Collaborating for Digital Health and Care in Europe

eHealth Governance - Country Report: Denmark

In collaboration with

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eHealth Governance - Country Report Denmark

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1 Introduction

1.1 Scope of the document

This report is one of the 6 reports on the eHealth Governance commissioned by EY Baltic to EHTEL in the context of a contract[1] aiming at proposing a new "Health ICT Governance Framework" to the Ministry of Social Affairs of Estonia (MoSA).

With these reports, EY and MoSA have access to a sample of international good practices on how to govern the deployment of digital health within a country or a region.

	Health system	Governance	EHR architecture
Belgium	Bismarck	Bottom-up/ Top-down	Decentralised
Catalonia	Centrally Managed	Top-down	Centralised
Denmark	Centrally Managed	Top-down	Decentralised
Israel	Bismarck	Bottom-up	Decentralised
Scotland	Centrally Managed	Top-down	Centralised
The Netherlands	Bismarck	Bottom-up	Decentralised

Figure 1: Profile of the countries and regions retained for their good practice in eHealth Governance

These reports have been prepared by EHTEL experts who either have an inside knowledge of the country or region subject to the report or worked in close collaboration with experts having such a knowledge.

They describe, for each country or region,

- The context, i.e. the health and care system and its enabling eHealth system, with its technical building blocks
- The organisation in place for involving stakeholder and
- The main governance processes

A short historical retrospective and a short analysis of successes and what could be done better helps to put these good practices in perspective.

This international experience is intended to be used as input for Deliverable 3 "To-Be model for eHealth system governance" defined in the above-mentioned contract.

This document was produced with the financial assistance of the European Union via the Technical Support Instrument. The views expressed herein can in no way be taken to reflect the official opinion of the European Union.

1.2 Methodology

The methodology for the developing these reports has been designed in two steps:

- Distinguishing IT governance from IT management
- Defining what should be included under the term eHealth governance framework.

[1] Contract reference: REFORM/SC2021/003, signed on 10.02.2021 between European Commission and EY.

The line between IT Governance and management has been drawn as follows:

- The governance function is responsible for determining strategic direction.
- The management function takes that strategic direction and translates it into actions to achieving the strategic goals.

To define what needs to be covered under the term eHealth Governance, a few models have been looked at and COBIT 5 has been retained as a relevant one to support health and care in systems in their digital transformation journey[2].

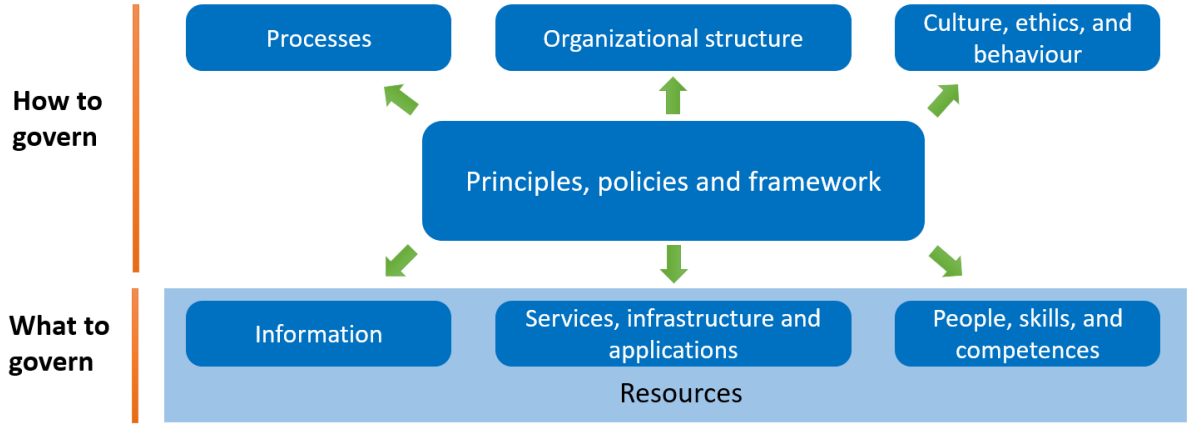

Figure 2: Governance Framework [MARCELO 2018]

2 Report on Denmark

For understanding purposes, definitions of terms used for different elements of the Danish health and care system is provided:

Health and care system	The overall system in which all health and care related provision of services (examination, diagnostics, treatment, rehabilitation) are part of and politically, organisationally, financially etc. administered.
Healthcare sector	Specific to services provided that relate to individuals' health issues within the health and care system, i.e., primary and secondary care, somatic and mental care. Includes health providers (public and private) as well as suppliers/vendors.
Sector	The healthcare sector is divided in different sectors. Overall, in primary and secondary care, but in a Danish context it refers to the division between types of actors, the main ones being hospitals, municipalities and general practitioners, but also groupings of other providers, for example dentists, pharmacies, specialist clinics, private hospitals, physiotherapists and chiropractors.
Cross-sectoral	Refers in the case of Danish eHealth to the exchange, sharing etc. of patient information across sectors, e.g., from

[2] See "Transforming Health Systems Through Good Digital Health Governance", Alvin Marcelo, Donna Medeiros, Kirthi Ramesh, Susann Roth, and Pamela Wyatt (2018)

	a GP sending a referral to a hospital, or a hospital sending a rehabilitation plan to the municipality taking over the rehabilitation of a citizen after the hospital.

2.1 Health and care System description

Denmark has a population of 5,8 million citizens and covers an area of 43.094 km2. GDP per capita is 53.470 EUR compared to an EU-average of 29.660 EUR. Life expectancy in Denmark is 80,9 years, which is less than countries in the EU which Denmark is comparable to.

Healthcare in Denmark is based on a centrally-managed model and on two main principles:

- **Universal coverage**. All residents in Denmark are entitled to public healthcare benefits in kind financed by general taxes.
- **Free and equal access to public healthcare**. This includes general and specialised practitioner services and all public hospital services. Private co-payment includes dentists and out-of-hospital medicines and aides.

For the citizens the vast part of healthcare is financed through general taxes and only few things are partly or fully self-financed.

The healthcare providers receive financing from central government to operate health and care services through block grants, activity reimbursements and equalisation schemes. The percentage of GDP spent on health is 10,4 in Denmark.

Healthcare is centrally-managed by the Ministry of Health (MoH) and provided by the regions, municipalities and private providers, incl. general practitioners (GPs) and specialists (see more in 2.3).

The Danish health and care system in numbers include:

- 5 Regions, who provide secondary care, incl. hospitals, and mental health
- 98 Municipalities, who provide homecare, rehabilitation and social care
- 54 public hospitals, incl. 21 acute hospital. Number of beds at public hospitals (pr. 1000 inhabitants) is 2.5 and the average length of stay is 5.5
- 9 private hospitals (mainly day surgery like orthopaedic and plastic surgery)
- Approx. 1850 General Practitioner clinics across the country
- Approx. 1200 private medical specialist clinics
- 519 pharmacies (physical + online)
- 150+ IT systems, e.g.:
    - 4 public hospital EHR systems – although recent procurement will bring this to 2 HER systems in the next 1-2 years
    - 9 EHR systems in GP and specialist clinics
    - 4 local electronic care systems
    - 3 pharmacy systems
    - 11 physio/chiropractor systems
    - 19 lab systems

The Danish health and care system consists of three political and administrative levels: the state (Ministry of Health), the 5 regions and the 98 municipalities.

The Ministry of Health (MoH) is the principal health authority at state level and is responsible for national health policies and legislation.

The five regions in Denmark are run by elected councils and are the largest service providers in the Danish health and care system. Their responsibilities include all hospital and psychiatric treatment and are responsible for providing specialised dental services for adults and parts of primary care sector, including general practitioners (private family doctors) and private practising specialists. As a rule, a general practitioner (GP) must refer the patient to a hospital for medical examination and treatment unless it is a question of acute illness. However, the vast majority of medical cases are handled by the general practitioner without referral to specialised treatment.

The regions do not collect taxes. Instead, regional healthcare services are financed through a block grant from the state, a state activity-related subsidy and a municipal contribution.

The 98 municipalities are the local administrative bodies with an average of approx. 57,000 inhabitants. The municipalities are responsible for a number of tasks including social services, primary schools and care for the elderly. In the field of health, the municipalities are responsible for home nursing and homes for elderly citizens with care facilities and associated care staff, public and school healthcare and rehabilitation.

The municipalities finance approx. 20 per cent of the total expenditure on healthcare in the regions. The payment consists of an activity-related contribution depending on their citizen's use of hospitals. The purpose of the local contributions is to encourage the municipalities to initiate efficient preventive measures for their citizens with regard to health issues.

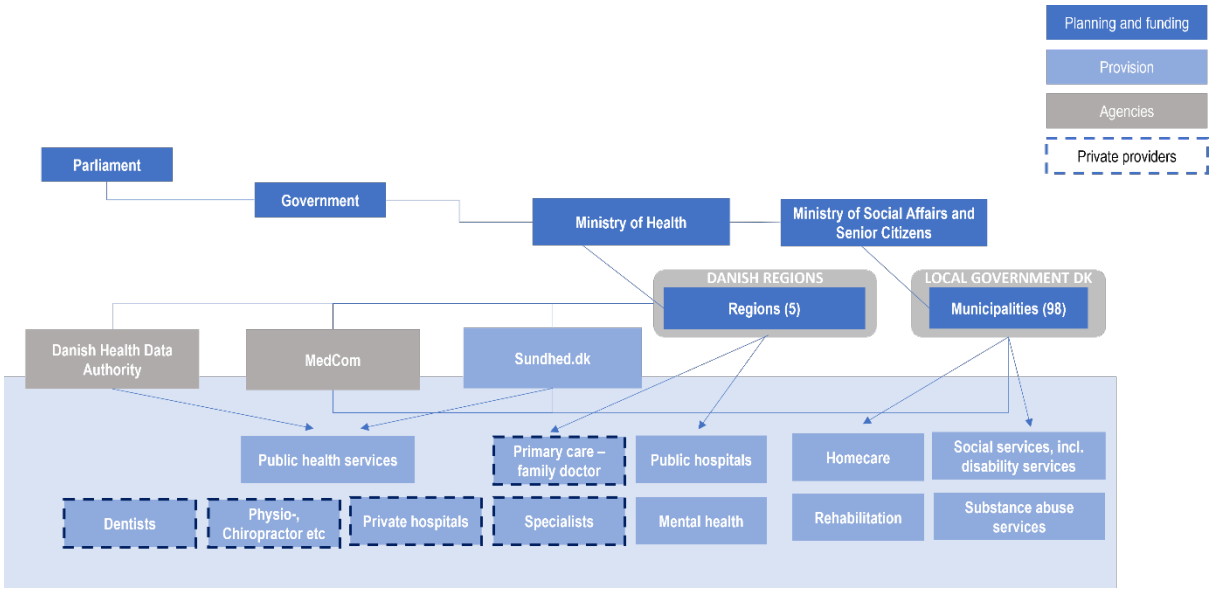

Figure 2: Overview of the Danish (e)Health System

2.2 eHealth System

Denmark has a long tradition in eHealth and the Danish health and care system is characterised by extensive digitisation.

2.2.1 National/Regional building blocks (infrastructure and services)

All hospitals, GP's and municipal healthcare providers keep their own electronic health records (EHR) and common IT-standards facilitates electronic communication between

providers. Examples of electronic communication are referrals to medical specialists and psychologist and all discharge letters from hospitals to homecare.

During COVID-19, the number of messages exchanged electronically in the healthcare sector has grown rapidly due to an automatic referral to COVID-19 testing for all citizens as well as laboratory requisitions and test results.

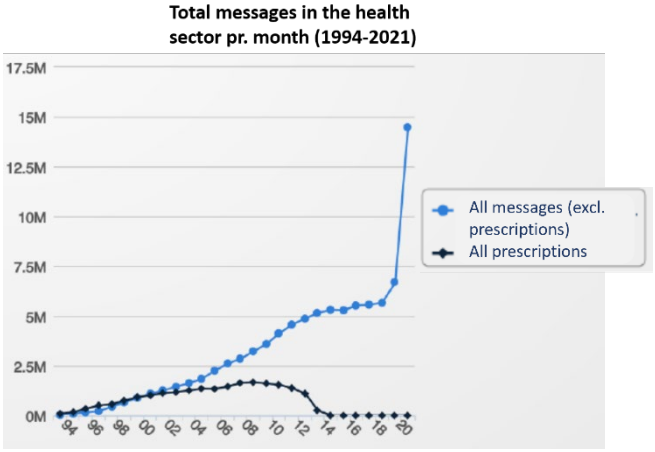

Figure 3: Average messages exchanged per month through the year in the Danish health sector

Solutions where both citizens and health professionals have immediate access to relevant and updated individual health information, such as the Shared Medication Record (Fælles Medicinkort (FMK)) and the Danish eHealth Portal (sundhed.dk), are nationally implemented since 2014 and 2003, respectively.
Because of the implementation and utilisation of FMK in 2014, the message type for prescriptions is no longer exchanged in the Danish healthcare sector as seen in Figure 3, since the system is now based on a central business service in the Nation Service Platform.

2.2.2 Data sharing and access

National level

Access to and sharing of health data in Denmark is overall based on three main components:

- Accessibility to national registries and services
- Sharing of information and data through shared standards in IT-systems and across VANS-system (Value-Added Network Service)
- Secure communication and transmission of data in the health sector through the Health Data Network

The National Service Platform (NSP) offer a robust national infrastructure for immediate accessibility for health professionals through their local IT-system to national registries and services. NSP is operated by the Danish Health Data Authority. New services are continuously added to support the existing network of IT-systems and their users to national essential registries and services as well as to support new national initiatives in progress. This could be a digital folder for pregnancy, national roll-out of telemedicine (FUT) and a complete patient overview etc.

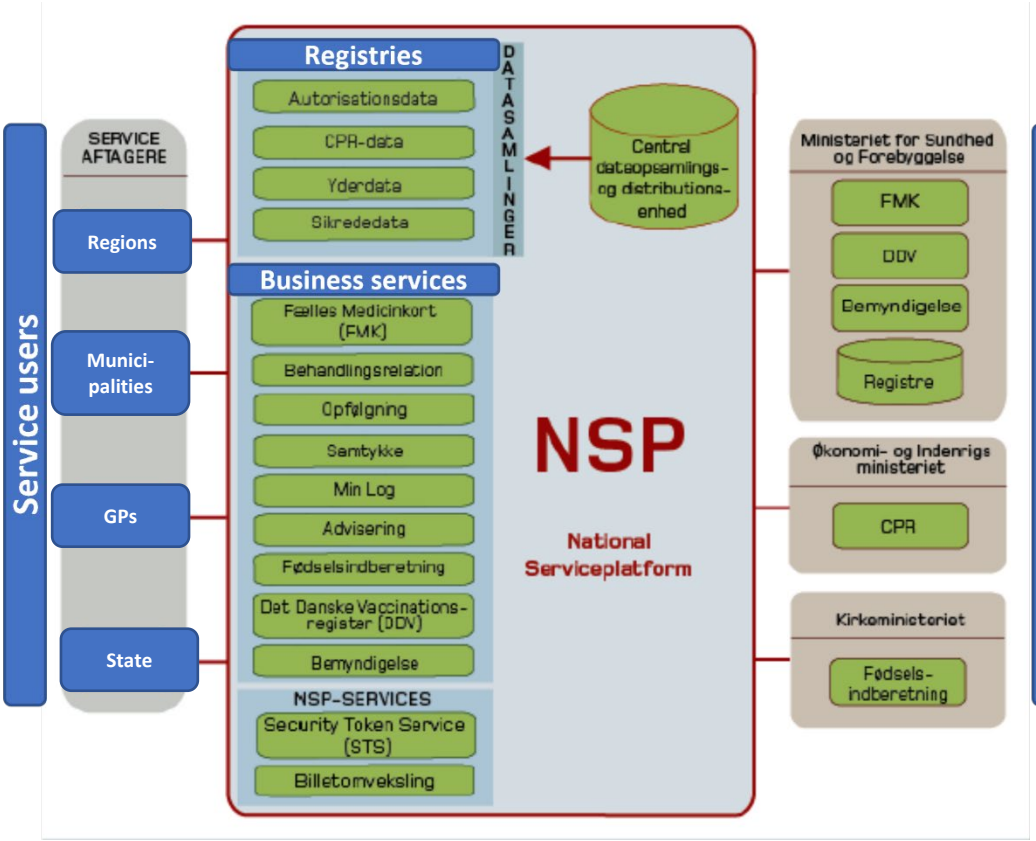

Figure 4: National Service Platform

All cross-sectoral exchange of data and information between healthcare providers takes place through an electronic "postal system" – VANS network - which is operated in Denmark by three private companies. The network transmits the messages exchanged between the different sectors of the Danish health and care system, e.g., discharge letter from hospital to GP, a rehabilitation plan from hospital to municipality, or a referral from a GP for examination at hospital.

All the messages are based on common communication standards (Danish profiles to international standards), which ensures that all IT-systems used across all healthcare provider organisations are able to send and/or receive structured data upon which the receiver can react as required.

Denmark has a secure network for all communication in the healthcare sector between public and private entities – the Health Data Network (SDN). It is operated by MedCom and used by services and organisations, e.g., municipalities, regions, NSP, sundhed.dk, Shared Medication Card (FMK), webservices etc. SDN's Agreement System ensures that proper agreements exist between all parties communicating, so that the communication takes place in a closed network with high security and proper governance and management in a central location.

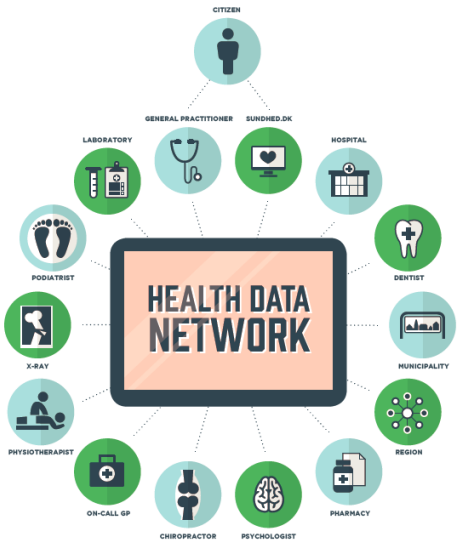

Figure 5: Communication through the Danish Health Data Network

Regional/local level

Data sharing and access at regional and local level takes place through the regional and local IT-systems and uses the national infrastructure to communicate and share relevant information.

The regions have a regional EHR and other systems, which is shared by all the hospitals in the region. Hence, there is no need for use of national infrastructure for internal exchange. The municipalities, GPs and other private providers have each their own patient information system, which is not shared with other organisations even if the vendor is the same. Any sharing and exchange of data is then done via the national infrastructure. Developments are in process to allow access by external actors into hospital EHR systems. For instance, the EPIC system ('Sundhedsplatformen') used by two regions has functionality to allow access by relevant municipalities.

2.2.3 People, skills, and competences

Internet and digital services utilisation are high and widespread in Denmark. 88% of 15–89-year-old (yo) Danes use the Internet every day or almost every day. The usage is also high among the elder population, where 77% of 55-64 yo, 60% of 65-74 yo and 35% of 75-89 yo are online multiple times a day. Still, there are some citizens who have never used the Internet and among the 75-89 yo, it is 18%.

Denmark has a 'Law on Public Digital Mail' which requires all citizens ≥15yo (4,8 Mill.) to receive digital mail from all public services. Approximately 348.000 are exempted from this law and can receive physical mail. In 2020, the public authorities sent 184 Mill. digital mails, and there was 58,7 Mill. visits to www.borger.dk, which is the public authorities' portal for all citizens services (excluding health information which is available on www.sundhed.dk).

Specific to health, the Danish population uses the Internet and online services widely. A study of Danes' use of the Internet in 2020[3] shows that 69% of the population (16-89 yo) has searched for health-related information online, 36% has made an appointment with their GP online, 34% has used online services, e.g. eConsultations with their GP, 34% has viewed their health data online (EHR), and 33% has been online to see test results, the Shared Medication Card, referrals etc.

Use of welfare technology[4] is also growing and in 2020, 12% of the population had used a welfare technology service. Just the year before, it was 8%. The positive attitude towards the use of welfare technology is high – even with people who have no experience with it (85%), while amongst those with experience, it is 93%.

Denmark, therefore, has a solid technological foundation for use of eHealth services amongst the population and work force.

eHealth is a common part of the curriculum in relevant educations, where you both in healthcare/medicine and IT/engineering related educations can take courses in use of health-related technologies as part of the professional, higher, or postgraduate education. In some cases, it is possible to specialise entirely in eHealth in the polytechnical educational domain.

2.3 eHealth system organisational structure - overview

2.3.1 Stakeholders of the national/regional layer

The main political stakeholders concerning healthcare – MoH, regions and municipalities (see 2.1) – each have a corresponding eHealth stakeholder organisation:

1. Danish Health Data Authority
2. Danish Regions, RSI
3. Local Government Denmark

The Danish Health Data Authority (DHDA) is the national eHealth authority acting on behalf of the MoH and is responsible for national eHealth coordination, terminology, architecture, standards etc. DHDA hosts the secretariat for the National Board of Health-IT, which has the overall national coordination of cross-sectoral eHealth activities. The Board was created in 2011 and has representatives from the state (3 members), the regions (3 members) and the municipalities (2 members). The Board's role is:

- to advice the Minister of Health on IT-strategy and IT-architecture as well as national requirements and standards for eHealth
- to oversee and monitor the eHealth strategy, incl. ongoing initiatives
- to coordinate development within eHealth
- to act as the authority for making cross-sectoral decisions on data use within the health domain
- to make joint decision on the initiation of national initiatives

[3] The survey was conducted in the Spring of 2020. That means some results are influenced by the COVID-19 pandemic and perhaps show an increase related to the current situation compared to past years.

[4] Assistive technology used to maintain or increase security, activity, participation or independence for people with a disability or the elderly.

- to initiate and quality assure new national cross-sectoral eHealth projects and initiatives

Danish Regions, RSI (Regional Health-IT) is the joint coordination of eHealth on behalf of the 5 regions. The regions in Denmark cover each a population between 590.000 to 1,85M people. Regional Health-IT in Danish Regions is responsible for the strategic coordination of eHealth development, implementation, and operation at regional level. See 2.3.2 for how eHealth is organised within the regions.

Local Government Denmark (KL) is the central association of all 98 municipalities in Denmark. The smallest municipality is 1.764 inhabitants and the largest is the capital with 638.117 inhabitants. KL is responsible for the strategic coordination of , implementation and operation at local (municipal) level. KOMBIT, which is owned by KL, is the municipalities joint IT-community and creates and manages shared municipal IT-solutions, incl. in the health domain.

The three political stakeholders jointly own and govern the activities of the national eHealth standardisation competence centre and eHealth online service provider – respectively MedCom and sundhed.dk.

As an online eHealth service portal, **sundhed.dk** is the official national access point for the public healthcare services. The portal hosts a range of information and communication for healthcare professionals and citizens, incl. access to own electronic records, prescriptions overview, lab results etc.

MedCom as an eHealth standardisation competence centre develops, tests and supports the local implementation of electronic communication standards for health data exchange across organisations and sectors. MedCom is also responsible for the Danish Health Data Network (SDN), the national video infrastructure for the healthcare sector (VDX) and the national home-monitoring database (KIH).

2.3.2 Stakeholders of the health service provider layer

National, regional and local level

Hospitals and homecare providers are represented as stakeholders though Danish Regions (hospitals) and Local Government Denmark (municipalities) in the political and practical processes surrounding eHealth planning, prioritisation, and implementation. Both organisations have both political and professionals (domain specific, e.g., IT) groups, which is working on eHealth overall and within sub-areas. Representatives from Danish Regions and Local Government Denmark as well as regional and municipal representatives are active in national activities that are either primary or secondary sector-limited or cross-sectoral oriented, which there is a strong tradition for in Denmark concerning eHealth.

Innovation and eHealth development and implementation within the hospital setting involves the clinical departments throughout both idea, plan and implementation phases. See 2.3.3 for how this is often organised at regional and local level.

Clinical level

Stakeholders also include the clinical associations. Approximately five medical associations represent doctors working in the hospital setting, in private clinics, in specialised positions etc. At a policy level, these organisations are very active in shaping the frame for the health

provision in Denmark. eHealth is part of this but especially, the Organisation of General Practitioners in Denmark (PLO) is very involved in eHealth strategies and practical initiatives.

The GPs, while financed by the regions predominantly through a service-based reimbursement scheme, are private entities. Therefore, PLO acts as the main stakeholder in representing the GP involvement in national eHealth initiatives and solutions. Other private specialists are also involved through Danish Association of Medical Specialists (FAS). Both PLO and FAS are authorised to commit to national initiatives on behalf of their members and are also directly involved in the processes and projects afterwards.

Other professional groups, such as nurses, are likewise organised and very active in terms of policies. Nurses as a group are essential for successful implementation and use of eHealth in respect to patient-oriented services and have been very active in the progress we have seen in Denmark to date.

2.3.3 Stakeholders of the innovation layer (including businesses)

National level

At the overall business layer, the main stakeholder is the Danish Chamber of Commerce (Dansk Erhverv), a network for Trade, IT, Industry and Service in Denmark. Some of the top priorities and goals of Dansk Erhverv are making Denmark best in start-ups, digitalisation and public-private collaboration – all comprising eHealth to some extent.

Dansk Erhverv is also part of the Digitalisation Partnership (an advisory board from private and public organisations) set up by the Ministry of Finance in relation to the further strategic work on all public sector services. The Partnership has no ministerial or authority members but has a strong presence of private innovators and IT-suppliers to the healthcare sector as well as members from Danish Regions and Local Government Denmark of the total 27 members.

The IT sector is also closely involved in the innovation taking place at both local, regional and national level:

- KOMBIT on behalf of the Danish municipalities is creating a platform for joint development and innovation across all the municipalities services, incl. homecare and rehabilitation.
- The regional innovation units and clusters has a strong relationship with businesses, incl. many SMEs and start-ups in addition to the larger IT-vendors. E.g. the Health Innovation Centre of Southern Denmark has a CO-LAB in which business, innovators and health providers can test new ideas and solutions together.
- National domain specific innovation in primary care involves the IT-vendors through their joint technology platform - PLSP.

Another innovation layer is the research institutions. Denmark has eight universities - of which five are traditional with an array of domains, two are technical/IT focused and one is business-oriented. The universities play a large role in research and innovation and collaborate with the private sector and other parts of the public sector, including hospitals.

Regional/local level

All regions have their own units charged with promoting and facilitating innovation, incl. digitalisation, telemedicine services etc.:

- *Idea Clinic* in the North Denmark Region
- *Innovation* in the Central Denmark Region

- *Health Innovation Centre of Southern Denmark* the Region of Southern Denmark
- *Data & Development Support* in the Region Zealand
- *Health Research & Innovation* in the Capital Region of Denmark

In addition, the regions collaborate with other both local and national stakeholders in regional clusters focusing on health innovation, eHealth, and welfare technology. The involvement of business, research, and users (patients and healthcare professionals/clinicians) is included in the remit of both these regional departments as well as through the involvement in the cluster(s). Each region sets its own innovation processes, collaborators, and services.

As of Spring 2021, a national Danish Life Science Cluster was established under the Ministry of Higher Education and Research and brings together a national joint-stakeholder collaboration platform between corporations, knowledge environment (incl. research institutions) and other organisations in respect to innovation and networking in life science and welfare technology. Some of the regional clusters are now part of the Danish Life Science Cluster and functions as regional hubs for the cluster.

2.4 Approach to main governance aspects:

2.4.1 Planning and strategizing

Three overall strategies form the foundation for the national eHealth activities:

Digital Strategy for all public services (2016-2020)

- Title of the strategy: 'A stronger and more secure digital Denmark'
- Overall framework for digitalisation of all public sector services, incl. health
- Developed by the Government, Local Government Denmark and Danish Regions
- Responsibility of the Ministry of Finance, monitored by the Agency for Digitisation and governed by a joint forum and three underlying topic-specific steering committees

↓ Elements of this strategy that have influenced the next one, i.e. the Digital Health Strategy are e.g. security, accessibility, sharing of information

Digital Health Strategy (2018-2022)

- Title of the strategy: 'A Coherent and Trustworthy Health Network for All'
- Overall ambitions for eHealth across all sectors, incl. initiatives and projects
- Developed by Ministry of Health, Ministry of Finance, Danish Regions and Local Government Denmark
- Responsibility of MOH, monitored by the Danish Health Data Authority and governed by the National Board for Health-IT (a cross-sectoral board)
- The strategy does not contain a direct funding scheme for the initiatives included in the strategy, but these are financed through e.g., contribution to MedCom, collective agreements with health providers, the financial agreements btw. the Government and the regions or municipalities, respectively, on a case-by-case basis.

↓ Elements of the strategy that have influenced the next one, i.e., the Life Science strategy are e.g. quality, structure and safety of health data

Life Science strategy (2021-2023)

- Title of the strategy: 'Strategy for Life Science'
- Government ambition for life sciences, incl. use of health data for research, innovation, and product development + public-private innovation (PPI)

- Developed by Ministry of Trade, Ministry of Health, Ministry of Foreign Affairs and Ministry of Education & Research in collaboration with the public and private stakeholders
- Responsibility of the Ministry of Trade and executed by the Danish Life Science Cluster, in which private organisations and companies are involved
- The strategy also contains earmarked funding for the priorities of the strategy

↓ Elements of the strategy that will influence future digital (health) strategies are e.g., health data usability and accessibility, research & innovation (incl. PPI, procurement), health apps, digital skills for HCPs etc.

The new digital strategy for all public services is expected in Fall 2021. In advance of this, the Government established a Digital Partnership, which will act as an advisor to the Government on future digital prospects for value, growth etc. The next Digital Health Strategy will thus base its ambitions and possibilities on the digital strategy as well as the health strategy, in which a future health reform potentially will play a significant role.

The national eHealth competence centres and providers work within their specialised domain to support the national strategies, their focus areas and prioritisation.

For MedCom, its Work Programme is defined every two years and builds on the current strategies, additional political agreements on eHealth as well as direct stakeholder input (prior to the planning of a new Work Programme, MedCom visits all relevant stakeholder groups to discuss focus areas, prioritisation etc.). The Work Programme and associated budget is approved first in the National Board of Health-IT and then by MedCom's Steering Committee (chaired by MoH and co-chaired by regions and municipalities). MedCom's Steering Committee then oversees the execution of the Work Programme and budget through quarterly meetings that also involve representatives from different sectors.

All of MedCom's standards and infrastructure components are processed and approved in the Advisory Committee for Standards and Architecture (RUSA) and the Regions' IT-architecture Committee's (RITA) before signed off by the Danish Health Data Authority as national components.

Sundhed.dk's four-year strategy and work programme is first approved by sundhed.dk's Political Board, as the main governance authority for sundhed.dk, and is subsequently overseen by the sundhed.dk Steering Committee.

2.4.2 Financing of eHealth investments

State level

The annual financial negotiations between the Ministry of Finance in collaboration with the Ministry of Health and the regions and municipalities, respectively, sets the frame for health expenditure for the coming year. The overall frame for the negotiations is the Government's National Budget, which is approved by Parliament.

Specific funding and investments in eHealth are mainly covered under these negotiations, where the areas of mutual interest and with cross-sectoral implications are discussed and prioritised in respect needs for reference architecture, standardisation, and other eHealth initiatives. Both in terms of what eHealth investments the regions (hospitals, mental health etc.) and municipalities (homecare, rehabilitation etc.) are obliged to undertake but also national eHealth investments under the responsibility of the state. The annual expenses and investments can be both running costs for eHealth infrastructure and services (NSP,

registries, databases, MedCom, sundhed.dk etc.) as well as grants for new developments and procurement.

In addition to state funds, national eHealth competence centres as MedCom and sundhed.dk also receive fixed annual funding for its operation and development and project activities from Danish Regions and Local Government Denmark. Both organisations are jointly owned and governed by the MoH, Danish Regions and Local Government Denmark.

Other ministries also contribute to eHealth-related expenditures e.g., Danish Life Science Cluster, as the focus is also on growth (Ministry of Industry, Business and Financial Affairs and Ministry of Education & Research).

Regional and local level
Regions and municipalities predominantly fund their own innovation units, IT systems and the development of new services.

Regions and municipalities are responsible for procuring their own IT-systems and services, incl. electronic health record (EHR). Currently, there are four EHR systems at regional level in Denmark. Two regions have jointly procured an EPIC EHR system, which is in operation, and the remaining three regions have also jointly procured one EHR system (Systematic). That system was already in operation in one region and will over the next few years be deployed in the two others as well. Consequently, only two EHR systems are soon used in Danish hospitals. Amongst the 98 municipalities, four providers (EG, KMD, CSC, Systematic) of electronic care systems are used. The regions' EHR systems contains patient health data for examination and treatment services, while the electronic care systems in the municipalities are used for citizens' health data related to homecare, rehabilitation, and partly social care.

In the regions, the EHR system is regional and not limited or specific to a hospital with e.g., the option to share data sets with other hospitals in the region through the system. User administration systems control the access of hospital staff and full logging systems and check of treatment relation btw. patient and HCP are used to monitor and control who accesses which records.

Private providers, incl. general practitioners, also select and purchase their own IT-systems from vendors of relevant IT-systems. Amongst the approximately 1850 general practice clinics in Denmark, seven Electronic Patient Records (EPR) systems are used.

Only one vendor provides both an EHR-system to hospitals as well as one to municipalities. All other EHR systems, whether in use at hospitals, homecare, or GP clinic, are provided by different companies.

In addition, regions, municipalities, GPs etc. finance other IT-systems and solutions and are mainly sole responsible for investments in new system and services. However, MedCom will financially support the IT-vendors or system owners for their implementation and test of updated or new standards used in cross-sectoral communication. MedCom uses both part of its fixed budget as well as dedicated project funding for such activities in alignment with MedCom's Work Programme.

2.4.3 Defining and enforcing an interoperability framework

Danish eHealth structure and market is based on some underlying but fundamental principles.

Technology always comes second to clinical and business needs and must be governed as such

Increased digitalisation is a fundamental prerequisite for a sustainable health sector in the future, so digitalisation must achieve the goal of better coherence, higher quality, and greater geographical equality in provision of health services.

The market is open for all - if they adhere to the requirements, e.g., standards and use of national infrastructure

The Danish health sector has a multi-vendor environment. All healthcare organisations must, however, adhere to and implement profiles and exchange interfaces for digital communication based on standards that are developed in a consensus process involving relevant sectors, vendors, HCP etc.

The Danish Health Data Authority is the main authority in defining and enforcing the interoperability framework at national level. Its role is to define and establish national eHealth programmes, national standards, and reference architecture as well as procedures for registration and reporting of data by healthcare providers. The organisation also operates and enforces semantic, technical, and organisational requirements for national registries and databases, such as the healthcare providers' organisation registry (identify markers for all electronic communication), the National Service Platform as well as the national Catalogue for Standards and Exchange Interfaces.

To enforce the use of standardised and structured sharing of health data between sectors, all vendors' IT-systems that implement a standard (i.e., a Danish profile to an international standard) enabling data sharing must be tested. The purpose of the test is to ensure that data is transferred and displayed correctly to avoid missing, flawed or misunderstood information being exchanged.

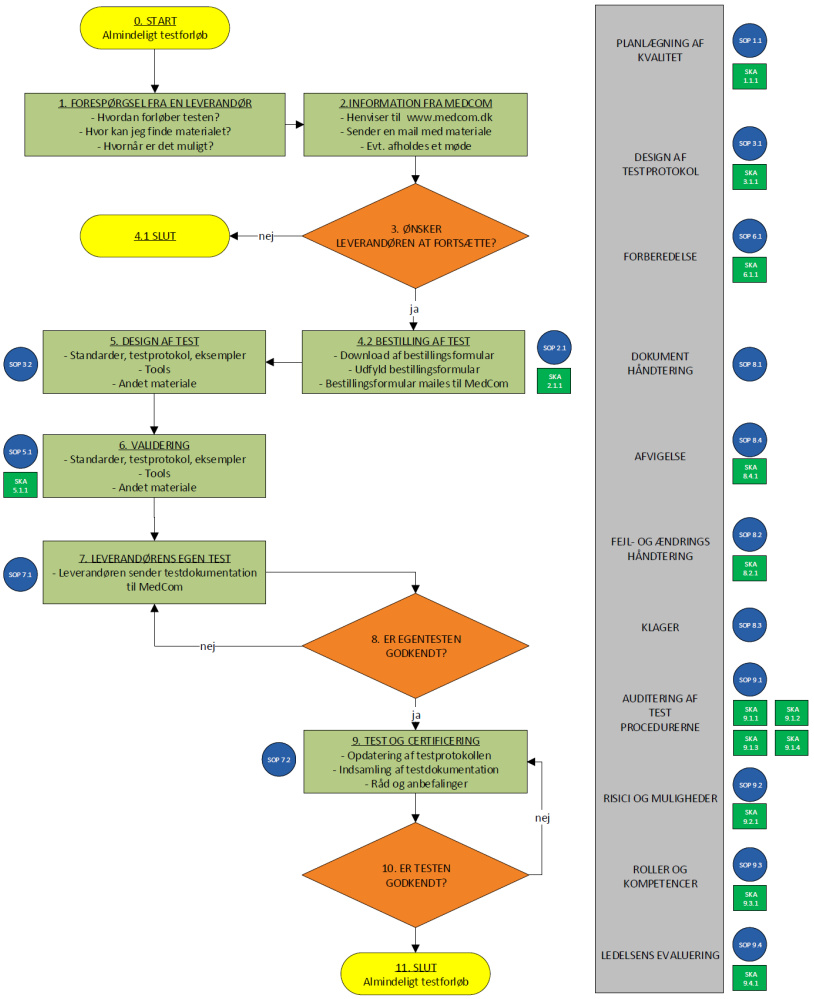

Figure 6: Flow of MedCom's test and certification procedure

MedCom is responsible for the majority of the standards in the National Catalogue for Standards and Exchange Interface. Consequently, MedCom has a detailed and systematic test and certification process, which in 2017 was ISO9001:2015 certified. Consequently, the vendors, who have system undergoing test, know exactly which process to follow and actions to take. A standard test procedure for an IT-system has a fixed flow and processes, which is supported by templates, test protocols, use case descriptions, tools, guidelines etc. In addition to single system tests, MedCom also hosts test camps biannually, where vendors meet to perform tests on the implementation of a specific standard in relation to ongoing national eHealth projects.

If a test is successful, the system under test is granted a MedCom certification for the specific standard. The result is published so there is full transparency on which systems have implemented which standards.

In the collaborative process amongst relevant stakeholders involved in developing new health services, apps etc., the responsibility to ensure that the technical solutions comply with the national interoperability framework is the organisation in charge of the project, initiative etc. This could be the Danish Health Data Authority or MedCom.

2.4.4 Developing new eHealth building blocks

It is a basic principle that development of architecture and standards happens within the context of healthcare sectors' business goals, meaning the purpose of the architecture and standardisation is to create a framework that ensures that the solutions developed and operated within this framework possess the qualities, which the 'business' demands.

Hence, the development of new eHealth building blocks at national level takes place in a collaborative process and is managed by the authority, organisation or eHealth centre leading in a given field but involving all the relevant stakeholders, including both the users (healthcare providers) as well as the vendors in order to obtain consensus across the different stakeholders.

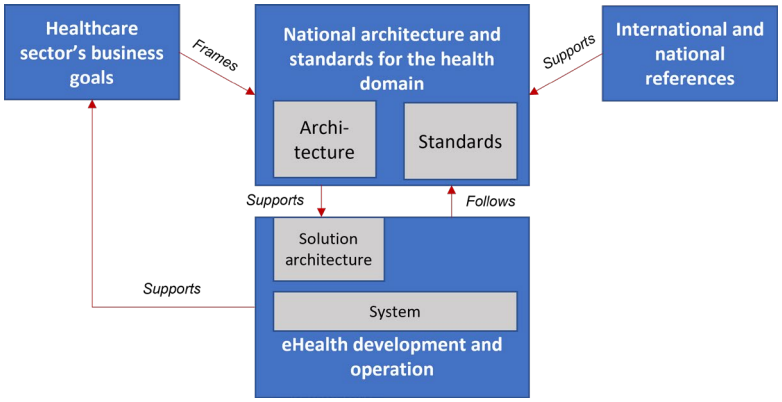

Figure 7: National eHealth model

Regional and local development must align to the national layers and requirements, e.g. solution architecture aligned to the indicators and principles from the national reference architecture as well as implementation of standards for cross-sectoral data exchange.

The Danish Health Data Authority is also responsible for the national eHealth architecture and reference framework. Danish profiles to international standards are mainly developed by MedCom and the Danish Health Data Authority.

For the development of a new standard or profile, the background principle is to ensure that it is the health and care professionals/providers' business needs and goals that are the driving factor of the process. The method is then to ensure consensus around the content of the standard before the standard is defined and documented. This takes place through joint meetings, workshops etc. with all relevant parties, incl. the vendors. All new standards and profiles, whether they are created by MedCom, the Danish Health Data Authority or others must be approved by the Advisory Committee for Standards and Architecture before the Danish Health Data Authority accepts them as part of the national standard catalogue.

The next step is then for IT-vendors to implement the standard in the relevant systems and agree on test with e.g., MedCom. Following a successful test, MedCom will then issue a certification and publication that the given IT-system is approved for the specific standard.

It is then possible to initiate the local implementation of a new standard or profile, meaning that the work and communication flows in the organisations providing healthcare relevant to the specific standard must be adopted accordingly. A national coordination of the implementation process – often through MedCom or the Danish Health Data Authority – will bring the new standard or profile into daily operation.

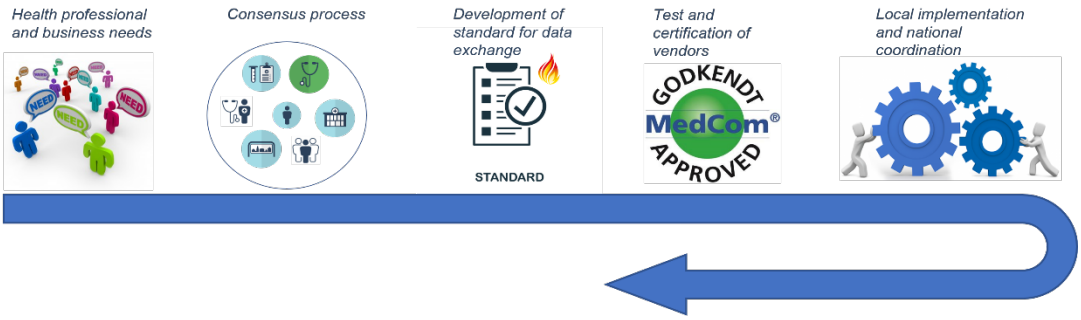

Figure 8: Development process cross-sectoral eHealth communication

The process is generic, but the specific purpose will define the needs and goals to be achieved, which are the stakeholders, what the details of the standard or profile required, where and how to implement it, i.e., in hospitals, municipalities, GPs or others, and ultimately what new eHealth service has been developed in the end.

2.4.5 Maintaining and improving eHealth building blocks

For maintaining the eHealth building blocks, the responsibility for operating and maintaining each profile or standard rests with the owner of the standard (ownership by organisation is defined in the national catalogue of standards).

New actors in the healthcare sector must adapt their services and/or IT-systems to meet the national requirements in respect to the domain in which they will be operating. Consequently, if a vendor has a new IT-system or is deploying an IT-system to a new customer segment of healthcare providers, then the IT-system must be tested and certified for the relevant existing standards in order for their customers (healthcare providers) to live up to the commitments.

For improving the eHealth building blocks, the process is overall similar to when new eHealth building blocks are developed, but which steps and scope of the process is context dependent. Again, the clinical / business needs can be the driving force for deciding to improvement the eHealth building blocks. It can also be due to changed legislation, which requires that the eHealth components also be changed, or the market or technological conditions initiate an improvement, i.e., a need to modernise some of the eHealth building blocks, which can be both related to the standards or infrastructure used.

For collecting bottom-up user feedback (authorities, providers, and vendors) for improvements and changes, MedCom keeps a public catalogue for suggestions to updates existing standards and profiles or develop new ones.

2.4.6 Monitoring and evaluating eHealth service delivery

The National Board of Health-IT is the main body in terms of monitoring progress against the national eHealth strategy and ensuring coordination and prioritisation of digitalisation initiatives across the parties in the health sector. The Board reports to the Ministry of Health (see more in 2.3.1).

Every six months, The National Board of Health-IT publishes progress report on the progress of the different initiatives of the strategy, so there is a frequent status of the milestones and objectives agreed, allowing the Board to mitigate risks and prioritise.

Specific to national eHealth infrastructure and data exchange, the Advisory Committee for Standards and Architecture (RUSA) has the role:

- to prioritise domains, perform quality assurance, ensure alignment with business and clinical needs regarding reference architecture and standards
- to make suggestions for new building blocks national principles in cross-public initiatives
- to assess the international development in respect to Danish activities

RUSA reports to the Danish Health Data Authority.

Specific to regional eHealth infrastructure and data exchange, the Regions' IT-architecture Committee's (RITA) role is:

- to make architectural clarifications and recommendations
- to decide on cross-public collaboration regarding architecture and standards

RITA reports to the IT-director group (IT5) under Danish Regions.

MedCom, as a national eHealth competence centre, will have its activities monitored and evaluated in each of these groups, i.e., MedCom's standards and infrastructure components are processed and approved in RITA and RUSA before signed off by the Danish Health Data Authority as national components.

Both sundhed.dk and MedCom's fulfilment of its strategy or work programme to support national strategies, agreements and priorities is monitored and evaluated through their respective Steering Committee. Both report on a quarterly basis detailed progress of activities, milestones, results, budgets etc. In addition, underlying programmes or service areas might have their own governance structure in terms of monitorering and evaluation. This could be the Digital Practise Programme in MedCom or the 'My Health' (Min Sundhed) app in sundhed.dk.

MedCom publishes monthly an updated statistic of all messages in the health sector by domain and segment. All MedCom statistics are freely and publicly accessible (https://medcom.medware.dk/).

2.4.7 Stimulating innovation in eHealth

Innovation is stimulated in different ways and from different actors and levels.

State level

Innovation in eHealth domain is covered through both health, digitalisation and life science initiatives and stimulus means in addition to eHealth specific ones. The strategies explained in 2.4.1 cover most innovation for public and private entities at state level.

The Government's priorities for health, incl. mental health, set the overall goals. Digitalisation, data, and technology are considered essential and there is financial and organisational support by MoH both directly and through the Danish Health Data Authority.

A Digitalisation Partnership has been set up to advise the Government on digitisation aspects, incl. input to the new digitalisation strategy for the whole public sector (expected Fall 2021). It will further strengthen innovation across public and private sectors and alignment of digital building blocks. The partnership consists of top leaders and experts from business, research, and civil society. It does not contain government or political members as the partnership's role is to make recommendations to the Government.

Regional and local level

Both regions and municipalities work at local level with innovation regarding their service provision to citizens/patients and work processes for their staff. For instance, all regions and main hospitals have dedicated innovation units across both somatic and mental care and treatment. Key topics for innovation have long been e.g., telehealth, telemedicine, and apps, but AI is now also a top priority and joint research centres with universities on AI are emerging. Funding for these activities vary and are often based on a combination of regional grants, local (e.g., hospital and university) grants and incoming funding from projects, research etc.

Coordination between regions also stimulates local innovation and the Regions' Coordination Forum for Telemedicine has been set up to promote and progress the implementation of telemedicine solutions through better knowledge-sharing. This is coordinated amongst the regions themselves and does not provide funds for innovation.

There are also examples of how local innovation becomes a new national service in a joint collaboration between state, regions and municipalities. The 'Joint Development of Telemedicine' programme is originally from a regional telemedicine service, i.e., Telecare Nord in the North Denmark Region. It is now developing a shared national platform for both regions and municipalities for different telemedicine services based on a national infrastructure and reference architecture, consisting of already established components such as the KIH-database (managed by MedCom) and technical services on NSP (managed by the Danish Health Data Authority). This will enable all locally collected data to be shared and integrated with all relevant IT-systems in regions, municipalities, and general practice. With a mature national infrastructure specific to telemedicine, it will be easier to locally implement telehealth and telemedicine services and thus to bring new innovative telemedicine services closer to 'production'. The programme is part of the eHealth strategy and received national funding and investments in addition to local investments.

Business level

The regions have traditionally also a responsibility for regional economic growth in addition to health and mental care provision. Although this is now centralised, there is still a strong tie between the regions and businesses in the respective regional area. Units and clusters working with public-private collaboration and innovation are located in all regions, so there is a close link to businesses being directly involved in the innovation processes. Some of these clusters are now part of Danish Life Science Cluster.

A national Danish Life Science Cluster, bringing together industry, research, and implementers/users, has recently been established on the basis of the Life Science Strategy and several regional innovation clusters. Digitalisation and health data is one of four focus areas in which the cluster has set as its mission to establish a Danish life science industry of international format. Through close public-private collaboration, the cluster will realise the full potential of innovation in the life science domain with the objective to contribute to growth and improve services. The cluster receives both government and industry co-financing.

2.5 Some historical retrospective - how the current state has been achieved

eHealth in Denmark started as a fragmented market and based on local initiatives. National coordination began in early 1990s. In 1994 MedCom was established as the link between the different sectors and providers in the Danish health system. It started as a 2-year project,

where the goal was to set up a coherent health data network in which the communication is based on European standards and directly from one computer to another.

The need for more digitalisation grew and MedCom was made permanent and now works across areas such as general practice, hospitals, laboratories, homecare, pharmacies, dentists, telemedicine etc.

Sundhed.dk was established in 2003 and now made it possible for citizens and healthcare professionals to access personal health data and communicate. Today, sundhed.dk also develops and operates health apps for patients on behalf of the healthcare sector.

Since then, eHealth and the digitalisation of the health sector has continued and has today reached a high level of maturity. A shift away from the traditional message-based exchange of data based on standards started in 2014 when the Shared Medication Card (FMK) was implemented nationally as a central service on the National Service Platform.

The eHealth environment in Denmark is based on a multi-vendor approach. This has been the approach from the start and has not changed over the past 25+ years. There are however tendencies to fewer providers in e.g., EHR-systems on the Danish market due to joint procurement between the regions, but as whole the multi-vendor legacy is still dominant today. Consequently, a close and governed collaboration and mutual commitment between authorities, healthcare providers, competence centres and IT-providers has been essential for the progress achieved to date.

The MoH always had a strong commitment to eHealth, especially in respect to how it can facilitate cross-sectoral collaboration by providing the necessary information and data to the right institutions in a standardised and structured manner. The current Danish Health Data Authority was established in 2015 and is now a formal government agency executing the MoH's eHealth ambitions.

2.6 Successes and what could be done better?

Denmark has in many years been recognised as a leader in eHealth and that is the result of a long journey.

Denmark has set up strong governance and financing structures in which the MoH plays both a strategic and coordinating key role through their direct engagement. eHealth is a priority, and it is evident from the MoH's involvement and continuous focus on eHealth as a supporting element to address health challenges.

A central principle in all eHealth development and implementation has always been to focus on the health and care business needs (i.e., clinical users, workflows, patients) first and foremost. Technical aspects are secondary to the business needs.

Another principle on which Denmark builds, develops, and maintains eHealth infrastructure and services, is to ensure consensus and that all stakeholders from the different sectors are involved to the extent possible. Meaning that building strong partnerships with e.g., medical associations, vendor networks etc. and getting all relevant parties engaged is part of the method. It is therefore important that the development and implementation processes are open and transparent.

Another lesson is to 'think small but implement big', meaning that Denmark develops and implements eHealth in stepwise approach, but with focus on full national implementation of every step, and not in a "Big Bang" approach. This is also due to health system's basic structure as a multiple independent sector healthcare system and with many legacy eHealth building blocks.

This also poses challenges and while digitisation in the healthcare system is extensive, then there are still many things to improve and challenges to overcome.

Despite the 6+ Mill. messages being exchanged monthly between the different healthcare provider organisations, the right information at the right time and to the right recipient is not always achieved - especially between sectors. >60% of Danish citizens think that more coherence is needed btw. hospital, GPs, and municipality.

A sector that it is not as digitalised as the others is social care and data and information sharing to and from social care can be improved considerably for better quality of care for the patients. This area is politically and clinically getting more attention and there is national eHealth building blocks and IT-systems available that can facilitate this.

The technological developments are moving away from some of the building blocks the Danish eHealth system is based on. The predominant part of the 200+ standards in which the exchange of health information in Denmark is based on are in an out-dated standard-format (EDI and OIO-XML). Use of HL7®, both CDA® but especially FHIR® is growing and work is in progress to transition fully to HL7 in respect to the national standards. Given the extensive use of standards in the Danish healthcare system, this will be a lengthy progress.

At an overall level, there is a decline in Denmark's position as a digital frontrunner. A 2021 account of Denmark's digital growth from the Ministry of Trade shows that the position is under serious threat because the general populations' digital competences are not as high as they should be to maintain the frontrunner position, companies have difficulties recruiting IT-specialists already and this will only worsen, and SMEs are not as digitally mature as they should be to make most use of growth opportunities.