Joint Initiative Council

Joint Initiative Council for Global Health Informatics Standardization

A JIC Foundation and Scope Report
for

Patient Summary Standards Set

1 October 2015
DRAFT 3.4

Executive Summary

The Joint Initiative Council (JIC), comprising the major Standard Development Organisations (SDOs) in Health Informatics, declared that it would focus its efforts by contributing "*to better global patient health outcomes by providing strategic leadership in the specification of sets of implementable standards for health information sharing*". The JIC seeks to operationalise this goal by developing a number of relevant Standards Sets for international use.

A Standards Set is currently described herein as a:

"coherent collection of standards and standards artefacts that support a specific use case".

The purpose of this document is to present our initial approach to this new way of working. It is a work in progress and as such we welcome comments on the content and processes described in this report. To make this undertaking more concrete we have selected a Topic to take forward in order to prototype the practicalities of our proposals.

The Topic 'Patient summary' is a requirement requested by a number of our stakeholders. This high-level Topic is defined as "*the minimum set of information needed to assure healthcare coordination and the continuity of care*" [see Appendix A references 1 and 3 for definition source] JIC will seek to engage its stakeholder communities to advise and validate its Standards Sets throughout the development process.

The primary business use case for the Patient Summary Standards Set is to "*Access patient summary in acute care setting"* which demonstrates a physician 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 JIC Standards Set is the result of a JIC process that delivers SDO content and is complementary to the work in ISO TC215 on normative bundle development which they name Referenced Standards Portfolio (RSP). The JIC brings timely value to all stakeholders from a collaborative of leading international SDOs in Health Informatics, facilitating agile whilst methodical development. The JIC developed Standards Set is targeted to be freely available and informative, but by having a process aligned with the ISO TC215 work means that there is shared learning as well as the potential long term for any resulting works to be converted to normative.

Value of JIC Standards Sets:

Stakeholders should be able to realize the value of Standards Sets in the following ways:

- Standards Sets represent well-defined use cases describing high-priority, real-world problems
- A Standards Set contains an extensive environmental scan of available options (from SDO's and other relevant bodies)
- Standards Set analytics highlight harmonization requirements, overlaps and gaps
- Best practice solutions are articulated
- Standards Sets are focussed on supporting the implementation of healthcare IT solutions
- Standards Sets are living documents, continually maintained and updated to reflect leading practices
- Standards sets are 'end to end', i.e. from data collection through to the delivery of the described Use Case

Moving forward

This document is a work in progress, and therefore we acknowledge the issues to be addressed and would value comments from reviewers in our different stakeholder groups on the approach being taken. We welcome contribution at the development stage and also for testing.

We acknowledge that there is a need to work closely with ISO TC 215 as they undertake their work in developing processes for the Standards Reference Portfolio and their initial use case. But as outlined above, there are fundamental differences

- The aim is that the JIC Standards set be free to stakeholders, whereas the business model of ISO (and CEN) is to charge.
- The timescale of development of the JIC and ISO processes; the JIC work is to be agile and iterative but the minimum ISO process is a year because of the formalities.
- The status of a JIC set as being recommendations for the user as opposed to the ISO normative one
- The acceptance by ISO TMB is still untested
- The constituent parts of a Standards Set are being informed by this initial development
- The resource to do the original guidance material that overarches the components of the Standards set.

Developing a Standards set

Background

Stakeholders are often confused by the myriad of choices that exist when conceiving, selecting and deploying standards in healthcare IT solutions. While most agree that a standardized approach is best, it is often challenging to agree on which specifications are actually the best, given a particular need.

The Joint Initiative Council (JIC) is in a unique position to clarify the choices available to stakeholders and to help them with standards use. JIC can provide authoritative commentary and guidelines about the concurrent use of specifications developed by different SDOs to support appropriate standardization of an informatics business requirement in this domain.

The JIC discussed at its meeting in April 2015 its strategic direction and agreed to 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.

At the next meeting of the JIC in early June 2015 it was agreed that work should be started on developing the first 'Standards set'. The first high-level topic suggested for a Standards Set was the International Patient Care Summary.

A number of settings, including local ones, will be considered to maximise the benefits whilst minimising the risks of underutilisation. The use case descriptions associated with the topic should satisfy the requirements of the different types of stakeholder, be they commissioners or implementers.

It was agreed that JIC should focus on the **Patient Summary** as a more generic high-level topic since this is an area which is likely to have engagement with most members of the JIC.

JIC identified an approach for the work that included:

- Establishing a work group to lead the work (Appendix 5)
- Seeking input and resources across all JIC members and leveraging their networks
- Enabling strategic direction and conflicting interests or issues management by the entire JIC
- Development that needs to be agile
- Applying lessons learned to further areas of development
- Engaging vendors and users for information, adoption and testing opportunities
- Incorporating existing work, content and information from outside JIC wherever possible.

To that end, all members of the JIC are supporting the development of the Primary Care Standards set.

Working Definitions

1. Standards Set

Definition

coherent collection of standards and standards artefacts that support a specific use case

NOTE 1: In this context the specific use case is focused on a goal that contributes to better patient health outcomes through the sharing of information.

NOTE 2: A Standards Set incorporates the development work of JIC and is complementary to ISO Standards Reference Portfolio development.

Purpose

A Standards Set, content developed by JIC, provides a package of implementable standards for health information sharing to meet stakeholders' specific requirements.

Value Proposition #1

Value proposition is a concept that is entirely stakeholder-centric. The benefits of an initiative or action should outweigh the costs and the associated risks. Consumers of standards, be they policy makers or developers, value choice but appreciate guidance on what specifications to choose and what standards to adopt such that their deployment will provide a coherent, workable solution for a particular problem.

The Standards Set is the strategic response to this need by the JIC representing the SDOs whose business is Health Informatics and assisting stakeholders in understanding, selecting, adopting and deploying standards to facilitate solutions. Standards Sets supply expert commentary and might contain:

- A well articulated use case, clarifying what is in and out of scope
- Currently available, applicable standards
- Leading practices
- Standards harmonization requirements
- Identification of standards gaps, with recommendations on how to address those gaps
- Implementation guidance
- Conformance considerations
- Adoption community, including reference implementations, case studies, support networks
- Business cases – to support adoption/investment from various stakeholder perspectives

The JIC Standards Set is the result of a JIC process that delivers SDO content complementary to TC215 normative bundle development. JIC brings timely value to all stakeholders from a collaborative of leading international SDOs in Health Informatics. The JIC developed Standards Set is targeted to be freely available, aligned and potentially branded in the future with the ISO/TC215 work that bundles normative references to support a use case with content, tool and rule standards and standard artefacts.

2. Requirements

Definition

requirement
need or expectation that is stated, generally implied or obligatory
[EN ISO 9000:2005]

Value Proposition #2

There are attempts to make 'requirement statements' much more rigorous as in the IEEE 830-style software requirements specification; these are generally more detailed and voluminous but are often needed to assist in software development by providing the means to measure and test.

The existence of both types of 'requirement' reflects the needs of different stakeholders, and the SDO community has to satisfy both.

3. Use Cases

Definition

Multiple definitions exist for Use Case. JIC at the present is not confirming one definition, but will seek consensus across the SDO's for the best working definition. For the moment, JIC are using the one used widely in the modelling community:

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.

Value Proposition #3

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 satisfy a range of stakeholders. They can be very light-weight, even abstract, or much more detailed and concrete as required. A use case is a generalised 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 one part of the overall development.

Use Cases are not exclusive to Health Informatics, but are more generic and often associated with the Unified Process of system development and with UML in particular. The internet provides many examples of templates for 'use cases' and often these tend to be specialised to a particular business domain to encourage adoption.

Use cases value often lies in satisfying the more technical implementer stakeholder. As an example the successful EU project called ANTILOPE [Adoption and take up of standards and profiles for ehealth interoperability. EU Project Grant 325077: 02/2015] had a mission to support the adoption of standards and profiles for interoperability. It was mainly IHE driven, but had CEN and HL7 input. It chose to use two levels of Use Case template, one high-level (more business oriented for the policy maker stakeholder) and one more technical to suggest/map particular specifications. The high-level template was an adaption of the CEN TC251 work and used as the business use case template in this document. It is proposed that the TR 19669 be the second level description.

SCOPE

In JIC Standards Sets, the importance of the particular 'topic' to be addressed is very significant. Not only does this provide a pointer to the scope of the work, it also determines the granularity of the description. One serious problem with 'use cases' is the tendency to proliferate descriptions making them difficult to catalogue and difficult to re-use in different contexts. For some stakeholders 'use case' is merely a high-level topic.

High-Level Topic, Use Case and Standards Relationship

A high-level topic can be described by multiple use case descriptions, and these can focus the requirements for a Standards Set. The relationship between high-level topic, use case descriptions and Standards Sets is illustrated below:

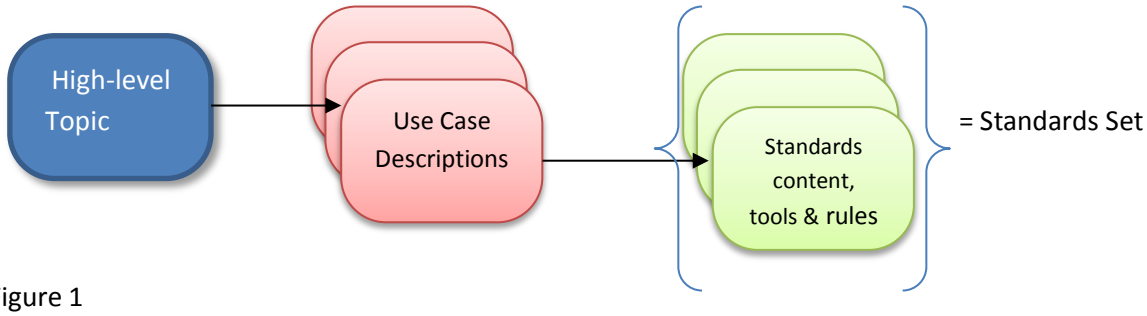


Figure 1

The Standards Set includes content, rules and tool related standards and related guidance. While it is recognized that there may be other standards that are usable and there may be standards gaps needing to be filled, the Standards Set to be provided should be a useful and comprehensive start to fulfilling the interoperability needs of stakeholders for the specified high level topic and use case description.

What is the Topic

The first high-level Topic suggested for a JIC Standards Set is the *Patient Summary* which is defined as follows.

patient summary
the minimum set of information needed to assure healthcare coordination and the continuity of care
Source [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]
Source [Interoperability enabling cross-border Patient Summary Exchange, Catherine Chronaki et al, 2014]

This description is generally aligned with EU work and the transatlantic Trillium Bridge project and builds upon the early ISO work on health summaries. Nevertheless the topic for a use case has to be more constrained to be useful.

A number of settings, including local ones, will be considered to maximise the benefits whilst minimising the risks of underutilisation. The use case descriptions associated with the topic should satisfy the requirements of the different types of stakeholder, be they commissioners or implementers.

There are multiple descriptions, views, definitions and types of patient summaries. **Appendix A** provides some of the past and current descriptive and definitional work.

Three summary observations from the initial patient summary information sourced to date:

- Currently in many countries the standards and related interoperability work consistently and commonly references *patient summary* as a clinical and/or interoperability need, often with similarities the definitional words being used.
- The type of patient summary needed and used varies considerably. In some countries discharge summary is a key starting point.
- From a process view (construct, make available, share, maintain) an overarching purpose and use case driver could be identified as *access to a patient summary*.

Standards Set Format

It is important that in undertaking the development of Standards Sets, the work within SDOs' and other key bodies, such as ONC, is considered so that harmonisation and interoperability is managed. One example is the emerging organization or format of standards being developed by ISO/TC215 in the Standards Reference Portfolio work.

ONC has produced a different model of categories of standards which are more detailed, and bodies such as the EU have done similar work. These differing approaches emphasise the need for JIC to produce a recommended Standards Set which will be usable across this spectrum so that there can be alignment – for example if there is a desire in the future for any JIC Standards Sets to become normative through the ISO approvals process.

This is work in progress for the JIC group so more information will emerge over the following months on the approach being taken. Both the models above are illustrated as examples in Appendix F

What is the primary business use case?

The primary business use case is "*Access patient summary in acute care setting*". It is further described in the following scenario or user story:

Patient presents as unconscious at emergency (acute center). Attending physician looks up prior record or patient summary information on file within HIS (hospital information system) within acute care setting. Attending physician identifies primary care physician and patient ID from the acute care record. Attending physician accesses the primary care patient summary from the EHR.

The patient summary standards set associated with this use case is usable by governments of countries or government agencies for adoption and use in their country and has a full list of associated and key stakeholders (see Stakeholder section)

A template provided through CEN/TC251 (See Appendix for template and associated rationale) is a trial framework for the development of the business use case with descriptions provided. The "topic" or name, *Access Patient Summary in Acute Setting*, requires the specification of other detailed use case description in order to map specifications and standards for use.

As figure 1 suggests, there may be multiple use case descriptions for a high-level topic, but the goal is to minimise the high-level business cases to help the would-be user. The detailed use case template sections, provided from an early draft of ISO/TR 19669, are included in Appendix C. For purposes of illustration, here is the CEN TC251 trial template, with use of certain EN ISO/FDIS 13940 terminology to maximise reuse through general, but well defined concepts and terms.

Sections	Business Use Case Description
A. Name/Topic	Access Patient Summary in acute care setting
B. Stakeholder story	As a physician *(ie a healthcare actor)*, I want relevant patient data so that I can address the *healthcare matter* of the patient (*subject of care)*. I want legitimate access and use of relevant 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. Example: A patient either presents in an acute setting (event trigger) or the patient requests a transfer of care between providers (moves or travels). Three common starting events of demand for care: 1. Patient presents at emergency or other healthcare setting, and responding health care provider (physician) requires patient summary information to inform treatment. 2. Patient transfers between primary care physicians, and "new" responsible physician requires patient summary information 3. Patient travelling abroad requiring healthcare support and responding health care providers require patient summary information to inform treatment
D. Actor and users	*Healthcare Providers* and Patients (*Subject of Care)*
E. Goal	To access and use relevant patient data to enable timely appropriate, coordinated care in accordance with the *healthcare mandate*
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 physician looks up prior record or patient summary information on file within HIS (hospital information system) within acute care setting. Attending physician identifies primary care physician and patient ID from the acute care record. Attending physician accesses the primary care patient summary from the HER *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 PCP for the patient's Clinical Care Summary. The PCP 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.*
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 context:	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 context:	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 and context	The Topic and terms used are general enough to support more specialised cases relating to professional, organisational, cultural and regional practices. Terms, in *italics*, are defined in relation to EN ISO/FDIS 13940 System of Concepts to Support Continuity of Care. The patient summary working definition is as defined elsewhere in this document.

Who are the Stakeholders and What Value do They Receive?

The following is a high level list of potential stakeholders. The specific stakeholders will depend on the Use Case/s being applied

- Governments/government agencies
- Clinical bodies – nationally and internationally e.g. Physician groups/colleges
- Vendors
- Vendor groups
- Healthcare organisations
- Regulators
- Insurance companies/purchasers
- Information specialists
- Information governance bodies
- Patient organisations
- Carers
- Standards bodies

Stakeholders are often confused by the myriad of choices that exist when conceiving, selecting and deploying healthcare IT solutions. While most agree that a *standardized approach* is best, it is sometimes challenging to agree on which standardized approach is best, given a particular need (or use case). The JIC, by virtue of its collaborative environment and the participation of leading international SDO's in Health Informatics, is in a position to help streamline the process, primarily through clarification of the choices available and commentary about best practice approaches.

Stakeholders should be able to realize the value of Standards Sets in the following ways:

- Standards Sets represent well-defined use cases describing high-priority, real-world problems
- A Standards Set contains an extensive environmental scan of available options (from SDO's and other relevant bodies)
- Standards Set analytics highlight harmonization requirements, overlaps and gaps
- Best practice solutions are articulated
- Standards Sets are focussed on supporting the implementation of healthcare IT solutions
- Standards Sets are living documents, continually maintained and updated to reflect leading practices
- Standards sets are 'end to end', i.e. from data collection through to the delivery of the described Use Case

Review and testing

There are different aspects which will come out of setting conformance criteria:

- Technical interoperability
- Semantic alignment
- Clinical validity
- Security

This might involve any of the stakeholder organisations who may want to participate or have facilities that can be used. Some initial options:

- It was interesting to note in the Trillium Bridge technical report that the platform they have developed is available and so it would be worth exploring what that might be able to provide.
- It will be also to explore what IHE may offer in the way of 'Connectathons'?

This topic needs further development and input is welcome from stakeholder groups reviewing this document. It will also benefit from work being undertaken in ISO TC 215.

Process Outline

Principles of Standards Set Development

JIC identified an approach for the work that included:

- Establishing a work group to lead the work (Appendix 5)
- Seeking input and resources across all JIC members and leveraging their networks
- Enabling strategic direction and conflicting interests or issues management by the entire JIC
- Development that needs to be agile
- Applying lessons learned to further areas of development
- Engaging vendors and users for information, adoption and testing opportunities
- Incorporating existing work, content and information from outside JIC wherever possible.

Suggested Development Process for any JIC Standards Set

The assumption is that existing work is always leveraged if possible. However, it may not be obvious depending on the way that the requirement is expressed. The best outcome possible is that the stakeholder's requirement has already been partially or, even better still, completely satisfied. In this case, reuse should be an objective rather than an aspiration.

1. A stakeholder requests a standardized solution that requires one or more JIC members' products to interoperate. (Typically the business requirement will involve a selection from a spectrum of standards, from across the interoperability stack.)
2. Query a catalogue, library or portfolio {not yet available] of existing use cases for possible reuse.
   a) If a match is found, the entry is updated to reflect that it can be directly used for the new business requirement and the stakeholder is passed the details of the successful Standards Set.
   b) If no match, then the JIC Standards Set has to be developed, beginning with use case descriptions.
3. Develop a high-level business use case using standardised concepts and terms [1] to describe and express the problem to be addressed; this is the scope of the standards set within the domain. This high-level business use case [2] is a more formal representation of what the stakeholder requires; the description will be independent or neutral of any implementation detail, confining itself to the identification of the problem to be addressed with lists of the most important constraints to be satisfied. As well as providing the new searchable case in the catalogue, it also provides the context for a more detailed, technical formulation of use case descriptions. These too may be catalogued for reuse.

4. Define the technical use case [3] in more depth for the requirement, specifying the requirement in such a way as to facilitate implementation of a testable specification(s) as plausible solutions. This description will typically use UML models and diagrams and the support of tooling.
5. Identify existing specifications (probably many) that can satisfy the implementation criteria and be part of the solution. These specifications will form the SDO specific content for the Standards Set for the specified business use case. Work will be required to make them work concurrently. It may be that options exist within the same Standards Set.
6. Determine the path to 'market' i.e. making the Standards sets and supporting processes and implementation guidance available to the defined stakeholder or stakeholder group. Complete the normative and informative parts of the Standards Set.
7. Address alignment and future branding opportunities with ISO/TC215.

Steps 1 and 2 might be carried out by any SDO who is given a topic to standardize. Steps 3-6 represent the core JIC activities of Standards Set development and will be done collaboratively. The outcome of steps 3-6 is a body of harmonized material ready for sharing, communication and use. Step 7 provides the complementary alignment with ISO/TC215.

JIC Patient Summary Standards Set Process

The following is an outline of planning processes and activities that are being used to initiate the JIC Standards Set work for the Patient Summary Standards Set.

1. Identify a JIC committee to drive the work forward (now identified as the *Standards Set Coordination Group*). One from each Member who is able to act on its behalf, in both planning and identifying resources to contribute to the work – be it individuals or products.
2. Define the 'trial' use case in more depth for Patient Care summary,
    a. Confirming scope
    b. Activities on the path to 'market' i.e. making the Standard set and supporting processes and implementation guidance available to the defined stakeholder group
3. Stakeholders
    a. Define the list of stakeholders to whom the Standard set is aimed e.g. government agencies, vendors, clinical organisations etc
    b. Identify stakeholder who will review/test the trial Standard set
4. Review resources and related activities that might contribute to the development of the trial Standard set,
    a. amongst JIC Members
    b. other related work internationally that relates to the use case area e.g. Trillium Bridge, EU joint action task force to update patient summary guidelines, US work on INTERPAS (International Patient Summary)
5. Identify gaps and proposals for filling the gaps, including any implications for costs
6. Develop the plan and timelines for the producing the starter Standard set, liaising across the various resources and contributions. This should include identification of any risks

7. Implement plan
8. Undertake appropriate testing of the standards set
9. Lessons learned and benefits realisation
10. Communications approach

Additional process steps that should be considered in the JIC Primary Care Standards Set work include:

a) Conduct an environmental/Jurisdictional scan
   - Which patient summary standards exist?
   - How or in which settings are they used? (context)
   - Are any representing a super set? (a applicable international patient summary standard?)

b) Create a library of patient summary standards that do exist and context in which it is being used

c) Provide guidance on usage

d) Conduct stakeholder consultations with clinicians and relevant jurisdictional stakeholder orgs to assess use cases for patient summary
   - Overlay with patient summary standards (duplicates or gaps), then assess (what do we have and what do we need?)

Draft timelines (to be further updated)

	Activity	**Specific timelines**
	Identify development team	
	Clarify 'use case', benefits and business proposition. Validate with stakeholders	
	Develop technical use case end to end, mapping to existing: - standards - specifications - guidance - profiles	
	Development: - Requirements and resources to populate gaps - selects standards to be included in the set - Testing requirements - Document optionality within the framework and how managed	
	Development of - guidance and other items identified - Testing framework	
	Drafting Standards Set specification and report	
	Testing	
	Updating of Standards Set based on Testing feedback – content and	

	documentation	
	Sign off	
	Publish	
	Feedback loop - process - product	
		1 year total

Appendix A

Patient Summary Descriptions, Views, Definitions and Types

The following example definitions and descriptions are useful background and starting points for discussing the topic, patient summary.

1. Patient summary is "defined at a high level as: 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]

2. A Patient Summary is an identifiable "dataset of essential and understandable health information that is made available at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in unscheduled 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

3. Patient summary is defined as "the minimum set of information needed to assure healthcare coordination and the continuity of care".

   Interoperability enabling cross-border Patient Summary Exchange, Catherine Chronaki et al, 2014

4. "Patient summaries, excerpts of Electronic Health Records used most frequently for emergency or continuity of care"…

   Patient Summaries: An International Perspective, IMIA 2015 Workshop Description, Catherine Chronaki, Philip Scott, Beatriz de Faria Leao, Michio Kimura, Morten Bruun Rasmussen, Anne Moen, Doug Fridsma

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

   Trillium Bridge recommendations for policy convergence for JIC discussion, June 2015

   Note: above reference noted stakeholders of Trillium Bridge for policy convergence discussion were EU and US policy makers including the US Department of Health and Human Services (DHSS), the US Office of the National Coordinator (ONC), the European Commission (EC) and the European eHealth Network (eHN).

6. Health summary record: health record extract comprising a standardized collection of clinical and contextual information (retrospective, concurrent, prospective) that provides a snapshot in time of a subject of care's health information and healthcare

   ISO_TR_12773 – 1_2009 Business requirements for health summary records

7. Others to be researched further

Types of a patient summary

- "Emergency data, discharge summary, continuity of care record, lab reports, encounter reports, clinical summaries addressed to specific medical specialties and medical problems as chronic diseases"

  Excerpts from Patient Summaries: An International Perspective, IMIA 2015 Workshop Description, Catherine Chronaki, Philip Scott, Beatriz de Faria Leao, Michio Kimura, Morten Bruun Rasmussen, Anne Moen, Doug Fridsma

- "Another lens to view patient summaries is the way they are constructed, maintained and shared." "(automatically generated, upon transfer, or GP maintained), (longitudinal, transactional) (information to support continuity of care after hospital discharge), (fit to purpose – ie telemedicine), (a clinical patient care summary using an HL7 standard format)"

  Excerpts from Patient Summaries: An International Perspective, IMIA 2015 Workshop Description, Catherine Chronaki, Philip Scott, Beatriz de Faria Leao, Michio Kimura, Morten Bruun Rasmussen, Anne Moen, Doug Fridsma

Examples of Health summary records (from 2009 ISO Technical Report)

- Care summary record (H7 CDA Care Summary Record)
- Continuity of care document (ASTM / HL7 CCD)
- Continuity of care record (ASTM CCR)
- Core Data Set (OntarioMD Clinical Management System EMR Specification)
- Emergency Care Summary (NHS GP Summary Dataset)
- Health Profile (BC Canada Electronic Medical Summary)
- Medical Summaries (IHE XDS Medical Summary Integration Profile)
- Medical Summary for transfer of patient data (Alberta, Canada, Information Standards Committee)
- National Discharge Summary (Australia, NEHTA)
- Summary Care Record (NHS)

  ISO_TR_12773 – 1_2009 Business requirements for health summary records

Description of health summary records

"The primary use of HSR's is the communication of targeted clinical information between and amongst health care providers and providers and subjects of care in support of ongoing care or delivering unscheduled / unplanned care and/or enabling appropriate self-care. The primary beneficiaries are subjects of care and their providers."

ISO_TR_12773 – 1_2009 Business requirements for health summary records

Content of a health summary record

"(first priority data groups of relevance in all clinical use contexts)

- active problems / diagnosis (problem list)
- allergies and other adverse reactions
- current and regular medication
- results of recent investigations and procedures
- encounters (recent and over specified time periods)
- alerts / special needs
- advance directives”

ISO_TR_12773 – 1_2009 Business requirements for health summary records

Content of International Patient Summary

- “clinical problems
- allergies
- medications
- past operations
- immunizations,
- implants”

Trillium Bridge recommendations for policy convergence for JIC discussion, June 2015
List re-ordered

Appendix B High Level Business Use Case Template

The following CEN template uses the Topic (Section A) and the stakeholder story (Section B) to provide a Use Case Summary for quick reference. The business use case for this high level topic, ‘‘access to a patient care summary in an acute care setting’, does not have to specify specifics such as realm e.g. international or local, organisation type, or source of data e.g. record, message, multiple feeds, etc. Business use cases should be technology independent in its description.

The high level business use case template includes a scenario, actors, actions and events, aligned with usual representations of a ‘use case’ description but in addition emphasizes some of the Strengths/Weaknesses/Opportunities and Threats (SWOT) to the forefront of the Health Informatics domain.

Note, a scenario is defined as a description of high level business activities defining process and requirements [ISO/IEC 19501:2005]

Use Cases are not the same as Agile User Stories. However the simple template used for an Agile User Story is useful because it highlights the goal (Section E). For this reason, a ‘stakeholder story’ has been included in the use case template, and it recognises that such stories can be large (sometimes called ‘epic’ in Agile terms), or very small (a single sentence).

User stories are short, simple descriptions of a feature told from the perspective of the person who desires the new capability, usually a user or customer of the system. They typically follow a simple template:
As a <type of user>, I want <some goal> so that <some reason>.” [ref]
This template was used in the example.

The Business model (SWOT) included in the CEN template has two functions:

1. To be recognisable to business users and therefore intended to encourage use (known to be difficult)
2. To permit the particular constraints of safety and threat to be addressed at a high level rather than to be lost in preconditions and post conditions.

Use-case sections	Description
Reference number & classification	Office Use
Use case name	An active verb phrase that describes a particular task in everyday language. The **Use Case Summary** is defined when the **Use case name** is used together with the **Stakeholder Story** section.
Stakeholder story	A requirement formulated as 2 to 4 sentences in everyday or business language
Starting event	A trigger that starts the use case, which can be external, internal or temporal.
Actor and Users	The actor that initiates this use case and all users who participate in this use case
Goal	A sentence describing what the initiating actor intends to achieve with this use case
Stakeholders	A list of those who are affected by the outcome (good or bad) of the use case
Primary Scenario	Typical and expected sequence of events (No alternative or exception paths here)
Strengths	Preconditions or Constraints that support the scenario (internal, benefits, personal &/or organisational)
Weakness	Post Conditions or Outcomes that oppose the scenario (internal, risks, personal &/or organisational)
Opportunity: Safety context:	Success factors, beneficial outcomes for safety, privacy, confidentiality etc;. for stakeholders
Threat: Security context:	Risk factors that may adversely affect safety, security etc.; for stakeholders
Notes (optional)	Additional Information that is felt to be relevant, but not found elsewhere in the template
UML Model(s) (optional)	Associated Use Case & Activity diagrams attached or referenced to this use case

Appendix C – Full Use Case Template

The following are the headings from the use case template document drafted as part of the ISO/TC215 Technical Report. The description of each section indicated by the headings is available.

1.0 Preface and Introduction
2.0 Initiative Overview
    2.1 Initiative Challenge Statement
3.0 Use Case Scope
    3.1 Background
    3.2 In Scope
    3.3 Out of Scope
    3.4 Communities of Interest
4.0 Value Statement
5.0 Use Case Assumptions
6.0 Pre-Conditions
7.0 Post Conditions
8.0 Actors and Roles
9.0 Use Case Diagram
10.0 Scenario
    10.1 User Story
    10.2 Activity Diagram
        10.2.1 Base Flow
        10.2.2 Alternate Flow
    10.3 Functional Requirements
        10.3.1 Information Interchange Requirements
        10.3.2 System Requirements
    10.4 Sequence Diagram
11.0 Risks, Issues and Obstacles
12.0 Dataset Requirements

Appendix D – Additional Patient Summary High Level / Business Use Cases

1 b) Example scenario: Patient transfers between primary care physicians, and "new" responsible physician requires patient summary information

Use case #2: Patient transfers or moves between cities and enrolls with a new primary care physician. Primary care physician uses EMR to look up primary care patient summary from the EHR. Or, alternatively, the patient requests previous primary care physician to create a patient summary for transfer.

1c) Patient travelling abroad requires healthcare support and responding clinicians require patient summary information to inform treatment

Use case #3: Patient, while on a trip to visit relatives, presents at the emergency department of an acute hospital in a community / country far away from their home and from their family physician and current specialist who is treating their chronic condition. Patient has a history of diverticulitis, bowel surgery and is in severe abdominal pain. Patient also has just had a meal in a restaurant and food poisoning is suspected. ER physician is in need of pertinent patient history and information and family member notes that a patient summary has been previously available but is unaware of how to access it, but does provide the family and specialist contact information. ER Physician contacts family physician and receives no answer (time zone change / clinic closed). Specialist physician is online, but at his cottage and does not have the patient summary on his laptop, however the hospital where the specialist practices is of course available and has the patient summary in their system. Specialist approves the transfer of the record, via the hospital system to the ER Physician in the 'far away' community / country. Acute hospital system 'transfers' the patient care summary to the ER Physician, with standardized content and terms, using an international message and content/payload carrier service, within the privacy, security and safety services necessary, all on the required technical, secure and open telecommunication carriers.

Appendix E

JIC Standards Set Coordination Group

The Standards Set Coordination Group has been meeting bi-weekly to initiate plans and identify initial scope, value, stakeholders and business use cases, all as part of the foundational work to deliver the first Standards Set. Members of the Group are:

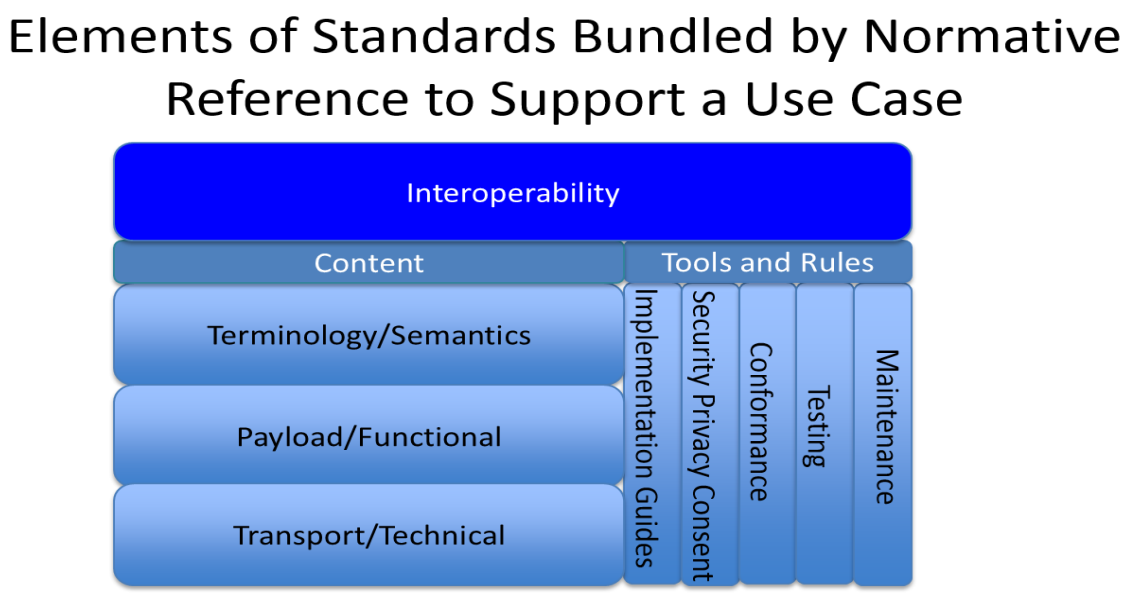
Jane Millar (Chair),	IHTSDO
Michael Glickman,	ISO
Christian Hay,	GS1
Chuck Jaffe,	HL7
Stephen Kay,	CEN
Elizabeth Keller,	ISO
Don Newsham,	ISO
Michael Nusbaum,	IHE
John Quinn,	HL7
Lisa Spellman	ISO
Tania Snioch.	GS1
Robert Stegwee,	CEN

A Standards Set Vendor & User Reference group will be identified and engaged to provide the JIC and the above Coordination Group with current state intelligence, adoption potential and testing opportunities for the standards set.

Appendix F

The following are examples of models being used to categorise standards for different use cases. These are only 2 being considered by the JIC in its work on developing Standards Sets

ISO TC 215



Office of the National Coordinator, US

CATEGORIES OF STANDARDS	FUNCTIONS OF STANDARDS	EXAMPLES OF REAL WORLD USE OF THE STANDARDS
VOCABULARY & CODE SETS (SEMANTICS)	The information is universally understood	RxNorm Code for Ibuprofen is 5640
FORMAT, CONTENT & STRUCTURE (SYNTAX)	Information is in the appropriate format	C-CDA packages up data in the appropriate format
TRANSPORT	The information moves from point A to point B	SMTP and S/MIME to send the C-CDA from one setting to another
SECURITY	The information is securely accessed and moved	X.509: to ensure it is securely transmitted to the intended recipient
SERVICES	Provides additional functionality so that information exchange can occur	DNS+LDAP: to find the recipient's X.509 certificate to encrypt a message