



Patient Summary Standards Set Development

Standards Categorization for Identifying and Analyzing the Standards in a Standards Set

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Background

The Joint Initiative Council (JIC) has launched an initiative 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 (defined as a “coherent collection of standards and standards artefacts that support a specific use case”). Full information on the scope and foundation of the Patient Summary Standards Set can be found at <http://www.jointinitiativecouncil.org/index.asp>.

To facilitate the development of a standards set and to ensure ease of understanding and a coherent comprehensive view of the scope of standards needed for a particular use case, a categorization of the standards identified is useful.

This work acknowledges the starting efforts of two related works:

- 1. The ISO/TC215 and JIC work item, ISO/DTS 18528.**

ISO/DTS 28528 Health informatics standards functional classification, initiated by Andrew Grant, was not completed and was removed from the TC215 and JIC work programs. A ‘HIWIKI’ was reviewed and it is acknowledged that the Canadian 2004/5 work on a health information framework provides additional impetus for this JIC work (see Annex A – for a pictorial view of that original 2004/5 work).

- 2. The ISO/TC215 published Technical Report – ISO/TR 14639.**

ISO/TR 14639 Capacity-based ehealth architecture roadmap (Part 2) provided an eHealth Infostructrue architecture model that incorporated the following key elements:

- EHR and health information repositories



- Identification registries and directories
- Clinical terminology and classifications
- Data interchanges and accessibility
- Consent/access, control and workflow management
- Privacy, security and safety regime
- Census, population information and data warehouse

While there are clearly standards categories in the 14639 model, there is also a further specific categorization of health data content (EHR, health information repositories, identification registries, census, population information). Data content of interest to standards sets may include additional categories, such as personal health records, medical record data, wearable device data, etc. The TR 14639 model is valuable and informative to this work on standards categorization.

This work will build upon the ISO/TR 14639 work and is not intended to replace that DTS 18528 work item, nor is it intended to be a standard in any SDO, nor a formal ontology. It is for standards set development use only, at this time.

This work is also supportive of the INFORMATIVE nature of the JIC standards set. It is fully acknowledged that the TC215 work on the first Clinical Imaging “Bundle”, currently noted as the Reference Standards Portfolio (RSP), will also be a complementary participant in standards categorization. The TC215 bundle work will result in a NORMATIVE document and as such may have additional specific requirements to fulfill in a categorization of standards. A commitment to all standards set and bundle work being complementary has already been noted by both JIC and TC215.

Standards Categorization – Determination and Sources

Determining the applicable standards categorization should take into account a balance between:

- Simplicity, which facilitates ease of understanding (and includes simplicity of the wording and terms of the standards categories)
- Nuance, which facilitates a clear distinction between various groups of standards
- Completeness, which ensures fulsome coverage within the standards set

The organization of standard working groups in various SDO’s provides some guidance, however 3 specific categorizations have been recently provided as possible templates.

The three sources of standards categorization are:

- Modified ONC Roadmap 2015 (as provided by Stephen Kay)
- TC215 Interoperability for RSP (as noted in Healthcare Informatics – Standards Reference Portfolio (RSP) (Bundle): Methodology, Organization and Approach)



- TC215 RSP Components for a Specific Domain (as noted in Healthcare Informatics – Standards Reference Portfolio (RSP) (Bundle): Methodology, Organization and Approach)
 - o This third categorization references three types of interoperability – semantic, technical and functional

In addition, the EU has defined a common refined framework for managing interoperability and standardisation challenges in the eHealth domain in Europe. This framework (Refined eHealth European Interoperability Framework (ReEIF)) for interoperability is based upon the output of the Antilope project (and specifically deliverable D1.1 of that project) that was closed in Q1 of 2015. The Antilope project took the eHealth European Interoperability Framework (eEIF) as a starting point.

Source – ONC	Source – TC215	Source - TC215	Source – ReEIF	Standards Categorization COMMONALITIES
Format, Content and Structure	Payload and Functional	Semantics - Terminology - Information - Content	Information (identified as Semantic in original EIF)	<i>Content, Information, Format, Structure</i>
Transport	Transport and Technical	Technical - Information Exchange - Identifiers - Privacy and Security	Applications, IT Infrastructure (Combined as Technical in original EIF)	<i>Transport, Technical, IT Infrastructure, Information Exchange, Exchange Services, Identifiers</i>
Vocabulary and Code Sets	Terminology and Semantics		Information (identified as Semantic in original EIF)	<i>Semantics, Terminology, Vocabulary, Code Sets</i>
Services		Functional - Business - Information Governance - Health IT Safety		<i>Functional Services</i>
Security	Security, Privacy and Consent			<i>Privacy, Security, Consent</i>
Safety				<i>Health IT Safety</i>
	Implementation Guides			<i>Implementation Guides</i>
	Conformance			
	Testing			
	Maintenance			
			Legal and Regulatory	
			Policy	
			Care Process	



In targeting simplicity, ease of use, clear distinction and comprehensive coverage and building from the sources noted above, the following is provided as a basis for a standards categorization for use in standards set development.

- **Conformance, testing and maintenance**, while certainly part of a standards development process, are not distinct categories of standards but more attuned to STANDARDS GOVERNANCE. As such there are requirements for leading practices in standards governance and there may or would be standards used to undertake the work of conformance, testing and maintenance, but such are governance or process supporting standards.
- Conformance is also a process undertaken by standards developers and standards users and includes the development and use of conformance statements as part of any high quality standard and standards compliance activity.
- For standards set development, the governance work of conformance, testing and maintenance would be addressed by the JIC, all in support of the standards set.
- The refined eHealth EU interoperability framework of **legal, regulatory, policy and care process** levels are focused on generic organizational and broad interoperability which addresses not only the organization of (technical) interoperability, but also the interoperability of (healthcare providing) organizations. Organizational interoperability is not a focus of the Standards Set work.
- If **safety** were to be combined with **privacy, security** and consent, and **profiles** (that offer an implementation path) are included **with implementation specifications**, 6 groupings of standards could be identified.
- ONC and its website and perhaps others (a search and further research has not been completed) have identified the term "Interoperability Stack". From references of ONC material and in simple terms (with extensions and reordering) the following may be considered the fundamental building blocks of interoperability or the interoperability stack for a Standards Set.
 - o *content and structure*
 - o *meaning*
 - o *transport*
 - o *security and safety*
 - o *services*
 - o *specifications*
- In broad terms the above interoperability stack can be said to address:
 - o Semantic interoperability (content, structure, meaning)



- o Technical Interoperability (transport, security and safety)
- o Functional Interoperability (services, specifications)

Standards Categorization

1. **Data-related standards** (content, format, structure)
 - o (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)).
2. **Semantic Content-related standards** (terminologies, vocabularies, code sets, terminology binding)
 - o 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.
 - o 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
3. **Transport-related standards** (Information exchange, technical, identifiers, exchange services)
 - o 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.
4. **Security, Privacy, Safety-related standards** (includes consent, data use)
5. **Functional-related standards** (for business, information governance, systems and other functional services such as API's)
6. **Implementation Specification-related standards** (Includes guides, profiles, reference implementations, workflow practices)



Communicating the Standards Categorization

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?

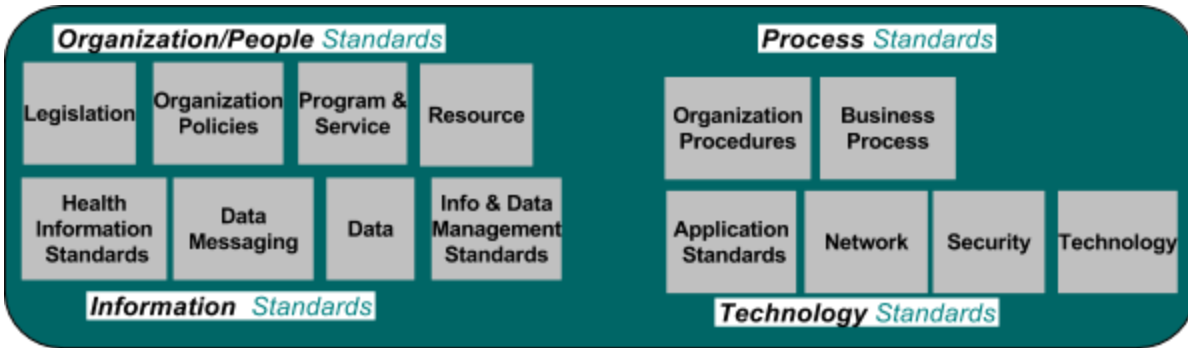
The Standards Categorization is underpinned by a standards governance and process that includes:

- o Standards development
- o Standards approval
- o Standards testing
- o Standards adoption
- o Standards compliance
- o Standards maintenance

Of particular interest for the Standards Set work are Standards testing, compliance and maintenance.

Annex A

2004/5 Canadian Advisory Committee on Health Information – Definition and Scope of Standards





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