POLICY MAPPING ON EHEALTH POLICIES AND INITIATIVES (INCLUDING ON CANCER CARE) IN SWEDEN

This Country Factsheet was prepared for the eCAN Joint Action. It is prefilled with publicly available information and was sent for review to country experts on eHealth and cancer care. The Country Factsheet serves as the basis for the preparation of an overview of eCAN relevant policies and initiatives in all EU and EEA countries.

eCAN is a Joint Action (JA) of 16 partners in EU-Member States on 'Strengthening eHealth including telemedicine and remote monitoring for health care systems for cancer prevention and care'. eCAN aims to bring the benefits of eHealth to all citizens and patients across EU-Member States (MS) focusing on cancer prevention and care. There is a need to harmonize telemedicine regulations and to explore the efficacy of teleconsultation programs and telemonitoring in the cancer field.

This country factsheet has been pre-filled with publicly available information by

- Morten Sønderskov Frydensberg, Region Syddanmark, The Region of Southern Denmark, Denmark
- Linda Justi, Region Syddanmark, The Region of Southern Denmark, Denmark

The pre-filled country factsheet was reviewed by contacted country experts

- Johanna Ulfvarson, The Swedish eHealth Agency
- Maria Hassel, The Swedish eHealth Agency
- Lina Keller, National Board of Health and Welfare, Sweden
- Mef Nibert, National Board of Health and Welfare, Sweden

The country factsheet includes chapters on:

1 definition

2 governance

3 strategies/policies

4 legislation

5 cancer specific eHealth solutions

Any questions? – Please get in touch via ecan@goeg.at.

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1 DEFINITIONS

Table 1 : Deviations in the use of international definitions for eHealth terms - Sweden

Term	Definition	Deviation
eHealth	The WHO defines eHealth as « the use of information and communication technologies (ICT) for health ». It also says that « eHealth is the transfer of health resources and healthcare by electronic means. »[1]	No deviation from definition.
mHealth	« Mobile health (mHealth) is defined by the World Health Organization's (WHO) Global Observatory for eHealth as « medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices ».[2]	No deviation from definition.
dHealth	The EU defines digital health (dHealth) and care as referring to « tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health-related issues and to monitor and manage lifestyle-habits that impact health ». [3] The WHO defines digital health as « the field of knowledge and practice associated with the development and use of digital technologies to improve health. Digital health expands the concept of eHealth to include digital consumers, with a wider range of smart-devices and connected equipment. It also encompasses other uses of digital technologies for health such as the Internet of things, artificial intelligence, big data, and robotics. »[4]	Yes. No apparent use of the term dHealth. Sweden does not distinguish between e/m/dHealth.
telehealth	The WHO defines telehealth broader than telemedicine « as it includes computer-assisted telecommunications to support management, surveillance, literature, and access to medical knowledge. »[5]	No deviation from definition.
telemedicine	The EU Commission defines telemedicine as follows (EU Commission definition, COM (2008)689): « Telemedicine is the provision of health care services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves the secure transmission of medical data and information, through text, sound, images, or other forms needed for the prevention, diagnosis, treatment, and follow-up of patients. »[6]	No deviation from definition.
teleconsultation	PAHO describes teleconsultation (also sometimes referred to as remote consultation or telehealth), as « interactions that happen between a clinician and a patient for the purpose of providing diagnostic or therapeutic advice through electronic means. »[7]	No deviation from definition.

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[1] 6. eHealth, Factsheet for European Parliament (who.int)

[2] World Health Organization *Frequently asked questions on Global Task Force on digital health for TB and its work.* [2017-02-27]. http://www.who.int/tb/areas-of-work/digital-health/faq/en/ *webcite.* In mHealth Assessment: Conceptualization of a Global Framework - PMC (nih.gov)

[3] Events - Smart4Health

[4] Digital health EURO (who.int)

[5] Telehealth – DigitalHealthEurope

[6] Telemedicine – DigitalHealthEurope

[7] https://www3.paho.org/ish/images/docs/covid-19-teleconsultations-en.pdf?ua=1

Term	Definition	Deviation
health app	Essén et al. 2022 define health apps as « a computer program or software application (designed to run on a mobile device) "intended to be used specifically for managing, maintaining, or improving the health of individual persons, or the delivery of care" (ISO https://www.iso.org/standard/78182.html (2021), p 5). »	No deviation from definition.

2 GOVERNANCE

Table 2 : Overview on eHealth governance - Sweden

Question	Answer	Comments/Experience
Is there a Ministry or State Secretariat explicitly in charge of eHealth/dHealth? If so, which Ministry?	Yes	The Ministry of Health and Social Affairs is responsible for issues concerning social welfare, such as public health, health care and care of older people as well as health data, eHealth, and life sciences.
Does the Ministry who oversees health care also have a specific Department or Unit in charge of eHealth/dHealth?	Yes	The Swedish eHealth Agency coordinates the government's eHealth initiatives and monitors developments in the eHealth field, both nationally and internationally. It is also responsible for registers and IT services linked to e-prescriptions used by individuals, healthcare providers and pharmacies.
Is there a national eHealth governance board?	Yes	Digital infrastructure is a central part of the government's digitization policy. The Swedish Agency for Digital Government, together with several other agencies, has been tasked with establishing a joint management of digital infrastructure for information exchange as well as a national framework for basic data. To complement this, the eHealth Agency has the task of establishing a sector specific framework for the health care and social welfare area.
Is there a public eHealth agency such as Elga GmbH in Austria or ANS in France? At which level (national, regional)? Which functions does this agency cover?	Yes	The Swedish eHealth Agency is a government agency that works to digitalize and improve the sharing of information between patients, the healthcare system, and pharmacies in Sweden. It offers several eHealth services and digital solutions for individuals as well as staff working in healthcare and social services. The e-prescription service and the Covid certificates service are the most well-known. They are working on achieving the vision set forth in the 'Vision e-hälsa 2025'. The eHealth agency, which is under the Ministry of Social Affairs, must coordinate the government's initiatives in eHealth and overall monitor developments in the eHealth area (ordinance (2013:1031) with instructions for the eHealth authority).[8] In addition, the regions and local and municipalities are supported by their members' organization, The Swedish Association of Local Authorities and Regions (SALAR). They also co-own the company Inera AB, who coordinates the development and management of joint digital solutions that benefit the public, employees and decision-makers in regions and municipalities.
Are dHealth / eHealth tools in the outpatient sector publicly paid or covered in your benefits package (e.g., by sickness	Yes	The provision of health care, regardless of in what way, is mainly tax-funded, financed by the regions and municipalities, and government grants. It is also

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[8] https://www.ehalsomyndigheten.se/languages/english/welcome-to-the-swedish-ehealth-agency/

Question	Answer	Comments/Experience
fund or national health service). If yes, please describe how.		financed to some extent by patient fees. Digital tools are provided by the regions and municipalities.
Are dHealth / eHealth tools in the inpatient sector automatically covered in your benefits package or do you need to pay extra (e.g., for telehealth consultations or telereha) compared to standard treatments?	No	See previous answer.
Are there any comprehensive cancer centers focusing on eHealth or telehealth treatments? If yes, which ones and for which specific fields?	Yes	Sweden has for the moment three CCCs. Since eHealth is an integrated part of Swedish health care, they all use tools for information and communication technologies, patient monitoring devices, personal digital assistants, and health-related apps to monitor and manage lifestyle-habits that impact health.

Further information:

The healthcare sector is subject to the rules and requirements set out in the General Data Protection Regulation (EU) 2016/679 (GDPR) and the Data Protection Act (2018:218) supplementing the GDPR. In addition, healthcare providers and employees working in healthcare are subject to rules on secrecy and confidentiality (including professional secrecy) set out in the Public Access to Information and Secrecy Act (2009:400), the Patient Safety Act (2010:659), the Patient Data Act (2008:355), the Health and Medical Services Act (2017:30) and the Pharmacy Data Act (2009:367). In the Penal Code (1962:700), there are provisions imposing penalties for breach of professional secrecy (including by healthcare professionals).

3 STRATEGIES/POLICIES

Table 3 : Overview on strategies and policies for eHealth and cancer care - Sweden

Question	Answer	Comments/Experience
Is there a national eHealth strategy?	Yes	Together with relevant stakeholders Sweden has developed a national strategy for eHealth.[9] The Swedish government has launched several strategies bearing on the eHealth area. These include the Digitization Strategy (Ministry of Infrastructure), the Standardization Strategy (Ministry of Foreign Affairs) and a roadmap towards a Life Science strategy (Ministry of Business and Industry). All these strategies address issues of interoperability and the importance of common standards, but also the need for coordination.[10]
If yes, which stakeholder groups have been included in drafting the national eHealth strategy?	Various	The nation strategy's partners are on the ministerial, regional, and local municipality level. The strategy has been developed with a broad

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[9] https://ehalsa2025.se/

[10] https://ehalsa2025.se/wp-content/uploads/2021/02/Strategin-for-genomforande-av-vision-ehalsa-for-2020-2022.pdf and
https://www.vardanalys.se/rapporter/granslosa-mojligheter-granslosa-utmaningar/

Question	Answer	Comments/Experience
		representation from both public and private partners including a public hearing process. The Swedish government and the Swedish Association of Local Authorities and Regions have endorsed a common vision for eHealth stating that Sweden will be the best in the world at using the opportunities offered by digitalization and eHealth to make it easier for people to achieve good and equal health and welfare, and to develop and strengthen their own resources for increased independence and participation in the life of society.[11] In the Vårdanalys report from 2019, it is mentioned that the 21 regions are responsible for the development of eHealth within these frameworks, with different responsibilities including financing, design, application of eHealth solutions etc. They work together in SALAR with Sweden's municipalities and the jointly owned company Inera AB (pg. 70).
Are there regional eHealth strategies? If so, can you indicate whether in all regions or only some? Can you provide some (exemplary) documents?	Yes	In Sweden, the healthcare system is decentralized, run either by the regions or municipality. Every county council or municipality is responsible for managing and prioritizing its own healthcare resources. As a result, the type of healthcare services available may vary as well as strategies.
If yes, which stakeholder groups have been included in drafting such regional strategy/ies?	Various	See above, may vary between regions.
Are there strategy/ies explicitly referring to / including eHealth cancer care?	Yes	See above, part of the regional plans. SALAR has an eHealth national vision that covers all regions.
If not, are there discussions ongoing to develop a national eHealth strategy?	N/A	No further information available.
Is there a National Cancer Plan? And does it refer to eHealth?	Yes & No	National cancer strategy, however, not explicit on eHealth strategy.
In the light of the EU „Beating Cancer Plan" – are there any recent plans to update or modify existing plans? If yes, what is the timeline?	Yes	Un updated strategy is planned within the next 2-3 years.
Are there any indicators in eHealth policy or national programmes on cancer care measuring the progress of the use of eHealth in cancer care?	No	No further information available.
Are there any other cancer care specific eHealth initiatives, f.e. by other stakeholders than policy makers / public authorities?	No	Smaller initiatives in different regions.

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[11] https://bmcprimcare.biomedcentral.com/articles/10.1186/s12875-021-01481-1

4 LEGISLATION

Table 4 : Overview on eHealth and cancer legislation - Sweden

Question	Answer	Comments/Experience
How would you evaluate the current state of legislation of eHealth in your country in general?	No	There is no specific law that regulates the provision of digital health services. Healthcare organizations, including, inter alia, conventional clinics and hospitals as well as digi-physical services and online medical consultation services, are considered healthcare providers, and in general the same rules apply to conventional healthcare and digital healthcare. In addition, Sweden is waiting for EHDS legislation.
Is there legislation on how to use telemedicine in general?	Yes	The regulatory aspect of using telemedicine is related to the following legislative framework. • Patient data act (SFS 2008: 355) • Patient data Regulation (SFS 2008:360) • The National Board of Health and Welfare's regulations and general guidelines concerning patient records and processing of personal data within healthcare (HSLF-FS 2016:40) • The National Board of Health and Welfare's regulation and general guidelines concerning management system for systematic quality of work (SOSFS 2011:9) The National Board of Health and Welfare's regulation on the use of medical devices in healthcare (HSLF-FS 2021:52).
Is there legislation explicitly referring to cancer prevention?	No	Not according to the National Cancer Control Plan Survey.
Is there legislation explicitly referring to / including eHealth cancer care?	No	See above; There is no specific law that regulates the provision of digital health services.
If yes, which of these legislation(s) do you consider most important in the context of eHealth and cancer care? And why?	N/A	No further information available.
If no, are there any reasons or barriers to the fact that there is no or only limited cancer specific eHealth legislation (i.e., discussions still ongoing, conflicting opinions or other).	No specific legislation applies to cancer.	
What could be improved or would need to be done to improve this legislation for eHealth in cancer care in your country?	Need for interoperable eHealth systems and coordinated interpretations of current legislation between different providers and regions.	

5 CANCER SPECIFIC EHEALTH SOLUTIONS

Table 5 : Overview on cancer specific eHealth solutions in use – Sweden

Note: No information available.

Area of application/ type of solutions	Login Websites	Apps	Webinars	Multi-disciplinary teleconferences (HCP-HPC)	Teleconsultation (HCP-patient)	Telemonitoring via devices
Ecosystem	Yes, for example, access to personal health data/record, medical prescription insights, data for science etc. but within each region	Yes, for example, reminder systems in general. All patients can access their eHealth record online or through an app.	Yes, for educational purpose and for information	Yes, cross-regional and national MDTs that are based on teleconferencing	Yes, frequently used as a supplement to in person consultation.	Yes, widely used in cardiology and diabetes, but not yet in cancer care. Developed in project form.
Prevention of Cancer	Yes	Yes	Yes	No	Yes	No
Treatment of Cancer	Yes	No	Yes	Yes, such as tumor boards	Yes	No
'Living with cancer'	Yes	Yes	Yes	No	Yes	No
Rehabilitation from Cancer	Yes	Yes	Yes	Yes	Yes	No
Palliative Cancer Care	Yes	No	Yes	Yes	Yes	No

Table 6 : Number of eHealth solutions available and in use – Sweden

Question	Answer	Comments/Experience
How many eHealth solutions (in the sense of medical devices and thus 'authority approved/certified') solutions are existing currently in your country in the context of cancer care/treatment?	About 400,000 (estimation)	No registry and no clear definition for what should be included, except for medical devices that are registered at the Medical Products Agency.
Is there a website or other information on solutions that are recommended to the public for use (e.g., a selection of health apps that are recommended to cancer patients or in general)?	No	Health apps are relatively unregulated unless they are classified as a medical device. In some cases, medical health apps are prescribed. Before that is possible, a solid evaluation and quality assurance takes place. The health app's area of use determines which regulations and quality requirements apply. There are standards and frameworks for medical devices. Technical and semantic standards are missing for health apps. There is no equivalent quality assurance for health apps in the lifestyle and security apps.
Can you give an estimation on how the split between private and public apps are available? Give an estimate percentage of public solutions.	N/A	No further information available.
How can providers and patients assess if the apps are reliable? Is there a certification or quality approval procedure in place? If yes, which kind of procedure?	Yes, however not covering all aspects	There are upwards of half a million health apps on the market. The majority of these lack CE marking because they are not considered medical devices. If the app provides health advice, unrelated to disease or medical treatment, it is a 'health app' that is not regulated by any specific legislation linked to patient safety. If the app has a medical purpose (for example, to diagnose, prevent, monitor, treat or alleviate a disease), it is considered a medical device. That type of app must have a CE mark. The Swedish Medicines Agency is the supervisory authority for medical devices.[12]
How many Health Care Providers use such solutions? Which sector uses rather which types of solutions?	No	No further information available.

Further information:

Video 'How does SWEDEN work with THE DIGITAL TRANSFORMATION OF HEALTHCARE?', see
https://youtu.be/2xmaGY5pcdQ.

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[12] Startar tillsynsaktiviteter mot tillverkare av medicinteknisk programvara | Läkemedelsverket (lakemedelsverket.se)