

# The Quest for National Digital Agility **Digital Responses to Covid-19 in Five Countries**

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Document Version Final published version

Published in:

Communications of the Association for Information Systems

10.17705/1CAIS.05332

Publication date: 2023

License Unspecified

Citation for published version (APA):

Kendziorra, J., Witte, A.-K., Winkler, T. J., Tong, Y., Kwon, J., & Mishra, A. N. (2023). The Quest for National Digital Agility: Digital Responses to Covid-19 in Five Countries. *Communications of the Association for Information Systems*, *53*, 767-795. https://doi.org/10.17705/1CAIS.05332

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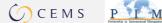
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Research Paper

# The Quest for National Digital Agility: Digital Responses to Covid-19 in Five Countries

## Supplementary Case Narratives to the Accepted Manuscript

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#### Cite as

Kendziorra, J., Witte, A., Winkler, T. J., Tong, Y., Kwon, J. & Mishra, A. N. (2023). The Quest for National Digital Agility: Digital Responses to Covid-19 in Five Countries, Communications of the Association for Information Systems.

# **Table of Contents**

Appendix A: Case Narrative of China	3
Health System Characteristics	3
Digital Responses	5
Cognitive Map for China	7
Appendix B: Case Narrative of Denmark	3
Health System Characteristics	3
Digital Responses	13
Cognitive Map for Denmark	17
Appendix C: Case Narrative of Germany	19
Health System Characteristics	19
Digital Responses	25
Cognitive Map for Germany	30
Appendix D: Case Narrative of South Korea	31
Health System Characteristics	31
Digital Responses	33
Cognitive Map for South Korea	34
Appendix E: Case Narrative of the United States	36
Health System Characteristics	36
Digital Responses	39
Cognitive Map for the United States	43

## Appendix A: Case Narrative of China

Table A 1. China

China		
Health system characteristics	Structure and funding	Three-tier hospital system with national leadership, regional and local levels. 95% of the population covered by at least basic health insurance.
	Policy framework	Boom of teleconsultation and Internet hospitals after regulatory and policy changes (e.g., 5YP, Internet+Healthcare, Healthy China 2030, etc.).
	Socio-cultural values	Collectivist values and general trust in governments. Privacy concerns trending lately.
	Information technologies	Fragmented EHR/EMR markets. Top internet companies (the "BAT") are given freedom for innovation.
Digital responses	Tracking and tracing	Mobile-based health QR code, close contact detector, and other data intensive tracking apps provided quickly by local/national authorities in collaboration with the Big Techs and adopted widely.
	Health data reporting	Covid-19-related numbers reported by local healthcare authorities on a daily basis through China's National Infectious Disease Information System, which is in place since the SARS pandemic.
	Teleconsultation	Use of existing telemedicine platforms steeply increased and new platforms were built to support specific areas (e.g., Hubei province).
	Vaccination mobilization	Information systems support the information flow for vaccination throughout the country.  Decentralized approach for the vaccine administration supported by existing apps to make appointments and check the records.  The vaccination status is integrated into the existing Health QR Code in some areas and the government plans to enable the information exchange across cities and across provinces.

#### **Health System Characteristics**

#### **Structure and Funding**

In the past 15 years, the Chinese healthcare system has undergone **major reforms** targeting at optimizing healthcare resource allocation and providing affordable public healthcare service for every resident. Today, about 95% of the population is covered by at least basic health insurance (Fang, 2020). This insurance generally covers a portion of the medical costs, although this portion varies and has been continually increased during reforms.

Hospitals in China can be public or private. While the number of private hospitals increases significantly in recent years, they are typically small in size and account for less than 10% of the total hospital revenue (Research and Markets, 2017). Public hospitals in China can generally be classified into three levels. Level 1 hospitals focus on providing primary care in one community, whereas Level 2 hospitals are furnished with better equipment and are able to provide healthcare services across several communities. Level 3 (especially 3-A) hospitals are highly reputable hospitals located in large cities and they enjoy high-quality healthcare resources, such as funding, equipment, and physicians. As a result, healthcare infrastructure is better in cities than in rural areas. While most physicians are employed by one hospital, the government has established a policy that allows physicians to work in multiple healthcare institutes (National Health Commission PRC, 2014).

There are a few other **major actors** in the Chinese health system:

- The National Health Commission of the PRC (NHC), a cabinet-level executive department of the State Council, supervises the formulation of health policies in mainland China.
- The Chinese Centre for Disease Control and Prevention (China CDC) provides technical guidance on disease control and prevention and supports public health.
- The National Healthcare Security Administration, a government agency under the State Council of the People's Republic of China, manages the public healthcare insurance in mainland China.

• The Hospital Management Authority of the PRC is responsible for setting regulations, supervising operations, and evaluating the performance of public hospitals.

The implementation of national-wide healthcare initiatives in China is often done through a combination of **top-down and bottom-up approaches**. Usually, the strategic direction is initially defined by the Chinese central government such as the National Health Commission. After proposing a new direction, the national government delegates the implementation to each state government. Next, the state government designs a detailed proposal and execution plan, and it will conduct some test runs in the province. When the national government sees successful outcomes, it will develop effective plans and test them in other parts of the country. Once the pilot programs are successful, the national government will regulate the implementation process and promote it nation-wide.

#### **Policy Framework**

There have been several major policy initiatives in China related to digital health. Telehealth was emphasized under *The Healthy China 2030* (the 2030 strategy), which is closely related to the central government's "Internet + Healthcare" initiatives, a guideline that encourages the use of Internet and information technologies in healthcare in various ways. Healthy China 2030 is a nationwide long-term action plan issued by the government in 2016 to promote health and well-being based on defined goals, principles and indicators (Tan et al., 2017; Xinhua, 2016). This also includes efforts to foster new business models in the health sector, such as online health services (Wei, 2018), and proposals to regulate and promote Internet + Healthcare services (Yang et al., 2021). Following the 2030 strategy, the 13th Five-Year Plan (FYP) documented that telemedicine should be developed to introduce a hierarchical medical system, so that the reform of the medical and healthcare system will be further deepened. A set of regulations were issued such as the *Regulation on Internet Treatment (Pilot)* (the Regulation) and the *Opinions of Promoting "Internet+Healthcare"* (the Opinions) (The State Council, 2018). According to the Regulation, telehealth activities can only be conducted in Internet hospitals offered by physical and government-permitted medical institutions. Individual doctors or third-party commercial platforms are not allowed to conduct telehealth activities.

Another important policy initiative is related to **hospital records and services digitalization**, including standards for:

- EMR levels: Notice on Management Measures (Pilot) and Evaluation Criteria (Pilot) for the Application of Electronic Medical Records Systems (National Health Commission PRC, 2018)
- Digital hospital services: Notice on Evaluating the Levels of Smart Hospital Services (Hospital Management Authority PRC, 2019)
- Smart hospital development: Notice on Further Improvement of the Appointment System to Strengthen the Construction of Smart Hospitals (Hospital Management Authority PRC, 2020).

## Socio-Cultural Values

Chinese citizens generally have **trust** toward their government. The 2021 Edelman Trust Barometer revealed that 82% of the Chinese surveyed trust their government and 70% trust their media (Edelman, 2021). The population tends to follow the direction that is given by the government. Chinese people are often ascribed **collectivist values**, that place the value of the group and cohesion above benefit to self.

**Privacy sensitivity** is a late trending topic in China. As a matter of fact, private information is less of a concern by Chinese citizens according to Harvard Business Review (The Economist, 2018). In late 2020, the Chinese government unveiled the first draft of the Personal Information Protection Law and opened it for public commenting. This law aims to not only regulate organisations' and individuals' actions related to personally identifiable information in China, but also outside the territory of China.

#### **Information Technologies**

The market for **Electronic Medical Records (EMR)** is fragmented in China. Some representative vendors of EMR systems are Neusoft, Goodwill, MedInfo, Mandala, PKU Healthcare IT, Haitai Medical, Yidan Software, and a few others. The call for telemedicine is triggered by the high number of patients in China. With the development of telemedicine, patients are able to consult their doctors without physically visiting the hospital and waiting in queues for hours.

In China, the top three **tech companies**—Baidu, Alibaba, and Tencent (the BAT)—form the keystone players of a digitized ecosystem. According to McKinsey Global Institute, 42 percent of the total Chinese venture capital investment came from the BAT (Wang et al., 2017). Apart from investing into incubators, the BAT are fiercely expanding their territories, combining fragmented online and offline markets, and offering consumers mobile apps. The BAT and its former BAT employees are leading the trend of technological development in China.

#### **Digital Responses**

## **Tracking and Tracing**

The mobile-based **Health QR Code app** was first launched in Hangzhou on Feb 11th, 2020 as a result of a collaboration between Alibaba and the local government. Every citizen who lives in the city had to enter their health status related to Covid-19, their home address, and the places visited in the last 2 weeks. After submitting the required information, a coloured QR code is displayed on the mobile phone. People with a green code are allowed to go outside and use public transport freely. If the health QR Code is yellow (e.g., if cases in a city are at a moderate level), the user has to stay at home for 7 days. A red health QR code signals the citizen that he or she had close contact with a confirmed case or lives in an area with many confirmed cases, which requires him or her to stay at home for 14 days. After that period of time, the code turns green again if no other incident is registered. In addition to the individual users' input, big data from the Alibaba platform, the government and mobile operators were also run at the back end to correct fraud (people at high risk did not enter or update the correct information) or changing behaviours (some "unknown" close contacts could be identified). This measure has helped the Hangzhou government substantially in controlling the Covid-19 pandemic (China Daily, 2020). By the end of March 2020, most areas in China used one Heath QR code to demonstrate the risk level (Xinhua, 2020) and the acceptance rate was comparably high. (Kostka & Habich-Sobiegalla, 2021; Mozur et al., 2021)

The contact-tracing app "Close Contact Detector" was launched by the National Health Commission, the General Office of the State Council and China Electronics Technology Group Corporation (BBC, 2020). The estimation of close contact is based on the big data analysis from authoritative sources such as the National Health Commission, the Ministry of Transportation, China National Railway Group Limited and Civil Aviation Administration of China. Users can inquire if they had close contact to an infected person by entering personal information in the application through the inquiry system. The system received over 130 million inquiries in the first week after its launch and it is expected to be used until the pandemic is over (CETC, 2020). In addition, the Chinese government launched a query service for people where users can inquire whether he or she was in the same means of transport as a patient infected with Covid-19 (National Health Commission PRC, 2020).

During the pandemic, Alipay and Wechat – widely used apps in China – provided **additional services** related to Covid-19. For example, the health QR code is integrated into Alipay and Wechat for people's convenient access. Furthermore, Alibaba – the company behind Alipay – launched the "patients with the same itinerary" service, which allows everyone who took a certain means of transport (such as airplanes, trains, subways, buses, taxis, ships) during the pandemic to check if there have been any Covid-19 infected patients in the same itinerary (L. Zhang, 2020). Another Covid-19 related service offered by these apps is the pandemic situation query. Using this service, individuals can check if there is any patient in nearby communities.

#### **Health Data Reporting**

Since February 3rd 2020, the National Health Commission has been publishing daily summary information online regarding Covid-19 in China (National Health Commission PRC, 2021). This summary information, called **daily briefing**, includes numbers of confirmed infections, suspected infections, deaths, cured patients and close contact with infected patients who were released from medical observation. According to the National Health Commission, this data is collected from the local medical institutions and authorities in China.

Health reporting is performed through **China's National Infectious Disease Information System (IDIS)**, a system that has been developed after the SARS outbreak in 2004. When a suspected or confirmed case is discovered, medical institutions that can report directly via IDIS must do so immediately. Institutions that do not have the opportunity should send the infectious disease report card within 2 hours to the county

level Center for Disease Control, which then reports these cases via IDIS to the higher-level CDCs on a daily basis (China CDC, 2020).

#### **Teleconsultation**

During the Covid-19 pandemic, the National Health Commission has been re-emphasizing the importance of Internet-based diagnosis and released a **special telehealth policy** named Using Internet-based Diagnosis for Covid-19 Prevention and Control Measures. In order to prevent and control the virus, the National Health Commission took the unique advantages of Internet-based medical care and made several efforts in conjunction with relevant departments.

First, local governments strengthened their efforts in **building online platforms** to serve public health needs. Specifically, local governments organised hospital-to-hospital and hospital-to-patient tele-medicine, and drug delivery services. The director of planning of the NHC said, "The data shows that in the hospitals affiliated to the National Health Commission, Internet-based diagnosis and treatment has increased 17 times over the same period last year. In addition, the number of medical consultations on some third-party Internet-based platforms has also increased 20 times over the same period in 2020, with the amount of prescriptions increasing nearly 10 times" (Joint Prevention and Control Mechanism of the State Council, 2020).

Second, the National Health Commission worked with several departments to provide **support for Hubei** province (the region with most infected cases in China) through telehealth solutions. As one example, the National Health Commission and the National Telemedicine and Connected Health Center built a national teleconsultation platform. Furthermore, the National Health Commission worked with the Chinese Medical Doctor Association to organise a telemedicine task force and an artificial intelligence expert group to provide intelligent medical services (CNS, 2020; Joint Prevention and Control Mechanism of the State Council, 2020).

Since the outbreak of Covid-19, the number of user visits on **independent internet consultation platforms** has increased rapidly. "Good Doctor Online", one of the most popular online consultation platforms in China, has called on doctors from all across the country to provide free online consultation for the public. As of Feb 19th 2021, Good Doctor Online has served 1.68 million free online consultations (X. Zhang, 2020). During the Spring Festival in February 2021, the daily number of newly registered users on the platform and the daily demand for online consultations increased by 350% and 648% respectively, compared to December 2020. Data from another popular Internet consultation platform, "Ping An Good Doctor", showed a similar trend. Since the beginning of the pandemic, the number of visits to Ping An Good Doctor reached 1.11 billion, the number of newly registered users of the app increased by 10 times, the average daily consultation volume of new users was 9 times higher than normal, and the cumulative number of videos related to pandemic prevention exceeded 98 million (X. Zhang, 2020).

## Vaccination Mobilization

At the national level, the website of the National Health Commission of China reports the **vaccination status** on a daily basis. As of August 2, 2021, a total of 1.688.683 million vaccine doses were administered (China CDC, 2021b), which corresponds to approximately 120.62 doses per 100 people in the country.

There are various **information systems** to support the information flow for vaccination throughout the country. An electronic vaccine tracing platform and a national immunization planning system keep the records of the vaccines from production to the administration in China. The information flow is supported by the related systems in each province and by vaccine administration organisations (China CDC, 2021a).

A decentralized approach is adopted for the **vaccine administration**. People can get vaccinated in community hospitals, schools or organisations. Local governments have developed own vaccination plans and strategies, some of which include incentives for vaccination. Decentralized apps are available to make appointments and check the vaccination records. Many of these functions are integrated into existing apps such as Alipay or Wechat. The vaccination status is integrated into the existing Health QR Code in some areas and the China CDC plans to enable the information exchange across cities and across provinces (China CDC, 2021a).

## **Cognitive Map for China**

The cognitive map for China (Figure A 1) illustrates the individual events per digital response, shows the influence of the sectoral characteristics on the events, and includes the facilitators and the predominant digital infrastructure evolution mechanisms.

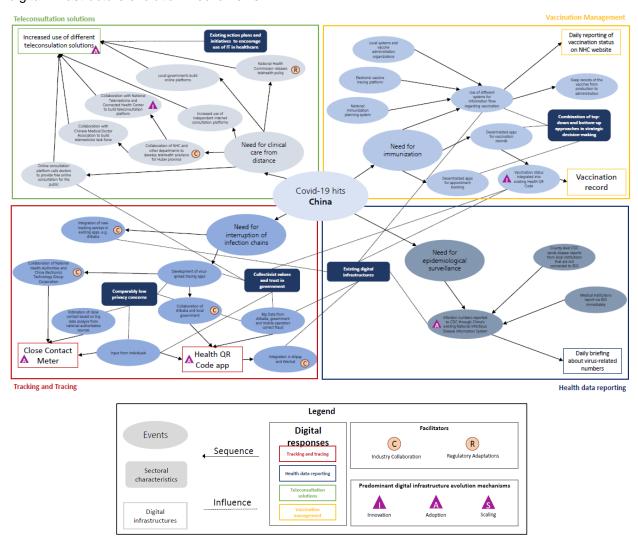


Figure A 1. Cognitive Map for China

## Appendix B: Case Narrative of Denmark

#### Table A 2. Denmark

Denmark		
Health system characteristics	Structure and funding	Free, tax-funded and public health care for every Danish citizen.  National health strategy but regional and local responsibilities.
	Policy framework	The EU's General Data Protection Regulation complemented with Denmarks' Data Protection Act regulate privacy issues.  The Health Act and The Authorization of Health Care Professionals and on Health Care Services define rights and obligations of patients and healthcare professionals.
	Socio-cultural values	Society with trust in the governmental actions, low uncertainty avoidance and a high mobile literacy.
	Information technologies	Nationwide digital health network connects providers via a standardized common infrastructure and enables communication and data sharing.  National patient portal (sundhed.dk) collates a lot of relevant information for citizens.
Digital responses	Tracking and tracing	Collaboration between the government and private companies leading to the development of two major tracking solutions: The contact tracing app Smittestop and the data donation platform COVIDmeter, where users can voluntarily share information about their health status with the Danish CDC (Statens Serum Institut).
	Health data reporting	Data sharing through existing infrastructure and integrating new functionalities. Statens Serum Institut releases surveillance data (about Covid cases and vaccines) in interactive dashboards on a daily basis.
	Teleconsultation	Strong increase in teleconsultation especially in the first few months of the pandemic. Inclusion of video consultation into the widely-adopted MyDoctor app (MinLaege).
	Vaccination mobilization	Centralized process supported by the existing IT infrastructure, where citizens receive an electronic notification as soon as it's their turn to be vaccinated. Vaccination distribution and administration managed by the regions. Vaccination certificate accompanies the reopening strategy.

## **Health System Characteristics**

## Structure and Funding

The Danish health system is divided into **three administrative levels** with national, regional and municipal responsibility. A reform in 2007 has restructured the public sector in Denmark and led to the redistribution of tasks and responsibilities and major changes in the health sector (Christiansen, 2012).

On a **national level**, the Ministry of Health defines the framework for the health system and is responsible for planning, monitoring and licensing tasks. The different tasks are managed by the agencies that are settled under the Ministry, such as:

- The Danish Health Authority (Sundhedsstyrelsen): advises and cooperates with the several stakeholders in the health sector to ensure high quality
- The Danish Health Data Authority (Sundhedsdatastyrelsen, 2021a): responsible for the several IT systems and registers in the country; supports coherent digital solutions and develops the IT infrastructure (Sundhedsdatastyrelsen, 2021e)
- Danish National Board of ehealth (nationale bestyrelse for sundheds-it) (Sundhedsdatastyrelsen, 2021b): consists of representatives from all three administrative levels (Sundhedsdatastyrelsen, 2021d); advises the Minister on all relevant IT-related topics in healthcare and develops certain standards and national requirements to ensure a common IT infrastructure in the country (Danish Ministry of Health, 2012; Sundhedsdatastyrelsen, 2021a)
- The Danish Medicines Agency (Laegemiddelstyrelsen, 2021): Approves new drugs and clinical trials
- The Danish Patient Safety Authority (Styrelsen for Patientsikkerhed, 2021b): Advise and supervise healthcare professionals in terms of patient safety

• The State Serum Institute (Statens Serum Institut, 2021d): Prevention, control and research of infectious diseases; responsible for vaccination programs

The second administrative level are the five Danish **regions** that are responsible for primary care (general practitioners) and secondary care (hospital services). Each region can adapt the health services to the specific regional conditions, but always in line with the national guidelines. The organisation *Danish Regions* has been established by the five regions to coordinate regional issues and interests on a national level, including the area of health. The implementation of eHealth strategies and initiatives in the regions is supported by the Regional eHealth Organisation (Regionernes Sundheds-IT organisation – RSI) that consists of members of the Danish Regions and the five Danish regions (Danish Ministry of Health, 2012).

The 98 municipalities are the third administrative level that govern the tertiary care (e.g. prevention, health promotion, elderly care). Local Government Denmark (LGDK) is the association of the municipalities and responsible for coordinating interests, informing and consulting the municipalities. The acceleration of ehealth is one focus area of LGDK.

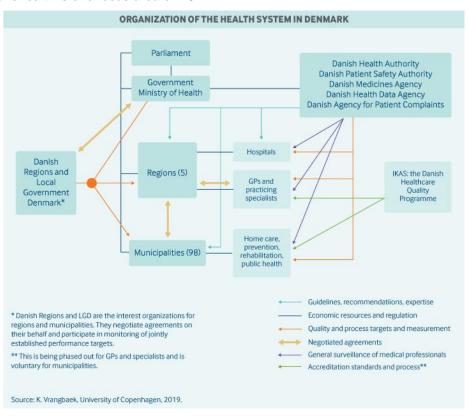


Figure A 2. Organisation of the Health System in Denmark (Vrangbæk, 2020)

The **healthcare expenditure** is mainly publicly funded (84%) through taxes and partly through patient copayments (16%) e.g., for medication or physiotherapy. The government collects the taxes and distributes defined block grants to the regions and municipalities. In addition, the municipalities collect local taxes and have to make a contribution to the regions' health expenditures depending on the citizens' use of the hospitals. This serves as an incentive for the municipalities to improve the tertiary care and by that reduce the use of primary and secondary care (Danish Ministry of Health, 2012).

All residents in Denmark have automatically access to **free and equal public health care**. A considerable part of the Danish population chooses in addition a private insurance, either as complementary (38%) or supplementary (26%) to the public one (Vrangbæk, 2020).

Denmark has already started to innovate the health system in the 1990s. One step of this strategy has been the founding of **MedCom**, a non-profit multi-stakeholder organisation that is owned by The Ministry of Health, Danish Regions and Local Government Denmark (MedCom, 2021a). According to its mission statement, MedCom "facilitates cooperation between authorities, organisations and private firms linked to the Danish healthcare sector"(MedCom, 2016).

## **Policy Framework**

With the dissemination of the internet by the end of the 20th century and increasing data protection concerns, the EU decided on the **Data Protection Directive 1995** (Directive 95/46/EC) to regulate the collection and processing of personal data. This directive has been translated into national law by each EU member, resulting in Denmark's "**Act on Processing of Personal Data**".

In 2016, the EU published the **General Data Protection Regulation** that was developed to replace the Data Protection Directive by May, 25th 2018 obligatory in all member states. Denmark has further developed and published the **Data Protection Act**, which is supplementary to the obligatory EU regulation on data protection and privacy. The Data Protection Act covers sections of data protection that are not set by the EU but rather up for interpretation and elaboration of each country (IT Governance Ltd, 2021).

In 2002 the EU has published the **ePrivacy Directive** that regulates privacy-related topics especially in electronic communication, focusing on issues such as cookies, the use of confidential information, spam, etc. In Denmark, the directive has been enacted through different acts and orders: The Act on Electronic Communications Networks and Services, the Executive Order on Information and Consent Required in Case of Storing and Accessing Information in End-User Terminal Equipment, and the Marketing Practices Act. The ePrivacy Directive is supposed to be replaced by the **ePrivacy Regulation** soon (IT Governance Ltd, 2021).

With regard to the health sector, more specific regulations and principles apply. The **Health Act** (HA, 913/2010) is a sectoral law governing the processing and the disclosure of patient data for treatment and other purposes, with special sections e.g., on patient rights (Time.lex & Milieu Ltd, 2014). The **Authorization of Health Care Professionals and on Health Care Services** (877/2011) includes the health care professionals' duties and obligations. Health care professionals are obligated to update the health data of the patients without needing their consent. Generally, if a health care professional is involved in the treatment of a patient which requires him or her to access the data ("need to know"-principle), the law relies on patients implied acceptance. However, the patient can actively prohibit it.

Furthermore, patients have **far reaching patient rights** as to the use of their data in healthcare delivery, including the right to self-determination and the right to access the own health data. The latter (access) is being enabled through the aligned IT architecture and the patient portal sundhed.dk (see Information technologies). The health data of the Danish citizens can be used for secondary purposes (e.g. research or quality control) if this is done in accordance with the General Data Protection Regulation and the other laws and principles. There are good possibilities for health data collection and usage, however, the Danish Data Protection Agency has to give approval (Ministry of Health, 2017).

At the same time, national and EU-level healthcare-related policies are implemented in Denmark with a **sense of pragmatism**, for example when it comes to managing patient consent. Patient consent to data processing is presumed by handing over the health card and most health professionals involved in the treatment of a patient have access to health data.

Furthermore, as technological possibilities advance, changes are also made to the regulatory environment to adapt to them and facilitate the introduction and usage of new solutions. A similar approach is taken when policy-related issues emerge. Recently, several patients missed the opportunity to receive a possible compensation, because their emergency calls have been deleted after five years, but compensation can be claimed within ten years after the incident. Because these two laws do not match, various health care and governmental stakeholders now aim for a regulatory adaptation, which might likely lead to an alignment, so that both laws refer to 10 years (Fed et al., 2021).

Requirements and standards for the national health IT in Denmark are defined by the Danish Health Data Authority and the National Board of e-health and published and updated in a catalogue on a quarterly basis. The standard catalogue builds upon the Health Act and all organisations that provide, purchase or develop IT solutions should make sure that their IT system applies to it (Sundhedsdatastyrelsen, 2021f). Examples of e-health standards used in Denmark are among others HL7, IHE and ISO (Danielsen et al., 2019).

Since the mid 1990s, Danish health authorities developed **e-Health and digitization strategies** in regular intervals to push and coordinate the implementation of nationwide digital health progress. Over time, the focus of these strategies has gradually shifted from technological considerations, such as building the

national infrastructures, to a greater focus on governance and stakeholder involvement (Bruun-Rasmussen et al., 2008) This is also reflected in the titles of these national strategies:

- 1996: Action Plan for Electronic Patient Records Strategy Report
- 1999: National It Strategy for the Hospitals 2000-2002
- 2003: National IT Strategy 2003-2007 for the Danish Health Care Service
- 2007: National Strategy for Digitalisation of the Danish Healthcare Service 2008-2012
- 2013: Making eHealth Work National Strategy for Digitalisation of the Danish Healthcare Sector 2013-2017
- 2018: Digital Health Strategy 2018-2022 'A Coherent and Trustworthy Health Network for all'

The current **Digital Health Strategy 2018-2022** builds on the strong existing IT-infrastructure and aims to extend the scope of accessing health data by including e.g., smartphones and tablets (Healthcare Denmark, 2021b).

#### Socio-Cultural Values

One key success factor for a digitalized, high-quality health care system in Denmark is the **trust** of the society in the IT systems themselves and in the people using them. Privacy concerns and data security are of course very important issues in Denmark, but Danes trust in the way the digital solutions are implemented in the different public and private sectors (Gimpel et al., 2021). Especially when it comes to the healthcare sector, the exchanged data is very personal and highly confidential, but people trust that the data is not misused by the authorities and only used for their benefit (Ministry of Foreign Affairs of Denmark, 2021b).

More generally, the level of **social cohesion** in Denmark is quite high and has even increased over the last three decades (Larsen, 2013). Virtues such as honesty, reliability, the willingness to help each other and cooperate promote the cohesion (Støvring, 2012). Danes believe that they share a moral community that makes them trust in the citizens and state institutions of their country (Larsen, 2013). Citizens find their shared informal norms and values reflected in the institutions' mentalities which leads to identification and the willingness to accept official decisions (Støvring, 2012).

Furthermore, Danish citizens are often said to have quite high **mobile literacy** and have integrated the digitized tools in their daily lives. The usage of these systems has become a standard and is not considered as an effort. Also, even the majority of the Danish society with no or low education make use of the digital public services (Digital Denmark, 2021). The Danish government has envisioned and is still committed to go "Digital by Default" (Digital Denmark, 2021; Ministry of Foreign Affairs of Denmark, 2021a).

This attitude is both a reflection of, and influence for the Danes **individual attitudes and values** and may be considered a part of their culture. Looking at the widely regarded Hofstede's cultural dimensions model (Hofstede, 2001), the Danish national culture is characterized by a relatively high individualism and a relatively low uncertainty avoidance (Hofstede Insights, 2021). While the former (high individualism) may be interpreted as an explanation for a population's need for individualized and privacy-preserving IT solutions, the latter (low uncertainty avoidance) substantiates why Danes trust their institutions and are comparably less concerned about sharing their health data with public institutions.

#### **Information Technologies**

Denmark is widely recognized as a **highly digitalized country** not only in terms of healthcare delivery (Ministry of Foreign Affairs of Denmark, 2021a; Thiel et al., 2018). From the very beginning of the Internet era, the Danish government has foreseen the opportunities and advantages of the technological advances and thus fostered changes in the society through the creation of several supporting institutions and the development of future-oriented digitization strategies.

Besides a high level of broadband penetration in Denmark (Ministry of Foreign Affairs of Denmark, 2021a), one of the most important enablers is the **national infrastructure for e-identity** called NemID which is connected to the CPR-number (a unique civil registration number assigned to every single Danish resident by birth or immigration to the country) and a digital key to access the majority of public and also private services (Ministry of Foreign Affairs of Denmark, 2021b). Already today "almost all interaction with the Danish authorities takes place online" (Ministry of Foreign Affairs of Denmark, 2021a).

However, national authorities have to offer citizens who cannot or do not want to use NemID alternative ways to access all public services (The Danish Agency for Digitisation, 2021).

Official communication with public agencies as well as some companies' interaction takes place via Digital Post which can be accessed through the website borger.dk or an **electronic mailbox** (e-boks) that most residents have, and which is only accessible by using a two-factor digital authentication based on NemID (Agency for Digitisation, 2021; Medaglia et al., 2017; Ministry of Foreign Affairs of Denmark, 2021a). Danish health providers can communicate with patients via this electronic mailbox as well. Patients receive for example notifications about upcoming appointments or test results from past examinations as digital post to their e-boks (Ministry of Foreign Affairs of Denmark, 2021a).

Over the past twenty years, all Danish hospitals have implemented **electronic health records (EHR)** and then gradually reduced the number of different vendor solutions in place. Different agreements between the state and the regions in the early 2000s have enforced the mandatory usage of EHR systems in hospitals and in primary care, leading to the implementation of various different IT solutions across the country (Kierkegaard, 2015). After a structural reform in 2007, the five regions decided to reduce the number to one EHR system for each region. The Capital Region and Region Zealand (Eastern Denmark) consolidated a number of prior solutions in a common EHR platform by the US American vendor EPIC implemented between 2016 and 2017 (Winkler et al., 2020). By 2021, the third of the three Western-Danish regions will implement the EHR System Columna Clinical Information System by Systematic, leading to further synergy potential and interoperability.

Different actors (such as health providers, national registries, regions, municipalities and others) are connected in the **Danish Healthcare Data Network** (SDN), which is the electronic exchange for most of the communication and data sharing across the health care system. It is operated by MedCom and users of the public and private sector can offer their services through this same secure connection (Danish Ministry of Health, 2012). Local platforms like the National Service Platform (NSP) or sundhed.dk are linked in this shared infrastructure (MedCom, 2021c). The NSP connects a variety of health-IT services and data collections and offers the use of national registers in the patient care in local medical institutions (Sundhedsdatastyrelsen, 2021c, 2021b).

Almost 100% of laboratory test results, prescriptions and referrals to hospitals are made or sent electronically (Ministry of Health, 2017).

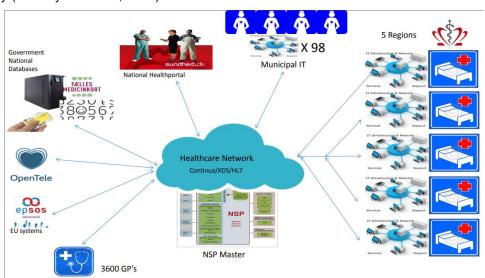


Figure A 3. Danish Healthcare Network (Henriksen, 2019)

One valuable outcome of this common infrastructure has been the **nationwide patient portal** sundhed.dk, which is the major front-end solution for all citizens in Denmark (Jensen & Thorseng, 2017). Sundhed.dk collates data from different sources that already exist, contextualizes them and enables easy access (Jensen & Thorseng, 2017). In this system, patients can find a lot of relevant information about the Danish healthcare system and personal health data (e.g., treatment history, test results, appointments) and they are able to communicate with healthcare professionals (sundhed.dk, 2021c). Patients can see who has accessed the data to reduce the risk of misuse by healthcare professionals. The services of

sundhed.dk have also been made available as the smartphone app MinSundhed (MyHealth) on all common mobile app stores and since then been continuously developed further. Examples for national records displayed in sundhed.dk (and the MinSundhed app) include the National Health Record (sundhedsjournalen), the E-Journalen (database collecting patient information from hospitals), the P-Journalen (database collecting patient information from private HCP) and the Shared Medication Record (lists all prescriptions and medicine purchases) (Danish Ministry of Health, 2012). General practitioners can log into their own EHR system and by clicking on an integrated button, they can see health data from their patient through accessing databases such as e-journalen or the shared medication record.

The **Shared Medication Record** lists all prescriptions, medicine purchases and vaccinations of a Danish citizen and all persons included in the treatment have access to this database (Trifork, 2021c). It has been developed by the Danish Health Data Authority in collaboration with the software company Trifork and it was launched in 2009 (Trifork, 2021c). It is integrated with about 40 different systems in the health sector, and today, almost every healthcare professional in Denmark works with it (Trifork, 2021c).

A recently provided digital solution is the app **MinLaege** (MyDoctor), which has been developed in 2018 based on a proposal of the Danish Organisation of General Practitioners (PLO) and the Ministry of Health. The collaboration partner Trifork combined the several existing systems across the nation (IT patient systems, national registries, 3400 GP systems) into one app, that should make it easier and similar for all patients to get in touch with their general practitioner (duckwise, 2021; Trifork, 2021b). Users can log into the app with their NemID and manage their appointments, see test results, contact their doctor (if he or she has integrated the system as well), and use other functionalities (Praktiserende Lægers Organisation, 2021). If questions or problems emerge related to MinLaege, the point of contact is the patient portal sundhed.dk (Praktiserende Lægers Organisation, 2021).

**Telehealth** (including teleconsultation and telemedicine) has been considered as a valuable and benefitting enabler for the health system already in the times before the global pandemic reached Denmark in 2020. With the introduction of the National Action plan for Dissemination of Telehealth in 2012 as one initiative in the Danish eGovernment Strategy 2011-2015, different areas and specific initiatives have been defined to speed up the dissemination of telemedicine in the whole country (The Danish Government et al., 2012). In 2018, Danish Regions stated that in the future, every third contact between patient and doctor (general practitioners and specialists) should be digital (Ølholm et al., 2020).

There have been various successful **telehealth projects**, such as TeleCare North, The Virtual Hospital, Telepsychiatry or Compliance and Prevention (Healthcare Denmark, 2018). From the 1st of June 2019 to the 31st of January 2020, a pilot project has been conducted by MedCom and the PLO (Organisation of General Practitioners in Denmark) to gather experience about video consultation in general and specialist practices. A total of 40 medical centres across the five regions participated either through the application MinLaege or the clinics own system. During the eight months period, 517 video consultations have been conducted. Although the participants considered the opportunity to use video consultation as valuable for the future, the doctors' feedback also showed that further technical knowledge and equipment, and integration into existing systems is required before a roll-out in a bigger context (Ølholm et al., 2020).

## **Digital Responses**

#### **Tracking and Tracing**

In collaboration with the IT service provider Netcompany, the Danish Government has developed digital solutions to help track, control and contain the virus:

First, the **data donation solution** COVIDmeter has been launched at the beginning of April 2020 (Digitaliseringsstyrelsen, 2020) and is linked to the Statens Serum Institut (SSI; the Danish Centres for Disease Control and Prevention). Citizens can voluntarily answer a questionnaire on a weekly basis, including questions about recent tests, contact to infectious people or a received vaccination. This health information is then transmitted to the Statens Serum Institut so that the authorities are able to estimate the status of the virus in the country. Although certain subscription information is required (e.g. age, sex, zip code), the information is transmitted pseudo-anonymously and the account can be closed at any time. The COVIDmeter is connected to sundhed.dk and the account and questionnaire can be accessed via the website by using NemID (Statens Serum Institut, 2023). Participants receive a weekly reminder via e-mail with a direct link to the survey.

The **contact tracing app** Smittestop has been developed by the Danish Ministry of Health, the Danish Patient Safety Authority, the Danish Health Authority, the Danish Agency for Digitisation and Netcompany (sundhed.dk, 2021b). It is based on the decentralized Google-Apple Exposure Notification (GAEN) (Council of Europe, 2020; sundhed.dk, 2021e) and citizens can download the application in the Appstore since June 2020 (GIP Digital Watch, 2020). Users who have been in proximity to another user that has been diagnosed with Covid-19, would get a notification on their mobile device. While identification is not required in order to receive alerts, users have to log in with their NemID when they have been tested positive and want to share their result (sundhed.dk, 2021d). Tech and human rights associations in Denmark raised considerable concerns about the intrusiveness of the tracking of individual citizens based on location data (Akhtar & Jørgensen, 2020; Rådet for Digital Sikkerheds, 2020). By January 2021, around 2.1 Million people have downloaded the application (Berlingske, 2021). However, the actual number of users might be lower if you take into account citizens who have more than one phone or people who have deactivated or deleted the application due to battery issues (A. Østergaard & Frøkjær, 2020). Furthermore only a small part of infected users actually warn their contacts via the app after getting a positive test result (C. Østergaard, 2020).

These digital solutions are free of charge for the end users, but very expensive for the state. While the first version of the Smittestop application has been developed by Netcompany pro bono, the IT company has been paid several millions DKK for the further development and maintenance (Grønnemann, 2020).

Besides these two major tracking solutions, other digital developments have emerged to respond to the Covid-19 pandemic, such as WARD. This system has originally been developed for cancer or COPD patients and has now been adapted to detect alarming signs if a Covid-disease progression is getting worse (Langemark, 2021).

In addition to the described tracking and tracing possibilities, the government offers **support in tracing** and informing the contact chain of infectious people. Since all test results go to the same database, the Styrelsen for Patientsikkerhed (Danish Patient Safety Authority) gets informed about infected people. The authority then offers help to find out telephone numbers and calls close contacts of the patient if wished so (Styrelsen for Patientsikkerhed, 2021a).

#### **Health Data Reporting**

The Danish Government has aimed to keep its citizens updated about the Covid-19 developments in the country. Through the common infrastructure, the data can be accessed and taken from the national registries. In addition, additional reporting functionality has been integrated into existing platforms.

The Statens Serum Institut (SSI) releases infection and vaccination numbers every day at 2pm in two interactive **dashboards**: The Covid-19 dashboard¹ and the vaccination dashboard². These dashboards show all relevant data with several break-down levels. For non-Danish speakers, the information is summarized and published in English (Danish Health Authority, 2021). For transparency reason, the SSI informs about changes in the testing strategy to give additional information on the numbers (Statens Serum Institut, 2021c).

 $<sup>\</sup>label{lem:covid-19} \ensuremath{^{1}} Covid-19 \ dashboard: \ https://web.archive.org/web/20210619004331/https://covid19.ssi.dk/overvagningsdata/daglige-covid-19-tal-lem:cov$ 

<sup>&</sup>lt;sup>2</sup> Covid-19 vaccination dashboard: https://web.archive.org/web/20210617044501/https://covid19.ssi.dk/overvagningsdata/vaccinationstilslutning

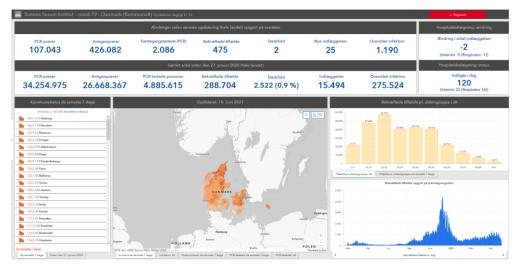


Figure A 4. Covid-19 Dashboard from the 11th of June 2021 (Statens Serum Institut, 2021e)

The patient portal sundhed.dk has also been used for publishing relevant information regarding the pandemic for the citizens besides linking to other systems, such as the booking of PCR tests on coronaprover.dk, accessing test results or a link to the vaccination platform vacciner.dk.

In addition, the website 'coronasmitte.dk' has been set up by Danish authorities to inform citizens about everything they might want to know about Covid-19, such as the current situation and news, the latest rules, regulations and announcements or links to relevant Danish authorities (Coronasmitte.dk, 2021). Furthermore, the pandemic has led to an increased usage of the already existing epidemiological information sources, such as the labresult database (Bitkom Events, 2020).

#### Teleconsultation

Although the Danish health system is very digitalized and telemedicine is included in the national and regional e-health strategies, **teleconsultation** (especially video consultation) has not played a major role in the daily treatments before the Covid-19 pandemic. Among the measures to contain the spread of the virus that have been presented by the national government in March 2020 has been the initiative to restrict hospital visits and physical consultations. Official authorities have encouraged the population to make use of more virtual consultations and a shift from physical to virtual consultations could be observed (Sundhedsstyrelsen, 2021).

The Danish Health Authority, which monitors the activities in the Healthcare sector, has tried to record and report the **numbers of different consultation methods** during the past year (Sundhedsstyrelsen, 2021). The published numbers are subject to changes, but they show some tendencies. With the start of the pandemic, physical consultations in general practices have decreased remarkably, accompanied by an increase in virtual consultation (e-mail, telephone, video). Especially video consultations have increased to more than 16.000 a day at the beginning of April 2020, steadily decreasing until summer and by the end of the year 2020 levelling off at about 4.000 video consultations per day (Sundhedsstyrelsen, 2021). According to a different governmental source, from March to October 2020, around 340.000 video consultations have been conducted in Denmark before decreasing to an almost pre-Covid level again (Bitkom Events, 2020).

Generally, the individual doctor can choose whether to introduce video consultation or not and also which technical option to use, including private provider solutions such as Hejdoktor, Skype or Zoom (Jessen, 2020). By the end of March, Trikfork and the Danish Organisation of General Practitioners (PLO) have worked to include **video consultation** as an additional function in the official MinLaege application for visits between general practitioners and patients (Trifork, 2020d). The chairman of PLO has encouraged the citizens to download the application and make use of the benefits especially during the pandemic (Trifork, 2020b; Woźniak, 2021). Within the first week, around 3.000 patients made use of the virtual consultations and general practitioners have reported that 50% of their visits have been shifted to virtual ones (Healthcare Denmark, 2021a). The number of video consultations increased to more than 30.000 per month (Health Europa, 2021) and in April 2020, MinLaege has been the most downloaded application

in Denmark (Trifork, 2020c). At the beginning of 2021, there have already been more than 1 million downloads of the app (Trifork, 2021a).

For citizens who do not have or do not want to use NemID, the app KontaktLaegen has been developed by the municipality of Copenhagen and the PLO as a **video consultation alternative** to MinLaege (Trifork, 2020a). In March 2021, already 30 municipalities had integrated this application and the number is constantly increasing (Trifork, 2021a). For other healthcare providers than general practitioners (e.g., physiotherapists), sundhed.dk has offered an alternative system for video consultation via the portal or the MinSundhed application, which are both accessible via NemID (sundhed.dk, 2020).

Some medical institutions have tried to follow the calls of the authorities actively as well and adapted their clinical practice by shifting as many visits from physical attendance to online consultations. For example, the Steno Diabetes Centre Copenhagen (SDCC), a public hospital in the Capital Region that treats patients with diabetes, has reduced face-to-face consultation from 350 to 10-15 per day (Nørgaard, 2020).

#### **Vaccination Mobilization**

According to a communication by the Danish Health Authority, the initial plan was that all Danish citizens will have been vaccinated by the end of June 2021 (Reuters, 2021). However, due to supply shortages of vaccine doses, the end of the **vaccination program** had to be postponed several times (target from June 1st: September 12th) (The Local, 2021e). The Statens Serum Institut publishes the vaccination numbers in an interactive dashboard on a daily basis, broken down into regions, first vs. second vaccination, age, gender, etc..(Statens Serum Institut, 2021b).

The government has centralized the whole **vaccination process** and collaborates closely with the regions, the municipalities, and all other involved stakeholders. The Statens Serum Institut provides a step-by-step guide to the vaccination and answers all relevant guestions on their website.

Like most countries, Denmark has defined different priority groups to receive the vaccination. The national systems enable the public authorities to sort and address the citizens by priority groups (O'Leary, 2021). As soon as a citizen belongs to the current priority group, she or he will receive a notification (via Digital Post at borger.dk and e-boks.dk or via letter in the mail) by the region or by the employer. Only with this vaccination offer in the mailbox, the citizen can make an appointment on the **central website** vacciner.dk which uses NemID for authentication and shows the available time slots (SynLab, 2021). These time slots are updated as soon as new vaccination doses arrive in the region.

In addition to this official vaccination process, the government has decided to offer the Covid-19 vaccines from AstraZeneca and Johnson&Johnson, which are not part of the national vaccination programme, to citizens on a voluntary basis (Barrett, 2021). The private company Practico has signed an agreement with the authorities and is now the official partner to distribute and administrate these **additional vaccines**.

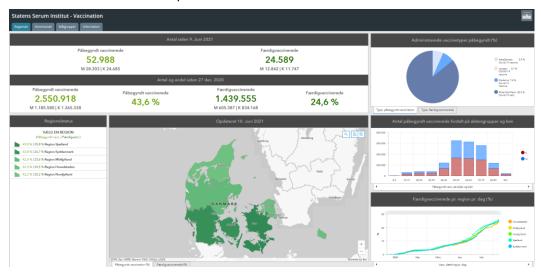


Figure A 5. Covid-19 Vaccination Dashboard from the 11th of June 2021 (Statens Serum Institut, 2021a)

Due to decreasing infection numbers in Spring 2021, Denmark has been working on a reopening strategy after being in a lockdown for three months. To gradually pave the way back to normal, the government

decided to implement a **Corona passport** which certifies "that the holder has had a negative test in the last 72 hours, a vaccination or has recently recovered from Covid-19, conferring immunity to the disease" (The Local, 2021b). Owners of a valid passport are granted more rights in different areas of the daily life. The government argued that the Corona passport is especially important for business activities: Since an important part of the Danish economy is related to trade, the government considers it as fundamental to let business people meet and go back to business as soon as possible (dos Santos et al., 2021). This system is then further extended to other sectors like hospitality and the entertainment industry and will be used until everyone in the country has been offered a vaccination. While Denmark was among the first countries to fully embrace and implement the idea of a Corona passport in Europe (Euronews, 2021), the idea was also discussed controversially in Denmark and even some petitions against it were in place (dos Santos et al., 2021). While some people feared a two-tier society resulting from a corona passport, others criticized the additional effort to control the passports.

Since re-opening of the Danish society started in April 2021 (e.g. hairdressers on April 6th, outdoor service of food and drinks on April 21st, etc.), there have been **alternative options** to obtain a Corona passport after vaccination or negative testing. Citizens could either access sundhed.dk, the application MinSundhed or MinLaege via NemID and receive a certification from the system, which they can save digitally or print. People without NemID can get the vaccination certificate via ordinary e-mail or order a printed version (coronasmitte.dk, 2021; sundhed.dk, 2021a; The Local, 2021c) and see their Covid-19 test results on the website Covidresults.dk (SSI, 2021).

At the end of March, the Danish government called for bids to build a new standalone **vaccination passport** application as a standalone mobile app. The work was divided into two parts and two Danish companies worked together on the development: Netcompany developed the app itself and Trifork updated the health system's infrastructure to ensure an easy transfer with and integration into other systems such as sundhed.dk. The goal that Danish citizens could download and use the application by May (The Local, 2021a) has been achieved on time, however, the previous options, such as MinSundhed, can still be used. The Coronapas application shows others (via a QR code with a green banner) only whether the passport is valid, but not the reason for the validity (The Local, 2021d). Since it is compatible with European standards, it can also be used for traveling within the EU. The government and the parties plan to make a decision about the proceeding and phasing out of the Corona passport in August (coronasmitte.dk, 2021).

#### Cognitive Map for Denmark

The cognitive map for Denmark (Figure A 6) illustrates the individual events per digital response, shows the influence of the sectoral characteristics on the events, and includes the facilitators and the predominant digital infrastructure evolution mechanisms.

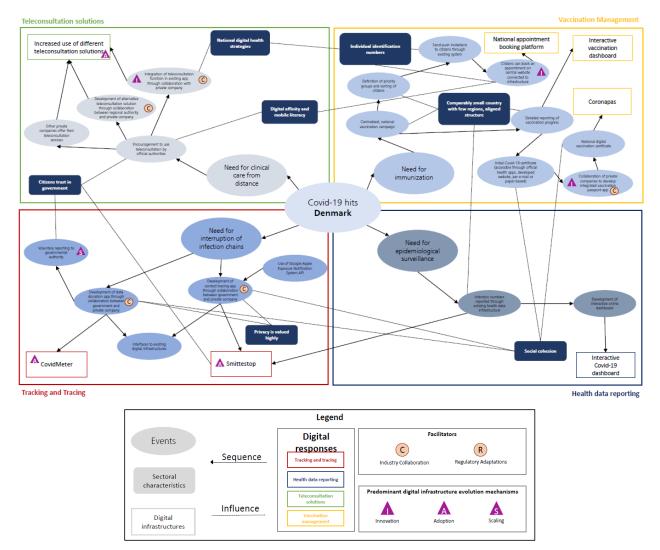


Figure A 6. Cognitive Map for Denmark

## Appendix C: Case Narrative of Germany

Table A 3. Germany

Germany		
Health system characteristics	Structure and funding	Principle of self-governance and social security with shared decision making in a federal system and Bismarck funding model.
	Policy framework	Generally regarded as a late mover in digital health, recent advances after long time of stagnation, e.g. 2019 Digital Healthcare Act and 2020 Patient Data Protection Act.
	Socio-cultural values	High attention regarding data privacy risks, individualism is held in high regard and uncertainty is avoided, digital affinity and mobile literacy are on the rise but still less pronounced among the elderly.
	Information technologies	Fragmented and incomplete digital health infrastructure, despite some tech readiness
Digital responses	Tracking and tracing	Development and release of a nationally endorsed privacy-preserving contact tracing app after considerable controversy, further voluntary apps, e.g., for data donation and symptom tracking.
	Health data reporting	Still highly paper-based (e.g., fax machine) with media disruptions and low data interoperability, since 2021 Germany is a member country of SNOMED International which enables semantic interoperability in electronic data exchange
	Teleconsultation	Unprecedented push for teleconsultations due to Covid-19 while regulatory prerequisites had been established previously (decision by the German Congress of Physicians in 2018).
	Vaccination mobilization	Digital support for vaccination differing within federal states, various service providers offering solutions. Paper-based vaccination certificate susceptible to forgery, digital vaccination certificate introduced in June 2021 which can be used within Europe.

## **Health System Characteristics**

#### **Structure and Funding**

The German health system is based on the **principles** of self-governance, compulsory insurance, funding through insurance premiums and solidarity (Bundesministerium für Gesundheit, 2020b) and mainly focuses on social security. The principle of self-governance implies that although the state provides the legal framework and tasks, the policy holders and the service providers organise themselves in associations that take responsibility for providing medical care to the population (Bundesministerium für Gesundheit, 2020b).

As a federal state, political **decision-making** regarding health is comparably decentralized, so there is a shared decision-making process. Health is principally a state (not federal) responsibility. The different healthcare actors that are part of this decision process can be divided into three different levels: (1) Establishment of the legal framework by state/government guidelines: Federal, state and local authorities in line with Germany's federal structure e.g. the Federal Ministry of Health; (2) Organisation of health care by the self-government with its bodies and associations, e.g. The Federal Joint Committee or The National Associations of Statutory Health Insurance Physicians and Dentists; (3) Provision of actual healthcare by health insurance funds, the medical profession, a wide variety of health care professions, hospitals and pharmacies, each of which has its interests represented by associations, e.g. Federal Association of German Pharmacists (Bundesministerium für Gesundheit, 2020b).

In Germany, there is an obligation for all citizens to enter either into the statutory or substitutive private **health insurance** if they have their place of residence or habitual abode in Germany (Bundesministerium für Gesundheit, 2020b). Germany has a universal, multi-payer health system with 87,7% of the population being covered by statutory health insurance (SHI) and 10,5% covered by substitutive private health insurance (PHI) (Verband der Ersatzkassen, 2019). The health insurance market is highly fragmented though there was a market consolidation within the last 50 years (e.g. 1815 SHIs in 1970 versus 103 SHIs in 2021) (GKV-Spitzenverband, 2021). Funding is equally shared by employers and employees (SHI: 14.6% gross wage, PHI: risk-based), often referred to as the Bismarck model. All those with statutory

health insurance jointly bear the costs arising from illnesses of the individual members (solidarity principle). There is an equal right to medical care for everyone covered by statutory health insurance, regardless of the paid insurance premium or income (Bundesministerium für Gesundheit, 2020b).

**Health care providers** are legally and economically independent. Hospitals are public (48%), private not-for-profit (32,9%), or private for-profit (19,1%) (Verband der Ersatzkassen, 2021). While the federal state and the states set the regulatory boundaries and supervision, providers and insurers representatives independently negotiate the coverage and reimbursement of treatments via the Federal Joint Committee (hence, self-governance).

Within the German healthcare system, the roles of existing actors can change over time. Recently, especially the Robert Koch-Institut (RKI) and Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) which are both involved in the establishment of the legal framework within the shared decision-making process (level 1) took on new responsibilities. The RKI is generally responsible for the detection, prevention and control of diseases, especially infectious diseases as well as to develop scientific findings as a basis for health policy decisions (Bundesministerium für Gesundheit, 2020b). Particularly in the context of digital health, the Federal Institute for Drugs and Medical Devices (BfArM) is very important, as it is responsible for the certification of medical devices (including software/apps) by assigning different risk classes, etc. (Zenner & Božić, 2019). The BfArM also provides a central directory for certified digital health apps (https://diga.bfarm.de/de) that are reimbursable by the health insurance.

## **Policy Framework**

In general, Germany can be regarded as a **late mover in digital health** among European and other industrialized nations. In 2018, the Bertelsmann study (Bertelsmann Stiftung, 2018a) evaluated policy activity, digital health readiness and actual data use of 14 EU and three OECD countries, in which Germany ranks third last. Within the last two decades, many laws related to the digitalization of the healthcare system have been drafted and passed. But so far, only some of these legal measures have been implemented at a national level or adopted by a majority of the population. Only recently there have been major advances in digital health policy, after a long time of stagnation. In this context, in particular the following legal initiatives appear worth mentioning:

- Act on the Modernisation of Statutory Health Insurance (Gesetz zur Modernisierung der gesetzlichen Krankenversicherung), 2004
- Secure Digital Communications and Applications in Health Care Act (Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen (E-Health-Gesetz)), 2016
- Relaxing of the Prohibition of Remote Treatment (Öffnung des Fernbehandlungsverbots), 2018
- Appointment Service and Care Act (Terminservice- und Versorgungsgesetz), 2019
- Digital Healthcare Act (Digitale-Versorgung Gesetz), 2019
- Patient Data Protection Act (Patientendaten-Schutz-Gesetz), 2020
- Hospital Future Act (Krankenhauszukunftsgesetz), 2020

The **Act on the Modernisation of Statutory Health Insurance** passed in 2004 forms the legal basis for the attempt to reform the German health care system from a cost perspective. It supplements the fifth book of the Social Code (SGB V) with paragraph 291, that provides the introduction of a telematics infrastructure (TI) as well as its operating company Gematik and the introduction of the Electronic health card (Digitales Gesundheitswesen, 2020a).

The **electronic health card** was originally decided by law to be in place by 2006. The actual implementation of the electronic health card was carried out in stages from October 1, 2011. Since January 1, 2015, only the electronic health card is valid as proof of entitlement to medical services for people with statutory health insurance. So far, it mainly stores the patient master data (e.g. name, address, birth date, etc.) and is connected to the telematics infrastructure (Bales, 2005; Bundesministerium für Gesundheit, 2020c).

The **telematics infrastructure** represents a vastly delayed and controversially disputed information technology mega project in healthcare that implements a country-wide network to connect healthcare providers, along with the electronic health card to enable patient identification and add-on functionalities. It has been labelled as a "digital data highway" (Bundesministerium für Gesundheit, 2020e) that securely

connects practices and hospitals to enable fast communication as well as provide patients health data for practitioners in a secure and timely manner. The society for telematics (Gesellschaft für Telematikdienste mbH) is responsible for the introduction of the telematics infrastructure and it was funded as the operating company of the telematics infrastructure in 2005 (original shareholders are: German Medical Association (BÄK), the German Dental Association (BZÄK), the German Pharmacists' Association (DAV), the German Hospital Federation (DKG), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the National Association of Statutory Health Insurance Physicians (KBV) and the National Association of Statutory Health Insurance Dentists (KZBV)).

A central part of the telematics infrastructure is the "Connector" which connects the information technology systems of the service providers with the telematics infrastructure. In November 2017, the Gematik certified the first connector and the first card terminal for connection to the telematics infrastructure. The project got delayed through multiple factors including ineffective governance through equal ownership of insurers and provider representations (represent own interests without focusing on the common goal), resistance from the medical profession due to concerns regarding increased transparency and the failure to meet communicated deadlines (AerzteZeitung, 2017). In March 2019, the Federal Ministry of health took over 51% of the Gematik as a response to the blockades in the governance. The decision has been criticized by both insurance representatives and physician representatives, as mentioned in a press release of the National Association of Statutory Health Insurance Funds: "Here, competences, responsibilities and financing are mixed up between state institutions and the joint self-government, which leads to intransparency and unclear responsibilities. We reject this." (GKV-Spitzenverband, 2019).

The overall aim of the 2016 Secure Digital Communications and Applications in Health Care Act (short E Health Law) has been to use the opportunities of digitalization for health care and to enable the rapid introduction of medical applications for patients. The main focus areas of the E-Health law have been: (1) usage incentives for medical applications, (2) to open up the telematics infrastructure and perspectively develop it as the secure infrastructure of the German healthcare system, (3) the creation of an interoperability directory to improve communication, and (4) the promotion of telemedical services, e.g. online video consultation. The self-regulating organisations of Germany's healthcare system have been given guidelines and deadlines, which in some cases would also lead to sanctions in the event of noncompliance (Bundesministerium für Gesundheit, 2020d). The E-health law specifies functions related to the electronic health card, such as an electronic medication plan, but it does not include the electronic prescription (Digitales Gesundheitswesen, 2020a). In summary, the E-Heath law can be regarded as a code of good intentions, while it provided little implementation support and activities.

In 2018, the 121st German congress of physicians passed a **relaxation of the prohibition of remote treatment** by deciding that physicians in Germany are from then onwards allowed to treat patients exclusively via telephone, video-conference, text message, e-mail or online chat provided that that they ensure due medical care and educate patients about online treatment. Specifically, physicians need to ensure medical care in diagnostics, counselling, therapy and documentation and inform their patients about online treatment (Zeit Online, 2018). In individual cases physicians can also provide advice or treatment exclusively via (online) communication tools to patients they do not yet know, but only if it is "medically justifiable and the necessary medical care" is observed. There are also a few restrictions, e.g. sick leave by telephone or video conference for unknown patients was rejected (Höhl, 2018).

The 2019 **Appointment Service and Care Act** (Terminservice- und Versorgungsgesetz, TSVG) is primarily targeted at patients getting physician's appointments faster so the health insurance services and healthcare provision are improved. The major thrust for this law has been a persistent complaint regarding the lower priority of patients with statutory health insurance, as opposed to privately insured patients, at many physician and specialist practices. In addition, the TSVG law was used to formulate an obligation of health insurance funds to offer electronic patient files (elektronische Patientenakte, ePA), i.e. a secure space for sharing mostly unstructured treatment-related documents with healthcare provides, to their insured members by January 2021 at the latest. By May 2021, the implementation of ePA has been in local pilot stages with limited functionality (verbraucherzentrale.de, 2021). From 2021, the TSVG law also specifies that certificates of incapacity for work (Arbeitsunfähigkeitsbescheinigung) are to be transmitted digitally only by the treating physician to the health insurance funds (Bundesministerium für Gesundheit, 2019).

The **Digital Healthcare Act** (Digitale-Versorgung-Gesetz, DVG) passed in 2019 offers the opportunity for large-scale reimbursement of and access to evidence-based digital health apps and is in effect since

December 19, 2019 (Gerke et al., 2020). The costs for digital health apps will be reimbursed for a trial period of one year by insurers. Within this period, the app providers have to prove the clinical effectiveness of their apps (to the Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) and may afterwards negotiate reimbursement prices with the SHIs. This procedure resembles the approval for new drugs. Additionally, the DVG law demands a mandatory digital network for the health sector including an obligation for pharmacies (by the end of September 2020) and hospitals (by January 1, 2021) to be connected to the telematics infrastructure. Midwives and physiotherapists as well as nursing and rehabilitation facilities can voluntarily connect to the telematics infrastructure. The costs for the voluntary connection are reimbursed. Physicians who still do not want to connect will have to accept an increase in fee deduction of 2.5% from March 1, 2020 (previously it was 1%). Next to this, physicians are allowed to provide information about tele- and video consultation on their websites in the future. The patient education that is required before tele and video consultations can now also be provided online, e.g. during the video consultation itself, and no longer has to be in advance, as it was previously the case (Bundesministerium für Gesundheit, 2020a).

The **Patient Data Protection Act** (Patientendaten-Schutz-Gesetz) is in effect since July 3, 2020 and it specifies the use of digital service offers in health care by patients, such as the electronic patient file and the electronic prescription. At the same time, it contains detailed legal requirements for the protection of patient data and liability issues (Digitales Gesundheitswesen, 2020a). With a new and secure app, insured persons shall be able to redeem electronic prescriptions at a pharmacy of their choice in the future. Specialist referrals shall be transmitted digitally and patients shall have the right to have their physician fill their electronic patient file (the ePA, see above). From 2022, the vaccination card, the maternity passport, the yellow medical check-up booklet for children, and the dental bonus booklet shall also be stored in this file and insured persons will be able to have their data transferred from the electronic patient file when they change health insurers. Additionally, also from 2022, insured persons shall be able to determine who can access each document stored in the electronic patient file individually via their smartphone/tablet and from 2023, insured persons shall even have the option of voluntarily donating the data stored in their electronic patient file for research purposes (Bundesministerium für Gesundheit, 2020g).

The **Hospital Future Act** (Krankenhauszukunftsgesetz) is in effect since October 29, 2020 and determines that the federal government will provide 3 billion Euro to enable hospitals to invest in modern emergency capacities, digitalization and their information technology security, e.g., through patient portals, electronic documentation of care and treatment services, digital medication management as well as cross-sector telemedical network structures (Bundesministerium für Gesundheit, 2020f).

Since March 15, 2020, **SNOMED CT** (Systemized Nomenclature of Medicine - Clinical Terms) can be used for the first time nationwide as part of the Medical Informatics Initiative funded by the Federal Ministry of Education and Research. With the help of SNOMED CT, clinical data from different contexts and different countries can be compared and used for research. There is great potential in the networking of routine healthcare data and cutting-edge medical research. On the one hand for better medical treatment, but on the other hand also for strengthening Germany as a business and science location (Klinik Management aktuell, 2020).

Following the mandate from the Appointment Service and Care Act the concept of **Medical Information Objects** (MIO) is introduced by the National Association of Statutory Health Insurance Physicians. MIOs define the semantic and syntactic interoperability for contents of the electronic patient record in cooperation with other institutions and organisations. The aim for MIO is to be readable and processable for every system in the sense of interoperability. Information should thus be exchanged much more easily between the individual actors in the health care system. In 2020, the National Association of Statutory Health Insurance Physicians has defined four medical information objects as planned which includes amongst others the vaccination record (Kassenärztliche Bundesvereinigung, 2020).

#### Socio-Cultural Values

**German culture** and people respect order and structure. In this context, the majority of Germans (61%) rather trust in the government (Statista, 2020). In general, Germans avoid uncertainty (cf. value 65 (Hofstede, 2001; Hofstede Insights, 2021)) and set a focus on long term orientation (cf. value 83 (Hofstede, 2001; Hofstede Insights, 2021)).

People in Germany are very attentive to **privacy risks**, especially in connection with personal (health) data which are perceived as especially sensitive and illustrate that privacy concerns can also depend on

the respective context (Lutz et al., 2020; Schomakers et al., 2019). This is illustrated by 56% of Germans doubting that their personal information is sufficiently protected (inside and outside of the internet) and almost as many (55%) feel they have no control over their data on the internet. At the same time, almost all Germans (93%) agree that the protection of personal data is important and 64% think that not enough importance can be attached to this topic (Sinus Institut, 2017).

Germans value the **freedom** to shape their own lives **and individualism** is held in high regard (cf. value 67 (Hofstede, 2001; Hofstede Insights, 2021)). The German welfare state regards the protection of all citizens as a priority task and is characterized by a pluralism of lifestyles. Most people in Germany have a high standard of living, which is illustrated by the United Nations Human Development Index that places Germany 6th out of 189 countries (Tatsachen über Deutschland, 2018; United Nations Development Programme, 2020).

Legislative procedures in recent years ensure social openness and acceptance of, e.g., alternative lifestyles (Tatsachen über Deutschland, 2018). At the same time, the **demographic development** with a growing proportion of older people poses new challenges for the social security systems. The local population will be significantly older in the future than it is at the moment. Forecasts predict that by 2060, one in three people will be at least 65 years old (Bundeszentrale für politische Bildung, 2017).

Digital affinity and **mobile literacy** differ depending on a person's age. In general, a majority (87%) of Germans has a "positive attitude" towards digital technologies. Fewer and fewer people in Germany feel threatened by digitalization (25%) and even 73% see digitalization as an opportunity. However, older people are more sceptical towards digital technologies than younger people, but they are also learning to look forward to the benefits of a digitized world, e.g. 56% of Germans over 60 years found that digital technologies "make their lives easier". Nevertheless, there are still difficulties and obstacles which include a lack of technical understanding (41%) and incomprehensible information on data protection (53%) (Bär et al., 2020).

## **Information Technologies**

In general, there are **good preconditions** for technological infrastructures in Germany. This is illustrated by the networked readiness index which assesses amongst others the overall environment for technology use and creation, the networked readiness in terms of information and communication technology infrastructure and technology adoption/usage by the government, the private sector, and private individuals. In this index Germany ranks 15th out of 139 countries (Baller et al., 2016).

Nevertheless, especially in the healthcare context, the **lack of a national digital health infrastructure** has been an increasingly pressing issue in recent years. The development of provider-specific solutions creates a heterogeneous technological landscape in Germany as well as a fragmentation of the market that is characterized by proprietary data formats and silo solutions. This especially causes conflicts if communication or cooperation between different providers or services is necessary (Benedict & Schlieter, 2015).

The use of **electronic health records** (EHR) and comparable hospital information systems (Krankenhausinformationssysteme, KIS) in the German health care system is highly developed but the market is still highly fragmented. The approximately 2,000 hospitals in Germany are estimated to use EHR/KIS solutions of over 200 different software vendors (CDU, 2017) creating potential interoperability challenges when moving to a more integrated digital landscape. Still today, clinical and administrative patient information mostly remains within the boundaries of single healthcare provider organisations and are rarely shared with third parties.

**Data exchange** via the national telematics infrastructure is not widely used beyond pilot stages. It is often in the responsibility of patients to transport data on paper, compact discs and other media. In some areas, health data exchange takes place via separate networks centred around specific geographical networks (e.g., university clinics and surrounding providers) or institutional networks (e.g., certain insurers).



Figure A 7. Telematics Infrastructure (Digitales Gesundheitswesen, 2020b)

The **telematics infrastructure** has not yet been introduced into routine care (see Figure A 7 for implementation timeline). In theory, the connection of medical facilities to the telematics infrastructure has been running since 2017, but in practice it has only really taken off in 2018. It consists of different parts and offers various functionalities, of which only a few are implemented so far. As soon as the telematics infrastructure roll-out has been completed nationally, the patient can access the electronic patient file (ePA) when visiting a physician. There are high standards and requirements for security and data protection when processing patient data, but there is no mandatory use of international standards for medical informatics (Bertelsmann Stiftung, 2018b). Only for uniform billing with the insurer physicians have to document their data in electronic files using the uniform classification ICD-10 (Kassenärztliche Vereinigung Sachsen, 2018).

The **technological architecture** of the telematics infrastructure can be divided into different parts. One of the most important ones is the connector which enables a connection to the digital health network. It therefore connects the practice or hospital information technology systems via the outside world to the telematics infrastructure for which an internet connection is necessary. The connector can be seen as a type of router, but with a much higher level of security. It must be approved by the gematik and certified by the Federal Office for Information Security. A connector can only establish a connection to the telematics infrastructure if the respective practice, medical care centre or hospital identifies itself.

A second important part are the **card terminals** which are used to read e.g. the electronic health card or the electronic health professional card. Like the connector, these special card terminals must be approved by the gematik and certified by the Federal Office for Information Security. Next to this, there are also different cards that store different information. The *electronic health professional card* is a chip card for e.g. physicians, psychotherapists, dentists, etc. It replaces the previous paper-based identification cards and identifies the owner as a member of the respective professional medical group. The counterpart on the patient site is the **electronic health card**. All people with statutory health insurance are already equipped with it today. On the one hand, the electronic health card is a data memory that stores the patient's master data e.g. name, address, birth date, etc. However, by law it is also an access ticket with which the insured person can use digital applications relating to him/her and view his/her own data (gematik, 2017).

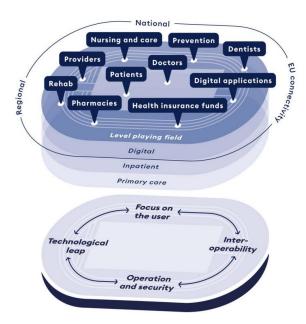


Figure A 8. Telematics Infrastructure 2.0 - Arena for Digital Health

While there were many delays in the rollout and implementation of the telematics infrastructure in the past, the gematik now advertises the telematics infrastructure 2.0 as an "arena for digital health" (see Figure A 8 (gematik, 2021)) for a federally networked healthcare system and to generate "stimulating momentum for the shared process of shaping digital health in die German healthcare system" (gematik, 2021).

**Secondary use** of patient data is mainly carried out by health insurance companies on billing documentation. In addition, these routine data are used for public health monitoring or for health care research. This happens rather sporadically, often with a time delay and not yet in a systematic manner (Bertelsmann Stiftung, 2018b). The digitization of processes e.g. in hospitals has partly started but is not yet completed. There are often media disruptions e.g. laboratory/test results are already available digitally, but are then printed out to be added to the paper form of the patient file, thus creating a hybrid form. For this reason, the healthcare system often runs on two tracks (analogue and digital), making it very confusing for both patients and physicians (Mumm et al., 2021). There is no centralized portal or directory for patients to obtain information about health-related topics (Bertelsmann Stiftung, 2018b) nor an application or interface which aggregates all officially obtained personal health data per patient.

## **Digital Responses**

#### **Tracking and Tracing**

After the Covid-19 pandemic hit Germany in early 2020, different **tracking and tracing applications** with a special focus on privacy preservation have been discussed. After considerable controversy regarding data privacy, user surveillance and the app's technological architecture, a contact tracing app (Corona Warn App) was introduced. It was mainly developed by a joint venture of two large companies (SAP SE and Deutsche Telekom) and launched on June 16, 2020. The German contract tracing app uses a decentralized, **privacy preserving architecture**. Users do not have to enter any personal information or register to use the Corona Warn app. The main functionality is provided by the exchange of pseudonym codes. These are transferred via Bluetooth between nearby devices that installed the Corona Warn App and stored locally on the device for 14 days. There is no storage of the user's location data (BARMER, 2021). Based on the collected proximity data there is an individual risk calculation on the smartphone of the user. Like many contact tracing apps worldwide, the app's functionality is based on the application programming interfaces (API) for the mobile operating systems by Apple and Google. This creates a dependence on these companies. There is also a debate whether privacy protection runs counter to effective and efficient containment of the pandemic, which could be enabled by the implementation of a wider range of functionality and tracking of more data (E. Park, 2020).

Since the introduction of this app, there were several updates including **new functionalities** e.g. the automatic transmission of test results thanks to the establishment of a technical infrastructure for the laboratories, the exchange of data with other decentralized contact tracing apps in the EU, voluntary documentation and sharing of symptoms in case of a positive test result, the voluntary contact diary which allows users to document who they have met where and the dashboard with selected key figures on the incidence of infection in Germany (Robert Koch-Institut, 2021d). More recently, in spring 2021, an event registration functionality that allows users to check in via QR code at events, retail stores or even private meetings. Event check-ins are stored locally on the user's phone and deleted after 14 days (Heine, 2021).

Despite great hopes in the positive effect of contract tracing for containing the pandemic, the German contract tracing app has fallen behind expectations in parts due to the overall moderate adoption. A German political leader called it a "toothless tiger" (Merkur.de, 2020). As of April 2021, the app has been downloaded 27.6 million times on a voluntary basis, which represents about 33 percent of the German population (Robert Koch-Institut, 2021e). For the app to be effective, experts stated that "we can stop the epidemic if approximately 60% of the population use the app, and even with lower numbers of app users, we still estimate a reduction in the number of coronavirus cases and deaths." (University of Oxford, 2020).

In December 2020 the luca App (developed by neXenio GmbH - a spin-off of the Hasso Plattner Institute-, and a number of creative artists) was introduced to reduce the burden on health authorities for **infection chain and contact tracing** (luca-app.de, 2021). The luca app (which is described as a complete system) is connected to health authorities and can be used by for public (e.g. restaurants, museums, concerts) and private events. Therefore, it integrates all involved parties while applying highest data protection and data security standards e.g. by double encryption of contact data (luca-app.de, 2021). In contrast to the Corona Warn App, the luca app is connected to SORMAS (Surveillance Outbreak Response Management and Analysis System), an open-source eHealth tool which was adapted by the Helmholtz Centre for Infection Research to fit the needs of the public health service in Germany to enable effective contact person management during Covid-19 (sormas-oegd.de, 2021). Still, the luca app is only used by certain federal states (dpa, 2021).

The Corona data donation app (Corona-Datenspende-App) enables the voluntary donation of smartwatch and fitness tracker data. It was developed by the Robert Koch Institute (German federal agency for disease control) and the private e-health company "thryve" that offers an application programming interface for simple health data access. The app was launched on April 7, 2020. As of April 2021, 537.406 people voluntarily donated their data (April 6, 2021).

There is also a **symptom tracking app** (CovApp) which includes an online questionnaire regarding clinically significant symptoms and previous illnesses to provide decision support regarding a Covid-19 infection. It was developed by data4life (non-profit organisation funded by the Hasso Plattner Foundation), Charité University Hospital Berlin, Robert Koch-Institut, the Federal Ministry of Health and the Federal Centre for Health Education. The app was launched on March 18, 2020 and has approx. 22.000 users (October 19, 2020). The source code is openly available via MIT-license so an own version of the app can be created to support the fight against Covid-19.

## **Health Data Reporting**

Not only in the German health sector, **fax machines** are still prevailing to enable communication between different stakeholders in healthcare. In general, 63% of surveyed companies in Germany report to use fax frequently or very frequently for internal and external communication (Statista, 2018). For example, the Chief Clinician of a university hospital in Essen explains that "in fact, the fax machine is still of outstanding importance" (Matthes, 2020).

During the Covid-19 pandemic, existing **media disruptions** mainly caused by the prevalent use of analogue communication media became apparent in the context of health data reporting. The reporting of infection numbers and incidences from the local to the national (RKI) level were found be delayed by up to ten days and susceptible to data quality issues as for example "important parts of the reporting system were still analogue and, in the absence of interoperable interfaces and suitable software solutions, were based on faxes" (Augurzky et al., 2020, p. 64). In this context, the Director of one of Germany's largest research hospitals, noted in an interview with the news magazine "Der Spiegel" that there was "a blatant maladministration without public outcry as we all saw for 15 months on the 'Tagesschau' [German evening news] that the latest infection figures were always wrong because the authorities didn't fax on weekends" (quote translated, Müller & Schmergal, 2021).

Still before the 2020/21 pandemic the federal ministry of health and RKI launched the implementation of the **German Electronic Reporting and Information System for Infection Protection** (DEMIS) to ensure that laboratory results for communicable diseases are available to the RKI in a more timely manner. According to the Infection Protection Act, DEMIS shall eliminate the use of fax between laboratories and health department and improve the reporting system for infectious diseases (see Figure A 9).

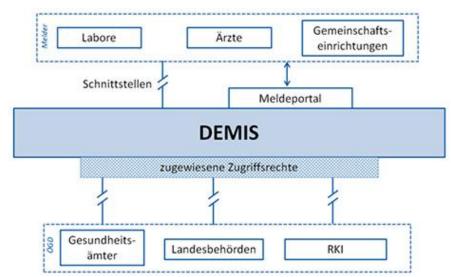


Figure A 9. Architecture of German Electronic Reporting and Information System for Infection Protection (Robert Koch-Institut, 2021b)

The gematik has been supporting the Robert Koch Institute (RKI) in the **implementation of the DEMIS project** since April 2020. In the first expansion stage of DEMIS since June 2020, laboratories have had the option to report Covid-19 infection numbers electronically to the responsible health authorities. By the end of 2020, the approximately 170 laboratories, 400 health departments, and the Robert Koch Institute should have been gradually linked to the new reporting system (gematik, 2020). As of April 2021, the status of the rollout is that 375 health departments are connected to DEMIS (Robert Koch-Institut, 2021b). The Covid-19 pandemic may have represented another push for the slightly delayed initiative around DEMIS and health data reporting.

A summary of the recent Covid-19 cases is provided online by the RKI. The **interactive online dashboard** aggregates current and historical infection numbers and incidence values in a centralized manner. There are different and adjustable panels that display Covid-19 related data in varying granularity depending on the selection of the user (Hovestadt et al., 2021). The evaluations that are presented are based on the reporting data that are transmitted from the health offices of all federal states (Robert Koch-Institut, 2021a).

#### **Teleconsultation**

While the regulatory prerequisites for teleconsultations had been established by the decision of the German Congress of Physicians in May 2018, the Covid-19 pandemic there led to an **unprecedented push of teleconsultation** in 2020. While in 2019 there were 3000 video consultations in total nationwide, only in the second quarter of 2020 1.2 million patients consulted a physician or psychotherapist via video (aerzteblatt, 2021). Currently, there are 44 certified teleconsultation providers (software vendors) on the German market.

The Corona crisis has led to a **quick action** and non-bureaucratic decisions in the area of teleconsultation. Previously, physicians or psychotherapists could only bill for video consultation services if they have previously notified their Association of Statutory Health Insurance Physicians (Kassenärztliche Vereinigung) that they use a certified video service provider. In some regions, this regulation has temporarily been suspended due to the demands caused by the pandemic (Kassenärztliche Bundesvereinigung, 2021). In addition, physicians could write patients with respiratory diseases sick for up to 14 days only after a phone call or video chat and without the need for a personal consultation (Schmidt, 2020).

Some Medical Associations of the Federal states made **further adjustments to enable teleconsultation** e.g. physicians in Baden-Wuerttemberg have been able to use remote treatment for new patients since June 1, 2020. Previously, the remote treatment of new patients was only possible within pilot projects. For existing patients, however, the possibility of remote treatment has always applied (Landesärztekammer Baden-Wuerttemberg, 2020). The statutory health insurance provider Techniker Krankenkasse was the first to provide teleconsultation at a greater scale starting April 28, 2020 with approximately 200 physicians of all specialties being available under a single phone number. In addition, persons insured at Techniker Krankenkasse can use teleconsultation services via the TK-Doc-App with resident physicians.

For an **electronic prescription** connection to pharmacies, the Techniker Krankenkasse cooperates with the pharmacy service provider Noventi (but so far only 3 pharmacies are signed up for the electronic prescription service, since the platform needs to contract individually with each pharmacy) (Pharmazeutische Zeitung, 2020). In general, and due to the Covid-19 pandemic, the medical profession experienced that teleconsultation can make a valuable contribution to healthcare provision, as summarized by the President of the Federal Medical Chamber "One of the most important findings from the past few months is certainly that video conferences can make a positive contribution to health care. This applies both to communication with the patient and between health care professionals." (Bundesaerztekammer, 2020).

#### **Vaccination Mobilization**

The approaches towards **vaccination mobilization** differed within the German federal states. In general, the European Commission centrally concluded the contracts with vaccine manufacturers that deliver the vaccine doses to central offices within the European member states. The further distribution of vaccine doses in Germany has been carried out according to the population share of the federal states and the Federal Ministry of Health coordinates this distribution to fixed locations. The federal states have been responsible for the safe storage and distribution of vaccines on site, therefore the vaccination mobilization highly differs (Bebermeier & Kummert, 2021).

The vaccination strategy is divided in two phases (see Figure A 10 (Robert-Koch-Institut et al., 2020): phase 1 (A & B) includes a targeted and centralized vaccination while phase 2 describes a broad and decentralized routine vaccination. In the beginning, the vaccinations have been mainly facilitated by vaccination centres and mobile vaccination teams with federal states being responsible for the organisation. As soon as sufficient quantities of vaccine with suitable storage conditions have been available, the vaccine distribution should be transferred to the regular supply system in a decentralized way (e.g., via pharmacies) (Robert-Koch-Institut et al., 2020). Since April 6, 2021 also general practitioners nationwide have been officially involved in the vaccination campaign in Germany and gradually also specialists are vaccinating against Covid-19 (Berliner Morgenpost, 2021). Since June 7, the prioritization for Covid-19 vaccination has been cancelled nationwide and company physicians are joining the vaccination campaign (bundesregierung.de, 2021).

STIKO, Leopoldina, Deutscher

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Figure A 10. Organisation and Implementation of Vaccination (Robert-Koch-Institut et al., 2020)

Deutscher Ethikrat

The digital support of the vaccination campaign in Germany is mainly facilitated by **appointment booking platforms**, even though there are various offers of integrated software solutions on the market (bitkom, 2021). There is no use of nationwide software solutions, but instead the respective tools are chosen locally. For example, the Berlin Senate Department decided to use Doctolib (which has also been used for regular online appointment booking before) as its official technology partner for the coordination of appointment scheduling and vaccination documentation (bitkom, 2021). Over 1 million vaccination appointments have been already booked in Berlin (April 7, 2021).

Next to the allocation of a time slot and a vaccination centre/physician to the respective patient, it is also important to ensure sufficient supply of vaccine doses. Even though there are various predictions in the context of vaccination delivery across manufacturers (Statista, 2021), the delay in vaccination doses supply caused the postponement of vaccination appointments (rbb24, 2021). This complication can be avoided by **integrated solutions** which also include supply chain management functionality. One example for this are vaccination management platforms, e.g. offered by the company Arvato Systems. These platforms integrate all parties involved in the vaccination process in a holistic approach (including appointments, supply chain management, central data storage, etc.) (bitkom, 2021). Information on adoption rates or implementation progress of integrated solutions within the federal states are not available.

On January 21, 2021, the European Council decided to launch an interoperable and standardized vaccination certificate via smartphone app, which is to be implemented and will be used on a voluntary basis. However, the official documentation of Covid-19 vaccinations in Germany are still paper-based and written in the citizen's vaccination card (the yellow paper booklet). This makes the vaccination certificate susceptible to forgery, especially if it becomes increasingly common to have to prove one's health status (e.g. vaccination doses given or negative Covid-19 test results) which is a prerequisite for accessing shops or going on holiday. According to research by a German television magazine (Report Mainz) there are fake German vaccination certificates which are being offered for sale e.g. via groups on the messenger service Telegram. The vaccination certificates are advertised with photos showing signatures, stickers with batch numbers and stamps, that identify the vaccination certificates coming from large German vaccination centres such as Bonn or Frankfurt (Report Mainz, 2021). Paul Maritz, who was responsible for product development at Microsoft and has developed a program for digital certificates (e.g. digital passports for vaccination and test results) states in an interview that "Trust plays a crucial role here. In the case of Germany, one could argue that many countries trust the authorities here. But paper documents can be easily forged. There are already reports of such cases." as well as that digital certificates are harder to forge than paper-based documents (Brause, 2020).

On June 10, 2021 the **digital vaccination certificate** was introduced and can be obtained by scanning a QR code, which is then imported in the CovPass App (project is commissioned by the German Federal Ministry of Health and was developed by companies such as IBM, govdigital, etc.) or the pre-existing Corona Warn App (ndr, 2021; Robert Koch-Institut, 2021c). As a large proportion of the population has been vaccinated before the introduction of the digital vaccination certificate, vaccination centres, medical practices and pharmacies issue the digital certificate on presentation of paper-based proof of vaccination and an identification card (ndr, 2021). The digital vaccination certificate (CovPass) is implementing the European certificate in Germany (which is already connected to the European gateway service) which means that the certificate can be used across borders e.g. to travel within Europe (Bundesministerium für Gesundheit, 2021).

There is a centralized and interactive vaccination dashboard provided by the Robert Koch-Institut and the Federal Ministry of Health that visualizes the progression of the vaccination campaign (27.8 million vaccine doses given (April 29, 2021)). Next to aggregated and detailed vaccination statistics, it also animates the daily and ongoing progress via a "vaccination clock" that tells you e.g. "So in the approx. 250 seconds you have spent on this website so far, 1519 people in Germany have – purely statistically – been given a vaccination dose." (Robert Koch-Institut & Bundesministerium für Gesundheit, 2021).

#### **Cognitive Map for Germany**

The cognitive map for Germany (Figure A 11) illustrates the individual events per digital response, shows the influence of the sectoral characteristics on the events, and includes the facilitators and the predominant digital infrastructure evolution mechanisms.

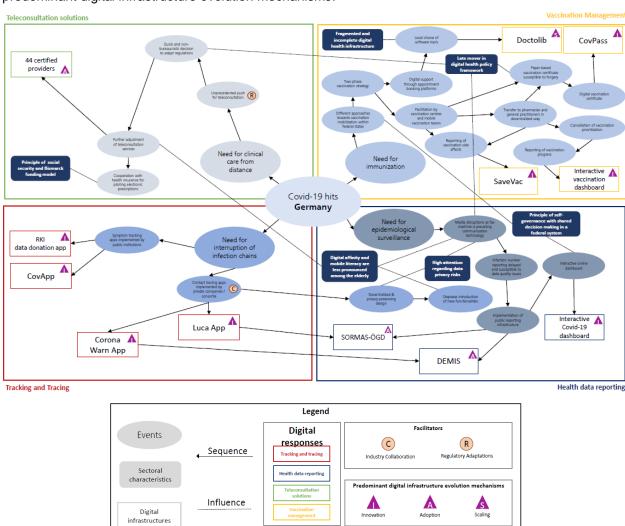


Figure A 11. Cognitive Map for Germany

## Appendix D: Case Narrative of South Korea

Table A 4. South Korea

South Korea		
Health system characteristics	Structure and funding	State-monopolized, single-payer system providing universal health insurance. The health insurance system has three funding sources: patient contributions, government subsidies, and tobacco tax.
	Policy framework	Increased flexibility in digital privacy laws since the MERS crisis in 2015.  Numerous digital health policy initiatives, while teleconsultation remained prohibited under the Medical Act.
	Socio-cultural values	Conformity and trust in the government's containment efforts due to Korea's collectivist culture which places the collective interests over individual privacy rights.
	Information technologies	More than 91% of hospitals and clinics adopted EHR/EMR systems by 2017. The lack of interoperability has led to a national project that aims at building a common data model.
Digital responses	Tracking and tracing	Rapid development of the "Smart city data hub platform" that gathers data of confirmed Covid-19 cases for real-time analysis, in collaboration with 27 public and private, 3 mobile carriers, and 22 credit card companies.
	Health data reporting	Medical doctors and institutions reporting into the web-based "Integrated Disease and Health Management System" without delay as soon as infectious diseases are confirmed. The collected data is published by the local authorities via the website.
	Teleconsultation	Temporary permission of teleconsultation since February 2020; several emerging teleconsultation platforms (e.g., Medihere).
	Vaccination mobilization	Centralized vaccination appointment booking through KDCA website or phone. Vaccination certificate can be downloaded from COOV, a mobile app managed by the KDCA.

#### **Health System Characteristics**

## **Structure and Funding**

South Korea has a state-monopolized national healthcare system that provides universal care (Song, 2009). The national health system consists of the players below.

- The Ministry of Health and Welfare (MOHW) supervises the operation of the entire healthcare system and insurance program and makes policy decisions.
- The Korea Disease Control and Prevention Agency (KDCA) is responsible for quarantine, testing, research, and organ transplant management for infectious diseases, chronic diseases and rare incurable diseases.
- The National Health Insurance Corporation (NHIC) manages the enrolment of insured individuals and their medical fee schedules.
- The Health Insurance Review and Assessment Agency (HIRA) evaluates whether medical institutions provide proper healthcare services and reviews medical fees.

The national health insurance puts a high financial burden on individuals due to high co-payments, up to 50% of costs (Jung, 2016), which has led to the necessity and increase of private health insurance. Private health insurance in Korea is both complementary and supplementary. The increasing elderly population and decreasing birth rate are two **socio-demographic trends** that will bring significant strain on funding: Aging is changing the country's disease profile and costly-to-treat diseases such as cancer and diabetes are increasing rapidly. Due to the increase in medical expenses for the elderly, the deficit in the national health insurance system is expected to grow and the burden of healthcare is increasing year by year.

The Korean government has considered **digital healthcare** as an effective part of the solution to the increasing cost and coverage issues. Policy makers believe that digital health can improve preventive and monitoring-based healthcare, which in turn can reduce medical expenses

## **Policy Framework**

As a consequence of the 2015 MERS<sup>3</sup> virus outbreak, which was reported to have caused the death of at least 39 South Koreans, lawmakers loosened **digital privacy laws** (S. Lee et al., 2020). Under the revised Personal Information Protection Act, authorities have since been allowed to access personal data in similar outbreaks without needing court approval. They can track infected persons using cell phone data, credit card information and surveillance cameras (Kuhn, 2020).

South Korea's **Medical Service Act (MSA)** does not allow physicians to treat patients remotely via videoconferencing or other forms of telecommunication. The MSA forces patients to see doctors in person and excludes a market for mobile health and telehealth services. In 2014, the government's attempt to legalize telemedicine was met with strong opposition from medical professionals and activists. Tensions surrounding the legalization of telemedicine led to a walkout by physicians. Large private hospitals generally support the introduction of more technological innovations in healthcare. However, the much more numerous smaller hospitals are afraid that technology could reduce the need for their services.

M. S. Kim (2016) shows that 65.2% of the surveyed doctors believed that telemedicine would lead to the collapse of primary care clinics and 29.9% argued that it would **harm** patients through misdiagnosis. Only about 1% stated that telemedicine would lead to the development of the medical industry and the improvement of primary care clinics (M. S. Kim, 2016).

#### Socio-Cultural Values

Strongly influenced by Confucian ideologies, South Korea is considered a collectivistic society. **Collectivist** culture fosters strong relationships among fellow members of the group. People value the collective interests over individual privacy rights. Therefore, ensuring the interest of the group can sometimes even require self-sacrifice or giving up personal freedom. Social mechanisms based on collectivism encourage compliance with governmental actions, from Covid-19 testing to social distancing. This culture is one of the reasons why Korea was able to efficiently curb the spread of the coronavirus (Sonn, 2020). Korea's response to tackling the unprecedented pandemic has been swift and efficient.

The Korean population has a **high mobile literacy** and willingness to adopt technological solutions. South Korea is generally known as a leader in information and communication technology (Mills, 2021). This has to do both with the strong presence of companies such as Samsung, LG, SK, and KT, and the mindset. Young Koreans generally score high in OECD surveys of digital literacy (The Korea Herald, 2011), while – as in many other countries – the elderly have been discussed as being digitally divided (Jun, 2020).

## **Information Technologies**

South Korea is one of the world's most tech-obsessed nations. The Korean infrastructure facilitates the development and implementation of next-generation health products and services with **high spending** per capita, particularly on ICT. A large proportion of the Korean population has mobile (115%) or Internet (84%) subscriptions, and desktops, notebooks and tablets are widely used (International Trade Administration, 2021).

In terms of the proliferation of **electronic health record (EHR)** systems, the HIRA indicated that 93.6% of hospitals and 91.6% of clinics adopted EHR systems by 2017 (Y. G. Kim et al., 2017; Y.-T. Park & Han, 2017). This wide EHR coverage is related to Korea's near-universal digitization of patient data, digital storage of clinical images, and electronic databases for hospital administration. However, there is a lack of functionality and interoperability. Most of the health information systems in hospitals have stand-alone EMRs for the treatment of their own patients (Y. G. Kim et al., 2017).

Due to persistent challenges regarding **EHR standardization** (Economist Intelligence Unit, 2011), a national effort is being made to improve and standardize EMR interoperability and build a common health data infrastructure. In 2018, the Korean government announced a three-year project called FEEDER-NET, the Federated E-Health Big Data for Evidence Renovation Network (FEEDER-NET, 2018). The Ministry of Trade Industry and Energy (MOTIE) allocated \$10.2 million USD to convert participating hospitals' EMRs into a common data model and develop a cloud-based open research platform. In December 2018, 41 hospitals had joined the initiative. This system is supposed to be launched in 2022 (Intralink, 2019).

<sup>&</sup>lt;sup>3</sup> MERS stands for Middle East respiratory syndrome, a species of coronavirus which infects humans, bats, and camels.

Nevertheless, South Korea's digital health industry has recently **lacked innovation drivers**. Due to restrictive regulations that only allow face-to-face medical diagnosis, most companies and start-ups have focused on developing self-management healthcare services rather than healing services including online consultation.

## **Digital Responses**

## **Tracking and Tracing**

The Korean government rapidly built the "smart city data hub platform", a new **virus tracker system** that allowed data of confirmed Covid-19 patients to be gathered and analysed within 10 minutes. Under KDCA's lead, 27 public and private, 3 mobile carriers, and 22 credit card companies have joined forces to expedite contact tracing. The new system has helped speed up the contact tracing process and stem the spread of Covid-19. It enables real-time analysis of big data in various areas from transportation and energy, to environment and safety (WeGO, 2021). The platform aggregates data from cell phones, GPS, and bank records, along with surveillance cameras. It allows the government to track the path of individual Covid-19 infections and to inform and isolate those who have been exposed (Gallo, 2020). The GPS locations of anonymized people confirmed to have Covid-19 are shared via SMS and mobile apps so that others can avoid those areas (Ladner, 2020; Nature, 2020). There are many mobile apps for reporting the locations where confirmed Covid-19 people have been, developed by individuals and private organisations. As one of the most popular mobile apps, "Corona 100m" collects data from the government database (e.g., KDCA) to show the date a patient was diagnosed with Covid-19, along with the person's nationality, age, gender, and travel history.

## **Health Data Reporting**

The KDCA serves as the command centre for prevention and control efforts. It requires physicians and institutions to report to the web-based "Integrated Disease and Health Management System", which has been in place since at least 2007 (ADB, 2021). This system allows real-time data analysis and links the KDCA to the local governments. It receives real-time data from a network of 101 private and 36 public diagnostic testing agencies and forwards it to the relevant agencies, which can then take timely public health action. To improve the response to any disease outbreak and to test the system's functionality, regular training and exercises are conducted. The data collected through the system are categorized by time and region and are published by local authorities or in a more aggregated form by the MOHW (MOHW, 2021).

#### Teleconsultation

With the rise of the Covid-19 pandemic, the Korean government has issued laws in February 2020 that **temporarily permitted** physicians to use telemedicine to prevent group contagion in vulnerable healthcare facilities, including Covid-19 dedicated hospitals, medical institutions and nursing homes (Yonhap, 2020). Since then, patients have been able to get teleconsultation over the phone and get prescriptions for medication without having to visit the physician in person. Physicians are reimbursed for these consultations. A few hospitals (such as the Seoul National University Hospital), have utilized video calls and electronic systems to monitor Covid-19 patients with mild symptoms hospitalized at an isolation facility called "Life Treatment Centre". According to the government, from February 24 to April 19 in 2020, more than 130.000 teleconsultations have been conducted and no misdiagnosis had been reported.

One popular new telemedicine solution in South Korea is the **Medihere app**, which allows patients to select the hospital they want to visit and make an appointment to see a doctor, for example. The app was launched in March 2020 after the government temporarily allowed telemedicine. Medihere makes it possible to receive remote medical advice via video call through the app. In addition, the app provides a service called "Coronavirus 119". Patients can self-report their symptoms and appropriate medical treatments are arranged based on the symptoms (Public Health Update, 2020).

#### Vaccination Mobilization

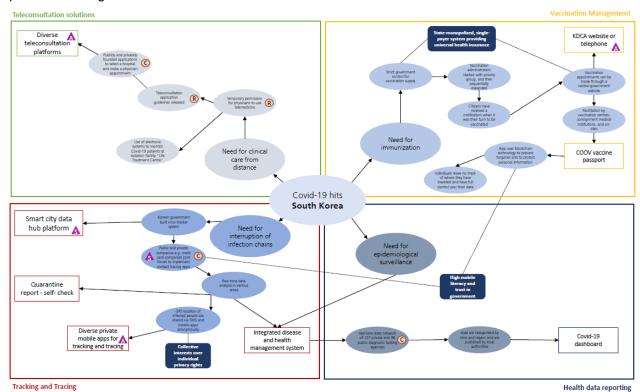
Due to a shortage of vaccines, the government has strictly **controlled** the supply of vaccines and the order of vaccination. The order of vaccination takes into account the supply of vaccines, the current vaccination status (vaccination rate) and clinical results for each vaccine. The vaccination administration has started with a first priority group, and then the number of vaccination targets have been sequentially

expanded (KDCA, 2021b). Citizens have received a notification when it was their turn to be vaccinated. Covid-19 vaccination **appointments** can be made through a central government website via the call centre, in person or by phone when one is vaccinated at a consignment medical institution (KDCA, 2021a). There are different places that provide vaccination based on the order of vaccine priorities and type of vaccines, such as vaccination centres, consignment medical institutions, and on-sites. The mRNA vaccines (Pfizer, Modena) are provided at the vaccination centre and the viral vector vaccines (AstraZeneca, J & J) are provided at a consigned medical institution. A Vaccination Centre is a large-scale inoculation facility established to inoculate the Corona 19 Nucleic Acid Vaccine (mRNA). As of May 27, in 2021, 265 vaccination centres were installed. Consignment medical institutions are medical institutions that receive support for the cost of Covid-19 vaccination. In order to participate in the existing national vaccination project, these institutions have signed a contract with local authorities. Furthermore, nursing hospitals create their own Covid-19 vaccination plan and distribute vaccinations to their patients.

In June 2021, South Korea launched the "COOV (Covid Overcome)" vaccine passport (Korean Consulate, 2021), which allows fully vaccinated travellers to be exempt from the two-week quarantine. COOV has been officially approved for use by the KDCA. The app uses blockchain technology to prevent forgeries and to protect personal information (J. Lee & Smith, 2021). All personal information is stored on a person's mobile device, and the data is only exchanged between a visitor and a host through blockchain. This way, individuals leave no trace of where they have travelled and the passport holders have full control over their data (Ledger Insights, 2021).

#### Cognitive Map for South Korea

The cognitive map for South Korea (Figure A 12 illustrates the individual events per digital response, shows the influence of the sectoral characteristics on the events, and includes the facilitators and the predominant digital infrastructure evolution mechanisms.



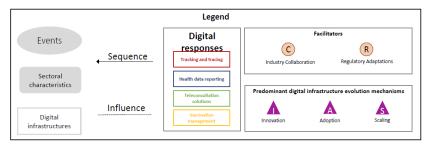


Figure A 12. Cognitive Map for South Korea

# Appendix E: Case Narrative of the United States

Table A 5. United States

United States		
Health system characteristics	Structure and funding	Pluralist, fragmented health care system funded through both public allocations and private insurance, relatively high numbers of under- and uninsured.
	Policy framework	Heavily regulated for patient safety through HIPAA and other laws. Substantial progress in EHR usage after 2009 HITECH Act, 2010 PPACA.
	Socio-cultural values	Individual freedom and liberty held in high regard, but privacy traded for benefits including in healthcare.
	Information technologies	Strong uptake and use of EHRs in hospitals and physician clinics post HITECH. Several HIEs being operational. Rural hospitals still suffering from limited health IT. Persisting interoperability challenges.
Digital responses	Tracking and tracing	Apple and Google have published specifications for a tracking and tracing app for use in the U.S. Virginia as a forerunner has launched COVIDWISE. By the end of 2020, less than half of the states have developed a tracking app and adoption rates are rather low.
	Health data reporting	Local jurisdictions report data largely electronically to the CDC, which consolidates and reports the data at a national level.  The HHS has defined certain reporting standards for laboratories.  Partly fragmented information systems hinder an easy data sharing.
	Teleconsultation	Strong surge in teleconsultations after facilitating law changes (e.g. technology allowed for telehealth or prescription of controlled substances via telehealth).
	Vaccination mobilization	Decentralized vaccination administration by different vaccine providers (pharmacies, physicians, offices, schools,) that have to enroll in the official CDC Covid-19 Vaccination Program.  Many individual ad-hoc solutions for appointment booking.  No mandatory vaccination passport.

## **Health System Characteristics**

## Structure and Funding

Healthcare is a heavily politicized sector in the U.S. Health as a right is heavily debated in the U.S. Due to historical reasons, there is not a universal health care plan in the U.S. In fact, the U.S. healthcare system is **heavily fragmented**, with a federal program – Medicare – for seniors (>=65 years), a joint state-federal run program for the poor and indigent – Medicaid – which is run differently for each of the 50 states, and hundreds of thousands of employer-sponsored private insurance plans, with different levels of benefits and financial obligations for beneficiaries. The public sector funds about half the expenses incurred by the U.S. healthcare system.

The **funding** for different public health programs comes from different sources, so the political parties in power at the federal, state and local levels shape which services are available and who has access to them. The system also fails to provide adequate care to a large number of uninsured people, who numbered 30.1 million in 2018 (CDC, 2021e). Finally, health care is provided in the U.S. in a wide variety of facilities, including primary care clinics, secondary and tertiary hospitals, veterans hospitals, federally qualified health centers (HRSA, 2018) and faith-based organisations. These facilities often do not share data with each other.

There are multiple national, state and regional **agencies** involved in the governance and coordination of healthcare. The overall organisation of the health system is shown in Figure A 13. For the purpose of this narrative, we focus on those agencies coordinating health information technology efforts and disease prevention. The Department for Health and Human services (HHS) is an executive branch of the U.S. federal government with the mission to "enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services." (HHS, 2021a).

The Centers for Disease Control and Prevention (CDC) mission is to protect America's safety, health and security and with that the lives of the American population (CDC, 2021b). It aims to fight diseases (i.e. stop pandemic contagions, control and eliminate diseases, end epidemics) and detect and respond immediately to emerging health threats. Therefore, scientists across the whole nation work with advanced computing and lab technology. Through research, surveillance and testing, huge amount of scientific data is produced and analysed to increase the knowledge to medical health care.

The **Centers for Medicare & Medicaid Services (CMS)** administers the major healthcare programs in the United states, i.e. Medicare, Medicaid, Children's Health Insurance Program and the health insurance marketplace. The agency aims at providing a better healthcare system with high-quality care and more citizens having access to insurance coverage. In addition, the CMS has other responsibilities such as the management and implementation of health insurance portability standards (see HIPAA).

The **Health Resources and Service Administration (HRSA)** helps the geographically isolated and economically or medically vulnerable citizens in the United States to receive high-quality health care services. The agency funds several programs and initiatives across the states and supports the training of health professionals (HRSA, 2021).

Within the HHS, the Office of the National Coordinator for Health Information Technology (ONC) has been founded in 2004 as a staff division to lead national health IT and coordinate nationwide efforts to implement health information technology and the electronic exchange of health information (ONC, 2021). Updates on the progress of the nationwide adoption and use of health IT (e.g. EHR adoption, interoperability, the digital prescription of drugs, etc.) are published in different dashboards on the ONC's website (ONC, 2019). The current "Federal Health IT Strategic Plan 2020-2025", developed in collaboration with federal organisations and with input from public organisations, aims to improve the access, exchange and use of electronic health information, with a particular focus on patients' access to their own health data (ONC, 2020). However, technical, financial, trust and business practice barriers still hinder this (Sullivan, 2019).

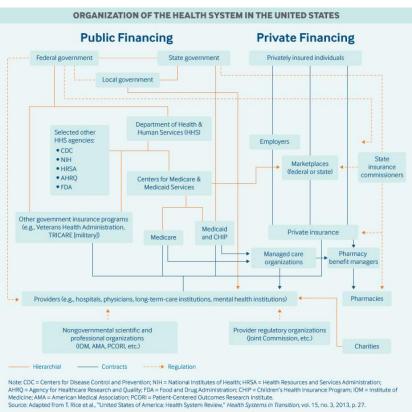


Figure A 13. Organisation of the Health System in the United States (Tikkanen et al., 2020)

## **Policy Framework**

The healthcare industry is **heavily regulated** in the United States, with strict laws to safeguard the welfare of patients. These include regulations regarding building and facility safety, access to emergency care, patient safety, and patient privacy. In particular, three laws have been discussed significantly in the recent literature: the HITECH Act of 2009, the PPACA of 2010, and HIPAA.

The Health Information Technology for Economic and Clinical Health (HITECH) Act provided financial incentives for health care providers to adopt certified and electronic health records (EHR) based on a set of 'meaningful use' criteria. This has led to an improved state of digitization in the US hospitals and physicians practices in the last 10 years. EHR usage rates today exceed 90% in every US state. Public health reporting is an integral part of meaningful use; these provisions became effective in 2018.

The Patient Protection and Affordable Care Act (PPACA) made it possible for the number of uninsured Americans to drop from about 45 million in 2008 to 26 million in 2017, before the numbers increased in the last two years because of significant relaxations of the provisions of PPACA by the current administration (Tolbert et al., 2020). However, despite the recent increase, the uninsured rate today is still below that in 2010, when the PPACA was implemented. The PPACA also has provisions for the elimination of lifetime caps, which could be relevant for "long hauler" Covid patients – those who may suffer long-term implications of contracting Covid-19.

Finally, the **Health Insurance Portability and Accountability Act (HIPAA)** of 1996 was adopted to enable health insurance portability for U.S. residents, meaning that people can move from one employer-sponsored plan to another without a loss of insurance coverage. The more commonly known and discussed aspect of HIPAA, however, is the safeguarding the privacy of patients' medical information. The HIPAA rules do not allow health care providers to use non HIPAA compliant IT tools to provide care to patients. Providers can be fined heavily for violations

#### Socio-Cultural Values

**Individual freedom and liberty** are two of the defining cultural values in the U.S. It is almost impossible to corral everyone toward a common cause if it entails personal sacrifice even if it is for the larger good of the collective. Because health care is largely a state matter in the U.S., imposing a total, national lockdown was not possible during the pandemic. However, state-level mandates were issued in many states (including California, Washington, New York, and others).

A share of the population was found to be **critical to safety measures** face masks, isolation, and quarantine rules. According to a prominent newspaper, Chicago Tribune, approximately 75% favoured requiring people to wear a face mask (Blood & Swanson, 2020). Pew Research reported that 65% people report wearing a mask regularly (Igielnik, 2020). The quarantine policy was largely unenforced in the U.S. Freedom of movement is afforded to everyone. Even those returning from international travel and out-of-state travel are only advised, but not required, to self-isolate/quarantine. People who test positive for Covid-19 but are not admitted in hospitals, are only advised to self-isolate/guarantine.

**Privacy** is prized, but not overly so. People will happily part with private information if they are offered suitable benefits (Data & Marketing Association, 2018). Widespread use of social media, entertainment apps, such as tik tok, and other mobile apps which require invasive access to user's personal info are evidence that people are willing to trade privacy for benefits. Sometimes, American users are parting with privacy without knowing they are. Americans are more sensitive about their health information because of a fear that it may be used to increase their insurance premium or used to discriminate against them in the labour markets.

Americans have shown their gullibility toward emotional and informational manipulation. **Misinformation** spreads rather easily in America. Some of the misinformation is spread deliberately by political operatives, some by other countries and some organically because of misinformed influencers. The fact that politicians have openly ridiculed the suggestions of public health officials and scientists and powerful media elements have portrayed science based suggestion as not sound, has resulted in people not taking scientific guidelines seriously.

## **Information Technologies**

The United States is a large producer and exporter of information technologies in the world. This also applies to healthcare technology. Some of the most prominent **HIT software companies**, including Epic,

Cerner Systems and Allscripts are headquartered in the United States. This ensures that employable technologies are available in the country.

There is widespread **acceptance of technology** and the penetration of technology at individual and societal levels is rather high. Of all people, 96% own a mobile phone, 81% have smart phones (Pew Research Center, 2021b), 75% own a laptop or a desktop, and 50% own a tablet computer. About 75% have access to broadband (Pew Research Center, 2021a) and about 72% use social media (Pew Research Center, 2021c).

Through the financial support provided by HITECH and other stimuli, the **use of EHRs** has reached 96% and 80% of hospitals and office-based physicians, respectively (Pew Research Center, 2021c). The vendor landscape is relatively well covered by market reports (Tate & Warburton, 2019), where the leading vendors (Epic, Cerner, Meditech, Allscripts, Medhost, Athenahealth, eClinicalWorks) take the large majority of the market share. The market has, also in the course of HITECH's meaningful use barriers, undergone significant vendor consolidation in the past decade.

The use of **health information exchange (HIE)** to share patient information and to achieve interoperability has increased significantly in the U.S. Researchers report that HIE use has risen substantially over time, with 82% of non-federal hospitals exchanging information (2015), 38% of physician practices (2013), and 17-23% of long-term care facilities (2013) (Devine et al., 2017). The Office of the National Coordinator for Health Information Technology (ONC) coordinates nationwide efforts to adopt the most advanced HIT as well as standard-based health information exchange (ONC, 2021).

However, there are persisting **interoperability challenges** making widespread sharing of accurate health information difficult. The US Healthcare sector is still rather a conglomerate of independent entities such as hospitals, clinics, individual practitioners, pharmacies, etc. The sharing of information among these independent entities can easily lead to errors, duplication of services or poor patient outcomes (Regan, 2021). In effect, patient information is often not shared and matching patient IDs in different systems remains problematic. While the HITECH Act was a trigger of bringing interoperable health technology to the providers, the meaningful use requirements on stages 1 and 2 have also been criticized for not being sufficiently binding in terms of interoperability standards to be adopted and implemented (Reisman, 2017). Connectivity across systems is still limited and the existing networks are mostly centred on specific providers (e.g., integrated delivery networks, IDNs) and thus from a national perspective still seem fragmented

### **Digital Responses**

#### **Tracking and Tracing**

Unlike some countries, the United States has provided **no single**, **national-level tracking and tracing app**. Apple and Google have published specifications (APIs) for a tracking and tracing app for use in the U.S. on which the states can build to develop their applications, which several US states did. Virginia has been one of the forerunners and has launched an app called COVIDWISE based on these specifications in summer 2020 (Wetsman, 2020). Other states, such as Pennsylvania and Alabama have also had apps in the making. In fact, 20 states have shown interest in these apps (Wetsman, 2020). However, by the end of 2020 fewer than half of the states have developed an application and the adoption rates within these states are quite low (Anderson & O'Brien, 2021; NBC, 2020).

Case investigation and **contact tracing**, which have been invaluable tools in public health for decades, have primarily been used to track and trace cases in the U.S. (CDC, 2020b). The key idea of contact tracing is that once a patient is tested positive, public health officials work with them to identify everyone who may have been in touch with that patient and then inform these people anonymously. Unlike the mobile app-based approach, where people can be identified based on the how close an infected person's phone was in relation to other phones, the case investigation approach takes a more people and memory-centric approach. In all likelihood, this approach is less scalable and prone to error. At the peaks of the pandemic in the US, newspapers reported that several states have been unable to keep up with contact tracing at the desired level of scale and precision (CBS, 2020; Steinhauer & Goodnough, 2020)

## **Health Data Reporting**

In the Unites States, **public health reporting** is conducted through multiple systems involving federal, state, territorial, and local governments. The data for Covid-19 analysis has been produced largely by

private hospitals, laboratories, and health clinics. Various jurisdictions (e.g., cities, counties, and states) can mandate that the testing data be reported to them. This data is then voluntarily reported to the CDC in de-identified form by the health departments. The CDC provides incentives and technical help to jurisdictions to report public health surveillance data. Because state and territory health departments report the numbers differently, there may be discrepancies compared to the numbers reported by the CDC (CDC, 2021i).

According the CARES Act, every laboratory that is involved in Covid-19 testing is required to report all test results to the HHS in line with defined **reporting standards**. This should be done through existing public health data reporting methods, at best by sending data to the state or local health departments (e.g., directly to the local health department, via a centralized platform or through an HIE) within 24 hours (HHS, 2021b). The HHS published a list with the reporting standards and guidelines on their own website (HHS, 2021b).

With the outbreak of the pandemic, an additional "Coronavirus Infectious Disease 2019 Module" (CDC, 2021h) was added to the National Healthcare Safety Network (NHSN), the largest reporting and tracking system for healthcare-associated infections (HAI). The system was already in use prior to the pandemic to manage and eliminate HAIs, and states had varying policies (Texas HHS, 2012) and percentages of facilities using the network (CDC, 2020a). The additional module allowed hospitals to report numbers related to bed availability and personal protective equipment to the CDC and help the official authorities keep track the current situation. However, in July 2021, the government decided that hospitals should stop reporting to the CDC and instead send information on Covid-19 hospitalization and equipment to the HHS directly through the HHS Protect System (Melillo, 2020). The platform centralizes data collected by various divisions to share them with first responders at all governmental levels (CDC, 2022; HHS, 2021c). The government requested "daily data reports on testing, capacity and utilization, and patient flows to facilitate the public health response to the 2019 Novel Coronavirus" (Data.gov, 2023). This unanticipated change has led to controversy and confusion (Huang & Simmons-Duffin, 2020; Melillo, 2020), for example, because hospitals had only 48 hours to adapt the new system while at the same time being on the front lines of fighting a pandemic. In addition, inconsistencies occurred between the numbers published by HHS Protect and other data-collecting sources, such as state public health agencies (Jercich, 2020). Because long-term facilities were not affected by the system change, the additional function of (voluntarily) reporting weekly vaccination data for residents and staff was integrated into the NHSN. This can support the monitoring of vaccination coverage over time and the CDC can use the data to identify vaccination coverage gaps (Madison, 2021).

Generally, there are some longstanding **issues with public health data reporting** in the United States. Prominent among these include differences in the jurisdiction law that mandate data reporting. The inadequacies in data reporting have made it difficult for public health professionals and researchers to ascertain the racial breakdown of Covid-19 cases and deaths. Despite prior crises such as Ebola and different pandemic simulations such as Crimson Contagion in 2019, the US has not been prepared for the Covid-19 outbreak (Madad & Spencer, 2021). In addition to the interoperability problems due to fragmented information systems that hinder an easy data sharing (Banco, 2021; Makulec, 2020), missing patient matching is a well-known and highly discussed issue in the US (Hackett, 2020; University of Ilinois Chicago, 2021).

Several **reporting dashboards** have been provided to report the data from the CDC and other sources. The CDC itself updates the total number of Covid-19 cases and death counts on a daily basis. Drawing upon this and other data, other sources, such as the Johns Hopkins Covid-19 Dashboard, Coronavirus Worldometer and CoronaWiki provide details on total cases, new cases, total deaths, new deaths, total recovered, active cases and critical cases in the United States. It is possible to break this data down to states and county levels to obtain information about the spread of the virus and the efficacy of the recovery efforts. The Johns Hopkins Covid-19 Dashboard also includes links which provide information on testing conducted in each state in the United States (Johns Hopkins University & Medicine, 2021). In addition, many state Public Health departments have created their own Covid-19 dashboards to provide customized data to citizens living in those respective states. For instance, the dashboard in Iowa (Iowa Department of Public Health, 2021a) has extensive details on Covid-19 cases, hospital admissions data, testing data, and outcomes data

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<sup>&</sup>lt;sup>4</sup> Covid-19 Integrated County View: https://covid.cdc.gov/covid-data-tracker/#county-view

#### Teleconsultation

To address the unique situation presented by the current pandemic, which manifested in hospitals and clinics being swamped with Covid-19 patients, the HHS endorsed teleconsultation and the CMS took a **discretionary regulative action**. It allowed health care providers, including hospitals and clinics, to provide telehealth services using remote telecom services, even if these are not fully HIPAA-compliant (HHS, 2021d). This step was taken to relieve the crowding of emergency areas in hospitals, to ensure that patients suffering from Covid-19 got the immediate care they needed, to triage sick people to assess if they needed to visit the hospital and to provide care to patients remotely.

HIPAA-covered health care providers, in good faith, were allowed to provide telehealth services to patients using remote communication technologies, such as **commonly used apps** – including FaceTime, Facebook Messenger, Google Hangouts, Zoom, or Skype – for telehealth services, even if the application does not fully comply with HIPAA rules. Nevertheless, for some of these apps, a HIPAA-compliant version was developed by third-party providers within a short time, such as Zoom for Healthcare (Zoom, 2021). However, healthcare providers should not use any platforms that are public-facing — for instance, Facebook Live, Twitch, and TikTok — to provide telehealth.

Despite the temporary approval of non-HIPAA-compliant services, more than 50 integrated delivery systems in the US (e.g., Kaiser Permanente, Cleveland Clinic, and Mount Sinai) had implemented their own **specific teleconsultation solutions** in the course of the pandemic and before. Other providers have partnered with commercial providers such as Teladoc Health and American Well (Hollander & Carr, 2020). Now that many healthcare providers wanted to adopt some type of communication technology, some providers have developed a HIPAA-compliant alternative.

Medicare and several state Medicaids have allowed **reimbursements for teleconsultations** and extended these from 2020 on (CMS, 2020a, 2020b). The billing and documentation requirements for teleconsultations are no different than those for in-person physical visits (Crawford, 2020; HHS, 2020). Further temporary law changes applied e.g. to the provision of telehealth within and across state-lines, the prescription of controlled substances via telehealth, and the delivery of care to both established and new patients through telehealth (HHS, 2020).

Additionally, the Centers for Medicare and Medicaid Services (CMS) has issued special temporary **guidance** to make it easier for physicians to provide virtual care to patients during this Covid-19 pandemic. To communicate these wide-ranging regulatory changes, the Health Resources and Services Administration's (HRSA's) at the HHS launched a new website with all relevant information for health care providers and patients.<sup>5</sup>

The numbers of **telehealth usage** hare risen steeply. According to the CMS Administrator, Seema Verma, before the pandemic, approximately 13,000 beneficiaries in fee-for-service (FFS) Medicare received telemedicine in a week. By the end of April 2020, this number had risen to nearly 1.7 million (Padmanabhan, 2020). A Commonwealth Fund report suggests that the numbers may have peaked and are even tending lower (Mehrotra et al., 2020). Overall, telehealth services have been valued by the majority of people during the first year of the pandemic and several healthcare groups urged the government to enable virtual health after the emergency status as well (Landro, 2021)

#### Vaccination Mobilization

In the course of the Covid-19 pandemic, US citizens have mixed and **changing attitudes towards vaccinations**. While misinformation about the vaccine has had a negative effect among the people to get vaccinated (Loomba et al., 2021), the overall tendency was a growing intention. Studies substantiated socio-political differences. Democrats have been much more likely to get a vaccine than republicans: Approximately 41% republicans did not want to get a Covid vaccine (Alcindor et al., 2021). Among the main reasons for denying a vaccine are concerns about side effects, the speed with which it was developed and a need for more data (Funk & Tyson, 2021).

The CDC collects the data about vaccination administration and distribution through different existing and new vaccination IT systems (CDC, 2021a), but the 'perfect tracking' of the doses is lost as soon as it arrives at the providers (Bellon & Spalding, 2021). The **vaccine reporting** to the CDC is done through

<sup>5</sup> https://telehealth.hhs.gov/

multiple sources (jurisdictions, pharmacies, federal entities) that again use different reporting methods and systems, which leads to reporting limitations and variation in Covid-19 Vaccine Data (CDC, 2021d). Although overall the vaccine data collection has improved from the beginning of the vaccination rollout in December 2020 to April 2021, the reporting still differs between the states and old systems, registries and laws complicate or even hinder the process. The data collection is partly uncoordinated, of low quality or incomplete (Bellon & Spalding, 2021) and due to different practices (e.g. some clinicians register the administered shots manually on paper and enter them into the system afterwards) the data may not reflect the real-time. However, most vaccinators achieve to report the shots within the required 72 hours.

The CDC continuously informs the public about the current vaccination developments (e.g., number of vaccine doses, vaccinated people split by demographic data, by state, by county) through an **interactive dashboard** on the CDC's website, the Covid Data Tracker, which is updated on a daily basis (CDC, 2021c). Additionally, different states have their own dashboards, which are more detailed and provide information at the county level to the own target group, e.g. lowa (lowa Department of Public Health, 2021b).

**Communication** plays a major role in vaccination management in the US to counteract potential misinformation. The CDC tries to answer all relevant questions around the vaccination process on their website. Citizens who want to book a vaccine appointment are either linked to the VaccineFinder, a portal where people can search for available vaccine doses near them or to the responsible state's website (CDC, 2021g). In general, there have been a multitude of different locations to get the vaccination, e.g., general practitioners, pharmacies, school doctors, or offices. The order of vaccination and the priority groups are determined by the states, but the government makes suggestions in this regard (Kates et al., 2020).

In order to become a Covid-19 vaccine provider, healthcare professionals are required to enrol in the official CDC **COVID-19 Vaccination Program** (CDC, 2021f). By signing the provider agreement, they agree to the conditions including the reporting duties about vaccine administration, vaccine supply, and vaccine adverse events. One requirement is the enrolment in the jurisdiction's immunization information system.

All 64 jurisdictions (will soon) have web-based **Immunization Information Systems** (IISs), which include people's vaccination records and are thus a centralized data repository. Jurisdictions can use the IISs for managing vaccine orders and administration, because most IISs enable data transmissions and connections to many different healthcare organisations and systems.

Alternatively, to ensure an easy and effective vaccine roll-out and management, the CDC has decided to collaborate with Deloitte (Deloitte, 2021) and offer a free software to all states, the so called **Vaccine Administration Management System (VAMS)**, which connects with other data reporting systems. However, due to many problems, bugs and a lack of flexibility, many states have decided to either build an own solution, pay for a private system or even shift the planning responsibility to the counties (Ferguson, 2021). These alternative solutions include dashboards, Eventbrite, or workarounds via surveymonkey or hotlines (Jercich, 2021).

Figure A 14 shows an initial idea of how the vaccination process in the US could have been set up and demonstrates the connections and communication strings between the different institutions.

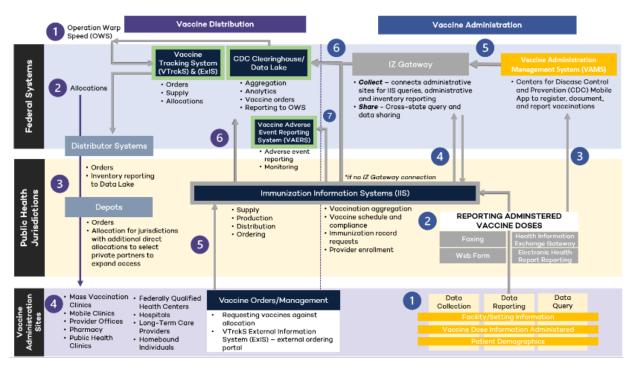


Figure A 14. Existing Systems and Infrastructures for Vaccination Management (Johnson et al., 2020)

Many voices have uttered **criticism** regarding the vaccination administration processes in different cities and states (Weise, 2021). Most of the appointment booking is done online, but there is not one single website and it was reported to have been difficult to find and book a shot. Some people drove hours to the next city to receive a vaccination when they did not find one nearby. As a response, private people as well as the government have written simple computer programs ('hacks') that can tell the users where to find a free spot, such as a bot on Twitter which sends notifications as soon as new appointments are available in the region (Dean, 2021). Unfortunately, some people were on several waiting lists and when getting a vaccine in one place they did not inform the other institutions, which has led to the process being slowed down.

In terms of the implications of being vaccinated, the White House has clearly stated in the beginning that in the US there will be **no mandatory vaccine** passport system which would give the owners more freedom in terms of mobility than those people without it. According to the government, the rights and the privacy of the citizens have to be protected and a passport would lead to unfair treatment of citizens and discrimination (BBC, 2021). However, the number of private companies and institutions demanding vaccine information increased over time. People who are unwilling or unable to show proof of vaccination may be subject to regular Covid tests, which is strongly supported by CEOs from the largest organisations in the US and the federal government (Kelly, 2021; The White House, 2021). US citizens can prove their status with either a physical copy or a digitized form of their immunization record. Due to the increased demand for proof of vaccination, a variety of different passport apps appeared on the market (DiValentino, 2021).

#### Cognitive Map for the United States

The cognitive map for the United States (Figure A 15) illustrates the individual events per digital response, shows the influence of the sectoral characteristics on the events, and includes the facilitators and the predominant digital infrastructure evolution mechanisms.

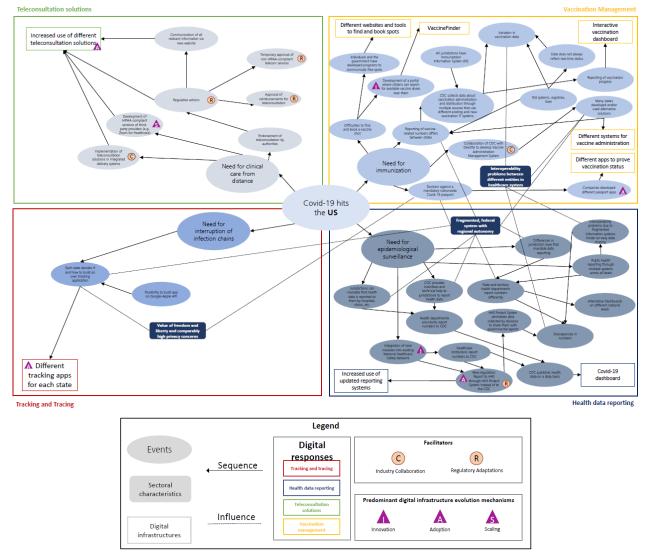


Figure A 15. Cognitive Map for the United States

# Acknowledgments

This research was supported by the Danish Agency for Science and Higher Education under grant 7059-00108B. We gratefully acknowledge the support of Tina Blegind Jensen (Copenhagen Business School) and Kai H. Lim (City University of Hong Kong) in the early stages of this project. The authors would particularly like to thank the participants of the international workshop series "Digital Health and Policy in Context" for their valuable contributions in helping the authors shape this work.

Yu Tong acknowledges that this research is partially supported by the National Natural Science Foundation of China (Grant no. 72022017), which was awarded to her.

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