Towards a Nordic Reference Architecture for Personal Connected health and care Technology

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Important notice:

This document is work-in-progress and does not define or describe the definite current or future architectures in the respective Nordic countries. The architectural and service concepts are being piloted in the each Nordic country, and the reader should refer to the national institutions for national reference architectures.

Content

Acronyms and abbreviations

FHIR   Fast Healthcare Interoperability Resources

HIE   Healthcare Information Exchange

IHE   Integrating the Healthcare Enterprise

PCHA   Personal Connected Health Alliance

PCH   Personal Connected Health

SDO   Standards Developing Organization

Background

The nordic countries have a relatively small population and share a common set of principles for delivery of public health care and social care services. Healthcare is heavily dependent on IT solutions for its operation. Since many years, it uses advanced medical equipment with supporting complex IT solutions. Efficient and patient-centric operation of the healthcare process depends on information utilization across IT solutions, healthcare facilities and even across healthcare organisations. The EU have visions of care processes spanning member states, calling for even broader context of care coordination. Successful HIE has become a prerequisite for a successful healthcare system, at regional and national levels.

From the perspective of most healthcare information system vendors, a Nordic country constitutes a smaller market. As of today, vendors typically approach small markets by offering extensive custom-specific development and customization. For a small country the cost for adaptation becomes proportionally very high. As a result, it may constrain the possibilities of purchasing international quality software since the best bid may often end up being a locally developed bespoke solution hardwired to the current, regional or national HIE requirements. Bespoke solutions fulfill the requirements, but typically lack common prerequisites for a long and happy life: a large installed base.

The Nordic countries try to compensate for a small market by establishing national bodies to select, implement and govern national HIE interoperability standards and architectures. Even if existing international standards and profiles - like those of HL7, Continua and IHE - are selected, advanced and costly country profiling work remains. Success depends on uptake and uptake depends on selecting and packaging standards that are appropriate and fit for purpose. Even then, international HIE standards are - due to their nature - complex matter to digest. Although there are plenty of off-the-shelf systems that support various IHE profiles,

they are not always user and implementor friendly. They require substantial amount of experience to succeed with adoption and there are so many areas of HIE that an individual Nordic country usually has to focus on a small set of use-cases at a time, leading to many years of work before a significant contribution to the national ehealth ecosystem can be measured.

The Nordic countries have identified a window of opportunity for sharing these efforts in order to cut time in development and adoption, decrease cost and raise the quality of national PCH standardisation.

The redundant work across the nordics would be minimal and the opportunities for re-use would be substantial. However - such re-use depends on a shared understanding of the specifics of each country. This document defines a reference model that the Nordic countries have outlined together, to be able to harmonize architecture descriptions and compare national architectures. The first area covered is Personal Connected Health. The domain reference model of Personal Connected Health is based on the work of the Continua Alliance now known as PCHA. The nordic reference model is a superset of the Continua reference model. This will probably also be the case in the long term, since there may occasionally be requirements not yet covered by Continua guidelines. The model will likely have a role in communicating Nordic requests for enhancements in the Continua Guidelines to PCHA. Among the most important requests is the use of more modern and developer-friendly frameworks, such as HL7 FHIR.

In order to further investigate opportunities and plan for initial activities, representatives of national bodies of Finland, Denmark, Norway and Sweden met in Oslo in early July 2015. As one of the outcomes, the team agreed on the need of a shared architecture reference model as a basis for collaboration. Such an agreement would allow a common vocabulary as well as a solid scope definition. Both aspects were identified as important cornerstones of a result-oriented collaboration. The architecture reference model is from here on labeled "reference architecture".

Purpose

This Nordic PCH reference architecture defines architecture elements and patterns shared by the Nordic countries. The purpose is to identify opportunities for nordic coordination of PCH interoperability standards selection and adoption. In its first version, it should at least support collaboration on the HIE domain of personal connected health. There is a shared agreement of building on the work of the Personal Connected Health Alliance and shifting the model towards more modern architectural building blocks, including HL7 FHIR and OAuth. The initial version will focus on telemedicine and related monitoring within healthcare. Social care alarms are in the planning for the next revision.

This document is aimed for vendors, national architecture and standard bodies, international SDOs and social and healthcare organizations interested in the Nordic development of PCH solutions. One specific goal is to work with PCHA to modernize the Continua framework with HL7 FHIR.

Usage scenarios

Nordic alignment of strategies to reach a shared market

One potential use for the document is to align nordic personal health technology architectures sufficiently to create a joint market. The eHealth leadership of the nordic countries could serve as a global hotspot of PCH technology development. The image below describes this and also brings in other areas of technological excellence in the Nordic countries.
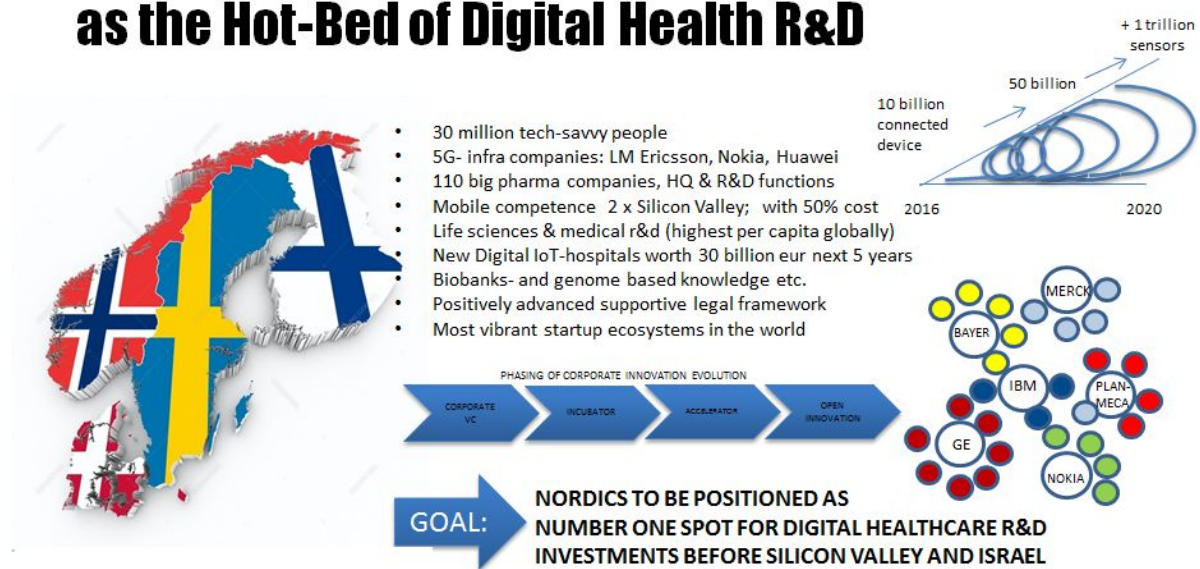
Image by Pekka Sivonen, Tekes - The finnish innovation agency

Basis for country-specific communication and adoption

This version of the reference architecture discusses existing standards and on-going development from all the Nordic countries. In many aspects the countries are doing similar things, but there are also differences in approaches and implementations. For example, in specific areas a single country might be moving ahead in an area others are not working on yet. We can use these examples as basis for discussion in other countries. Also successful and failed piloting initiatives can be used to refine to common reference architecture in the future.

On areas where the countries are harmonised on an issue, we can push for nationwide or regional adoption and help with the creation of a standards based marketplace which goes beyond the Nordic countries.

Background material to procurements

Procurements define what eventually gets implemented and deployed in the social and healthcare service system. Having the reference architecture as a background material for procurement serves the purpose of declaring that the ongoing procurement is aligned with broader international development.

Scenarios/Use-cases

Personal connected health scenarios

There are two main scenarios of personal connected health that are currently shared across the Nordic countries. The scenarios share a set of information exchange requirements, but they also have their specific characteristics, calling for specific (yet standardized) information exchanges. The most applied scenario within the Nordics is *Healthcare-initiated data collection*, typically in the context of telemedicine. The second scenario is Citizen-initiated data collection, including "quantified self" use cases. In this scenario, the person shares data collected within a personal data collection initiative with a healthcare provider. In real life these scenarios can be mixed and the subject of data collection can move between the different roles (patient/citizen) while the data collection technology remains the same.

Healthcare-initiated data collection scenario

In the healthcare-initiated data collection scenario, a care provider prescribes a self treatment plan (also referred to as action plan). Typically the goals set in the plan are agreed upon in collaboration with the patient and healthcare professional. As part of the prescription process, the healthcare professional configures the setup of the treatment. Apart from assigning a patient, it may also include setting up the patient's smartphone with apps associated with the treatment and to register and hand over sensors to the patient. In another organizational arrangement the treatment support team may handle the configuration.

Action plans typically include information about which symptoms to look for, used to place the patient into three categories, green, yellow and red. Green is the normal state, while red is a severe worsening. Each state indicates a number of actions that the patient should initiate, including which medication to take. The action plan may also include information about which data to report, including frequency of submitting questionnaire responses and sensor data, and a prescribed action plan could therefore be the basis for managing the data reporting specifics.

The following figure illustrates the scenario and its associated roles and processes:
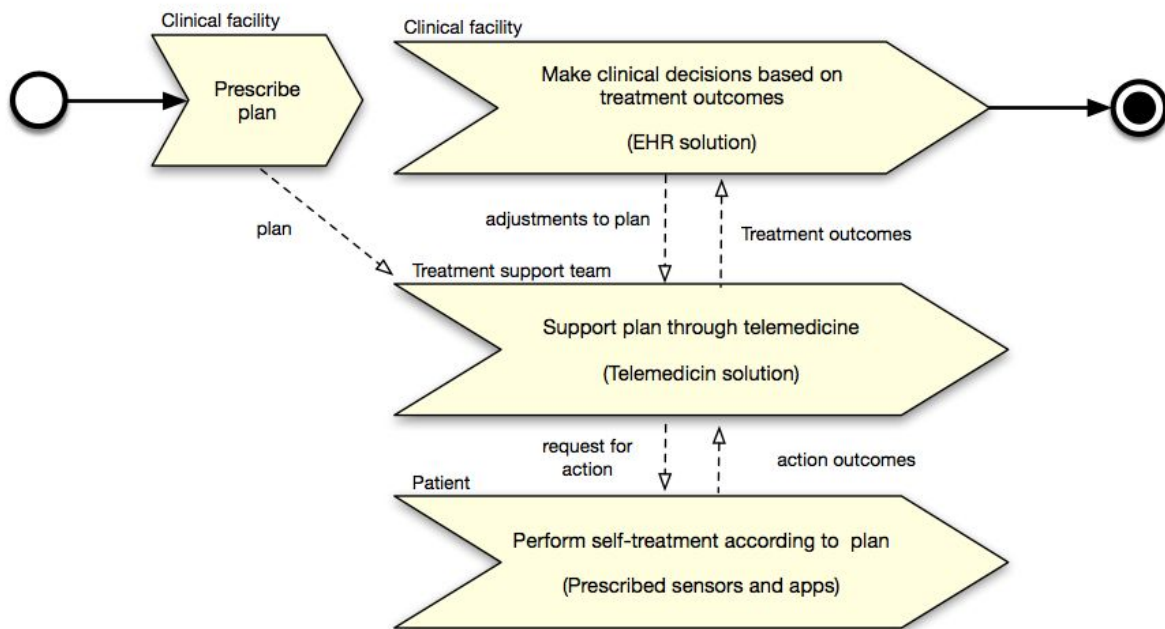
This is the primary scenario to drive requirements on the reference architecture in this revision of the document.

Citizen-initiated data collection scenario

In the citizen-initiated data collection scenario, the person collects health data based on personal preferences. Data is typically collected through self tracking using smartphone apps and/ or external sensors. The citizen uses sensors and apps out of personal preferences. These may or may not be certified medical devices. The patient typically wants to reference this data and analytics carried out on the data, when approaching the care process. The care professional has a lot of considerations to make before using these data as basis for clinical decision making.

As of today, there is little research available and thus no systematic approaches available at the national level of the Nordic countries. However, all countries report that it is a growing area of innovation. New kind of collaboration-oriented m-health solutions are in the coming. The solutions tend to strive for a shared clinical collaboration arena centered around the citizen with data based decision support for the citizens "clinical family" (doctors, home care, caring relatives etc). A common pattern seem to be the need to submit selected portions of the citizen-generated data (physical measurements or structured self judgements) into the EHR, which will then require the patient's consent as well as the acceptance of the healthcare provider.

This new kind of citizens-centric services seem to approach data sharing as mutual exchanges. The citizen provides her data to the healthcare provider and healthcare provider may offer the citizen healthcare-sourced structured access to or copies of EHR content. The following figure illustrates the scenario as two related but not formally connected processes:
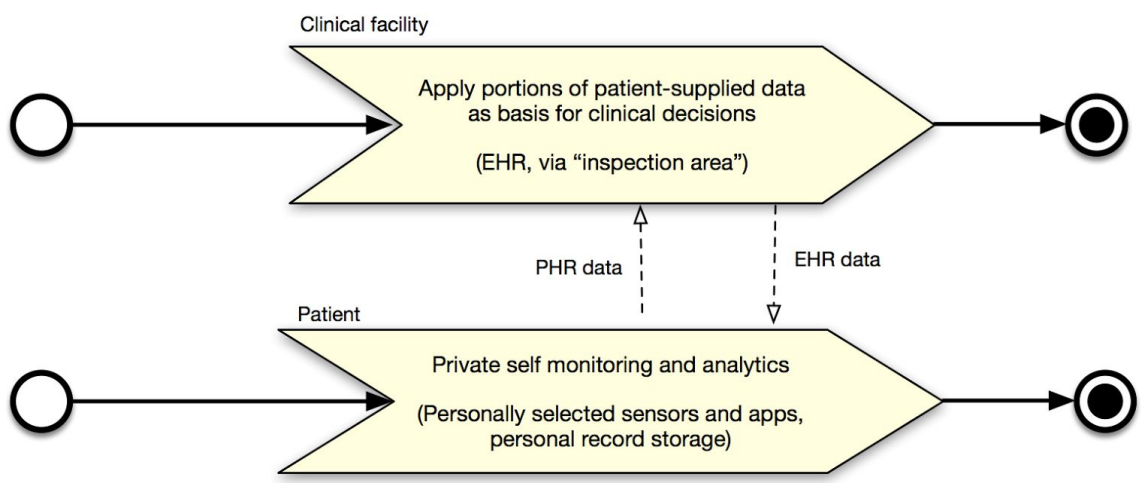
This scenario is not yet covered by the reference architecture.

Reference architecture

This section defines the logical model of the portion of national architectures that relates to personal connected health. Its scope is to cover relevant parts of the Continua Design Guidelines [CDG] as well as areas within personal connected health interoperability not yet covered by the Continua guidelines. The purpose is to map national architecture elements and standards selections in such a way that they become comparable across national reference architectures. The reference architecture is also useful when comparing and purchasing personal connected health solutions in terms of support for open interfaces.

The high-level figure outlines the reference architecture elements required by the healthcare initiated data collection scenario:
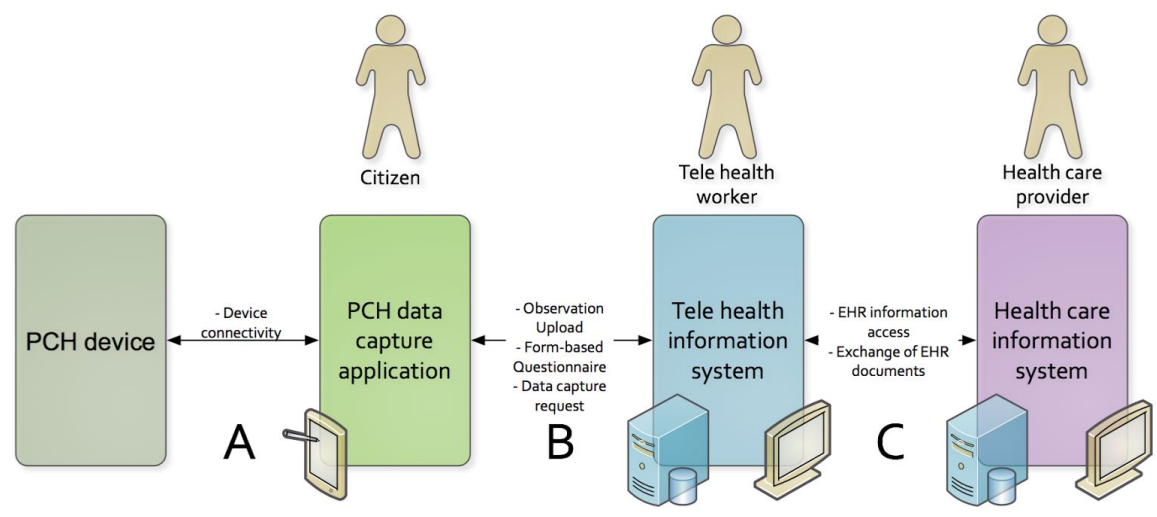
The country-specific sections describes how the shared reference architecture maps to the architecture of telehealth initiatives within each country. The details of the reference

architecture and its components (interfaces and functional components) is defined by the next figures and the adjacent tables. There is one figure for each of the included principal scenarios.

Architecture definition for the healthcare initiated data collection scenario

The following figure highlights the reference architecture elements required by the healthcare initiated data collection scenario:
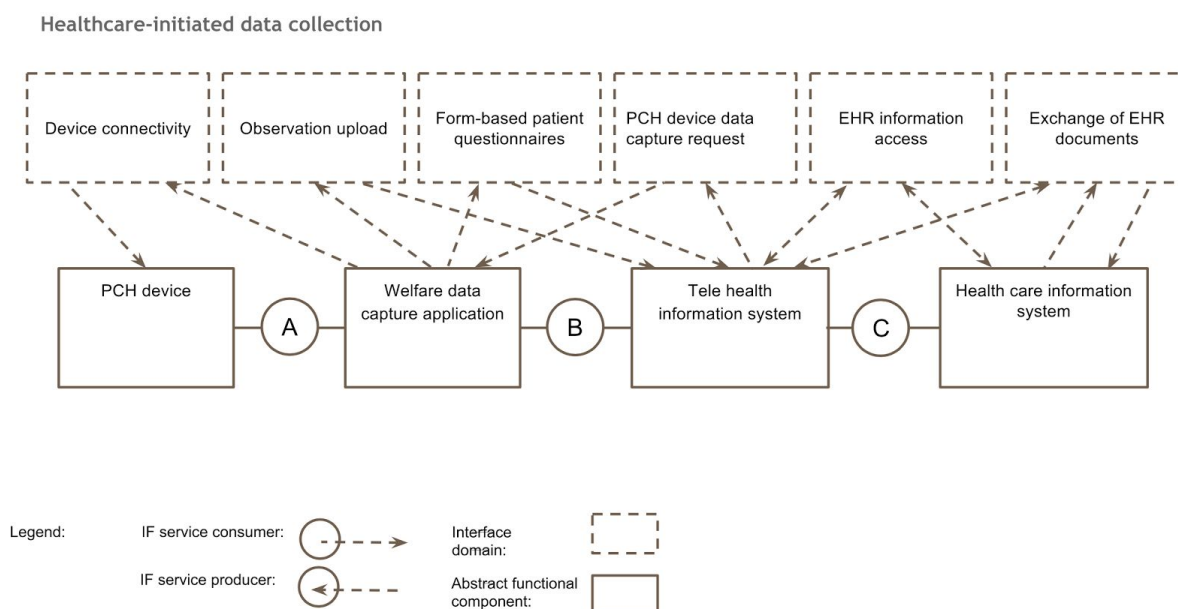
Reference architecture functional components

The following table defines the functional components of the reference architecture.

Name/Class	Description	Examples
PCH device	Typically a sensor based data capture device for use in home/telecare settings.	Blood pressure sensor, wireless weighing-scale
PCH data capture application	An application or functional component that interacts with PCH devices and back-end tele health information systems. It may be tightly coupled to a specific Telehealth system/platform or coupled to a generic tele health monitoring infrastructure.	An android application running on a personal android device, connected to home sensors. The application receives monitoring orders (data subscriptions) and monitoring procedures from a tele health information system.

Telehealth information system	A telehealth coaching or treatment information system or functional component. Such a component typically offers functionality to define, initiate, monitor and follow up telehealth treatment procedures (plans). The data collected is likely temporal during the lifespan of the treatment. Long term storage is handled by other functional components, such as health care information systems or national health data stores.	A software-as-a-service web based tele health solution offered by a commercial supplier, or a tax funded governmentally sourced solution. Another example is a functional component (module) of a healthcare information system.
Healthcare information system	The information system hosting the EHR functional component. This is typically the enterprise system shared by care providers within a region, hosting the electronic records in line with legally regulated care provider responsibilities.	Products of the EHR Market.

Reference architecture, interface components

The following table defines the interface purpose (Continua: "capabilities")

Interface class	Interface purpose	Description	Applicable standards (Continua-referenced when available)
A	Device connectivity	Interface to connect PCH devices to PCH data capture applications.	The Continua Personal Health Devices Interface.
B	Observation Upload	Interface for a personal health data capture application to report captured observations to the Tele health information system.	The Continua Observation Upload capability of the Services Interface, The HL7 FHIR Observation resource with POST method.
B	Form-based patient questionnaires	Interface to conduct form based data capture, based on dynamic form templates. The personal connected health data capture application is the client serving forms to the user. The Tele health	HL7 FHIR Questionnaire and QuestionnaireResponse. The Continua Questionnaire capability

		information system serves the client with templates and forms yet-to-be-completed. It stores the intermediate and finalized forms posted by the user of the client.	of the Services Interface.
B	PCH device data capture request	Interface used by the Tele health information system to send data capture requests to a PCH data capture application (or application infrastructure). This standard interface is required if manual or proprietary procedures need to be avoided when getting data capture requests from the Tele health information system to the PCH data capture application.	Using FHIR resources may be an option. IHE had PCD-02 but withdrawn in 2015. (Not covered by Continua in sufficient detail)
C	EHR information access	Interfaces for service-oriented information re-use across telehealth information systems and healthcare information systems. In this context, information access primarily pertain to sharing of observations captured within clinical and telehealth processes. Any interacting party may be client or server or both. It is also offered as a patient-controlled information sharing API (e.g. OAuth2) to support patient-directed sharing of EHR to Patients personal health tools not under the control of the healthcare system.	GET- and LIST-methods of the HL7 FHIR Observation resource, IHE XDS Request-Response, IHE MHD. (Not covered by Continua)
C	Exchange of EHR documents	Interfaces to push data captured in telehealth process to an EHR system for clinical use of the data.	Continua HIS Interface (PUSH using HL7 CDA PHMR with IHE XDR/XDM), applicable HL7 FHIR resources

Summary of national standardization

The following table summarizes the current and envisioned standard selections for each interface of the reference model. The strategic direction for most interface purpose converge to HL7 FHIR (Observation upload etc) in the longer term. Norway is currently actively

collaborating with Continua to have HL7 FHIR integrated into a future version of the guidelines, primarily for Observation Upload. Each country has a row and there is one column per interface purpose. Each cell documents the current standard endorsed by the organization representing the country in this collaboration. In some cases, the cell also document thoughts about a future direction (labeled "next:"). The level of adoption may vary among the countries. Some details regarding how the standards are currently applied within a country may be found in the country-specific sections.

	Device connectivity	Observation upload	Form-based patient questionnaires	PCH device data capture request	EHR information access	Exchange of EHR documents
Finland	Current: Vendor specific Next: Eval. Continua	Current: FHIR for upload to national PHR	Current: FHIR	Current: Not defined Next: Looking into FHIR Subscription	Current: FHIR / REST + CDA R2 + DICOM + PDF	Current: HL7 V3, XDS-I + XCA, CDA, DICOM
Denmark	Current: Vendor specific & Continua	Current: PCD-01 Next: PCD-01 & FHIR	HL7 CDA Questionnaires	Current: Not defined Next: To be defined	Current: Not defined Next: To be defined	IHE XDS & IHE XDS-I CDA R2 & DICOM
Sweden	Current: Continua Next: Continua	Current: Continua IHE PCD-01 Next: Continua FHIR	Current: SE-specific Next: Continua FHIR	Current: Vendor specific Next: To be defined	Current: Green CDA WS Next: To be defined	Current: Event WS + Green CDA WS Next: To be defined
Norway	Current: Vendor specific & Continua	Current: Not defined Next: PCD-01 & FHIR	Current: Not defined Next: FHIR	Current: Not defined Next: To be defined	Current: National msg Next: FHIR (?)	Current: National msg Next: XDS (?)

Strategic interfaces of the Nordic collaboration

Membership status of standardization and profiling organisations

	National HL7 Affiliate	IHE International - national deployment committee	IHE Europe participation	PCHA (key organization as a member)
Finland	Yes	Yes	Yes	Considering
Denmark	Yes	?	Planning	Yes
Sweden	Yes	Yes	Planning	Yes
Norway	Yes	No	No	Yes

National sections

Each country describes the personal connected health intersection of the national reference architectures, by means of the nordic reference architecture. The purpose is to facilitate mutual understanding across the Nordic countries as well as across the industry. This is

also a statement of adherence to the architecture concepts of the Nordic reference architecture. The purpose of the national mappings is to communicate the level of alignment of standardization strategies across the Nordic countries.

Denmark

Denmark - General health architecture for PCH

This covers the Danish recommendations for personal connected health, which primarily deals with questionnaires and home monitoring of COPD, diabetes as well as other diseases. It does not encompass the full enterprise architecture of Danish health care. The existing point-to-point clinical message exchange in the Danish health sector based on MedCom[1] message specifications has been sending clinical information since the nineties. The message standards are based on profiled EDIFACT standards and VANS communications[2].

A common national query based Health Information Exchange based on IHE XDS document exchange, was initiated 2012. There are two main areas for clinical document sharing in Denmark: one is a running project for using IHE XDS-I.b for sharing images across regions. The other is within the area of telemedicine with a current special focus on clinical home monitoring data and Questionnaires shared within the common national IHE XDS infrastructure.

Personal Connected Health in Denmark

Denmark released in 2013 the first and current reference architecture for collecting health data from citizens. It defines guidelines for standardised, efficient and secure transfer of measuring and monitoring results, including images, video and text messages, so that these made available to the health professionals that need them in treatment of patients. The data may have been collected by the individual citizens themselves under health care instructions or by health professionals assisting the individual citizen. For further information from the Danish reference architecture for collecting health data from citizens, visit this reference [Ref:RA-CHDC-DK].

The reference architecture for collecting health data from citizens forms the framework for approving national standards for collecting health data from citizens and it will act across organisational boundaries and ICT systems. This reference architecture is to support the dissemination of telemedicine solutions by ensuring a standardised and simpler way of collecting data and making it available to employees in the healthcare sector.

The focus of the reference architecture is on the health monitoring data flow from the individual citizen. The data collected from the citizen and passed on electronically to data repositories from which health professionals across all organisations can access the data that is relevant for the individual patient's treatment. Introducing standards for how data is communicated and shared enhances the possibility for reusing both data and ICT solutions. By making data available to health professionals as entire sets of data or as 'documents' (see the reference architecture for document and image sharing [Ref:RA-DIS-DK].), data is

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[1] MedCom is a Danish standardization organization that profile Health standard for message communication and document exchange: http://www.medcom.dk/
[2] VANS is a Communications network that distributes digital messages and bills, using EAN addressing (European Article Numbering).

made available in a simple and efficient manner to all relevant parties working together for the individual citizen.

The reference architecture for collecting health data from citizens is based on the primary use of data for patient treatment. Any use of the collected data for secondary purposes (research, quality development) is not described.

Personal Health Portal

Denmark has a citizen health portal Sundhed.dk [Ref:S-DK], where citizen-related public health issues are collected. Some of the services exposed at Sundhed.dk are going to use XDS as part of the architecture to present documents from IHE XDS repositories from for example municipalities and hospitals for both citizen and health care professional's access.

HL7 CDA R2 is used to share home monitoring data, through Personal Health monitoring Report (PHMR), which were the first official Danish CDA profile. Next in line was Questionnaires (2015), with both Structured Form Definition Document (SFDD) and Questionnaire Response Document (QRD). This set of Danish HL7 templates are part of personal connected health initiatives in Denmark with a primary focus on the home monitoring of COPD, which have a national rollout plan ending 2019. Sharing health collected data for treatment across health sectors, Questionnaires and home monitoring data can be retrieved as HL7 CDA documents querying the common IHE XDS infrastructure.

There is not an official statement for using FHIR though, there is interest in finding mHealth pilot projects that can expose and prove the strengths of using FHIR.

The past ten years of telemedicine

The substantial strain on Danish healthcare services has brought about increased interest in testing telemedicine solutions that allow for the monitoring and treatment of patients in their own homes, thus reducing costs, particularly of hospital treatment.

In recent years, several pilot projects have been completed or commenced which test telemedicine solutions and which have provided the various healthcare providers with greater knowledge about the possibilities for using telemedicine.

However, many of the projects have been established as single, independent projects that have not been linked to the overall use of eHealth. Each project has ended up with its own solutions and architectures and has applied different technologies.

The fact that the various solutions do not 'speak the same language' (i.e. that the semantic content has been perceived differently) has obstructed the dissemination of solutions for telemedicine.

Target architecture for PCH

In general terms, the figure describes the logical division in which the system - technical target image can be grouped and it gives a clear indication of the most important interfaces addressed by the Danish reference architecture for collecting health data from citizens [Ref:RA-CHDC-DK].

Provisioned equipment operated by the instructed citizen
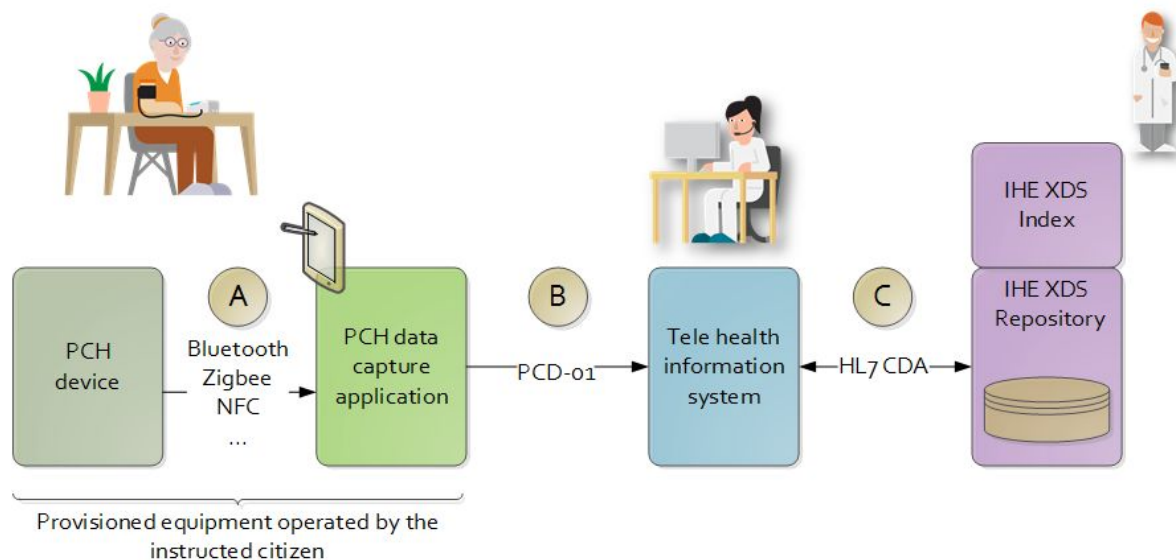
Framework for Health data collection

Continua has been chosen as the framework for PCH device and PCH data capture application devices, but the reference architecture also includes collection of monitoring data via other channels (not shown in the figure above) as formulas to input information and images, but where collection is done at the citizen. The reference architecture does not describe how these data is to be collected and processed locally (eg. home), but dictates that the monitoring data collected must be delivered to a tele health information system in a similar manner.

Relationship to other Danish reference architectures

This reference architecture has a limited scope. Firstly, this depends on the Danish reference architecture for document and image sharing, which sets the framework for how to make various types of information available to several providers and consumers in a standardised way that does not require prior knowledge about the internal structure of other ICT solutions.

This reference architecture for collecting data from citizens does not address the display of collected data for consumers; however, it describes the interface between the two reference architectures.

With regard to the fundamental elements in information security (accessibility, integrity, confidentiality, authenticity and non-repudiation), for health data collection at the citizen's home and within the Health Business further description can be found in the Danish reference architecture [Ref:RA-SEC].

Danish mapping to standards for PCH technology

The following table shows the current status as well as preliminary strategies regarding the use of standards. The table is structured according to the nordic reference model:

| Interface class	Interface purpose	Current standards	Strategic direction
A	Device connectivity	The data and exchange formats are recommended as specified in the Continua Framework by using the IEEE standards 11073-20601, and 11073-104xx.	Measuring device using exchange formats are recommended as specified in Continua frame using the IEEE standards from 11073 -20601 and 11073-104xx. And support Bluetooth LE and Personal Health Devices Transcoding White Paper
B	Observation Upload	PCD-01	Selection of standards should be made on the basis of international standards, possibly with elaboration through Danish profiling, if necessary.
B	Form-based patient questionnaires	Questionnaires; structured as HL7 CDA QRD.	CDA-2-based document specification: Questionnaires (SFDD & QRD).
B	PCH device data capture request	Not yet defined	No plans presently
C	EHR information access	No current standard except for document sharing.	No further plans
C	Exchange of EHR documents	HL7 CDA R2 is used for sharing home monitoring data, Questionnaires and the Telehealth information system has to support the functionality for a document source for XDS	IHE XDS is sharing paradigm in Denmark. The current status of Danish CDA profiles can be found in Danish health standards catalog.

		infrastructure.	

Finland

The appendix describes the overall architecture and main drivers of the Finnish eHealth and eSocial development. Reader is referred to the appendix for further details. Personal connected health and measurement solutions will extend the pre-existing national health IT infrastructure whose main components include centralized services for EHR repository and ePrescriptions, citizen portal and various different EHR and specialized systems as well as regional or provider-specific electronic services for citizens.

Finnish wellbeing architecture in relation to the reference architecture

After several pilots in self care services the decision to start building a national PHR was taken in 2015. Government is also funding the development of PCH applications into primary and specialized and social care. Interfaces to wearables and medical devices are left to vendors although Continua is being looked at as a potential standard for device interfaces. Also some 3rd party adapters provide capability to extract wellbeing data from multiple global health and wellbeing ecosystems. HL7 FHIR was chosen as the standard for storing and communicating PCH data between the apps, the PHR and professional systems. Wellbeing apps will also be able to use data from the national health archive and prescription center.
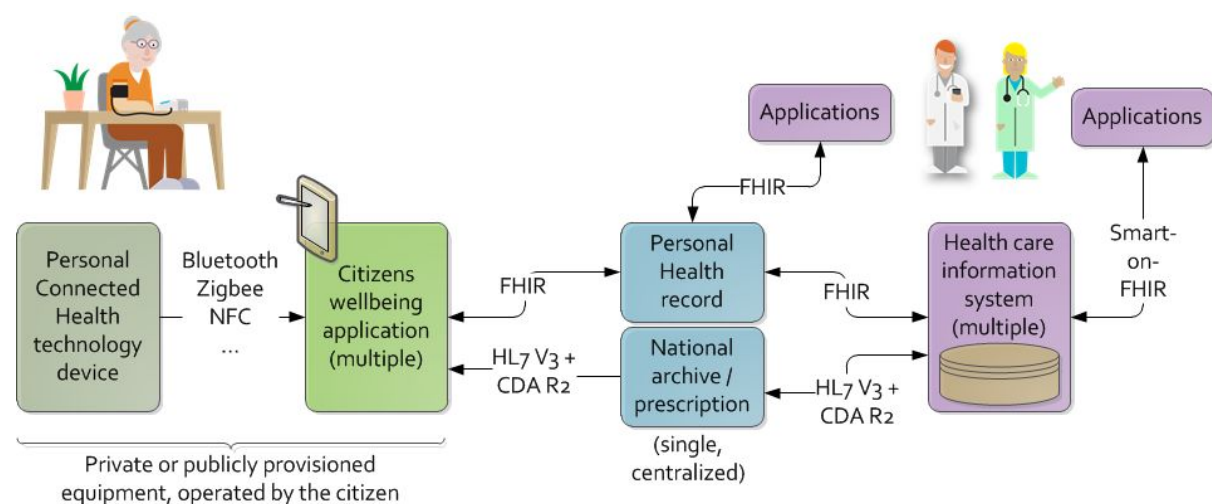
Components:

- **PCH Device**: Medical devices and sensors that are operated by the citizen, collecting data for submission. Devices can be prescribed by a healthcare provider or by used in a citizen initiated fashion.
- **Citizens wellbeing application**: A device and software at home or on the go, possibly a tablet, smartphone or a fixed device, which is used to collect data from severals devices. The application can store wellbeing data into the national PHR, retrieve data stored by other applications.
- **The personal health record**: This is centralized national service providing data storage for wellbeing apps. Healthcare can access the data stored by citizens apps if a consent has been given. The applications can be intelligent, for example virtual coaching for the patient uses artificial intelligence and machine learning in the

coaching protocol. Human interventions are done in certain steps and if needed. The PHR replaces the "telehealth information system" in the reference architecture and is used to relay information between the citizen and the service system.

  ○ The national archive is similar centralized system but for official and professional records. The wellbeing apps can access official patient records (healthcare) and customer data (social care) if needed.
  ○ Apps are certified according to the requirements level posed by the information sources they access.

- **Healthcare information system**: There are numerous systems that healthcare providers use to access the PHR data and nationally stored EHR data. The provider can receive information from a sympton checker, results of a virtual coaching program or results of the jointly (doctor & patient) agreed upon self care plan.The stored data can be accessed as granular resources or as documents, depending on the use case. Goal is that telehealth aspects are integrated in health information systems and there is no strict separation between telehealth and other professional systems. Many telehealth services already operate using basic health information systems and general purpose tele-working tools.
- **Applications** are components accessing the Healthcare IS using the FHIR interface and Smart-on-FHIR framework. These applications can be used for reviewing citizen's personal health record or commenting on citizen's progress towards the goals set in the jointly agreed upon care plan.

Finnish mapping to standards for personal health technology

The following table shows the current status as well as preliminary strategies regarding the use of standards. The table is structured according to the nordic reference model:

Interface class	Interface purpose	Current standards	Strategic direction
A	Device connectivity	No formal national decision. Various protocols are being used and this is vendor specific. Some adapters extract wellbeing data from multiple wearables.	Follow international and Nordic development. Evaluate Continua as a potential standard.
B	Observation Upload	HL7 FHIR Observation resource	Follow profiling efforts of countrywide or otherwise large PHR development projects. Prepare for normative standard.
B	Form-based patient questionnaires	FHIR Questionnaire + QuestionnaireResponse,	-

		system specific queries and user interface level integrations	
B	PCH device data capture request	Not yet defined. Applications can poll and query for data from the PHR.	-
C	EHR information access	HL7 FHIR, HL7 CDA R2 implementation guides	-
C	Exchange of EHR documents	HL7 V3 + XDS/XDS-I, CDA R2, DICOM, PDF	Introduce FHIR and Smart-on-FHIR in suitable application areas

Overview of interoperability standards used

- In sharing of healthcare data:
    - HL7 V3 medical records
    - HL7 CDA R2
    - IHE XDS and other relevant IHE profiles
- In sharing of wellbeing data (personal health data)
    - HL7 FHIR DSTU 2
   - OAuth

Legal background in Finland

Finnish legal framework considers national health IT infrastructure through centralized services, requirements for service providers including self-supervision, and essential requirements for health IT systems (functionality, interoperability, security). New legislation will be introduced in 2017, extending the scope to the national personal health record infrastructure and requirements for personal health solutions. Data controller responsibility changes and consent / access policy changes are also expected, partially also related to the national social and health care reform and the GDPR.

Norway

This document covers the draft norwegian recommendations for home monitoring using personal connected health technology as of December 2015 [NO-VFT-2015], and does not encompass the full enterprise architecture of norwegian health care.

Continua has been chosen as the basis for the Norwegian personal connected health activities, and the project is currently outlining which parts of Continua guidelines to use and how this will work together with other technologies such as SCAIP [SCAIP] and FHIR [FHIR]. Norway are working actively within PCHA to include FHIR into the Continua guidelines. Telehealth pilots are ongoing in 4 municipalities and will be concluded during 2018. The diagram below shows the norwegian outline draft architecture, but this architecture vision may change as a result of ongoing pilots.

The proposed Norwegian architecture from December 2015 did not contain the "Telehealth information system", but only the Health care information system where data was stored (a planned national storage for patient reported data called "Central Hub"). Experience from pilots show that local systems at municipalities or other service providers may in some cases need to be between the "PCH data capture application" at the patient's home and the national health care information system, which stores the reported data as part of the patient's record. Introduction of this in-between collection component also mirrors the danish reference architecture and the Continua design guidelines. In the diagram below, this component is called "Telehealth information system" and reflects the Continua Health & Fitness service.
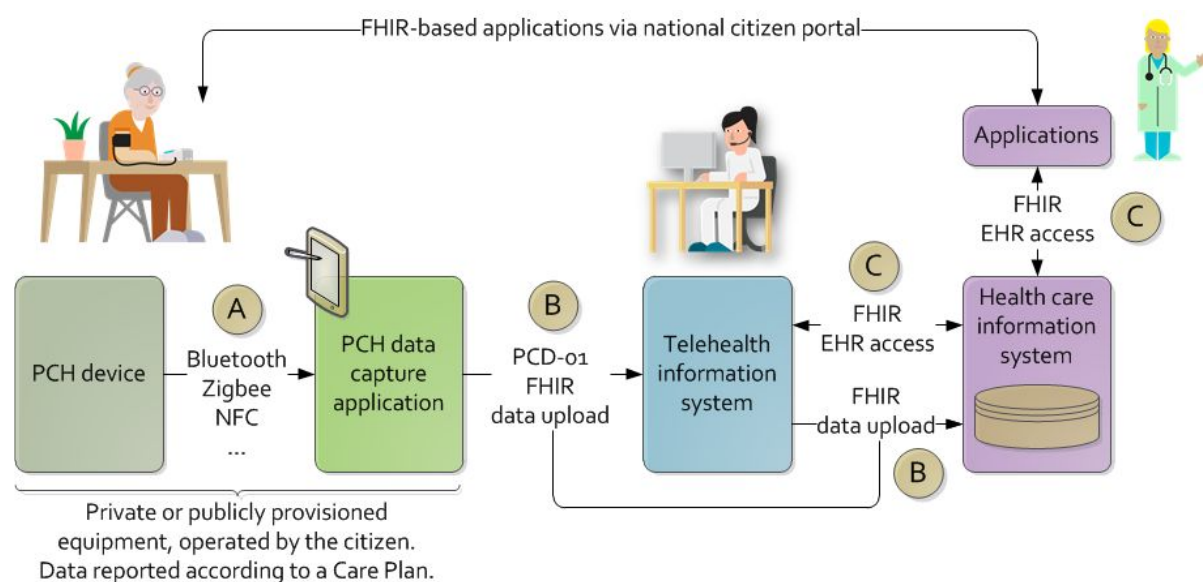
Components:

- **PCH Device**: Medical devices and sensors that are operated by the citizen, collecting data for submission.
- **PCH data capture application**: A device at home, possibly a tablet or a fixed device, which is used to collect data from severals devices.

- **Telehealth information system**: This is one or more central servers, operated at a municipality, regional or national level, which collects, monitors and forwards data from several PCH data capture applications to a healthcare information system. The system uses the Health care information system for sharing data.
- **Healthcare information system**: This is a number of central EHR components, including a planned national component for storing PCH data centrally, including sensor measurements and questionnaires. The stored data can be accessed as granular resources or as documents, depending on the use case.
- **Applications** are components accessing the Healthcare IS using the FHIR interface, presenting the data in a human-readable format. The applications can be web-based or use other technologies. Dynamic information consumers, such as the operators of the response center evaluating medical information collected at the citizen's premises, require access to dynamic sensor data and the ability to comment data and collate collections of data that is to be submitted to the citizen's health record.

Norwegian mapping to standards for personal health technology

The following table shows the current status as well as preliminary strategies regarding the use of standards. The table is structured according to the nordic reference model:

Interface class	Interface purpose	Current standards	Strategic direction
A	Device connectivity	No formal national decision. Various protocols are being used, including Continua.	Align to Continua TAN-IF, PAN-IF and LAN-IF CDCs as soon as possible. Other devices and technologies will also be accepted.
B	Observation Upload	No formal standard, but proprietary technology based on JSON/REST and MQTT are being used.	HL7 FHIR Observation resource and HL7 PCD-01 (draft recommendation)
B	Form-based patient questionnaires	Most existing healthcare questionnaire applications are silo applications using proprietary standards.	FHIR Questionnaire for PCH (draft recommendation). A national gateway for residents to submit questionnaires to the EHRs via the national health portal is under development. This gateway is planned to support multiple technologies.
B	PCH device data capture request	Not yet defined. Handled manually.	FHIR CarePlan and related resources (draft

			recommendation)
C	EHR information access	No current standard, but message based information exchange is in place and partly covers the use case.	HL7 FHIR (draft recommendation). XDS is considered for document exchange of PCH documents.
C	Exchange of EHR documents	No current standard, but message based information exchange is in place and partly covers the use case. .	Norwegian specific messaging standards are used for document exchange.

Legal background in Norway

The legal framework for PCH and related health services are outlined on the website
http://normen.no [NO-Normen].

Sweden

Sweden applies the principles of a distributed service-oriented architecture for national health information exchange The B and C interfaces of the reference architecture are integrated into the enterprise architecture and thus available as connectivity offerings through the national service-oriented health information exchange infrastructure ("Tjänsteplattformen"). There are however few connected solutions in the space of personal connected health. The architecture supports distributed solutions/storage locations for any of the three architecture elements interacting through the B and C interfaces. In order to support unified access of data from distributed data locations, the national HIE infrastructure acts as a national, virtual EHR (and Telehealth information system). As a result, a PCH data capture application can send data to the Observation Upload endpoint of the the HIE infrastructure regardless of which telehealth solution the receiving telehealth service center is using. The data will end up at the telehealth information system in use by the telehealth service center for which the data is intended.

Continua-guidelines are applied at the A and B interfaces. Sweden is currently in the process of planning Continua certification for the virtual Observation Upload (PCD-01) endpoint of the National HIE infrastructure. The strategy is to require the same certification for all connected Tele health information systems.

Sweden has a country-specific standard for the Questionnaire interface purpose. It is in use since several years. Sweden has identified the opportunity of migrating to Continua guidelines of the Continua Questionnaire capability although plans are not yet formalized.

The C interface (Information access) consists of a list of Green CDA-based national web service specifications. Every EHR connected to the national HIE infrastructure supports at least a couple of them, to facilitate information access and aggregation to clients of the HIE infrastructure API:s (through the same list of web service specifications).
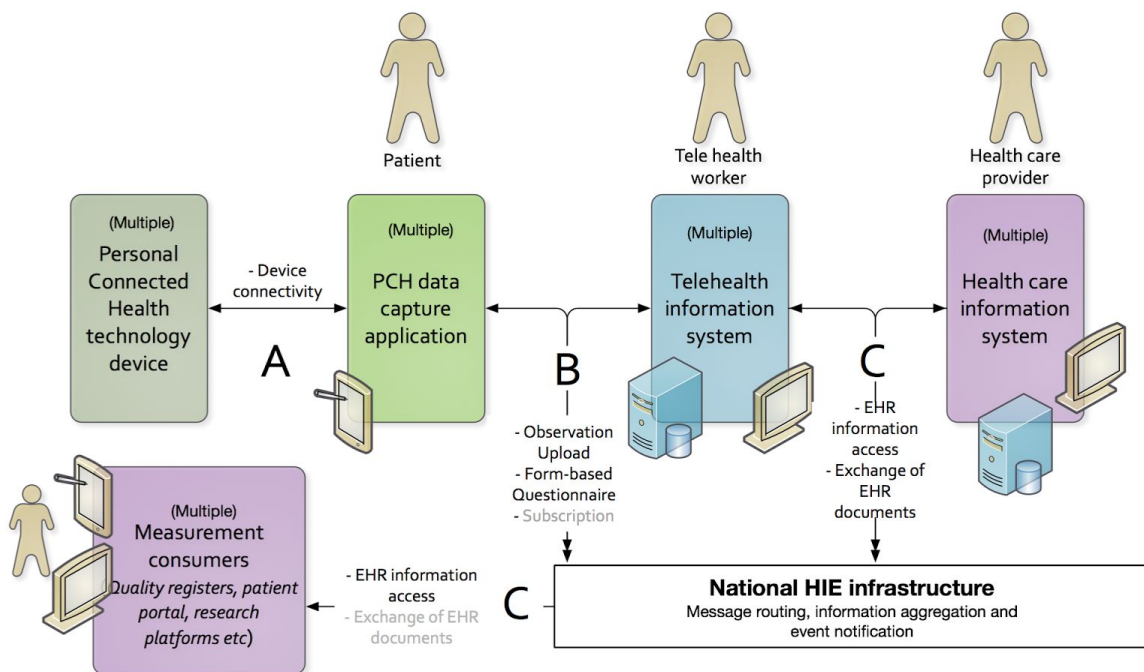
So far, the personal connected health projects have applied in two patterns: "Integrated telehealth solution" and "Personal Monitoring as a Service". All projects are within the Healthcare-initiated personal monitoring scenario.
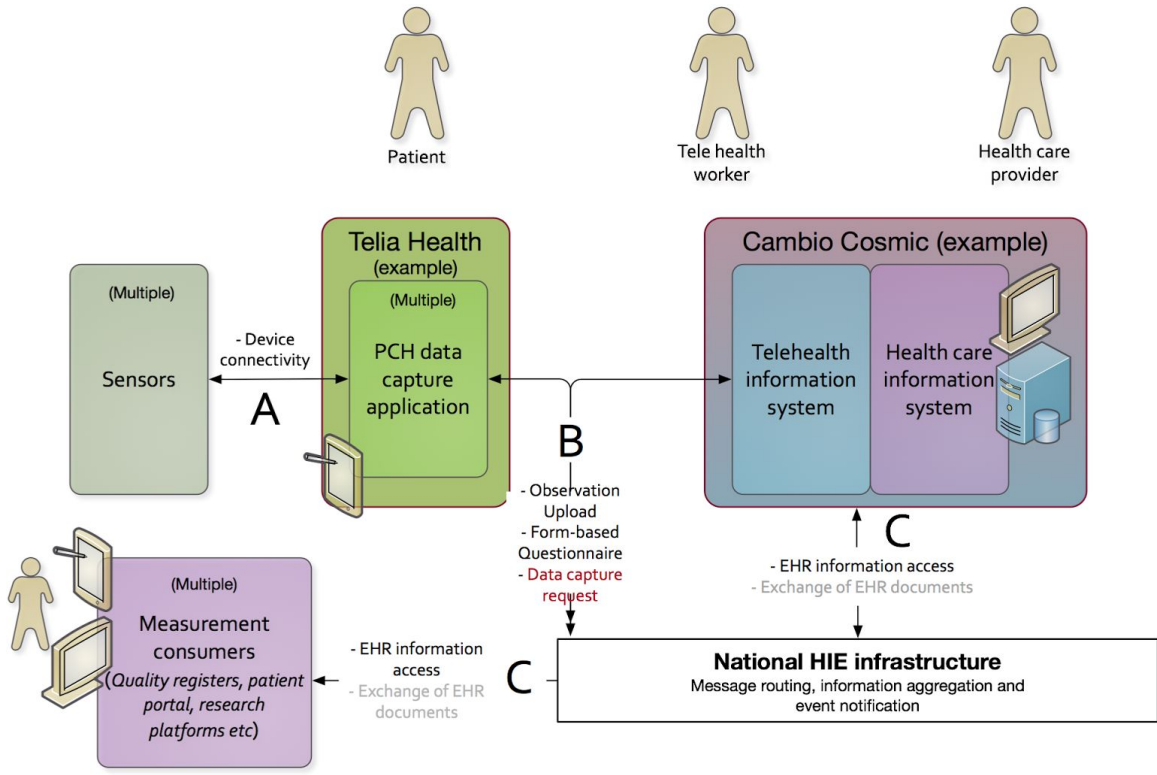
Integrated telehealth solution

In the integrated telehealth solution pattern, the Telehealth information system has a bundled data capture application as part an end-to-end solution. The B interface is not external and thus not subject to standardization.
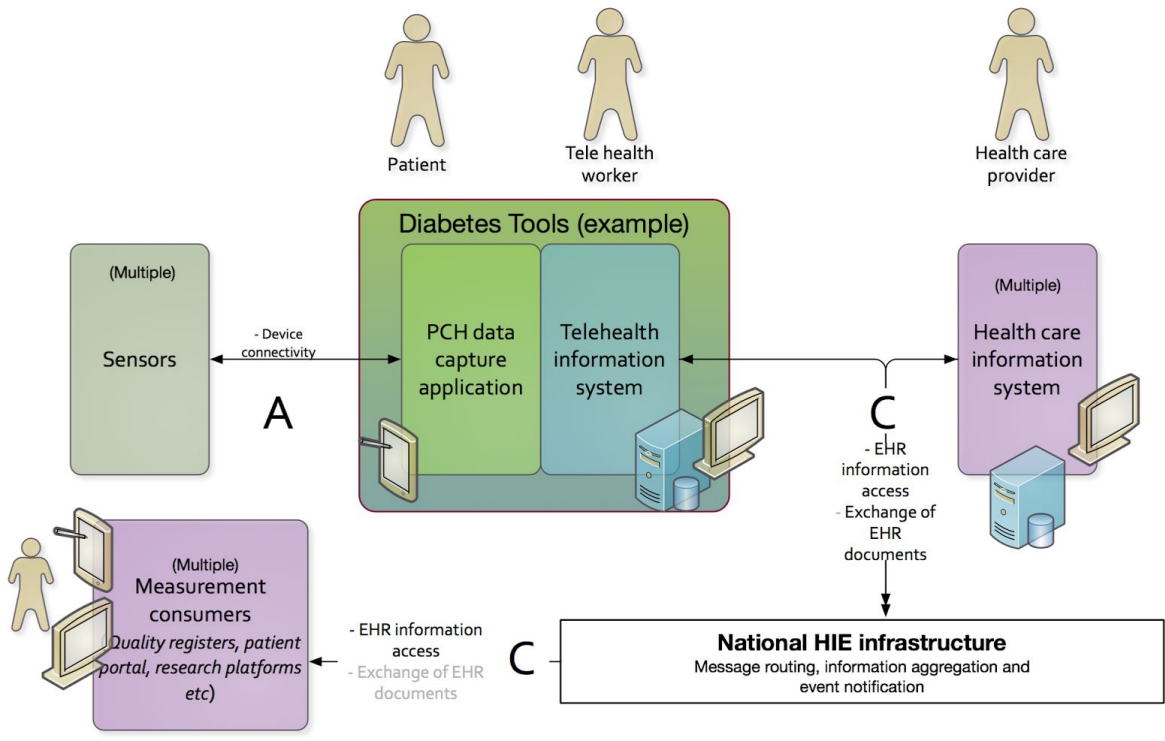
Personal Monitoring as a Service

Personal monitoring as a service refers to actors on the market that offer a generalized PCH data capture infrastructure independently of telehealth information systems that depend on personal connected health data input. For this pattern, the data capture application and associated PHR, need a ordering interface that allows the telehealth information system to request personal monitoring. Such a request associates a patient with a sensor (e.g. a weighing scale) available in the home, connected to the generalized monitoring infrastructure (e.g. a set-top box), with a prescribing care provider and with the monitoring prescription. The prescription typically states a time period, a frequency for measurements and the a value range that indicates when values should be sent through the B interface (Observation Upload). The order requests are generated by the telehealth information system based on a treatment plan deployed at the telehealth information system. This corresponds to the "PCH device data capture request" interface of the reference architecture. Continua guidelines currently lack a corresponding capability. For that reason, Sweden currently doesn't support a national definition/standard for that interface. As a consequence, each Personal Monitoring as a Service-vendor has to offer its vendor-specific interface to their customers operating a telehealth information system.

<u>Swedish mapping to standards for personal health technology</u>

The following table shows the current status as well as preliminary strategies regarding the use of standards. The table is structured according to the nordic reference model:

Interface class	Interface purpose	Current standards	Strategic direction
A	Device connectivity	No formal national decision.	Align to Continua TAN-IF, PAN-IF and LAN-IF CDCs as soon as possible.
B	Observation Upload	Currently implementing Continua Observation Upload SOAP CDC [SE-Observation-Upload]	Continua HL7 FHIR Observation resource. Collaborate with PCHA through the Nordic collaboration.
B	Form-based patient questionnaires	National standard [SE-Questionnaire]	Continua FHIR Questionnaire. Collaborate with PCHA through the Nordic collaboration.
B	PCH device data capture request	None. A vendor-specific profile based on national concepts exists:: https://bitbucket.org/rivta-domains/riv-telia.clinicalprocess.activity.order	Discuss with PCHA about general market business case for inclusion of use-case in Continua guidelines
C	EHR information access	16 National SOAP-based service contracts with "resource-specific" Green CDA payloads (rather than generic CDA format + CDA templates) [SE-Information-Access]	Existing + HL7 FHIR counterparties
C	Exchange of EHR documents	National event web service combined with EHR Information Access (PUSH Event + data PULL).	This is a rare use-case in the national Swedish SOA architecture. As is.

Legal background in Sweden

The legal framework assigns the end-to-end data controller responsibility to the prescribing healthcare provider. As an implication, patient consents is not needed to process the data collected by the patient within the scope of a treatment plan. However, if the patient uses a monitoring infrastructure (a Personal Monitoring as a Service) which additionally features

more generalized data sharing (like a PHR), the care provider must assure that mechanisms are in place so that the data collected as part of the prescribed self treatment is not re-used for other purpose without an explicit consent from the patient.

Identified areas for future work

- Independent living
    - Social care alarms
    - Surveillance
    - IOT and smart home etc
- The use of Personal Connected Health technology in social services
- Secondary use for health data and personal data
- Machine learning, artificial intelligence and coaching apps for the citizen / patient
- Health apps code of conduct / certification of health apps
- Sweden is planning a self declaration based on EU Code of conducts for health apps that patients can use as targets for exported EHR data
- Finland is creating a set of requirements which the app vendor needs to handle to be allowed in the Omakanta PHR ecosystem. Apps accessing health data it could be self declaration. Apps accessing official EHR data must pass a heavier set of requirements. EU Code is one reference, omakanta guidelines based on OAUTH for access management.
- Authorization protocols and other security mechanism

References

[FHIR]

Fast Health Interoperability Resources: https://www.hl7.org/fhir/

[CDG]

Continua Design Guidelines, published by the Personal Connected Health Alliance: http://www.pchalliance.org/continua-design-guidelines

Danish references of relevance to PCH

Some in English:
http://sundhedsdatastyrelsen.dk/da/rammer-og-retningslinjer/om-referencearkitektur-og-standarder/referencearkitekturer

[Ref:RA-CHDC-DK]

Reference architecture for collecting health data from citizens (Denmark): http://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammer-og-retningslinjer/referencearkitektur-og-it-standarder/referencearkitektur/referencearchitecture-collecting-health-data-citizens.pdf?la=da

[Ref:RA-DIS-DK]

Reference architecture for sharing documents and images (Denmark): http://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammer-og-retningslinjer/referencea

ktitektur-og-it-standarder/referencearkitektur/reference-architecture-sharing-documents-images.pdf?la=da

[Ref:S-DK]

Danish Health Portal for Citizens: http://www.sundhed.dk/

[Ref:RA-SEC]

Reference architecture for Information Security (Only in Danish)
http://sundhedsdatastyrelsen.dk/da/rammer-og-retningslinjer/om-referencearkitektur-og-standarder/referencearkitekturer

References to Finnish architecture specifications and solutions

[FI-Kanta]

Kanta - information for IT and connection operators:
http://www.kanta.fi/en/web/ammattilaisille/tietotekniikan-ja-yhteyksien-toteuttajille

[FI-PHR]

My Kanta Pages PHR specifications:
http://www.kanta.fi/en/web/ammattilaisille/omakannan-omatietovarannon-maarittelyt

[FI-Omakanta]

Finnish Health Portal for Citizens: http://www.kanta.fi/omakanta

References to Norwegian PCH solutions

[SCAIP]

Norwegian explanation of use of SCAIP, a Swedish standard for Social Care Alarms:
https://ehelse.no/Documents/Velferdsteknologi/Anbefaling%20for%20trygghetsalarmer%20(SCAIP).pdf

[NO-VFT-2015]

Report on Norwegian proposed architectures (in Norwegian):
https://ehelse.no/Documents/Velferdsteknologi/2015-12%20Rapport%20anbefalinger%20arkitektur%20velferdsteknologi%20v1%20f.pdf

[NO-Normen]

Code of Conduct for information security in the healthcare and care services:
https://ehelse.no/personvern-og-informasjonssikkerhet/norm-for-informasjonssikkerhet/documents-in-english

Swedish reference architecture references of relevance to PCH

[SE-RIV-TA]

> Landing page for the Swedish reference architecture with links to the architecture itself as well as all conformant national integration profiles: http://rivta.se

[SE-Observation-Upload]

> The Swedish implementation of Continua Observation Upload interface
> http://rivta.se/domains/ihe_pcd_dec.html

[SE-Information-Access]

> A table that summaries the swedish implementation of the C-interface Information access capability. The list covers all EHR information types - not only those relevant to the PCH domain:
> http://www.inera.se/TJANSTER--PROJEKT/Journal-och-lakemedelstjanster/Tjanstek ontrakt/

[SE-Questionnaire]

> The Swedish (national standard) implementation of the Questionnaire interface capability: http://rivta.se/domains/infrastructure_eservicesupply_forminteraction.html