



Nordic Council  
of Ministers



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standardisation as a strategic  
means for realising national  
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*Thor Schliemann, Camilla Danielsen, Teemupekka Virtanen, Riikka Vuokko, Gudrun Audur Hardardottir, Magnus Andre Alsaker, Bjarte Aksnes, Niklas Eklöf and Erika Ericsson*

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# About the Nordic Council of Ministers' eHealth group

The Nordic Committee of Senior Officials for Health and Social Affairs (ÄK-S) of the Nordic Council of Ministers (NCM) established the eHealth group (the Nordic Council of Ministers' eHealth group) in 2011 for ensuring knowledge transfer between the Nordic countries and help strengthen the global leadership position of the region in the eHealth area.

The scope of the group places emphasis on current political priorities at national levels and in the EU framework. The eHealth Group is both a central forum for knowledge transfer between the Nordic countries as well as a platform for them for joint formulation of strategic initiatives to enable communication of a common Nordic view in a wider perspective. Nationally all Nordic countries have during these years been successful in digitalizing their health care systems further and parallel to being actively involved in the developments at the European and even global level.

## Standardisation is a key issue in the NCM eHealth group work plan 2019–2021

The eHealth group's work plan for the present mandate period places considerable importance on the issue of standardisation. The aim is to:

*Support Nordic cooperation on identifying common standards in eHealth – with a special emphasis on electronic health records (EHRs). This work is not only a prerequisite for a successful exchange of health information across borders with the aim to support patient mobility between the countries, but also between mobile applications, health data bases and registers and consequently for secondary use of such data.*



# Summary

This report summarizes the discussions in a seminar late 2018 in Copenhagen on eHealth standardisation in the Nordic countries. The seminar was organized by the Nordic Council of Ministers' eHealth group. The report represents the beginning of a more permanent Nordic collaboration in this area. Following the seminar and the work on this report, the eHealth group has decided to establish a subgroup on eHealth standardisation.

The scope of the report is limited mainly to technical standards, with some examples including semantic standards. The work of the sub group will take on both the former and the latter and will be contextualized within the broader framework of the European Interoperability Framework in which organizational and legal standards are included.

Standardisation is a multifaceted issue. The content of the report illustrates a range of areas in which the Nordic countries have shared interests. The report demonstrates how the countries developed approaches which are both similar and different, thus making shared Nordic collaborative work interesting.

First and foremost is the shared emphasis on standardisation as a key strategic means for realizing the aims and objectives in the countries' current eHealth policies. In all the countries, except from Iceland, there are ongoing local and regional processes of modernizing the health care sectors EHR portfolio and making these connect to the different national systems and services available. With a myriad of systems in use, the role for standardisation becomes a key strategic issue.

The regulations are one of the most important strategic instruments to ensure that standards are being put into service. This is important to strengthen the implementation capacity and ensure more efficient use of eHealth tools in the health sector. Specific standards and the use of these are regulated by law in all the Nordic countries. The scope and strength of these regulations do however vary. National standards tend to be defined and published in official catalogues. National bodies are mandated to keep these updated and accessible for health care enterprises and system developers.

When it comes to financing, several countries have defined the use of national standards as a prerequisite for development projects that are funded by national bodies or through national agreements. It seems to be most common that national authorities are funding standard development activities, and that they finance the promotion of their use, for instance through national test centers offering services for free for vendors.

The Nordic countries organize their normative role differently when it comes to standardisation. In some countries the responsibility is placed within the Ministry or a Directorate, in others health care enterprises or regional alliances have taken responsibility. A shared topic for many of the countries is the establishment of national architectural steering. This seems to be a tool of growing importance following the increasing ambition and complexity of national eHealth systems. To build and maintain infrastructures is an expensive endeavor, to have an overall plan and a system for

securing that different actors relate to this plan seems to be a highly prioritized issue for policy making in the eHealth domain.

When it comes to the actual standards being in use, all the Nordic countries use both national standards and different international standards. Especially HL7 standards are mentioned and so is SNOMED CT. However exactly which parts of the standards are being used and how differs. Therefore, it is interesting to both share experiences on the differing use of standards; learn from others about standards they use, as well as to probe the possibilities of collaborating on testing standards and sharing these in between the countries afterwards.

International standardisation is an important tool that contributes to competitiveness as it allows vendors to avoid having to adapt to different requirements for the same product in different export markets and instead participate in the specification of standards. To use the same standards in the Nordic countries can lead to lower entering barriers and costs for vendors to start operating in the Nordic countries.

The Nordic countries are represented in different international standardisation organizations and workgroups like HL7 international, ISO/TC215, CEN/TC251, Personal Connected Health Alliance and eHaction. As members of different standardisation organizations and international workgroups, if the Nordic countries work more together, there is a potential for the Nordic countries to strengthen their position in these international arenas.

# 1. Introduction

This report is the written result of a seminar gathering 22 standardisation experts from all the Nordic countries in Copenhagen, Denmark in August 2018. The seminar was organized by the Nordic Council of Ministers' eHealth group. The aim of the seminar was to explore issues related to standardisation as a strategic means for realizing national eHealth policies.

The backdrop for this seminar was the recognition that in all the Nordic countries, standardisation figures as a key element in national strategies on eHealth (see the picture below). Mutual goals and objectives combined with shared challenges make the topic of standardisation a relevant topic for sharing of knowledge and experiences across the Nordic region.

Figure 1: This report is the outcome of a Nordic seminar on standardisation



The following issues were addressed during the seminar:

What are the policy instruments used to setting standards and securing adherence to standardisation at a strategic level?

How does the countries organize their normative role (e.g. Standardisation bodies, Architectural governance, etc.)?

Which international standards are chosen within the countries' national eHealth strategies and what are the experiences with these?

Which international information models and architectural models are chosen within the countries' national eHealth strategies and what are the experiences with these?

What role can standardisation play with regards to improving conditions for vendors, speeding up innovation and enabling a Nordic eHealth market?

#### *Denmark*

Common standards and infrastructure that can better connect local IT systems are being developed. Further there is a need for a modernizing IT security standards in health care.  
(<https://sundhedsdatastyrelsen.dk/da/diverse/download>)

#### *Sweden*

Technical standards is a prerequisite for interoperability between different actors. Interoperability is the ability of systems to share information and knowledge with other systems.  
(<https://www.government.se/information-material/2016/08/vision-for-ehealth-2025/>)

#### *Finland*

Structured information will be consistent at the national level, and national definitions of information architecture will be in use by the sector as a whole. Open interfaces and international standards will be enable interoperability. A national service architecture will be used in the development of social welfare and health care services.  
([http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/74459/URN\\_ISBN\\_978-952-00-3575-4.pdf](http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/74459/URN_ISBN_978-952-00-3575-4.pdf))

#### *Iceland*

Not anymore strategic issue, as Iceland have one shared EHR system.  
([https://www.landlaeknir.is/servlet/file/store93/item28955/National\\_eHealth\\_Strategies\\_January\\_2016\\_final.pdf](https://www.landlaeknir.is/servlet/file/store93/item28955/National_eHealth_Strategies_January_2016_final.pdf))

#### *Norway*

In order for decision making processes to become more efficient, national architecture governance and the processes surrounding standardisation has to become more transparent.  
(<https://ehelse.no/publikasjoner/nasjonal-e-helsestrategi-og-mal-2017-2022-oppdateret-2019>)

In preparation for the seminar a questionnaire was circulated among the Nordic participants (see Appendix 1). The questionnaire had a set of questions about standardisation work at a national level. The country representatives came with various knowledge of the scope and status of standardisation work in their countries. Therefore, the input to the seminar, and consequently this report, does not provide an

exhaustive description of the situation across the Nordic region. Thus, this report does not provide a complete comparative view on the situation across the countries. The value of the report lies in it being the starting point for further examination of similarities and differences between the Nordic countries and thus also for probing the potential for collaboration in specific areas and specific ways.

Following the seminar, the Nordic Council of Ministers' eHealth group has decided to establish a subgroup on standardisation. The subgroup will gather Nordic standardisation experts from the Nordic countries in regular meetings and will serve as a platform to enhance understanding and collaboration on specific standardisation issues. The group will also be an important arena for preparing participation and position in the ongoing international work on standardisation at the EU and global level.

As a result, this report brings Nordic eHealth standardisation alive. It is alive, as the initial questions and answers presented in this report marks the beginning of an endeavor for more learning and collaboration based on a shared conceptual framework and within the organizational structure of a new Nordic Council of Ministers' subgroup on eHealth standardisation.

Following this, the purpose of this report is to give the reader a glimpse into the topic of eHealth standardisation. The hope is that this will spur further interest in the possibility for Nordic collaboration in this area. The report offers references to relevant actors and documents, and a listing of key contributors in the different countries (see Appendix 2) which can be approached for those who want to dig deeper into specific countries and issues.



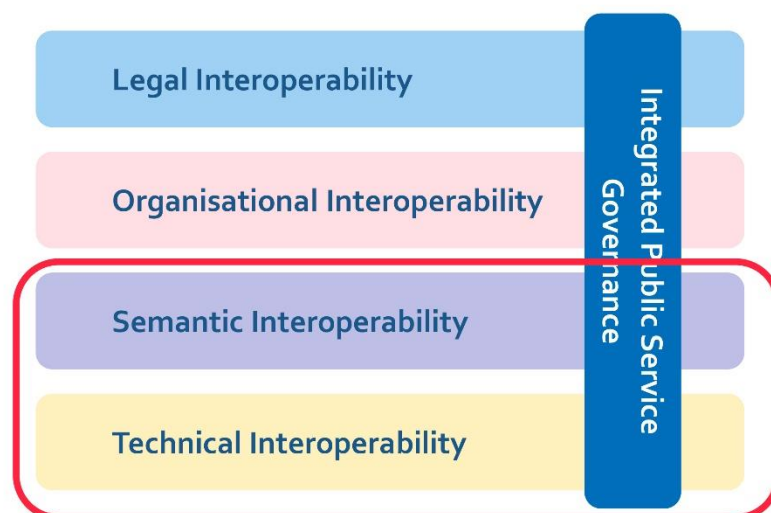
## 2. International context and conceptual framework

Standardisation is an international issue indeed. This is apparent both through the development and use of standards across countries, the organization of interests concerning standardisation for instance through SDOs and in the development of conceptual frameworks for building knowledge, policy and practices on standardisation.

At a European level, an important common reference point for standardisation is the “European Interoperability Framework” (EIF).<sup>1</sup> The framework gives specific guidance on how to set up interoperable digital public services. The European eHealth Network has adopted a refined eHealth European Interoperability Framework (ReEIF), which acknowledges aspects of crucial importance in eHealth.<sup>2</sup>

European Interoperability Framework offers public administrations specific recommendations on how to improve governance of their interoperability activities, establish cross-organizational relationships, streamline processes supporting end-to-end digital services, and ensure that both existing and new legislation do not compromise interoperability efforts.

Figure 2: European Interoperability Framework covers four interoperability domains



<sup>1</sup> [https://ec.europa.eu/isaz/eif\\_en](https://ec.europa.eu/isaz/eif_en)

<sup>2</sup> [https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev\\_20151123\\_c003\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_c003_en.pdf)

Figure 3: Refined eHealth European Interoperability Framework covers six interoperability levels

Legal and regulatory	Legal and regulatory constraints
Policy	Collaboration agreements
Care Process	Alignment of care processes
Information	Defining and coding of information
Applications	Integration in healthcare systems
IT Infrastructure	Communication protocols

The European Interoperability Framework and the refined eHealth European Interoperability Framework refers to areas of interoperability that needs to be managed to establish cross-organizational relationships, streamline processes supporting end-to-end digital services. These are *legal interoperability*, *organizational interoperability (covering both policy and care process aspects)*, *semantic interoperability*, and *technical interoperability (covering applications and IT infrastructure)*.

At the Nordic standardisation seminar, and referring to the figure 2 above, the main topic was technical interoperability. Throughout the course of the seminar, and the later input to this report, the actors have shown great interest in further the scope to also include semantic standardisation. This shared interest in semantic issues is not thoroughly reflected in this report. However, it will be explored in-depth throughout the upcoming meetings in the sub group on standardisation.

The issue of organizational and legal interoperability has been addressed in earlier work within two sub groups of the eHealth group, one on Legal Interoperability and one on ePrescription. The context for that work was the ongoing EU project epSOS and the Joint Action to Support the eHealth Network.

The choice to focus on technical standardisation, later expanding the scope to include semantic standards, was made with reference to the shared importance of these issues within the Nordic countries' eHealth strategies. Furthermore, the issue of standardisation is one of high importance for the ongoing EU collaboration on eHealth.<sup>3</sup> Enabling citizens to securely access and share their health data across borders is one of the priorities of the Communication on enabling the digital transformation of health and care in the Digital Single Market<sup>4</sup> and the implementation of the General Data Protection Regulation which (GDPR) which underlines that citizens have the right to access their personal data, including their health data. The European Commission has accepted a recommendation that sets out a framework for the further development of an European EHR Exchange Format (EHRxF) that will enable citizens to securely access and exchange their health data across borders in the EU.<sup>5</sup> Together with laying down a

3 <https://ec.europa.eu/digital-single-market/en/exchange-electronic-health-records-across-eu>

4 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:233:FIN>

5 <https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format>

set of shared technical specifications for the cross-border exchange of data, the Recommendation delineates a set of principles that should govern this exchange and a process for further development, monitoring and review. A joint coordination process involving the Member States and the Commission is envisaged to support the further elaboration of the EHRxF. For the Nordic countries, the newly established sub group on standardisation will serve as a highly relevant and important collaborative arena for exploring Nordic interests and positions within the context of the EU project.



### 3. Policy Instruments used to set standards and secure adherence

#### 3.1 Legal instruments related to the use of standards

##### 3.1.1 Denmark

Denmark have an Executive Order no. 160 of 12 February 2013 on Standards for IT application in the Health Sector (Danish title: Bekendtgørelse om standarder for it-anvendelsen i sundhedsvæsenet).<sup>6</sup> The Danish Health Data Authority (DHDA) (da *Sundhedsdatastyrelsen*), shall approve standards, including data standards, classifications for use in national registries and interface standards, for IT applications in the health sector upon consultation with the national board of eHealth. DHDA lays down requirements which include some documentation that standards must satisfy to be approved. DHDA may withdraw the approval of a standard if the prerequisites for approval are changed. The government, regions, municipalities, private hospitals and clinics, etc., including practising health professionals, are required to ensure that their IT systems use the standards for IT application in the health sector approved by the DHDA pursuant to the provisions of this executive order. When approving a standard, the DHDA establishes a grade of recommendation of the standard, what the standard must be used for, who must use the standard, how to adhere to the standard, the time when the standard is to be applied. An approved standard must include information about the name and version of the standard as well as a detailed description of its content. The DHDA has published a catalogue of approved standards and candidate standards. The catalogue is updated 4 times a year.<sup>7</sup>

##### 3.1.2 Finland

In Finland there has been legislation since 2007 that makes it mandatory for most healthcare organizations to store electronic patient records to a national repository and ePrescription Centre (Kanta). The same legislation gives the National Institute of Health and Welfare (THL) a mandate to give executive orders related to the essential requirements of systems connected to the national health IT services, and to specify the content and terminology of records stored to the national health IT services. Technical

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<sup>6</sup> Complete English version of Executive Order no. 160: <https://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammer-og-retningslinjer/referencearkitektur-og-it-standarder/standardkatalog/engelsk-version-af-bekendtgørelse-af-standarder.pdf>

<sup>7</sup> Catalogue of eHealth Standards in Denmark: <https://sundhedsdatastyrelsen.dk/da/rammer-og-retningslinjer/om-referencearkitektur-og-standarder/standardkatalog>

document and messaging specifications related to the national health IT services are published by the Social Insurance Institution of Finland (Kela). These specifications are mainly based on international standards. Currently all public healthcare providers and larger private providers are connected to the national health IT services and have modified their EHR-systems to comply with the national specifications.<sup>8</sup>

### 3.1.3 *Iceland*

In Iceland there are regulations and directives (including Minimum Data Sets) which make it mandatory for health professionals to use standardised documentation within Electronic Health Records (EHR's). The Hospital Minimum Data Set and the Minimum Data Set for Primary healthcare and specialty outpatient health services, addresses mandatory international health classification systems to be used to document health services. Mandatory, coded health data, using ICD-10, ICPC-2, NCSP, ICNP, ATC and SNOMED-CT flows in real time via the secure Icelandic HealthNet to Government Health Registries.

Furthermore, there are regulations and requirements on health record security. The National eHealth strategy states that all EHR systems in use in Iceland need to be able to connect to the Icelandic HealthNet "Hekla" for seamless and continuous health information exchange. However, before healthcare organizations can become a part of the nationally, interconnected health record they need to fulfill certain security requirements issued by authorities. The security requirements are based on ISO-27001 or an equivalent standard.

A great majority of health professionals use the same EHR system. Currently, all hospitals, primary health care clinics and a majority of both private specialty clinics and nursing homes have interconnected EHR's sharing important patient information on a national level. It is the Directorate of Health (DoH) in Iceland, the National Centre for eHealth unit, that is responsible for eHealth implementation on a national level. The Icelandic HealthNet is owned and run by the DoH and is free of charge for users. The Icelandic HealthNet supports local XML and HL7 messaging standards for information exchange.

### 3.1.4 *Norway*

Norway have regulations for the use of ICT standards for health and care services (Forskrift om IKT-standarder i helse- og omsorgstjenesten<sup>9</sup>). The purpose of the regulations is to ensure that organizations in the health and care services that provide healthcare adopt ICT standards to promote secure and effective electronic collaboration. The regulations include requirements for organizations in the health and

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<sup>8</sup> Specifications are published in the National Code Service and Kanta web pages, <https://thl.fi/en/web/information-management-in-social-welfare-and-health-care>  
Specifications are published in the National Code Service and Kanta web pages, <https://thl.fi/en/web/information-management-in-social-welfare-and-health-care>  
<sup>9</sup> <https://lovdata.no/dokument/SF/forskrift/2015-07-01-853>

care services to use software compliant with the requirements of a set of eHealth standards. Some examples of standards included in the regulations are referral messages, discharge letters and laboratory reports. The regulations entered into force in 2015 and is in process of being revised.

The regulations apply to private and public organizations in the health and care services that make use of electronic health record (EHR) systems established for therapeutic purposes. This means that the healthcare organizations must ensure that the ICT systems fulfill the regulations.

The regulations are one of the most important strategic instruments to ensure that standards are being put into service. This is important to strengthen the implementation capacity and ensure more efficient use of eHealth tools in the health sector. Today the regulations are focused on messaging standards for collaboration. In the future, we see the need to expand the scope to include areas like reference architectures, information models, code systems and terminologies.

In addition to the regulations, The Norwegian Directorate of eHealth is publishing a catalogue of standards listing mandatory and recommended eHealth standards. (Referansekatalogen for e-helse<sup>10</sup>). The catalogue lists standards which are mandatory by regulations, and standards recommended by public authority.

### 3.1.5 Sweden

Sweden has generally few obligations concerning technical standards for health information transferring within the health care sector. Areas that could be mentioned include e-prescriptions – where the Swedish eHealth Agency has an infrastructure that enables care givers to send e-prescriptions to pharmacies via the agency – and dental care where dentist has to send information about which treatments they have done to the Swedish Social Insurance Agency. In both these cases governmental agencies set up technical rules for how the information should be transferred.

There are also government agency regulations when it comes to reporting information to different types of health registers. For the National Patient Register the care givers must report using ICD-10-SE<sup>11</sup> and when reporting e-prescriptions there is a national format that must be used. Furthermore there are agreements between stakeholders, e.g. on how to manage e-prescriptions. When it comes to electronic health records, there are government agency regulations including generic recommendations to use the National Information structure<sup>12</sup>, SNOMED CT, as well as national and international and some classifications. In the domain of laboratory medicine the NPU Terminology has wide-spread use.

There are also more general rules outside the health care sector when it comes to standardisation. For example, according to the Swedish Public Procurement Act (chapter 9, section 4 in the act) the technical characteristics of the supplies, services or

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10 <https://ehelse.no/standarder-kodeverk-og-referansekatalog/referansekatalogen>

11 <https://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/19298/2013-12-23.pdf>

12 <http://sos.se/ni>

works are to be stated as technical specifications and if these technical specifications are not in the form of performance or functional requirements, they shall refer to standards and assessments and, in descending order of priority, to either one of the following:

- Swedish standards that correspond to European standards.
- European technical assessments.
- Common technical specifications.
- International standards.
- Another technical reference system drawn up by a European standardisation organisation.
- Another Swedish standard, Swedish technical approval or, in the case of works or usage of a product, a Swedish technical specification for design, calculation and execution<sup>13</sup>.

## 3.2 Financial instruments related to the use of standards

### 3.2.1 Denmark

In Denmark there are different sources for financing standardisation work:

#### Annual tri-party agreements

The annual economic agreement between the three main actors in the health care sector – the regions, municipalities and the government (*Økonomiaftaler*) determines the municipal and regional budget for health in general and eHealth is normally a part of the agreement. The funding of the national eHealth infrastructure is agreed upon through these annual economic agreements.

#### Finance Act

The yearly state budget which is agreed upon during the autumn might also allocate funding for various investments in different areas including eHealth initiatives.

#### Special fundings

Finally funding might come from various special funding instruments. Previously a foundation on welfare technology was put in place from which funding for various projects was allocated. The national strategy for digital health as well as the strategy for digitalization of the public sector is in some cases accompanied by finding for specific projects.

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<sup>13</sup> <http://www.konkurrensverket.se/globalassets/english/publications-and-decisions/swedish-public-procurement-act.pdf>

### 3.2.2 *Finland*

All projects funded by the ministry of Social Affairs and Health or other national agencies have requirements to use national services and standards related to those services. I.e. funding of development and implementation projects is one steering mechanism, and use of standards is both a prerequisite and a criterion for the projects.

### 3.2.3 *Iceland*

There is no special funding earmarked for the development and implementation of standards in Iceland. The Icelandic Government (Ministry of Health) funds national eHealth projects via the annual Finance Act. The eHealth projects are executed by the National Centre for eHealth unit at the Directorate of Health, and they mirror the national eHealth strategy and yearly strategic planning. Furthermore, the Ministry of Health sometimes allocates extra funding to some chosen projects.

The National Centre for eHealth is responsible for decision making and management of eHealth standards, including classification systems and terminologies.

The National Centre for eHealth provides national standards free of use to vendors of EHR's. Moreover, it provides test services for new applications free of charge to ensure proper implementation.

### 3.2.4 *Norway*

The Norwegian Directorate of eHealth is responsible for developing and managing standards, including classifications, for use in and exchange of clinical and administrative information between EHR systems used by different healthcare providers. The cost of developing and managing these standards are part of the state funding of The Norwegian Directorate of eHealth. The standards are freely available for vendors and organizations that provide health care services.

In general, each healthcare organization must finance their vendors for the development of software compliant with the requirements of the standards. There is no basic funding from the government to cover such costs. The exception is a limited number of national projects and solutions, that are partly covered by central government funding. An example of this is a national project which focuses on improving functionality in EHR systems for general practitioners (EPJ-løftet). This project includes implementing a selected number of standards.

Another area with government funding is the test services offered by Norwegian Health Network (Norsk Helsenett). The Norwegian Health Network provide test services for vendors and healthcare organizations to ensure correct implementation and use of eHealth standards.

### 3.2.5 *Sweden*

The national government provides funding for the maintenance and development of some national standard resources, such as SNOMED CT, ICD-10-SE, ICF and the National Information Structure. Further examples are specific commissions to the National Board of Health and Welfare to develop and maintain a National Knowledge Base for Reasons for Prescription and Alert Information. As an example of financing outside the national government, the maintenance of the Swedish edition of the NPU Terminology is financed jointly by the county councils and regions.

## 3.3 Other strategic instruments related to the use of standards

### 3.3.1 *Denmark*

Reference architectures serve as a common reference point for a certain area of interest, e.g. making data available for everyone involved in the treatment of a patient and provide a framework for standardisation in this area. It could be the description of infrastructure components that logically must be present in the infrastructure and describes how systems and infrastructure components interact. It identifies areas that may benefit from standardisation, as well as a description of a shared goal and provide a shared direction for digitalization and standardisation in an area where it makes sense.

A reference architecture outlines and frames architecture descriptions to harmonize national and local architecture needs. The Danish reference Architectures describes the tendencies for a certain area identified, and it clarifies business, informational and technical principles for the area in scope. An example is the Danish national infrastructure and its development, which is based on the Reference Architectures for Information security, sharing documents and images and collecting health data from citizens. Technical standards are in general based on IHE and HL7 standards, where they can solve a specific business need.

Another example is Continua Design Guidelines (Personal Connected Health Alliance [PCH Alliance]) as a template and foundation for a reference architecture and it frames the direction standardisation and use of standards.

### 3.3.2 *Finland*

National level reference architectures steer social and health care development and implementation of nationally standardised documentation structures. National code service for social and health care (maintained by the National Institute for Health and Welfare) publishes data structures, code sets and classifications; these are either required or recommendations from standardisation point of view. When required, they need to be implemented by all service providers.

### 3.3.3 *Iceland*

Other strategic instruments that relate to standards are several. The National Centre for eHealth unit at the Directorate of Health in Iceland issues what eHealth standards shall be used on a national level. Moreover, the National Centre for eHealth is the management and national release centre for both national and international coding standards.

The Icelandic National Infrastructure is based on a National Reference Architecture involving either homemade standards or international standards. These standards encompass data and information security, information sharing, data collection and storage of data.

Iceland already has an interconnected healthcare system where health information is shared seamlessly at point of care between healthcare professionals, across different healthcare institutions, across different health service levels and across national health districts. Health information is shared via the Icelandic HealthNet, which is owned and run by the Directorate of Health.

Furthermore, the National Patient Health Portal is connected to the EHR for digital eHealth services on a national level. Moreover, all drug stores in the country are connected to the Icelandic HealthNet for e-prescriptions.

The National Infrastructure on data structure and coding for electronic health records supports seamless collection of health data in real time to national health registries.

### 3.3.4 *Norway*

The Norwegian Directorate of eHealth also gives recommendations for which international standards to use in Norway for different purposes. The directorate has established a governance model for eHealth standards.

Another instrument which is established is the national test centre run by The National Health Network. The test centre offers services freely available for healthcare organizations and vendors. The main goal for the test centre is to help vendors with correct use and proper implementation of eHealth standards. The test services are offered for standards that are enlisted in regulations for the use of ICT standards for health and care services.

### 3.3.5 *Sweden*

For many national digital services, the county councils and the regions cooperate via Inera, a limited company owned by Swedish county councils, regions and municipalities, as well as the Swedish Association of Local Authorities and Regions (SALAR). The owners have tasked the company with developing joint digital solutions that will help to streamline their operations. Some examples of services that Inera provides are Nationell patientöversikt (National Patient Summary), which contains information for healthcare providers, 1177 Vårdguiden (1177 Healthcare Guide) which is a national healthcare resource, which provides information, advice and services to the public and Identifieringstjänsten (Identification Service) SITHS is a system for secure identification, based on "strong authentication".

The standards Inera refer to can be said to be de facto standards since the company's national services are widely used. Inera has set up so called "Common requirements" (gemensamma kravunderlag) which includes guiding principles, examples and a technical reference architecture for care. These principles are published on website called RIV TA which is an acronym for "Regelverk för Interoperabilitet inom Vård och omsorg" och "Tekniska Anvisningar" (RIV – regulations for interoperability in health and care and TA – Technical Instructions).

From a national perspective there are ongoing discussion between the government and SALAR on how to best agree on standards in a more informal way. The Government and SALAR want to support efforts to make use of the opportunities of digitization in social services and health care and have decided to endorse a common vision for eHealth towards 2025.<sup>14</sup> According the vision action plan areas for action include Standards and More consistent use of terms, both focusing on consistent use of information and terminology standards.

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<sup>14</sup> <https://ehals2025.se/in-english>

## 4. Organizing the normative role within the area of standardisation

### 4.1 Overview of the actors in e-health standardisation in each country

#### 4.1.1 Denmark

The Danish Health Data Authority is among others maintaining and is involved in development of the NPU terminology along with Norwegian and Swedish national release centres and collaborators from International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and International Union of Pure Applied Chemistry (IUPAC). Moreover, the Danish Health Data Authority is engaged in hearings of ISO and CEN standards within laboratory medicine, interoperability, security and semantics through the national standards body, Danish Standards Foundation.

The Danish Health Data Authority is providing and maintaining development of the Sundhedsvæsenets Klassifikationssystem (SKS; en: Health Classifications system), which contains several classification and codesystems (e.g. ICD10, ICF). These are used for reporting to different systems, including the National Patient Registry etc.

As mentioned previously strategic instruments like national eHealth strategies and priorities, the eHealth Standards Advisory Board and artifacts like reference architectures is provided by the Danish Health Data Authority.

HL7 Denmark is the Danish affiliate of HL7-International managed by Danish Standards Foundation<sup>15</sup>, and we are following and participating in the work on developing international HL7 standards in health informatics. HL7-Denmark focuses on profiling and application of standards at national level. HL7 Denmark is working towards a shared definition of rules and frameworks, as well as how we use the standards most appropriately. The actors that has chosen to be member of HL7 Denmark are regions, MedCom, vendors, GS1, Alexandra Instituttet, Aalborg University and Danish Health Data Authority.

MedCom is our main provider of profiling and maintaining International standards for use in Denmark. They lead the working groups where all parties are invited to join in this effort, which at most i.e. Regions, Municipalities, GP's organisation, vendors, The GTS institutes that offer knowledge, technology and consultancy (GTS – Advanced Technology Group is a network consisting of independent Danish research and technology organisations<sup>16</sup>) and the Danish Health Data Authority.

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<sup>15</sup> <https://www.ds.dk/da/udvalg/kategorier/sundhed/hl7-denmark>

<sup>16</sup> GTS: <https://en.gts-net.dk/>

#### 4.1.2 *Finland*

Information processing related standardisation work (ISO and CEN) is funded and participated by the Ministry of social Affairs and Health directly, mainly focused on voting and observation of relevant standards. There is a cross ministerial board to supervise this work. eHealth is a part of this work. There is a national eHealth mirror group in the national standardisation agency. A ministry representative is the chairman of the group. The participation of vendors and health service providers has been small in the national mirror group. Some relevant participation of individual experts from different organizations takes place also in other than eHealth related ISO and CEN committees.

Since 1995, there has been a national affiliate organization of HL7 that takes care of HL7-related issues, which currently has more than 70 organizational members. This organization has gathered also national IHE (Integrating the Healthcare Enterprise) activities under its umbrella. Implementation guides and profiles of international standards on technical level are developed by national programmes and other projects, and accepted according to open standardization process through this association. The national authorities participate in all committees (board, technical steering committee, IHE Finland, Personal Health Special Interest Group) of the association. They also coordinate the work between the association, national projects, various expert groups and the national standardization agency. Majority of eHealth-specific standards activities of vendors and health service providers are related to the association.

The National Institute for Health and Welfare updates and publishes many international and national classifications and terminologies for eHealth through the national code service. It also facilitates the national release center for SNOMED CT.

#### 4.1.3 *Iceland*

The National Centre for eHealth unit at the Icelandic Directorate of Health, is responsible for eHealth standardisation on a national level. Furthermore, it is responsible for national eHealth policy and implementation.

Iceland has an eHealth Steering Committee that works with the National Centre for eHealth in decision making at the policy level. The Surgeon General is head of the committee. Moreover, the Ministry of Welfare may establish working groups to address certain issues. The tasks relating to the working groups often result in some recommendation that may later become policy, for example the regulation on telehealth in Iceland.

Furthermore, the National Centre for eHealth is a release center for international terminologies for the country. Moreover, it provides and maintains a national platform and a browser for some of the classification systems.

#### 4.1.4 Norway

The Norwegian Directorate of eHealth is a sub-ordinate institution of the Ministry of Health and Care Services. The Norwegian Directorate of eHealth is responsible for implementing the national policy on eHealth, establish the requisite standards, and administrate the use of eHealth methodology nation-wide. The directorate has an overall responsibility for the development and governance of standards at a national level in Norway.

In addition to the Norwegian Directorate of eHealth, there are other national institutions that establish standards for eHealth: the Norwegian Directorate of Health (Helsedirektoratet), the Norwegian Institute of Public Health (Folkehelseinstituttet), the Norwegian Health Economics Administration (Helfo) and Norwegian Labour and Welfare Service (NAV). The Directorate of eHealth's catalogue of eHealth standards gives an overview of these with links to requirement documents and technical files.

HL7 Norway is an organization which promotes standardised exchange of clinical and administrative information between health care services with international HL7 standards. The HL7 standards are developed and controlled by a technical committee and working groups of HL7 Norway in cooperation with the international HL7 organization. The work of HL7 Norge is done in cooperation with vendors and users to achieve technical, semantic and organizational interoperability. The Norwegian Directorate of eHealth participates both in the board of HL7 Norge and in the technical steering committee.

Standards Norway (Standard Norge) is a private and independent member organization responsible for standardisation activities in all areas except the electrotechnical field and the telecommunications field. The organization is the national member of the International Organization for Standardisation (ISO) and the European Committee for Standardization (CEN). Standards Norway publishes Norwegian Standards (NS), which are established based on national draft standards as well as of European and International Standards.

#### 4.1.5 Sweden

In Sweden, several actors with different areas of responsibility are involved in eHealth standardisation.

The Ministry of Health and Social Affairs do not have any formal responsibilities when it comes to eHealth standardisation. However, the Ministry of Health and Social Affairs are supporting and financing some national initiatives. Most of these initiatives are delegated to, or performed by, the government authorities, mainly the Swedish eHealth Agency, the National Board of Health and Welfare and the Medical Products Agency. There are also initiatives done by other ministries that affect standardisation within the health care sector. One such example is the national standardisation strategy that was presented in 2018 which included issues such as government administration, environment and energy, housing and community planning and health care.

The Swedish eHealth Agency are responsible for choosing and implementing relevant standards for their own products and services. The National Board of Health and Welfare are providing certain semantical standards for others to use in e.g. health records or when reporting to national health data register or quality registers.

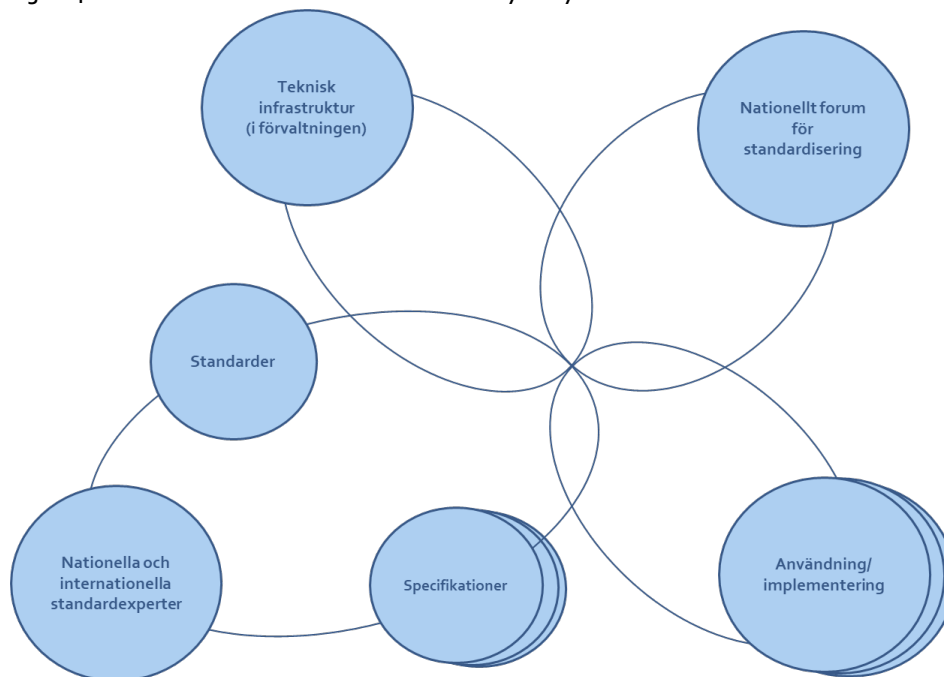
The local and regional health authorities have the main responsible for choosing and implementing standards for the information systems they use within and between these organizations. The standardisation on the local and regional levels is somewhat mandated by the standards used in the national infrastructure services, provided by e.g. the Swedish eHealth Agency and Inera AB. The local and regional authorities are supported by their members organization, The Swedish Association of Local Authorities and Regions (SALAR). They also co-own the company Inera AB, who coordinates the development and management of joint digital solutions that benefit the general public, and employees and decision-makers in county councils, regions and municipalities.

There are several standardisation development organization acting in the eHealth sector. *the Swedish Institute for Standards* (SIS) represents Sweden in the European standardisation organisation CEN and the global organisation ISO. There are also other SDOs active on a national level, for example *HL7 Sverige*.

In 2018, the Ministry of Health together with SALAR established the *National Forum for eHealth Standardization*, which will be an arena for coordination and collaboration, with representatives from all of the actors above.

An often used picture to illustrate the situation is the one below. The idea is to show that there are many ongoing initiatives and involved actors when it comes to standardisation, but little coordination. There are also few formal agreements in place on how to govern this.

Figure 4: Standardisation in Sweden is characterized by many actors and little coordination



## 4.2 Overview of the standardisation process and governance

### 4.2.1 Denmark

The report (da: *Standarder og referencearkitekturer vedr. sundheds-it området*<sup>17</sup>) describes the governance model that supports a broad involvement of the parties in relation to prioritization and implementation of the work with reference architectures and standards. A national board has been set up, which will advise the responsible minister of responsibility for overall IT architecture and setting standards. An advisory committee has been established to assess and select standards and assess architecture in the field of health that treat The Danish Health Data Authority recommendations prior to a possible presentation for the National Board of eHealth.

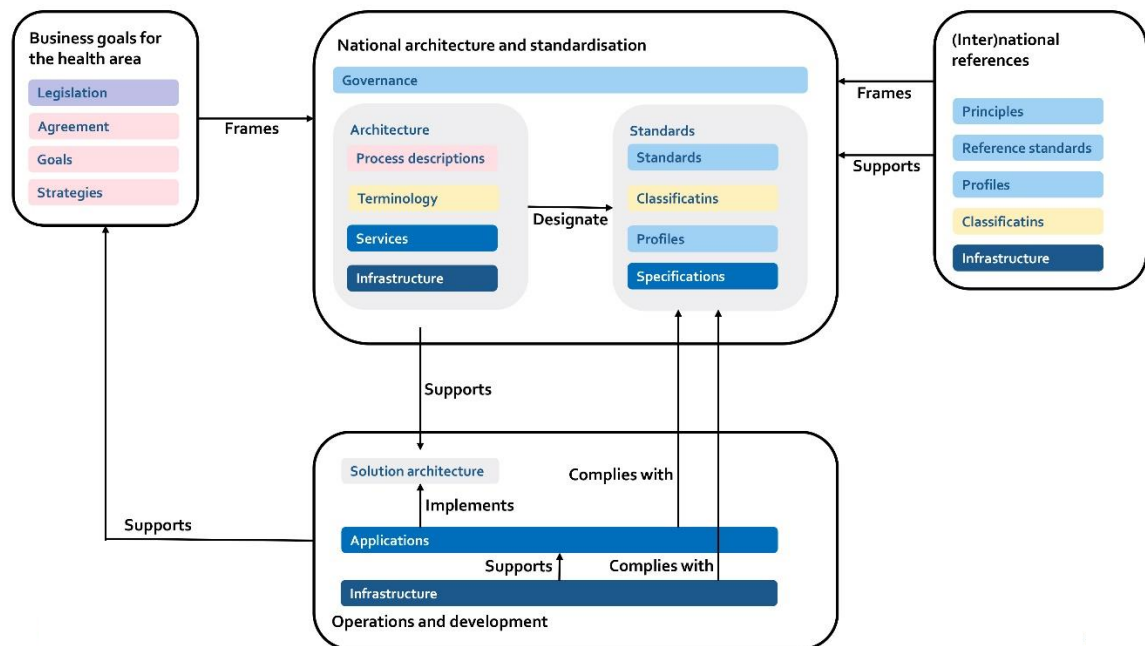
The advisory committee on standards and architecture (da: Rådgivende udvalg om standarder og arkitektur [RUSA]) consists of 10 members who have different business approaches in the field and will help ensure that The Danish Health Data Authority's assessments and options are dealt with from political, business and professional perspectives. The committee meets 4–6 times annually – organized so that the committee can process recommendation to be presented for the National board of eHealth.

The digitalization strategy is based on the tasks that meet the business needs of the main players. The strategy thus supports the performance of all tasks under the Health Act, covering all authorities as well as public and private actors involved in the carrying out of the tasks. This covers actors ranging from hospitals to GPs, from fertility clinics to nursing homes and hospices, and from pharmacies to auxiliary centres. The strategy has focus on the citizen as an individual and patient, and thus the individual's ability to influence his or her own health and actively contribute to prevention and treatment.

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<sup>17</sup> In Danish: <https://sundhedsdatastyrelsen.dk/da/rammer-og-retningslinjer/om-referencearkitektur-og-standarder/referencearkitekturer>

Figure 5: National architecture and standards can support the development of concrete solution architectures and systems that support the healthcare business goals, including contributing to and supporting the healthcare service and quality development



The architectural governance of standards is related to standardisation processes and governance described in the Danish model for governance, where the National Board of eHealth is the main responsible. Recommendations to the National Board of eHealth, based on the recommendation of the Advisory Committee on Standards and Architecture.

#### 4.2.2 Finland

Governance of eHealth-related standards activities is performed by the Ministry of Social Affairs and Health, the National Institute of Health and Welfare, and the Social Insurance Institution. National specifications produced by the authorities and national programmes are produced in a way that ensures feedback by stakeholders (e.g. requests for comments, workshops, seminars). Implementation guides and profiles of international standards go through open consensus-based processes before acceptance in the national HL7 / IHE association. Relevant standards for different parts of health services and national IT infrastructure are connected to the national level architectural steering instruments by the MSAH. The national eHealth strategy work has produced recommendations for further development of standards governance and participation.

Resources to participate standardisation work is limited and restricted to certain areas only. There are some national experts who work in some EU-funded projects that prepare standards.

Ministry of Social Affairs and Health takes care of some administrative processes as required by standardisation bodies. Coordination of recommended ISO standards is performed together.

The Ministry of Social Affairs and Health is responsible for and governs high level architectures for social and health care, both for primary and secondary use, using enterprise architecture methodology. The National Institute for Health and Welfare is responsible for information architecture and data modelling. The overall architecture of national eHealth services is maintained jointly by the authorities and governed by the Ministry.

#### 4.2.3 Iceland

The Directorate of Health in Iceland, mainly the National Centre for eHealth unit, has the main responsibility on which eHealth standards are being used within the country. There is an eHealth Standards Advisory Board that consists of experts within the field and is led by the National Centre for eHealth. Furthermore, there is an eHealth steering committee working with the National Centre for eHealth that participates in prioritisation of projects and decision making regarding the National eHealth strategy.

#### 4.2.4 Norway

The Norwegian Directorate of eHealth has an overall responsibility for standards and architecture within the healthcare. This include a governance responsibility for IT-architecture. The directorate has as a part of this overall responsibility established a governance model for the eHealth domain. The governance model consists of three levels which are described below (see Figure 6).

Figure 6: National Governance Model for eHealth



The Health Professional and Architecture Advisory body (NUFA) has broad representation of both technical and health professionals from the main organizations in the health sector. It is used to present project deliverables, discuss issues of common national interest and gather recommendations/experiences from the health sector. Examples are proposed use of SNOMED CT, standardisation of message formats or national XDS-architecture for cross-enterprise document sharing.

National Forum for Prioritization (NUIT) consists mainly of CIOs from the main organizations in the health sector in Norway, e.g. the 4 health regions, representatives from the municipalities, directorates, health professionals and patient organizations. Their main role is to prioritize the national eHealth portfolio. Proposed standardisation tasks or architecture choices with substantial financial or other impact on the health sector, may be submitted NUIT for anchoring and recommendation.

The National Advisory Board for eHealth consists mainly of the CEOs of the main organizations in the health sector. The board's main tasks are to endorse the National eHealth strategy and the national eHealth portfolio. In rare cases, proposals about standardisation which has a large financial or other impact on the health sector may be submitted to this board for endorsement.

Based on the advises from NUFA, NUIT and/or the National Advisory Board, as well as input from other sources (like the Product Board for eHealth Standards), the Directorate of eHealth is authorized to approve a standard (or choice of terminology or a reference architecture). Most standards are recommended, but some are compulsory (by regulations).

*The National Governance Model for eHealth Standards* (forvaltningsmodellen<sup>18</sup>) describes an executive process for governance of eHealth standards which cover the process from need arises through the phases; study, specify, test and verify, plan implementation, implement and governance. Every phase ends with a decision point where to decide whether the process will go further or not. The Norwegian Directorate of eHealth has the main responsibility for each phase, and is also responsible for the final decisions throughout the governance model.

The governance model for eHealth standards is a part of the national governance model for the eHealth.

An essential part of the governance model is the eHealth Standards Advisory Board (Produktstyre for e-helsestandarder). The board consist mainly of by IT-leaders from the 4 health regions, representatives from the municipalities, the Norwegian Directorate of eHealth, the Norwegian Health Network and the Norwegian Institute of Public Health. It will ensure a joint national priority and anchorage of decisions regarding development, and introduction of eHealth standards, in line with national strategies and priorities. The eHealth Standards Advisory Board has a key role in the decision points in governance model as an advisory board for the Directorate of eHealth, which has the responsibility for the final decisions.

A forum called SamUT is also a part of the governance Model for eHealth Standards. SamUT is a coordinating body that is the link between the national governance level and the organizations in the health and care services. The members represent the 4 health regions, representatives from the municipalities, representatives for general practitioners and the Norwegian Institute of Public Health. The Norwegian Directorate of eHealth and the Norwegian Health Network is the national governance level in the governance model and are both members of SamUT. SamUT has an

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<sup>18</sup> <http://ehelse.no/publikasjoner/nasjonal-forvaltningsmodell-for-e-helsestandarder-og-fellestjenester-for-elektronisk-samhandling-i-helse-og-omsorgstjenesten>

important role for discussions and coordinating of issues related to electronic collaboration in the health care. Recommendations from SamUT is also an important input to prioritization made by the Standards Advisory Board.

#### 4.2.5 Sweden

Sweden do not have one common standardisation process, but different actors do things in parallell for different parts of the health care system. Some examples are the Swedish eHealth Agency's work with e-prescriptions<sup>19</sup>, Equalis work with standards for clinical laboratories,<sup>20</sup> the Swedish Institute for Standards development of some health informatics standards,<sup>21</sup> the National Board of Health's work with semantical standardisation<sup>22</sup> and Inera's de-facto standards used in their services.<sup>23</sup>

In 2018, the Ministry of Health together with SALAR established the *National Forum for eHealth Standardization*. Once it's up and running, the Forum will suggest and establish common national standardisation processes and agreements.

The health care regions and municipalities are autonomous and have taxation rights and their own finances. Therefore, standardisation of eHealth must rely voluntary collaboration. Such collaborative structures are being set up through the eHealth vision 2025.

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<sup>19</sup> <https://www.ehalsomyndigheten.se/other-languages/english/>

<sup>20</sup> <https://www.equalis.se/en/start>

<sup>21</sup> <https://www.sis.se/en/sok/?q=health&searcharea=all>

<sup>22</sup> <http://www.socialstyrelsen.se/e-health>

<sup>23</sup> <http://rivta.se/>



## 5. International standards – The use of international standards in the Nordic countries

### 5.1 Examples of e-health standards in use in the Nordic countries

#### 5.1.1 *Denmark*

The Danish catalogue of standards<sup>24</sup> contains more than 200 standards in use. Some of the international standards in use are:

- Security: ISO 27001, OASIS (IDWS & SAML2);
- Clinical Documents: HL7 (V3 CDA);
- Infrastructure: IHE (XDS, ATNA etc), CDG (Continua);
- Terminology: ISO (IEC 13066, CONTSYS etc);
- Web/SOA: W3C (SOAP 1.1/1.2 MTOM/XOP);
- Messaging: EDI-FACT;
- Classification and terminology: WHO ICD10, SNOMED CT, NPU, ICPC-2, ATC, NCSP, ICF, DICOM.

#### 5.1.2 *Finland*

Finland utilizes international standards. Mainly these standards belong to the HL7-standard-family:

- HL7/ISO CDA R2;
- HL7 FHIR;
- HL7 version 2;
- HL7 version 3 Medical Records;
- DICOM, IHE XDS.b, XDS-I.b, XCA-I, XUA/SAML2, CT, ATNA for national imaging information sharing;

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<sup>24</sup> The Danish catalogue of standards: <https://sundhedsdatastyrelsen.dk/da/rammer-og-retningslinjer/om-referencearkitektur-og-standarder/standardkatalog>

- Several ISO/CEN originated standards for various eHealth related aspect including general topics and security;
- XUA / SAML2;
- JSON / XHTML;
- NEMESIS as base for national emergency data structures;
- Several international standards or their localized versions for terminology, e.g. WHO ICD-10 & ICF, LOINC, ATC, ICPC-2, NCSP, MeSH, UCUM, CCC as base for nursing classification, various ISO classifications;
- SNOMED CT (initial use since 2018, will be increased in future);
- Some recommended reference standards by ISO (e.g. 10781, 17269, 16527, 13940, 14265, 18038, 20514, 21090, 27001/27799).

### 5.1.3 *Iceland*

The following international standards are currently being used in Iceland:

- ISO 27001 or an equivalent standard is required to protect health information within electronic health records;
- HL7 v3 and FS ENV 13607:2000 are used for transaction of ePrescriptions;
- The International Classification of Diseases or ICD-10 is mandated for coding diseases;
- The Nomesco Classification of Surgical Procedures or NCSP is mandated to code surgical procedures;
- The International Classification for Nursing Practice or ICNP has been partially implemented. The ICNP is the classification that the Icelandic Nursing Association has recommended to be used for clinical nursing practice;
- The Anatomical Therapeutic Chemical Classification System or ATC is mandated to use for coding of drugs within the country;
- The International Classification of Primary Care, Second edition or ICPC-2 is mandated to use for coding reason for encounter within primary healthcare;
- The SNOMED-CT clinical terminology is used for pathology results and reporting of communicable diseases;
- The Digital Imaging and Communications in Medicine or DICOM is the standard being used for sharing of digital imaging;
- There are some proprietary standards or "home made" standards being used, i.e. for EHR systems and procedures other than surgical procedures.

#### 5.1.4 Norway

The current eHealth standards used for electronic collaboration on national level are mainly based on a message exchange architecture. Several specific standards have been developed to serve the requirements from different parties communicating.

Some of the standards are based on European CEN pre-standards, examples of such standards are:

- Referral message used for sending referrals from referring health care providers to an organization in the specialized health services;
- Discharge letters used for electronic transfer of discharge letters at the time of discharge from a health institution to admitting or referring healthcare providers or the patient's GP;
- Requisition/referral and reporting of results from laboratory tests like radiological or pathological examinations.

Recently profiles of HL7 FHIR have been developed. This include areas like:

- Critical information from the patients Summary Care Record (Kjernejournal, [5]);
- The Welfare Technology domain;
- The national patient portal at <https://helsenorge.no/>

Other HL7 standards such as v2, v3 and CDA are also in use in Norway. These HL7 standards are mainly used between different EHR systems within the hospitals.

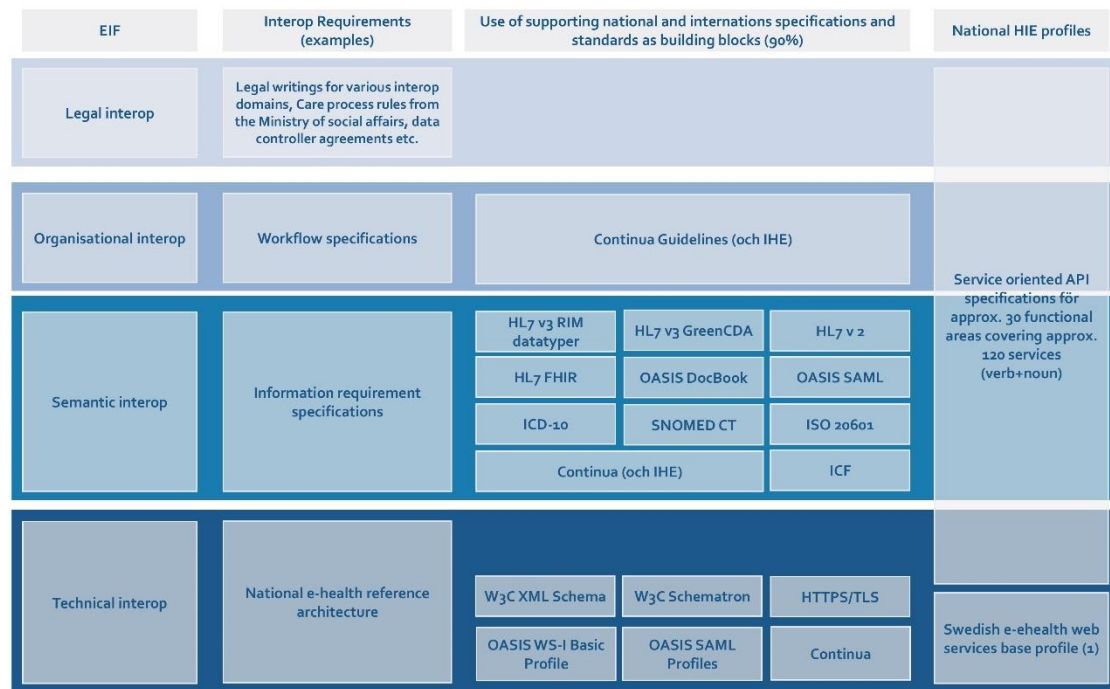
Norway have also some message standards that have been developed for specific purposes. These include messages related to electronic prescriptions which are currently in wide use in the value chain between the doctor and pharmacy. More than 90% of prescriptions were digital in the beginning of 2018.

Message standards have also been developed for communication to the Norwegian Labour and Welfare Administration (NAV). These messages include for example sick leave certificate from doctor and inquiry about patient.

#### 5.1.5 Sweden

For more than ten years, Inera has together with the county councils and regions developed integration profiles and common specifications to support the need of interoperability in Sweden. The development of the integration profiles is based on the county councils and regions need. More than 100 integration profiles has been developed and maintained. The integrations profiles use international standards where appropriate. The picture below describe which international standards is used in the integration profiles. During the work over the last ten years the use of international standards has increased and today the information exchange is mainly based on HL7 v3 Green CDA.

Figure 7: Swedish eHealth interoperability standards and architectures



To give the care providers the possibility to exchange data the Integration profiles has been implemented to the Swedish Health Integration Platform connecting more than 400 care provider systems and more than 1 billion data transactions per year.

The standardisation work is also managed by reference architectures, commonly agreed by the parties i.e. the county councils and regions and the industry. A reference architecture is an architectural pattern in a given context pointing out standards and integration profiles for instance:

- Reference architecture for interoperability in Swedish healthcare;
- Reference architecture for identity and access management;
- Reference architecture for telehealth.

Inera has completed a Proof of Concept validating the use of FHIR on REST in coexistence with the existing SOA approach:

- <https://riv-ta.atlassian.net/wiki/spaces/RTA/pages/506855608/RIVTA+on+FHIR>

Inera has evaluated different interoperability standards for use in the national collaboration model:

- [https://www.inera.se/globalassets/aktuellt/upphandling/stodmaterial-infor-landstings-och-regioners-upphandlingar/utvardering\\_av\\_internationella\\_standarder-pa8.pdf](https://www.inera.se/globalassets/aktuellt/upphandling/stodmaterial-infor-landstings-och-regioners-upphandlingar/utvardering_av_internationella_standarder-pa8.pdf)

## 5.2 Plans for future standards (next 3 years)

### 5.2.1 Denmark

Efforts in HL7 CDA is continued as a matured and recommended for document-based collaboration on document sharing platforms that is IHE XDS.

New standards like FHIR and other RESTful services needs to be supported by security standards like OpenIdConnect, OAuth2 and IDWS. All of them need to mature for operational business use and need to be profiled for national purposes.

We continue to develop CDA profiles for sharing information across sectors, regions and municipalities. The Program for Patients with Complex pathways develops CDA profiles for appointment, shared personal datacard and treatment plans and activities.

MedCom have plans evolving for the message infrastructure within the European eDelivery framework. eDelivery is a network of nodes for digital communications. It is based on a distributed model where every participant becomes a node using standard transport protocols and security policies.<sup>25</sup>

An analysis of the implications of implementation of WHO ICD11 is being prepared and DHDA is working on a strategy for national classifications and terminologies.

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<sup>25</sup> Connecting Europe Facility: eDelivery <https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/eDelivery>

### 5.2.2 *Finland*

The role of HL7 FHIR will increase in personal health information management and possibly other new areas. Evaluation of FHIR for social services records has been planned.

SNOMED CT introduction has started gradually since 2018. Finland participates in the development of ICPC-3 and plans the introduction of ICD-11. A national terminology strategy for future years is in preparation phase.

### 5.2.3 *Iceland*

For the next three years there is a plan in Iceland to replace the “homemade” documentation standards for an internationally recognized terminology. The focus is currently on common coding for laboratory results, but different laboratories in Iceland are using different “homemade codes”. Moreover, the implementation of the nursing classification ICNP within the EHR system will continue. There are also plans to make the International Classification of Functioning, Disability and Health or ICF available for coding within the EHR system. Furthermore, close focus is kept on ICD-11 and the International Classification of Health Interventions or ICHI. Iceland will be keeping an eye on HL7-FHIR and other international recommendations for eHealth standards, i.e. by the European Commission.

### 5.2.4 *Norway*

Within the next 3 years there will be high focus on implementation of necessary new and updated standard for referrals, implementations of standards where messages are sent to and from healthcare organization’s clinical field instead of clinics (tjenestebasert adressering) and clinical dialogue between healthcare professionals in the continuity of care of patients. These are all message-based standards and are necessary to improve the digital communication and strengthen the patient safety.

We also see an increased focus on other collaboration models like document sharing and data sharing. There is an expectation that new requirements and demands mainly will arise within these two models, and that the message exchange will be rather stable for the next years.

Currently a roadmap for more extended use and coordination of international standards in the future is being developed. Important short-term initiatives are related especially to HL7 FHIR, and includes for example establishing national base profiles, cooperation arenas (communities) and best practice principles for developing interfaces based on FHIR.

The Directorate of eHealth has performed an evaluation of different interoperability standards for use in the national collaboration [1]. The standards were chosen as they may be relevant for future standardisation. The following results of the evaluation were published:

- HL7 FHIR – supports several collaboration models, but not yet normative (expected in 2018) – recommended usage in smaller solutions/interfaces for testing purposes and gaining experience;
- HL7 version 3 – mature standard, but limited development expected – not recommended for new solutions/interfaces;
- HL7 CDA – mature standard – recommended for document-based collaboration on document sharing platforms (for example IHE XDS);
- openEHR – for interoperability openEHR should only be considered for collaboration between system that already is based on openEHR;
- Linked data – limited use in the healthcare environment, more relevant for open data sources – not recommended;
- IHE XDS – mature infrastructure for sharing documents – should be considered for this purpose but also requires a document standard for the content (document).

#### 5.2.5 *Sweden*

To increase the support for Interoperability in the next three years the work with integration profiles will continue. The use of HL7 FHIR will increase but mainly in areas where HL7 FHIR is considered mature or normative. In other areas the use of HL7 v3 GreenCDA will remain.

Many of the twenty one County councils and regions in Sweden are about to implement or procure new EHR-systems. The procurement phase will be ongoing until the end of 2019. The result of the procurements will probably speed up the adoption of standards.

There are ongoing discussions between the government and SALAR on how to best agree on standards. These discussions are done as part of the cooperation within the work with the e-health vision for 2025: <https://ehalsa2025.se/in-english/>

### 5.3 Experiences with the standards (positive and negative)

#### 5.3.1 *Denmark*

Implementing new standards is in reality a question of how mature a vendor organization is to grasp new standards. What is very easy to use for some, may be very difficult for others. Another aspect of standardisation is vendor specific flavors, meaning each vendor may have their own and different style compared to others in relation to the implementation of standards. It is important to have as precise as possible descriptions to a solution to common technical implementation for standards, and they must support the national semantic rules, to avoid vendor own styles and flavors. Besides the actual standards profiles for national use, this can be supportive to have technical implementation guides, software tools (CDA builders), CDA validation tools and IHE XDS search tools (GUI) for testing new clinical

standards like CDA's. These types of deliveries have a positive tendency to increase both technical and semantic interoperability by being operational, inspirational and easy to use.

### **5.3.2** *Finland*

Standards have provided readily specified basis for many local, regional and national interoperability, functionality and security requirements. Many organizations feel standards are too difficult and slow to develop and change. Despite of using standards a lot of verification and testing is needed. Participation in standards development is too small and fragmented, most actors focus on use of standards or non-standard-based interface development. It is also noted that standards need to be complemented and adapted according to local needs and legislation, for example the national IT services provide information exchange point which relies on national specifications to which systems and actors need to comply with. Basing these specifications on standards increases quality, reliability and completeness, and eases international interoperability and market development.

### **5.3.3** *Iceland*

There are both legal and financial incentives for implementing standards. The use of mandated standards within healthcare can increase the quality of healthcare delivery. Standards are necessary for the collection, exchange, storage, and retrieval of healthcare information. They are necessary for mutual understanding and sharing of health information. Standards are necessary for comparability and research. If we don't have standards we cannot communicate health information effectively and patient safety and quality of care can be at risk. Common standards are crucial for interoperability, and necessary for meaningful communication between health professionals. They are needed to support decision making for managers, directors of health institutions, policy makers and for patients themselves, across local, national and international boundaries. The negative about standards is that it usually takes a long time to implement them, they can be expensive, and sometimes new versions are not compatible with older versions.

### **5.3.4** *Norway*

HL7 FHIR has been used in more and more software during the last couple of years. So far, the experience is good, but there is an increasing need of coordinating the development so that base profiles can be developed, and that best practices and guidelines are made available for the implementers.

### 5.3.5 *Sweden*

Ther experience from more than ten years of work with interoperability and integration profiles based on standards has given the following experiences:<sup>26</sup>

- Increases quality and stability in the specification work;
- Sometimes Increases the complexity of the solution;
- Reduces the cost for the specification work but initially prolongs the learning time for developers.

Regarding Semantic interoperability – a standard code system is very important, e.g. the National Information Structure from the National Board of Health and Welfare. The HL7 base data types provide good support – good balance between flexibility and complexity.

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<sup>26</sup> [https://www.inera.se/globalassets/aktuellt/upphandling/stodmaterial-infor-landstings-och-regioners-upphandlingar/utvardering\\_av\\_internationella\\_standarder-pa8.pdf](https://www.inera.se/globalassets/aktuellt/upphandling/stodmaterial-infor-landstings-och-regioners-upphandlingar/utvardering_av_internationella_standarder-pa8.pdf)



## 6. The use of international information models and architectural models

### 6.1 Overview of the present integration standards, information standards and architecture models in use

#### 6.1.1 *Denmark*

We have to note, that national models are being used, though based on international standards for modeling. The Danish Agency for Digitization have made shared model rules (da: Modelregler) aiming at promoting modeling that can ensure that the data collected and handled in public organizations can be easily understood and recycled across the public sector. The rules are based on a number of principles of good modelling and a modeling method that promotes business clarification and recyclability.

Therefore, congruence between the national domain specific requirements should be seen in connection with national cross sectoral requirements as well as international requirements.

The modeling method involves separating the modeling work in such a way that independent business areas are modeled independently – this breakdown allows reuse of foreign domain models in self-modeling and supports the dialogue on how best to coordinate the shared business processes.

1. Integration standards and information standards has been mentioned previously with the addition of HL7 V3 Reference Information Model (RIM)
2. Business process modelling: BPMN
3. Architecture models: Archimate and UML

Archimate is an international drawing and notation standard at enterprise architecture level. Archimate is taken as an open standard under the Open Group and is today part of the TOGAF architecture framework. Archimate, UML and BMN is part of the Danish Common model rules.

HL7 V3 RIM has been accepted as a domain requirement for health area in Denmark.

### 6.1.2 Finland

In Finland, several HL7 based information models have been used. National specifications based on consensus of expert groups and published through the National Institute for Health and Welfare are implemented through implementation guides and profiles of standards. FHIR resources are profiled in some areas (especially national PHR).

For enterprise architecture methodology, a national architectural framework, loosely based on TOGAF is used. Recommended notational standards in public administration, including BPMN, UML and Archimate are used.

“Information standards” also include terminologies and classifications discussed in previous sections.

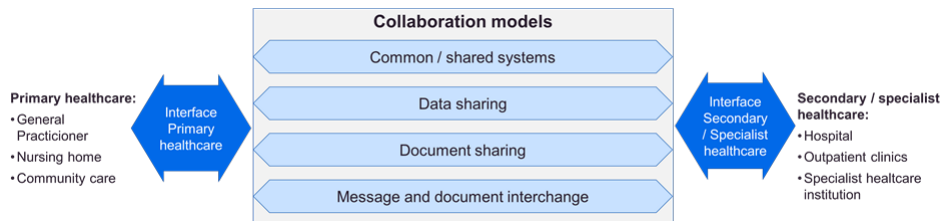
### 6.1.3 Iceland

Iceland has interconnected EHR's on a national level and an integrated national patient health portal. Use of standards is described in chapter 5.1. on international standards.

### 6.1.4 Norway

Message and document exchange is widely used in the digital collaboration in Norway. However, other collaboration architectures are expected to develop in the coming years. These models are mainly based on architecture schemes like direct access, data sharing and document sharing. Currently these new ways of collaborating have a very limited use, and the use of message exchange encompasses nearly 100%.

Figure 8: Collaboration models



- Unified Modeling Language (UML) is a widely used standard for information modeling in Norway. The main standards for collaboration is based on this information modeling standard;
- FHIR is a standard with increased momentum the last couple of years. It is mainly used in interfaces but there has also been some discussion about using it for information modeling;
- openEHR is used for creating archetypes in the specialist healthcare. One of the main EHR systems in Norway (DIPS) is based on archetypes.

The message exchange architecture is based on the international standard ebXML, which describes a framework for digital communication.

#### **6.1.5 Sweden**

Same answer as question 1 from chapter 5 “International standards”.

### **6.2 Plans for future standards for the next years (integration standards, information standards and architecture models)**

#### **6.2.1 Denmark**

As mentioned before Archimate is a new method and tool to model and describe architecture, so our need is to use this method on a regular basis.

In our shared effort to use each others models, we collaborate e.g. with the organisation Local Government Denmark (the confederation of Danish municipalities) to align models for common understanding and re-use. To achieve this we share the Danish shared model rules as a common ground.

#### **6.2.2 Finland**

In addition to document based system there is a need for data warehouse type of systems. In such systems the data specifications will probably be similar as current system but structure and meta information will be different. Experience from HL7 version 3 modelling and implementation has been found to produce a very steep learning curve for implementers. More implementer-friendly standards such as FHIR will be emphasized. A more modular approach for data modeling for health information modeling is being developed. Such an approach for social services core data components is already in place. The national terminology strategy will guide the introduction of central terminology and code system versions in next five years.

#### **6.2.3 Iceland**

Same answer as in section 5.2 *Plans for future standards*.

#### **6.2.4 Norway**

The Directorate of eHealth is establishing reference architectures for the different collaboration models: message-/document exchange, data sharing and document sharing. These architectures will be published for use when the necessary technical solutions blocks are developed to ensure unified implementation. These models and architecture will be building blocks in a foundation for digital services that will be developed in the next years.

We expect that there will be more focus on standardisation of the information content in the future, which is assumed to give more flexibility when implementing interfaces. In a long-term horizon we expect that there will be a set of re-usable common information models which can be used to establish more specific information models for the actual use cases. This is expected to ensure more efficient development of collaboration solutions and standards.

For communication purposes, the Advanced Message Queuing Protocol standard (AMQP) has been investigated. Currently there is no decision on whether we will start using this standard.

#### **6.2.5 Sweden**

Same answer as question 2 from chapter 5 "International standards".

### **6.3 Experiences with these standards (positive and negative)**

#### **6.3.1 Denmark**

HL7 V3 RIM seems for some vendors as a very handy method for modeling, and others find it too difficult to get their job done. The RIM helps terminology as an "information model" covering all information that must be communicated in support of health care interoperability.

#### **6.3.2 Finland**

In architectural and data level HL7 based standards have been useful. In technical level there are many possibilities to implement systems and thus testing and verification is needed despite of using standards.

#### **6.3.3 Iceland**

Same answer as in section 5.3 *Experiences with the standards (positive and negative)*.

#### **6.3.4 Norway**

We have limited experiences with new international standards and needs more time before we can conclude.

We have however recently performed an evaluation of a set of standards for information modelling [2]. The following standards are recommended:

- HL7 FHIR - recommended when information should be exchanged;
- openEHR- recommended for storing of information where the systems already are based on openEHR data structure;
- Unified Modeling Language (UML) – recommended for consolidation of information models based on different standards/specifications;
- Detailed Clinical Models (DCM) – the parts in the standard related to processes and maintenance are recommended for documenting the principles and methods for information modeling.

#### 6.3.5 *Sweden*

Same answer as question 6 from the chapter 5 "International standards".



## 7. The vendor market – The role of standardisation in speeding up innovation and enabling a Nordic eHealth market

### 7.1 Existing follow up activities to vendors

#### 7.1.1 *Denmark*

Denmark uses meetings where developers meet to connect to each others systems and request and read data. Like Connectathon, “FHIR Hackathon”, Plugathon (CDG) and alike.

4S (Stiftelsen for Softwarebaserede Sundhedsservices) is a shared ecosystem consisting of a board, a coordinator, a software group and a number of professional forums. They support knowledge sharing and provides open tools, platforms, tutorials and guides available. 4S works closely with users like regions, municipalities and companies for use and further development. They support and supplement the dissemination of telemedicine that is embodied in national strategies, action plans and reference architectures.

Open source tools:

- CDA builders, Open Tele 3
- IHE Connectors
- Implementation guides to vendor based on national profiles
- CDA Validation tool
- IHE XDS Viewer

As mentioned previously, supportive activities like technical implementation guides, software tools (CDA builders), CDA validation tools and IHE XDS search tools (GUI) for testing new clinical standards like CDA's. These types of deliverables has a positive tendency to increase both technical and semantic interoperability by being operational, inspirational and easy to use.

### 7.1.2 *Finland*

In Finland many EHR system vendors are concentrated on fulfilling their customers need to store and retrieve EHR data to national repository. They are not interested using standards as such but think those more like system specifications they have to take into account. Some vendors have been active in national standardisation, concerning their product areas, very few have been active in international standardisation. Use of recent standards such as FHIR and IHE profiles has boosted significant participation in interoperability demonstration events. Majority of vendors perceive the use of standards and readily made specifications is more useful than participation in the standards development and voting activities.

### 7.1.3 *Iceland*

Iceland is constantly working with the vendors of the Saga system, which is the EHR system, which is implemented in over 90% of healthcare organizations in the country, to make the system better and more user friendly. Different vendors using different systems are allowed to connect to the Icelandic HealthNet, if they fulfill certain security requirements and mandated standards. Implementation of international standards is part of the eHealth policy.

### 7.1.4 *Norway*

In Norway we are working towards more use of international standards, like HL7 FHIR. Some of the existing and future vendors of EHR in Norway are also vendors in other Nordic countries. If we are using the same standards in the Nordic countries this can give lower entering barriers and costs for vendors to the Nordic countries.

For some years there has been a national project which focus on improving functionality in EHR systems for general practitioners (EPJ-løftet), that aim at prioritizing which functionality that the vendors to the GPs should develop. The vendors are partly refunded when they have developed prioritized functionality.

The Regional Health Authorities have for some years worked on specifications of archetypes using OpenEHR. The archetypes are being implemented in the next version of the EHR-system that 3 out of 4 hospital regions are using (DIPS).

The Nordic countries have coordinated work within the personal connected health domain through a series of workshops and the development of a joint document called "Towards a Nordic Reference Architecture for Personal Connected health and care Technology" [3]. The Nordic coordination work has been linked to our joint activities in the PCHA-Continua organization, where all the Nordic countries and many central PCH vendors are members. The preliminary conclusion is that all countries choose to loosely adhere to the overall PCHA-Continua architecture in different ways, taking on different positions as to how strictly one should place requirements on specific points of the architecture. The trend in all four countries has been a long-term movement towards FHIR-based interfaces on the EHR-interfaces within the PCH architecture.

For social care alarms, the directorate was closely involved in a functional specification for social care alarms in CEN. As this work has moved over to a technical specification in CENELEC, the directorate has taken a bystander role and asked the vendors to be more closely involved in the actual specification.

#### **7.1.5 Sweden**

The general answer to all three questions in this chapter is that international standardisation is an important tool that contributes to Sweden's competitiveness as it allows vendors to avoid having to adapt to different requirements for the same product in different export markets and instead participate in the specification of standards. Standardisations is an important part of the Swedish e-health vision and the Swedish export strategy.<sup>27</sup>

Ineras is also working with vendor associations to discuss and collect comments in the work with reference architectures and standards. The main vendor associations is the Association for Medical Technology in Sweden (Swedish Medtech) which has approximately 180 member companies.

The Nordic coordination work has been linked to our joint activities in the PCHA-Continua organization, where all the Nordic countries and many vendors are members. The Swedish Vendor associations as Swedish Medtech has been involved to give comments to this work. As mentioned earlier (chapter 5.1) one way to manage the use of standards is via reference architectures. In the development process of reference architecture vendor associations are involved.

There are implementation guides to all the integrations profiles to help the vendors to integrate. All guides are available via the web site: [www.rivta.se](http://www.rivta.se)

## **7.2 Planned activities to speed up innovation (related to standards)**

### **7.2.1 Denmark**

The tools mentioned previously is used in projects like PRO-data (questionnaires), and new standards within the Program for a consolidated patient overview to improve implementations guides with good examples, CDA builders for Questionnaires, Appointment document, Treatment plans; updating CDA validation tools and IHE XDS search tools.

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<sup>27</sup> <https://www.government.se/4a3e02/contentassets/bofd09051c6c4af59c8e33a3e71fff24/vision-for-ehealth-2025.pdf>,  
<https://www.regeringen.se/4b003b/contentassets/e2b2f540107143e99907cbe604a87ce2/swedens-export-strategy.pdf>

### **7.2.2 Finland**

In the national eHealth strategy one component is speeding up innovations around national health records system. There has been an innovation competition for start up companies to create new eHealth services using the national PHR (Using FHIR). The use of standards can speed up development through increased quality and readily-made models for implementations.

### **7.2.3 Iceland**

Currently, there are no planned activities to speed up innovation related to standards.

### **7.2.4 Norway**

To speed up innovation we are focusing on using standards and building ecosystems that different vendors can use to integrate their solutions. We must think bimodal (Gartner) where some systems, like core-EHR, will be quite stable and have a long life, while we need other applications that is more flexible and agile, where different vendors can innovate and integrate with the core systems. Examples of standards used for this is FHIR, SMART on FHIR, but it can also be different types of APIs that vendors can use to integrate systems.

The current Nordic cooperation within the Personal Connected Health space, both with the Nordic countries and vendors who are not directly involved in projects, is through the participation in PCHA-Continua specification activities. Our future role as a directorate in this standardisation organization is currently being evaluated. One other important activity has been the establishment of a Nordic cooperation for PCHA equipment, connected to the PCHA-Continua standard, and it is believed that further development of test facilities for these purposes is an important activity to speed up innovation. These test facilities are intended to operate outside the control of the directorate.

### **7.2.5 Sweden**

The development of national Integration profiles based on FHIR over REST will help to speed up the innovation because of less complexity for vendors to use them.

A Nordic cooperation around the PCHA-Continua standard and further development of test facilities for these purposes will speed up innovation.

## 7.3 Involvement in Nordic or international initiatives related to standards

### 7.3.1 *Denmark*

The NPU terminology is providing laboratory codes to the Danish, Norwegian, and Swedish laboratories. The terminology is hosted and maintained by the Danish Data Health Authority in cooperation with Norwegian and Swedish national release centres. The development of the terminology is carried out on an international level.

The Danish Health Data Authority is represented in different international standardisation organizations and workgroups. Our current focus on using international standards are at Personal Connected Health Alliance (Continua Design Guidelines) to increase interoperability.

The Danish Health Data Authority participates among others in:

1. Nordic Council of Ministers
2. eHealth Network, eHAction
3. DS: HL7
4. DS: ISO/TC215, CEN/TC251
5. Personal Connected Health Alliance (PCHA)
6. SNOMED CT
7. WHO
8. NOMESCO

A central issue regarding national activities as well is appropriate to mention. The Danish Agency for Digitization within the Ministry of Finance was established in 2011 to be in charge of the government's digitization policies. With the aim of renewing the Danish welfare, the agency is responsible for the implementation of the government's digital ambitions and the use of digital welfare technology in the public sector. By sharing infrastructure components and by using open standards they ensure that digitization in the public sector does not develop the same components more than once, but reuse shared components where possible, and by using open standards to avoid provider lock-in with proprietary solutions.

A central remark is that international standards need to be customized – profiled for national use, but national profiles, though they are based on international standards, can still pose a threat to interoperability.

### 7.3.2 Finland

Some Finnish national experts have participated in the specification of several European and international level information exchange standards.

Finland votes regularly in all relevant international ISO TC 215, HL7 International and CEN TC 251 votings and there are 1–2 Finnish participants in most ISO TC 215 meetings, and 1–2 Finnish participants in 1–2 HL7 international meetings per year, and some meetings related to IHE and classification standards. Finland recently joined SNOMED International and participates in its General Assembly and Member Forum.

Finland participates in several standards-related European projects and groups, including eHDSI / CEF, eHAction, and Trillium II.

### 7.3.3 Iceland

Iceland participates in the following Nordic/International initiatives related to standards:

- Nordic Council of Ministers, eHealth group and sub-group Nordic eHealth Research Network (NeRN);
- NordClass;
- SNOMED International.

### 7.3.4 Norway

The Directorate of eHealth and vendors in the Norwegian healthcare are represented in different international standardisation organizations and workgroups. Related to our focus on using international standards and see how we can increase innovation by getting more in line with initiatives in other countries, we will strengthen our strategic role as a member of different standardisation organizations and international workgroups. The directorate of eHealth participate in the following organizations/groups:

- ISO/TC215 Represented in the underlying working groups; WG1, WG3, WG4, WG6 (e-prescription);
- CEN/TC251 The Norwegian head of delegation and is represented in the two underlying working groups; WG1, WG2;
- HL7 Norway: Member of the board and represented in the national working group;
- eHAction/EHR Exchange format;
- Personal Connected Health Alliance (PCHA), manage the Continua specification.

### 7.3.5 *Sweden*

Different organizations in Sweden participates among others in:

- HL7 Sweden: Inera is in the board of HL7 Sweden;
- eHAction/EHR Exchange format. Sweden has representative in the working group;
- Personal Connected Health Alliance (PCHA), SALAR and Inera is member of the PCHA organization;
- Active participation in SNOMED International advisory and working groups;
- Active participation in WHO-FIC work;
- SALAR participating in formal standardisation on national (SIS TK 334), European (CEN TC 251), and international level (ISO TC 215);
- NOMESCO via the Ministry of Health and Social Affairs and the National Board of Health and Welfare.



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# Sammenfatning

I regi af Nordisk Ministerråd har de nordiske lande siden 2011 arbejdet sammen omkring strategiske forhold inden for e-sundhed. Frem til 2018 har arbejdet bl.a. fokuseret på etableringen af et sæt af indikatorer der skal understøtte de enkelte lande i arbejdet med e-sundhed. I 2018 er det nordiske samarbejde udvidet, så der nu også er fokus på standardisering inden for e-sundhed.

På et seminar afholdt 30. og 31. august 2018 i København, hvor eksperter og policymakers fra de nordiske lande var til stede, blev der arbejdet intensivt med at kortlægge hvordan standarder kan understøtte nationale mål inden for e-sundhed. Forud for seminaret var der gennemført en undersøgelse af hvordan arbejdet med standarder er tilrettelagt i de enkelte lande, hvilke strategiske mål der er på området, hvilke internationale standarder der anvendes og hvilke planer der er for fremtiden i hvert enkelt land.

Det har resulteret i denne rapport om "eHealth standardisation in the Nordic countries". Rapporten er produktet af seminaret og en efterfølgende viderebearbejdning og analyse af den tilvejebragte viden. Rapporten afspejler de nordiske landes aktuelle arbejde med standardisering inden for e-sundhed og skaber grundlag for videndeling på tværs af landene, både i forhold til hvordan arbejdet tilrettelægges i de enkelte lande, men også i forhold til hvilke standarder det kan være relevant at bringe i anvendelse på området.

Arbejdet med standarder inden for e-sundhed udvikler sig med stor hast og rapporten skal ses som et øjebliksbillede af hvordan situationen er i de enkelte lande. Derfor fortsætter samarbejdet imellem de nordiske lande, for hele tiden at sikre optimale forhold for videndeling mellem landene. Der er etableret en standardiseringsgruppe i regi af det nordiske e-sundhedssamarbejde, der vil videreføre arbejdet med standardisering med udgangspunkt i nærværende rapport. Rapporten skal ses som et dynamisk dokument der løbende opdateres og tilpasses, så det afspejler aktuelle forhold i de nordiske lande.



# Appendix 1 – questionnaire

Questions asked to the countries in preparation for the seminar on standardisation:

1. What are the policy instruments used to setting standards and securing adherence to standardization at a strategic level?
  - 1.1. Legal instruments related to the use of standards
  - 1.2. Financial instruments related to the use of standards
  - 1.3. Other strategic instruments related to the use of standards.
2. How does the countries organize their normative role (e.g. Standardization bodies, Architectural governance, etc.)?
  - 2.1. Overview of the actors in e-health standardization in each country
  - 2.2. Overview of the standardization process and governance
  - 2.3. Architectural governance related to the use of standards.
3. Which international standards are chosen within the countries' national eHealth strategies and what are the experiences with these?
  - 3.1. Overview of the e-health standards used
  - 3.2. Plans for future standards (next 3 years)
  - 3.3. Experiences with the standards (positive and negative).
4. Which international information models and architectural models are chosen within the countries' national eHealth strategies and what are the experiences with these?
  - 4.1. Overview of the present integration standards, information standards and architecture models in use
  - 4.2. Plans for future standards for the next years (integration standards, information standards and architecture models)
  - 4.3. Experiences with these standards (positive and negative).
5. What role can standardization play with regards to improving conditions for vendors, speeding up innovation and enabling a Nordic eHealth market?
  - 5.1. Existing follow up activities to vendors
  - 5.2. Planned activities to speed up innovation (related to standards)
  - 5.3. Involvement in Nordic or international initiatives related to standards.



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### **eHealth standardisation in the Nordic countries: Technical and partially semantics standardisation as a strategic means for realising national policies in eHealth**

This report summarises the discussions from a seminar held 30 and 31 August 2018 in Copenhagen on eHealth standardisation in the Nordic countries. The seminar was organised by the Nordic Council of Ministers' eHealth group. The report represents the beginning of a more permanent Nordic collaboration in this area. Following the seminar and the subsequent analysis of the input from the seminar, the eHealth group has decided to establish a subgroup on eHealth standardisation.

The scope of the report is limited mainly to technical standards, with some examples including semantic standards. The work of the sub group will take on both the former and the latter and will be elaborated further within the broader framework of the European Interoperability Framework in which organisational and legal standards are included.

