Medtech 4 Health

Common Framework of Standards for Interoperability and Change Management

Final Report – StandIN Project, Phase 1

PREFACE

The final report from the StandIN project has been translated into English. Unfortunately, the appendices are not translated. But, if you are interested in reading them and have the opportunity to get them translated from Swedish you can download them from the site: http://medtech4health.se/standin/

The following Swedish appendices with an English title in brackets are available:

• Sammanställning system i landstingen 2015 (Compilation systems in county councils in 2015)

• Exempel på hur teknisk interoperabilitet kan bidra till god vård och omsorg (Examples of how technical interoperability can contribute to good health and medical care and social care

• Omvärldsbevakning (Knowledge of the world around us)

• Framtidens vård – Framtidens vårdinformationssystem (Future healthcare – Future healthcare information systems)

• Contsys och teknikperspektivet (Contsys and the technology perspective)

• Exempel på Verksamhetsledning (Examples of business management)

• Relevanta standarder som inte avser teknisk interoperabilitet (Relevant standards that do not relate to technical interoperability)

• Standarder som rör teknisk interoperabilitet (Standards relating to technical interoperability)

• Begreppsmodell över StandIN:s ramverk (Concept Model of StandIN's framework)

• Genomgångna men exkluderade standarder (Analyzed but excluded standards)

• eHAM modellens tillämpning i StandIN projektet (The application of the eHAM model in the StandIN Project)

• Genomförbarhetsexempel – Hjärtsviktsprocessen (Feasibility Example – The congestive heart failure process)

• Projektplan version 1.1 (Project plan, version 1.1)

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1 1 BASIC INFORMATION

1.1 Summary

The final report describes the project's mission, approach and results. We describe the business/operational, semantic and technical common starting points based on international standards for the future healthcare information systems. The project focuses on the technical interoperability that supports the business/clinical work. In addition, the preconditions for systematic change management with the patient's needs in focus are described.

A framework of standards has been identified and categorisation of these standards has been made by placing them in an architectural framework. Of the 70 or so standards, we have identified 45 that are directly relevant to the assignment/mission. Eighteen (18) of these have a technical perspective which establishes the prerequisites for technical interoperability. The other twenty-seven (27) are categorised within the business and information perspectives, and are absolutely essential to the whole.

However, there may be standards with technical perspectives and/or conventions relevant to StandIN that we have not identified.

This report also includes examples of a clinical process (the congestive heart failure process) for the purpose of relating how the selected standards can contribute to information management appropriate for its needs.

The current situation regarding standards and their applications are described as a basis for further work, national coordination and application of standards. A number of shortcomings and gaps are identified. Among other things, we can see that the selected international standards for interoperability in the report have, in the current situation, little national coverage (see the Masters' thesis section below, in this report) if one looks at the market-leading products.

The problem with this is that the customer side finds it difficult to take advantage of the beneficial effects a national and regional exchange of information would mean for the clinical business and its patients/residents. The vendors' competitiveness is not only weakened when it comes to reaching out to the global market, but also on the basis of the home market.

In the long term, this can lead to an undermining and erosion of Swedish industry's innovative capacity, plus reduced vendor offerings when the healthcare provider needs to procure clinical and administrative IT systems.

One of several reasons why the standards have not become more widespread is that the knowledge and thus the demand is weak, which means that purchasers and vendors cannot financially justify a standards-based development for existing and new products. This may be due to that the knowledge and overview in terms of interoperability standards is in the early stages of its development. Another reason may also be that the previous focus was placed, to a large extent, on technical capabilities and less on the clinical/business' processes and need for development. In order to achieve the desired effects, the purchasers and vendors must reach a consensus view in terms of identifying and expressing the needs of the clinical practice, the vendors' part in the solution, and the funding that is required.

The results from the project provide an overview of how international standards can contribute to new and further development of the transboundary future healthcare information systems. However in order for this to become reality, a long-term stable national coordination, maintenance and funding is required.

Common standards facilitate for Swedish healthcare as well as for vendors of healthcare information systems and enable vendors to participate and compete in an international market. The delivery contributes to predictability, internationalisation and sustainability.

Business models should support both large and small healthcare providers and vendors, and the thresholds for implementing new, innovative solutions must be low while maintaining a high level of quality.

One conclusion is that continued coordination is necessary in order to achieve the desired effects for Swedish healthcare and social services care as expressed in "Vision eHealth 2025," among other places.

1.2 Background

The current status of healthcare information systems and interoperability in Sweden's County Councils and Regions

Today's healthcare environments include a number of healthcare information systems which need to be made more interoperable in order to obtain effective solutions for the healthcare system and replace a continued extensive handling of information on paper. This is, for instance, an electronic medical record and various laboratory systems for the exchange of electronic patient referrals and results, as well as the status of these. Other examples are the administrative systems such as finance and personnel systems that need to be integrated with the healthcare information systems. Within the various categories of systems, there are usually 2-4 different systems (and vendors) who dominate within the County Councils and Regions (see Appendix: *Compilation – Systems in the County Councils, 2015*; presented in Swedish only).

Most of these systems have been developed in Sweden or another Nordic country. In recent years, we have also seen a clear trend towards increased integration with medical systems such as Patient Data Management System (PDMS) and also integrations with independent process supporting solutions, such as Operations Planning and Delivery Support.

The integrations that currently exist and which in many cases have been in operation for a long time, consist in the vast majority of situations of the local solutions, and those developed especially for this purpose, i.e. to a very small extent are these based on established international standards, even if technical standards such as web services, XML and HL7v2 are common. The solutions are in most cases message-based and use "message brokers" for the converting of formats and transmission. In many cases, this is associated with high costs for development and maintenance. In addition, it makes the change to a new system more difficult (lock-in effects).

If instead, one would use modern solutions and international interoperability standards, this would most likely reduce maintenance costs and increase predictability concerning the costs as well as reducing the lock-in effects.

This applies to both technical as well as semantic interoperability. The problem is and has been to agree on uniform standards and implement them in a coordinated way. National coordination concerning integrations and standardised service offerings within areas such as the laboratory and radiology domains have also been weak during the past ten years. Interoperability is a capability that must be strengthened in order to support possible future Regional formations, and one ??that will facilitate healthcare providers having a freer choice of providers of medical support services.

Common standards facilitate the provision of care and make it easier for those carrying it out, they simplify the implementation for vendors who are developing healthcare information systems and they simplifies procurement.

This also gives the Swedish vendors greater opportunities to participate and compete in national and international market with the Swedish healthcare information systems solutions.

1.3 Mission and mandate

The assignment was awarded to Swedish Medtech via Vinnova and is a part of the national government's initiative and investment in Life Science.

StandIN's purpose and goals focus on the technical aspects of the healthcare information environment and thus supports the digital information management via technical interoperability. The mission includes clarifying the dependencies of the business/clinical and information perspectives for the technical aspects.

In parallel, the 3H3R project (SWElife) has a focus on the business/clinical operational requirements, on how the information management will be able to provide support for the systematic business development and research, based on semantic interoperability.

Taken altogether, the projects require that information shall be accessible and be understood by everyone involved for the operation of healthcare, healthcare planning, communication in the care pathway, monitoring/follow-up and research.

The projects have certain mutual interdependencies, which is clarified in the report.

1.4 Purpose, objectives, project goals, and beneficial effect according to the project plan

Purpose
The strengthening of Sweden's innovative capacity, competitiveness, and attractiveness.

Objectives and goals
Contribute – in close cooperation between healthcare/social care services, business, government, universities and other institutions of higher education – to the healthcare and social care of the future by developing a foundation for determining the framework for standards that contribute to:

- Provision of a support for vendors in their product development (ongoing further development, as well as new development).
- Support software for interoperability between different systems and solutions.
- Serve as a support in the establishment of requirements/specifications from the customers in a procurement.

Project goals

- Establish a framework of international standards, conventions[1] and coordinated implementation of these enabling interoperability for joint collaboration in healthcare and social care.
- The framework is aimed at facilitating procurement and the development of information systems for healthcare and social care services for municipalities, county councils, Regions and vendors.
- Identify what is missing in order to contribute to interoperability.
- Contribute to the preconditions for the business to manage, control, govern, and transform the business in order to attain good quality.
- Show examples that enable the business to establish goals and to measure the progress towards fulfilment of the goals.
- Identify one (1) national actor who will ensure that the framework of standards and guidelines are maintained and regularly updated (Identify expertise for a national expert in the area of interoperability and operational/management who can continuously monitor developments).

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1   Formal agreement on matters of common interest.

Effect and impact goals

- Healthcare information systems are made accessible for proper Interoperability.
- National coordination of a framework of standards and guidelines.
- Sweden takes a more active role in compliance with international standardisation efforts.
- Common standards facilitate the implementation of new solutions.
- Opportunities are provided for innovation for actors in healthcare and social care, including companies operating in Sweden.
- Increased availability of healthcare information systems for follow-up, information for research, development and quality assurance.
- Facilitates long-term maintenance.
- Preconditions are improved within healthcare and social care (see Appendix: *Example, how technical interoperability can contribute to good healthcare and social care;* presented in Swedish only) such as:
  - Patient/client and relatives' involvement
  - Transboundary information, irrespective of organisation
  - Increased patient safety
  - Business development

1.5 Limitations/restrictions

Limitations of the business areas for eHealth

eHealth is a term for information management within areas related to human health. The measures and business areas encompassed within eHealth varies somewhat depending upon the context. StandIN intends to cover business within primary municipalities, county councils/Regions as well as corresponding activities in non-public organisations. "Health and social care" is the composite term for all activities conducted pursuant to the legislation and principles of the Swedish Health and Medical Care Act (HSL), Dental Services Act and the Social Services Act (SoL). All operations under the Health and Medical Care Act, thus even municipal primary health and medical care, are included. Even activities pursuant to the Act concerning Support and Service for Persons with Certain Functional Impairments (LSS), Act concerning the Care of Young Persons (Special Provisions) Act and the Act concerning the Care of Drug Addicts (LVM), are included.

However, in this phase 1, StandIN has not delved deeply into all the operations carried out within the legislation mentioned above.

StandIN has chosen to avoid using any adopted term for only a part of the operational areas included, i.e. neither health and medical care, social services, nor health and social care. Instead, we have chosen the term "care" (*vård* in Swedish) as an independent separate term and prefix when describing the scope of the activities for StandIN. This area of activities is in relatively good correspondence with what is covered by the international term "healthcare."

Boundaries and limitation of the assignment according to the project plan

- Semantic Interoperability
- To deal with the work in progress in Sweden within the area (to be monitored and to be taken into account)
- To concretise the activities done within 3H3R
- Standards for Financial Management
- Standards for Personnel Management

Definition of Semantic Interoperability

Semantic interoperability, meaning common interpretation of information between actors, is handled primarily within the 3H3R project.

StandIN has been given the task to prepare a proposal on the framework of international standards that supports technical interoperability. Semantic interoperability is dependent upon technical interoperability and the standards used to achieve this.

One consequence of this dependence is that StandIN also includes, to a certain extent, standards for semantic interoperability in the framework of standards for the entirety included in this report.

Demarcation concerning the current work in Sweden

The mission of StandIN is to analyse international standards. Therefore, a general demarcation will not include specifically Swedish approaches.

Examples of the Swedish work which therefore is not included in StandIN's assignment include, inter alia: The National Information Structure (NI) which is managed by the National Board of Health and Welfare (Socialstyrelsen), National Service Platform (NTjP) which is developed and operated by Inera AB and RIV TA, which is a national framework of rules for connecting to NTjP.

Standards for financial and personnel management

Support functions for the healthcare activities in the form of processes for accounting/finance and compensation systems, plus personnel/payroll/scheduling and recruitment issues are not included in StandIN, as they often are generic and applicable in other sectors.

Interoperability in the Cloud

The discussions that have been conducted concerning interoperability in the Cloud usually have a different perspective than StandIN and deal with the ability of a specific system or component to move to or between different Cloud service providers. Systems and components that are written or modified in order to operate in the Cloud have the same capability for interoperability as if they are locally installed.

With Cloud or hybrid installations, it should be particularly noted that the Cloud provider supports open standard interfaces. This issue is particularly important with communication between different XaaS solutions (X as a service). There are several security issues which need to be dealt with, such as that support is available for the authentication and authorisation methods that have been decided upon, encryption, how the data storage occurs in the Cloud, secure communications to and from the Cloud, etc.

2 THE WORLD AROUND US

Several countries at the forefront in the use of eHealth have created national bodies in order to ensure coordination and information standardisation. This includes the following (among others): The Danish Health Data Authority/Sundhedsdatastyrelsen, The Norwegian Directorate of eHealth/Norska Direktoratet för e-helse (NDE), the U.S. Office of the National Coordinator for Health Information Technology. In the United States, work on healthcare information is largely driven by the Meaningful Use (MU) legislation with requirements for functionality and value in healthcare digitisation (see Appendix, *Knowledge of the world around us*; presented in Swedish only).

The majority of national and international projects within eHealth, has lacked business/clinical-based development applying standards as a ground. The epSOS Project (Smart Open Services for European Patients) achieved technical interoperability between the 17 countries but generally lacked business perspective for development of healthcare and social care services. After epSOS, an active leadership has occurred at the EU level from the eHealth Network with a reactivated eHealth Stakeholder Group as well as a Multi-Stakeholder Platform (MSP) and their Rolling Plan for Standardisation (2016).

2.1 Examples of work in progress

EU – eHealth Network and JAseHN
The eHealth Network is a network between the Member States (Ministries) and the European Commission, which among other goals has the purpose of promoting cross-border eHealth within the framework of the EU Patient Mobility Directive. The eHealth Network has established a 3-year plan (Multi-Annual Work Plan), which describes the main areas of work within eHealth that they are looking to work with, and to assist with this has established a 3-year project (Joint Action to Support the eHealth Network – JAseHN 2015-18) which is to prepare the basis for discussion for joint decisions. What is of great interest for Sweden is the collaboration platform (SDO Platform) between SDOs within eHealth (initially CEN, HL7, IHE, Continua, GS1 and IHTSDO) and national centres of excellence which is taking shape. This is intended as a meeting place where common requirements from the Commission and the Member States concerning standardisation should be able to be described and discussed with the standardisation bodies in an attempt to harmonise the standards that are being developed, in order to avoid gaps and overlaps.

EU – Connecting Europe Facility (CEF)
There is a funding mechanism within the EU, the Connecting Europe Facility, for projects and initiatives to propel developments. Within this program, there is a part that is concerned with pushing the development of eHealth between countries at a quicker pace. Sweden and 20 other countries have now applied for and will receive funding from the CEF to set up a National Patient Summary (*Patientöversikt*) and/or ePrescription (*eRecept*) services.

EU – The eStandards Project
An EU project that is in line with StandIN's areas of interest and conclusions is eStandards. The initiator of the project is HL7, CEN TC 251 and IHE. The project is further supported by the eHealth Network, including ISO TC 215, GS1, IHTSDO, IEEE 11073 and IMIA. The project has established overall objectives, for example:
- Together with stakeholders both within Europe as well as globally, establish a consensus on standards within eHealth, increase the exchange of knowledge, and support the widespread adoption of standards.

- Deliver an evidence-based "Roadmap" for consistency, iterative consolidation and broad acceptance of standards within eHealth, which will be launched by SDOs, eHealth Network, healthcare providers and industry/vendors.

The ambition is to strengthen Europe's voice and role within international eHealth developments. At the same time, the intention is to strengthen the bridges that have been built up over the Atlantic via cooperation around the guidelines for the "International Patient Summary" in Trillium Bridge and INTERPAS.

EU – Multi Stakeholder Platform (MSP) – Rolling plan for ICT Standardisation

The European Multi Stakeholder Platform on ICT Standardisation is a platform that the European Commission has set up in order to decide on standards and to advise on potential future needs for standardisation within IT. The MSP is much broader than only eHealth and encompasses all sectors. Representatives from the Member States and standardisation organisations are included in this constellation.

EU – The Digital Economy & Society Index (DESI)

The Digital Economy and Society Index is a composite index that summarises relevant indicators of Europe's digital capabilities while simultaneously it captures the EU Member States' digital development. DESI's structure is based on five fundamental dimensions: Connectivity, Human Capital, Usage of the Internet, Integration of Digital Technology, and Digital Public Services.

Europe is moving forward, even if the pace and rate of increase has slowed down a bit last year. Improvements occurred primarily in the areas of Connectivity and Integration of Digital Technology. The countries were grouped into clusters based on developments during 2015. The only country in Europe that has a negative trend compared with previous measurements is Sweden.

USA – Office of the National Coordinator for Health Information Technology (ONC)

ONC, which is part of the federal U.S. Department of Health and Human Services (HHS), started a process in 2015 called "The Interoperability Standards Advisory (ISA)" – which aims to coordinate the identification, assessment and evaluation of the "best available" interoperability standards and related specifications for implementation. The focus of the work is entirely on clinical information and applications in the healthcare process. The aim is to create a public list of eHealth standards, which also expresses the ongoing debate and consensus, and to describe the known limitations and dependencies. The list in and of itself is not exhaustive and is expected to grow incrementally in future audits. The list of standards can also be used for regulatory purposes, as part of a test or certification procedures, or as requirements/specifications for procurement – The list itself should however be seen as a document in order to create clarity, consistency and predictability. It can also "look ahead" so as to thereby influence the parties in a specific direction.

HIMSS – EMRAM

The Healthcare Information and Management Systems Society (HIMSS) is a cause-based global non-profit organisation dedicated to improving the quality of healthcare and its safety, cost-effectiveness and access through the best use of information technology and management systems. More than 11 years ago, the organisation created a model to assess the level of maturity in the use of information technology in healthcare – EMRAM (Electronic Medical Record Adoption Model) an 8-stage model, moving through stages 0–7. In many parts of the world EMRAM has been used as a benchmark for the modernisation of the healthcare information system; the County of Kronoberg in Sweden was one of the first healthcare system outside of the United States which attained stage 6. In Sweden, the discussion of EMRAM has stalled – unlike in our neighbouring countries, where Denmark and Norway is currently conducting a discussion of the model and maturity targets at the national level.

During 2017, the requirements in EMRAM will be tightened up significantly where the focus will be shifted from technology to functionality obtained in the activities. The purpose of the changes is to further improve the functioning of the healthcare IT system where one has identified risks and needs. While simultaneously, it provides a uniform scale for both the EU and the US.

3 OVERVIEW, APPROACH AND PROCESS

3.1 The framework of standards for the entirety

In order to ensure traceability to the needs of the business and to highlight how technical interoperability has its place in a context, StandIN analysed a number of frameworks for architecture. StandIN has primarily used 3.0 Zachman, TOGAF 9.1 and the healthcare specific eHAM (ISO TR 14639-2:2014). StandIN was founded on Zachman and a simplified matrix was made in order to show how and where the standards fit into place. For space reasons, only examples of some of the analysed standards will be discussed.
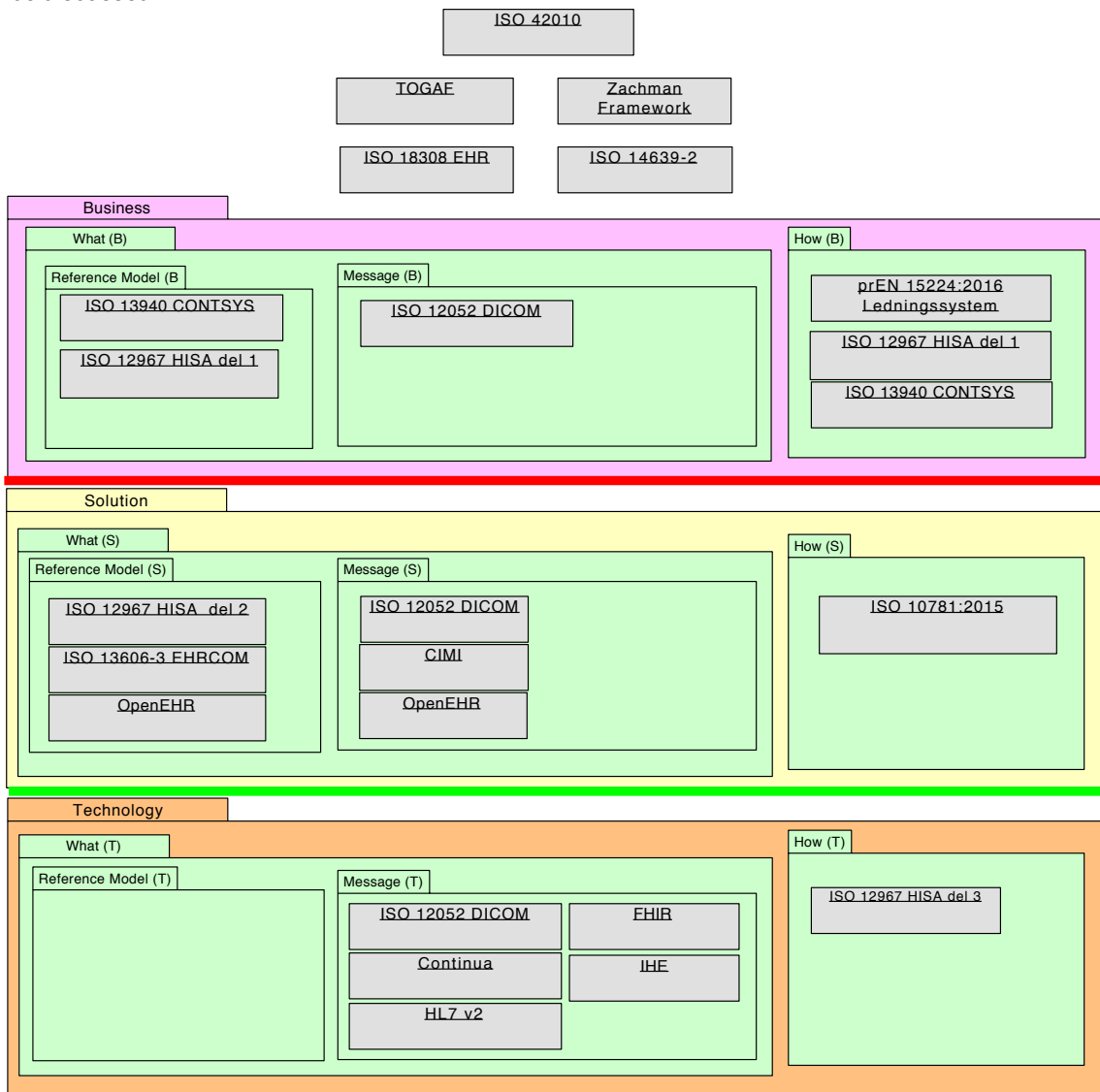

Illustration 1: Examples of standards in a simplified Zachman model.

Illustration 1 shows the three main levels (rows) in a framework which constitutes the description of a potential architecture of a healthcare information system including some examples listed. The image is a simplification of Zachman's framework describing the different elements that should be included in an architecture. The three levels described are:

- *The Business,* containing a description of the business to be supported. The descriptions consist among other things of definitions of goals, process- and flow models, concept models and needs for information. The business/clinical perspectives are described completely independent of any solution (informatics and/or technical) and are intended to be used for both development of the business and as a basis for establishing requirements concerning IT (e.g. in a procurement).
- *Solution,* containing a logical solution for the needs that have emerged in the description of the business, consists among other things of the reference information model (RIM), message models (such as archetypes) and functional descriptions. This description is completely independent of the technical solution.
- *Technology,* description of how the logical solution is to be implemented in the selected technical solution, consists among other things of database models, message notification/specifications, technical communication interfaces, etc. StandIN has not identified any standard for a database model.

Additionally, the architecture model contains two parts which express WHAT is to be managed and HOW it is to be managed. WHAT in turn, is divided into two parts: Reference Model and Message.

- *WHAT* contains for instance (top to bottom): Concept Models, Information Needs, Information Models, Message Models (e.g. archetype descriptions), database models and message specifications (e.g. in XML)
- *HOW* contains, in a corresponding manner, for instance: Process Models, Flow Models, Functional Models and Service Descriptions.

It is essential that traceability is contained in the descriptions all the way from the technology level up to the business level, and vice versa.

Based on the above division (Fig. 1) we have placed the standards we looked at in each respective cell (combination of row and column). This is a great help in determining where the standard comes in and what its main purpose is. Since our focus is on health, we have also gone further and placed standards into the eHAM framework which is described in section 5.3.

The simplified diagram above illustrates the main features of the approach and the emplaced standards are just a few examples of the standards we have analysed in the project. Note that some standards manage all three areas of the business, solution and technology.

## 3.2 Technical interoperability in StandIN

Semantic and technical interoperability has interdependencies. Both of these aspects of interoperability also have dependencies and an impact on healthcare business such as in organisational interoperability. Both semantic and technical solutions regarding interoperability must therefore be directly traceable to the descriptions and requirements in a business/clinical perspective.

Interoperability can be described as the ability of systems, organisations or business processes to work together and communicate with each other via that agreed rules are followed (National Information Structure, National Board of Health and Welfare).

Interoperability is divided into four types:

- Legal interoperability
- Organisational interoperability
- Semantic Interoperability
- Technical interoperability

In the StandIN project, technical interoperability is defined as the digital application and the care and service specific infrastructure that is implemented to support the business processes and information needs in a collaborative architecture.
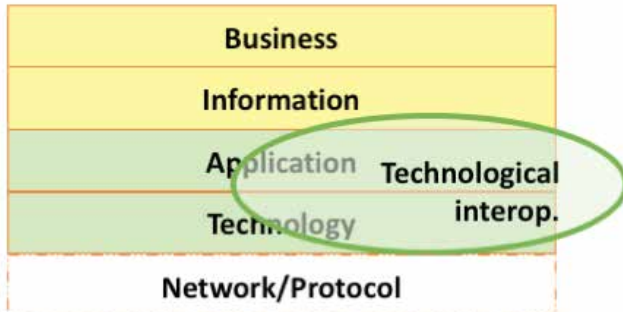
Explanation of the definitions:

- The *digital application* refers to applications (information systems)
- *Healthcare and social care specific infrastructure* means we are not looking at the overall infrastructure standards (e.g. communication standards such as http/https).

StandIN has focused and enhanced descriptions of international standards for the technical aspects for the future healthcare context and its traceability vis-à-vis the business' perspective. (see Appendix, *ISO 13940/Contsys as the basis for information management – Consequences for the technology perspective;* presented in Swedish only)

3.3 Enterprise Architecture based on Contsys

International standards for the business/clinical perspective have largely been lacking until now. Therefore, StandIN has made use of the reviewed and updated global ISO 13940 standard (published in 2015) with the designation "Contsys."

Development and/or procurement of information systems in healthcare is strongly linked to the healthcare business. Information management in healthcare can help to improve quality for patients and the entire social welfare system in many different ways and from various perspectives. For this potential to be realised, it is required that the future healthcare information systems are based on and interact with all of the aspects of the health and medical care business that can contribute to better quality. StandIN uses the international standard Contsys with the concept system and model of the clinical process as the basis for describing the business/enterprise architecture, which the future healthcare information systems will operate within.

Concerning factors that one needs to take into account for the development of an IT support, people generally speak of three different perspectives:

- *Business* – primarily the direct care of patients/clients but also management and organisational aspects.
- *Information* – how does one organise/categorise/specify the information needed in order to manage, conduct, monitor, and follow up the healthcare activities/operations.
- *Technology* – which technical solutions should be used to store, communicate and reuse information.

These three perspectives have clear links and interdependencies. Only when all three perspectives can work together as a whole, is it possible for an IT support to optimally support the operations. The mutual dependencies are bidirectional as follows:

- Information management is dependent upon the requirements from the business/clinical perspective.
- Technology is dependent upon the requirements from the information perspective.
- The business perspective is dependent upon the possibilities in information management.
- The information perspective is dependent upon the possibilities within technical solutions.

The conclusion of these interdependencies is that the business/clinical perspective is the foundation for building up an IT support. The more comprehensive, consistent and systematically the business perspective can be described in order to clarify the needs of information and technology, the better the preconditions will be in order to establish an efficient and well-functioning IT support. Via the business perspective, a clarified meaning and an understanding of the information is provided, and as such, it can be said that "one converts information into knowledge". This results in the information having an increased value.

A more detailed description of an enterprise architecture based on Contsys is described in appendix to this final report (refer to the Appendix: *The Future Healthcare – The future healthcare information system;* presented in Swedish only)

In addition, a brief description of which consequences Contsys specifically may have for the technical perspective which constitutes the focus of StandIN is included (refer to the Appendix, *Contsys and the technology perspective;* presented in Swedish only)

4 CHANGE MANAGEMENT

4.1 Background

The future healthcare will be conducted in an increasingly changing environment where knowledge and prerequisites are in a constant and rapid state of change. The future healthcare information systems will need to fulfil the requirements concerning how information management is to support, control and optimise the development activities in a systematic and structured way.

The mission statement of StandIN has this aspect included by the concept of change management. A term for this concept, which is more commonly heard in the context of healthcare, is operational/clinical development.

The project interprets change management to be a prerequisite for conducting quality care needed to be included in the description and requirements for future information systems. Change management for quality care is equated with systematic quality management – and the requirements for such are formulated in standards for quality management systems (prEN 15224:2016) and for Sweden in accordance with the National Board of Health and Welfare Regulation (SOSFS 2011:9).

4.2 Standards for change management

StandIN has applied the ISO 13940:2015 (Contsys) standard as a basis for business/operational perspective/architecture upon which the future healthcare information system can be built up. In order to the future healthcare to be able to be developed and optimised, with the support of and in tune with the future healthcare information system, a common model of the clinical operations is needed. Contsys can, via a system of concepts and a clinical processes model, provide this common foundation.

The generic standard for quality management systems is ISO 9001:2015. For healthcare, there are sector-specific concretisations and supplements in the pr-EN 15224:2016 standard. The latter is compatible with the concept world and process model in Contsys. Additional guidance for the particular Swedish situation is provided in the technical report, SIS-TR 49.

4.3 The interrelationship between change management and information systems

Preconditions for effective change management with the support of a health information system can be created, if both are based on the descriptions of the business as defined in Contsys. Illustration 2 below shows this relationship.
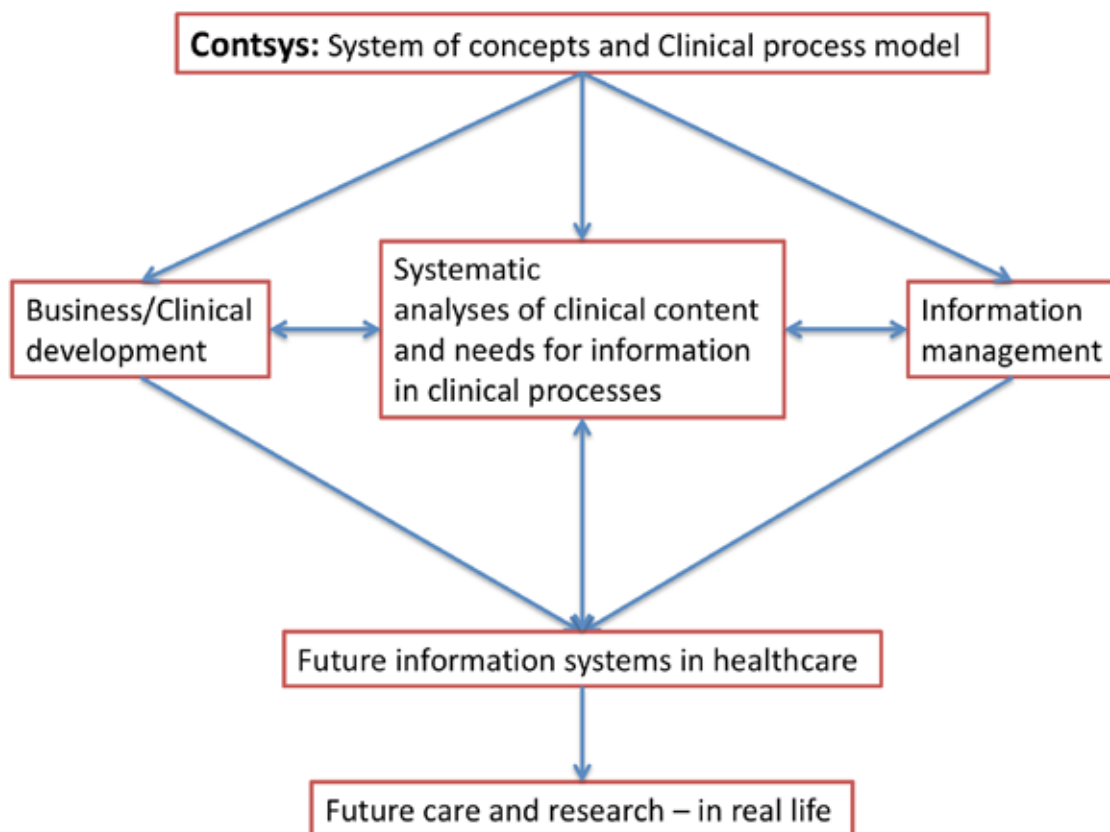
Illustration 2: The diagram shows StandIN's descriptions how the development of the business- and information management can be integrated in a systematic and structured approach.

4.4 Change management and clinical processes

The common denominator in the relationships between change management and healthcare information systems is the focus on clinical processes, in which patients and healthcare professionals interact together around the patient's health issues. It is in analysis, knowledge management and information management for collaboration and monitoring of clinical processes where the core is found. The link to the actual impacts and consequences, and increased quality, lies in the management of clinical processes.

4.5 Examples of change management from the healthcare business – a summary

In the Appendix, *"Examples of healthcare management of the business development"* (presented in Swedish only), examples of approaches within change management are described, and how these relate to the general approach described above. The examples highlighted are:

- Collaboration and cooperation between organisational units
- Application of a Quality Management System
- Lean production
- Value-based care

- Continuous improvements
- Patient Safety Efforts
- Standardised care processes within oncology care
- Mapping and analysis of clinical processes.

These examples are described very briefly concerning their purpose and approach. Each example is also related to the above-described general strategy for change management/ business development. In future work, these should be harmonised with the proposed framework.

4.6 Conclusions for change management

One conclusion from the above is that change management can certainly, and quite appropriately, be integrated into a strategy that focuses on clinical processes based on Contsys and the requirements for quality management systems. If the future, where healthcare information support systems aim also to support change management, Contsys should be the basis also for information management.

5 APPROACH IN THE SELECTION OF STANDARDS

Initially, a gross list of standards assessed to be possibly relevant was developed. The selection was based on that the standards would either be relevant to healthcare or be overall architecture standards that would help us to see the big picture and ensure traceability in technology activities. The selection was based partly on the experience held by the group obtained over many years of participation in international standardisation and application of standards as well as in the development of systems. In these standards, references were also found to other standards, which in turn were analysed. Additionally, international works which referenced standards were studied (e.g. Office of the National Coordinator for Health Information Technology (ONC) and the Multi Stakeholder Platform (MSP). The group's professional networks were also contacted for additional suggestions for standards. StandIN's list of standards may be increased in the course of further work.

Based on this gross list, a description of these standards was produced. This description then formed the basis for a selection process in order to identify the standards to be described in greater detail. In the analysis was assessed which ones were relevant to StandIN in general, irrespective of the level of interoperability/perspective. The purpose of this was to identify the standards considered to be necessary for the purpose of ensuring traceability between the activities and technology, i.e. managing the entirety. After that, a further delineation with an in-depth description of the related technical interoperability was made.

- In total, some 70 standards were analysed (Illustration 3). Of these, 45 have been deemed relevant and should be regarded as our delivery of a framework. Of the 45, 27 are described briefly (see Appendix, *Relevant standards that do not relate to the technical interoperability;* presented in Swedish only) and 18 of these standards are relevant and relate to technical interoperability (see Appendix, *Standards for Technical Interoperability;* presented in Swedish only).
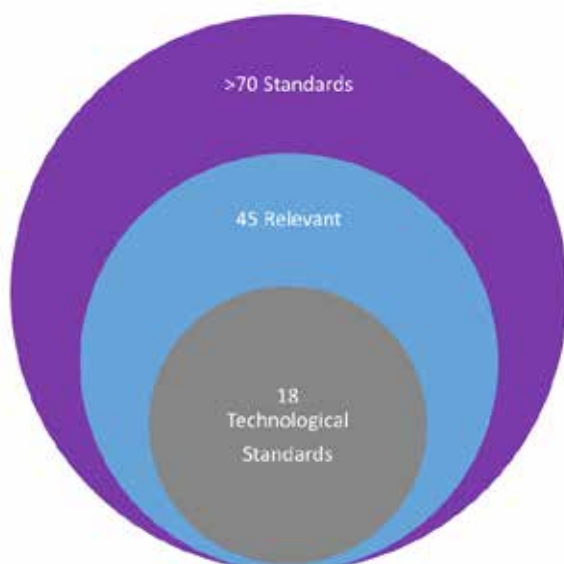

Illustration 3: Standards and conventions for Interoperability (IO)

The criteria used in the assessment, of which one or more must be fulfilled (the 45 standards), are as follows:

- Be a standard (ISO, HL7) and/or which are disseminated widely and is used as a convention (IHE, openEHR).
- Be international (standards/conventions which only apply in e.g. USA or Sweden were excluded).

- Be current and to be further developed (e.g. via that implementation specifications are available or developed).
- Be future-proof, i.e. that they will be available over a long term or alternatively are currently extensively used (e.g. HL7v2) where it is assessed that they will not be replaced in the immediate future.
- Describes a manner to fit into an overall picture (city map/eHealth architecture) e.g. eHAM or TOGAF.
- Be specific for healthcare (except for TOGAF, ISO 42010, Zachman), e.g. general protocols were excluded.
- Have the possibility to correspond to requirement of dependencies and traceability, between layers of interoperability, (Technical interoperability – Semantic interoperability – Organisational/Business interoperability).

Those which have been more deeply explored (18) shall thus apply to the care-specific technical interoperability.

5.1 Concept Model of the basic concepts in StandIN's delivery

In order to obtain a common and uniform picture of what will be delivered, a concept model has been developed (Illustration 4). In addition, they are matched and harmonised with the ISO 42010 standard, which is a standard specifying how architectures and frameworks are to be described.
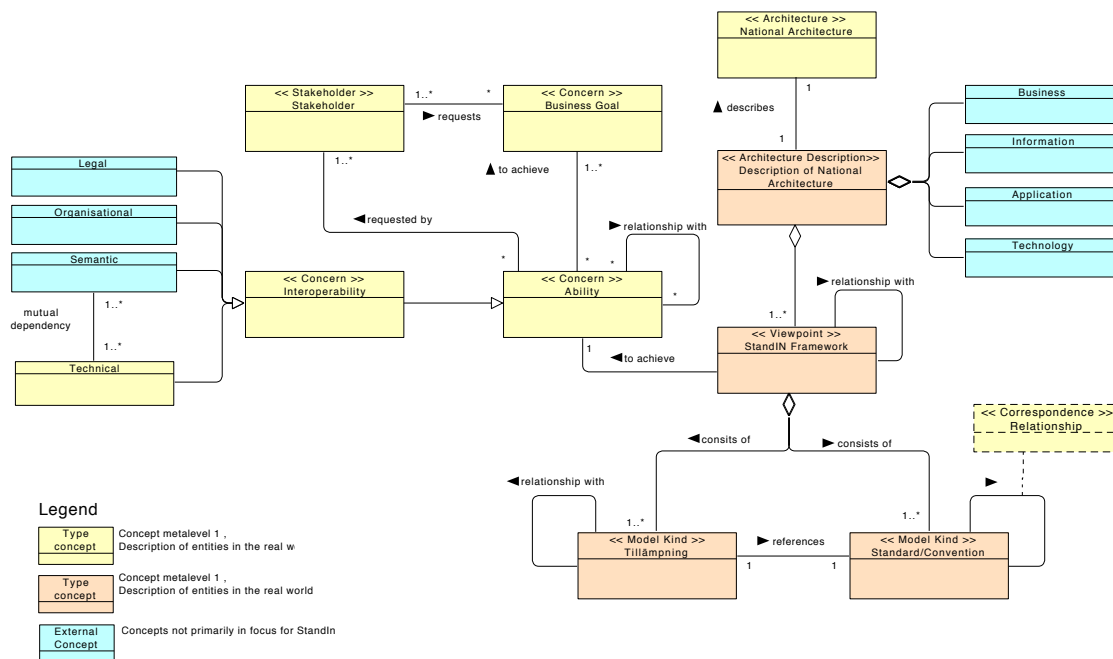

Illustration 4: Conceptual Model

The model shows that the StandIN Framework consists of Standards/Conventions and Applications of these in order to achieve Abilities, specifically Interoperability (especially Technical Interoperability). An Ability, in addition to the requirements and demands relating to interoperability, can be of various types, e.g. goals, objectives, needs. This is always expressed by a Stakeholder (an individual, organisation or another system). An Ability must always achieve at least one or more Business Goals. One example of a Business Goal may be ensuring that the patient is to be involved and be able to read their healthcare information.

- The StandIN framework is only part of a larger Description of a National Architecture. It could be, for example, a national architecture for eHealth in Sweden. In addition, the StandIN framework includes several other dimensions, such as Business, Information, Application and Technology. Such a description of the national architecture can for example be expressed with Zachman's framework in (see Appendix, *Concep Model of StandIN's framework*; presented in Swedish only)

5.2 Flow Model
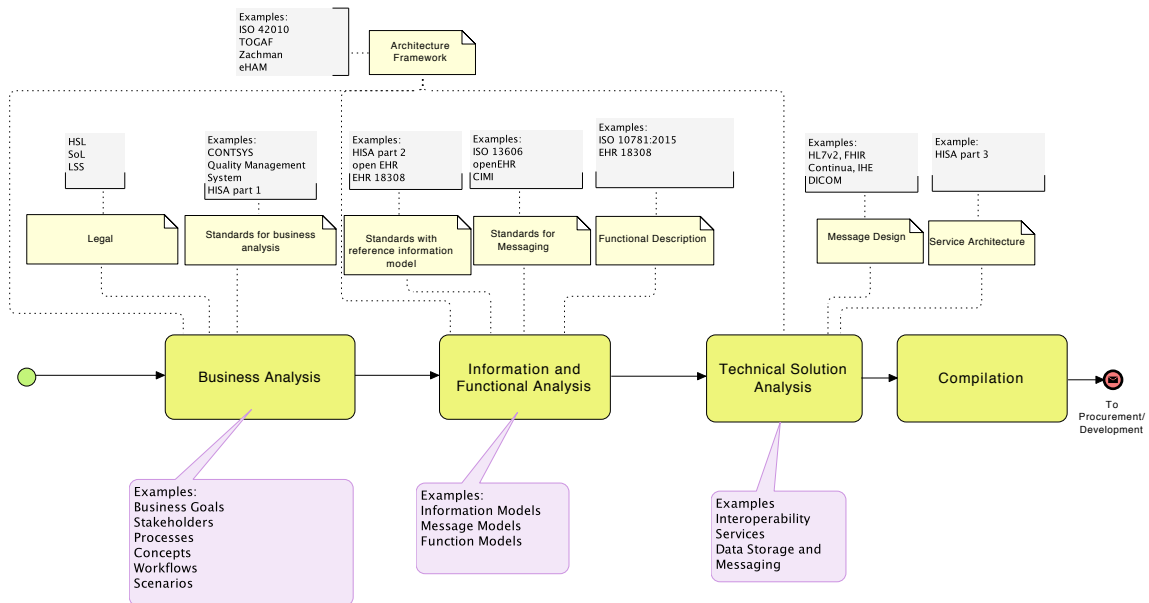
Illustration 5: An example of how the standards can be incorporated into a potential workflow.

As an example of how standards can be incorporated into a potential workflow describing a procurement of a healthcare information system, is illustrated in the above simplified flow model. The illustration is only a simplified example for the purpose of illustrating where the different standards can contribute and is not a proposal, nor a suggestion, of how such a process should be conducted.

In the first step, the Business Analysis, standards such as Contsys, HISA Part 1 and Quality Management Systems are relevant. In the second step, Information and Functional Analysis, are Informatics standards such as ISO 13606, EHR ISO 18308, ISO 10781:2015 and HISA Part 2, will be relevant. In the third step, Analysis of the Technical Solution Analysis, IHE, HL7,v2 and DICOM-Continua and HISA Part 3 is relevant.

The third step is the main focus for StandIN but is dependent of the results in the previous steps. This is also described in the traceability requirements of the Zachman model.

6 RESULTS

6.1 List of technical standards for technical interoperability

The 18 standards we have deemed relevant for technical interoperability, according to the criteria described in the above approach (see Appendix: *Standards Relating to Technical Interoperability*; presented in Swedish only).

Designation	Name	Description
CCOW	Clinical Context Object Workgroup	Aimed at minimising the risks of mixing up patients. Means that applications cannot simultaneously present information for different patients on the user's monitor
CDISC	Clinical Data Interchange Standards Consortium	Comprehensive framework of standards within biomedical and clinical research.
Continua	Continua Design Guidelines	Aimed at facilitating the connection of personal medical devices in the home with the healthcare principal's healthcare information system.
FHIR	Fast Healthcare Interoperability Resources	FHIR is designed to enable the exchange of health-related information. This includes clinical data, health-related administrative data, as well as public health and research data.
HL7 v2	ISO/HL7 27931	This communication standard allows the exchange of clinical data between systems.
HL7 v3		HL7 v3 is a suite of specifications based on the HL7 Reference Information Model (RIM) and allows developers to work with the full set of messages, data types and terminology needed to build a complete implementation.
IHE	Integrating the Healthcare Enterprise	Composed of a number of profiles that describe specific solutions for integration. A profile documents how existing ISO standards are to be used by each system's actors, so that they can work together to resolve the problem.
ISO 12052:2006 Health informatics – Digital imaging and communication in medicine	DICOM	Used for the exchange of digital images and information related to the production and management of these images, from both medical imaging equipment and systems involved in the management and communication of this information.
ISO 12967-3	HISA Part 3	The standard describes a number of services and their interfaces at different levels. These correspond to both the information model classes (ISO 12967) and system-wide services.
ISO 13606-4		ISO/TS 13606-4 is intended to solve the requirements which are imposed with the communications of specific EHR information to the systems for access, and identifies the technical solutions and the required standards of services in order to satisfy these security requirements.
ISO 13606-5		ISO 13606-5 relates to the specification of the information architecture for interoperability at the communications level between systems and services that manage EHR data.
ISO 18812:2003	Clinical analysis interfaces to laboratory information systems	The standard specifies the general messages for the exchange of information between analytical instruments (AI) and laboratory information systems (LIS).

ISO 21090:2011	Harmonised data types for information interchange	ISO 21090:2011 provides a set of data type definitions in order to represent the exchange of basic concepts that often occurs in healthcare.
ISO 21091:2013	Directory services for health-care providers, subjects of care and other entities	ISO 21091:2013 defines the minimum requirements for directory services in the healthcare industry. It can be used to establish communication between organisations, devices, servers, application components, systems and technical actors.
ISO/IEEE 11073	Health informatics – Medical / health device communication standards	The purpose of 11073 is to facilitate communication between medical devices in eHealth and external IT systems through data capture of measurements and values and other patient-related data plus technical information from the device.
ISO/TS 22600-1&2&3:2014	Privilege management and access control Overview and Policy Management Formal models Implementations	Objective of the standard is to support the exchange of information within an organisation (intra-domain) or between organisations (inter-domain) with different security domains within healthcare.
OpenEHR		Aims to specify the clinical information in a systematic and structured manner through archetypes in order to enable semantic and technical interoperability.
UDI	Unique Device Identification	Enables the traceability of medical devices (MT)

6.2 List of standards relevant to the whole (except technical interoperability)

The 27 standards we have deemed to be relevant in the overall perspective but which are not intended specifically to relate to technical interoperability. Here are architectural standards, standards for semantic interoperability, description of the business, management system, security and identification, etc. (see Appendix: *Standards Relating to Technical Interoperability*; presented in Swedish only).

Designation	Name	Description
CIMI	Clinical Information Modeling Initiative	CIMI is attempt to solve a number of issues concerning semantic interoperability which openEHR, 13606, HL7 DCM, FHIR have attempted to resolve.
HL7 Genomic Testing Report (GTR) (DSTU)		Complements the disease history with genetic information.
ISO 10781:2015	EHR-system Functional Model (EHR-S FM)	ISO 10781:2015 includes a list of functions that may need to be contained in a medical record system.
ISO 11238		Information Model for substances, in pharmaceutical drugs for instance.
ISO 11239		Information Model for dosing, packaging, etc. for pharmaceutical drugs.
ISO 11240		Information Model for medical products.
ISO 11616		Identification of medical products
ISO 12967-1	HISA Part 1	Business Viewpoint – describes the clinical process and information needs for health care.
ISO 12967-2	HISA Part 2	Information Viewpoint – information model for healthcare based on ISO 12967-1.

ISO 13606 -1	Health informatics – Electronic health record communication – Part 1: Reference Model – CD Stage	ISO 13606-1 covers the overall reference model for patient journal components and how they are to be aggregated into a coherent document.
ISO 13606-2	Electronic health record communication – Part 2: Archetype Interchange Specification	ISO 13606-2 specifies requirements/rules for how archetypes should be structured in order to correspond interoperability requirements and describes a basic model of archetype called the Archetype Object Model (AOM).
ISO 13606-3	Electronic health record communication – Part 3: Reference Archetypes	ISO 13606-3 describes reference archetypes for specification of clinical content and context.
ISO 13940	Contsys	International standard for health Informatics. Process model and conceptual model for healthcare.
ISO 14199:2015	CDISC BRIDG v3.2	Concept model for biomedical and clinical research.
ISO 18308:2011		Requirements for an electronic health record architecture
ISO 21090:2011		Data type definitions for concepts of care.
ISO 27799:2008		Information security management in health and medical care based on ISO/IEC 27002
ISO 42010		This standard specifies the way in which architecture descriptions of systems are to be organised and described.
ISO TR 14639-2:2014	Health informatics -- Capacity-based eHealth architecture roadmap -- Part 2: Architectural components and maturity model	The standard provides a guide for developing the business requirements and principles for best practices to a country's, or healthcare authority's, planning and implementation of information and communication technology (ICT).
ISO/TR 20514:2005	Electronic health record – Definition, Scope and Context	Pragmatic classification of information in a healthcare information system.
ISO/TS 22220	Health informatics – Identification of subjects of healthcare	Identification of individuals in healthcare.
ISO/TS 25237:2008	Pseudonymization	Principles and requirements for protection of privacy via using Pseudonymization services for the protection of personal healthcare information.
ISO/TS 27527	Health Informatics – Provider Identification	Identification of healthcare professionals and healthcare organisations.
PRSS-EN 15224:2016	Quality Management System Requirements - ISO9001 with extensions for healthcare, to be applied as a healthcare quality management tool	Requirements for quality management. Published in 2012 as a European standard. Presently under revision (expected be completed sometime in 2016). Has a link to Contsys ISO 13940. Strong link to change management (business development)
SIS-TR 49:2015		Tutorial to develop and apply quality management in healthcare with the support of the PRSS-EN 15224:2012 standard and SOSFS 2011:9 – with a focus on the clinical perspective
TOGAF 9.1		TOGAF is an open group architecture framework that provides methods and tools to assist with the acceptance, production, use and maintenance of an Enterprise Architecture.
Zachman 3.0		Zachman is an architectural framework that provides the basic structures and an ontology to create a complete view of the architecture's different perspectives. Zachman is not a method and therefore does not provide processes or modelling language.

6.3 eHAM – A model for categorisation of standards

The framework of standards described on the basis of the eHAM

eHAM is a technical report from ISO that includes an architectural model for eHealth. In-depth description (see the Appendix, *The eHAM Model's Application in the StandIN Project*; presented in Swedish only)

This specifies the functional areas as well as the best practice requirements and principles which a country needs to manage in order to be able to provide Information and Communication Technology (ICT) in their healthcare systems. StandIN uses the model in order to create a comprehensive picture of the need for interoperability standards within the field.

StandIN uses eHAM in order to describe participants in a national eHealth architecture including all stakeholders needs for services and functionalities in a healthcare context. Thus, the model is also suitable to describe the interface between the participants' different information systems, which means that it is also possible to identify and describe the need for interoperability in the eHealth model's various healthcare domains.

eHAM also describes the basic components required in the information and infrastructure areas in a national architecture for eHealth. The section in eHAM which handles governance and national ownership is deemed to be not directly relevant to StandIN.
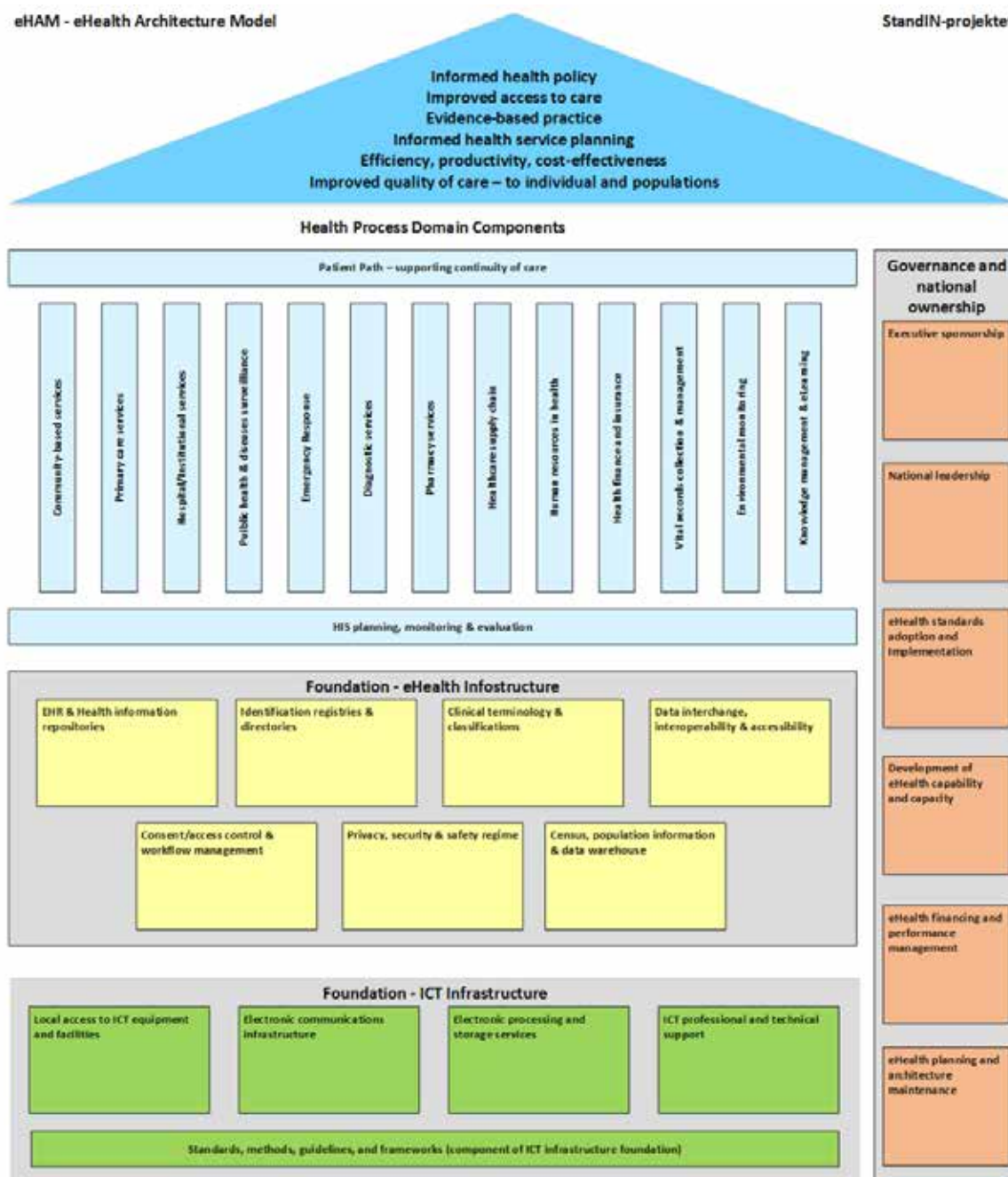
Illustration 6: eHAM in the original language

Identified gap

StandIN, has for each domain and/or component in the model, identified where our proposed standards can contribute to interoperability. This has primarily been done in order to identify any gaps. The conclusion StandIN can draw from this survey is that we have not found standards within more specific areas, such as home-based care and pre-hospital emergency activities, which are domains with high demands on mobility and interoperability. However, there is a relatively good coverage when it comes to information/infrastructure components (Illustration 7).

eHAM Model's Application in StandIN

eHAM - eHealth Architecture Model   StandIN-projektet

Informed health policy
Improved access to care
Evidence-based practice
Informed health service planning
Efficiency, productivity, cost-effectiveness
Improved quality of care – to individual and populations
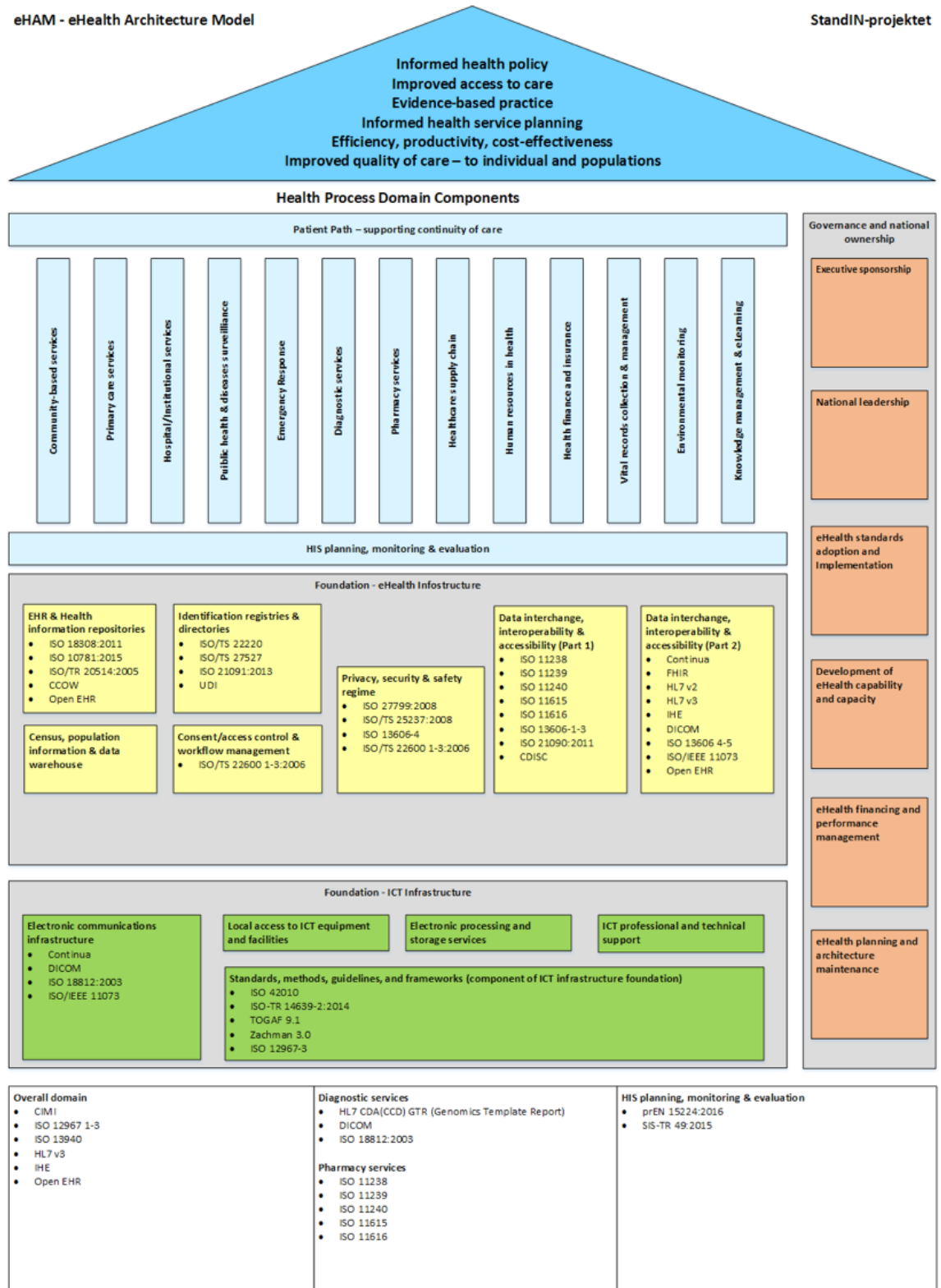
Health Process Domain Components

Patient Path – supporting continuity of care

- Community-based services
- Primary care services
- Hospital/Institutional services
- Public health & diseases surveillance
- Emergency Response
- Diagnostic services
- Pharmacy services
- Healthcare supply chain
- Human resources in health
- Health finance and insurance
- Vital records collection & management
- Environmental monitoring
- Knowledge management & eLearning

HIS planning, monitoring & evaluation

Foundation - eHealth Infostructure

EHR & Health information repositories
- ISO 18308:2011
- ISO 10781:2015
- ISO/TR 20514:2005
- CCOW
- Open EHR

Identification registries & directories
- ISO/TS 22220
- ISO/TS 27527
- ISO 21091:2013
- UDI

Privacy, security & safety regime
- ISO 27799:2008
- ISO/TS 25237:2008
- ISO 13606-4
- ISO/TS 22600 1-3:2006

Data interchange, interoperability & accessibility (Part 1)
- ISO 11238
- ISO 11239
- ISO 11240
- ISO 11615
- ISO 11616
- ISO 13606-1-3
- ISO 21090:2011
- CDISC

Data interchange, interoperability & accessibility (Part 2)
- Continua
- FHIR
- HL7 v2
- HL7 v3
- IHE
- DICOM
- ISO 13606 4-5
- ISO/IEEE 11073
- Open EHR

Census, population information & data warehouse

Consent/access control & workflow management
- ISO/TS 22600 1-3:2006

Foundation - ICT Infrastructure

Electronic communications infrastructure
- Continua
- DICOM
- ISO 18812:2003
- ISO/IEEE 11073

Local access to ICT equipment and facilities

Electronic processing and storage services

ICT professional and technical support

Standards, methods, guidelines, and frameworks (component of ICT infrastructure foundation)
- ISO 42010
- ISO-TR 14639-2:2014
- TOGAF 9.1
- Zachman 3.0
- ISO 12967-3

Governance and national ownership
- Executive sponsorship
- National leadership
- eHealth standards adoption and Implementation
- Development of eHealth capability and capacity
- eHealth financing and performance management
- eHealth planning and architecture maintenance

Overall domain
- CIMI
- ISO 12967 1-3
- ISO 13940
- HL7 v3
- IHE
- Open EHR

Diagnostic services
- HL7 CDA(CCD) GTR (Genomics Template Report)
- DICOM
- ISO 18812:2003

Pharmacy services
- ISO 11238
- ISO 11239
- ISO 11240
- ISO 11615
- ISO 11616

HIS planning, monitoring & evaluation
- prEN 15224:2016
- SIS-TR 49:2015

Illustration 7: StandIN's standards are inserted in StandIN's translation of eHAM into Swedish

eHAM adaptation based on Contsys – example

Within StandIN, an architecture model for eHealth which has been taken from a technical report from ISO with the official name "ISO/TR 14639-2:2014 – Health informatics - Capacity-based eHealth architecture roadmap – Part 2: Architectural Components and Maturity Model," (eHAM) is used.

This model has been assessed to describe, in a clear and relevant way, the perspectives for information and technology within eHealth. However, as it concerns the content and description of a business/enterprise architecture for healthcare, there are objections. eHAM, as presented in the technical report, does not provide a complete and comprehensive business/clinical perspective.

ISO 13940 – Contsys with the system of concepts and model for the clinical process is the basic standard for enterprise architecture within the field of international health informatics. From this background, this report shows how eHAM can be supplemented by application of Contsys.

eHAM and Contsys
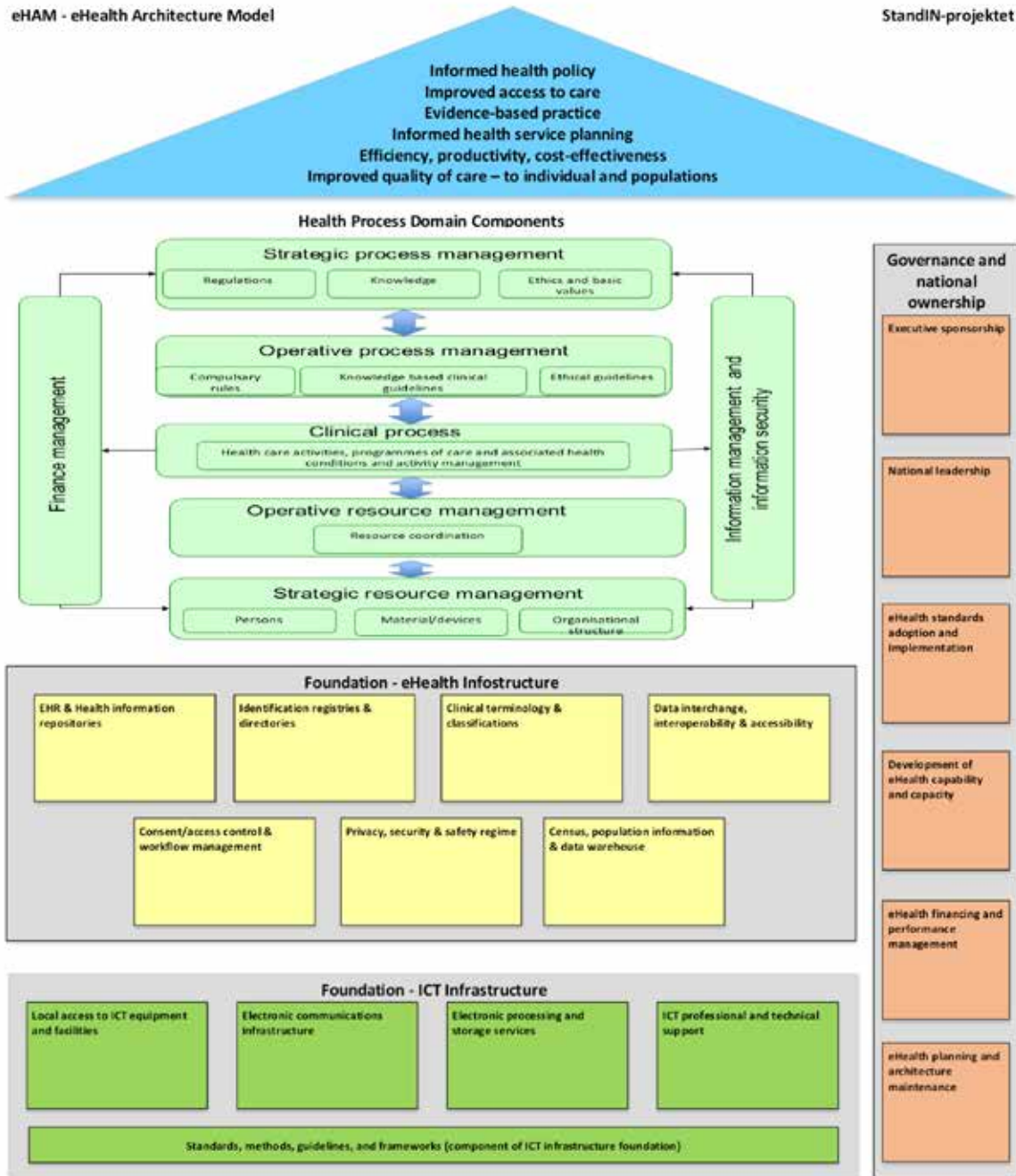
Illustration 8: The upper blue layer is now replaced with an architecture model from Contsys.

This alternative business model is shown above (Illustration 8), in which patients and healthcare providers work together concerning the management of the patient's health problems, has the clinical process in the centre. Management and control of the clinical processes with a focus on knowledge management is shown above the clinical process. The two upper layers represent different degrees of concretisation in relation to the clinical process layer. In addition, ethical guidelines and other rules, such as regulations, are illustrated within management and governance.

From below the clinical process, the supporting functions are shown. The different organisational structures the various healthcare systems apply are included here (for example, primary care and hospital units), as well as human and material resources.

Alongside these horizontal fields are two areas that are important for all processes (clinical processes as well as management and support processes) – information management and financial management.

The content of information management and the relationship to the processes is one of the basic foundations of eHealth. Note that the information management includes the following information for the different purposes:

· for cooperation with continuity and interoperability relating to the individual patient

· for follow up and supplementation of the knowledge base and knowledge management

· for the monitoring of the utilisation of resources and the basis for the management of resources.

Concretisation in an expanded national reference architecture
The Interoperability is an ability within an overall architecture which is created in order to fulfil the stakeholder's objectives. In order for purchasers and vendors to be able to concretise a common architectural solution, the interoperability needs to be set in a context, which in this case may suitably be described as part of a national reference architecture for the future eHealth environment. The reference architecture should be built around the clinical processes, workflows and be concretised in use cases, similar to a IHE profile, but with a more adequate granularity. This would make it easier for all stakeholders to understand the role they play in a national architecture and why a specific eHealth standard must be followed.

6.4 Feasibility Example – The clinical process for congestive heart failure

Approaches and the congestive heart failure process

For the purpose of clarifying how the standards analysed can contribute to the provision of information in a specific situation (ability to be implemented), the congestive heart failure process has been chosen. The reason for this particular choice is that many in the project team have previously worked in analyses of this type of clinical process.

The process is described on the basis of Contsys' basic process model and concepts. The two levels of interoperability are illustrated via two objects, semantic interoperability and technical interoperability, in order to later connect each respective standard to the corresponding level. The information is taken from a virtual data store, which in turn is to be created by services for technical interoperability. The virtual data store can be compared with the middleware level that is described in HISA (ISO 12967). Initially the different steps in the process to obtain information from the virtual data store is described:
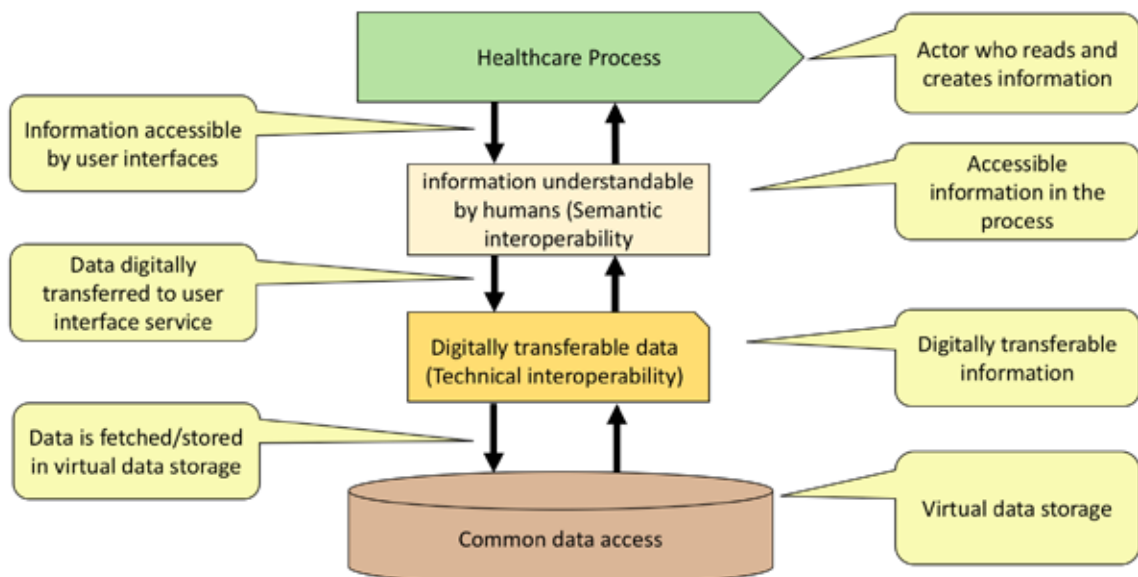

Illustration 9: The different layers from the virtual data store to the business process

Illustration 9 also shows that the interoperability has two parts, the format which is to be transferred and the transfer in itself which requires a service. These services and their interfaces are described in HISA Part 3. However, we have focused on the standards for the format in the information/data sets that have been transmitted in our feasibility example.
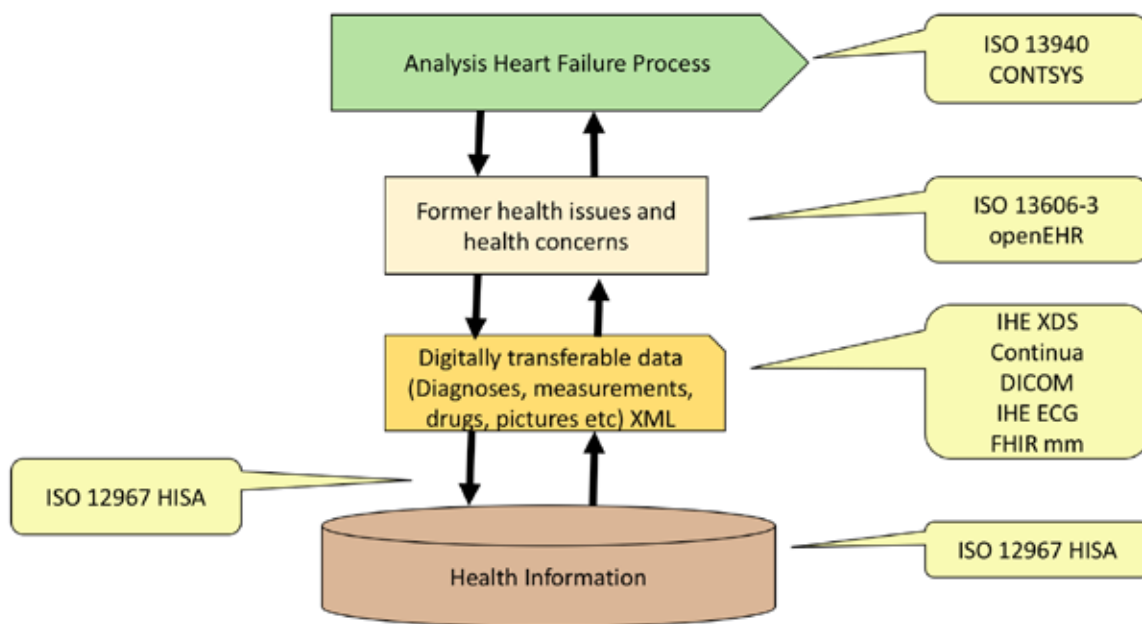
Illustration 10: Examples of standards that support the different layers

StandIN has identified the standards that support the different layers, but we have focused on technical standards for interoperability. The project has analysed the need for information (at an overall level) for each step in the process in order to find the standards for technical interoperability that support these information needs. As many of the information needs are complex, several options will arise. These options can also point to underlying standards such as e.g. various IHE profiles, often referring to HL7. The profiles of the technical framework (IHE) describe the standard processes where the actors (the systems) are to use existing standards for its transactions in order to achieve interoperability. One of these profiles, IHE XDS, is used to share documents in any format (e.g. PDF).

In this delivery however, time was not available to specify in detail the processes' need for information and associate standards to each elementary amount of information. This is work that is proposed be done in a continuing mandate in order to obtain a more thorough feasibility study.

In this work, information needs in the process have also been identified where we have not found international standards for technical interoperability. This applies above all to coordinated care planning with home-based care services as well as the self-care activities done within the in-home care.

The detailed description of the process is described in an appendix (see Appendix: *Feasibility Example – The congestive heart failure process;* presented in Swedish only).

The virtual data store
The big challenge is to obtain access to all the information needed in the process irrespective of where it is geographically and what provider/vendor system it is in. In order to conduct the analysis, we have used ArchiMate, which is a notation to describe the architecture developed by the Object Management Group (OMG).
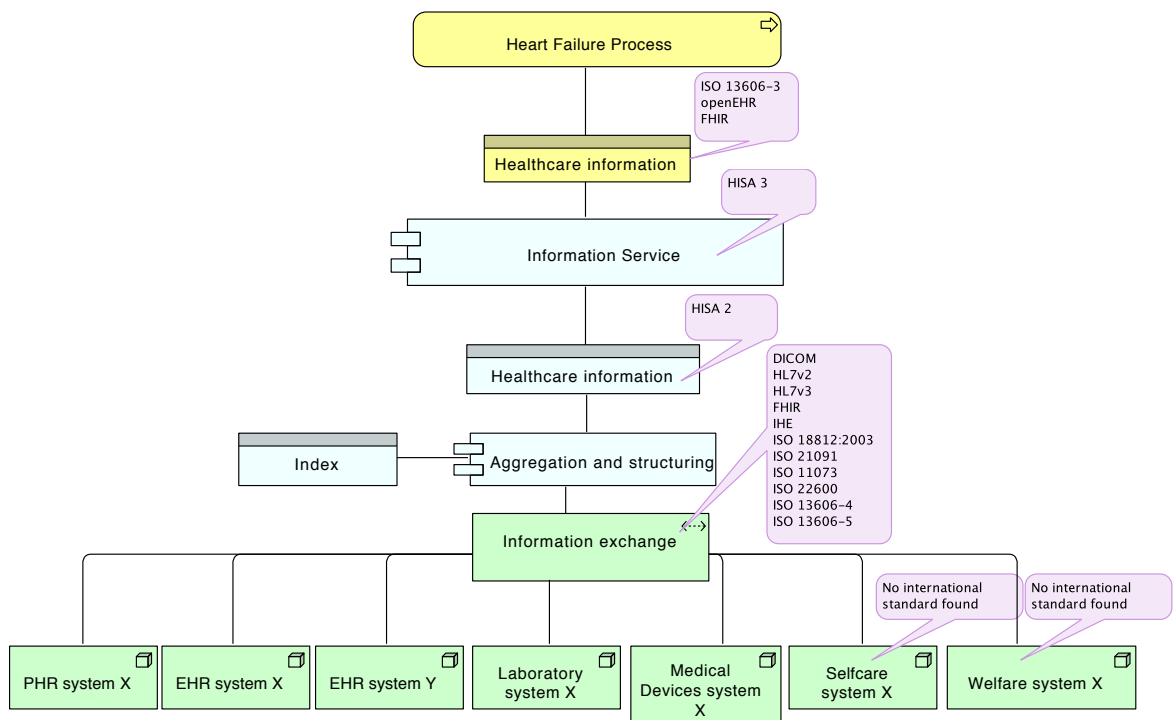
Illustration 11: Simplified architecture for a common virtual data store

Illustration 11 shows how architecture can contribute to a common virtual data store. Based on various source systems, there is a transboundary communication of data in a uniform manner with the assistance of a number of identified standards. This is then aggregated and structured in a service via an index and a virtual data store is created based on the information structure in HISA 2 (ISO 12967-2) and the service architecture in HISA 3 (ISO 12967-3), the future audits which are based on Contsys. This can then be used later by the service(s) that correspond to the needs for the information that may be available, for instance the congestive heart failure process in its various stages.

Even here, StandIN has not identified international standards for the patient's self-care and the care system that includes data from in-home care or assistance services. For the other standards StandIN has identified, we have made the assessment that we can cover the need for information.

7 MASTER'S DEGREE THESIS[2]

7.1 The healthcare information system today

There is a current lack of information about how vendors of healthcare information systems (HIS) relate to the standards considered for the StandIN framework. There is limited information on both the knowledge level and the adaptation level regarding the relevant standard, which hampers the assessment of its degree of maturity. Therefore, a present-situation analysis was performed, by the means of a survey sent out to vendors of healthcare information systems and follow-up interviews. The vendors and the standards were based on the work of the StandIN project.

7.2 Method and results of the survey

The survey aimed to identify whether the standards considered for the StandIN framework were (1) well known, i.e. if the vendors had knowledge about them, (2) were adopted today, or (3) were planned to be introduced in the near future. The questionnaire also included questions about the reasons why certain standards are not applied. Moreover, it ought to assess the importance of different factors when introducing new standards or frameworks.

The questionnaire was divided into two parts; the first part contained questions about the knowledge and application of selected technical standards for interoperability, and the second part contained questions about to what extent and how much the various different factors affected the introduction of new standards and frameworks.

All the data from the first part of the survey has been collected in a database, together with information about which of the vendors supply systems in Sweden's county councils and Regions. The Pivot chart in Illustration 12 shows the county councils and Regions in which the different vendors have systems integrated. The information is taken from the SLIT Study in 2015 (see Appendix: *Compilation – Systems in the County Councils, 2015*; presented in Swedish only) and all county councils and Regions are included.

From the diagram, it can be seen that there is a large diversity in the number of county councils and Regions among the different vendors. Some vendors and are large and can be found in many areas, whilst others have few integrations concentrated in only a few county councils and Regions.
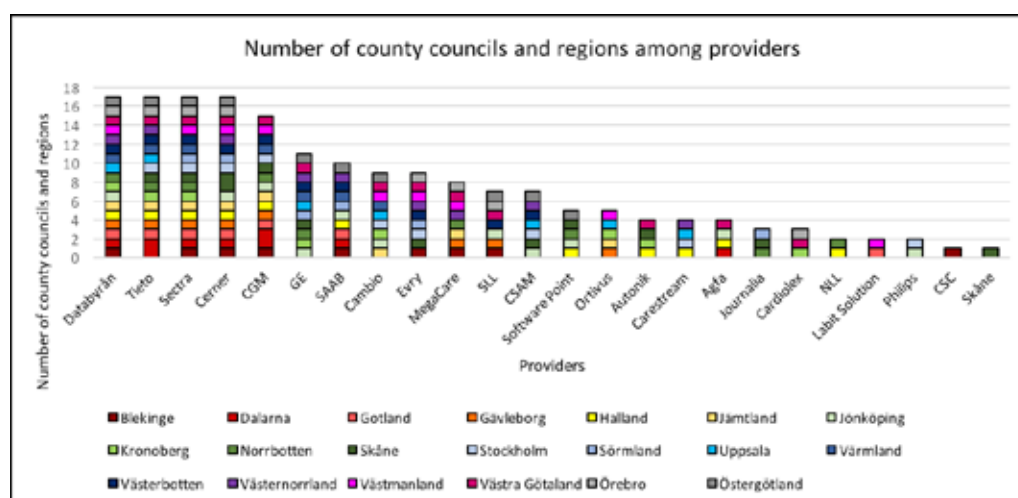

Illustration 12 Distribution of County Councils and Regions among a subset of HIS vendors Compilation systems in County Councils, 2015)

2   Anna Hagman

Illustration 13 shows a Pivot chart, created from the database, of the knowledge level the vendors have for the selected standards for technical interoperability. It can be seen that the knowledge level was high for all HL7 standards, including FHIR – which is not yet a fully established standard. The level of knowledge of CDISC is low, as is the case with UDI. More than half of the vendors have knowledge of Continua, however, all of them were large vendors with multiple kinds of systems. The level of knowledge for the ISO standards varied widely. The DICOM standard was the most well-known, followed by ISO 13606, parts 4 and 5. The vendors had the least knowledge about ISO/IEEE 11073, ISO/TS 21091 and ISO 18812.
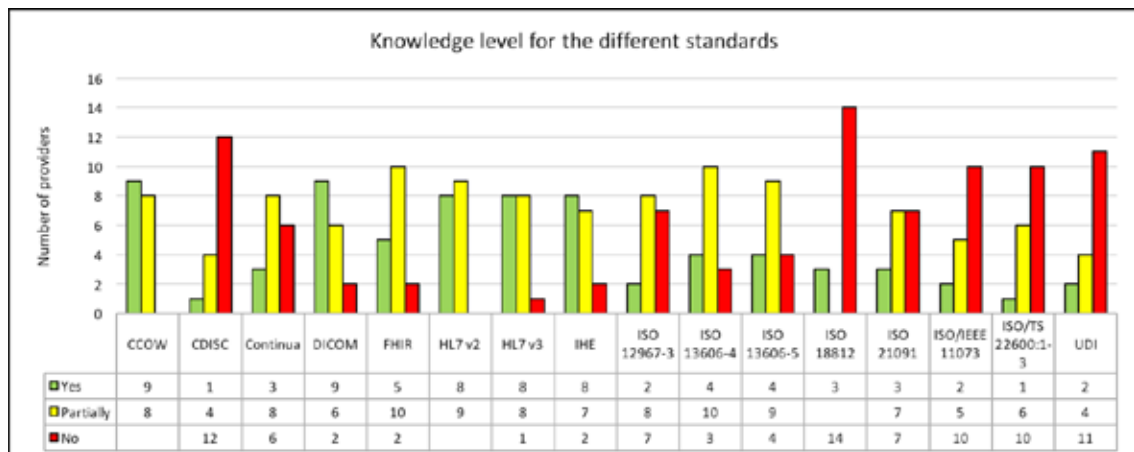

	CCOW	CDISC	Continua	DICOM	FHIR	HL7 v2	HL7 v3	IHE	ISO 12967-3	ISO 13606-4	ISO 13606-5	ISO 18812	ISO 21091	ISO/IEEE 11073	ISO/TS 22600:1-3	UDI
Yes	9	1	3	9	5	8	8	8	2	4	4	3	3	2	1	2
Partially	8	4	8	6	10	9	8	7	8	10	9		7	5	6	4
No		12	6	2	2		1	2	7	3	4	14	7	10	10	11

Illustration 13: The level of knowledge among the vendors for selected standards for technical interoperability

In general, the adoption of the different standards was low. Many of the small vendors were using few of the investigated standards, and the main reasons were that they did not think that the standards were applicable to their system, or that the customers did not demand them. Other common causes are lack of knowledge, and that they provide no clear market advantage.

It is possible to see patterns in the survey data between the knowledge and adoption levels, especially for the HL7 standards – which were both most recognised and applied. In the survey results it can also be seen that some vendors had plans to introduce FHIR, HL7 v3 and IHE profiles. None of the vendors that had plans on introducing FHIR were presently applying HL7 v3. A few vendors also have plans to introduce CDISC and HL7 v2.

The responses from the second part of the survey are summarised in the two tables (see Illustrations 14 and 15). The tables comprise the different answer options with an assigned weight, as well as the number of participants for each alternative. The arithmetic mean and the standard deviation are indicated to the right.

Illustration 14 shows how the vendors valued various factors at the introduction of a new standard. It can be seen that it is about as equally important that the new standards entail market advantages in Sweden as well as internationally. The illustration also indicates that almost all vendors thought it was important to achieve short-term cost-efficiency. However, it is considered to be significantly more important that the introduction of new standards provides a long-term gain.

	Not important (1)		Important (2)		Very important (3)			
	Σ	%	Σ	%	Σ	%	∅	±
Market benefits in Sweden	0	0,0%	13	56,5%	10	43,5%	2,43	0,51
Market benefits international	2	8,7%	12	52,2%	9	39,1%	2,30	0,63
Cost efficiency short-termly	2	8,7%	20	87,0%	1	4,3%	1,96	0,37
Cost efficiency long-termly	0	0,0%	10	43,5%	13	56,5%	2,57	0,51

Illustration 14: How important are the following factors when introducing new standards for technical interoperability?

Illustration 15 shows the importance of different factors when introducing a new framework with standards for technical interoperability. The single most important factor, also with the lowest variability, was that the framework should include future-proof standards, i.e. strong in a perspective looking into the future. In addition, many vendors thought it was important that it was possible to harmonise the new framework with the current state of the architecture.

   The largest variance among vendors was found with the proposition that it is important that the framework enables and strengthens innovation – but generally speaking, the average is high. It is also possible to conclude that vendors thought it was very important that the customers required a common framework, that it is important to follow the standards for technical interoperability, and that customers are willing to pay for the introduction of new standards.

	Not important (1)		Important (2)		Very important (3)			
	Σ	%	Σ	%	Σ	%	∅	±
The framework is possible to harmonize with as-is architecture	2	8,7%	12	52,2%	9	39,1%	2,30	0,63
The framework includes standards that are future-proof	1	4,3%	4	17,4%	18	78,3%	2,74	0,54
The framework strenghtens the power of innovation	4	17,4%	7	30,4%	12	52,2%	2,35	0,78
The customers require a common framework	2	8,7%	10	43,5%	11	47,8%	2,39	0,66
The customers are willing to pay for the standards included in the framework	3	13,0%	5	21,7%	15	65,2%	2,52	0,73

Illustration 15: How important are the following factors when introducing a new framework with standards for technical interoperability?

8 NATIONAL COORDINATION – SKILLS NEEDS AND ORGANISATIONAL REQUIREMENTS

8.1 Background

Swedish health and social care is one of the foundations of the Swedish welfare system. The responsibility for providing these welfare services in Sweden is distributed among the Regions, county councils and municipalities. The future healthcare information systems as well as the operational preconditions for this requires extensive resources and expertise for the development and application.

The complexity and scale of efforts needed to create the future healthcare information systems definitely requires national coordination. An important part of the coordination requirements is related to the implementation of international standards.

Therefore national coordination should include inter alia:

- Identification/choice of standards as starting points for eHealth
- Choice of standards for application within eHealth services
- Common interpretation and implementation guides for standards
- Common information structure based on the standards in order to achieve:
  - integrated knowledge management
  - documentation for individual patients in both professional and personal health records with adequate semantic interoperability follow-up of performance/quality of care and research also including national quality registers.

8.2 Current situation – national coordination

The need for national coordination is becoming increasingly important in the situation with substantial purchases of new healthcare information systems. The business/clinical/quality and information management are highly integrated. If the leadership in Sweden base their healthcare information systems on different foundations, there is an associated risk of reducing the preconditions for equivalent care.

One effect of the lack of coordination is that vendors of healthcare information systems do not have adequate and sustainable bases for adaptation and development of systems that are able to be competitive. Major social consequences of a development with lack of coordination should be a sufficient argument for a robust coordination of the future healthcare information systems.

StandIN presents some arguments and grounds for such coordination. A number of new preconditions could possibly mean that the opportunities and incentives for coordinated development towards the future healthcare information systems have increased. These include:

- The principals have a need for continuous improvement of healthcare information systems and the establishment of support for clinical processes.
- The national government has recognised the need to assist and coordinate – based on the Report from the eHealth Commission (SOU 2015:32), the Swedish eHealth Agency – eHälsomyndigheten, and the Vinnova project.
- The vendors in Sweden are squeezed by the competition – new incentives for development/innovation/collaboration.
- International standardisation in health informatics is a new stage, where among other things, Contsys is published and forms the basis for revisions of a number of other standards.

Great time pressure prevails in the development of the future healthcare information systems. The risks associated with these time requirements constitutes a crucial balance for the ongoing procurement projects and the relevant decision-makers. The development of the future healthcare information systems with the support of international standards also entails requirements/needs of Swedish participation in the process of international standardisation.

The standards which StandIN includes as relevant in this context are presently, in many cases, under development/revision or recently published with the need of implementation instructions/guidelines.

8.3 The needs of resources and expertise for national coordination

Sweden has traditionally been an active participant in the standardisation of health informatics. However, this has rarely occurred via active and strategic measures, or the allocation of resources in order to have the possibility to actively participate. It is difficult for individual Regions/county councils/municipalities/vendors to allocate the necessary resources or to determine which priority is to be given to interventions. Coordination and allocation of resources at the national level is a prerequisite so that the healthcare future information systems will become able to be developed in an innovative manner with the support of international standards.

National coordination of development based on international standards requires expertise in international standardisation. This need is particularly evident in the current situation where many standards in eHealth/health informatics are under development or revision.

A coordinated development of the future healthcare information systems also implies that Sweden actively participates in activities related to international standardisation. Sweden has expressed the ambition to be a world leader in the development of eHealth.

The development work that eventually may be based on this report may well be in the forefront internationally – and thus also requires insight into the standards, and give experiences that should influence the design of the standards and application even internationally.

The needs for skills and expertise in a sector that is undergoing tremendous and rapid development requires that resources can be obtained from various different organisations and participants with great flexibility. However a single party for coordination cannot alone establish, on their own, comprehensive internal expertise regarding all the complex matters that need to be coordinated.

A proposal for the identification of a national actor proposal for a national party who has a national mandate for the coordination/management of national eHealth has been implemented as a separate activity within StandIN.

Regardless of proposals and decisions concerning the choice of the actor, there will be a need for flexible groups of experts with various different perspectives and a wide range of in-depth expertise. All stakeholders in eHealth should be able to be represented within such expert groups. Both organisational representativeness as well as expertise in the substantive issues should be represented. Examples of expertise that should be represented include:

- Experience with direct and active participation in the development/revision of international standards within the domain.
- Active and understanding of the changes in the world around us, for example, IoT, Big Data, AI, etc.
- Understanding of policy directions, strategies and legislative changes at the national and EU levels.
- Knowledge of how information management can contribute to a good quality of care.
- Expertise in clinical research and the requirements of data quality as a basis for this.
- Expertise and skills for the development, delivery and operation of healthcare information systems within a particular area.

- Experience in the application and adaptation of healthcare information systems in healthcare.
- Knowledge and experience of the patient perspective for patient groups who are directly affected by the functionality related to the current fields of standardisation.
- Professional experience in the clinical areas concerned.
- Expertise which corresponds to the overall scientific and professional credibility as well as sections within the medical associations and/or corresponding organisations for other groups of professionals.

8.4 Basic requirements/criteria for national parties

In light of the above, certain basic requirements for a national actor can be identified.
The need for diversity and flexibility of the advisory expert groups requires that the coordinator has certain basic skills as a coordinator. The specialised expertise comes via the expert groups, but in order to be able to coordinate the experts and, above all, to be able to make informed decisions concerning recommendations and guidelines, requires a good knowledge base including within the field of standardisation is required.

Another aspect of the requirements for coordinators is not to mix the decision mandate in the overarching issues with execution/implementation/decision-making in the limited context of parts or aspects of eHealth. A role where the actor is an executor is very inappropriate to be combined with a role as an overall and impartial coordinator with a high degree of integrity. In the current national situation, most of the national parties are involved in the design or the decisionmaking concerning the sub-issues in this context.

In a report from the eHealth Commission, a proposal for such coordination was also presented. As of yet, no decisions have been made based on the report.

9 PROPOSAL FOR CONTINUED WORK

9.1 Activities in the continued work[3]

- Coordination of continuing to work with all perspectives included (business/clinical information and technology perspective). This assumes that all the stakeholders in the field are represented, for instance vendors, public and private healthcare providers, purchasers of the activities and IT perspective, public agencies and authorities, etc.

- Analyse 3H3R's and StandIN's results in order to describe the consistent consequences and possible gaps for the future healthcare information systems.

- Concretisation via 2-4 use cases for clinical processes that will also be able to serve as a full feasibility study – from start to finish.

- Contsys is presented in Phase 1 as fundamental for the business/clinical perspective. The conclusion that this International Standard can form the basis for the development of the future healthcare information system places demands on phase 2 and a continued management of the Vinnova project's results. The National Information Structure and the National Board of Health and Welfare's term bank should be harmonised with Contsys; this presumes and requires that Contsys is translated into Swedish.

- Concretisation of knowledge management – how can knowledge management be fully integrated in the future healthcare information systems and made immediately available in conjunction with each health care contact without "sidestepping" or jumping out of the system.

- Concretisation of research and follow-up – including national quality registers.

- Concretisation of communication with both archetypes and FHIR – comparative pilot tests of technology and technical solutions.

- All relevant current existing national services should undergo a review or audit and be related to the international standards and profiles, and as well undergo testing in a Connectathon in order to clarify its future technological relevance, and then be assessed for its potential for value adding.

- A requirements management tool should be used by the national coordinator; for example, used in the examination of interoperable components of Integration Competency Centre (ICC) in Inera AB.

- After establishing an information structure with clinical information for specified health problems based on this structure, a strategy and supporting modern tools for terminology binding should exist.

- Actively seek interoperability with the Swedish eHealth Agency's National Contact Point for eHealth (NCPeH) work via CEF.

- Review the possibility of a regulatory framework that can control a distributed national resource set ICC Health Technology Assessment review of all IT and medical studies that have been made by those preforming them.

- Further development of testing tools for national coordination.

- Investigate opportunities for using standards within Health Data Banking, for example, a quality register.

- Harmonise existing national reference architecture for eHealth based on international standards.

- Draw up guidelines and commence work in complementing and supplementing, and further developing, the national reference architecture for eHealth.

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3   The proposals are not ranked in any degree of priority and have a varying degree of detail

- Prepare a detailed gap analysis concerning specified amounts of information vis-à-vis the selected standards.
- Further develop StandIN's list via categorising standards with "use cases." Describe the situations in which one should use FHIR or IHE profiles, etc.
- Show the traceability back to Contsys.
- Develop proposals on implementation guidelines for selected standards.
- Advanced and expanded collaboration with principals including municipalities in phase 2.
- Dissemination of knowledge and anchoring with all stakeholders.
- Continued cooperation regarding IHE/Continua on a Nordic basis.
- Include the new EU Data Protection Directive.
- Promote international cooperation around standardisation.

10 APPENDICES

The appendices are listed in the order that they are referred to in this report.

- Compilation systems in county councils in 2015
- Examples of how technical interoperability can contribute to good health and medical care and social services care
- Knowledge of the world around us
- Future healthcare – Future healthcare information systems
- Contsys and the technology perspective
- Examples of business management
- Relevant standards that do not relate to technical interoperability
- Standards relating to technical interoperability
- Concept Model of StandIN's framework
- Completed but excluded standards
- The application of the eHAM model in the StandIN Project
- Feasibility Example – The congestive heart failure process
- Project plan, version 1.1

11 PUBLICATION

- http://medtech4health.se/standin/

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