May 2017

Continua®

Continua Adoption Playbook

Deploying Interoperable Connected Health in Your Health System

A product of Personal Connected Health Alliance

Continua Adoption Playbook

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About the Continua Design Guidelines

Published by the Personal Connected Health Alliance, the Continua Design Guidelines are available to the public free of charge and define an open, flexible framework for simple, end-to-end connectivity (interoperability) of personal connected health devices and systems, enabling the convenient exchange of health data for improved health, wellness and disease management. Standards underlying the Continua Design Guidelines include the IEEE 11063 Personal Health Devices family of standards; Integrating the Healthcare Enterprise (IHE) PCD-01 standards, and HL7 Personal Health Monitoring Report. 2016 marked the ten-year anniversary of the Continua Design Guidelines, which are recognized as an international standard for personal health systems through the International Telecommunication Union (ITU), the standards-setting body within the United Nations. By certifying products to the Continua Design Guidelines, companies opt in to the personal connected health economy and demonstrate their commitment to customers.

Executive Summary

Healthcare systems are under pressure, and personal connected health technologies are demonstrating benefits for improving quality care delivery, clinical outcomes and patient engagement. But before we can implement telemonitoring and telehealth solutions to support integrated care, we must clear the barriers for the transfer of data generated by citizens and patients to the healthcare system. We need interoperability built on open standards. Yet today's market has not yet delivered interoperability, and available standards have not been universally adopted.

Some advanced health systems have explored ways to promote interoperability along international standards. They are working with the Personal Connected Health Alliance (PCHAlliance) and its Continua Design Guidelines (adopted as International Telecommunication Union (ITU) Standard ITU-T H.810), the only recognized global interoperability standard for open personal health systems. PCHAlliance is the only forum for personal connected health where industry and users come together to keep the Guidelines relevant and up-to-date.

These early adopters, and the PCHAlliance, would like to invite more health systems to join them. To that end, we developed this Continua Adoption Playbook. The core of the playbook is the section "Paths Towards Adoption," a set of examples of how these first health systems arrived at the decision to adopt Continua Design Guidelines. Key observations and recommendations include:

- **Political Leadership and Strategy:** The decision in favor of interoperability along international standards requires political vision and leadership, particularly at this point when the market does not seem to deliver a universally recognized standard.
- **Stakeholder Support:** Ensuring support from stakeholders and especially small and medium sized enterprises (SMEs) is critical. Often, education is required. Anecdotal evidence suggests that local and regional governments and providers welcome guidance from national policymakers.
- **Communication:** Communicate clearly and early about your commitment to interoperability and standards. Work with the PCHAlliance to ensure vendors learn about upcoming opportunities.
- **Membership:** Consider joining the PCHAlliance to indicate your commitment to interoperability, to send a signal to markets, and to share deployment and adoption lessons with your peers. Also, it's the right thing to do: standards rely on contributions from everybody, making the standards more robust and keeping them up-to-date.

This Continua Adoption Playbook is brief and concise, and we invite all interested parties to contact PCHAlliance for more information or to become involved in the Alliance. Contact details of key PCHAlliance staff are at the end of this document.

Introduction

Healthcare systems are under pressure. The surge in costs for diagnosis and treatment, the tidal wave of chronic conditions and the shortage of healthcare professionals, combined with many other factors, are straining resources and putting pressure on policymakers to reform and innovate, in order to make the delivery of healthcare more efficient. One very promising route is the pursuit of personal connected health technologies, which empower citizens and patients with information, generate data to assist in diagnosis and treatment, and enable the delivery of care services remotely at lower cost.[1]

Indeed, we are living through a personal connected health revolution. Devices and gadgets are widely available on the market, activity trackers are no longer just for fitness fanatics, and people with chronic conditions, such as diabetes and heart disease, can choose among dozens of connected health monitoring devices. Apps, mobile phones and tablets are becoming more powerful and sophisticated in aggregating data and displaying results. Never before has so much data been readily available to inform us about our health.

But a closer look reveals: the data remains locked. Proprietary systems, closed APIs and the proliferation of portals define the field. The smartphone has become yet another data silo, isolated and separated from the healthcare system. Thus, before we can take advantage of personal connected health and implement telemonitoring and telehealth solutions to support integrated care, we must clear the barriers for the transfer of data generated by citizens and patients to the healthcare system. We need interoperability built on open standards — on a global scale.

Today's market has not yet delivered interoperability. More than ten years after the Continua Health Alliance was founded to address personal connected health interoperability, the Continua Design Guidelines have not been universally adopted. Downward economies, industry consolidation, the slowness of the healthcare sector to embrace telehealth, and other factors have kept the demand for Continua-certified products low, despite the fact that there have been consistently more than 70 devices available since 2010. Some vendors lost interest in bringing certified products to market, so much so that in some countries they can be difficult to find.

More recently, some advanced health systems have developed telehealth and telemonitoring services as a way to improve efficiencies, move care from hospital to the home, and deliver integrated, patient-centered care. They have also explored ways to promote interoperability along international standards, as the only way to ensure that telehealth can deliver the triple win: better quality care and outcomes for citizens and patients, more sustainable care services, and innovation and business opportunities for industry.

These early adopters, and the Personal Connected Health Alliance (PCHAlliance), would like to invite more health systems to join them, and consider helping create the market for interoperable personal connected health products and services. For those health systems, we developed this Continua Adoption Playbook. The core of the playbook is the section, "Paths Towards Adoption," a set of examples of how these first health systems arrived at the decision to adopt Continua Design Guidelines, and how they went about implementing the Guidelines. Every health system is different, so no one path can serve as a model; but in the aggregate these examples may serve as inspiration for others.

These cases will be complemented by observations and recommendations. The playbook also delivers a summary of the current adoption status, a section which may require periodic updating. The following section contains a discussion of why health systems adopt Continua Design Guidelines for personal connected health interoperability: the Case for Continua.

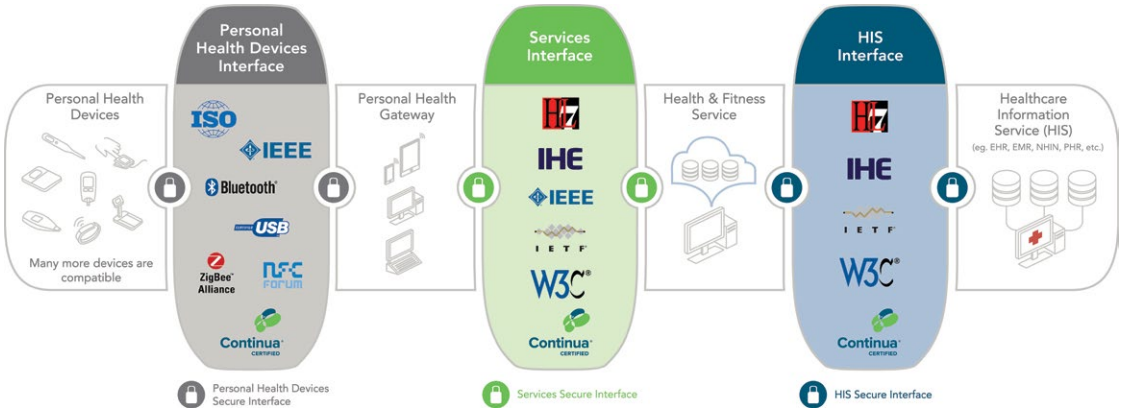
[1] **The 2013 GSMA report *Socio-economic impact of mHealth: An assessment report for the European Union* estimated that the EU could save 99bn Euros in annual healthcare spending if mHealth technologies were applied consistently. See www.gsma.com/connectedliving/socio-economic-impact-of-mhealth-an-assessment-report-for-the-european-union/.**

THE CASE FOR CONTINUA

The Case for Continua

PCHAlliance is the developer of the Continua Design Guidelines for personal connected health interoperability. The Continua Design Guidelines (CDG) facilitate the integration of personal health devices (sensors and trackers transmitting physiological data) in the health system. The CDG are developed and revised regularly in an open collaboration of industry and providers, while Continua Certification confirms the conformity of devices and systems with the CDG. The Continua Design Guidelines are recognized by the International Telecommunication Union (ITU) as the international standard for safe, secure, and reliable exchange of data to and from personal health devices (adopted as Recommendation ITU-T H.810), and have been referenced by the European Commission's *eHealth European Interoperability Framework*. A growing number of European national governments have formally committed to Continua Design Guidelines (Denmark 2012, Norway 2014, others are expected to do so in 2017), and the United States referenced Continua Design Guidelines in the 2017 Interoperability Standards Advisory of the U.S. Office of the National Coordinator.

CONTINUA SYSTEM ARCHITECTURE



"But there are no devices on the market!"

PCHAlliance has forged agreements with other relevant standards organizations and initiatives (IEEE, IHE, HL7, FHIR and others) to ensure collaboration. Our membership includes leading industry organizations as well as public institutions and ministries of health from Denmark, Norway, Sweden, and others. Through our collaboration with ITU-T, PCHAlliance ensures open, collaborative and appropriate consultative processes on the Continua Design Guidelines.

In short: the Continua Design Guidelines/ITU-T H.810 series are the only recognized global interoperability standard for open personal health systems. PCHAlliance is the only forum for personal connected health where industry and users come together to keep the Guidelines relevant and up-to-date.

Yet, market forces alone have not led to universal adoption of the Continua/ITU-T H.810 series guidelines. The market remains fragmented, proprietary protocols dominate the field, and no standard has emerged. Given the ongoing lack of actual demand for standards-compliant devices, vendors have limited incentives to bring them to market. This limited supply makes it difficult for public buyers to mandate compliance with international standards in their procurements. This is a classic case of "chicken and egg," of a market stuck because of misaligned incentives. One of the only players who can move the market towards open standards are large-scale buyers: governments and other public healthcare systems that can, gradually, direct public procurements to demand standards-compliant products. In other words, governments need to adopt standards.

The Early Adopters

The adoption of the Continua Design Guidelines by European public healthcare systems began when the government of Denmark published the *National Action Plan for the Deployment of Telemedicine* in August 2012. Realizing that the large-scale deployment of telemedicine solutions required political leadership and guidance, the **Danish Ministry of Health (MoH)** convened several national agencies, Danish regions, municipalities, industry representatives and other stakeholders to agree on guidance in the Action Plan that referenced the Continua Design Guidelines for personal connected health interoperability.

In December 2014, the **Norwegian Ministry of Health** announced that Norwegian welfare technologies would be standardized to comply with Continua Design Guidelines. The announcement also hinted at the cooperation among other Nordic countries (which include Denmark, Finland, Sweden and Iceland), to align their architectures and work together on other areas.

In 2015, the **Austrian government** began work on the conditions for telemedicine services, supported on the technical side by the Fachhochschule Technikum. Building on the rollout of the national electronic health record ELGA, Austria plans to deploy services for the remote monitoring of diabetes, heart disease and patients with implanted cardiac devices. The release of the framework directive ("Rahmenrichtline"), which will include references to Continua Design Guidelines, is expected in 2017.

In Sweden, the **Swedish Association of Local Authorities and Regions (SALAR)** is responsible for linking the 21 counties that are delivering healthcare services. In 2016, the Swedish government and SALAR together published their vision for the digitization of health and social services, including a commitment to international standards and interoperability. Shortly thereafter, SALAR joined the PCHAlliance. The December 2016 SALAR publication, *Evaluation of international standards — Basis for the national coordination of standards*, recommended Continua Design Guidelines for the transmission of personal health data.

The European Dimension

It takes courage for a small country to champion an international standard that is not yet universally adopted. Further, on their own, small countries have limited power to move or drive markets, and the limited supply of Continua-compliant devices and solutions at reasonable prices has fueled skepticism.

The early adopters have thus been looking to Europe to provide guidance. The European Commission has been reticent to go beyond the references in the *eHealth European Interoperability Framework* (2013, refined 2015), and has been deferring to the eHealth Network (eHN), the collaborative body of the 28 European Member States. While the eHN has overseen considerable progress on eHealth Interoperability, progress in the field of telehealth has been slow.

This is the context in which six governments — a mix of early adopters and others — delivered a letter to the eHealth Network on June 22, 2016, asking for a European approach for an end-to-end interoperability framework based on international standards for personal connected health.[2] The response of the eHealth Network indicated friendly interest, and invited the signatories to present their case at the eHealth Network meeting in May 2017 in Malta. While the next steps on the European level are unclear, the letter has raised awareness and visibility among the Member States, and may give more European health systems the confidence to choose Continua.

Who is Next?

The following is a discussion of additional health systems that have been considering the Continua Design Guidelines.

- **Finland:** The Finnish Ministry of Social Affairs and Health (STM) has been embarking on an ambitious program to integrate mHealth apps and services with the country's electronic health record. STM was one of the six signatories of the June 2016 letter to the eHealth Network."

[2] **The letter is available at http://www.pchalliance.org/news/six-european-governments-request-support-interoperable-teleheath-joint-letter-ehealth-network**

- **Switzerland:** In March 2017, *eHealth Suisse*, the coordinator of eHealth activities among its member states and the federal government, recommended international standards for mHealth and referenced the Continua Design Guidelines. While these recommendations are not binding, they provide critical guidance to regional governments.
- **Spain:** Similar to Switzerland, Spain gives responsibility for healthcare delivery to its 17 autonomous communities. The region of **Catalonia** was one of the signatories of the letter to the eHealth Network, and with the support of the Catalan TicSalut Foundation, more regions will learn about the benefits of Continua adoption in 2017.
- The governments of **Estonia, Ireland, the Netherlands, Portugal,** and **Wales** have expressed interest to learn more about the Continua Design Guidelines. So has the government of France, after PCHAlliance convened key policymakers and stakeholders in Paris in June 2015.

PCHAlliance liaises with these governments to make the case for Continua adoption, and reaches out to others. There are a number of dedicated initiatives to raise awareness and engage with governments:

- PCHAlliance has been a champion of the European Commission's Blueprint for the *Digital Transformation of Health and Care*, giving PCHAlliance a platform to make the case for Continua to European regions in the *European Innovation Partnership* for Active and Healthy Aging. The Blueprint document comes with strong language on interoperability and repeated references to international standards and Continua.
- The renewed cooperation with Integrating the Healthcare Enterprise (IHE) has offered PCHAlliance new outreach opportunities in Europe. IHE promotes the coordinated use of established standards to address specific clinical needs to achieve optimal patient care. Health systems that rely on IHE will come to Continua when they are ready to integrate personal connected health: Austria and Switzerland have already done so. Under the auspices of the Blueprint, IHE and PCHAlliance organized a joint interoperability workshop in April 2017 during the IHE Europe Connectathon in Venice, and may organize more joint activities in future Connectathon events.
- Both IHE and PCHAlliance participate in the EURO-CAS project which, in 2018, will deliver an eHealth conformity assessment scheme, a set of resources that will help governments assess the conformity of eHealth products and solutions with international standards (including Continua Design Guidelines). The consortium includes governments agencies from Croatia, Denmark, France, Greece, Italy (regions of Lombardy and Veneto), Luxembourg, Poland, and Portugal. More information is at www.euro-cas.eu.

For updates on Continua adoption in these and other health systems, visit **www.pchalliance.org/continua-adoption**

Outside of Europe, the Office of the National Coordinator in the **United States** included in its 2017 Interoperability Standards Advisory (ISA) references to specific Continua cases. The Continua Design Guidelines (specifically, ITU H.810 – H.813) are listed in the ISA as an implementation specification for four interoperability needs that support the sharing of patient-generated health data to enable effective, safe, high quality health care.[3]

In addition, the government of **India** has also indicated an interest in the Continua Design Guidelines. In fact, during the 2016 Connected Health Conference in Washington, DC, a senior advisor to the Indian Ministry of Health and Family Welfare presented at the Adoption Workshop. Both the government and the technology sector have expressed considerable interest in international standards, both as a way to level the playing field for the booming technology sector and to open export opportunities for Indian start-ups and SMEs.

Continua adoption will accelerate and spread, as more health systems engage and realize the benefits of personal connected health interoperability. For updates on Continua adoption in these and other health systems, go to http://www.pchalliance.org/continua-adoption.

[3] **For more information and the link to the ISA, go to www.pchalliance.org/news/continua-design-guidelines-recognized-oncs-2017-interoperability-standards-advisory-isa.**

PATHS TOWARDS ADOPTION

Paths Towards Adoption

DENMARK

In 2012, Denmark became the first country to formally adopt the Continua Design Guidelines as a framework for personal health interoperability. The initiative was launched at a meeting in Copenhagen on May 9, 2012, between representatives of the Danish Ministry of Health, key stakeholders, and the leadership of the Continua Health Alliance. Danish stakeholder representatives included the National Board of eHealth, hospitals and healthcare professionals, regions and municipalities and industry representatives. The meeting established a consensus to work together and to define next steps.

Various ministries of the Danish government, in cooperation with the regions and municipalities, then developed the *National Action Plan for the Deployment of Telemedicine* (August 2012) which outlined among other items the development of a national reference architecture, to be built on international standards including IHE and Continua.[4] The Reference Architecture for Collecting Health Data From Citizens (June 2013) contained detailed references to Continua Design Guidelines.[5]

In December 2013, the Ministry also began mapping existing telemedicine projects in the country. Under contract with the Ministry, Medcom, the national eHealth competence center (located in Odense in Southern Denmark), identified more than 600 individual projects ranging in purpose, scope and technology.[6]

In 2013, Denmark also began discussions to build a testing lab in Odense. This testing lab opened in 2015, when several supporters in the Southern Denmark region (including the region, the municipality and the Odense University Hospital) signed an agreement for *CoLab Denmark* to advance healthcare technologies and testing services.

An ongoing concern in Denmark has been the availability of certified solutions on the market. In January 2016, Medcom released a study on the availability of products in Denmark, showing that the share of Continua-certified products was not yet at the desired level in all product categories, though trends were going in the right direction.[7]

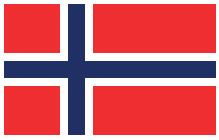
The Danish Health Data Authority, a division of the Ministry of Health, joined the PCHAlliance in November 2016. It is currently considering making compliance with the Continua Design Guidelines base standards (IEEE 11073) mandatory for public procurement. An announcement is expected before the summer of 2017.

[4] The Action Plan "National handlingsplan for udbredelse af telemedicin" (August 2012), in Danish, is available at http://www.sum.dk/Aktuelt/Nyheder/Digitalisering/2012/August/~/media/Filer%20-%20Publikationer_i_pdf/2012/Telemedicin/Telemedicinsk-handlingsplan.ashx (accessed March 2017). Continua issued a media release, available at https://www.mdtmag.com/news/2012/08/denmarks-national-telemedicine-action-plan-be-built-continua-health-alliance-design-guidelines

[5] The "Reference architecture for collecting health data from citizens" (June 2013) is available in English at http://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammer-og-retningslinjer/referenceaktitektur-og-it-standarder/referencearkitektur/referencearchitecture-collecting-health-data-citizens.pdf?la=da (accessed April 2017)

[6] Naturally, with the absence of national guidelines, there was also enormous diversity of technology solutions. The December 2013 report, updated since then periodically, is referenced on the Medcom website at http://medcom.dk/projekter/basisaktiviteter/telemedicinsk-kortlaegning

[7] The report indicated satisfactory availability of devices in most categories, but showed a limited supply of device managers. See www.medcom.dk/servicemeddelser/kortlaegning-af-telemedicinske-produkter



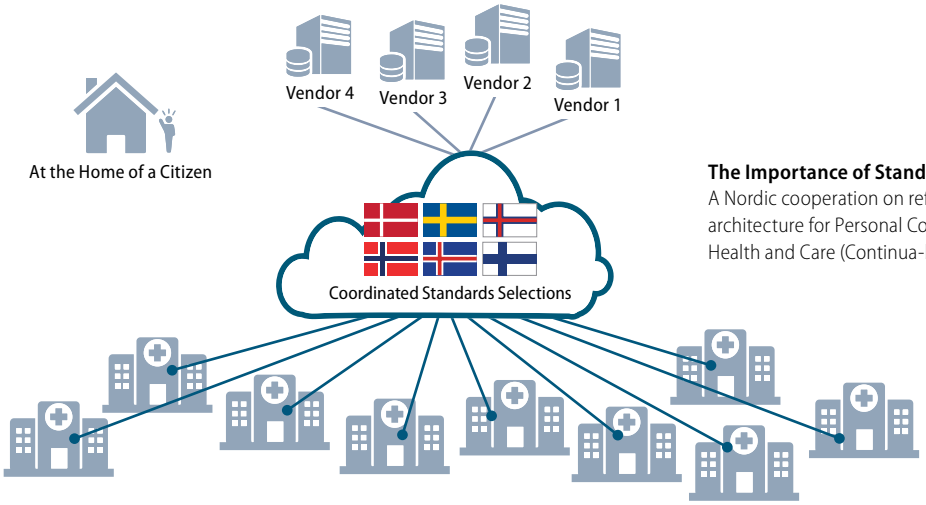
NORWAY

The Norwegian government has been keen to advance Personal Connected Health and Care (PCHC) technologies to improve healthcare services for its 5.3 million citizens. With a low population density of just 15 people per square kilometer, the provision of services over distance has been of critical interest to Norwegian policymakers. In December 2014, the Norwegian government, represented by the *Direktoratet for e-helse* (eHealth division) of the Ministry of Health and Care Services, announced the endorsement of Continua Design Guidelines in an official media release.[8] The principal motivation was to move the field from pilots to nationwide implementation, and to create an open market for personal health applications and systems that would be flexible to adapt to new technologies.

Norway embraced Continua because it offered a flexible framework to align international standards with specific requirements from the Norwegian market. Specifically, Norway wanted to see additional elements added, including HL7's Fast Healthcare Interoperability Resources and a Social Care Alarm Internet Protocol (SCAIP). To augment its influence and take advantage of voting rights in the PCHAlliance, the Direktoratet for e-helse joined the Alliance as a Promoter member (later renamed "Strategic" member).

To assist and advise municipalities with their innovation and implementation, the Direktoratet for e-helse delivered technology guidance in the form of the reference architecture for welfare technology (*Arkitektur for velferdsteknologi*) in December 2015.[9] In addition, the Ministry of Health and Care Services has provided grants for local projects (municipalities and regions are the principal providers of health services), while the Norwegian Association of Local and Regional Authorities (KS) has delivered roadmaps and technical assistance.

NORDIC REFERENCE ARCHITECTURE



The Importance of Standards:
A Nordic cooperation on reference architecture for Personal Connected Health and Care (Continua-based)

Norway has also been one of the principal drivers of a pan-Nordic effort to remove technology barriers and integrate markets for telemedicine products by aligning their telehealth architectures. A collaboration of Ministries and authorities in Denmark, Finland, Norway and Sweden, this reference architecture is expected to be published in the first half of 2017.

[8] **The announcement is available in Norwegian at https://www.regjeringen.no/no/aktuelt/standardisering-av-velferdsteknologi-med-continua/id2356200/**

[9] **https://ehelse.no/nyheter/ny-rapport-om-arkitektur-for-velferdsteknologi**

AUSTRIA

The key driver of the eHealth infrastructure in Austria (a republic of nine states in Central Europe with a population of 8.7 million) has been the Austrian government. Through its Federal Ministry for Women and Health, its intention is to develop the national electronic health record ELGA ("ELektronische GesundheitsAkte").

The history of ELGA dates back to 2006. The Ministry for Women and Health, with the Austrian states and key social insurance organizations, initiated working groups on the ELGA in 2006; and detailed planning started in 2008. The ELGA law of January 2013 provided the legal and regulatory basis for the national electronic health record, defining a number of key components including the patient portal, the master patient index, the registry of healthcare professionals, and others. ELGA began rollout in December 2015, first in the states of Vienna and Styria. Full coverage, including resident doctors, is expected by the end of 2017. IHE Profiles play a critical role in ELGA's infrastructure.[10]

In 2013, the Federal Ministry for Women and Health convened an expert commission to explore the feasibility and potential for telehealth services. In 2015, the commission issued recommendations to implement telehealth services for patients with diabetes and chronic heart disease, as well as for patients with recent implants. The Health Ministry contracted with the Technikum University Vienna to develop the technical guidelines and a reference architecture, working with all relevant stakeholders, including providers, users, industry, and others. The Ministry's framework directive ("Rahmenrichtlinie") with the technical guidelines is expected in 2017.

For telehealth services and the integration of personal patient devices with ELGA, a key challenge is the availability of Continua-compliant devices at a reasonable cost. Stakeholders have repeatedly voiced this concern when asked about the feasibility of mandating Continua compliance. As a result, the drafts for the telehealth architecture presented in 2016 do not require it. Over time, as the specifications further evolve and customers procure compliant devices, Continua specifications may become mandatory.

SWEDEN

Sweden is another country that combines low population density, advanced communication infrastructures, high internet literacy, and widespread trust in the healthcare system — the perfect conditions for the deployment of telehealth services. The principal driver of the national eHealth infrastructure and telehealth services in Sweden is the Swedish Association of Local Authorities and Regions (SALAR), which serves the 21 regions that are responsible for delivering health services for Sweden's 10 million people.

In March 2016, SALAR and the Swedish government published their "Vision for eHealth 2025 — common starting points for digitization of social services and health care," that laid out a plan for the development of telehealth services and clarified the role and responsibilities of SALAR and the national government.[11]

In regard to standards, the vision specified:

> "Here the Government and SALAR share responsibility. The Government's primary role is to work to ensure that national and international standardization efforts linked to social services and health care can be implemented smoothly, while SALAR's role is to seek to ensure that municipalities and county councils introduce agreed standards in their systems."

[10] Detailed documents on the ELGA structure and specifications are available on the ELGA portal: https://www.elga.gv.at/technischer-hintergrund/technischer-aufbau-im-ueberblick/index.html (accessed 7 March 2017).

[11] Available on the website of the Swedish eHealth agency "eHälsomyndigheten", in English, at https://www.ehalsomyndigheten.se/globalassets/dokument/vision/vision-for-ehealth-2025.pdf

In June 2016, SALAR joined the PCHAlliance to gain access to technical knowhow and expertise. (In the same month, SALAR also co-signed the letter to the eHealth Network.) Since then, SALAR has been evaluating Continua and other international standards as a basis for Swedish implementation, and in December 2016 circulated an evaluation document (*Utvärdering av internationella standarder*) among Swedish stakeholders that recommends the use of Continua Design Guidelines for the transmission of personal health data. Results are expected in 2017.

SWITZERLAND

In Switzerland, a federal republic of 26 member states (or cantons) with 8.5 million people, healthcare delivery is a prerogative of the cantons, and local control is fiercely guarded. Navigating this delicate policy environment is *eHealth Suisse*, a small office in Bern set up in 2008 to coordinate the actions of the national and the regional governments. The principal tool of eHealth Suisse are recommendations which are not legally binding but serve as orientation to guide the actions of regional and national policymakers and other stakeholders. In 2011, the regional and national governments agreed to an eHealth framework ("eHealth Rahmenvereinbarung") to work towards a national EHR system, called "elektronisches Patientendossier" (EPD) or "Dossier électronique du patient" (DEP).

In 2012, Switzerland hosted the IHE Europe Connectathon, which many observers credit as sparking the interest among key Swiss opinion leaders in IHE. This work culminated in the federal law for EHR (Bundesgesetz über das elektronische Patientendossier, EPDG) that was passed in 2015 and will take effect in 2017.

The EPDG included a mandate that patients can enter data into their EHR, setting in motion eHealth Suisse's work to explore the necessary requirements. eHealth Suisse contracted with St. Gallen University to explore the potential of apps and personal devices, subsumed under the category "mHealth." In its 2015 report, *mHealth and the electronic health record,*[12] St. Gallen University discussed Continua Design Guidelines and noted the growing importance of Continua profiles and their recognition by the ITU.

Based on this assessment and after a stakeholder consultation in 2016, eHealth Suisse released its *Mobile health recommendations* in March 2017 and included as an action recommendation:

> "*eHealth Suisse* recommends technical and semantic standards for the communication of information between mHealth applications and the electronic health record, with an emphasis on those standards that are established internationally (for example the IHE Patient Care device Framework (PCD), Continua Design Guidelines or FHIR from HL7 International)."[13]

Next steps in advancing an interoperable eHealth infrastructure include the "EPD Connectathon" in September 2017. Modeled after the IHE Connectathon, this event will allow interested parties to test their products and solutions against the EHR reference architecture and with each other.

[12] eHealth Suisse, "mHealth im Kontext des elektronischen Patientendossiers" (2015, in German), available for download at https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2015/D/150309_Bericht_FHSG_mHealth_D.pdf (access on 26 April 2017)

[13] eHealth Suisse, mobile Health (mHealth) Empfehlungen I - Ausgangslage und erste Schritte, 16 March 2017, available for download at https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2017/D/170316_mHealth_Empfehlungen_I_d.pdf (accessed 26 April 2017)

OBSERVATIONS AND RECOMMENDATIONS

Observations and Recommendations

POLITICAL LEADERSHIP AND STRATEGY

In each of the health systems under discussion, the decision to advance telehealth services comes from the political leadership and is the result of a long-term strategy

- In Denmark it is part of a comprehensive strategy to reform the healthcare services, including modernization of hospitals and moving care from the hospitals to the home. As part of this strategy, the Ministry sought to embrace international standards rather than local solutions.
- In Austria, it follows the completion of the national electronic health record system, ELGA, and the goal to build an infrastructure for telehealth services.

RECOMMENDATION: The decision in favor of interoperability along international standards requires political vision and leadership, particularly at this point when the market does not seem to deliver a universally recognized standard.

STAKEHOLDER SUPPORT

In all countries under consideration, the political leadership has sought and received support of all stakeholders for standards.

- In Denmark, the Health Ministry has involved several other ministries, regions and municipalities in the development of the Action Plan in 2012. Critical decisions are made that ensure representation of all stakeholders.
- The Austrian Fachhochschule Technikum conducted a series of workshops in 2015 before finalizing the report; recommendations will form part of the Ministry's framework directive, which will, in turn, be the subject of a further public consultation in 2017.
- *eHealth Suisse* commissioned its report from the renowned *Fachhochschule St. Gallen* and then conducted an open, public debate between September and December 2016, inviting all stakeholders to voice their opinions. A meeting in October 2016 in Bern convened all critical stakeholders.

Other health systems have either already undertaken this evaluation, or are in the process of doing so.

RECOMMENDATION: Ensuring support from stakeholders and especially small and medium sized enterprises (SMEs) is critical. Often, education is required. Anecdotal evidence suggests that local and regional governments and providers welcome guidance from national policymakers.

COMMUNICATION

Health systems should communicate their commitment to interoperability and to Continua clearly, so that innovators, SMEs and all vendors can adjust their product development and bring compliant products to market. Only through combined efforts can we move the needle and change market dynamics.

- Before adopting the Continua Design Guidelines, Denmark convened a critical meeting of all stakeholders with the Continua leadership in 2012 to clarify commitments and mutual expectations.
- Both Denmark and Norway issued media releases, working with the PCHAlliance media team, to communicate their commitment to the market.

There are signs that the dynamic in some markets is changing. Some markets report that availability of certified devices is improving, and the "certification pipeline" (PCHAlliance's informal tally of devices that await certification) has grown. Further, PCHAlliance members have indicated that they will move devices to certification as soon as there are tenders that demand it.

RECOMMENDATION: Communicate clearly and early about your commitment to interoperability and standards. Work with the PCHAlliance to ensure vendors learn about upcoming opportunities.

MEMBERSHIP

Membership in the PCHAlliance can be an important political sign of commitment to the Continua Design Guidelines and interoperability. There are several additional reasons why a government or an agency may want to consider joining the Personal Connected Health Alliance.

- The Norwegian *Direktoratet for e-helse*, part of the Norwegian Ministry of Health, joined the PCHAlliance at the strategic level, to be part of the technical discussions and decision process on Use Cases.
- The Austrian Ministry of Health cannot join the PCHAlliance due to institutional constraints, but Fachhochschule Technikum has joined to contribute to the policy and technical discussions.
- In Denmark, various stakeholders have been members of the PCHAlliance, including Medcom and DELTA/FORCE Technology. The Danish Ministry of Health, through its Health Data Authority, joined the PCHAlliance in the fall of 2016.
- SALAR/Inera joined the PCHAlliance in the summer of 2016 as an indication of its commitment to the Continua Design Guidelines, and to contribute to the policy work specificallyrelated to the European Commission and eHealth Network.

RECOMMENDATION: Consider joining the PCHAlliance to indicate your commitment to interoperability, to send a signal to markets, and to share deployment and adoption lessons with your peers. Also, it's the right thing to do: standards rely on contributions from everybody, making the standards more robust and keeping them up-to-date.

ABOUT THE PERSONAL CONNECTED HEALTH ALLIANCE

The Personal Connected Health Alliance (PCHAlliance) aims to make health and wellness an effortless part of daily life. The PCHAlliance, a non-profit organization formed by HIMSS, believes that health is personal and extends beyond healthcare. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world. To support its vision, PCHAlliance convenes the global personal connected health community at the annual Connected Health Conference, the premier international event for the exchange of research, evidence, ideas, innovations and opportunities in personal connected health. The Alliance publishes and promotes adoption of the Continua Design Guidelines. Continua is recognized by the International Telecommunication Union (ITU) as the international standard for safe, secure, and reliable exchange of data to and from personal health devices. PCHAlliance accelerates technical, business, policy and social strategies necessary to advance personal connected health through its flagship Academy for Healthy Longevity to promote lifelong health and wellness.

CONTACT

To learn more about PCHAlliance, Continua Design Guidelines and the benefits of interoperability, please contact:

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FURTHER READING

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