audit prior to go-live')	X			
Possible feedback route through JIC (e.g. addition and updating of Guidance Fact Sheets)		X		
Raise awareness of current market place			X	
Present opportunities (e.g. Guidance includes leading practice, Standards selection identifies gaps)			X	X
Understand obligations (e.g. Conformity Assessment Framework, Guidance Fact Sheets)			X	

1.5 Scope of the JIC Patient Summary Standards Set

The content of the Patient Summary Standards Set reflects the contribution of the JIC membership and experts from across the globe. The content restricts itself to only those parts of the problem that fall into the domain which is often referred to as eHealth, or more accurately Health Informatics. Furthermore, this guide is deliberately focused upon the Health Informatics standardization aspects of the problem space and therefore concentrates on the clinical information, technical, functional and implementation aspects of standardization and not on the engineering and technology levels that are the purview of the more general IT sector (e.g. databases, networking and cabling) and which are assumed to be present and appropriate for implementation. The scope of the document is in the remit of the JIC and the content is the product of experience and expertise.

Secondly, whilst the political, environmental and social factors are in many ways beyond the JIC scope, some of this context is indirectly and implicitly embedded and captured within the datasets and standards that members of the JIC manage and develop. The JIC Standards Sets are to be current, informative guides that can be used as trusted and useful resources for the would-be users of their standards. JIC provide this information cost-free.

1.6 JIC Patient Summary Standards Set development approach

In the Foundation and Scope Report published on the JIC website, a Standards Set was described as a *"coherent collection of standards and standards artefacts that support a specific use case"*.

The principle of 'coherence' is taken forward in two ways by the authors of this Patient Summary Standards Set:

- we have strived to make the contents of the Standards Set both logical and consistent;
- in terms of the guidance material, we have strived to present the Patient Summary Standards Set as a unified whole.

A Coordination Group, consisting of JIC Members, undertook the work plan development and overall management of the processes and task groups developing the elements of the standards set. That group, with all Task Group leads participating, initiated, planned, coordinated, resolved issues and presented recommendations to the JIC.

The work was structured and assigned to task groups, with international subject matter, standards and clinical experts as members, that undertook specific work with leads from Coordination Group.

1.7 Other Initiatives related to the JIC's Patient Summary Standards Set

A number of projects have been key influencers on the Patient Summary Standards Set since JIC members have been and continue to be involved, the projects are supported by government agencies and have global relevance. Key projects are:

Trillium Bridge project. This was one result of the United States Department of Health and Human Services (US-DHHS) and European Commission (EC) Memorandum of Understanding (MoU), signed in December 2010. The Trillium Bridge project (2013-2015) focused on a feasibility study for the EU/US electronic exchange of patient summaries. Starting with the gap analysis, it compared the HL7 C-CDA Continuity of Care Document (CCD) specification cited in US MU-II [5] and the epSOS PS IG cited in the EU PS Guideline. The results of this work were significantly beneficial to the JIC Patient Summary work and also to the HL7 INTERPAS project which produced a WHITE PAPER summarizing the results of the first phase of work of INTERPAS.

EU Guidelines For Patient Summary. The Trillium Bridge project was also concurrent with this initiative and makes extensive use of emerging guidelines. The guidelines (2013), built on the earlier epSOS work (2011) of the EU, were published as "Guidelines on minimum/non-exhaustive patient summary dataset for electronic exchange in accordance with the cross border directive 2011/24/EU release 1". A Release 2 was agreed and published in November 2016, the main difference being the removal of the Basic and Extended conformance categories for the identified data elements. The early work of the EU Guidelines was very informative for the Use Case data elements identification and development of the JIC Standards Set, which used the first version of the Guidelines in the description of its dataset.

The IPS Projects. In response to the ongoing EU/US work and the interest in Patient Summary roadmaps, the HL7 INTERPAS project moved to the next phase of its development, directed towards an implementation of the patient summary data set standard in 2018.

At the same time the European Commission supported an initiative based upon the idea of formalizing the EU Guidelines version 2. This is being led by CEN/TC251 and a major part of its work was to collaborate and participate with the HL7 project. The project, named the International Patient Summary and CEN IPS, came into being in 2016. The HL7 INTERPAS project was renamed HL7 IPS shortly afterwards and the two standardization bodies and the projects declared a common vision and project, and a commitment for collaborative activity for International Patient Summaries, in Oslo (2016). Both projects are working towards agreeing on the same dataset, and targeting implementation and its associated guidance by 2019. The projects will inform and be informed by later versions of the JIC Standards Set on Patient Summaries.

1.8 Contents of JIC Patient Summary Standards Set

The JIC guidance comprises a set of coherent information covering important facets of Patient Summary development and implementation. It has identified a number of elements to support users/consumers of the guidance. The elements of the Standards are identified in this section with a brief description of purpose along with a link to the section in this document.

This guidance document is not a standard nor is it the intent of JIC to make a new standard. The Patient Summary Standards Set does not claim to be exhaustive as this information, requirements, and the means to represent them, are very dynamic and therefore a Set is subject to change. The Standards Sets are 'living documents' and as experience is gained with applications becoming more mature then additional material can be added and existing content can be updated. The recommendations are time-stamped in that the content captures the present known information, but the Patient Summary Standards Set is open-ended, serving as a foundation for any future versions.

1.8.1 Introduction to the JIC Patient Summary Standards Set

This 'context' chapter provides a concise overview of the Patient Summary Standards Set and points to the other chapters with a brief description explaining how it forms part of the whole. The links makes it easy to assess the relevant chapters.

In addition to explaining the rationale and authority behind the Patient Summary Standards Set, this section identifies the intended audience and suggests how it might be used by the different stakeholders. The guidance seeks to be grounded, avoiding jargon where possible and showing the relevance of its contents to the different users.

1.8.2 Use Case Descriptions

The team considered a number of Use Case models for this work which is outlined in the 'JIC Foundation and Scope document'. The decision was made to base the Use Case model and descriptions on *ISO Technical Report: 19669: 2017* which provides a method that identifies a set of reusable components that can be applied to the construction of a use case. The chapter describes the Use Case for the JIC Patient Summary Standards Set in a way that should enable a User to further refine or develop for local/national/international use. Clinical experts have input to ensure that clinical needs are met.

1.8.3 Patient Summary Dataset

This chapter presents a draft dataset based on the JIC Patient Summary Standards Set Use Case. This can act as a starting point for those considering alignment between the Use Case and data items, and provides a linkage then to the standards which are needed to support the data content.

1.8.4 Categorization and Selection Criteria for Standards/Profile Inclusion

This chapter discusses the need for categorization as the basis for the identification of the interoperability standards included in the Standards Set. Principles have been applied to determine standards and artefacts to be assessed and specific criteria have been used to review, evaluate and finalize the identification of standards in the Patient Summary Standards Set.

1.8.5 List of standards, standards artefacts and profiles meeting the criteria

The list of standards artefacts in the Patient Summary Standards Set is provided through 6 tables that group and organize the Standards Set based on the JIC Standards Categorization Report.

1.8.6 Framework for Conformity Assessment

Given the number of standards and profiles that make up the Standards Set, it is impossible to provide a detailed conformity assessment scheme that combines specifications for all. What is considered more useful is a conformity assessment framework that defines leading practices around how to establish and implement an appropriate conformity assessment program, in the context of the Patient Summary Standards Set. The framework can be found at here.

1.8.7 Conformity Assessment Artefacts supporting a Patient Summary Standards Set

Outlined in this section are specific conformity assessment artefacts that are considered necessary in building a program to support the Patient Summary Standards Set, including an example from the Use Case of how these artefacts might best be assembled.

1.8.8 Information sheets on leading practice, landscape and resources for Patient Summaries

Standards Sets are to be 'living documents' and capture the position at the time. The Standards Set covers multiple specifications, some with implementation guides that users review or reference. These Information Sheets complement the work by providing an 'implementation context' as guidance to support choice. Current practice and related information, based on current knowledge, are also presented and will be updated over time.

1.8.9 Glossary

This provides definitions for acronyms and abbreviations applied in this package as used in the context of the JIC Patient Summary Standards Set. This should enable a global understanding of the Patient Summary Standards Set though it is recognised that locally and nationally terms may need to be applied differently.

2.0 A Use Case for Patient Summary

2.1 Defining the Use Case

The Standards Set is developed to "support a specific use case". Use Cases are heavily used in Health Informatics and, like 'requirements', are expected to address a range of stakeholders. A Use Case can be 'lightweight', even abstract, or much more detailed and concrete, as required. A Use Case is a generalized description of a set of interactions between a system and one or more stakeholders, and as such might be considered as a requirements specification for agreed aspects of the overall system's development.

The Use Case model and descriptions is based on *ISO Technical Report (TR): 19669: 2017* which provides a method that identifies a set of reusable components that can be applied to the construction of a use case. This method produces a fully-dressed use case and includes 'activity' and 'sequence' models from the Unified Modeling Language or UML; the model diagrams are intended to amplify and formalize some of the scenarios in the use case. This detailed description, based on clinical requirements, makes up one of the major elements of this Standards Set. There are some minor adaptations to section headings to ensure consistency and alignment with the rest of the Standards Set and also ensure reader's understanding. In addition, some sections of the ISO TR were not required for this Use Case description.

The overarching issue that this initiative and specific Use Case aims to address is the lack of access to up to date patient information by emergency clinicians in an acute setting – caused by lack of standardization and interoperability within and between healthcare systems of healthcare providers.

This Use Case addresses the requirements of a broad range of Communities of Interest including; patients, their significant others and family members, providers, payers, vendors, standards organizations, public health organizations, and Federal agencies as well as clinicians themselves. The Use Case contains the Patient Summary use case description along with an exemplar Patient Summary standards data set – both of which have been developed in collaboration with practising clinicians from different global locations. To further define the work, the JIC Council, in the *Foundation and Scope Report*, identified that the use case focus of this first Patient Summary Standards Set will be an unplanned, cross- border or cross-jurisdiction event to "access patient summary in acute setting".

This Use Case describes:

- the operational context for the data exchange;
- the stakeholders with an interest in the Use Case;
- the information flows that must be supported by the data exchange;
- the types of data and their specifications required in the data exchange.

The Use Case is the foundation for identifying and specifying the standards required to support the data exchange and for developing reference implementations and tools to ensure consistent and reliable adoption of the data exchange standards.

2.2 Challenge Statement

The biggest challenge is one of cross-border or cross-jurisdictional information sharing. The different levels of difficulty in sharing patient summary information across borders are well documented in projects such as epSOS and Trillium Bridge. Also data portability (hospital to primary doctor, city to city, healthcare region to health region or state to state) is a huge challenge.

Next to this, multiple standards on patient summary data and data exchange exist. The challenge is not only of existing multiple standards that are not interoperable, but also on getting the right data available at the right time for the right patient. Currently there are a number of additional challenges that can be identified:

- summary data may not exist at point of care;
- summaries may exist at one or more locations;
- summary data may contain variable levels of detail in terms of data content;
- summary data may not be the most relevant given the particular health condition;

- summary data may not be standardized in regard to the types of data captured;
- multiple standards on patient summary exchange exist;
- unavailability of readable, credible and relevant data from external systems, timely at the point of care.

2.3 Use Case Scope

The scope of this Use Case is in support of improved coordination of services and transition of care with all parties able to access a consolidated history and status for each patient (summary). This Patient Summary should support transitions of care across providers, communities and cross-borders or cross-jurisdictions and inform decision-making for maximum benefit to patient.

The Patient Summary working definition is defined as "the minimum set of information needed to assure healthcare coordination and the continuity of care". Healthcare coordination and the continuity of care in this specific use case is focused on patients suffering from a pre-existing chronic disease, such as Chronic Obstructive Pulmonary Disease (COPD).

The business use case for accessing a patient summary in an acute care setting demonstrates an emergency department clinician wanting legitimate access and use of relevant summary patient data at the point and time of care, irrespective of where and how it is held, in order to better address the healthcare needs of the patient and improve the patient's health outcomes.

The requirements for a Patient Summary Standards Set will assist all stakeholders in standards development, adoption, implementation and ongoing use.

2.3.1 In Scope

The scope of this Use Case is:

- all relevant patient data which needs to be exchanged between caregivers in order to give optimal care at the emergency department of a hospital;
- focuses on unplanned events relating to pre-existing chronic disease condition (such as COPD);
- and is applicable across borders or jurisdictions (e.g. between regions, states or countries).
- secure electronic patient summary data. (i.e. not paper)

There are many use cases that may relate to the use case described in this framework, in this document we focus on the COPD case. It is however important to try to target a general use case as much as possible, and only use the COPD as a checkpoint for normal data requirements.

2.3.2 Out of Scope

Out of scope items include the following:

- The patient use of the patient summary.
- Financial transactions.
- Referrals for the patient as a planned event.
- Disease specific data requirements.

2.4 Communities of Interest/Stakeholders

The direct communities of interest participating in this use case are as follows:

Member of Communities of Interests	Working Definition
Patient	Healthcare consumers who are recipients of health care services and products.
Family	Family member or legal caregiver.
Health Care Providers	Persons or organizations that are licensed to give health care. A Provider can enter into an agreement with an insurer to provide services (e.g. Medicare, Health Plan).

Hospital Administration Staff	Including those involved with intake, admitting and discharge, including record-keeping and updating.
EHR/EMR/PHR Vendors/Suppliers	Vendors/suppliers which provide specific EHR/EMR/PHR solutions to manage patient health information to clinicians such as software applications and software services. These suppliers may include developers, providers, resellers, operators, and others who may provide these or similar capabilities.
Other Healthcare Technology Vendors/ Suppliers	Vendors that provide health care solutions other than EHR/EMR/PHR solutions such as software applications and services. Examples include: integration vendors, data providers, medical device vendors, RMMS (Remote Monitoring Management System) vendors, diagnostic imaging service provider, laboratory service providers, clinical order system supply vendor, transcription service vendors, clearinghouses, drug knowledge suppliers, network infrastructure provider, Clinical Decision Support (CDS) resource system, practice-based registry system suppliers, public health registry system, immunization information system providers, clinical genetic database/repository system vendor, pharmaceuticals, hospital supplies, biomedical devices, etc. (e.g. in definition).
Government	Applicable regional/country level of government. Providing policy and relevant legislation context relating to the care of patients.

Table 2: Communities of Interest

2.5 Value Statement for Patient Summary Standards Set

At the highest level, and founded in the JIC purpose 'to better global patient health outcomes by providing strategic leadership in the specification of sets of implementable standards for health information sharing', the requirements for a Patient Summary standards set will assist all stakeholders in standards development, adoption, implementation and ongoing use. This includes governments, ministries of health, clinical bodies (nationally and internationally), clinicians and other health providers, vendors, healthcare organisations, regulators, insurance companies/purchasers, information specialists, patient organisations, patients and patient families and also standards bodies.

Successful outcomes and metrics of the Use Case include:

- better treatment outcomes because the clinician has the availability of trusted information;
- improvement of patient safety because of the availability of information about the history of the patient which prevents mistreatment;
- saving time which can be spent on other patients, because the care provider does not need to go looking for information, or question the patient – all relevant information is available;
- improved quality, up-to-date information
- saving cost (resources, time or financial) because patients can be treated in a safer and more efficient manner;
- less unnecessary examinations/duplication of activities/services which are unpleasant for the patient;
- better patient experience.

2.6 Use Case Assumptions

The following identifies what needs to be in place to meet the requirements of this Use Case:

1. Patient Summaries will be in electronic format.¶
2. Patient Summaries will be largely comprised of structured data where available. The use of free text data should be minimized.
3. The information comprising a patient summary may be retrospective (historical), concurrent (where the extraction of information occurs at the point of care) or prospective (e.g. providing a protocol or care plan for future care).
4. A Patient Summary may be persisted as a unit.
5. A Patient Summary is attestable, and is a unit of communication.

1. Patient Summary data items (data groups; data elements) will have clinical value to a broad range of providers across multiple care settings.
2. Patient Summary data should be collected as close to the subject of care and time of treatment as possible.
3. A standard Patient Summary template can be further and locally customized by a particular integrated EHR authority to filter or identify additional document types which can be viewed (e.g. a "diabetic summary").
4. A Patient Summary supports the transition of care, continuity of care, health care coordination and patient safety across organizational or regional/country boundaries.
5. A Patient Summary may support planned care as well as unplanned / unscheduled care.
6. A Patient Summary is not the entire medical record, but the relevant set of information needed to assure healthcare coordination and the continuity of care.
7. A Patient Summary is to be prepared or produced fit for use, as given above.
8. A Patient Summary is consumed in two ways:
    a. being visualized by a healthcare provider
    b. being incorporated or imported into an electronic record (EHR, EMR, EPR, or other)
9. A patient / health provider demand for care exchange or a health provider / health provider transition of care exchange is responsible for and triggers the Patient Summary request.
10. A trigger for a Patient Summary initiates a request for either:
    a. a Patient Summary that was prepared in advance and available from the patient or the patient primary care provider
    b. a Patient Summary to be produced ad hoc / on demand when care is required.
11. A Patient Summary should be human readable, as well as computer / system exchangeable, available or sent from one healthcare provider, system or setting, to another healthcare provider, system or setting.
12. The Patient Summary is a 'snapshot in time' of the most relevant aggregated demographic and clinical data to enable continuity of care, healthcare coordination and patient safety.
13. Healthcare providers will need to be alerted to the dynamic nature of the Patient Summary, e.g. via on-screen warnings, disclaimers and alerts that appear automatically after Healthcare Providers obtain access to a Patient Summary; patient summary screen alerts should indicate that only a part of the subject of care's health information is being displayed.
14. Patient Summaries should be attested by the healthcare providers who create them or authorize their creation.
15. Patient Summaries should be designed for easy exchange between systems and settings, and easy portability via transportable and mobile media (e.g. health smartcard; USB mass storage device, smartphone).
16. Patient Summaries should be timely, reliable, relevant to the care context, and accurate.
17. Patient Summary data can be used for secondary uses (i.e. health system planning, population health surveillance).
18. A Patient Summary priority user is the healthcare provider (professional). The patient use of the Patient Summary, while entirely valid as a use case, is out of scope for this particular standards set.
19. Patient Summaries are subject of care (consumer) centric, i.e. each instance of a Patient Summary and the health and contextual information it contains should pertain to a subject of care.

2.7 Pre-Conditions

This section describes what needs to be in place before a Patient Summary can exist:

1. Identification and confirmation of all stakeholders (patient / care provider / locations / used products or services)
2. All systems used by care providers should be in place and be interoperable
3. Clinicians are available to define the use case and agree on the data items; thus ensuring the needs are met for the Patient Summary – be it local, national or for cross border or cross jurisdictional sharing
4. Patient Summary data should be accessible at all time
5. Patient Summary data items should be clearly and unambiguously defined and collected to standard definitions.
6. A Patient Summary is generated by the originating clinicians' information system and is viewable by the originating clinician and receiving clinician(s), such as in a final form document reader (e.g. PDF) or in a browser or in an exchanged and imported message.

2.8 Post-conditions

1. Any updated patient summary data is available for all relevant stakeholders upon request.
2. When the updates are provided by an emergency facility, that facility will hold the patient summary updated record as per jurisdictional policies and legislation for required duration.

2.9 Actors and Roles for Use Case

Actor	System	Role
Patient	EHR	Identify Primary Care physician. Validate information as needed
Primary Care Physician	EHR	Send / Receive / Subscribe / Display / Publish
Health Care Clinician / Specialist	EHR	Send / Receive / Subscribe / Display / Publish
Healthcare third party	EHR	Send / Receive / Subscribe / Display / Publish

Table 3: Actors and Roles.

2.10 Use Case Diagram

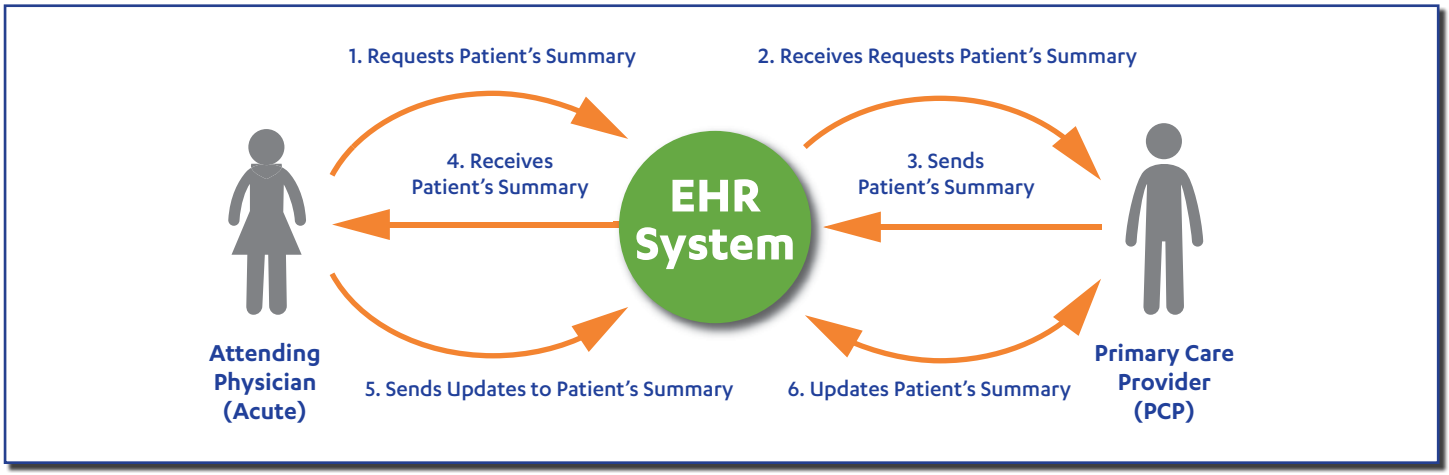

Figure 1: Use Case Diagram

2.11 Scenario

The scenario for this use case describes a patient with breathing difficulty in emergency (acute center). Concurrent with the attending clinician conducting rapid assessment and stabilization of the patient airway, breathing and circulation, another member of the clinical team searches for information about the patient. Attending clinicians identify Primary Care Physician (PCP) (family physician) and local Patient ID from his medication label and acute center Hospital Information System (HIS) patient ID from the acute care record. The attending clinician requests the Patient Summary from the remote Primary Care Physician, the PCP successfully receives the request, understands the request, and sends the Patient Summary back to the attending Emergency clinician via the EHR System. The attending clinician receives the Patient Summary online, accesses the Primary Care Patient Summary from the EHR HIS, treats the patient with the best available information received, updates the patient's record and sends it back to original Primary Care Provider (via EHR).

2.11.1 User Story

Cyril Lambert is 60 years old living in a small community in the northern part of his province. Up to this point in his life, Cyril has rarely gone to the doctor; but over the past two years, he has been suffering from a persistent cough, with intermittent episodes of shortness of breath. Cyril has a new family physician, Dr Martin, who took a history (which included smoking 45-50 packs of cigarettes a year) and after chest x-ray and pulmonary function tests, Dr. Martin confirmed Cyril has Chronic Obstructive Pulmonary Disease (COPD) with asthma. Dr. Martin electronically orders a chest x-ray and refers Cyril for pulmonary function tests. He prescribes inhalation therapy and counsels Cyril to stop smoking. Dr. Martin records the findings of Cyril's visits as chart notes in Cyril's EMR, which contains Patient Summary information and can generate an online Patient Summary.

In a subsequent visit, and as part of Cyril's care plan, a referral is made to the community pharmacist for education on the use of an electronic peak flow meter and needed revisions to his medications. Cyril loads the electronic peak flow meter software on his home computer and completes the vendor's mandatory electronic peak flow meter registration and also enrolls in an online smoking cessation program offered by the public health unit.

Cyril decides to visit his daughter in the capital city of his neighboring province for the summer holidays. He has brought his medications and physician information. During the visit, Cyril's breathing worsens and Cyril decides to go to the local large city hospital Emergency Department and take his current medication with him in its original containers. He also brings his physician contact information.

The emergency attending physician or other clinician looks for any prior records or Patient Summary information on file within his acute care HIS (hospital information system) and finds a previous ankle injury emergency visit record for Cyril from 6 years ago, on file. From Cyril the attending physician identifies Dr. Martin as his primary care physician and requests a Patient Summary from Dr Martin's EMR. Attending physician accesses the primary care patient summary from the EHR.

After accessing the patient summary, Cyril is assessed, his medications are adjusted and he is subsequently released, with instruction that if his symptoms do not improve by Monday, he is to return to emergency. He is also informed if he feels well enough to travel, that when he returns home, and care is transitioned back to his family physician, he should speak to Dr. Martin on the adjusted medications as per an updated care plan and associated guidelines for COPD.

2.11.2 Activity Diagram

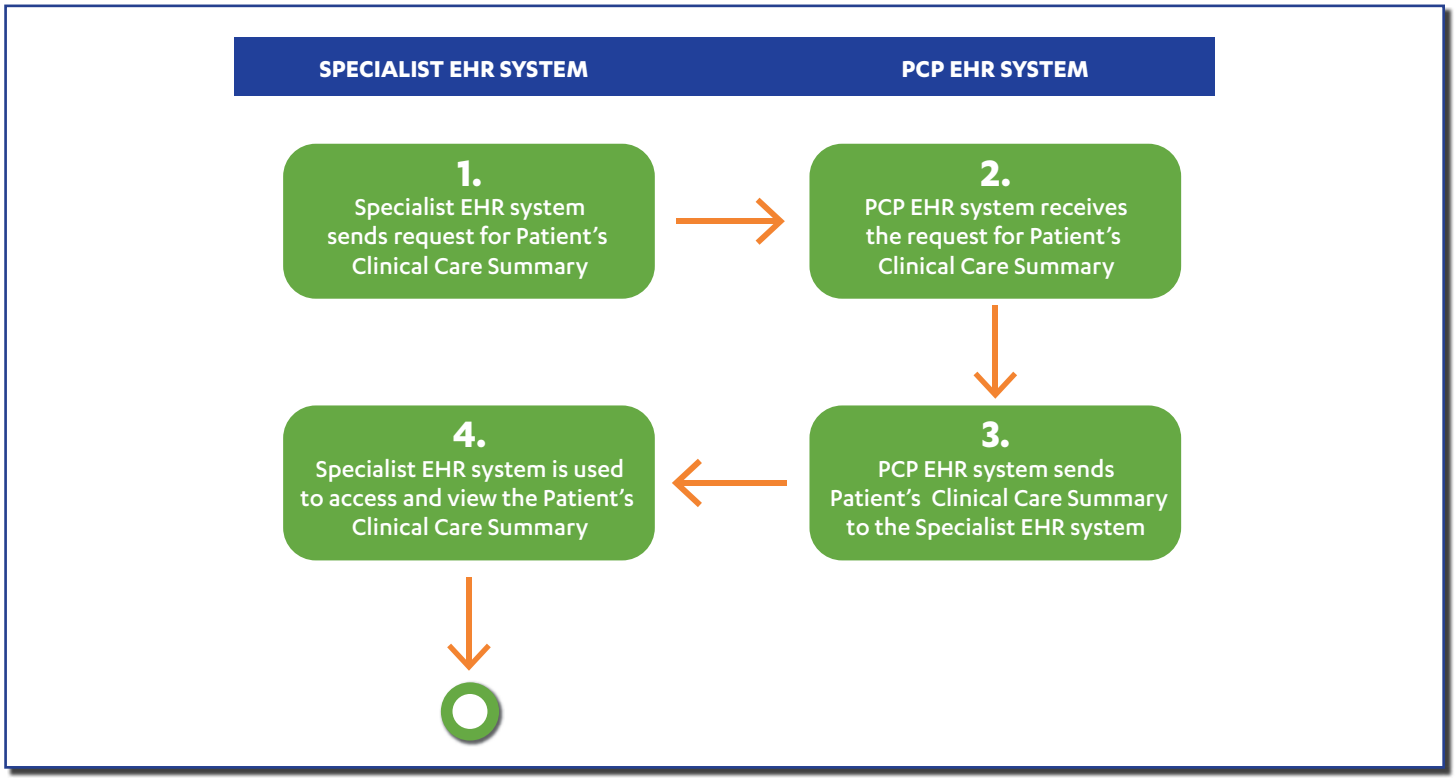

Figure 2: Activity Diagram

2.11.2.1 Base Flow

Step	Actor	Role	Event/Description	Inputs	Outputs
1	Attending Emergency Physician	Request	Attending Emergency Physician EHR System Requests Clinical Care Summary	Attending Emergency Physician selects patient of interest from their EHR system.	Initiated Clinical Care Summary Request in standard format and content specification where possible
2	PCP	Send Publish	PCP Receives Request for Clinical Care Summary through PCP EHR System and understands it	Initiated Clinical Care Summary Request	Clinical Care Summary in standard format where possible
3	PCP	Send Publish	PCP Sends Clinical Care Summary to Attending Emergency Physician through PCP EHR System	Clinical Care Summary	Clinical Care Summary in standard format where possible
4	Attending Emergency Physician	Subscribe Display	Attending Emergency Physician Receives Clinical Care Summary through EHR System and understands it	Clinical Care Summary	
5	Attending Emergency Physician	Send	Attending Emergency Physician sends updates to Patient's Summary back to Primary Care Provider	Clinical Care Summary	
6	PCP	Updates	Updates the patient Summary to a new version based on discharge information, keeping original intact	Clinical Care Summary	End

Table 4: Base Flow of Scenario 1

2.11.2.2 Alternate Flow

Step #	Actor	Role	Event/Description	Inputs	Outputs
5	Attending Emergency Physician	Updates	Updates Patient Summary in EHR		

Table 5: Alternate Flow

2.11.3 Functional Requirements

1. Primary provider office electronic record systems can support the ability for healthcare providers to create, maintain, send and/or export a patient summary record for an individual patient.
2. Patient Summaries are data-centric, i.e. accumulators of persistent data that are structured/organized and easily computable to enable rapid assimilation and communication of health information for a subject of care.
3. Patient Summary content may be extracted from one or more health records pertaining to the subject of care held by or sourced from one or more health providers.
4. Patient Summaries should be extensible, in that additional (local) data for specific purposes may be added to the core (standardized) dataset.
5. Patient Summaries may include links to data that the subject of care has stored in other systems, e.g. shared EHR repositories; document registries; local systems.

1. Patient Summaries should be designed to enable data aggregation for research and administrative purposes, especially Patient Summaries intended for use in a shared EHR.
2. The source of Patient Summary data is to be provided.
3. Optimum value and utility of a Patient Summary depends on agreed upon standardised vocabularies.
4. Patient Summary content should be flexible to accommodate country or localized needs and differences.

2.11.4 System Requirements

1. Patients' privacy and controlled access should be protected in line with local and national policies
2. All relevant Electronic Health Systems should be able to exchange all data.
3. Primary provider electronic record systems can support the ability for healthcare providers to create, maintain, send and/or export a patient summary record for an individual patient.
4. A Patient Summary is generated by the originating physicians' information system and is viewable by the originating physician and receiving physician(s), such as in a final form document reader (e.g. PDF) or in a browser, having been exchanged in an agreed formatted message.
5. A Patient Summary may be persisted as a unit.
6. A standard Patient Summary template can be further and locally customized by a particular integrated EHR authority to filter or identify additional document types which can be viewed (e.g. a "diabetic summary").

2.11.5 Sequence Diagram

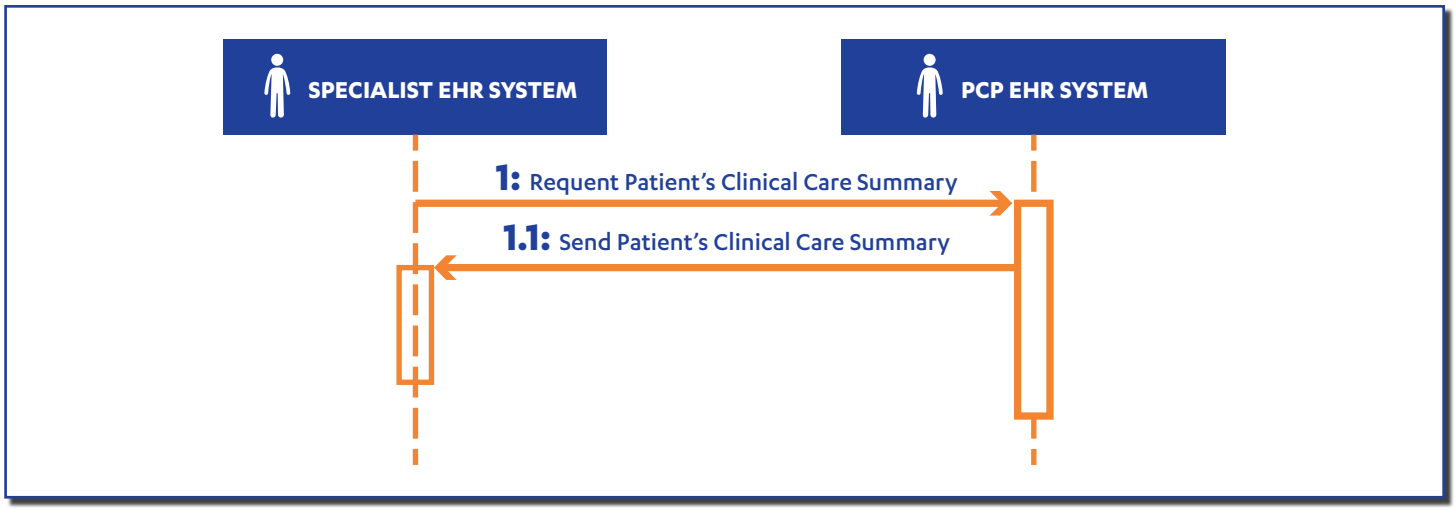

Figure 3: Sequence Diagram

2.12 Risks, Issues and Obstacles

- Many summaries may exist at one or more sites
- Unavailability of readable, credible and relevant data from external systems, timely at point of care
- Maturity of EHR systems vary among jurisdictions so data exchange is often problematic
- Standardization of data across the acute sector
- Standardization of data in primary care sector
- Prevalence of free text non-standardized records in primary care environment
- Non-standardized data entry by clinicians
- Maturity of EHR systems and variation of utilization of advanced functionality of such systems (including integration and exchange of data between primary care and hospital EHRs)

3.0 Patient Summary Standards Set Dataset

It is accepted that the clinical data/information or content of a patient record or related message is the most important element, one that is intended to be durable irrespective of the technology that reads, transports, or presents it. The same is true of the Patient Summary. The importance of the dataset is emphasized as one of the components in the detailed use case description in this Standards Set.

At the time of writing there is no global standard for the Patient Summary content, although there is a growing acceptance of international guidelines and guidance issued by various clinical bodies.

Content for the Patient Summary has different levels of granularity and different information models exist to describe it in the EHR. For example, 'blood pressure' can be modeled by Archetypes and Detailed Clinical Models which are fine-grained artefacts and their value is that these small fragments are reusable and independent of any use case, as well as being clinically meaningful.

The dataset referred to in this guidance has been designed with the 'unplanned cross-boundary care' use case in mind; it therefore comprises sections such as Allergies, Medications and Problems that might be expected to be found in any such summary. This dataset is described as a 'minimal but non-exhaustive' dataset, recognizing that not all countries and organizations are alike, rather they all have different capacities and expectations with respect to section coverage or detail, and different views and policies on any patient summary implementation. The dataset has been developed by an international group of clinicians and can be found.

3.1 Dataset details

PLEASE NOTE:

- REQUIRED (R) means if the data is available it MUST be provided
- OPTIONAL (O) means that the data MAY be provided, based on data availability and decisions of Patient Summary author/owner
- A header core data element is in **BOLD**
- Deleted items from HL7 INTERPAS or EU data sets are "crossed out" by highlighting to grey

3.1.1 Demographic/non-clinical data items

JIC Care Section	JIC Core Data Elements	Source (INTERPAS –I) (EU Guidelines – EUG) (JIC)	Required Or Optional	Comment / Notes
Patient	**Patient Name**	I/EUG	R	
	Family Name or Surname	I/EUG	R	
	Given or First Name	I/EUG	R	For those with no first name, this field would be blank. If first name is available it must be provided
	Administrative Gender	I/EUG Modified JIC	R	Was Gender Code – Renamed (in some cases (AU), patients can choose admin gender)
	Date of Birth	I/EUG	R	May not be known in every instance (Unknown should be part of the value set)
	Patient ID	I/EUG	R	

JIC Care Section	JIC Core Data Elements	Source (INTERPAS –I) (EU Guidelines – EUG) (JIC)	Required Or Optional	Comment / Notes
	Primary: Regional/ National Health ID	I/EUG	R	Not all countries have a national level patient identifier but the data element should be able to accommodate both regional and national
	Address	I/EUG	R	
	Street	I/EUG	R	
Patient	Street Number	I	O	Street number does not exist in every country
	House Number	EUG	R	Include House #. May not exist in every country but more likely than street #
	City	I/EUG	R	City also encompass smaller levels, like town, village or commune.
	State / Province	EUG	R	
	Postal Code	EUG	R	Postal Code reflects Zip Codes or other types of country codes.
	Country	I/EUG	R	Value set to include country name and country codes
	Telecommunication	I/EUG	R	
	Telephone	I/EUG	R	Allow more than one phone number and identify / classify type. (home, work, mobile, other)
	Email	I/EUG	R	
Patient	Preferred Language (of patient)	I	R	Required for Spoken. Written will be needed when wanting to hand out information to patient on discharge or other
Responsible Health Care Professional/ Document Author	Preferred Health Provider Organization	I/EUG	O	Depends on context for physician
	Preferred Health Provider Family Name or Surname	I/EUG	R	Primary author of the patient summary would be the primary care physician, unless otherwise noted below under Other Author
	Given or First Name	I/EUG	R	
	ID Number (code)	I	R	Not every provider may have a unique ID number but if there is an ID, it should be recorded. (Physician Registration number or Health Practitioner Identifier)
	Telecommunication	I/EUG	R	
	Telephone	I/EUG	R	Allow more than one phone number and identify / classify type. (home, work, mobile, other)
	Email	I/EUG	R	
Contact Person / Legal Guardian / Next of Kin	Name	EUG	O	

JIC Care Section	JIC Core Data Elements	Source (INTERPAS –I) (EU Guidelines – EUG) (JIC)	Required Or Optional	Comment / Notes
	Family Name or Surname	EUG Modified JIC	O	
	Given or First Name	EUG Modified JIC	O	
	Role of the Person	EUG	O	Most required is someone who can make a decision on patient's behalf
	Telephone Number	EUG	O	Allow more than one phone number and identify / classify type. (home, work, mobile, other)
	Email	EUG	O	
Document Identification	Date of Creation	I/EUG	R	
	Date of Last Update	I/EUG	R	This is the date of previous iteration of last summary. Assume new summary record is created and links to previous summary record. New one is current date. Outstanding process questions on errors, notifications, alerts, etc.
Document Identification	ID	I	R	Unique ID required, if there is more than one type of summary for different purposes for the same patient.
	~~Code~~	I		Part of metadata
	Title / Name of Document)	I	O	For uses of multiple types of summary records
	~~Confidentiality Code~~	I		Part of metadata
	~~Legal Authenticator~~	I		Duplicative or not required
	Language Code	I	O	Language in which document recorded
	~~Nature of the PS~~	I		Unknown use
	Author Organization	I	R	
	Other Author Name (if not Responsible / Preferred Provider)	JIC	O	Identifies an author of the patient summary, other than the primary care provider
Patient Access Alert	Patient Summary Review Indicator	JIC	O	Identifies whether or not the patient subject of the summary has reviewed the summary
Patient Access Alert	Last Review Date	JIC	O	Date that patient last reviewed the patient summary (with or without corrections or additions)
~~Insurance Information~~	~~Insurance Number~~	EUG		Not required (county localization only)

Table 6: Demographic/non-clinical data items

3.1.2 Clinical data items

JIC Core Section	JIC Core Data Elements	Source (INTERPAS –I) (EU Guidelines – EUG) (JIC)	Required Or Optional	Comment / Notes
Allergies	Allergy Description including: - substance - reaction - severity of reaction	I/EUG Modified JIC	R	Aligned with FHIR data elements https://www.hl7.org/fhir/allergyintolerance.html Based on simplicity and safety. Note, if patient is able to speak, patient validates. http://wiki.hl7.org/index.php?title=FHIR_Allergy_Sample Examples noted include: -Anaphylactic Reaction to Peanuts -(Mild, Moderate, Severe) Eye swelling reaction to cat dander -(Mild, Moderate, Severe) Tongue swelling reaction to Bactrim.
Allergies	Allergy Type	I/EUG Modified JIC	R	Aligned with FHIR data element https://www.hl7.org/fhir/allergyintolerance.html Types are allergy, intolerance
	Allergy Substance Category	JIC	R	Aligned with FHIR data element https://www.hl7.org/fhir/allergyintolerance.html Substance category types are food, medication, environment, other
	Allergy Onset Date	I/EUG Modified JIC	R	Aligned with FHIR data element https://www.hl7.org/fhir/allergyintolerance.html Onset refers to when the allergy first manifested itself in the form of an allergic reaction
	Agent Description (Allergen Description or Name)	I/EUG	R	Represents the specific allergen or other agent/ substance to which the patient has an adverse reaction propensity. A substance is a physical material which can mean a drug or biologic, food, chemical agent, plants, animals, plastics etc. Includes substance, and product hierarchies. (SNOMED has list of agents)
	Agent Code (Allergen Code)	I/EUG	R	SNOMED has (Substance or Product Code) value set
Medic Alert	Healthcare alert Description	EUG	O	Include if not captured elsewhere in the summary INCLUDES MEDICAL DEVICE OR IMPLANT Alerts
	Healthcare alert ID code	EUG	O	Include this if not captured elsewhere in the summary (could be medical device code, if alert is on a medical device)
Home Care Alert	Home Care Monitoring Program Participation	JIC	O	Identify if patient is on home monitoring program for broad range of chronic conditions
	Home care Monitoring Condition(s)	JIC	O	Identify monitoring condition (If coded data exists, then include (BP, vitals, trending, etc.)
Vaccinations	Vaccinations (Name)	EUG	R	If available, populated and coded Last tetanus shot (mandatory in most countries) for adults is the minimal vaccination data needed.
	Brand Name	EUG	O	

JIC Core Section	JIC Core Data Elements	Source (INTERPAS –I) (EU Guidelines – EUG) (JIC)	Required Or Optional	Comment / Notes
	Vaccination ID Code	EUG	O	Value set that includes both brand name and immunizing agent values (Substance ID).
	Vaccination Date	EUG	O	
Problems (Illnesses, Diseases, Diagnoses) – Current	Current Health Condition Description (health issue)	I/EUG Modified JIC	R	Preferred term is Health Condition which includes problems & diagnoses – see FHIR. https://www.hl7.org/fhir/condition.html Health Issue is a reasonable alternative term. (see ISO 13940 Contsys). Includes presenting issue, diagnosis and also chronic diseases,
	Problem Code	I/EUG	R	SNOMED preferable
	Problem Onset Date	I/EUG	R	If available. Associate a different date with each condition / problem provided. Dates may be approximate as the person may have had problems for some time prior to an actual diagnosis being made
Problems Resolved, closed or inactive	Problem Description	EUG	R	Separate from current problems list.
	Problem ID Code	EUG	R	SNOMED preferable Must be easy to capture
	Onset Date	EUG Modified JIC	R	"Time" changed to "Date" for consistency. If available. (seen above Onset Date)
	End Date	EUG	R	
	Resolution Circumstances	EUG	O	Relevant and useful only for surgical procedures. Structured data may not be available. (Eg. A treatment data value set)
	Resolution ID Code	JIC	O	SNOMED Preferable (if structured resolution data available)
Procedures (investigative, diagnostic or treatment)	Surgical Procedure, Non-Invasive Procedure or Intervention and Other Procedure Description	I/EUG	R	Includes interventional procedures that change physical properties of a body, surgical procedures and other procedures, limited to last 6 months, and any procedures relevant to the presenting health condition prior to 6 months. Other procedures also Include alcohol /addictions / acute psychiatric presentations with service names and numbers. (use SNOMED and PHR's) ***(NOTE – Current and Past Procedures combined into one category – see 6 month requirements above)***
	Procedure Code	I/EUG	R	SNOMED preferable .Must be easy to capture
	Procedure Date	I/EUG	R	Valuable if dates available
~~**Treatment Recommendations**~~	~~Treatment Recommendations~~	~~EUG~~		Not included as too vague and contained in other summaries (ie Discharge or Medication Summaries).
	~~Recommendation ID (code)~~	~~EUG~~		Not included

JIC Core Section	JIC Core Data Elements	Source (INTERPAS –I) (EU Guidelines – EUG) (JIC)	Required Or Optional	Comment / Notes
Competency/ Capacity / Invalidity	Decision Making Competency or Invalidity Description	EUG Modified JIC	R	Use WHO ICF 2000 for terminology
	Invalidity ID Code	EUG	R	Use SNOMED Terms
Do Not Resuscitate Alert	DNR Order On File	JIC	O	Alert to specify whether or not a "do not resuscitate order" is on file with the primary care provider
	DNR Order Source	JIC	O	Indicates the source of the order (ie. patient, substitute decision maker, primary care provider)
	DNR Order Date	JIC	O	Date of last DNR order update
Medications	Medication (Name Brand or Generic) or Active Ingredient Description (Active Ingredient Name)	I/EUG	R	For Current and past 3 months of medications
Medications	Medication Brand Code or Active Ingredient Code	I/EUG	R	SNOMED covers drug, and substance (active ingredients). Brand code covered by national extensions or national data base (ie DMD in UK, Aust –ANT, US – RxNorm)
	Strength	I/EUG	R	Content of the active ingredient expressed quantifiably per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500 mg (per tablet)
	Pharmaceutical dose form	EUG	R	
	Number of Units Per Intake	I/EUG	R	
	Frequency of intake	I/EUG	R	
	Duration of Treatment	I/EUG	R	
	Date of Start of Treatment	I/EUG Modified JIC	R	Name and context of element changed to Date of "Start" of Treatment
Social History Observations	Social history observations related to smoking, alcohol and diet	EUG	O	Optional. Add ID code below if such exists. Users may also decide to class smoking, alcohol and diet history under Risk Factors and keep this section for items such employment status,whether they have a carer etc
Social History Observations	Social history observation ID code	JIC	O	Using SNOMED or LOINC (ie smoking, substance abuse)
	Reference Date Range	EUG	O	Likely estimates in most cases
Pregnancy	Expected or past date of delivery	EUG Modified JIC	O	Added "or past". (Issue is keeping this information up-to-date – current pregnancy; past pregnancies)

JIC Core Section	JIC Core Data Elements	Source (INTERPAS –I) (EU Guidelines – EUG) (JIC)	Required Or Optional	Comment / Notes
Physical Findings (vital signs, Observations)	Blood Pressure	EUG	O	BP reading is minimum required vital sign
	Date when blood pressure was measured	EUG	O	May be unknown or an estimate only
	Additional Vital Signs Respiratory rate Heart rate Oximetry Temperature	JIC	O	As available
~~**Medical Equipment (Medical Devices)**~~	~~Device or Implant Description~~	~~I/EUG~~	Capture only / as Medic Alert Info or Medication data	Capture all of this information as Medic Alert data or capture as medication data (inhalers, spacers, patches) Note: HL7 / GS1 working on Unique device identifier (UDI). Legislation expected in Europe in 2017 and will require UDI's to be issued. Would also need type of device, manufacturer, etc
	~~Device or Implant Code~~	~~I/EUG~~	See above	
	~~Device Implant Date~~	~~I/EUG~~	See above	
Diagnostic Test Results -Blood Group	Blood Group Observation Description (Name) (Blood group only)	I	R	epSOS standard includes ABO and Rh Blood Group (blood and Rh groupings should not change over time). Note: C-CDA standard includes any types of diagnostic result however other test results are only a point-in-time reflection of the person's health status. *There is an issue of currency of the PSR data, as noted for other data elements. For further / future discussion.*
	Blood Group Observation Code	I	O	If it exists
	Blood Group Observation Value	I/EUG	O	
	Blood Group Determination Date	I/EUG	O	
Other Non- Time Variant Diagnostic Test Results	Test Name	JIC	O	ie. HLA type, acetylation status (fast/slow) etc. Definitely useful for disease markers such as HbA1C, WCC in lymphomas etc
	Date of Test	JIC	O	
	Result of Test	JIC	O	

Table 7: Clinical data items

4.0 Categorization and selection criteria for Standards/profile inclusion

The 'Patient Summary' concept is deceptively simple, but to be shared and used in practice the Patient Summary requires a number of complex things to be put in place. Furthermore, the pervasive nature of the Patient Summary has led to many localized solutions arising and a variety of different clinical and technical specifications created to support their application. There are many implementations already in existence. However, the varied interpretations of specifications, types and meanings of summary make it difficult to share the content. The Patient Summary is a classic interoperability problem; on the plus side there are many specifications from which the customer can freely choose but at the same time the choice can be very confusing and the specifications themselves can be incompatible in the sense that they were not necessarily designed to interoperate or to even address the same problem.

One well accepted strategy is to use categorization as a means of simplifying complexity. The categorization can also help direct the reader to their area of interest by narrowing the focus to suit the use context and case. However, it is also necessary to consider what and how much should go into each category to make life easier. This is particularly difficult because there are still too many specifications to choose from. To try and eliminate any preferential bias, validated selection criteria have been produced for the Standards Set and these are then used to include or disregard particular specifications from a category.

4.1 Standards Identification Approach

With the foundation guidance of providing a "coherent collection of standards and standards artefacts that support a specific use case" and the use case of "access patient summary in acute care setting", a recommended set of standards and standards alternatives has emerged.

There were three overarching steps used to identify the set of standards for patient summary, all three undertaken and with content developed through the expertise and months of work by the members of the Patient Summary Standards Set Identification and Analysis Task Group, from across 5 different SDO's;

- document a standards categorization
- use a set of principles to identify a list of possible standards for inclusion
- use a set of criteria to identify the standards of the Patient Summary Standards Set.

As a starting point to the Standards Set, a standards categorization was necessary to organize the Standards Set. This categorization is certainly aligned and complementary with the ISO/TC215 Reference Standards Portfolio work, and was targeted to a balance of simplicity, nuance and completeness.

The criteria for standards identification, and indeed also the principles and standards categorization, were developed to be adapted and used for future and further Standards Set use cases.

4.2 Categories or levels of standards

The six (6) categories or levels of standards of the Patient Summary Standards Set support:

- Semantic interoperability
  - Level 1 – content, structure and format
  - Level 2 – semantic content
- Technical Interoperability
  - Level 3 – transport
  - Level 4 – security and safety
- Functional Interoperability
  - Level 5 – functional services
  - Level 6 – implementation specifications

See **APPENDIX A** for a summary of the standards categorization and also the following linked reference for the entire report.

4.3 Principles for standards identification and assessment

From the plethora of standards to be considered the following *Principles* were applied to the Patient Summary Standards Set (PSSS) identification and assessment process to determine inclusions and exclusions in a starting standards listing:

- The standards included are based on the needs of the **use case of patient summary in acute care**.
- The **standards necessary to fulfill the functions of data exchange, transfer, access, viewing and use are included** in the PSSS, while standards focused on creation and capture of the data are not specifically included.
- Standards Set identification is – **to be reasonably high level and simple** (ie not identifying every code set or term list)
- The standards necessary to fulfill the base internet access, communication and information exchange (ie, TCP/IP, and the entire internet protocol suite including current and newly desired standards such as HTML, XML, REST, JSON) are components, tools, and architectural concepts that underpin transport standards, are often identified as **web-based technology and services, are base requirements for health information exchange and are not specifically included in the PSSS**. Any country may be using or choosing particular subsets of those standards to fulfill their health information exchange infrastructure.
- The standards set is targeted to be **"architecture agnostic"**, and **"information model agnostic"** as opposed to being constrained to or by any particular health information technology architecture (ie service oriented, peer to peer, family of apps, etc) or any particular information model (HL7 RIM, open EHR logical model, archetypes model).
- The standards to be included must be **International Standards** and available through one of our member or related international SDO's. National standards are understood to be used by a particular country to meet that country's needs and may be 'mappable' or complementary to international standards.

4.4 Standards outside scope of the PSSS

Conceptual and high level logical standards are not included in the PSSS, including those that underlie clinical information, such as the systems of concepts, the clinical data model structures and the archetypes structures. Conceptual or foundation standards (see discussion in the FOUNDATION STANDARDS SECTION) are, however, applied as needed by countries in the capture of all their clinical and health information and may be included in a region/country PSSS, if applicable to specific design or use case needs.

4.5 Criteria for Standards inclusion in the PSSS

From the standards listed as possible candidates for the PSSS (see APPENDIX B), it was necessary to use specific criteria for artefact inclusion and for choosing, where necessary, from among various standards that may fit for patient summary. This process is and continues to be iterative, as further information on the standards is determined and as experts provide their input and commentary.

There is a natural tendency to attempt to include a number of favored standards from various Standards organisations (SDO) constituencies. And in various instances a valid case has or may yet be made for inclusion.

The application of criteria builds objectivity and support and gives a means to think effectively on the use of a particular standard – however, expert knowledge, considerations and information are applied in the fulfillment of the criteria.

The criteria considered is that the standard to be included:

- Is an international standard
- Is *fit to the use case (applicable to use case requirements and/or use case data set,* (and in particular applicable to the Patient Summary use case flow steps)
- Is *architecture agnostic* (not constrained to or by any particular health information technology architecture (i.e. service oriented, peer to peer, family of apps, etc).
- Is *information model agnostic*, providing the minimum information required in a patient summary, and providing semantic consistency
- Is a *standard required for interoperability*
- Include all standards required and supporting any of the levels/parts of the information interoperability framework(supports semantic, technical, functional interoperability)
- *Is a unique standard with no identified overlapping standard OR is a standard with possible overlapping coverage of requirements* (included to enable stakeholders to choose the standards that are applicable to their domain and jurisdiction).
- *Is a standard identified as an alternative*
- either available in the future or
- available to fit specific architecture or information requirement or
- available to fulfill a standards need that is additional to other common standards used.
- Applies to the standard section of the patient summary and *does not restrict disease or treatment specific standards additions,* or personalized patient specific content standards additions
- *Or may be locally 'mappable'*
- International patient summary standards may need to be mapped to local / contextual needs where localization or differing national standards requirements exist

4.6 Patient Information Conceptual and Foundation Standards

Having knowledge of the conceptual basis for patient summary information is a useful foundation for interoperable exchange and access of that data by a health provider for a patient. Such a foundation, as may be outlined in associated standards, may be of significant interest in the design and development of related patient summary systems, particularly for the capture and collection of the patient data. The standards listed below can be used to provide a generic and conceptual basis to the patient summary data and associated systems.

As stated in the use case and in the Standards Set inclusion principles above, standards focused on creation and capture of the data are not part of this use case and not part of this Standards Set. Furthermore, the use of the Patient Summary Standards set does not require adoption or implementation of any one or more specific conceptual standards or clinical information models noted below. The criteria noted for standards identification specifically states that the standards in the set are information model agnostic.

Patient Information Conceptual / Foundation Standards noted:

- *ISO/IS 13940 – System of concepts to support continuity of care*.

  SCOPE – This International standard defines a system of concepts for different aspects of the provision of healthcare. The concepts aim to support the continuity of care in healthcare and clinical processes

  This standard provides a comprehensive, conceptual basis for content and context in healthcare services. It is a generic foundation for health information interoperability at all levels and information systems in healthcare organizations.

- OpenEHR Reference Model.

  SCOPE – An EHR information model of an interoperable EHR in the ISO RM/ODP information viewpoint. (Note, this may be viewed as a logical model and not a conceptual model – however it is included here as a foundation standard; if solely a logical model, then it would be excluded as the PSSS is information model agnostic – see criteria)

  This foundation clinical model, consisting of archetypes and templates, enables the specification and sharing of clinical content.

- ISO/TS 13972:2015 Detailed clinical models, characteristics and processes

  SCOPE – Describes requirements and recommended methods against which clinicians can gather, analyse and, specify the clinical context, content, and structure of Detailed Clinical Models. Defines Detailed Clinical Models (DCMs) in terms of an underlying logical model. They are logical models of clinical concepts and can be used to define and to structure clinical information.

  This standard provides precise semantic consistent data and terminology specification that are comparable and sharable between multiple care providers, health enterprises and standards-based Healthcare Information Technology. Conceptually, a detailed clinical model (DCM) is an information model of a discrete set of precise clinical knowledge which can be used in a variety of contexts. *(Note, this may be viewed as a logical model and not a conceptual model – however it is included here as a foundation standard; if solely a logical model, then it would be excluded as the PSSS is information model agnostic – see criteria)*

5.0 List of standards, standards artefacts and profiles meeting the criteria

For each of the standards categorization levels, a table is provided for the standards that are included in the Patient Summary Standards Set. Each table includes the following fields:

- ARTEFACT – standards, profiles, guides or implementation specifications used to achieve interoperability
- NAME REFERENCE (TYPE OF STANDARD) – provides the formal number and name of the artefact, along with a link for information on the artefact and a note on the specific type of the artefact.
- SOURCE (SDO) – provides the standards development organization for the artefact
- SDO PROCESS MATURITY – identifies, in the language of the SDO and its processes, the status of the artefact
- COMMENT – notes to the standard
- COST – identifies if the artefact has a cost associated with the acquisition of the full artefact document or is free
- APPLICABLE INTERACTION STEPS – identifies the patient summary basic flow steps applicable to a particular standard, from the use case and as noted in the use case table 10.2.1 (see **Appendix C**)

5.1 Table 8 Semantic Interoperability – Data Related Standards (for content, format or structure)

Artefact (International SDO based artefact (note otherwise))	Name, Reference (Type of standard)	Fit to Use Case (applic to req's and/ or data set	Architect'r Agnostic/ Informt'n Model Agnostic	Required for Interopera-bility	Is a standard w/o overlap or identified to reduce overlap	Is identified as a standards alternat'v	Standard supports/ not restricts disease, treatment or personal data additions	Able to localized or mapped to other context	Comments
Set Standards	ISO 22220:2011 ISO 27527:2010 ISO 8601:2004 ISO 21090:2011 C-CDA CCD R2.1 epSoS v1.4 PS HL7 FHIR Resource (Allergy Intolerance)	Y	Y/Y	Y	Y	N	Y	Y	

TABLE 8 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Semantic Interoperability Standards						
Data-related standards (content, format, structure)						
SET Standards						
Standard	ISO 22220:2011 Identification of Subjects of Care (content and structure)	ISO	Final		Cost (see ISO)	1-6
Standard	ISO 27527:2010 Provider Identification (Content and Structure)	ISO	Final	Other SDO's or countries (ie HL7, US) may have ID's or national ID's, mapped as needed	Cost (See ISO)	1-6
Standard	ISO 8601:2004 Date and time format (format)	ISO	Final		Cost (See ISO)	1-6

TABLE 8 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Semantic Interoperability Standards						
Data-related standards (content, format, structure)						
SET Standards						
Standard	ISO 21090: 2011 Harmonized data types for information exchange (structure)	ISO	Under Systematic Review		Cost (See ISO)	1-6
Standard	C-CDA CCD R2.1 Consolidated Clinical Document Architecture (C-CDA) Continuity of Care Document (CCD) Release 2.1 (content and structure (document))	HL7	Final	A standard for certain patient summary data items content and structure	Free	2-4 (CDA cannot do request, cannot do updates without external structures)
Standard	epSoS v1.4 PS European Patients Smart Open Services (Content and Structure)	CEN	Final	A standard for certain patient summary data items content and structure	Free	2-4
Standard	HL7 FHIR Resource Allergy Intolerance – (Content, format and structure)	HL7	V3.0.1 FHIR Release 3 STU	A standard for allergy data elements	Free	1-6
ALTERNATE Data-related standards						
Standard (available future)	International Patient Summary (IPS) template	HL7 jointly with ISO/ TC215	Standard (balloted)	Building from C-CDA R2.1, epSoS V1.4 PS, IHE PCC and early Interpas / Trillium Bridge work	Free	1-6
Standard (available specific requirement)	ISO/TS 18530:2014 Automatic Identification and Data Capture, Marking and Labelling https://www.iso.org/standard/62805.html	ISO/ TC215, GS1	Final	Used specific to AIDC technology, and associated as a data qualifier or metadata for patient and provider in Patient Summary	Cost (see ISO)	1-6
Standard (available additional)	FHIR v1.0.2 Resources (other clinical related)	HL7	STU 3	Other FHIR resources usable if patient summary requires detail and data	Free	1-6
Standard (available future)	IDMP group of standards ISO 11615:2012 ISO 11616::2012 ISO 11239:2012 ISO 11238:2012 ISO 11240:2012	ISO	Final	IDMP, including implementation guides, originally targeted to regulators, now being prepared for use as basis for clinical practice (see ISO Focus)	Cost (see ISO)	1-6

5.2 Table 9 Semantic Interoperability – Semantic Content Related Standards (terminologies, vocabularies, code sets, terminology binding)

The semantic related standards listed in Table 9 were assessed by criteria and all set standards (not including alternate standards listed below) were assessed as YES's, as summarized below:

Artefact (International SDO based artefact (note otherwise))	Name, Reference (Type of standard)	Fit to Use Case (applic to req's and/ or data set	Architect'r Agnostic/ Informt'n Model Agnostic	Required for Interopera-bility	Is a standard w/o overlap or identified to reduce overlap	Is identified as a standards alternat'v	Standard supports/ not restricts disease, treatment or personal data additions	Able to localized or mapped to other context	Comments
Set Standards	HL7 Administrative Gender (FHIR) ISO 3166-1 ISO 639 HL7 V3 Address Part Type and FHIR Address Type HL& v3 Address Use HL7 Telecommunication Use (v2) SNOMED-CT HL7 LOINC Document Type Vocabulary LOINC Universal Code System	Y	Y/Y	Y	Y	N	Y	Y	

TABLE 9 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Semantic Content-related standards (terminologies, vocabularies, code sets, terminology binding)						
SET Standards						
Standard	Administrative Gender Administrative Gender FHIR (Code Set)	HL7	Final	HL7 V3 Admin gender already mapped to FHIR	Free	1-6
Standard	ISO 3166-1 Country Codes (code set)	ISO	Final		Cost (see ISO)	1-6
Standard	ISO 639 Language Codes (code set)	ISO	Final		Cost (see ISO)	1-6
Standard	HL7 v3 Code System Address Part Type (code set) HL7 FHIR Address Type	HL7	Final		Free	1-6
Standard	HL7 v3 Code System Address Use (code set)	HL7	Final		Free	1-6
Standard	HL7 Version 2 Table 0201 Telecommunication Use Code (code set)	HL7 (v2)	Final		Free	1-6

TABLE 9 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Semantic Content-related standards (terminologies, vocabularies, code sets, terminology binding)						
Standard	SNOMED CT	SNOMED International	Final (6 monthly releases)		Licensed (free in Member countries)	2-6
Standard	HL7 LOINC Document Type Vocabulary Domain (code set)	DICOM (HL7 FHIR)	Final		Free	2-6
Standard	LOINC Universal Code System for tests, measurements and observations (terminology)	Regenstrief	Final (regular updates)	SNOMED CT may also be used however LOINC is commonly used in a number of countries	Free	2-6
ALTERNATE Semantic-related standards						
Standard (available additional)	ICD-10: 2016 International Statistical Classification of Diseases and Related Health Problems 10th Revision (Classification System)	WHO	Final	Usable but for certain Use Cases ICD-10 does not have needed granularity.	Free	2-6
Standard (available specific requirement)	International Nonproprietary Names for identification of pharmaceutical substances or active pharmaceutical ingredients	WHO	Final	INN is a flat list, with unique names, globally recognized used to create drug terminology. IDMP points to it and is followed by SNOMED CT for naming convention		2-6

5.3 Table 10 Technical Interoperability – Transport Related Standards (information exchange, technical, identifiers, exchange services)

The transport related standards listed in Table 10 were assessed by criteria and all set standards (not including alternate standards listed below) were assessed as YES's, as summarized below:

Artefact (International SDO based artefact (note otherwise))	Name, Reference (Type of standard)	Fit to Use Case (applic to req's and/ or data set	Architect'r Agnostic/ Informt'n Model Agnostic	Required for Interopera-bility	Is a standard w/o overlap or identified to reduce overlap	Is identified as a standards alternat'v	Standard supports/ not restricts disease, treatment or personal data additions	Able to localized or mapped to other context	Comments
Set Standards	HL7 V2 (2.8) HL7 FHIR (v3.0.1) with RESTful Services IHE XDS (Transport)	Y	Y/Y	Y	Y	N	Y	Y	

TABLE 10 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Technical Interoperability Standards						
Transport-related standards (Information exchange, technical, identifiers, exchange services) [2][3]						
SET Standards						
Standard	HL7 V2 Application Protocol for Electronic Data Exchange in Healthcare Environments (information exchange)	HL7	Final (v2.8)		Free	1-6
Standard	HL7 FHIR (with RESTful Services) Fast Healthcare Interoperability Resources (information exchange)	HL7	STU Release 3 (v3.0.1-11917)		Free	1-6
Standard	IHE XDS (Transport) Vol 2 of IT Infrastructure Technical Framework) (exchange service)	IHE	Final		Free	1-6
ALTERNATE Transport-related Standards						
Standard (available additional)	HL7 V3 Normative Edition—suite of specifications based on HL7's Reference Information Model (RIM) (information exchange)	HL7	Final	Two HL7 v3 Care Record messages noted for use for patient summary query and transfer (HL7 V3 Care Record Query, Care Record)	Free	1-6
Standard (available specific requirement)	13606-5 2010 Electronic health record communication – Part 5: Interface specification (exchange service)	ISO	Final (Under Review 2017)	ISO 13606-5:2010 effectively defines payload communicated at interfaces.	Cost (See ISO)	3-6

5.4 Table 11 Technical Interoperability – Security and Safety Related Standards (Security, privacy, safety, consent, data use)

The security and safety related standards listed in Table 11 were assessed by criteria and all set standards (not including alternate standards listed below) were assessed as YES's, as summarized below:

Artefact (International SDO based artefact (note otherwise))	Name, Reference (Type of standard)	Fit to Use Case (applic to req's and/ or data set	Architect'r Agnostic/ Informt'n Model Agnostic	Required for Interopera-bility	Is a standard w/o overlap or identified to reduce overlap	Is identified as a standards alternat'v	Standard supports/ not restricts disease, treatment or personal data additions	Able to localized or mapped to other context	Comments
Set Standards	ISO 27799:2016 ISO/TS 14441 ISO/TR 27809:2007 IEC/FDIS 82304 ISO/TR 17791:2013 HL7 v3 Healthcare Access Control Catalog	Y	Y/Y	Y	Y	N	Y	Y	

TABLE 11 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Security, Safety-related standards (includes security, privacy, safety, consent, data use)						
SET Standards						
Standard	ISO 27799:2016 Information security management in health using ISO/IEC 27002 (security)	ISO	Final	Parts are applicable at the Primary care and Hospital level for transfer, view and access	Cost (see ISO)	1-6
Standard	ISO/TS 14441 Health informatics – Security and privacy requirements for EHR systems for use in conformity assessment	ISO	Final	Provides security and privacy requirements and guidance for electronic patient record systems at the clinical point of care (also interoperable with EHRs).	Cost (see ISO)	1-6
Standard	ISO/TR 27809:2007 Health informatics – Measures for ensuring patient safety of health software	ISO	Final	Use for control measures	Cost (see ISO)	1-6
Standard	IEC/FDIS 82304 Health software – Part 1: General requirements for product safety	ISO	Final	Needed for original systems development, implementation and use	Cost (see ISO)	1-6
Standard	ISO/TR 17791:2013 Health informatics – Guidance on standards for enabling safety in health software	ISO	Final	Use for guidance on health standards for safe health software	Cost (see ISO)	1-6
Standard	HL7 Version 3 Standard: Healthcare Access Control Catalog, Release 3	HL7	Final	Extending the role based access in systems	Free	1-6 (if the primary care provider undertakes the actions manually. If the PCP system automatically deals with the request and updating then this standard would apply only to steps 1, 4 & 5.

TABLE 11 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Security, Safety-related standards (includes security, privacy, safety, consent, data use)						
ALTERNATE Security, Safety-related standards						
Standard (available additional)	ISO/TS 13606-4:2009 Health informatics – Electronic health record communication – Part 4: Security	ISO	Final and Under Review	An alternative to ISO 27799	Cost (see ISO)	1-6

5.5 Table 12 Functional Interoperability – Functional Service Related Standards (Business, information governance, systems, API's and other)

The functional service related standards listed in Table 12 were assessed by criteria and all set standards were assessed as YES's, as summarized below.

Artefact (International SDO based artefact (note otherwise))	Name, Reference (Type of standard)	Fit to Use Case (applic to req's and/ or data set	Architect'r Agnostic/ Informt'n Model Agnostic	Required for Interopera-bility	Is a standard w/o overlap or identified to reduce overlap	Is identified as a standards alternat'v	Standard supports/ not restricts disease, treatment or personal data additions	Able to localized or mapped to other context	Comments
Set Standards	ISO/HL7 10781:2051 ISO/TR 21089:2004 ISO 22600-1:2014 ISO/FDIS 21298 HL7 Healthcare Requirements for Emergency Access	Y	Y/Y	Y	Y	N	Y	Y	

TABLE 12 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Functional Interoperability						
Functional-related standards (for business, information governance, systems, API's and other)						
Set Standards						
Standard	ISO/HL7 10781:2015 HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM) (systems functions)	ISO and HL7	Final	Use for EHR system requirements related to patient summary	Free (In ISO a Cost)	N.a. to the use cases steps, but assumed in overall system creation
Standard	ISO/TR 21089:2004 Trusted end-to-end information flows (system functions)	ISO	Being balloted and published as a TS	Use for traceability, audit provenance system requirements		1-6

TABLE 12 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Functional Interoperability						
Functional-related standards (for business, information governance, systems, API's and other)						
Standard	ISO 22600-1:2014 Health informatics – Privilege management and access control – Part 1: Overview and policy management	ISO	Final	Use for the principles and specifies services needed for managing privileges and access control to data and/or functions. (Future work to address any overlap with HL7 RBAC and level placement)	Cost (See ISO	1-6
Standard	ISO 22600-2:2014 Health informatics – Privilege management and access control – Part 2: Formal models	ISO	Final	Use for communication and use of health information distributed across policy domain boundaries.	Cost (see ISO)	1-6
Standard	ISO/FDIS 21298 Health informatics – Functional and structural roles	ISO	FDIS (2008 previous version)	Use for expressing functional and structural roles	Cost (see ISO)	1-6
Guide	Healthcare Requirements for Emergency Access (HL7)	HL7	Final	Guidance on requirements applicable to enforcing Authentication and Authorization (A&A) in emergency access contexts	Free	1-6

5.6 Table 13 Functional Interoperability – Implementation Specification Related Standards (Includes guides, profiles, reference implementations, workflow practices)

The implementation specification related standards listed in Table 13 were assessed by criteria and all set standards (not including alternate standards listed below) were assessed as YES's, as summarized below:

Artefact (International SDO based artefact (note otherwise))	Name, Reference (Type of standard)	Fit to Use Case (applic to req's and/ or data set	Architect'r Agnostic/ Informt'n Model Agnostic	Required for Interopera-bility	Is a standard w/o overlap or identified to reduce overlap	Is identified as a standards alternat'v	Standard supports/ not restricts disease, treatment or personal data additions	Able to localized or mapped to other context	Comments
Set Standards	IHE RID Retrieve Information for Display IHE HPD Healthcare Provider Directory IHE XCF Cross Community Fetch IHE DEN Document Encryption IHE DSG Document Digital Signature IHE ATNA Audit Trail, Node Authentication IHE XUA Cross-Enterprise User Assertion ISO 22600-3:2014	Y	Y/Y	Y	Y	N	Y	Y	

TABLE 13 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Implementation Specification-related standards (Includes guides, profiles, reference implementations, workflow practices)						
Set Standards						
Information Retrieval and Transfer Related						
Profile	RID Retrieve Information for Display	IHE	Final	Use for PDF, CDA, Jpeg (browser-based) read-only access to clinical information	Free	1 and 4
Profile	HPD Healthcare Provider Directory.	IHE	Final	Needed to know where the patient summary is being sent (which physician and using a query against a directory of physicians)	Free	1,2,3,5
Set Standards						
Information Retrieval and Transfer Related						
Profile	XCF Cross Community Fetch .	IHE	Final	Used where community is known and patient summary is requested (fetch a document from another community)	Free	3-4

TABLE 13 Artefact	Name, Reference (Type of standard)	Source (SDO)	SDO Process Maturity	Comments	Cost to Acquire	Applicable Interaction steps
Implementation Specification-related standards (Includes guides, profiles, reference implementations, workflow practices)						
Security and Privacy Related:						
Profile	DEN Document Encryption	IHE	Final	Used for Encrypting individual documents	Free	1-6 as paired encryption and decryption is needed for each of steps 1, 3, and 5
Profile	DSG Document Digital Signature	IHE	Final	Used for digital signatures for documents.	Free	1, 3, 5
Profile	ATNA Audit Trail and Node Authentication	IHE	Final	Used for (a) functional access controls, (b) security audit logging and (c) secure network communications.	Free	1-6
Profile	XUA Cross-Enterprise User Assertion	IHE	Final	Used for identity of authenticated principal (user, application, system...) in transactions that cross enterprise boundaries.	Free	1, 2, 3, 5
Standard	ISO 22600-3:2014 Health informatics – Privilege management and access control – Part 3: Implementations	ISO	Final	Used as examples of 22600-2 models and Instantiates requirements for repositories for access control policies and privilege management infrastructures.	Cost (see ISO)	1-6
Alternate Implementation Specification-related Standards						
Profile (available specific requirement)	XDS Cross-Enterprise Document Sharing (XDS) (Integration Profile)	IHE	Final	Use depends on system being used – if XDS (or other options, ie point to point)	Free	1, 2, 3, 5
Alternate Implementation Specification-related Standards						
Profile (available specific requirement)	XDR Cross-Enterprise Document Reliable Interchange (XDR) (Integration Profile)	IHE	Final	Use depends on system being used and need for direct document interchange between systems (EHR, EMR) using a reliable messaging system and in absence of document sharing infrastructure (ie XDS)	Free	1, 2, 3, 5

[1] JIC Foundation and Scope Report for Patient Summary Standards Set, October, 2015

[2] TCP/IP, HTML, XML, JSON are components, tools, and architectural concepts that underpin transport standards (broadly identified as web-based technology and services)

[3] TCP/IP and the entire Internet Protocol Suite are base requirements for health information exchange

6.0 Conformity Assessment

Conformity Assessment will be presented in this section as guidance to developers, users, and implementers of software and systems that create, update, consume or communicate a Patient Summary document. This guidance is comprised of two parts:

- Conformity Assessment Framework;
- Specific Conformity Assessment artefacts that support a Patient Summary Standards Set (PSSS).

The guidance is designed to ensure that the user recognizes the importance, and the value, of Conformity Assessment, as a necessary companion to the implementation of a standard, and a necessary step along the Standards Development Lifecycle. The conformity assessment discussion focuses largely on the process of designing and implementing a program to test and certify that a system implementation is, indeed, compliant with the standards it claims to be based upon. The value to the implementer is the assurance that such a system will perform as advertised.

The Conformity Assessment Framework outlined in section 6 alerts the user to the components of a conformity assessment program, and recommends the ingredients necessary to ensure that conformance needs are indeed met. The Framework is largely built on two ISO standards, one for testing (ISO/IEC 17025:2005 *General Requirements for the competence of testing and calibration laboratories*) and one for certification (ISO/IEC 17065:2012 *Conformity assessment – Requirements for bodies certifying products, processes and services*), and is also compliant with the ISO/CASCO (Committee on Conformity Assessment) guidance.

Section 7 ties the Framework to the set of standards that have been identified for the Patient Summary, according to the use case that was defined for this purpose. Leading conformity assessment practices were used to illustrate how the standards set could be utilized to design and build a conformity assessment program, at implementation time.

6.1 ISO/CASCO

Accepted international conformity assessment standards have an impact on market access and can facilitate international trade, therefore a harmonized approach at national, regional and international level is essential. For this reason, all ISO and IEC International Standards must be developed in accordance with the ISO/IEC Directives. One of the areas covered in ISO/IEC Directives, Part 2, *Rules for the structure and drafting of International Standards,* is *subclause 6.7, Aspects of conformity assessment*. The ISO Committee on Conformity Assessment (ISO/CASCO)[1] oversees the implementation of this clause and provides advice to ISO technical committees (TCs) on how to word their standards in a compliant manner. ISO and IEC have published ISO/IEC 17007:2009*, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment*, which sets out some of the principles and guidance that are reflected in the Directives. The principles, language and guidance offered in ISO/IEC 17007:2009 have been reflected in this PSSS document.

6.2 Conformity Assessment Framework

Conformity Assessment is defined as the *"demonstration that specified requirements relating to a product, process, system, person or body are fulfilled" (ISO/IEC 17000)*. The need for Conformity Assessment is primarily driven by risk, in that the perception of risk associated with non-conformity fuels the need for regulatory and market confidence. According to the United States National Institute for Science and Technology (NIST), a successful Conformity Assessment Program (CAP) provides the required confidence at minimal cost.[2]

The framework described in this section is based on a risk model, as articulated by ISO/IEC/CASCO guidance, and considered "best practice" by NIST and other standards/testing/accreditation organizations around the world[3]. It is assumed that any instance of a CAP program will likely incorporate one or more elements of this framework, but specific implementations of these standards should not be considered prescriptive, or mandatory, in any way.

6.3 Description of the Framework

Figure 4 below illustrates that a Conformity Assessment Program can be established with increasing levels of rigor, requiring increasing levels of compliance, but at increasing cost. Standards have been established to ensure that components of a CAP are governed and managed worldwide in a consistent way, and a sampling of these are also identified in Figure 4.

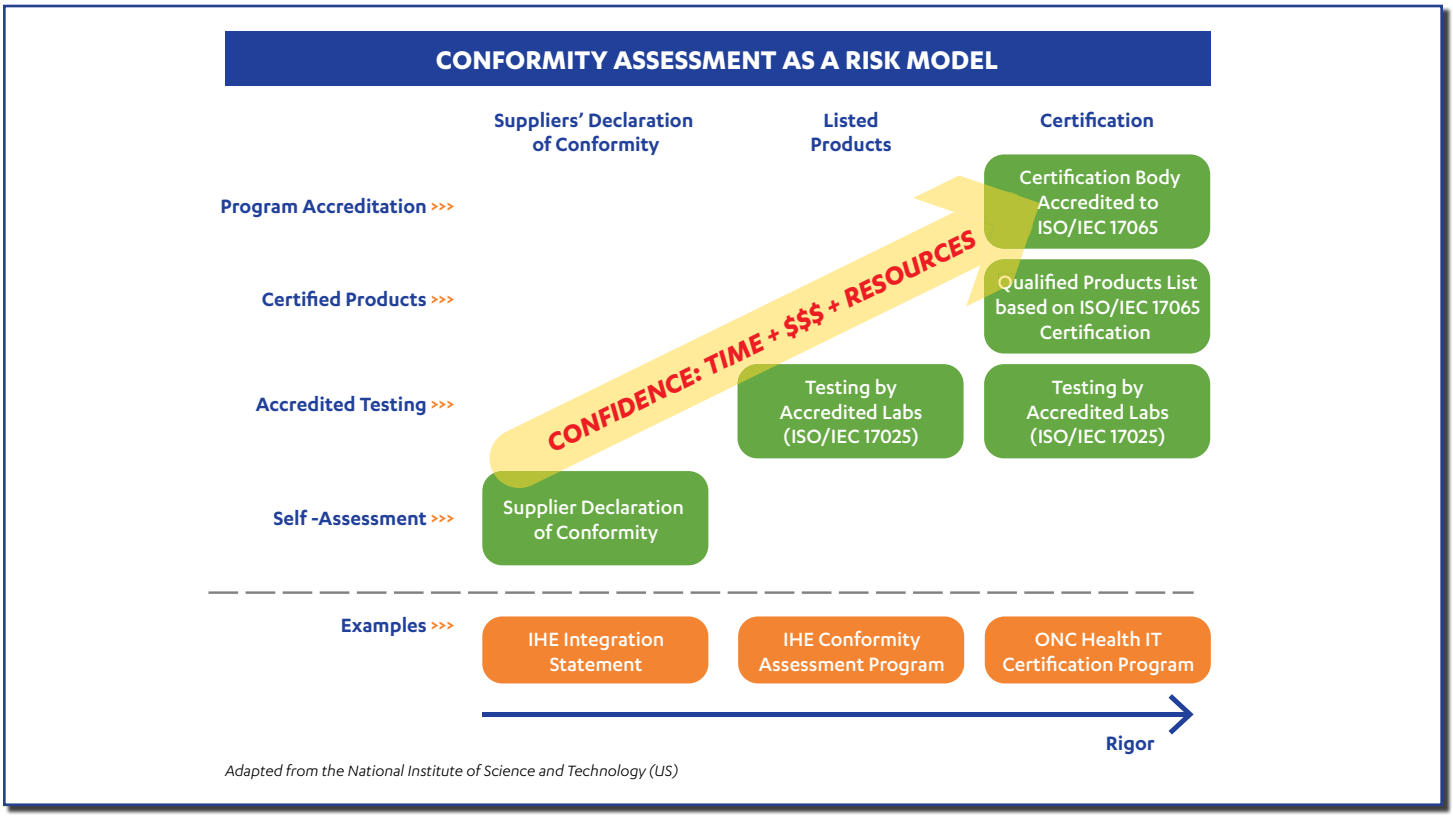

Figure 4: Conformity Assessment as a Risk Model

A Conformity Assessment Program is typically made up of the following components: Testing, Supplier's Declaration of Conformity, Certification, Accreditation, and Surveillance. This document is written in accordance with the "neutrality principle", such that conformity can be assessed by a manufacturer or supplier (first party), a user or purchaser (second party), or an independent body (third party)[4]. A CAP will typically be characterized by components as defined in *Table 14* below:

CAP Component	Use	By	Relationships	Standards
Specification of Conformance Criteria	Critical characteristics are defined by users and vendors	1st and 2nd parties	Conformance criteria are specified to develop testing scenarios, plans and metrics	RSP-CI
Development of a Conformity Assessment "Scheme"	A set of specifications that form the basis for the CAP testing component.	1st and 2nd parties	A "scheme owner" is the organization responsible for operating the CAP.	ISO/IEC Directives

CAP Component	Use	By	Relationships	Standards
Conformance Testing	Critical characteristics can be evaluated via measurement under specified conditions	1st, 2nd or 3rd parties	Test report may be used for (1) evidence of conformance in supplier's declaration; (2) evidence of conformance in a certification system; (3) in surveillance (see below)	ISO/IEC 17025
Suppliers' Declaration of Conformity	Risk associated with nonconformity is relatively low. Adequate penalties (consequences) exist for placing non-conformant products in the market. Includes adequate mechanisms for removing non-conformant product from the market.	1st party	May use test report as evidence of conformity	ISO/IEC 17050 Parts 1 and 2
Certification	Risks associated with non-conformity are relatively moderate to high	3rd party	Certifier is usually accredited by a recognized accreditation body (eg. ANSI) Test reports are used as evidence of conformance Normally requires one or more accredited testing laboratories	ISO/IEC 17065 ISO/IEC 17025
Accreditation	Results in increased rigor for certification and/or testing bodies, leading to relatively high confidence in the tested/certified product.	3rd party	Accreditation may be a requirement of the conformity assessment program for either testing or certification bodies, or by a certification body for all testing laboratories, or by a scheme owner for either testing or certification bodies.	ISO/IEC 17011
Surveillance	Surveillance is designed to ensure ongoing adherence to the intent and process of conformity assessment, used to enhance confidence in ongoing conformity. The frequency and rigor of surveillance should be balanced with the cost and confidence needs required by the CAP.	3rd party	This is a key part of a quality management program.	ISO 9000 series ISO/IEC 17011 ISO/IEC 17065

Table 14 – Components of a Conformity Assessment Program

6.4 Implementation of a Conformity Assessment Framework: an example

Many jurisdictions around the world have adopted a "certification framework" as their implementation of conformity assessment. Figure 5 below illustrates how a conformity assessment *scheme* can combine reference standards with specific user-customization to create the basis for a fully-configured testing and certification process. This example cites an approach that allows portability to any international jurisdiction, due to the extensive adoption of ISO standards describing both process and content.

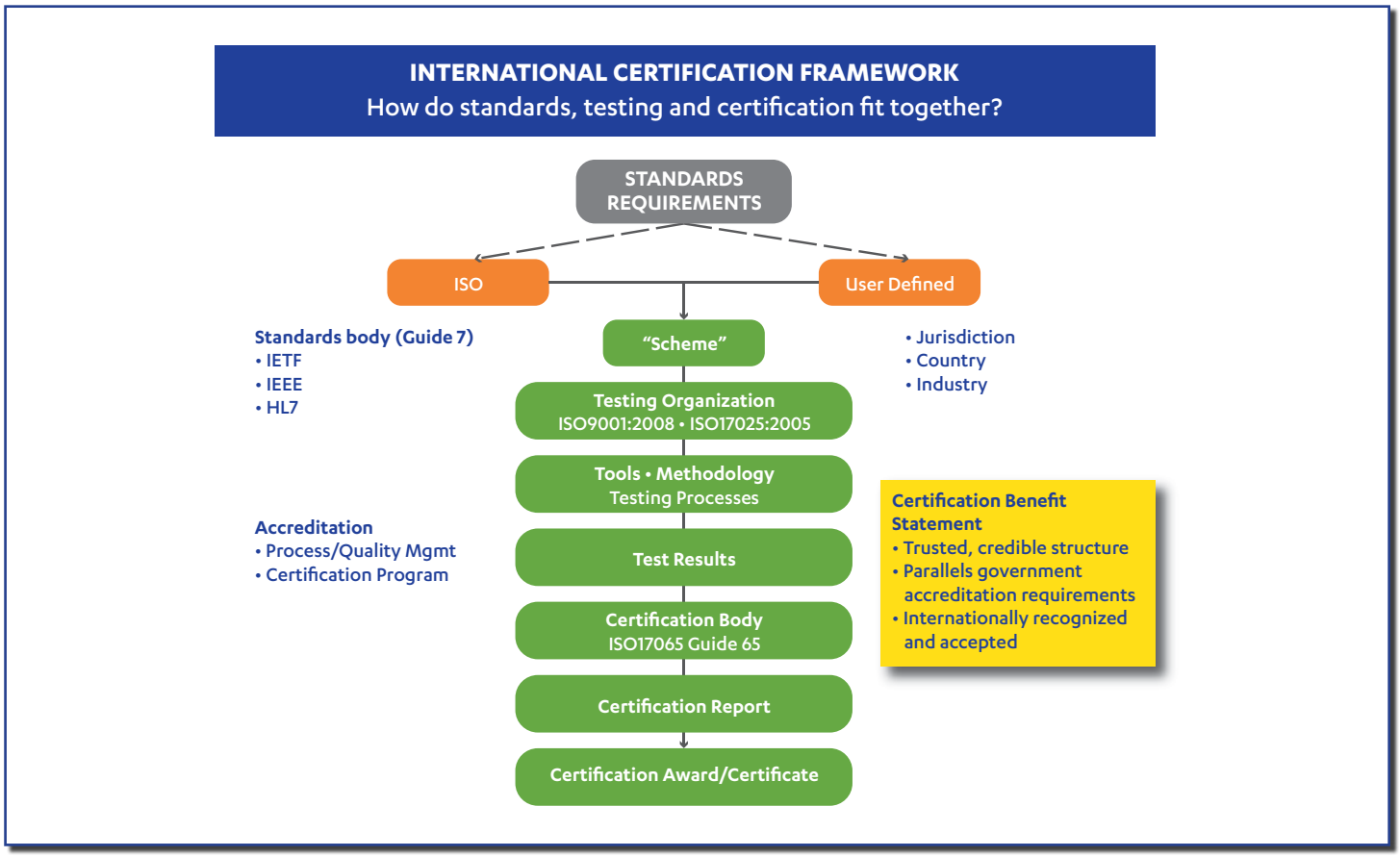

Figure 5: Components of a Certification Framework

6.5 Definitions to clarify CAF content

6.5.1 Conformity Assessment Criteria

The basic building block that defines requirements which relate to a particular group of individual standards selected into a Standards Set that should work together to enable semantic, functional and technical interoperability in a specific domain. These criteria can be used in building the conformity assessment "scheme". When it comes to specifying the requirements to which conformity is to be assessed, "best practice" suggests these come from standards developed by international Standards Development Organizations (SDOs) such as ISO, IEC, HL7, IHE, OASIS, DICOM, etc.

6.5.2 Conformity Assessment Scheme

The basic building block of a CAP is a *scheme* which describes a particular group of objects having sufficiently similar characteristics that the same set of rules and procedures can be carried out under the same management for assessing conformity with the same set of specified requirements. The scheme may include:

1. Qualitative schemes: laboratories are required to identify a component of a test item;
2. Data transformation exercises: laboratories are furnished with sets of data and are required to manipulate the data to provide further information;

1. Inter-Laboratory Testing comparisons: single item testing where one item is sent to a number of laboratories sequentially and returned to the organizer at intervals;
2. One-off exercises: laboratories are provided with a test item on a single occasion; and
3. Continuous schemes: laboratories are provided with test items at regular intervals on a continuing basis.

6.5.3 Nonconformity

Non-fulfillment of the Scheme Owner's requirements for testing or certification; may also be referred to as a Deficiency.

6.5.4 Proficiency testing

Testing Laboratory proficiency testing represents broad activity of the testing laboratory that include items 1-5 listed under the definition of ***Conformity Assessment Scheme*** above.

6.5.5 Conformity Assessment Scheme Owner

A person or organization that is responsible for developing and maintaining a specific Conformity Assessment scheme. Note that the scheme owner can be the certification body itself, a governmental authority, trade association, group of certification bodies or other (ISO/IEC 17067

6.5.6 Conformity Assessment Program (CAP)

A conformity assessment program consists of test methods used by authorized testing laboratories to test specifications as defined by the conformity assessment scheme.

6.5.7 Conformance Statement

A conformance statement is a key part of an overall conformance framework. It is used as a statement of the features of actual software, or of a set of rules for an application to conform to. This statement connects to all the detailed statements of functionality, such as Structured Definitions and Value Sets. This composite statement of application functionality is used as either the source or target of a conformity assessment.

The presence, and strength, of *conformance statements* that make up a standard directly impact the robustness of the specification itself, and ultimately the usefulness of the *conformity assessment scheme* that is directly derived from the specification. Conformance statements vary in language from standard to standard, but generally express both mandatory and optional characteristics and requirements imposed by that standard. According to ISO 9001: 2015 *Quality Management*, section 0.1, the following verbal forms are used:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" indicates a possibility or a capability.

Examples of conformance statements include:

- Data element "A" shall be present
- Data element "B" shall contain values 0, 1 or 2
- Data element "C" may contain a value, or may be left blank

6.5.8 Accredited Certification Body

An organization providing auditing and certification/registration services related to conformity assessment, to demonstrate that specified requirements relating to a product, process, system, person or body are fulfilled.

A Certification Body that has been accredited by an ISO/IEC 17065 accrediting body and has been authorized by the Scheme Owner to award certification based on the Conformity Assessment Scheme.

6.5.9 Accredited Testing Laboratory

A Testing Laboratory that has been accredited by an ISO/IEC 17025 accrediting body and has been authorized by the Scheme Owner to perform testing based on the Conformity Assessment Scheme.

6.5.10 Accreditation

Formal recognition by an Accreditation Body that a Testing Laboratory is competent to carry out a specific test methodology, as outlined in the Conformity Assessment Scheme.

6.5.11 Approved Signatory

An individual designated by an Accredited Testing Laboratory and deemed competent and authorized to sign a Conformity Assessment test report and assume responsibility for the results they contain. An Approved Signatory is responsible for the technical content of the report and is the contact person for questions or problems with the report. An Approved Signatory is also required for an Accredited Certification Body.

6.5.12 Assessment

Systematic, independent, and documented process for determining Testing Laboratory competence and for obtaining records, statements of fact and other relevant information by assessors at the Testing Laboratory facilities and other places where test services are provided, with the objective of determining the extent to which requirements are fulfilled. (ISO/IEC 17000:2004 *Conformity assessment – Vocabulary and general principle*). While "audit" applies to management systems, "assessment" applies to conformity assessment bodies.

6.5.13 Authorized Representative

An individual authorized by a Certification Body and/or Testing Laboratory management to fulfil the conditions for accreditation. The Authorized Representative reports to the Scheme Owner's authorized accreditor any changes that may affect the Certification Body or Testing Laboratory's capability, scope of accreditation, or compliance with accreditation requirements, including any changes in key personnel.

6.5.14 Certificate of Accreditation

Document granted to a Certification Body or Testing Laboratory issued by an accreditation body approved by the Scheme Owner. A Certificate of Accreditation is always issued with a Scope of Accreditation. (See Scope of Accreditation).

6.5.15 Certificate of the Scheme Owner

Document issued by the Scheme Owner to an accredited Testing Laboratory or Certification Body, confirming that it is properly accredited.

6.5.16 Customer

Any person or organization that engages the services of a Testing Laboratory or Certification Body to perform testing or certification of a customer's product or service.

6.5.17 Competence

Ability of a Testing Laboratory or Certification Body to provide services in accordance with the specifications contained in the Scheme to produce accurate, proper, fit for purpose, technically valid data and test results.

6.5.18 Inter-Testing Laboratory comparisons

Evaluation of tests on the same or similar systems by two or more laboratories in accordance with predetermined conditions. (See also Proficiency Testing).

6.5.19 Measuring and test equipment (M & TE)

All of the instruments, standards, reference materials, auxiliary apparatus and instructions that are necessary to perform a measurement and test.

6.5.20 Nonconformity

Non fulfillment of the Scheme Owner's requirements for testing or certification; may also be referred to as a Deficiency.

6.5.21 Proficiency testing

Testing Laboratory proficiency testing represents broad activity of the testing laboratory that include items 1-5 listed under the definition of ***Conformity Assessment Scheme*** above

6.5.22 Quality Management System

A system to establish a quality policy and quality objectives and to achieve those objectives (ISO 9000:2000 *Quality management systems – Fundamentals and vocabulary* section 2.2.3)

6.5.23 Quality Manual

A document specifying the quality management system of an organization (ISO 9000:2000 section 2.7.4)

6.5.24 Requirement

A provision that conveys conditions that must be fulfilled to achieve and maintain accreditation (ISO/IEC Guide 2:2004 *Standardization and related activities – General vocabulary*, section 7.5)

- **Requirement:** need or expectation that is stated, generally implied or obligatory (ISO 9000: 2015, section 3.1.2)
- NOTE 1 "Generally implied" means that it is custom or common practice for the **organization** (3.3.1), its **customers** (3.3.5) and other **interested parties** (3.3.7), that the need or expectation under consideration is implied.
- NOTE 2 A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement.
- NOTE 3 A specified requirement is one that is stated, for example in a **document** (3.7.2).
- NOTE 4 Requirements can be generated by different **interested parties** (3.3.7).
- NOTE 5 This definition differs from that provided in 3.12.1 of ISO/IEC Directives, Part 2:2004.

Requirement: expression in the content of a document conveying criteria to be fulfilled if compliance with the document is to be claimed and from which no deviation is permitted (ISO 9000: 2015, section 3.1.2.1)

6.5.25 Revocation

The removal of the accredited status of a Testing Laboratory or Certification Body if found to have violated the conditions for accreditation.

6.5.26 Scope of Accreditation

The Scope of Accreditation lists the test methods or services for which the Testing Laboratory or Certification Body is accredited. (See also Certificate of Accreditation). Shall be documented with the accreditation granted to a Testing Laboratory or Certification Body.

6.5.27 Specification

Document stating requirements (ISO 9000: 2005, section 2.7.2)

6.5.28 Suspension

Temporary removal of the accredited status of a Testing Laboratory or Certification Body for all or part of its Scope of Accreditation when it is determined (by the Scheme Owner or Accreditor) that the Testing Laboratory or Certification Body does not meet the conditions for accreditation.

6.5.29 Test method

Defined technical procedure, test cases, test tools, test data and processes to determine one or more specified characteristics of a product.

6.5.30 Testing Tool

A conformance testing tool can be viewed as an initiator emulator (to test a target) or a target emulator (to test an initiator). A good conformance testing tool should meet the following requirements: executable test scripts, a testing engine, format validation, ability to modify content/data, error recovery, multiple sessions/connections, results and test log, and batch capability.

6.5.31 Traceability

Property of the result of a measurement or the value of a standard whereby it can be related to a specific requirement, usually in international standards, through an unbroken chain of comparisons (called a traceability chain), each of which has stated uncertainties.

[1] casco@iso.org
[2] U.S. National Institute for Science and Technology (NIST). Conformity Assessment Summary Presentation to the IHE International Board, 07-Mar-2013.
[3] See http://www.publicsectorassurance.org/topic-areas/healthcare/ for examples of CAP programs that rely on ISO/IEC/CASCO guidance. Note that while many regulators (national gov'ts) make use of the same base standards, their thresholds/profiles/acceptance/requirements may be different
[4] ISO/IEC Directives, Part 2, Clause 6.7.1

7.0 Conformity Assessment Artefacts supporting the Patient Summary Standards Set (PSSS)

The objective of defining artefacts of Conformity Assessment for the PSSS is to provide confidence that Patient Summary information is fully compliant with its designed Functional, Semantic and Technical requirements. Further, artefacts must ensure that a vendor implementation of a Patient Summary system within a product fully complies with its specification as designed and intended.

The presence, and strength, of *conformance statements* that make up a standard directly impact the robustness of the specification itself, and ultimately the usefulness of the *conformity assessment scheme* that is directly derived from the specifications. Conformance statements vary in language from standard to standard, but generally express both mandatory and optional characteristics and requirements imposed by that standard. Examples of conformance statements include:

- Data element "A" must be present
- Data element "B" shall contain values 0, 1 or 2
- Data element "C" may contain a value, or may be left blank

Test methods and tooling can be built to test a software application, or system, against these conformance statements. Standards Development Organizations (SDOs) often publish very strong conformance statements along with their standards, and sometimes produce and publish associated testing tools. When these artefacts are present, then a meaningful assessment of conformity can be made within a Conformity Assessment Program.

7.1 Describing Conformity for Patient Summary Standards

With over 30 standards initially referenced as part of PSSS standards selection section above, it would be extremely laborious to define a traditional *conformity assessment scheme* to support the standards set articulated in this document. Further, since this document seeks only to provide guidance, without the specificity related to a particular implementation, the definition of a traditional *scheme* would not be particularly useful.

Instead, the authors have chosen to provide an example of how conformity can be incorporated into the Patient Summary Standards that have been identified, and using the framework presented above, illustrate how leading practices can be leveraged to design, build and utilize a conformity assessment program as a key component of implementation.

7.2 Evaluating Conformity Assessment Readiness for Patient Summary Standards

Leading practice suggests that conformance capability is best evaluated by major functions identified for Patient Summary, as expressed in the Use Case. Each function is supported by one or more interoperability standards, and each standard is classified as technical, semantic, and/or functional.

In general terms, it is prudent to examine and evaluate the following assertions associated with each of the identified standards, to determine the ease by which a conformity assessment scheme can be constructed:

7.2.1 Conformance Statements

The presence of conformance statements contained within the standard's specification is an indicator of the degree to which an implementation of that standard can be tested. In practice, SDOs employ a variety of depth and rigor, not always ensuring that strong conformance statements are present.

7.2.2 Tooling

Are there tools readily available that can be used to test a software product's adherence to the Conformance Statements contained within the standard? Are these tools available and accessible?

7.2.3 Optionality

Some claim that optionality is the enemy of interoperability, although there are times when optionality is indeed justified. However, it is fair to assess whether there is an undue amount of optionality contained within the standard under evaluation. Are options minimized and supported by strong conformance statements?

7.2.4 Conformance Process

Leading practice suggests that the SDO that produces a standard under evaluation maintains strict processes to ensure conformance to that standard can be easily met and validated. Are implementers aware and using these processes for their intended purpose?

7.3 Illustration of Leading Practice for Conformity Assessment, using an example

The Use Case section identifies a Base Flow that describes use case activities as a series of steps. Table 4 – Base Flow can be used to illustrate, in simple terms, the major activities where a patient summary can support the use case. These steps include, for example, a request by the Attending Emergency Physician's EHR System for a Clinical Care Summary from the Primary Care Physician, who responds by sending that patient summary document.

To continue this illustration, the standards identified to support these use case base flow steps are driven largely by the data set identified as germane to this clinical activity, and these are well-articulated in Dataset Details.

Further, standards that have been assembled as part of the standards "set" are further grouped as Semantic (content, structure and format), Technical (transport, security and safety) and Functional (functional services, implementation specifications), see Categories or levels of standards.

As stated above, a conformity assessment program begins with the design of a scheme, containing standards specifications that can actually be tested. The complexity of establishing a testable Conformity Assessment scheme for a patient summary standards requires assembly which combines (1) multiple steps in a use case; (2) derived data set requirements; and (3) the resulting 'sets' of standards grouped as semantic, technical and functional.

In an attempt to further illustrate how an implementer might choose to formulate a testable scheme, let's consider a single step, as identified as Step 1 of the base flow:

Step	Actor	Role	Event/Description	Inputs	Outputs
1	Attending Emergency Physician	Request	Attending Emergency Physician EHR System Requests Clinical Care Summary	Attending Emergency Physician selects patient of interest from their EHR system.	Initiated Clinical Care Summary Request in standard format and content specification where possible

This step is probably the most straightforward of the six base flow steps defined. It is a simple request by an Emergency Physician, using his/her system, for a clinical care summary record, for a particular patient, directly from the patient's Primary Care Physician's system. In its simplest form, this initial "request" step requires, at a minimum, the following:

- A positive identity of the patient
- A positive identity of the patient's primary care physician, and the destination address of their system
- Authorization from the patient for this access request
- Standardized identification of the document type requested (eg. a "patient summary" record)

The conformity assessment scheme required to test a system's compliance to this "request" step must describe, in precise detail, the specifications of the standards selected from the "set" to perform each of the above tasks.

According to the set of standards identified for base flow step 1, the following standards would become part of the scheme. This table is repeated below for clarity.

It should be noted that, of the 31 standards listed below, the first 10 are for data that are, or may be, inherent in the correct positive identification of the patient, for which the request is being sent. The next 3 are the 3 primary standards for actually sending that message / request – Hl7 v2, FHIR or XDS, again depending on requirements of the country / user in question. The next 6 are privacy, security and safety standards, that can certainly apply overall to any exchange between any two organizations (ie. acute care ER and primary care physician's office). The next 5 provide the functional exchange capabilities, largely around role based access, and the last 7 provide the implementation specifications and profiles needed to put the request for a Patient Summary into place:

Applicable Standards (attributable to Step 1)
ISO 22220:2011 Identification of Subjects of Care (content and structure)
ISO 27527:2010 Provider Identification (Content and Structure)
ISO 8601:2004 Date and time format (format)
ISO 21090: 2011 Harmonized data types for information exchange (structure)
ISO/TS 18530:2014 Automatic Identification and Data Capture, Marking and Labelling
Administrative Gender Administrative Gender FHIR (Code Set)
ISO 3166-1 Country Codes (code set)
ISO 639 Language Codes (code set)
HL7 v3 Code System Address Part Type (code set) HL7 FHIR Address Type
HL7 v3 Code System Address Use (code set)
HL7 Version 2 Table 0201 Telecommunication Use Code (code set)
HL7 V2 Application Protocol for Electronic Data Exchange in Healthcare Environments (information exchange)
HL7 FHIR (with RESTful Services) Fast Healthcare Interoperability Resources (information exchange)
IHE XDS (Transport) Vol 2 of IT Infrastructure Technical Framework) (exchange service)
ISO 27799:2016 Information security management in health using ISO/IEC 27002 (security)
ISO/TS 14441 Health informatics – Security and privacy requirements for EHR systems for use in conformity assessment
ISO/TR 27809:2007 Health informatics – Measures for ensuring patient safety of health software
IEC/FDIS 82304 Health software – Part 1: General requirements for product safety
ISO/TR 17791:2013 Health informatics – Guidance on standards for enabling safety in health software
HL7 Version 3 Standard: Healthcare Access Control Catalog, Release 3
ISO/TR 21089:2004 Trusted end-to-end information flows (system functions)
ISO 22600-1:2014 Health informatics – Privilege management and access control – Part 1: Overview and policy management
ISO 22600-2:2014 Health informatics – Privilege management and access control – Part 2: Formal models
ISO/FDIS 21298 Health informatics – Functional and structural roles
Healthcare Requirements for Emergency Access (HL7)

Applicable Standards (attributable to Step 1)
RID Retrieve Information for Display
HPD Healthcare Provider Directory.
DEN Document Encryption
DSG Document Digital Signature
ATNA Audit Trail and Node Authentication
XUA Cross-Enterprise User Assertion
ISO 22600-3:2014 Health informatics – Privilege management and access control – Part 3: Implementations

For each of the standards identified as pertinent to Step 1 above, a number of assumptions need to be brought forward related to Conformity Assessment:

- While an entire standard is referenced (eg. FHIR Resources), only a part of that standard is directly applicable to this step
- There are a number of standards in the "set" that perform the same function relative to Step 1, so choices must be made by an implementer
- At an implementation level, the number and breadth of standards would likely be dramatically reduced from what is listed in the "set", with the resulting collection of specifications much more practical and suitable to be part of a conformity assessment scheme
- The user must **not** assume that each of the standards in the set is equal in containing robust conformance statements, nor accompanied by suitable testing tools

7.4 Applying Conformity Assessment

As guidance, the following is recommended:

- Use this framework, or one based on this framework
- Ensure the resulting framework is based on the ISO standards for conformity assessment
- Selection of standards from the "set" should consider their strength for conformity assessment, including strong conformance statements, as well as the availability of the necessary tooling to support testing
- Do not be overwhelmed by the complexity of standards selection, or by the effort necessary to build a conformity assessment scheme – the benefit of assurance more than outweighs the effort required to implement a conformity assessment program.

8.0 Guidance for Implementation

Standards Sets are to be 'living documents' and capture the position at the time. The Standards Set covers multiple specifications, some with implementation guides that users review/reference. These Information Sheets complement the work by providing an 'implementation context' as guidance to support choice. Leading practice and related information, based on current knowledge, are also presented and will be updated over time.

8.1 What is an Information Sheet?

The concept of an Information Sheet supports the 'living document' intent by providing focused but open-ended material from existing and emerging implementation. The Information Sheets will be maintained and updated based on usage/implementation and changing/emerging guidance, remaining in line with other aspects of the Standards Set. In addition, Users will be encouraged to share their experience of usage via Information Sheets.

Each Information Sheet will focus on a single topic and contain the following:

- Purpose and the scope (to enable the user to make a decision on relevance)
- Detailed content
- Any references for further reading
- Conform to the same pattern and style
- Will be dated
- Contributors will be acknowledged.

The Information Sheets do not duplicate the main body of the Standards Set but provide related complementary material and aim to be minimally concise. Together, the Information Sheets form a reference folder at the end of the Standards Set. Although the material is 'informative' from a formal standards perspective, the Information Sheet is intended to be implementable providing only a brief rationale before giving practical advice or up to date information. The information might be used to make informed decisions on implementation as well as supporting implementation itself.

8.2 Organisation

Potentially, many Information Sheets could be relevant for each Standards Set. For ease of access, there is scheme provided. The broad index/classification headings are as follows:

1. Landscape and Horizon Scanning (e.g. International initiatives, life-cycle)
2. Preparation (e.g. Business use case and Governance, readiness)
3. Usability (e.g. clinical guidelines)
4. Value and Evaluation (e.g. Stakeholder value, scorecard)

Note: for the first published version of the Patient Summary Standards Set the number of Information Sheets is not extensive. As Information Sheets are produced and updated over time, they will be added to the appropriate index/classification and the table of content at the front of the document will contain the full set with links.

8.2.1 Landscape and Horizon Scanning Information Sheets

Information sheet: International Patient Summary projects from 2009 to 2020

June 2017
Contributors: Giorgio Cangioli (HL7), eStandards project WP5

Category and Scope: Patient Summary/ Landscape & Horizon Scanning

Purpose:

This Information sheet presents a number of regional and international initiatives regarding the Patient Summary. It provides a brief introduction and the means to read further if required[1]. All the initiatives featured are primarily concerned with the act of exchanging health information (EHI). As Borgeman noted, "moving data over networks involves a delicate balance of security, rights, protections, interoperability, and policy" [1].

Content:

ISO TC 215 produced two technical reports on 'Health Summary Records' in 2009. The first, ISO/TR12773-1:2009, noted the variety of terms and provided a set of use cases exploring the Business case for standardisation. The second technical report, ISO/TR 12773-2:2009, was an Environmental Scan which was a comprehensive attempt of capturing the state of the art at that time. Both ISO reports still have value and are worth reading despite their age.

From the introduction in part 1 the authors noted that: ... various "summary" or "snapshot" health records have been developed to meet these communication needs. Many similarities are evident in these initiatives, but their conceptual foundations have not always been articulated with a set of business requirements as their starting point. The purpose of ISO/TR 12773 is to identify the common business requirements these initiatives are seeking to address as well as the requirements for standards for [Patient Summaries] that can guide future [PS][2] development efforts."

Since those reports, there has been a flurry of national and international activities based around the common business requirements (see the Introduction of this Standards Sets for examples and Figure 1), and arguably the JIC initiative on Patient Summary Standards Set guidance has been produced in response to those activities beginning in the Spring of 2015.

Earlier though, the collaboration between Europe and US on eHealth, formalized with the first the 2010 EU US EU/US Memorandum of Understanding (MoU)[3] on 2010 and consolidated by the Cooperation Roadmap signed on 2013[4], became part of the actions foreseen by the EU eHealth Action Plan 2012-2020[5].

	LEGAL	ORGANIZATIONAL	SEMANTIC	TECHNICAL
eHN/JAseHN				
epSOS				
EHDSI				
CEN IPS prEN				
CEN IPS prTS				
HL7 IPS				
JIC SS on PS				
IHE XD* /XC* profiles and XDS metadata				
ISO/HL7 EHR-S Functional Model				
Trillium Bridge				
Trillium II				
US MU / BlueButton+				

Figure 1: Projects related to Patient Summaries using an Interoperability Framework

The eHealth Network (eHN) comprises 27 countries' policy leads and competency centres. It has established guidelines (version 1 in 2013 and version 2 ratified in November 2016) for the Patient Summary comprising a minimal but non-exhaustive dataset and built upon the epSOS project for Patient Summary and ePrescriptions across borders. Starting from that experience a new draft "Transatlantic eHealth/health IT Cooperation Roadmap"[6] was then published on November 2015.

On 26 July 2016, the European Commission published the results[7] of this consultation on the next phase of EU-US cooperation in eHealth/Health IT[8] and, contemporary, the final version of the revised roadmap[9] and its annex[10], in which, actions to be taken in the next 18 months, deliverables and milestones have been defined. The consultation confirmed the stakeholders support to the activities foreseen by the European Commission and the United States Department of Health and Human Services. In particular for the *Interoperability work-stream*, the EU and the US collaborate for the **development of an International Patient summary taking into account the various governance challenges**, having as declared goal:

- To enable a standardized international patient summary (IPS) to be in use by 2020

Projects have been and will be founded in order to support the realization of these objectives (see e.g. The PHC-34 projects under H2020 including eStandards; the EC CEN grant agreement on the International Patient Summary; the call for proposal under the Coordination and Support Action (SC1-HCO-14-2016) [Trillium II].

1. Borgman, C. L., *Big Data, Little Data, No Data*

[1] This fact sheet centres almost exclusively on European and latterly American activities that have been part of inter-governmental cooperation and policy. They have had explicit SDO involvement. This fact sheet also includes mention of early and current ISO activity in relation to the 'Patient Summary'. Note; this fact sheet excludes the many national and local initiatives concerning the Patient Summary within the same period. No disrespect is intended and we would welcome further additional fact sheets on other important initiatives, be they local, national or of a different scale to provide a grander landscape and a wider context

[2] The ISO TRs use the term 'Health Summary Record' and the acronym 'HSR'; to be consistent throughout the Standards Set we use the term 'Patient Summary' with the associated 'PS'.

[3] ec.europa.eu/newsroom/dae/document.cfm?doc_id=1784

[4] https://ec.europa.eu/digital-single-market/news/eu-and-us-step-cooperation-ehealth-it

[5] https://ec.europa.eu/digital-single-market/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century

[6] http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=12123

[7] Details about the 71 responses received are available on https://ec.europa.eu/eusurvey/publication/EU_US_Survey_eHealth_HealthIT

[8] https://ec.europa.eu/digital-single-market/en/news/contributions-public-stakeholder-consultation-next-phase-eu-us-cooperation-ehealthhealth-it

[9] http://ec.europa.eu/information_society/newsroom/image/document/2016-30/eu_us_roadmap_16674.pdf

[10] http://ec.europa.eu/information_society/newsroom/image/document/2016-30/eu_us_roadmap_annex_16675.pdf

Information sheet: Ecosystem, Complexity and Urgency

June 2017

Contributors: Stephen Kay, Robert Stegwee (CEN TC/251), Catherine Chronaki (HL7 International)

Category and Scope: Patient Summary/ Landscape & Horizon Scanning

Purpose:

JIC Standards Sets inevitably concentrate upon standardisation in the Health domain. It is, after all, a contribution from the SDOs whose area of expertise is almost exclusively in that domain. The Patient Summary is part of an ecosystem and even can be considered to be an ecosystem in its own right; it is a complex, urgent and increasingly interconnected infrastructure and any guidance needs to be seen in that wider context.

Content:

It is a belief that if informatics works in the challenging healthcare domain then its solutions will be automatically useful, applicable and beneficial to other domains.

The Health domain is ever changing. Whereas the WHO definition of 'Health' in 1948 was both aspirational and comprehensive, the current usage of 'Health' is seen as too exclusive and often, to make the point, the 'and Care' is added to widen the scope to include 'social care' too. Furthermore the SDO's are increasingly seeing the need to address bio-informatics and genetics as part of their work plans. The biology aspects have brought the idea of the ecosystem to the business community and it has been taken up by health informatics and health business researchers.

At the more technical, engineering and generic IT levels, there are solutions to hard problems that impact and have generic value for health and care, e.g. security standards. Indeed many of the standards referred to in this Standards Set are not exclusively designed for the 'Patient Summary'; "specifications are unlikely to require new standards, given that much of their content is deemed "common", "core", "essential" or "emergency" in nature and is therefore part of most EHR initiatives world-wide as evidenced in ISO/TR 12773-2".

More generally it seems that artefacts recently developed in other domains may be beneficial to the health domain too. For example, there is growing emphasis on the data and underpinning data architectures as the foundations for clinical information, e.g. for record systems, warehouses, registries, analytics.

Even more recently it would seem that the finance sector with its blockchain innovation is the herald for the cure of the health domain's interoperability problems, providing improved security (Ransom-ware more difficult) and providing the data integrity, provenance attribute that electronic Health Records have tackled in various, more-or-less satisfactory ways (for example, see http://mcdonnell.mit.edu/blockchain_ehr.pdf). Furthermore, it could be argued that the Patient Summary is no longer important because new Cloud technologies and the ability to exchange huge quantities of data make the need to summarise redundant.

Yet, the Patient Summary itself can be considered to be an ecosystem comprising stakeholders, technologies, organisations, objects, and the relationships between them. The Patient Summary then, even if it is regarded as being a simple extract of a bigger record, is still a very complex artefact. The successful interchange of the relatively small quantity of quality data represented by the Patient Summary is difficult even at a local level, let alone an international one. In an analogous way to that of developing intelligent systems, starting small and working bottom up has proven to be a much more successful strategy than a simple top-down one [1], so the same strategy with respect to interchanging a core set of standards-based clinical data is at least worth considering.

Standards are rarely examples of innovation, but more often provide an invaluable platform for innovation. "Any future ISO initiative to create standards for a generic [Patient Summary (PS)] specification or specifications for one or more types of [PS] will leverage existing initiatives and adopt/adapt relevant standards utilized therein. ISO/TR 12773-1".

Patient Summary standards are also part of a broader life-cycle of development and adaptation.

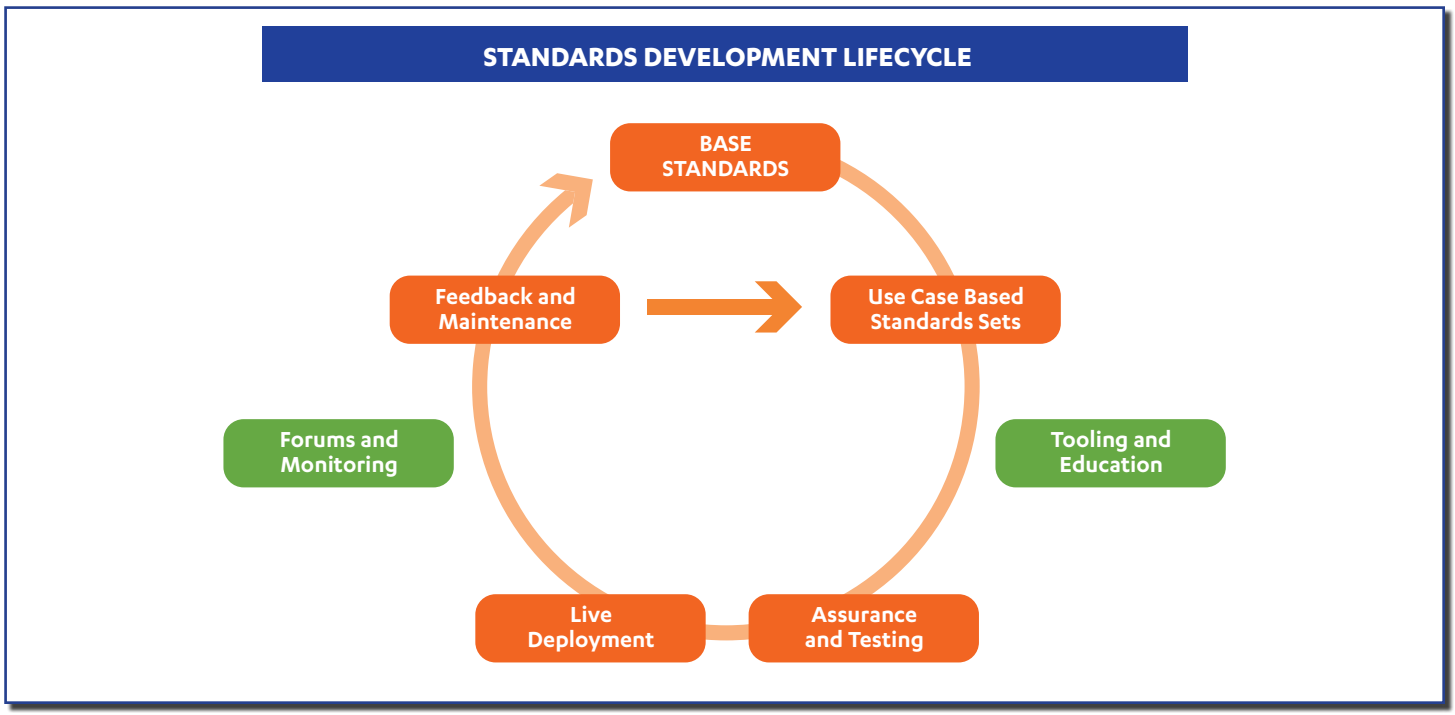

Figure 1: Standards Development lifecycle, adapted from "Tools for interoperability – Time for eStandards" Workshop at MedInfo 2015

The above figure positions the Standards Set activity within the same standards development cycle. This figure is part of the paper endorsed by the JIC [2]. When this figure refers to Standards Set, however, it is primarily referring to the selection of specifications, classified and given in the body of this Standards Set document. The figure includes consideration of tooling and education as an integral but softer part of the whole and this also represents the guidance aspects within the Standards Set that must also evolve with time. Note, in this Patient Summary Standards Set there is no tooling as yet.

1. Brooks, R. A. (1990). Elephants Don't Play Chess, in P. Maes (ed.) *Designing Autonomous Agents: Theory and Practice from Biology to Engineering and Back*. MIT Press, Cambridge, MA, pp.3-16.
2. Stegwee, R., Chronaki, C., "The Case for Formal Standardization in Large-Scale eHealth Deployment", endorsed by JIC, April 2017.

Information sheet: Life-Cycle of Patient Summaries

June 2017

Contributors: Giorgio Cangioli (Hl7) and eStandards project WP5

Category and Scope: Patient Summary/ Landscape & Horizon Scanning

Purpose:

Most of the current initiatives related to Patient Summary focus upon the exchange of Health Information. The Life-Cycle approach provides a broader perspective when considering implementation.

Content:

Figure 1 shows a simple life-cycle of the Patient Summary. It distinguishes between Strategic perspectives, which are typically the business of stakeholders whose role is to define and evaluate the Patient Summary and the operational perspective, where the stakeholders create, optionally share and use the Patient Summary. The life-cycle approach complements the use case approach.

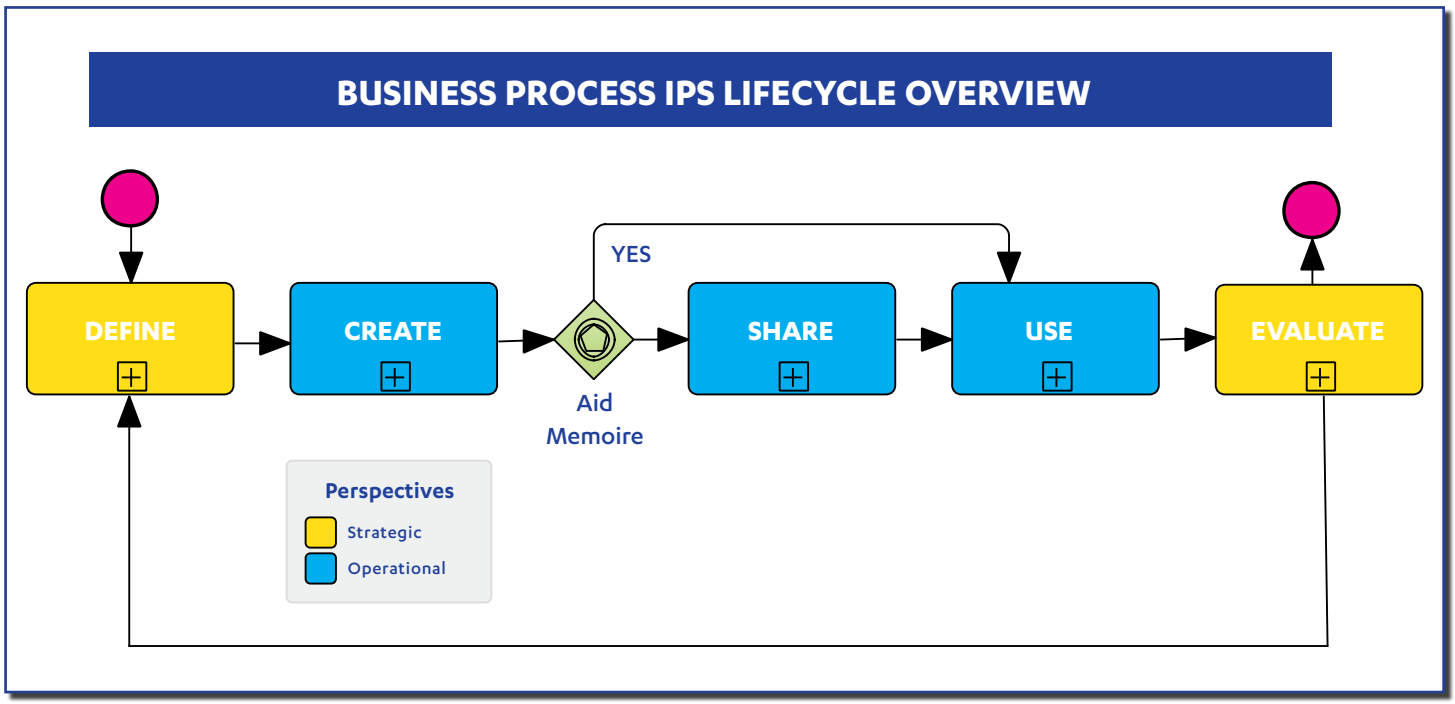

Figure 1: The Patient Summary Record life-cycle.

In the eStandards project (Ref), it has been used to position other Patient Summary initiatives depending on their main interests (see figure 2 below).

	DEFINE	CREATE	SHARE	USE	EVALUATE
eHN/JAseHN					
epSOS					
EHDSI					
CEN IPS prEN					
CEN IPS prTS					
HL7 IPS					
JIC SS on PS					
IHE XD* /XC* profiles and XDS metadata					
ISO/HL7 EHR-S Functional Model					
Trillium Bridge					
Trillium II					
US MU / BlueButton+					

Figure 2: Patient Summary initiatives with respect to the life-cycle.

8.2.2 Preparation Information Sheets

Information sheet: Business Use Case

June 2017
Contributors: Stephen Kay (CEN TC/251

Category and Scope: Patient Summary/ Preparation

Purpose:

Use Cases have proven to be an effective means of communicating service requirements between lay and technical stakeholders. A Use Case template is given here that has been specialised for the particular business of eHealth. Business use cases are precursors to the more detailed use case description that supports implementation and such a description can be found in the main body of the Standards Set, based on the ISO Technical report (ISO TR 19669:2017 Health informatics – Re-usable component strategy for use case development).

Content:

This Business Use case template or form (see below) captures the high-level requirements for the Patient Summary Standards Set. It is a combination of generic use case notation, Agile user stories, and a basic business model (SWOT) that describes a topic in a consistent and concise way.

Sections	High level Patient Summary Use Case Description
A. Name/Topic	Access Patient Summary in acute care setting
B. Stakeholder story	As a clinician, I want relevant data about a patient I haven't met before. I want legitimate access and use of summary patient data at the point and time of care, irrespective of where and how it is held.
C. Starting event	*Demand for Care*, planned or unplanned, requires patient summary information to act. Examples: A patient either presents in an acute setting or the patient requests a transfer of care between providers. Three common starting events: 1. Patient presents at emergency or other healthcare setting, and clinician requires patient summary information to inform treatment. 2. Patient transfers between primary care clinicians, and "new" responsible clinician requires patient summary information. 3. Patient travelling abroad requiring healthcare support and responding health care providers require existing patient summary information to inform treatment
D. Actor and users	*Healthcare Providers, Clinicians* and Patients
E. Goal	To access and use relevant data to enable timely appropriate, coordinated care.
F. Stakeholders	Primarily healthcare providers and *patients*, although *Next of Kin*, family members and a *healthcare third party* may be involved.
G.Primary scenarios	Scenario #1 Patient presents as unconscious at emergency (acute center). Attending clinician looks up prior record or patient summary information on file within the hospital information system within acute care setting. Attending clinician identifies primary care clinician and patient ID from the acute care record and accesses the primary care patient summary from the EHR. *Scenario #2 A Specialist receives a referral and requires more information to treat the patient properly at the point of care. Using an EHR System, the Specialist sends a request to the* primary care clinician *for the patient's Clinical Care Summary. That clinician successfully receives the requests, understands the requests, and sends the patient's Clinical Care Summary back to the Specialist via the EHR System. The Specialist successfully receives the patient information, understands it, and makes an informed decision that can provide better quality of care to the patient.*

Sections	High level Patient Summary Use Case Description
H. Strengths	Relevant, concise data, specific to patient, available at point of care to inform a healthcare professional's decision making.
I. Weaknesses	Summary data may not be the most relevant given the particular *health condition; Summary may not exist at point of care; Many summaries may exist at one or more sites*.
J. Opportunities & safety:	Improved co-ordination of services with all parties able to access a consolidated history and status for each patient. This patient summary should support transitions of care across providers, communities and borders. Informed decision-making for maximum benefit to patient.
K. Threats & security:	Multiple standards on patient summary data exist. Unavailability of readable, credible and relevant data from external systems, timely at the point of care
L. Assumptions, Additional details	The Topic is general enough to support more specialised cases relating to professional, organisational, cultural and regional practices. No specific reference as to the data content of a patient summary is made. 'clinician' is defined as: "health professional who delivers health services directly to a patient/ client [ISO/TR 20514:2005, definition 2.6]"

Information sheet : Agreements and Governance

June 2017
Contributors: Stephen Kay (CEN TC/251)

Category and Scope: Patient Summary/ Preparation

Purpose:

Arguably, technical, interoperability standardization is all about achieving a relatively few strategic agreements in order to prevent a surplus of operational agreements. Patient Summaries are pervasive and ubiquitous but the differences in use, format, structure and content of these documents reduce their value and potential to communicate for the purposes of safe continuity and coordination of care. The consensus processes are key.

Content:

This Information sheet will not attempt to convince the user that standards are worthwhile. It is assumed that the reader of this information sheet already accept that standards are an essential infrastructure for information systems to work in health and care. Furthermore that there is a shared belief that 'standards-based' is the way to go in the future. The Standards Sets are intended to be informative guides, supporting that direction of travel by assisting the user with the selection of relevant specifications for the journey.

The success of the standard or standards, however, is not the choice and adoption of it in practice, although this is of course an essential contributory factor. For it to work and be fit for purpose requires a number of important agreements to be put in place. This information sheet highlights some of the important agreements that are necessary to consider and comply with for a Patient Summary implementation to work.

One of the main drivers for Patient Summaries is the increasing propensity of people to travel away from their homes either because of work, leisure or forced mobility such as that suffered by the refugee. Crossing boundaries, however, of any sort brings with it challenges for the Patient Summary. For consideration:

- Different jurisdictions have different regulations, e.g. data protection laws, but so too do different enterprises, e.g. perspectives on Information Governance.
- Organisational culture and clinical processes within an enterprise may offer resistance to proposed changes.
- External Agreements and critical mass might impact transport formats and information elements for exchange. Readiness agreements with partners also need to be agreed.
- Conflicting standards may exist between neighbours, and licences from vendors may also hinder patient summary exchange. Harmonization is an SDO process.
- Even the seemingly inoffensive identification of an individual to support access and retrieval of a patient summary are potentially fraught with problems.

These examples serve a cautionary note, not overselling the standards as a panacea for all ills, but stressing that standards and the patient summary in particular, are the key to unlock the benefits of health data for patient care, subject to agreements being reached at local, national, and international levels.

Information sheet: Readiness and Peer Audit

June 2017

Contributors: Jeremy Thorp(eHN), Dipak Kalra (eStandards project WP2)

Category and Scope: Patient Summary/ Preparation

Purpose:

This Information sheet presents frameworks that might be useful for decision maker's strategy in preparing for a Patient Summary implementation.

Content:

Technical interoperability requires a number of agreements to be put in place between would-be communicating parties. This step is required irrespective of the scale of the operation, be it local, national, regional or even global.

First of all there has to be some form of governance model put in place. There will be responsibilities and also dependencies between the policy and technical considerations. If there is an interoperability framework already in place, then its components need to be satisfied. For example in the European Interoperability Framework, legal considerations and organisational considerations are the first requirements that need to be satisfied. Legal base-lines need to be established, principles and requirements need to be satisfied and similarly the principles and requirements for the organisation need to be stated and capable of satisfaction. Compliance and coordination mechanisms need to be put in place.

The preparation for each party will involve creating a deployment plan for services and interactions. Testing will follow and a recommendation made when to go to live operation will be made. If there are more than two parties then part of the governance model will have procedures in place and be prepared to oversee the test results, to agree with a recommendation to go-live and to assess the progress made during the period of operation.

The communication partners are effectively the peers of the would-be communicator and it is in their interest to ensure that the interoperability succeeds and is robust across all their systems. An audit checklist can help assess the readiness state. The eHealth Network in Europe, comprising 27 countries, have adapted the ISO 27002:2013 *Information technology – Security techniques – Code of practice for information security controls* standard to help with assessing and auditing cross-border exchange of Patient Summaries and ePrescriptions. This process has been agreed to be put in place for the eHN as of May 2017.

A similar but perhaps finer grained process is illustrated in Figure 1, which was developed in eStandards to assess the clinical relevance of the proposed standards and profiles, leading to conformance testing.

Figure 1 represents a guideline for the development of clinical content for standards and profiles. This is meant to be a generic model that looks at interoperability assets across the range of eHealth not just the Patient Summary and it was an early deliverable 2.2 of the eStandards project, which concluded by proposing a workflow for content development. For further details see deliverable 2.2.

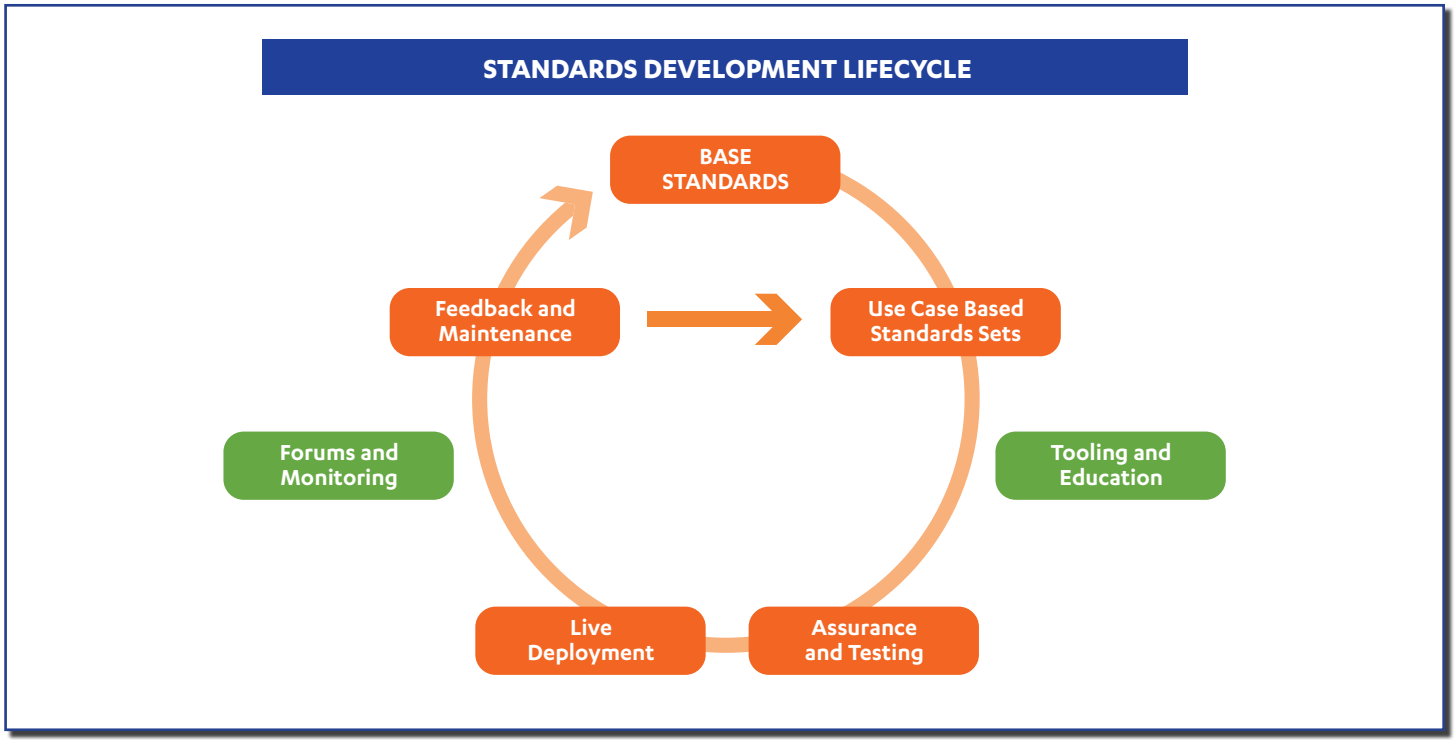

Figure 1: structure of the recommendations, reproduced from eStandards, Deliverable 2.2

The follow-up deliverable in eStandards made recommendations of clinical and SDO workflows based on Figure 1; an example being:

"Verify the interoperability need (function, European Interoperability Framework use case or realisation scenario)

Define and verify the need for addressing the use case or interoperability scenario that the clinical content is intended to support. This should be sufficiently clear to scope the area of coverage needed, the level of granularity and the kinds of actor and decisions that need to be enabled through the communicated information."

For more details of a similar nature, see eStandards, WP3.3. final report.

8.2.3 Usability Information Sheets

Information sheet: Interfaces and Use Cases

June 2017
Contributors: Stephen Kay(CEN TC/251) and other JIC members

Category and Scope: Patient Summary/Usability

Purpose:

The value of the Patient Summary is not just the exchange of the right data. User interfaces are critical, and the use cases often determine the requirements. The value of the Patient Summary lies in its use.

Content:

Patient Summaries are clinically focused and pervasive. For optimal use, it is necessary to determine how the patient summary is to be used and in what circumstances. For example a Patient Summary for urgent or emergency unplanned care has a number of distinct requirements. In this case, given the urgency and potential severity of the condition, the time constraints on the attending clinician mean that presenting what in fact is a full electronic health record to browse is unhelpful and possibly dangerous.

Patient Summaries are concise subsets of health data that are relevant for the attending clinician to act in an informed way. However, relevance is a difficult concept. Many clinicians would argue for as much information as possible (back to the full EHR approach) and they would then wish to filter the data and decide for themselves what is and what is not relevant. However, if a section of the Patient Summary is Medication, a full list of a patient's medication over a lifetime may be daunting and wasteful to scroll down, and this problem of scale is also applicable to many of the sections in a patient summary. Unqualified terms in guidelines and specifications e.g. 'relevant' and 'current', are unhelpful as they are subjective and open to interpretation as filters.

The use case approach is useful to determine requirements, particularly in relation to the clinical context, but it may still be down to organisational approach that will determine the configuration policies of their EHR Systems and the content and structure of a Patient Summary.

Patient Summaries for urgent, unplanned care have to be concise and the core data agreed to facilitate quick and safe access by the attending clinician. Such Patient Summaries might be designed like a concise, one page 'executive summary' or a 'front page' with the core/common data accompanied by following links to further material if and as required for treatment (e.g. specialist data for a specific health condition that the patient has in their history). Again this human factor consideration or user interface design regarding layout and content might already be styled by the receiving organisation's record system.

Note, in addition to this Patient Summary Standards Set, the ISO technical report (ISO/TR 12773-1:2009 *Business requirements for health summary records – Part 1: Requirements*) provides a number of use case descriptions from a business perspective that are still relevant and can be considered for different applications of patient summaries.

8.2.4 Value and Evaluation Information Sheets

Information sheet: Stakeholder Considerations

June 2017
Contributors: Catherine Chronaki (HL7 International, Robert Stegwee (CEN TC/251)

Category and Scope: Patient Summary/Value & Evaluation

Purpose:

The members of the Joint Initiative Council for Global Health Informatics Standardization (JIC) endorsed 'The Case for Formal Standardization in Large-Scale eHealth Deployment' and thereby recognized the four perspectives on relevant stakeholder groups (citizens, workforce, eHealth market, and health system) in the development and use of standards.

Content:

Stakeholder analysis is important and perhaps one of the first steps to take when considering implementation. There are various ways of classifying the stakeholder community and their perspectives, of which two are introduced here and one of these is discussed in more detail. The main body of the Patient Summary Standards Sets mentions a range of stakeholders and classifies them so as to support delivery of the guidance and information material.

Vest and Gamm consider 4 stakeholder types, Patients, Payers (e.g. public/private services and insurance), Providers (e.g. healthcare organisations)and Government entities (e.g. Regulators) [1]. The JIC endorsed case for formal standardization [2] has a different way of classifying stakeholders and is more comprehensive. In this instance, the case is asserted from four distinct perspectives that entail a balance of roles with different interests, costs, and benefits.

The four perspectives given in the paper and are relevant to the Patient Summary are:

1. Citizens (as consumers of health services) –
   a. Navigating the health system (or systems) for prevention, care, and wellness
   b. Seeking active involvement and engagement in health maintenance and decisions on their care
2. Workforce (in the delivery and administration of health services) –
   a. Communication and coordination of care by sharing relevant and trusted information within and across health systems
   b. Dissemination and availability of knowledge for better decisions at the point of care
   c. Workforce training in making the most of new technologies
3. eHealth Market (where eHealth solutions and services are traded) -
   a. Creation of markets for new health and IT services
   b. Expanding the choices for providers and consumers in existing markets
4. Health System (where care is delivered and cost, quality, and access decisions are made)
   a. Evidence-based rules and guidance for sustaining and innovating the health system
   b. Public health reporting, surveillance, and analysis-
   c. Communication and coordination across health systems.

Integral to the wider ecosystem are the community of innovators (including researchers, entrepreneurs, developers and start up companies) who utilise standards for innovation in the eHealth market and are in all 4 perspectives and contribute by producing outputs that lead to standardisation. The vendors and the SDO community are stakeholders found in the eHealth market, and regulators are increasingly positioned in the Health system.

The Stakeholder community across the world have a range of starting points with respect to the Patient Summary. It is not possible to provide detailed descriptions to fit all.

For those that do not have electronic health records, the Patient Summary becomes an entry point or base-line on which to build more comprehensive information system. This was the case for many European countries who gladly adopted the epSOS cross-border outputs for internal use as their national solution. At the other extreme, those countries with existing, mature systems were much more wary of accepting the outputs. New standards can be disruptive and require expensive change which is nothing if not challenging. These countries resisted wholesale adoption (there was no compulsory mandate), but still considered how the outputs might serve as a checklist and a strategy for future alignment. The Patient Summary Standards Set attempts to provide guidance and information suitable for both extremes.

Vest, J. R., and L. D. Gamm. "Health Information Exchange: Persistent Challenges and New Strategies." Journal of the American Medical Informatics Association 17.3 (2010): 28894. Web.
Stegwee, R., Chronaki, C., "The Case for Formal Standardization in Large-Scale eHealth Deployment", endorsed by JIC, April 2017.

Information sheet: Scorecard for Patient Summary Standards Set implementation

June 2017

Contributors: Stephen Kay (CEN TC/251)

Category and Scope: Patient Summary/ Value and Evaluation

Purpose:

A Score Card is trialled here to consider the Patient Summary Standards Set with respect to the four stakeholder types (citizens, workforce, eHealth market, and health system). Please provide feedback as to its value.

Content:

The score card starts with the Citizen/Patient column, which is filled with desirable requirements expected from that perspective. The requirement list in the column is not exhaustive but what is there has been drawn up with the Standards Set Patient Summary use case in mind.

The next step is to consider the same requirement from the other stakeholders' perspectives. So the 'available patient summary' might suggest 'faster access to relevant data?' for the attending clinician. The vendor might consider 'how is the summary integrated? The system/regulator might think of 'lower costs/ improvement in care?' because needless procedure/tests can be avoided. The cells beneath the question, take 'N/A', 'LOW', 'MEDIUM', 'HIGH' and some explanation. The Costs rows can take the same Values. The Value proposition is given by the simple formula.

Value = B - C (Including Risks)		Citizen/Patient	Workforce/ Clinicians	Market/Vendor	System/Regulator
Costs (C)	Impact				
	Financial				
Benefits (B)		Patient Summary is available for planned care?			
		Patient Summary is available for my unplanned care?			
		I have access to my summary record?			
		My summary record is comprehensive?			
		My summary record is current?			
		Patient controls privacy of Summary?			

Appendix A

1.0 Standards Categorization Framework

This standards categorization framework was developed and approved by the Joint Initiative Council. The framework includes:

1.1 **Data-related standards** (content, format, structure)
- (Content standards may also include a variety of sub-classifications of standards related to electronic health records, health information repositories, identification registries, census, population information (all as examples)).

1.2 **Semantic Content-related standards** (terminologies, vocabularies, code sets, terminology binding)
- The details of this category of standards may be further informed by the ISO/TC25 Working Group 3 framework on semantic content and it is anticipated that such detail would elucidate and potentially expand the sub-categories of semantic content standards.
- Semantics in simple terms – that which is necessary (vocabularies, code sets, value sets and structure) to consistently represent and maintain the meaning of data elements

1.3 **Transport-related standards** (Information exchange, technical, identifiers, exchange services)
- Technical includes referencing the lower 6 levels of the International Standards Organization Open Systems Interconnection (ISO-OSI) specification (levels 6-Presentation. 5- Session, 4-Transport, 3-Network, 2-Data link and 1-Physical). In some cases this is also known as IT Infrastructure.

1.4 **Security, Privacy, Safety-related standards** (includes consent, data use)

1.5 **Functional-related standards** (for business, information governance, systems and other functional services such as API's)

1.6 **Implementation Specification-related standards** (Includes guides, profiles, reference implementations, workflow practices)

2.0 Communicating the Standards Categorization Framework

To aid in understanding the standards categorization in use for development of a standards set it may be useful to consider interoperability, at its basics, as being about delivering data to a recipient and ensuring the understanding of that data, in essence communication.

Standards categorization targets a balance of simplicity, nuance and completeness. With that target and a basic communication focus, interoperability standards and the Standards

Categorization provides answers to:

1. What is the data?
2. How data is correctly understood?
3. How data is transported, moved or exchanged?
4. How do we ensure privacy, security, safety and correct use of the data?
5. What functions are necessary and supported in transporting and understanding data?
6. How does one use the set of interoperability standards in a digital health system implementation for an identified use case?

The Standards Categorization Framework is underpinned by a standards governance and process that includes:
- Standards development
- Standards approval
- Standards testing
- Standards adoption
- Standards compliance
- Standards maintenance

Appendix B

1.0 Initial Standards List

Patient Summary – Initial List of Standards for Consideration	
Category	**Number or Name** **Reference**
Data-related Standards	ISO 22220:2011 ISO 27527:2010 ISO 8601:2004 ISO 21090: 2011 ISO 19133: 2005 C-CDA CCD R1.1 epSoS v1.4 PS HL7 FHIR Resource (Allergy Intolerance) HL7 IPS Template ISO 18530;2014 All FHIR Resources (as available) ISO 11615:2012 ISO 11616::2012 ISO 11239:2012 ISO 11238:2012 ISO 11240:2012
Semantic Content-related Standards	HL7 Administrative Gender (FHIR) ISO 3166-1 ISO 639 HL7 v3 Address Part Type and FHIR Address Type HL7 v3 Address Use HL7 Telecommunication Use (v2) SNOMED CT HL7 LOINC Document Type Vocabulary LOINC Universal Code System ICD-10:2016 Global Medical Device Nomenclature (GMDN) Anatomical Therapeutic Chemical (ATC) classification system Current Procedural Terminology 4 International Non-proprietary Names ISO TS 13972
Transport-related Standards	HL7 V2 (2.8) HL7 V3 HL7 FHIR (v3.0.1) with RESTful Services IHE XDS (Transport) ISO 13606-3:2009 ISO 13606-1:2008 ISO 13606-5:2010
Security and Safety-related Standards	ISO 27799:2016 ISO/TS 14441 ISO/TR 27809:2007 ISO/TR 25238:2007 IEC/FDIS 82304 ISO/TR 17791:2013 HL7 v3 Healthcare Access Control Catalog ISO/TS 13606-4:2009

Patient Summary – Initial List of Standards for Consideration	
Category	**Number or Name** **Reference**
Functional-related Standards	ISO/HL7 10781:2015 ISO/TR 21089:2004 ISO/TS 17975:2015 ISO 22600-1:2014 ISO 22600-2:2014 ISO/FDIS 21298 HL7 Healthcare Requirements for Emergency Access HL7 Version 3 Standard: Medical Records; Data Access Consent
Implementation Specification-related standards	Cross-Enterprise Document Sharing (XDS) Cross-Enterprise Document Reliable Interchange (XDR) XDS-MS Cross Enterprise Sharing of Medical Summaries XPHR Exchange of Personal Health Record IHE RID Retrieve Information for Display XCPD Cross-Community Patient Discovery XCA Cross-Community Access IHE HPD Healthcare Provider Directory. IHE XCF Cross Community Fetch PIX Patient Identifier Cross Referencing IHE DEN Document Encryption IHE DSG Document Digital Signature IHE ATNA Audit Trail, Node Authentication BPPC Basic Patient Privacy Consents IHE XUA Cross-Enterprise User Assertion ATS 5822-2010 E-health secure message delivery ISO 22600-3:2014

Appendix C

1.0 Patient Summary Use Case Base Flow

The section from Patient Summary Use Case and Business Requirements: Base Flow, replicated here:

Step	Actor	Role	Event/ Description	Inputs	Outputs
1	Attending Emergency Physician	Request	Attending Emergency Physician EHR System Requests Clinical Care Summary	Attending Emergency Physician selects patient of interest from their EHR system.	Initiated Clinical Care Summary Request in standard format and content specification where possible
2	PCP	Send Publish	PCP Receives Request for Clinical Care Summary through PCP EHR System and understands it	Initiated Clinical Care Summary Request	Clinical Care Summary in standard format where possible
3	PCP	Send Publish	PCP Sends Clinical Care Summary to Attending Emergency Physician through PCP EHR System	Clinical Care Summary	Clinical Care Summary in standard format where possible
4	Attending Emergency Physician	Subscribe Display	Attending Emergency Physician Receives Clinical Care Summary through EHR System and understands it	Clinical Care Summary	
5	Attending Emergency Physician	Send	Attending Emergency Physician sends updates to Patient's Summary back to Primary Care Provider	Clinical Care Summary	
6	PCP	Updates	Updates Patient Summary based on discharge information received electronically	Clinical Care Summary	End

Bibliography

ISO standards

The following ISO Standards are referenced or used in this document as part of general Standards Set guidance. This list does not include those which are specific to the Use Case.

1. ISO 9000:2000, Quality management systems—Fundamentals and vocabulary
2. ISO 9001:2000, Quality management systems—Requirements
3. ISO/IEC 17000:2004, Conformity assessment—Vocabulary and general principles
4. ISO/IEC 17011:2004, Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies
5. ISO/IEC 17020:1998, General criteria for the operation of various types of bodies performing inspection
6. ISO/IEC ISO/IEC 17025:2005, General requirements for the competence of testing laboratories
7. ISO/IEC Guide 65:1996, General requirements for bodies operating product certification systems
8. ISO/IEC 17065:2012, Conformity assessment—Requirements for bodies certifying products, processes and services
9. ISO/IEC 17067:2012, Conformity assessment—Fundamentals of product certification and guidelines for product certification schemes

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Glossary

This is a live document so that Glossary will be added to over time.

requirement
need or expectation that is stated, generally implied or obligatory
[EN ISO 9000:2005]
standards set
a coherent collection of standards and standards artefacts that support a specific use case
[JIC, 2016]

patient summary
the minimum set of information needed to assure healthcare coordination and the continuity of care
[GUIDELINES ON MINIMUM/NONEXHAUSTIVE PATIENT SUMMARY DATASET FOR ELECTRONIC EXCHANGE IN ACCORDANCE WITH THE CROSS-BORDER DIRECTIVE 2011/24/EU, Version: 1.0 Date: 19 November 2013]
[Interoperability enabling cross-border Patient Summary Exchange, Catherine Chronaki et al, 2014]

use case
set of activities of a system from the point of view of its actors, which lead to a perceptible outcome for the actors.
[Source: UML]

NOTE 1
A use case is always initiated by an actor. In all other respects, a use case is a complete, indivisible description.