Study on the legal and organizational frameworks for delivery of healthcare services at a distance

Country Reports for Israel, Germany and France

Authors: Rachelle Kaye, K-Tor Consulting Services Ltd and EHTEL
Moritz Mumme, Marie Klimpel, Martin Knüttel, Merret Scheunemann, OptiMedis AG,
Stéphan Haaz, Maxime Beuzelin, CATEL
Marc Lange, EHTEL

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Executive Summary

The purpose of this study is to explore legislation and regulation for telemedicine in three countries: Israel, Germany and France - in order to provide insight and possible directions for telemedicine legislation and regulation in the Czech Republic.

For purposes of the study, we have used the European Commission's definition of telemedicine: "*the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.*"

In the introduction to the document we have briefly reviewed the approach of the National eHealth Strategy of the Czech Republic for the development and implementation of telemedicine in the Czech Republic, as well as the current legislative and regulatory frameworks regarding telemedicine at the European level.

The study of telemedicine legislation and regulation in the three countries is organized on a country-by-country basis and each country report is divided into two sections:

- The first section is intended to provide a context for better understanding of the legislation and regulation for telemedicine in each country and includes a short description of the healthcare system, the status of digitalization of the healthcare system, cultural aspects, the organizational framework for telemedicine and the supportive digital health infrastructure.
- The second section focuses on the existing legislation and regulation for telemedicine in each country and addresses the general scope of service, eligibility of professionals, healthcare organizations and patients, the security and safety of the telemedicine service, liability of health professionals and of technical operators when providing telemedicine services, data governance, standards of care, reimbursement and financing, ethical guidelines and current legal and ethical challenges

The three countries have significant differences but also commonalities, particularly in the content of their regulations.

1. The countries are different in **size** – Israel is small in both size and population (9.5 million people) compared to Germany (83.2 million people) and France (67.8 million people).

2. All three countries have mandatory/statutory **public health insurance systems**.
   a. Israel and Germany are closer to the Bismarkian model , in which there is a free choice of health insurance and regulated competition between health insurances. A major difference however is that in Israel, all citizens must join one of the four nationwide health plans, whereas in Germany, people above a certain income level can choose Private Health Insurance.
   b. In Israel, Health Plans are both payers and providers and selectively contract directly with doctors (GPs and specialists) whereas in Germany the sick funds are payers only and contract with the local physician organizations who pay the doctors according to a nationally negotiated fee structure.
   c. The French public system is defined by a national administration, whose roles and responsibilities are delegated to the territorial administrations, accompanied by an optional private system, managed by complementary organizations, that provide co-insurance/co-payments to their beneficiaries. Doctors may elect to deviate from the

nationally negotiated fee structure but the patient must make up the difference, usually by complementary co-insurance.

d. In Israel and Germany, GPs are not gatekeepers although by and large the majority of citizens have a regular primary care doctor. In France, there is a voluntary "gatekeeping" system for people aged 16 and older, with financial incentives offered to those who opt to register with a GP or specialist as their point of first contact in the system.

3. There is a significant difference in **digital health maturity** among the three countries as demonstrated in the Digital-Health-Index 2018 (Bertelsmann-Stiftung) (see *Figure 7*). The Israeli system is totally digitized (and began its digital health journey in the 1990s) whereas France and Germany have been gradually moving toward digitization during the last decade and only in recent years have made significant strides in this area.

4. There is a significant difference with respect to the **legislation applicable to telemedicine**:
    a. In Israel, there is no legislation mandating eHealth. eHealth evolved at the initiative of the Health Plans in the early 1990s order to support the doctors who were and continue to be the key actors in the healthcare system – they diagnose, order tests, prescribe and refer to other providers. All of the legislation and regulation regarding digital health is much more recent. There is a specific Ministry of Health regulation for Telemedicine, published in 2019.
    b. In Germany, the E-Health Act for secure digital communication and applications in the healthcare system passed at the end of 2015. This was the first foundation to establish a secure telematics infrastructure. It enabled the introduction of digital health applications(DIGAs). This first milestone enabled the monitoring of patients with a defibrillator to be included in the Public Finance Scheme in Germany as the first telemedical service in 2016. In 2019 the Appointment Service and Supply Act was passed obliging health insurance companies to offer an electronic patient record (ePA) for their patients starting 2021, There were also additional laws passed in 2019 enabling the gradual introduction of electronic prescriptions, and entitling people with statutory health insurance to DIGAs.
    c. In France, "digital health" is not defined under French Law. Since 2012, a voluntarist policy of digitalization of care has been implemented. The "Hospital Patient Health Territory" (HPST) law passed in 2009, introduced the definition of telemedicine. It defines 5 types of acts in the public health code: teleconsultation, remote monitoring of patient, tele expertise, tele assistance, and Medical response, provided as part of the medical regulation of emergencies or the permanence of care . More recently - tele-care and guided teleconsultation have been added.

5. The **governance for digital health (including telemedicine)** is also different in each country.
    a. In Israel, while policy and overall regulation is the responsibility of the Ministry of Health, the main drivers and managers for digital health are the Health Plans and the hospitals who have significant autonomy in the development and implementation of digital health services including telemedicine. Doctors and other Health professionals, as a rule, perform telemedicine within these organizational contexts using the technology and IT systems of their organization.
    b. In Germany, the gematik is responsible for operation and further development of the telematics infrastructure, the electronic health card and associated specialist services

and is the central provider of telemedicine infrastructure (TI) on a national level. The Ministry of Health has 51 % of gematik company shares.

c. In France , the governing structure for digital health and telemedicine is more complex. At the national level, the Ministry Delegation for Digital Health (DNS), is directly linked to the ministry of health, and is responsible for setting the main orientations of the digital health policy. For this, the DNS heavily relies on the expertise of the ANS (Agence du Numérique en Santé : National Digital Health Agency). At the regional level, ARS (Agence Régionale de Santé : Regional Health Agency) can rely on regional groups of actors called GRaDES for the development of digital health and the implementation of the information systems master plan (SDSI).

The commonality among the countries is that they all have clearly defined the governance structure for digital health and telemedicine, and the division of authority and responsibility among the various actors.

6. **Reimbursement** for telemedicine is addressed in the regulations for all three countries.
   a. In Israel, the majority of eHealth financing is at the Health Plan and Hospital level and they have yearly budgets for both development and maintenance of their eHealth systems including telemedicine. In the Health Plans, health care professionals may be employees or independent contractors. If they are employees, providing the telemedicine service is just a part of their regular salary. If they are independent contractors, the fees for providing a service is the same whether provided physically or remotely. The principle is that a “visit is a visit is a visit” regardless of how it is provided. In hospitals, most professionals are employees and their salary includes all their activities including teleconsultations. There are no limitations on the number of teleconsultations, nor is there a requirement of a physical visit as a condition.
   b. In Germany, for video consultations, the treating doctor initially receives the respective basic and insured flat rate . In addition, if the requirements are met, there are different surcharges: for basic specialist care, for the performance of the general practitioner's care mandate, for support of general practitioner care by qualified non-medical practice assistants and for treatment by conservative ophthalmologists as well as other cases The remuneration for video consultations also includes items for video case conferences and video case discussions as well as for outpatient specialist care. The video consultation is possible if the patient has not previously been treated by the doctor, but the doctor is only paid in full if there is personal contact with the patient in the same quarter. If this is not the case and contact is made exclusively via video, there will be a reduction (deduction of 20, 25 or 30 percent depending on the specialist group). The number of pure video treatment cases is also limited to 30 percent of all treatment cases by the doctor/psychotherapist.
   c. In France, teleconsultation is billed at the same rate as a physical consultation (25€ for a GP in sector 1), depending on the doctor’s specialty and sector of practice, as mentioned before. The coverage rules are the same as for face-to-face consultation, with the same distribution between National Health Insurance and complementary health insurance. A doctor cannot carry out more than 20% of his activity remotely. Tele-expertise is remunerated since 2018. The bill is not invoiced to the patient, but directly to the National Health Insurance by the doctors who performed the act with a limit of 4 acts per year per doctor per patient. Modalities of reimbursement and financing remote monitoring acts are not yet known.

7. **The role of the technology industry** is increasingly important in the development and expansion of telemedicine in all 3 countries.
    a. Innovation in Digital Health in Israel, including telemedicine, is a national commitment to global leadership with multiple players from top government, healthcare providers and tech and industry partners. For example, HealthIL is a non-for-profit digital health innovation ecosystem - a joint venture of the Israel Innovation Institute, Israel's Ministry of Economy, Digital Israel at the Ministry of National Digitization, Israel Innovation Authority and Ministry of Health. HealthIL supports innovation management for healthcare stakeholders, engaging entrepreneurs in the field of healthcare innovation, and bridging the gap between the tech community and the public health sector.
    b. In Germany, the gematik acts as the provider and central hub of a developer ecosystem. In this ecosystem, interested parties (mostly private companies) can use the application infrastructure and telematic infrastructure of gematik to build their own applications for different markets. Digital Health Applications (DIGAs) can be developed by all interested organizations, but so far only private companies or private-public joint ventures have developed them.
    c. In France, the development of telemedicine has been very gradual and heterogenous. It has been the subject of numerous territorial experimentations, with variable levels of success, from one region to another and from one medical sector to another. Nowadays, a large panel of solutions are available and are provided by either Regional Health Agencies or private companies. About 104 solutions have been referenced by the Ministry of Health. There is a high level of competition between those providers in all French regions.

8. The importance of **Investment in Telemedicine** is apparent in all three countries.
    a. In Israel, investment in eHealth innovation comes from a number of sources including government (the Ministries of Heath, Economy and Industry), the Israel Innovation Authority, venture capital, multinational corporations and international R&D such as the European Research Framework, US and Canadian R&D funds. Government policy is particularly important. In Israel, for example, in March 2018, led by the Ministry of Health and the Headquarters for the national Digital Israel Initiative through the Ministry of Social Equality, and in collaboration with the Prime Minister's Office, the treasury, the Innovation Authority, the Planning and Budgeting Committee, and the Ministry of Economy, the Israeli government set its sights on advancing digital health as a national engine of growth. This included investment in a number of key digital health programs.
    b. In Germany, currently, there are several funding schemes directed towards - or specifically including – projects for telemedicine. Funding in this area ranges from large projects at the federal level to many small and regional projects. On the federal level the German Innovation Fonds support new forms of healthcare and healthcare research in the SHI. A lot of these projects include some sort of telemedicine. Some other examples for public funding program are at the regional level by the ministries of the federal states. There is also support from foundations regarding e-health and telemedicine, e.g. Bertelsmann Stiftung: "The Digital Patient" project examines the impact of digitization on healthcare and Robert Bosch Stiftung: Projects on challenges such as demographic change, globalization, digitization, biotechnology.

c. In France, the SEGUR, an investment program of €2Mdrs for the digitalization of the ongoing patient management and to facilitate widespread ease and secure sharing of health data between health professionals and with users to improve prevention and care, was implemented in 2022.

9. One of the challenges faced , particularly in France and Germany, is the **integration of telemedicine in healthcare organizations**.
    a. In France, telemedicine is now used by city doctors and some specialists but there still a lot of work for professionals working in organisations to be accustomed to using telemedicine services.
    b. In Germany, physicians working in their private clinics are not really part of an organizational framework and are reimbursed for telemedicine in accordance with a nationally agreed upon fee structure, but via their local physicians' organization who receive the money from the Health Insurers.
    c. In Israel, this is less of a concern as most telemedicine occurs between healthcare professionals and patients within the context of the Health Plans or hospitals and using organizational infrastructure. The telemedicine encounter, be it e-prescriptions, e-referrals, messaging or a teleconsultation are automatically recorded in the shared organizational electronic medical record.

In summary, the key lessons learned from the study are the importance of a well defined governance structure and process, the importance of well-directed investment at the national and regional level and encouragement of private investment, building strong collaboration between public providers, government and the health technology industry, and clearly defined reimbursement for healthcare providers and professionals for telemedicine. The pivotal role of doctors is apparent in all three countries and the recognition that their adoption of telemedicine is the key to successful deployment.

1 Introduction

1.1 Purpose

The purpose of this study is to explore existing and planned legislation and regulation in selected countries in order to provide insight and possible directions for telemedicine legislation and regulation in the Czech Republic.

1.2 Definition of Telemedicine for purposes of the Study

Telemedicine can be defined, according to the European Commission, as 'the provision of healthcare services ,through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound ,images or other forms needed for the prevention, diagnosis , treatment and follow-up of patients.[1]

- Telemonitoring relates to the transmission and control of vital signs at a distance, through remote systems including portable devices and sensors used by the patient, that send information including alarm signals to a remote control centre.
- Tele-education is the provision of general and technical information made accessible to the general population or other health professionals, respectively.
- Teleintervention relates to surgical interventions applied at a distance, using technology – such as robotized and computerized machines – which allow the physician to perform procedures on the patient without direct contact
- Teleconsultation is similar to the traditional medical consultation, with the difference that the doctor and the patient are physically separated and communicate at a distance, establishing a real-time conversation through videoconference, phone or chat.
- Another embodiment of telemedicine that may also be called teleconsultation refers to contacts between two or more healthcare professionals regarding medical issues involved in the care of the patient.

1.3 Current Situation in the Czech Republic

The National eHealth Strategy of the Czech Republic defines telemedicine as a part of its overall strategic objective of increasing the quality and accessibility of healthcare services. The specific objective in the strategy (3.1) is Telemedicine and mHealth. Extension of the current range of health services for telemedicine solutions is perceived to be a way to reduce the number of necessary outpatient visits and hospitalizations of chronically ill patients. The increase in incidence of chronic diseases in the general population, along with an increase in higher ages exert pressure on the availability of health services resulting in growth in both the number of outpatient visits and hospitalizations in the acute and follow-up inpatient care segment. The strategy asserts that "The government's task is to establish a legislative framework for the safe use of telemedicine technology. It must also create conditions for the safe use of telemedicine solutions and set rules for verification and approval of the technical and safety parameters". [2]

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society /COM/2008/0689 final/. [cited 2015 Nov 10]. Available from: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52008DC0689 (last access 12/09/2022)

[2] The National eHealth Strategy of the Czech Republic 2016-2020 published by the Czech Republic ministry of Health p.101

Currently, there is no specific law regulating telemedicine in the Czech Republic and it is regulated only by general rules: Act No.: 372/2011 Coll., on Provision of Health Services (the " **Act**") and Decree No.: 98/2012 Coll., on Health Documentation (the " **Decree**"). The Czech Ministry of Health is preparing amendments to the Act and Decree which shall set up rules of telemedicine. In addition to the above, the Czech Ministry of Health is also preparing a new Act on Digital Health Services. The amendments as well as the new Act on Digital Health Services are pending in the legislative process.[3]

The draft Amendment to the Act on Healthcare Services could legalize the so-called "consulting services", which could be provided through remote access or in the patient's own social environment, or in another place of his current location. Pursuant to the draft Amendment, the provider will need to have a physical contact point.

There are private online projects offering online reservations and physicians' consultancy. Furthermore, the Society of General Medicine (a professional society) has published recommended diagnostic and therapeutic procedures for general practitioners in the field of telemedicine.[4]

1.4 Legislation and Regulation for Telemedicine at the EU Level

As a healthcare service, telemedicine is included in the scope of Articles 56 and 57 of the Treaty on the Functioning of the European Union (TFEU), and is thus, a service, and to that extent is subjected to the general freedom regarding free movement of services. Nonetheless, this is not the only set of norms applicable to telemedicine within the European legal order.

In the framework of European law, telemedicine is simultaneously a healthcare service and an information service (a service normally provided for remuneration, remotely and by electronic means at individual request), therefore, both regulations – the ones regarding healthcare and the ones regarding information society services – apply.

Concerning information and telecommunications, the following documents are relevant:

- Directive 95/46/EU [18], the Data Protection Directive,
- Data Protection Regulation (GDPR)
- Directive 98/34/EC, the Directive on Services of the Information Society
- Directive 2000/31/EC, the Electronic Commerce Directive
- Directive 2002/58/EC, the Directive on Privacy and Electronic Communications or e-Privacy Directive.

Concerning health services the most relevant existing regulation is Directive 2011/24/EU, the so-called Cross-Border Directive.

New proposed regulations, specifically on the (European) Health Data Space, may affect telemedicine in Europe. The intended goals of the proposed act will be "to make the healthcare sector more efficient and advance scientific research in the telehealth area, and 'unleash the health data economy', fostering the development of new digital health services and products and outline individuals' rights on the 'primary' use of health care data".

[3] CMS Expert Guide to digital health apps and telemedicine Digital health apps and telemedicine in Czech Republic. December 2020. https://cms.law/en/int/expert-guides/cms-expert-guide-to-digital-health-apps-and-telemedicine/czech-republic# (last access 12/09/2022)

[4] Biologis TELEMEDICINE LEGAL FRAMEWORK IN EUROPE & ISRAEL, July 2021 https://biologis.com/wp-content/uploads/2021/09/EU-Legal-Framework-on-Telemedicine.pdf (last access 12/09/2022)

Concretely, the proposed Article 8 is specific to Telemedicine and states, in the version of the proposal released on 3rd May[5], that "Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States."

Furthermore, as proposed in Article 3, European citizens would have electronic access to a minimum set of 'primary' health data i.e., vaccinations, electronic prescriptions, digital images, laboratory results, and reports on a patient's discharge from clinical settings. Citizens would also be able to use an electronic access service that is "free of charge".

There are no existing European norms dealing with the medical liability (or, as a matter of fact, with tort or criminal liability in general terms), nor with the standard of care for healthcare providers. The only competences that the Treaty on the Functioning of the European Union (TFEU) assigns to the EU regarding health issues relates with public health (Articles 4/2/k and 168 TFEU though Article 168. TFEU assigns the responsibility for organizing and delivering health care to Member States, while the EU only holds limited competences in this regard) and questions connected with the four fundamental freedoms of the internal market, as for instance the patients' or physicians' freedom of movement. All the remaining issues are each Member State's exclusive responsibility.[6]

The danger of COVID-19 in Europe has required the necessity for patient-accessible telemedicine services. While Telemedicine is regarded as both a health service (Directive 2011/24/EU) and an information service (Directives 95/46/EU, 2000/31/EC, and 2002/58/EC) in Europe, a Europe-wide framework is far from being implemented due to the absence of Pan-European common medical responsibility and medical legal rules. Many countries in Europe passed temporary legislation or exemptions to enable the use of telemedicine during the Covid Pandemic. For example, the European Society of Medical Oncology issued guidelines concerning patient care during the pandemic. In breast cancer management. Tthey clearly recommended switching to telemedicine as much as possible for patients who present new symptoms or side effects, despite being considered high-to-medium priority patients. [7] In France, MOH regulation in 2020 allowed reimbursement of telehealth / virtual consultations. In Germany, comprehensive policy regulated Virtual Health and Care reimbursement and recognized Digital Health Applications (DiGA) as therapeutics that can be prescribed. In the UK, policies provided for capacity building, change management and regulated telehealth, triage infrastructure procurement and data governance in a COVID tracing app.[8]

1.5 Current Legal and Ethical Challenges at the EU Level

A major challenge at the EU level is the lack of permanent legal frameworks providing clear rules and conditions for delivering online consultations. Doctors feel uncertain about the long-term viability of COVID-19 measures that enable telemedicine. Lack of reimbursements or coverage of the statutory health insurances for online consultations is also a major barrier. While countries such as France,

[5] Proposal for a Regulation of the European Parliament and the Council on the European Health data Space (COM(2022) 197 Final https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2022:197:FIN (last access 12/09/2022)

[6] Telemedicine: The legal framework (or the lack of it) in Europe Vera Lúcia Raposo GMS Health Technology Assessment 2016, Vol. 12, ISSN 1861-8863

[7] ESMO. Cancer patient management during the COVID-19 pandemic. Available at: www.esmo.org/guidelines/cancer-patient-management-during-the-covid-19-pandemic (last access 12/09/2022)

[8] The Future of Virtual Health and Care; Driving access and equity through inclusive policies. Draft Findings of the global landscape review of Virtual Health and Care policies February 07, 2022

Sweden and Germany have more telemedicine-friendly frameworks, many other EU countries have not yet provided a roadmap for its broader adoption.[9]

A critical concern is data privacy. The maintenance, use, and replacement of devices (which age in a short time) are also objects of concern. Another important aspect is the training and professionalism of those who carry out the telemedical activity. Two additional issues are: ethical arguments and costs. The ethical aspects of telemedicine include protection of patient information, informed consent, and recognition of the fact that behind the screen there is, however, a suffering person, not making the patient just a number to take care of. Several articles examined the high costs of telemedicine implementation due to automation, security, and legality, etc..[10]

In order to provide an environment that is conducive to the widespread delivery of teleconsultations and other telemedicine applications, several elements must be in place. These include:

1. A clearly defined regulatory environment creating certainty, safety and security for telemedicine services;
2. Treatment of health data,
3. Medical liability.
4. Policies governing the establishment and consumption of telemedicine services,
5. strategies at national or regional level that provide a vision, role of and pathway to telemedicine within the broader healthcare context.
6. Certification of healthcare professionals to provide remote services in countries other than their own.
7. Funding and reimbursement and the existence of a single coherent governance, management and funding strategy.[11]

[9] Giulio Nittari, Ravjyot Khuman, Simone Baldoni, , Graziano Pallotta, , Gopi Battineni, , Ascanio Sirignano, Francesco Amenta, , and Giovanna Ricci. TELEMEDICINE IN EUROPE Opportunities and Challenges: Case Study Report 2020. https://alliedforstartups.org/wp-content/uploads/2020/09/Telemedicine-report-2020.pdf (last access 12/09/2022)

[10] Telemedicine Practice: Review of the Current Ethical and Legal Challenges. , VOL. 26 NO. 12 DECEMBER 2020 TELEMEDICINE and e-HEALTH p 1427

[11] The Changing Fortunes of Telemedicine in Europe – Past, Present, and Future beyond COVID-19 Greg Chittim, Vice President, Anastasios Pappas, Consultant, and Justyna Bomba, Analyst https://healthadvancesblog.com/2020/05/06/the-changing-fortunes-of-telemedicine-in-europe/ (last access 12/09/2022)

2 Country – Israel

2.1 Context

2.1.1 Country profile

Israel is a small country located at the juncture of Africa, Asia and Europe. Its population is just over 9.5 million[12], and its population density is among the highest in the western world: in the European Union (EU), only Malta and the Netherlands are higher. Israel is a democratic state with a parliamentary, multiparty system. It is an active member in many major international organizations, and in 2010 it formally joined the OECD as a full member. Although it is geographically located in the Middle East, Israel is classified by the WHO as part of the European Region. Israel has a modern market-based economy with a substantial high technology sector.[13] 100% of Israeli citizens are covered by public health insurance. In 2019 the total health expenditure was $3456 [14](€3172) per capita, 7.5% of GDP. In 2017 there were 38,523 doctors (3.1 doctors per 1000 inhabitants). There are 45 acute care hospitals. 18 are government-owned, either by the Ministry of Health or by municipalities (57% of beds), 16 private non-profit hospitals are owned by health plans or non-profit organizations (40% of acute care beds) and 11 are for-profit hospitals (3% of bed capacity). [15]

2.1.2 Healthcare System

The Israeli healthcare system is essentially a Bismarkian system. It began as a classical Bismarkian system which underwent significant change with the passing of the National Health Insurance Law in 1995 that legislated universal compulsory statutory health insurance for all citizens and centralized the collection of health insurance payments from the citizens as an earmarked health tax paid to the National Insurance Institute (NII). The funds from the tax were pooled with the employer portion and allocated to the Health Plans by a capitation formula based primarily on age. Two years after the passage of the Law, the employer portion was replaced by an allocation from the National Budget, thus resulting in a system financed by earmarked and general taxation.[16]

Under the Law, coverage for health care services is provided by the four competing nationwide health plans (HMOs): Clalit, Maccabi, Meuhedet and Leumit. In contrast with sick funds and mutualites in Europe, the Health Plans are, in fact, similar to US HMOs in that they are directly responsible for the provision of healthcare services, not only their financing. Every citizen must join a health plan but is free to choose and move from one to another. Health Plans must provide a legally defined public basket of services to all their members (updated annually). The Health Plan budget covers all of the health care services in the public basket of services for all members. Health Plans may offer their members plans for supplementary services for a premium. 84% of Israeli citizens have voluntary complementary health insurance from their Health Plan, and 57% have private commercial supplementary insurance.

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[12] https://www.cbs.gov.il/en/mediarelease/pages/2021/population-of-israel-on-the-eve-of-2022.aspx (last access 12/09/2022)

[13] Rosen B, Waitzberg R, Merkur S. Israel: health system review. Health Systems in Transition, 2015; 17(6):1–212. https://eurohealthobservatory.who.int/publications/i/israel-health-system-review-2015 (last access 12/09/2022)

[14] https://knoema.com/atlas/Israel/Health-expenditure-per-capita# (last access 12/09/2022)

[15] R. Waitzberg and S. Merkur, "Policy Efforts to Strengthen Public Hospitals in Israel," EuroHealth 23, no. 4 (2017): 34–38.

[16] B. Rosen, R. Waitzberg, and S. Merkur, "Israel:Health System Review," Health Systems in Transition 17, no. 6 (European Observatory on Health Systems and Policies, 2015): 1–112; and "Israel," The Health Systems and Policy Monitor (European Observatory on Health Systems and Policies).

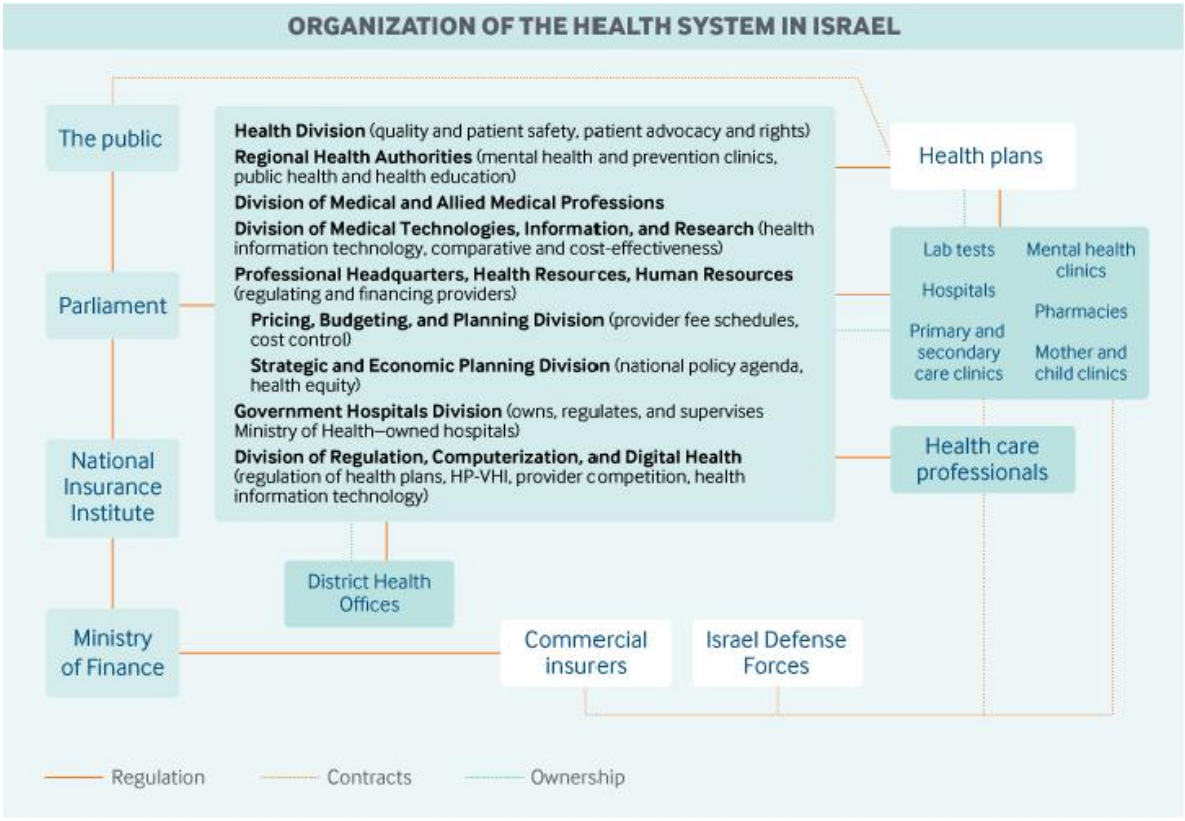

Figure 1: Israel - Organisation of the health system[17]

Health Plans are considered healthcare managers for their members and provide services themselves with either employed staff or through contracting with independent, private and public clinicians and providers (differs among Health Plans), thus care is provided by public and private providers of services including physicians, hospitals, pharmacies and other health care professionals. Similar to Germany and Belgium, both primary care doctors (GPs) and specialists work in community clinics, either in solo or group practices. In Clalit, the majority of primary care doctors are employees, whereas in the other Health Plans, the majority of doctors (both GPs and specialists) are independent with contracts with the Health Plans. The most common form of reimbursement for independent practitioners is quarterly capitation + fee for service. The GP is not a gatekeeper, although access to some subspecialties requires a GP referral (policies differ among Health Plans).

All of the Health Plans have contracts with all of the public hospitals. Payment to the hospital (either by DRG, per diem for inpatient, by visit or by service for ambulatory clinics) by the Health Plan requires Health Plan authorization (either preauthorization for elective or post-authorization for non-elective hospital services). Overall, the Israeli health care system is quite efficient. Health status levels are comparable to those of other developed countries, even though Israel spends a relatively low proportion of its gross domestic product on health care (less than 8%) and nearly 40% of that is privately financed. Life expectancy is 83.3 years– 84.7 years for females and, 81 years for males. Similar to the global ageing rate, Israel is experiencing a rapid rate of elderly population growth. Since 1950, the number of adults aged 65+ has increased 18-fold. Nevertheless, due to the high fertility rate in Israel (3.01), this group constitutes only 12.41% of the population.[18]

[17] Waitzberg R, Rosen B. (2020) "Israel" in International Health Care System Profiles edited by Tikkanen R, Osborn R, Mossialos E, Djordjevic A, Wharton GA

[18] Mainstreaming Ageing in Israel. Permanent Mission of Israel to the United Nations and Other International Organizations in Geneva. Geneva May 2020

Factors contributing to system efficiency include regulated competition among the health plans, tight regulatory controls on the supply of hospital beds, accessible and professional primary care and a well-developed system of electronic health records. Israeli health care has also demonstrated a remarkable capacity to innovate, improve, establish goals, be tenacious and prioritize.[19]

2.1.3 Digitalisation of the health and care system

Israel is considered a pioneer in Health IT, having begun its Health IT implementation in the mid 1980's. Health IT in Israel was Health Plan-driven, resulting in the implementation of comprehensive, shared organization-wide Electronic Medical Records(EMR) in all Health Plans by the mid 1990s, followed by one of the first nationwide teleradiology systems in 1997, and patient portals in the early 2000s, enabling citizens online access to their medical information.[20] The digital health system in Israel is a decentralized system. Each Health Plan and Hospital has its own eHealth system. There is a National Health Information Exchange for sharing EMR data across organizations. It is important to note that there is a national ID number in Israel that is used across the board for everything including healthcare. The National Information Exchange enables hospitals to access Health Plan records for patients being treated on an inpatient or outpatient basis and likewise, the patient's primary care doctor can access information on the care of his patient in the hospital. It should further be noted that doctors and healthcare professionals use the EMR system of their organization – health plan or hospital - so that there is a very limited number of EMR vendors.

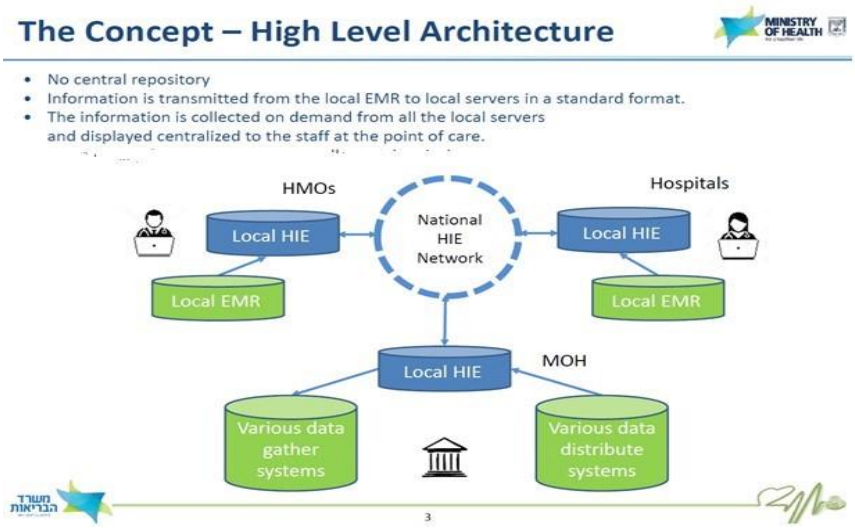

Figure 2: Israel - high level architecture

There is a full E-prescription system in all of the Health Plans via the EMR. E-prescriptions are generated by the doctor in his EMR and sent to the patient with an electronic signature through the patient portal. Prescriptions are simultaneously transmitted to the pharmacy system which dispenses the medications.

All of the Health Plans have Patient Portals that provide patients with access to their medical data. The patient can communicate with his doctor via the portal, including requesting a prescription, a referral or messaging. In most Health Plans, both clinicians and citizens have mobile access to the EMR.

[19] Rosen B, Waitzberg R, Merkur S. Israel: health system review. Health Systems in Transition, 2015; 17(6):1–212.

[20] Peterburg Y. Israel's Health IT Industry: What Does the American Recovery and Reinvestment Act Mean for Israeli Collaborative Opportunities. Milken Institute. 2010. Kaye R, Kokia E, Shalev V, Idar D, Chinitz D. Barriers and success factors in health information technology: A practitioner's perspective. Journal of Management & Marketing in Healthcare. 2010 Jun 1;3(2):163-75.

Due to the fact that the Health Plans have been collecting computerized comprehensive data on the entire population for over 25 years, Israel has been a front runner in “Big Real World“ data analysis based on EMR data and registries at Health Plan and National Level. This has served to create an eco-system in which tech companies including AI companies have thrived and “Big Data” research at the national level is gaining momentum. [21]On the downside, there is still limited data sharing with social services who have not progressed as rapidly in computerizing their systems.

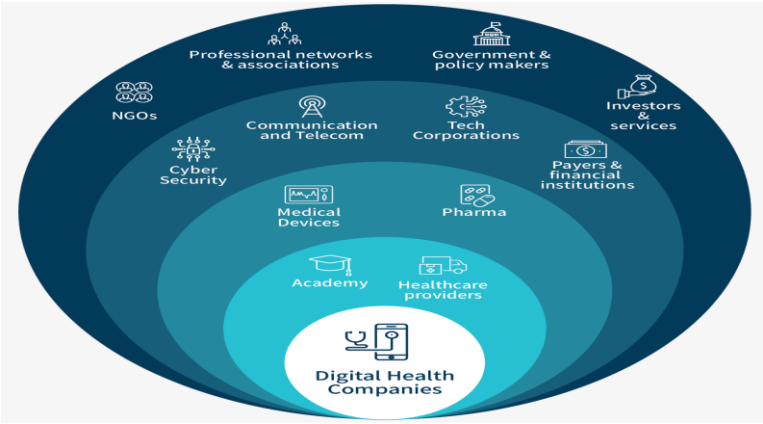

Figure 3: Israel - eHealth Ecosystem

2.1.4 Cultural Aspects

Israel has been “digital” since the mid-90’s so there is a high degree of digital literacy, both at the professional and citizen level. As all of the Health Plans have had organization wide central electronic medical records since the mid-90s, patients take it for granted that all of their doctors have access to their medical information and in fact, are seriously annoyed when their healthcare provider does not access the information (which occurs infrequently). While citizens have the right to “opt out” and limit access to their electronic medical record, it is inconceivable to most Israelis that there would be any value in doing this. They are very used to having access to their own medical information via their patient portal and they expect their healthcare providers to be completely aware of the information when making care decisions. The Ministry of Health’s Project "health in the palm of your hand" reflects this by aiming to facilitate access to a larger and more detailed amount of information for each patient, and by means of expanding the existing information in the online health record, including information coming from organizations that are connected in a secured communication with the Health Plans.[22]

The four NHI health plans (Clalit, Maccabi, Meuhedet, and Leumit) have different approaches to organizing care. Clalit, the largest health plan, provides most primary care in clinics that it owns and operates, and GPs are salaried employees. The typical clinic is multidisciplinary, with three-to six GPs and several nurses, pharmacists, and other professionals. Clalit also contracts with independent physicians who tend to work in solo practices, with some access to administrative and nonphysician services at Clalit district clinics. The other three health plans also use a mix of multidisciplinary clinics and independent primary care practices. In Maccabi (the second-largest plan) and Meuhedet, almost all of the primary care is provided by independent physicians, while in Leumit the clinic model predominates.

[21] A digital quantum leap in the healthcare system: The Ministry of Health’s vision. Israel Innovation Authority. Retrieved from: https://innovationisrael.org.il/en/article/digital-quantum-leap-healthcare-system (last access 12/09/2022)

[22] https://www.health.gov.il/English/News_and_Events/Spokespersons_Messages/Pages/20112018_1.aspx (last access 12/09/2022)

Members of all plans can generally choose their GP from among those on the plan's list and can switch freely. In practice, nearly all patients remain with the same GP for extended periods. Doctors are paid entirely by the health plans; they cannot collect additional fees from their patients.[23]

Approximately one-third of Israel's nurses work in community settings, primarily as salaried employees of the four NHI health plans. Their roles have been expanding beyond traditional routine nursing care.[24] In 2018, the Ministry of Health extended the responsibilities and scope of practice for specialist nurses in the community, to relieve some of the pressure on primary care physicians. Specialist nurses can now treat mild cases of acute diseases and cases that are urgent but simple to treat; treat and monitor patients with chronic diseases; provide preventive care and handle health promotion; and prescribe medications and contraceptives. Specialist nurses can also provide palliative care and refer patients for diagnostic tests, to specialists, and to Emergency Departments.[25]

2.2 Organisational Framework for Telemedicine

2.2.1 Telemedicine service implementation

Telemedicine was first implemented by the Health Plans as early as 1987 and was a direct outgrowth three developments: the implementation of shared electronic medical records, the digitalization of diagnostic services such as the laboratory and imaging and their interface with the electronic medical records, and the shortage of resources that created unnecessary bureaucracy and queues that had a direct impact on the quality and timeliness of patient care and required a more efficient organization of the service process. Implementation of telemedicine in hospitals lagged behind the implementation in the Health Funds by more than a decade, concomitant with the widespread implementation of electronic medical records in hospitals.

2.2.1.1 Telediagnosis

The first telemedicine services to be developed in Israel by the Health Plans were Teleradiology and Tele-laboratory services. X-ray clinics were set up all across the country to save patient travel but there was a shortage of radiologists to interpret them. Therefore, teleradiology diagnostic centres were established in central locations where there was a constant presence of radiologists to interpret the images that were transmitted digitally from the x-ray labs to the centres. Digitalization also enabled the implementation of advanced diagnostic tools. The interpretations were entered into the system and transmitted to the ordering physician's medical records who could then contact his patients and instruct them as to next steps. This also eliminated the need for film which was a substantial cost -savings. Likewise, there were many laboratory collection points, but the processing of specimens was more centralized. The digitalization of the labs enabled the results to be sent immediately to the doctors' medical record, thus avoiding patients having to go to the collection points to pick up the results and then schedule an appointment with their doctor to show him the results. Another early implementation was tele dermatology, whereby nurses in remote clinics using digital cameras to transmit images to a tele dermatology centre for diagnosis and decision for treatment.

[23] Waitzberg R, Rosen B. (2020) "Israel" in International Health Care System Profiles edited by Tikkanen R, Osborn R, Mossialos E, Djordjevic A, Wharton GA.
[24] R. Nissanholtz-Gannot, B. Rosen, and M. Hirschfeld, "The Changing Roles of Community Nurses: The Case of Health Plan Nurses in Israel," Israel Journal of Health Policy Research 6, no. 1 (Dec. 23, 2017): 69.
[25] Ministry of Health, Specialist Nurses in the Community, circular, 136/17 (in Hebrew) https://www.health.gov.il/hozer/ND136_2017.pdf (last access 12/09/2022)

Figure 4: Israel - Teleradiolgy Interpretatio9n Center

2.2.1.2 Teleconsultation and Online services

The second level of implementation of telemedicine was spurred by three additional developments: the movement from shared information from medical records to centralized organization wide medical record platforms, the development of web-based patient portals, and the emergence of mobile technology and the widespread use of mobile phones. These enabled the development of online prescriptions and referrals, online messaging, and making appointments online. More recently, and greatly accelerated by the COVID pandemic, are teleconsultation by telephone and video and telemonitoring using home devices. Remote heart monitoring has been available in Israel since 1987 using home heart monitors, initially transmitted over the phone to a dedicated call centre but now using more sophisticated monitoring devices and transmitting via mobile apps. Call centres are staffed by clinicians 24/7. There are subscription services, paid either out of pocket or by the Health Plan. These services continue to expand their tele-services to include remote electrocardiograms, blood pressure monitors and emergency call devices.

Figure 5: Israel - Remote Monitoring Devices

2.2.2 Supportive digital health infrastructure

There are two main forms of telemedicine – that which takes place in the context of the ongoing relationship between a specific doctor/healthcare professional and his patient, commonplace in the Health Plans but also in hospitals, and call-centre based teleservices – either within a healthcare organization or as a freestanding subscription-based service.

Teleservices can usually be accessed by contacting call centres (by phone or online) and increasingly there are apps for contacting a healthcare professional with a specific problem. Telemonitoring is supported today both by apps with associated devices and increasingly by wearables.

2.2.2.1 Telemedicine – An extension of doctor-patient relationship

The most common form of telemedicine in Israel takes place as part of an ongoing doctor-patient relationship. In the Health Plans, the digital health infrastructure for telemedicine between doctor and patient rests on two main components: the electronic medical record and the patient portal (accessed by computer and mobile app). The vast majority of remote care in Israel between doctors

and patients is mediated by an interface between these two components. The most frequent forms of remote care are tele-prescriptions and tele-referrals. These can be initiated either by the patient or by the doctor, but by and large, patients initiate a request using the patient portal that is transmitted to the doctor's electronic medical record where he creates and then sends the prescription/referral/document with an electronic signature to the patient portal. The second most common form of digitally enabled telemedicine is messaging which works in the same way. Teleconsultations may be initiated by the patient who can make an appointment for a teleconsultation via the patient portal. Telemonitoring as part of ongoing care is increasing and some examples of this are Tytocare (a handheld exam kit and app that enables a patient to perform guided medical exams with a healthcare provider from home including ears, lungs, heart, throat, blood pressure etc,), home ultrasound, cardiac monitoring and foetal monitoring.

2.2.2.2 Teleservices

Teleservices in Israel are generally call centre - mediated and they take different forms. All of the Health Plans operate a number of call centres such as: a call centre for medical advice that is active 24 hours a day, children's healthcare centre, Gynaecology counselling, call centre for Pregnant Women, Breastfeeding Counselling Centre, Smoking Cessation Centre, and Consultation with experts. There are also independent teleservice centres, predominantly focused on high-risk elderly and cardiac patients and have a strong telemonitoring component, now supported by apps and related devices, and more recently by wearables, although the most frequent use of wearables is still for self-monitoring.

2.2.2.3 Project level organization

Innovation in Digital Health in Israel, including telemedicine, is a national commitment to global leadership with multiple players from top government, healthcare providers and tech and industry partners. The investment in digital health innovation is not only at the project level, but in active promotion of partnerships between healthcare providers and industry.

For example**, HealthIL** is a non-for-profit digital health innovation ecosystem - a joint venture of the Israel Innovation Institute, Israel's Ministry of Economy, Digital Israel at the Ministry of National Digitization, Israel Innovation Authority and Ministry of Health.

HealthIL supports innovation management for healthcare stakeholders, engaging entrepreneurs in the field of healthcare innovation, and bridging the gap between the tech community and the public health sector.

Investment in eHealth innovation comes from a number of sources including government (the Ministries of Heath, Economy and Industry), **the Israel Innovation Authority**, venture capital, multinational corporations and international R&D such as the European Research Framework, US and Canadian R&D funds.

The Israeli Telemedicine Community (ITC) was established in August 2020 by the Digital Health Division of the Ministry of Health, in which the representatives of the health organizations share, learn and work to promote the effective and responsible use of remote medicine services in a variety of fields including research on the use of remote medicine.[26]

[26] https://www.gov.il/he/departments/news/16092020_04 (last access 12/09/2022)

2.3 Legislation and regulation for telemedicine

2.3.1 General scope of the services

In Israel, telemedicine is defined as "Remote Health Services - a session performed by technological means and through electronic communication for the purpose of providing health services between an identified patient and caregiver, not necessarily in the same place and time."[27] As such, it is a subset of digital health.

There is no general definition of "digital health" in Israel. However, the definition can be derived from the government's "National Digital Health Plan as a Growth Engine" approved on 25 March 2018, that defines digital health as follows: "The vision of the digital health strategy as published by the Ministry of Health is to enable a leap in the healthcare system so that it will be a sustainable, advanced, innovative, renewable and constantly improving health system, by leveraging the best available information and communication technologies."[28] The key technologies in digital health in Israel include digital tools and platforms that support healthcare professionals' management of patient care, digital tools and platforms that enable consumers to proactively track and manage their own medical conditions, as well as digital tools of remote monitoring, decision support, clinical workflow, diagnostics, patient engagement and assistive devices.

From an overall legislative perspective, the following general regulations for healthcare in general apply to digital health as well all healthcare provision and provide the regulatory framework within which regulation for digital health and telemedicine has evolved:

- National Health Insurance Law, 1994.
- Public Health Ordinance, 1940.
- Public Health Regulations (Clinical Trials in Human Subjects), 1980.
- Patients Rights Law, 1996.
- Public Health Ordinance (Food) (New Version), 1983.
- Protection of Privacy Law, 1981 and Protection of Privacy Regulations (Data Security), 2017.
- Class Actions Law, 2006.

The provision of digital health services is currently not regulated by law. However, the Ministry of Health (MOH) has published several circulars that specifically address and regulate some areas of digital health and telemedicine[29] pursuant to its "Digital Health Strategy" document in April 2017:

- Regulation for the use of health data (goals, manner of use, users, transparency).
- Regulation for the use of remote medical care (the manner in which the service is provided and service provider obligations).
- Regulation for the access of personal electronic health record files by patients. On 19/11/18, the Ministry of Health published a circular promoting, encouraging and regularizing making medical information accessible to patients in a digital fashion.[30]
- Regulation for determining the minimum content of the electronic health records.
- Regulation applying to outcome measures of health data, which collect and monitor health data.

[27] General Director Circular No. 6/2019 on Standards for Provision of Telemedicine Services dated June 26, 2019, Israel ministry of Health, translated from the Hebrew at https://www.health.gov.il/hozer/mk06_2019.pdf by the author (last access 12/09/2022)

[28] https://www.health.gov.il/About/projects/DigitalHealth/Pages/default.aspx (last access 12/09/2022)

[29] https://www.lexology.com/library/detail.aspx?g=2ebc7677-043e-4f68-a07d-cb3ee60e73c8 (last access 12/09/2022)

[30] https://www.health.gov.il/English/News_and_Events/Spokespersons_Messages/Pages/20112018_1.aspx (last access 12/09/2022)

- Regulation for the development and maintenance processes of clinical information systems.
- Regulation for aspects of cyber protection of data.[31]

Specific regulations for telemedicine are in The General Director Circular No. 6/2019 on Standards for Provision of Telemedicine Services (2019) as well as a supplement to the Circular on remote health services in hospitals. The purpose of the Circular is to set standards for providing health services remotely to ensure a high quality, accessible and available health service to patients. The regulation applies to healthcare organizations, mainly the four Health Plans that operate under the National Health Insurance Law, as well as other healthcare organizations such as hospitals and clinics that fall under the jurisdiction of the Ministry of Health.

2.3.2 Eligibility of professionals, healthcare organizations to provide services

As aforementioned, the responsibility for the provision of telemedicine rests upon duly recognized healthcare organizations such as Health Plans and hospitals. The eligibility of professionals to provide services is within the context of their healthcare organization with which they have a contract or are employed.

2.3.2.1 Healthcare Organizations

The Management of the health care organization is responsible for determining whether the service provided remotely is appropriate and must approve its operation, detailing the situations for when it is appropriate to provide the service remotely and when it is not appropriate and requires a physical meeting. The health organization may not close or reduce the existing availability of parallel physical services or refrain from developing such services in the necessary places by virtue of the availability of the service remotely. It is recommended that the service be provided in a hybrid fashion – a combination of physical service and remote service, depending on the patient's preference and medical needs.

2.3.2.1.1 Telemedicine Service Portfolio

Prior to operating the service, the organization must formulate a detailed Telemedicine Service Portfolio that will be available to the Ministry of Health upon demand and includes the following:

- Detailed description of the service. If the service is one for which there is a regulation requiring co-payment by the patient, it must be specified.
- Type of patients targeted for the service.
- Alternative services that exist in an outpatient or ambulatory framework and details of the advantages and disadvantages as well as risks of providing the service remotely compared to the existing alternatives and services.
- The use of this service or a similar service in remote health services in other countries around the world, to the extent that such information is available.
- Established research evidence from Israel and abroad, if available, relating to the efficacy and safety of said service.
- Confirmation of registration in the Medical Equipment Register in the Ministry of Health, of medical equipment and technologies to be included in the service, if they require registration.
- Means of securing information in the service and means of transmitting medical and professional content electronically.
- Identity of the professional manager in charge of the Telemedicine service.
- The professional training of the therapists, in particular, their unique training in providing remote medical services.

[31]Bareket E., Cohen A. "Israel" Chapter 13 in Digital Health 2022 eds: Roger Kuan, Norton Rose Fulbright. Published by Global Legal Group, London.

- Safety procedures, and particularly guidelines for medical conditions that may not be diagnosed or treated using remote medical technology and for which it is required to refer the patient to a physical meeting
- Adaptation of the type and quality of the technological devices used for the diagnosed medical conditions.
- Defining quality control and security procedures with an emphasis on working in accordance with service procedures, reporting exceptional cases, quality of documentation in the medical record and maintaining the continuum of treatment.

2.3.2.1.2 Management of the Telemedicine Service

The healthcare organization must appoint a professional manager who will be in charge of the telemedicine service. If doctors provide the remote health services, the professional manager will be a recommended specialist in the field of service provided. If nurses or other healthcare professionals provide the service, the professional manager will have a license and vocational training in the same field of service. The professional manager is responsible for the conduct of the service in all legal and professional aspects, including:

- Establishing work procedures, implementing them and controlling their implementation.
- Ensuring that the service providers are trained to provide the service remotely and operate in accordance with the professional procedures in the service.
- Performing professional monitoring on the work of caregivers, maintaining processes to improve the quality and safety of care, managing risks and reporting exceptional events, conducting investigations and producing lessons learned.
- Managing a medical record according to the law.
- Implementing procedures for maintaining the continuum of treatment with the patient's personal physician in the Health Plan.

2.3.2.1.3 Additional Requirements for Telemedicine provided by Hospitals

The addendum to the Circular on hospitals addresses questions about how to operate remote medical services in hospitals, with an emphasis on the economic relations between hospitals and Health Plans. The policy of the Ministry of Health is that remote health services should be encouraged and developed both in the community and in hospitals in accordance with the following guidelines:

- Hospitals may offer remote health services to Health Plan insured members for any medical service and for which the insured member receives a preauthorization form from the Health Plan (as is required for any hospital service).
- The waiting time for the service will not be longer than the duration of waiting time for the physical service.
- The hospital will make sure that there is a written summary of the virtual visit that will be transferred to the Health Plan.
- If, during the visit, the therapist concludes that it is not possible to provide/complete the necessary treatment in the framework of the virtual visit and a face-to-face meeting is needed, an appointment will be made for a physical visit in as short a period of time as possible according to medical priority. The total waiting time (virtual visit + physical visit) may not exceed the waiting time of an average visit at the relevant clinic in the same hospital.
- For such a physical visit (i.e., a visit that is required because the treatment cannot be provided in the framework of a virtual visit) the hospital will not charge an additional fee to the Health Plan or the patient.
- Hospitals will establish a field for "virtual visit" in their computer system that for billing the Health Plan.

2.3.2.2 Professionals

All professionals providing remote services must have a valid Israeli license or recognition of status by the Ministry of Health.

- Doctors: Doctors with a specialty in the field of service provided.
- Nurses: Qualified nurses, with recognized training in specific fields, in accordance with the guidelines of the Nursing Directorate at the Ministry of Health.
- Healthcare Professionals: with a valid Israeli license and recognized training in their field

The professional's responsibility in the framework of remote health services is the same as his responsibility in a physical session and includes:

- Professional responsibility for the quality of the treatment and its safety.
- Documentation of the encounter in the computerized medical record.
- Referring the patient for a physical examination, in cases that require it.
- In a medical emergency as defined in the Patient's Rights Law 1996, the healthcare professional must immediately contact the rescue and emergency services authorized in Israel and call for assistance to the patient.
- Referring the patient for medical advice on a problem that requires an examination by a consultant from another field.

Unique training is required for the provision of remote health services for all professional managers and therapists in the service. Required training topics will include:

- Characterization of situations in which diagnosis and treatment in the absence of a physical examination of the patient can be performed and situations in which this is not acceptable.
- Familiarization with the technology employed in the service, including advantages, limitations, how to use it correctly and solve simple problems. Experience and actual use of technology must be included.
- Patient caregiver relationships: Communication through technological means, how to verify understanding of the medical instructions by the patient, aspects of confidentiality and medical confidentiality.
- Ethical and legal issues: including medical responsibility, the principles of documentation and registration unique to the service, aspects of privacy and privacy in the use of technology and service.

2.3.3 Eligibility of patients to receive telemedicine services

From the perspective of national regulation, there are no limitations to a patient's eligibility to receive telemedicine services. However, health care organizations may define categories of patients or specific situations for specific types of patients for which telemedicine services are deemed inappropriate from a medical or safety perspective. Healthcare organizations are responsible for informing patients as to whether a telemedicine service is available to all or available to specific patient populations. Remote services provided on a healthcare organization's patient portal such as tele-prescriptions, tele-referrals, chats/messaging are available to all patients. Likewise, all patients have the right to request a teleconsultation with a professional as opposed to a physical visit. However, it is the responsibility of the healthcare professional to assess and determine that a tele-visit is medically appropriate for a given patient.

2.3.4 Security and safety of the service

Any provider of telemedicine must ensure the use of a secure system at the security level that corresponds to the type of service, as is customary. Health service providers in Israel must be certified in international information security standards 27799 ISO and ISO 27001. It is the responsibility of the

service provider to ensure frequent and regular operation of monitoring and control processes for the technicalities of connection to the site.

The provider of the telemedicine service is responsible for verification of the patient's identity: A remote health services system must include a mechanism for identifying the professional providing the service and identifying the patient with a high degree of certainty, with varying levels of identification and by techniques appropriate to the circumstances and the type of action performed. The act of Identification will be recorded in the system. All the levels of identification must take into account all of the following:

- The level of identification that exists in the treatment of the same type, when it is not performed remotely.
- Existence or lack of prior (direct) familiarity between the therapist and the patient, or between the therapist and another therapist.
- The type of visit and type of action performed, with an emphasis on the degree of risk to the patient if the identification is incorrect.
- The degree of medical urgency in the execution of the treatment, and the risk of delaying the service in order to verify identification.

2.3.5 Liability of health professionals and of technical operators

There is no specific legislation for liability relative to digital health; hence, general tort law applies. This includes, primarily, the tort of negligence and the regime of strict (no fault) liability under the Defective Products Liability Law, 5740-1980. Breach of contractual warranties may also come into play. Professional and legal responsibility for the actions of the service providers in the framework of remote health services is identical to professional and legal responsibility in the provision of physical health services. Use of the service from abroad as part of the treatment of the patient in Israel must be provided by therapists with an Israeli license, who meet the requirements of all professionals providing telemedicine services.

2.3.6 Data Governance

Data governance for telemedicine is the same as data governance for face-to-face medical care. Since, from the perspective of Ministry of Health regulation, telemedicine is provided by authorized health organizations, it is expected that all forms of telemedicine will be documented in the organization’s electronic medical record. All Health Plans and hospitals have organization wide electronic medical records. The management of the medical record must be carried out according to law (as noted earlier there is regulation for determining the minimum content of the electronic health records). The patient must be given a written summary of the session performed, referrals for further treatment, prescriptions and approvals, in accordance with the standard in the field of treatment and in accordance with the manner of transfer agreed with him. As all citizens are members of one of the four national Health Plans, follow up care after a telemedicine encounter within the context of the Health Plan, such as prescriptions and referrals, will be transmitted from the clinician’s electronic medical record to the patient through the patient portal. If, as a result of a teleconsultation, there is a referral to the Emergency Room (ER), referrals to the ER must be sent to the patient and in addition directly to the ER to which the patient is expected to arrive, in accordance with the agreement with him. The urgency must be recorded in the record.

In order to maintain the continuity of treatment, it is recommended to allow access for all caregivers in the telemedicine service to the patient's medical record, subject to his consent. In addition, if possible, it is recommended to allow access to information from the medical record in the patient’s Health Plan [relevant for hospitals and free-standing teleservices], subject to the patient's consent. As all Israeli citizens have de facto given their consent to provide access to their medical information to all clinicians associated with their Health Plan, if the telemedicine is being carried out within the

context of the Health Plan, this would be automatic. The question arises when the patient is using a standalone telemedicine service such as subscription telemedicine services monitoring cardiac patients or elderly patients at risk. As a rule, at the time of subscription, patients are asked to identify their personal physician and any other relevant physician and to consent to sharing his data (generated as a rule by biometric devices transmitting data to the service's telemedicine centre as well as any interaction with call centre staff).

2.3.7 Standards of care

Most of the medical/professional standards of care have been addressed in the preceding sections. Overall, it is expected that the same standards that apply in a physical encounter will apply to telemedicine. The qualifications of professionals providing telemedicine services are enumerated in detail in 3.2.2 above, including specialty certification and specific training in the use of telemedicine. Documentation in the medical record is the same with the additional requirement of a specific summary of the teleconsultation for the patient. The issue of waiting times for a teleconsultation, or a resulting physical consultation in a hospital is addressed in paragraph 3.2.3. Overall, the Circular on Telemedicine focuses predominantly on standards of care for Telemedicine.

However, there are some additional service -related standards for the service providers not mentioned above that apply to all providers of telemedicine services, whether it be the Health Plans, the hospitals, or freestanding teleservices:

The service provider is responsible:

- to establish ongoing work procedures, including procedures for operation in cases of a communication failure event
- to ensure that the equipment used is registered under the Medical Devices Law (AMAR)
- to ensure that a response is available for solving technical problems for professional staff and patients
- to ensure compliance with information security requirements
- to ensure compliance with procedures for implementing new technologies
- to ensure the accessibility of the service to users, including disabled and linguistic accessibility
- to ensure the training of the staff in the framework of dedicated training as required (previously mentioned)
- to ensure the existence and management of a computerized medical record
- to ensure the transfer of necessary medical information and the existence of a therapeutic continuum, especially with the personal doctor in the Health Plan
- to appoint a professional manager for the service (previously mentioned).

2.3.8 Reimbursement and Financing

2.3.8.1 Financing

Financing for telemedicine can be divided into 2 main types: ongoing financing and project – specific/investment financing.

2.3.8.1.1 Investment Financing

There is a significant amount of project- oriented or investment financing in Israel to encourage telemedicine development and implementation within the context of promoting digital health in general. This was accelerated greatly by the COVID pandemic during the past 2 years. Investment in eHealth innovation comes from a number of sources including government (the Ministries of Heath, Economy and Industry), the Israel Innovation Authority, venture capital, multinational corporations and international R&D such as the European Research Framework, US and Canadian R&D funds. Investment at the national level is government financed.

2.3.8.1.2 Ongoing Financing

The majority of eHealth financing is at the Health Plan and Hospital level that have yearly budgets for both development and maintenance of their eHealth systems. During the COVID pandemic, this was supplemented by additional government funds, but this was an exceptional situation. The Health Funds, as a rule, do not receive any additional financing for offering telemedicine service as, from a financial perspective, telemedicine is not perceived as any different from regular services, many of which are in any case digitally enabled. Likewise, collecting co-payment by the Health Plan from the patient for remote health services may not exceed the approved amount for the same service, when it is provided face-to-face with the patient and will be managed according to the same conditions. The extent of Digital Services made available by a Health Plans to its members is a significant part of its attractiveness, in competition with other Health Plans. Competition among Health Plans is a key element of the system and is a great motivator for maintaining and improving service excellence.

2.3.8.2 Reimbursement

Reimbursement of service providers for medical services of all kinds for all services in the public basket of services is the direct responsibility of the Health Plans. Overall, there are 3 types of service providers that are reimbursed: hospitals, individual professionals, and private clinics or clinical service companies.

2.3.8.2.1 Public hospitals

The Ministry of Health has a fee schedule for public hospitals. Health Funds may enter into contracts for discounts on these fees with specific hospitals, although the freedom to do so has been seriously constrained in recent years. As noted above, the fees for telemedicine services in hospitals are essentially the same as the fees for the same service provided physically.

2.3.8.2.2 Private Hospitals and Clinics

Private hospitals and clinical service companies negotiate fees with the Health Plans for services, including telemedicine services.

2.3.8.2.3 Doctors and other Healthcare Professionals

Professionals may be employees or independent contractors. If they are employees, providing the telemedicine service is just a part of their regular salary. If they are independent contractors, the fees for providing a service is the same whether provided physically or remotely. The principle is that a "visit is a visit is a visit" regardless of how it is provided. This principle was established, particularly for doctors, in the very early days of remote care such as providing tele-prescriptions based on the premise that provision of the service mainly benefits the patient, and that the doctor bears the same responsibility regardless of how the service is provided. For example, tele-prescriptions require that the doctor review the medical record before prescribing and the act of generating the prescription from the medical record is the same – whether the patient is or is not physically present.

2.3.9 Ethical guidelines Patient consent to be treated with telemedicine

2.3.9.1 Patient consent

Before providing the service remotely, the service provider must receive an informed consent document from the patient, which will detail the following topics:

- How to identify the service provider and the recipient of the service.
- The essence of the service offered
- Limitations of the service provided compared to face-to-face service.
- Limitations of the system in the areas of privacy and medical confidentiality, and the
- possibility of communication failure events
- The patient should be informed that in case of an urgent problem, emergency or
- situation of distress (physical and/or mental) the patient should seek immediate

- medical attention at the nearby hospital's EMR or at another medical center that provides emergency medical services.
- The patient must be informed that when entering the health service system remotely, the information that appears on the personal digital monitor may be exposed to those around him, and that the responsibility for maintaining the confidentiality of the medical information, which appears in the service system on the personal digital monitor, is in his hands, including preventing access to information and/or service to those who are not authorized by him.
- The payment involved in receiving the service.

2.3.9.2 Privacy

In general, the Authority for Law, Technology and Information (responsible for, among other things, the protection of privacy) is the entity responsible for regulating, monitoring and enforcing Israeli privacy laws, including personal data in digital databases. This would apply to any medical data used for purposes of telemedicine. As mentioned above, uses of health data and collaborations involving health data are also regulated and monitored by the MOH. The courts have jurisdiction over all issues.

2.3.9.3 Equity

Equity in healthcare is an overall challenge of the healthcare system. There are geographic disparities as well as socioeconomic disparities. Reducing inequality in Health is a major strategic goal of the Ministry of Health, with a clear action plan as described in the Ministry's Strategic Plan to Reduce Inequalities in Health. Telemedicine is viewed as an important mechanism for reducing inequality in access to health services.

Digital literacy is an additional factor for inequality. However, Israel has been "digital" since the mid-90's so there is a high degree of digital literacy, both at the professional and citizen level. Health Plans and Hospitals have structured courses as well as online support for all clinicians, healthcare professionals and administrative staff in the use of all Health Plan and Hospital Digital systems. Health Plans provide instruction and online support for their members in using the patient portals and other digital systems including kiosks for populations that do not have computer access. Doctors and HCPs strongly encourage their patients to use the Health Plan digital systems.

The National Digital Program of the Government of Israel is also driving digital literacy forward. The Ministry for Social Equality is focusing on digital literacy for the population from the geographic and social periphery who may suffer from less access to advanced infrastructures and end-user equipment, and from a lack of digital and technological skills.

The Israel Internet Association (ISOC-Il) has been working to reduce the digital divide among communities, including the elderly, children at risk, and the Arab society in Israel since 2000.

2.3.10 Legal and Ethical Challenges to date

The Israel Ministry of Health is currently reviewing its regulations for digital health and telemedicine in view of the rapid growth of new technologies in Israel and abroad. Some of these new technologies may raise new challenges. Legal and ethical issues such as: informed consent (information about the risks and benefits of remote therapy) and autonomy, patient privacy and confidentiality, data protection and security, malpractice and professional liability/integrity/equity of access, quality of care and the professional–patient relationship continue to be of concern although they are all largely addressed by the current regulation. Probably the greatest challenge facing telemedicine in Israel is not legal or ethical but practical. Remote care such as tele-prescriptions and tele-referral are routine and taken for-granted. However, for teleconsultation, professionals and patients still overwhelmingly prefer face-to-face encounters, supplemented predominantly by telephone conversations between visits and to an increasing extent, messaging. If there is a major legal and ethical challenge – it is instant messaging using platforms such as Instant Messenger and WhatsApp. These are user friendly,

for even those with limited digital literacy, and are being used increasingly because they are so easy to use, but they are completely unmonitored by the healthcare system and leave no trace in the electronic medical record. While some healthcare systems (such as the NHS) have come out strongly against their use for healthcare, it is virtually impossible to stem the tide. In a cross-sectional study based on an anonymous web-survey conducted among Primary Care Physicians (PCPs) and medical specialists working in the Israel Défense Forces Medical-Corps during September and October, 2019, it was found that 86.9 % of Primary Care Physicians (PCPs) and 86.5 % of specialists used WhatsApp every day in professional settings. Added workload, potential breaching of patient confidentiality and lack of full documentation of consultations were the main concerns among physicians using the application. However, 60.7 % of PCPs and 95.7 % of specialists stated that these consultations have reduced the need for in-person appointments at least once a week.

3 Country – Germany

3.1 Context

3.1.1 Country profile

In the Federal Republic of Germany, a total of 83.2 million people were registered in 2021, of whom just under 79 million were considered to have health insurance. Of these, 69.8 million - almost 90 % - had statutory health insurance (SHI) and 8.8 million people had private health insurance (PHI) (Bundesministerium für Gesundheit, 2021, pp. 9, 108).

Looking at the variety of different health insurers, it can be observed that the numbers have been declining significantly for years, especially in the SHI-system. Currently, there are a total of 103 statutory and about 50 private health insurances in Germany (2021) (Bundesministerium für Gesundheit, 2021, p. 111). Together, they achieved a new peak in health care spending in 2020 with a total of 441 billion €. This corresponds to a share of 13.1 % of the gross domestic product (GDP) and means an average health expenditure of just under 5,300 € per inhabitant in Germany (Destatis, 2022). In the field of medical care, more than 400,000[32] physicians were employed in 2021, of which about two-thirds[33] were employed in the inpatient sector and one-third[34] in the outpatient sector (Bundesärztekammer, 2021, p. 10). Looking at Germany as a whole, almost 2,000[35] hospitals with a total of about half a million[36] beds are available for the inpatient care of patients, although these figures have declined slightly in recent years (Bundesministerium für Gesundheit, 2021, p. 98).

3.1.2 Healthcare System

Germany has a dual health insurance system consisting of two parts: SHI and PHI. The SHI operates on an apportionment procedure with the health insurance funds covering the costs of health care expenses incurred (defined by the G-BA in the SHI benefits catalogue). In contrast, PHI operates according to the capital cover method. PHI insured must pay for the costs of health care expenses, which they are subsequently reimbursed by PHI (cost reimbursement principle) (Bäcker and Kistler, 2020). Within the framework of PHI, not only supplementary and additional insurances, but also full insurances (full health cost insurances) are concluded.

[32] 416,120 employed physicians in Germany (2021)
[33] 214,845 physicians in the outpatient sector (2021)
[34] 163,805 physicians in the inpatient sector (2021)
[35] 1,914 hospitals in Germany (2019)
[36] 494,326 total number of beds in hospitals (2019)

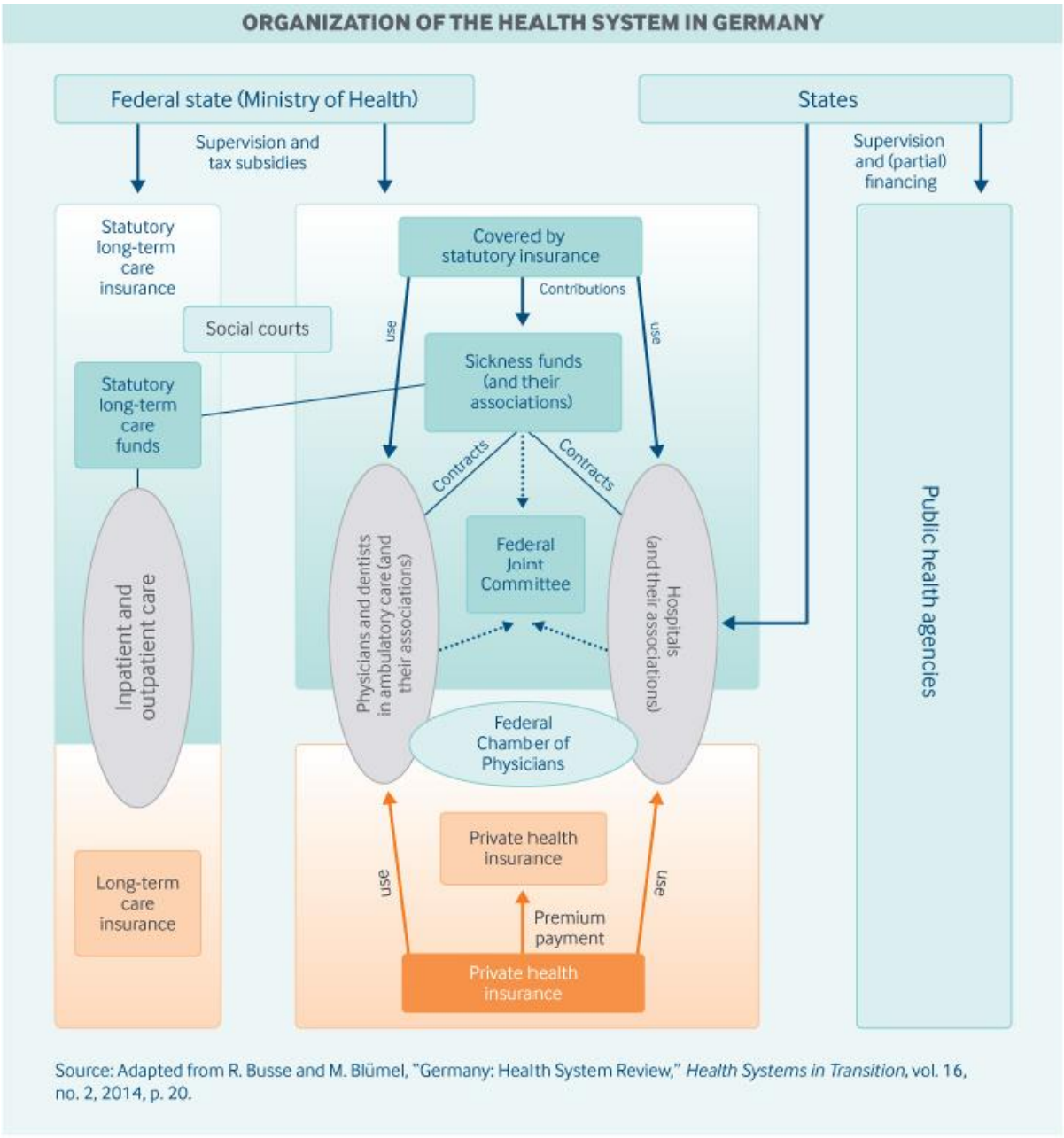

Figure 6: Germany – Organisation of the health system[37]

Basically, among other things, the amount of an insured person's annual income determines whether he or she is exempt from so-called compulsory insurance and wishes to take out voluntary statutory or private insurance[38] (Bundesministerium für Gesundheit, 2022b). According to current figures for 2022, 10.5 % of the population had PHI and about 88 % had SHI (vdek, 2022).

The GKV system is based on the following principles (Krankenkassennetz.de, n.d.):

- Principle of self-administration → as a public corporation
- Principle of benefits in kind → insured persons receive services whose costs are borne directly by the insurance companies

[37] Blumel M, Busse R. (2020) The German Health Care System in International Profiles of Health Care Systems ed: Roosa Tikkanen, Robin Osborn, Elias Mossialos, Ana Djordjevic, and George Wharton.

[38] > 64,350 € annual income (2022)

- Principle of economic efficiency → assumption of costs in accordance with § 12 SGB V for sufficient, appropriate and economic services
- Principle of solidarity

Here, in addition to the employers, all those with SHI pay monthly percentage and thus income-dependent contributions, which are pooled in a health fund, from which the health services of each individual member of the SHI are consequently paid. In summary, the German health care system is a **social health insurance system** based on the **Bismarck model**, in which there is a free choice of health insurance and regulated competition between health insurances (e.g. a health insurance-dependent additional contribution) (AOK-Bundesverband, n.d.; Gerlinger, 2017).

3.1.3 Digitalisation of the health and care system

Looking at the Digital-Health-Index by Bertelsmann-Stiftung from 2018, Germany is at the bottom of the list in 16th place out of 17 countries in the OECD/EU with a score of 30 (Bertelsmann-Stiftung, 2022).

Country	Average of Index Ratings	Policy Activity Index Rating	Digital Readiness Index Rating	Actual Use of Data Index Rating
Estonia	81,93	88,06	86,05	71,67
Canada	74,73	87,34	71,58	65,28
Denmark	72,47	80,81	65,96	70,65
Israel	72,45	78,50	69,49	69,35
Spain	71,35	73,83	76,92	63,31
NHS England	69,98	78,14	72,54	59,26
Sweden	68,26	79,92	67,37	57,5
Portugal	67,19	72,04	68,63	60,89
Netherlands	66,05	85,16	51,79	61,2
Austria	59,82	78,82	60,72	39,91
Australia	57,31	60,34	64,39	47,19
Italy	55,81	73,57	56,59	37,28
Belgium	54,67	73,77	53,68	36,57
Switzerland	40,62	63,91	43,96	13,98
France	31,61	39,93	33,17	21,72
Germany	30,02	44,16	30,08	15,83
Poland	28,53	47,96	25,86	11,76

Figure 7: Germany - Digital-Health-Index 2018 (Bertelsmann-Stiftung, 2022)

The legal foundations for the introduction and application of telemedicine in Germany were mainly launched in the last legislative period (2018-2021). Some important milestones regarding the legal anchoring of digitization in the healthcare system are presented in the following table:

Year in effect	Shortcut	Name	Brief description
12/2015	E-Health-Act	Act for secure digital communication and applications in the healthcare system	• 1st foundation stone for the establishment of a secure telematics infrastructure (TI) • Enables introduction of digital health applications (DiGA)
05/2019	TSVG	Appointment Service and Supply Act → Act for faster appointments and better care	• Obligation of health insurance companies to offer an electronic patient record (ePA) for their patients starting in 2021 • creates prerequisites for the electronic certificate of incapacity for work (eAU)
08/2019	GSAV	Act for more safety in the supply of medicines	• Gradual introduction of the electronic prescription (e-prescription)
12/2019	DVG	Digital Supply Act	• Entitlement of people with statutory health insurance to DiGAs (can be prescribed) • Expansion of the digital network in the healthcare system is ensured • Definition of IT security requirements through standards
10/2020	PDSG	Patient Data Protection Act → Act on the Protection of Electronic Patient Data in the Telematics Infrastructure	• Regulations on ePA & e-prescription & Patients get a legal right to digital care • Pharmacies & hospitals to be connected to the TI on a mandatory basis • Requirements for the TI in Germany (including data protection)
10/2020	KHZG	Hospital Future Act	• Promoting & improving the digital infrastructure in hospitals
06/2021	DVPMG	Digital Supply and Care Modernization Act	• Expansion of telemedical applications in care & modern networking in the healthcare sector • transfer of data to the ePA (e.g. electronic emergency) • future financing of digital care applications (DiPAs)

Figure 8: Germany - Overview of the most important legal sources in the context of digitization in healthcare in Germany, own illustration according to: (Bundesministerium für Gesundheit, 2022b; Interoperabilitäts-Navigator (INA), n.d.)

At the end of 2015, the E-Health Act passed for secure digital communication and applications in the healthcare system. This first milestone enabled the monitoring of patients with a defibrillator or CRT system to be included in the EBM (public finance scheme in Germany) as the first telemedical service in 2016 (Kassenärztliche Bundesvereinigung, 2022a).

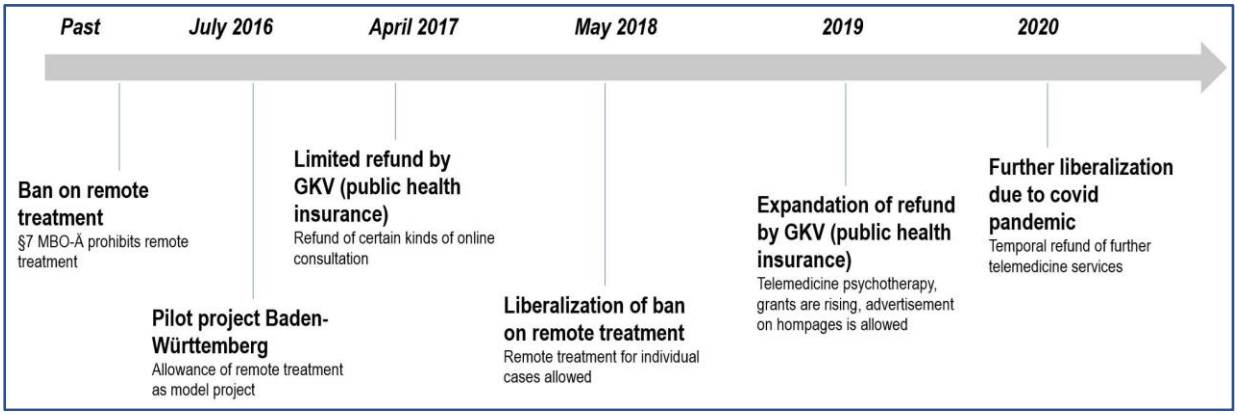

Figure 9: Germany - The implementation of telemedicine organization in Germany was not possible until 2018, own illustration according to (Silberzahn et al., 2020)

At present, there is still no universal definition of *telemedicine* in Germany. One possible definition from the working group Telemedicine, adopted by the Board of the German Medical Association, is: "*Telemedicine is a collective term for various medical care concepts have in common the basic approach that medical services of healthcare for the population in the areas of diagnostics, therapy and rehabilitation as well as in medical decision-making advice over physical distances (or time delay) can be provided. Information and communication technologies are used here.*" (Bundesärztekammer, 2015, p. 2).

See also the corresponding table below:

eHealth		examples
eCare	health care	teleconsultation, telemonitoring/remote patient management
eAdministration	Administrative processes	eGK, eDoctor's card, electronic files, ePrescription
ePrevention	Prevention	Age-appropriate assistance systems, coaching
eResearch	Research	Genome research using ICT, Internet trend analyzes (e.g. Google Flu)
eLearning	Teaching	blended learning via platforms (e.g. ILIAS)

Figure 10: Germany - Explanations of eHealth terms, own illustration according to (Bundesärztekammer, 2015)

3.1.4 Cultural aspects

Germans – in comparison with other European nations – are an outlier when it comes to value on protection of their privacy (European Union Agency for Fundamental Rights, 2020). The cultural significance of data protection in Germany is expressed by its constitution's core articles. The principle of practical concordance applies in the landscape of the following German laws: Right to informational self-determination, right to protection of life and physical integrity, academic freedom, general prohibition of processing sensitive data (with certain exceptions) (Möhring, 2022). Despite the value of protection of their privacy, the population has a positive attitude towards digital health (Bitkom Servicegesellschaft mbH, 2021). Also, patients broadly trust in security of health data (gematik GmbH, 2021). In comparison to patients, healthcare professionals are more hesitant when it comes to the use of digital technologies for their work. Even if digital tools are broadly used in outpatient care, the trust in digital tools of professionals is limited(Albrecht et al., 2021; gematik GmbH, 2021).

The German healthcare system evidences a strong hierarchy between doctors and nurses/MFA (medical assistants) that is reflected by an imbalance of wage, societal view and educational degree in favor of the doctors (Ärzteblatt, 2011). Both nurses and MFA have gained more power by the following developments: A rising number of nursing classes at universities promotes the academization of nursing. Internationally, the aim is to achieve an academization rate of around 15 to 20 percent within nursing. In Germany, this rate is currently around one percent (Ärzteblatt, 2021). Also, reasons like staff shortage, economic requirements and organizational developments demands delegation and substitution of medical activities to nurses and MFAs. In 2013, an agreement was concluded on the delegation of medical services to non-medical staff in outpatient contractual medical care[39]. Delegation presupposes the presence of the physician or his availability at short notice in the practice or hospital. Section 63 (3 c) SGB V enables the substitution of medical tasks by nursing care within the framework of model projects (Ärzteblatt, 2015).

The outpatient healthcare sector is characterized by a rising number of employed physicians. The number of employed physicians doubled in the last ten years. In 2020, nearly a third of outpatient physicians were employed (Statista, 2022).

3.2 Organisational Framework for Telemedicine

3.2.1 Telemedicine service implementation

The gematik is the central provider of telemedicine infrastructure (TI) on a national level (gematik GmbH, 2022). It was founded in 2005 by the public healthcare system in order to implement an electronic health card in Germany. Today, the legal mandate of gematik includes the introduction, operation and further development of the telematics infrastructure, the electronic health card and associated specialist services and so-called other services for communication between healthcare professionals, payers and insured persons.

[39] In accordance with § 28 (1) Sentence 3 SGB V

Gematik tasks[40] in particular (gematik GmbH, 2022a):

- Regulation of functional and technical specifications as well as a security concept,
- Defining the content and structure of the data records to be used,
- Creation of the specifications for the secure operation of the telematics infrastructure,
- Ensuring the necessary testing and certification measures
- Defining the procedures for managing legally regulated access authorizations and controlling this access
- Approval of components, services and providers

In order to fulfill their tasks, gematik has defined six supporting pillars (gematik GmbH, 2022b):

1. Electronic Identities (Federal Identity Management)
2. Internet access and mobile use (universal availability)
3. Distributed Services
4. Structured data and standards
5. Modern security architecture
6. Common TI Rules

The gematik acts as the provider and central hub of a developer ecosystem. In this ecosystem, interested parties (mostly private companies) can use the application infrastructure and telematic infrastructure of gematik to build their own applications for different markets (see diagram below). A developer (company) could – for example – use the specification and technical elements of gematik's Electronic Patient Record to develop an application that is secured by and connected to gematik's telematic infrastructure's identity management.

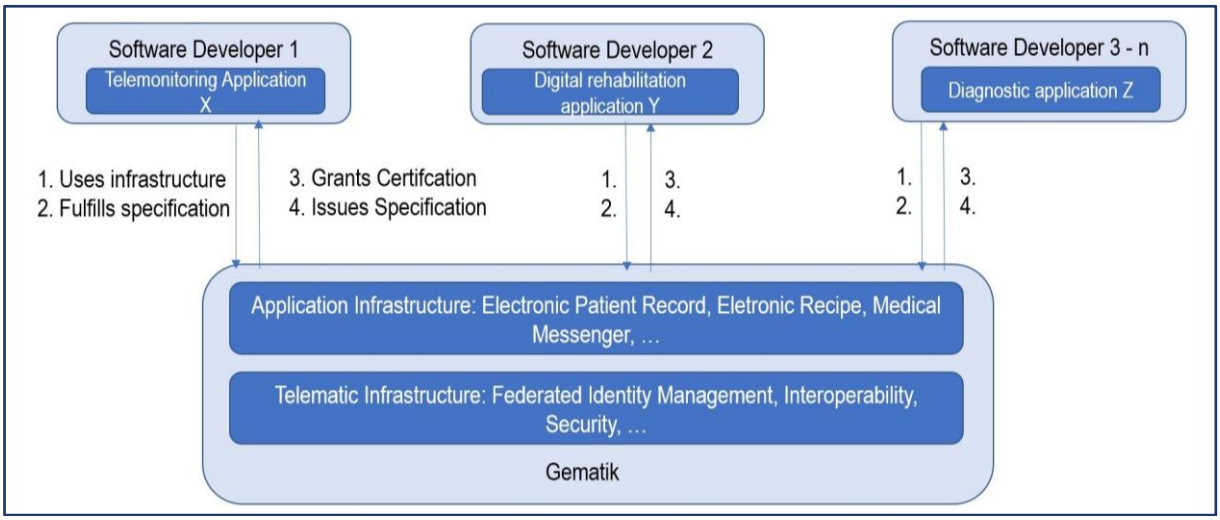

Figure 11: Germany - The gematik's services act as infrastructure to telemedicine applications, own illustration

3.2.2 Project level organization

Currently, there are several funding schemes directed towards - or specifically including – projects for telemedicine. Funding in this area ranges from large projects at the federal level to many small and regional projects.

On the federal level the German Innovation Fonds supports new forms of healthcare and healthcare research in the SHI. A lot of these projects including some sort of telemedicine. From 2016 to 2019,

[40] In accordance with § 311 SGB V (Basics of the telematics infrastructure see § 306 SGB V)

the annual budget was €300 million and from 2020 to 2024, €200 million for all projects (not limited to telemedicine) (Gemeinsamer Bundesausschuss, n.d.).
Some other examples for public funding program at the regional level by the ministries of the federal states are (Bundesministerium für Wirtschaft und Klimaschutz, n.d.):

- Hamburg funds up to 200.000€ per project for research, development or innovation projects in Healthcare (including telemedicine)
- Lower Saxony funds up to 200.000€ per digital or telemedicine project in healthcare
- Saxony funds projects developing digital applications in healthcare. The funding size depends on the yearly available budget of Saxony.
- Bavaria funds companies that do research or development in healthcare (including telemedicine) for up to 50% of the total necessary budget.
- Bavaria funds multi-partner projects (including Life Sciences) for up to 100% of the total necessary budget - if deemed strategically relevant.

There is also support from foundations regarding e-health and telemedicine, e.g.

- Bertelsmann Stiftung: "The Digital Patient" project examines the impact of digitization on healthcare
- Robert Bosch Stiftung: Projects on challenges such as demographic change, globalization, digitization, biotechnology

Two of the main points of criticism in the evaluation of the German Innovation Fonds in 2022 was the lack of systematic and focused selection and channelling of project funding and the networking of projects with each other (Prognos AG, 2019).

3.3 Legislation and regulation for telemedicine

3.3.1 General scope of the services

The evaluation committee (Bewertungsausschuss) sets the general conditions for the reimbursement and decides on a directory that specifies the service content and compensation. (There are two bodies in this process – the Federal Joint Committee (G-BA) that introduces new services in outpatient care, and the evaluation committee – a self-governing body made up of equal numbers of the National Association of Statutory Health Insurance Funds and the National Association of Statutory Health Insurance Physicians that .decides on their remuneration). The committee examines the requirements for telemedical services and the extent to which outpatient telemedicine services can be provided to patients (“§ 87 SGB 5 - Einzelnorm,” n.d.). On this basis, the KBV and GKV-SV come to an agreement (in the event of a disagreement, an arbitration procedure must be used). Annexes 31, 31a, 31b & 32 to the BMV-Ä (Federal General Contract for Physicians) regulate the general requirements for telemedical performance of services. The requirements for telemedical implementation for the respective application are specified in the respective appendices to the federal framework agreement, see figure below. In addition, § 378 SGB V provides for financial compensation for doctors when using the electronic patient file as well as the use of electronic medical prescriptions for pharmaceuticals that have to be sold in pharmacies.

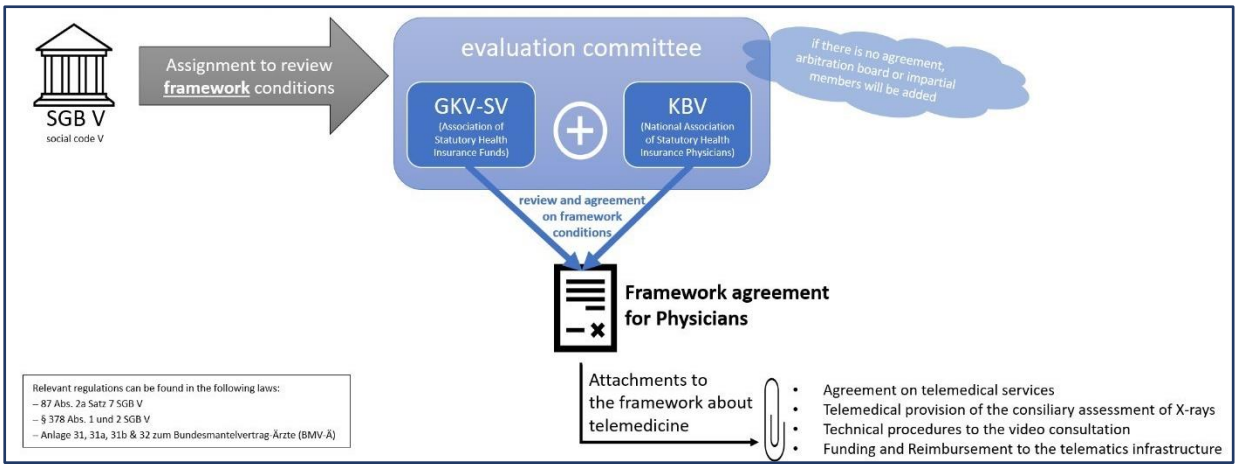

Figure 12: Germany - The framework-setting for the German healthcare system is organized by shared evaluation and arbitration, own illustration

The assessment of individual telemedicine treatments is carried out by the joint federal committee (G-BA) consisting of various players of the health care system. They decide which services the insured persons of the SHI can claim ("Wer wir sind - Gemeinsamer Bundesausschuss," n.d.). The gematik is the official approval body for all TI products as well as for providers of operating services and other applications. If manufacturers can prove the requirements for interoperability, security and functionality according to the profile, gematik will issue approvals and confirmations for the TI.
With regard to medical devices, The BfArM is responsible for the approval of clinical trials, the decision on the legal status of products and their classification. In addition, the BfArM decides on applications for inclusion in the directory of digital health applications, so called DiGAs ("BfArM - Medizinprodukte," n.d.).

Since September 2020 the German healthcare system became the first worldwide to introduce legislation ("Referentenentwurf Digitale-Gesundheitsanwendungen-Verordnung - DIGAV," n.d.) that enables a new type of publicly financed prescriptions – next to pharmaceuticals and medical products – that are digital. Digital Health Applications (in German „Digitale Gesundheitsanwendungen", **DIGAs**) are software products that are certified by the Federal Institute for pharmaceutics and medical products (in German "Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). DIGAs are aimed at "supporting the detection, monitoring, treatment or mitigation of diseases of patients" with digital means. DIGAs are also applicable when it comes to "injuries or disabilities" (Kassenärztliche Bundesvereinigung, n.d.). In general, DIGAs can only be "low-risk-class" applications that are categorized within the EUs Medical Device Regulation risk classes I or II a ("Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB," n.d.). DIGAs can be developed by all interested organizations, but so far only private companies or private-public joint ventures have developed them. As mentioned above DIGAs are approved by and listed in a repository of BfArM that can be accessed by a publicly available website. If the developer of a DIGA can prove a positive healthcare effect of a DIGA, it is listed permanently in the BfArM repository with access to all publicly insured persons with a physician's prescription or successful request to a SHI provider ("DiGA-Verzeichnis," n.d.).

In the context of **medical telemonitoring**, the German public healthcare system so far has issued regulation regarding the **telemonitoring of heart insufficiency.** This telemonitoring program is reimbursed for heart insufficiency patients in the SHI that match specific medical status criteria and only with the use of cardiac implant aggregates and medical products for cardiac measurement (Kassenärztliche Bundesvereinigung, n.d.). Specifically, this does not include wearables (fitness or medical wearables, see also section 3.3.2).

There are several services in eHealth and telemedicine that have already been developed or are currently in development. The scope of services covers many important areas of the health care sector. Besides general services, MIOs (Medical Information Objects) started to play a big role within the ehealth services and telemedicine developments. MIOs ensure that interoperable medical data can be understood by any system in healthcare and by documenting in a defined format based on international standards and terminologies. The following overview contains the general benefits and the MIOs:

General services

- **eArztbrief** (electronic medical certificate of inability to work)
- **eMedikationsplan** (electronic medication plan)
- **ePA** (electronic patient file)
- **eDMP** (electronic data transfer in disease management programs)
- **eRezept** (electronic prescription)
- **eNotfalldatenmanagment** *NFDM* (electronic emergency data management)
- **Telekonsil** (teleconsultation)
- **VSDM** (master data management of insured persons)
- **Videosprechstunde** (online consultation)
- **KIM** (communication in medical field)
- **TI-Messenger** (telematic infrastructure messenger)
- **ISIK** (technical information system in the hospital)
- **DEMIS** (German electronic reporting and information system for infection protection)

Defined MIOs

- **eImpfass** (electronic vaccination passport)
- **eMutterpass** (electronic Maternity log)
- **Zahnärztliches Bonusheft** (dental bonus booklet)
- **U-Heft 1.0.1**. (medical checkup booklet for children)

MIOs in progress

- **Überleitungsbogen** (transfer sheet)
- **KH-Entlassbrief** (hospital discharge report)
- **DigA toolkit** (app on prescription)
- **Patientenkurzakte** (patient summaries)

3.3.2 Eligibility of professionals, healthcare organizations to provide services

There are some limiting factors when it comes to the eligibility of professionals and healthcare organizations to provide telemedicine services. The video consultation is possible if the patient has not previously been treated by the doctor, but the doctor is only paid in full if there is personal contact with the patient in the same quarter. If this is not the case and contact is made exclusively via video, there will be a reduction (deduction of 20, 25 or 30 percent depending on the specialist group). The number of pure video treatment cases is also limited to 30 percent of all treatment cases by the doctor/psychotherapist. Almost all groups of doctors can use the video consultation, but there are the following exceptions: laboratory doctors, nuclear medicine specialists, pathologists and radiologists. There is no restriction to specific indications. (Kassenärztliche Bundesvereinigung, n.d.) & (Kassenärztliche Bundesvereinigung, 2022b).

DIGAs are provided to patients in two ways: a) a physician or psychotherapist that is part of the statutory insurance system prescribes a recipe to a citizen that is a member of a statutory insurance or b) a citizen makes a request to the citizen's SHI. Physicians and psychotherapists that can prescribe

DIGAs are prohibited from commercial cooperation with developers of a DIGA and other service providers that redirect citizens to a DIGA (Kassenärztliche Bundesvereinigung, n.d.).
In the context of so-called **Fitness-Wearables** (e.g. a smart-watch, wristband or an application on a smartphone), statutory insurance providers in Germany are prohibited from adapting a person's insurance tariff based on Fitness-Wearables' self-tracking data (Verbraucherzentralen, n.d.). However, public insurance providers are allowed to offer a bonus to their members if they participate in fitness programs that require digital non-invasive self-monitoring solutions.

There are currently no **Medical-Wearables** (e.g. a smart-watch, wristband or an application on a smartphone) that are certified for medical use (e.g. telemonitoring) on the German healthcare market, since the requirements of German law regarding medical products ("Medizinproduktegesetz") are quite demanding for Medical-Wearables. German statutory insurance providers have therefore currently not acknowledged any of the existing Fitness-Wearables as a Medical-Wearable to be prescribed for medical purposes (DKE, n.d.).

However, the joint federal committee (G-BA) has issued regulation to allow the use of certain **medical products** (but not wearables, see above) for the **telemonitoring of heart insufficiency** within the public insurance system. Eligibility of professionals require the cooperation of the primary attending physician (PAP) of a patient and a telemonitoring centre (in German Telemedizinzentrum, TMZ). The TMZ must fulfil several service and quality requirements in fulfilling the monitoring of patients (Kassenärztliche Bundesvereinigung, n.d.).

3.3.3 Eligibility of patients to receive telemedicine services

In the context of the eligibility of patients to receive telemedicine services patients do not need any special technology: Computer, tablet or smartphone with screen, camera, microphone and loudspeakers and an internet connection are sufficient. The technical connection runs via a video service provider (must meet the security requirements, see 3.3.7) commissioned by the practice. A sick note via telemedicine is also possible (Kassenärztliche Bundesvereinigung, n.d.).

In the context of **DIGAs**, any citizen that is member of SHI can use a DIGA if a) a physician or psychotherapist prescribed a DIGA or b) a citizen makes a request to the citizen's public healthcare insurance that is in turn approved by the insurance. In both cases, the patient's indication has to match the respective DIGA's area of indication (e.g. anxiety treatment or other indications). It must be documented and possible contraindications have to be excluded. In the case of a), the citizen then has to contact his/her public insurance provider, which generates an access code for the citizen based on the prescription (Kassenärztliche Bundesvereinigung, n.d.). The access code is used by the citizen to download or access the DIGA from several distribution channels (Apple App Store, Google Play Store or Web Application) ("DiGA-Verzeichnis," n.d.).

In the context of **telemonitoring of heart insufficiency**, patients must satisfy all of the following criteria in order for public insurance providers to pay for telemonitoring: a) progressed state of heart insufficiency, b) has a cardiac implant or received stationary treatment in the last year, c) heart insufficiency treatment based on guidelines and d) no factors recognized that could prevent the transfer of monitoring data or self-management of the patient (KBV, n.d.).
The figure below shows some of the available digital tools in the German healthcare system. It makes it clear that there is a large discrepancy in the frequency of use. However, the potential of all these tools has not yet been exhausted.

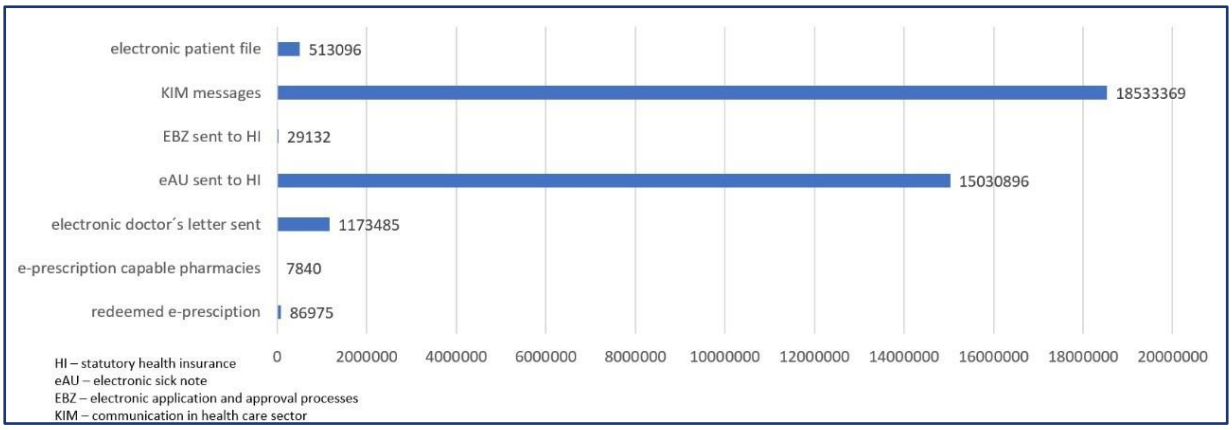

Figure 13: Germany - The extent of use of digital tools is expandable, own illustration according to: (gematik, 2022)

3.3.4 Security and safety of the service

Procedures can be used for data transmission that are known either as secure procedures (Section 291b Paragraph 1e SGB V) or as other electronic applications of the health care system (Section 291b Paragraph 1b SGB V in conjunction with Section 291a Paragraph 7 Clause 3) and have been confirmed by gematik. With regard to data protection, the general legal framework applies to the collection, processing and use of personal data in the context of telemedical applications. Written consent from the patient is required. The security of the central federal telemedicine infrastructure – by gematik - is governed by law (SGB V) (gematik GmbH, 2021).

Nine goals are defined for data security, which are confidentiality, authenticity, integrity, availability, auditability, validity, non-repudiation and usage determination.

- An electronic health card secures the identity and access check for all insured persons with basic registration data (The extent of this basic data is defined by law as well).
- All medical data is either saved on the electronic health card or the electronic patient record.
- Only medical professionals may have access to medical data. This can be reduced to certain medical professionals by the insured person.
- Medical professionals may only use data for medical purposes. Misuse of medical data with non-medical purposes are sanctioned to the extent of prison sentences for medical professionals.
- Only if an insured person has decided on using a digital application, medical data may be used. If this decision is revoked, data has to be deleted.
- While gematik provides the infrastructure for telemedicine, it is not able to read any data transported or used with its infrastructure. To this end, the gematik is not allowed to be the provider of any applications.
- All insured persons have access to a log of all activities with their data, to make sure everything is in order.
- The gematik must certify all components, services and providers that operate on the gematik's infrastructure. In doing so they must cooperate with the Federal agency for information security.

In order to achieve these legal goals, the gematik's infrastructure security relies on three main technical pillars:

- Information security by design: the major Federal Information agency, Data Protection Office and gematik cooperate on definition of security aspects during the design phase of technical specifications and development of alle components of the infrastructure.

- Information security auditing: all components, applications and services on the infrastructure must be audited by gematik and Federal information security agency before being permissioned. this can also be processed by an independent report in some cases.
- Information security in operations: application providers that operate on the infrastructure must a) notify gematik of all incidents and b) transfer data for gematik to inspect the level of information security in applications.

All **DIGAs** – temporary or permanent listing – need to have a CE marking ("Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB," n.d.).

3.3.5 Liability of health professionals and of technical operators

Regarding telemedicine doctors can use the video consultation flexibly in all cases in which they consider it to be therapeutically useful. In addition to an Internet connection with a firewall, screen and camera + microphone/speaker, the practice must choose a certified video service provider and register there. The KBV provides doctors with an overview of the possible providers. After registration, the doctor receives a certificate from the respective provider. Practices must show the certificate and report that they offer the video consultation to their "Kassenärztliche Vereinigung" (Kassenärztliche Bundesvereinigung, 2022b).

In general, the developer is liable for the **DIGA**'s approved functionality while the primary attending physician is liable for the selection of DIGA matching the patient's indication. In general, the match between functionality and indication has a low liability risk since the matching is quite clear (DIGAs are specifically approved for certain indications) (Bertelsmann Stiftung, n.d.).

The KBV has a more critical perspective on the intersection of **DIGAs** and liability. Physicians should be aware that some DIGAs are listed temporarily in BfArM repository and – for these DIGAS – the specific healthcare effect cannot be guaranteed. Furthermore, the regulator's medical evidence requirements are not as demanding as for "normal medical products". From a physician's point of view there are several factors when it comes to liability: a) the physician must make an independent and patient-individual cost-benefit analysis by using all available information on a DIGA, b) when in doubt the physician should not prescribe a DIGA, c) the physician must inform the patient about the cost-benefit-analysis and d) document all steps taken to avoid liability risk. The KBV also makes clear that – from their point of view – DIGAs can have harmful effects even they are classified as low risk in MDR and that there are no information regarding risks and side effects of a DIGA published by BfArM (KBV, n.d.).

3.3.6 Data Governance

The gematik's infrastructure can be described by three connected areas.

1. Decentralized area: This area includes all those with statutory and private insurance and those involved in their care. There are components such as the connector and the card reader. These are required for access to the telematics infrastructure. In future, insured persons will also be able to access TI from home or on the go.
2. TI-Access area: There are stationary and mobile Devices for use by the insured, such as card terminals, smartphones and Tablets. The healthcare professionals use a connector, so everyone in medical care involved uses one secure access to the telematics infrastructure.
3. Central area: Last there is the central area that is accessed via the Internet. This is the infrastructure heart of the telematic infrastructure. It consists of central data transfer and functions, which allow the TI to work reliably and safely: for example platform services for identification and access control (gematik GmbH, 2022c).

DIGAs have very strict data protection requirements that are certified by BfArM and defined by the federal data protection officer and the Federal agency of information security (BSI). The public regulators use DSGVO and the DIGAV-Legislation to make data protection requirements towards the

DIGA developer in multiple categories: a) the developer company, b) the DIGA product and c) all systems in connection with the DIGA product. The BfArM evalutes within these categories if only the DSGVO allowed data usages are in place and if there are no unallowed data usages in countries outside the EU ("Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB," n.d.).

3.3.7 Standards of care

The regular care standards of telemedicine and eHealth are described in the chapter 3.3.1. Therefore, this chapter focuses on the newly implemented DIGAs and telemonitoring of heart failure.

DIGAs undergo a thorough approval process by the responsible regulatory body (the BfArM, see above) that involves multiple categories: e.g. data protection, user experience, positive healthcare effect. Crucially, positive healthcare effect includes "medical usefulness" but also "patient focussed structure and process improvements". This new evaluation category was introduced to acknowledge the changemaking nature of digital healthcare application and their potential positive healthcare effects by new forms of coordination, adherence, easiness of access to healthcare etc. ("DIGA Report 2022," n.d.). A positive healthcare effect needs to be proven by the DIGA developer using at least a retrospective comparative study (but not necessarily a more demanding randomized control trial) ("Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB," n.d.; "DIGA Report 2022," n.d.). Proving a positive healthcare effect is often mentioned as a problem for developers of DIGAs that come from a software development background and are often unfamiliar with the specific and high scientific expectations of German public healthcare actors. Since this became apparent, the regulatory body tries to communicate to DIGA developers that they need to plan studies early in the software development process.

In the context of **telemonitoring of heart insufficiency**, the public healthcare system has formulated several standards: a) 3 and 12 months after start of telemonitoring and in case of changes in the patient's situation, the primary attending physician has to approve that telemonitoring is still a valid option for a patient. b) the telemonitoring centre (that cooperates with the primary attending physician) has to guarantee a daily data transfer from patient to the centre. c) the telemonitoring centre has to check all data anomalies and evaluate if the primary attending physician needs to act on them. d) If the primary attending physician cannot be reached, the telemonitoring centre is allowed to take over the physician's role (KBV, n.d.). See also below a diagram of the interaction between telemedicine centre, patient and primary attending physician.

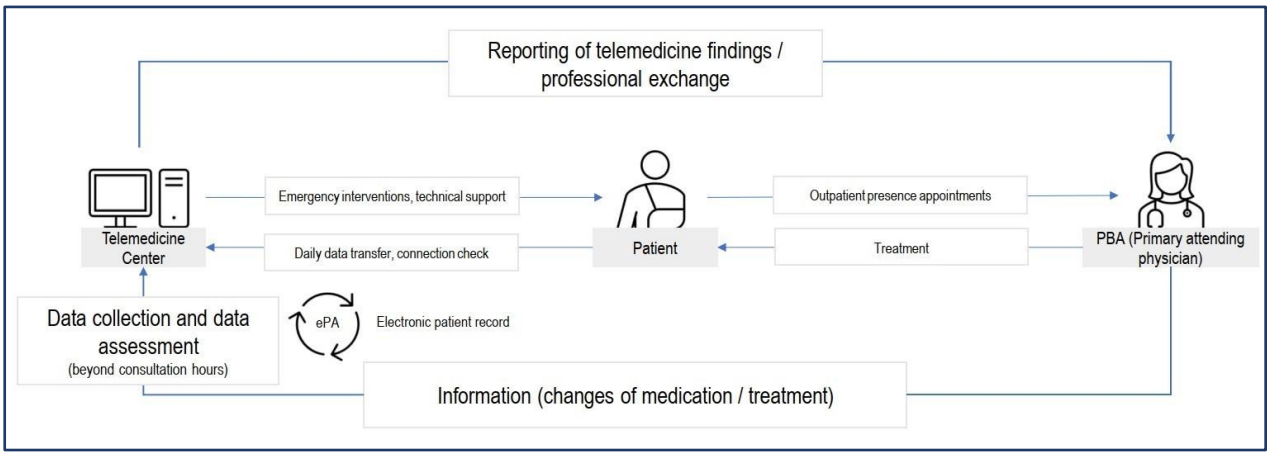

Figure 14: Germany - Collaboration between a telemedicine center and the primary treating physician (PBA) in the telemonitoring of patients with heart failure, own illustration according to: (Spethmann and Köhler, 2022)

3.3.8 Reimbursement

In context with the remuneration for the video consultation, the treating doctor initially receives the respective basic and insured flat rate41. In addition, if the requirements are met, there are different surcharges: for basic specialist care, for the performance of the general practitioner's care mandate, for support of general practitioner care by qualified non-medical practice assistants and for treatment by conservative ophthalmologists as well as other cases42. Finally, the remuneration for the respective call performance takes place, which can take place both as individual and as group treatment. In psychotherapy, a distinction is made between individual and group psychotherapy as well as other psychotherapeutic services and neuropsychological therapy with regard to remuneration. The remuneration for video consultations also includes items for video case conferences and video case discussions as well as for outpatient specialist care (Kassenärztliche Bundesvereinigung, 2022c). A complete overview of the remuneration for the video consultation can be found here: https://www.kbv.de/media/sp/Videosprechstunde__uebersicht_Verguetung.pdf

DIGAs are certified software products that are reimbursed by German public insurance providers to the developers of DIGAs. In general, public insurance providers pay DIGA developers based on the number of accesses to the DIGA granted by the public insurance provider. The prices for reimbursement are structured mainly in two phases: a) for the first year after listing in BfArM's DIGA repository, DIGA developers can choose a price for DIGA access relatively freely albeit limits in comparison with other digital health applications ("FAQ Digitale Gesundheitsanwendungen (DiGA)," n.d.). After the first year within the BfArM repository, prices are determined by negotiation between DIGA developer and the association of public insurers. Currently, the German healthcare system is discussing if growing numbers of DIGA accesses could - in the future - lead to a potential financial problem for public insurers.

In the context of **telemonitoring of heart insufficiency**, the public finance scheme (in German "Einheitlicher Bewertungsmaßstab", EBM) issued finance positions (in German "Gebührenordnungsposition", GOP) for primary attending physicians and the telemonitoring centre. These positions assign a certain monetary value to the services and are used by physicians and centres to finance their activities (Kassenärztliche Bundesvereinigung, n.d.).

A recent paper by McKinsey claimed that the German healthcare system could gain 42 billion Euro p.a. in cost-savings or increasing productivity by introducing digitalization (Biesdorf et al., 2022). In comparison to Germany's total spending on healthcare of 425 billion Euro p.a. (vdek, 2022), digitalization could present a financial improvement of around 9,9%. More specifically for telemedicine, the financial improvement could be around 14 billion Euro p.a. These improvements within telemedicine could be mostly realized in teleconsultations (5,7 billion Euro p.a.) and telemonitoring (4,3 billion Euro p.a.).

[41] and, if relevant, a consultation flat rate after radiation therapy treatment

[42] Surcharge for authentication of an unknown patient; Emergency flat rates in the organized emergency (emergency) service; Emergency consultation flat rates in the organized emergency (emergency) service; technology surcharge; Additional flat rate Issuing an initial prescription for a digital health application; Additional flat rate follow-up and evaluation of the digital health application (DiGA) somnio

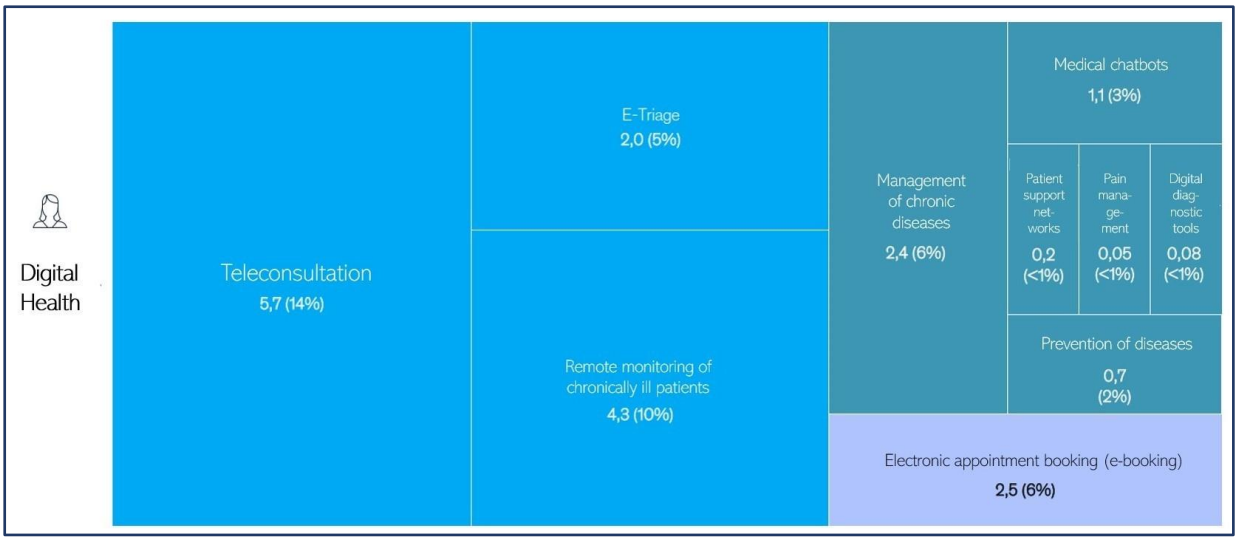

Figure 15: Germany - Potential savings in the German healthcare system through the use of telemedicine (Biesdorf et al., 2022)

3.3.9 Ethical guidelines Patient consent to be treated with telemedicine

In Germany, one of the major national drivers of ethical guidelines is the "German Ethics Council". The German Ethics Council is an independent expert council that is tasked with "pursuing those ethical, societal, scientific, medical and legal questions, which arise in relation to research and development of Life Sciences" (Wikipedia.de, 2022). The German Ethics Council issues opinions on these questions that define frameworks for and influence the creation of policy in the relevant area. In 2017 the Council issued a major opinion on the use of data in healthcare that also highlighted the areas of a) patient consent, b) privacy and c) equity. In their opinion, the council showed the interconnectedness of these areas. Therefore, in the following, we will treat these three areas as one major ethical topic that should be treated as one.

The German Ethics Council issued the following opinions (Deutscher Ethikrat, 2017) (abstract guidelines) for the use of data in healthcare to improve freedom and **privacy** of patients:

- The data giver (i.e. the patient) should have as much influence as possible on his/her personal healthcare data use. This becomes especially relevant with the open-ended useability and connectivity of many data processing systems ("big data").
- Wherever the use of data by a data giver (i.e. the patient) cannot be precisely defined a priori, there should be "data agents", which go beyond a simple **patient consent** form. These data agents are software-tools that should have access to the system, which process data. There, these data agents should administrate the data from data givers to offer them more control, transparency and traceability regarding his/her data.
- Any **consent** to give data should be reversible and the data given to a system reversible and transferable to another system. This would apply the idea of "data agents" (see above), which would act in this case to reverse and/or transfer the data of a data giver (i.e. the patient) on his/her behalf. This would also apply that software companies or other owners of a data using system would be able to delete the data once ingested by a data giver.
- In general, **consent** should be given as a use-case-oriented opt-in model: data givers (i.e. the patient) should be able to give consent to individual decisions on a regular basis (when new possible decisions come up). Furthermore, this model should be able to be delegated to other institutions that administrate the consent for the data-giver.
- In general, data processing systems should have **privacy by design**/**privacy by default** settings. Basically, if a data giver (i.e. the patient) uses a system he/she should not need any information or decision making in **consent** settings, to have a **privacy-guaranteeing system** environment.

- Education for children and adults should allow data givers (i.e. the patients) to be aware of legal, social and ethical implications of data in healthcare. This would improve their self-determination for **privacy** and increase **equity** between them.
- The state should improve the public discourse on the use of data in healthcare and facilitate discussion. This would improve **equity** between data givers.
- The frontend use of data processing systems should be as easy as possible for all users with an easy and accessible design. This would increase **equity** for all users and data givers.
- In order to prevent the - in any data processing analytical system possible - discrimination of user groups or individuals, algorithms and any other decision support components should be checked regularly and sanctioned if any discrimination becomes known. This is all to maintain **equity**.
- It should be possible to not **consent** to automatic decision making processes and their results. This becomes especially relevant for cases where insurances deny claims. Therefore, a cost-free and easy to use access should be granted to data-givers to not consent to decisions or to neutral arbitration bodies.
- Chatbots should be regulated especially strict, since they have potential to exploit users with limited capabilities and infringe on their **privacy**.
- Support Data protection officials
- Establish independent data inspectors that regularly inspect data processing systems (in comparison to "car inspection systems") that ensure quality standards measure up for **privacy**, **consent** and **equity**.
- Establish data trust models that function as an independent middleware between data givers and data processing systems. This could especially be to increase **equity** between private data givers and large firms processing data (as well as other quality goals like **privacy** and **consent**).

Furthermore, the German federal chamber of physicians issued some more concrete guidelines on concrete questions of consent and privacy in telemedicine ("Fragenkatalog zur Fernbehandlung," n.d.):
Consent management with patients:

- The physician has to thoroughly inform each patient about the telemedicine treatment before the patient can consent to it.
- In simple medical cases and if the patient agrees, the physician can simply inform the patient of the procedure by "telephone" or other non-personal means.
- In complex medical cases, the physician needs to inform the patient about the telemedicine treatment "verbally" in-person.
- Patients should always have the opportunity to have a (remote) verbal conversation with the consulting or treating physicians. Information that is not provided in person, based solely on algorithms,such as an automatic computerized response to monitoring data like blood pressure measurements or input from a glucometer, does not meet these requirements. The diagnosis and treatment must be communicated verbally by the physician to the patient.
- In a telemedicine treatment, the patient always has to have the option to be informed by the physician again.
- In general, it is not advised to accept a patient's refusal to be informed before a telemedicine treatment, especially if the physician and patient only have the telemedicine interaction (without prior interaction).

Privacy with data protection:

- The responsibility of protecting privacy by GDPR standards is either with a) the physician if the physician uses a technology for telemedicine, b) with a technology provider if the technology provider has a larger part in data processing. In case of b) the technology provider and the physician can share the responsibility by a transparent agreement that regulates who has to take care of which GDPR requirements.

- From the start the physician and/or technology provider have to have a GDPR data processing overview in place.
- In cases of innovative treatments with a high risk for the privacy of the patient, a Data Protection Impact Assessment has to take place beforehand. The German Federal and Regional Data Protection Officials have published lists of cases where this needs to take place. If such a Data Protection Impact Assessment has to take place, the corresponding physicians have to also instruct a data protection officer to regulate their medical offices.

3.4 Legal and Ethical Challenges to date

The current debate discusses the benefit of using health data to improve the health care and enhance prevention of diseases. In order to digitalize the health care sector it is necessary to consider all affected norms (ethical, legal, social,…). Modern data protection belongs to health protection. Therefore, data should not be generally protected from use. The risk of omission of reasonable use of (individual) health data is underestimated. It is unethical to misuse health data, but it is also unethical to **not use** existing (individual and common weal) health data. Data sovereignty goes hand in hand with data solidarity. Data sharing might mean better caring: This is why in a community of solidarity; it needs to be discussed to make health data accessible for public purposes.

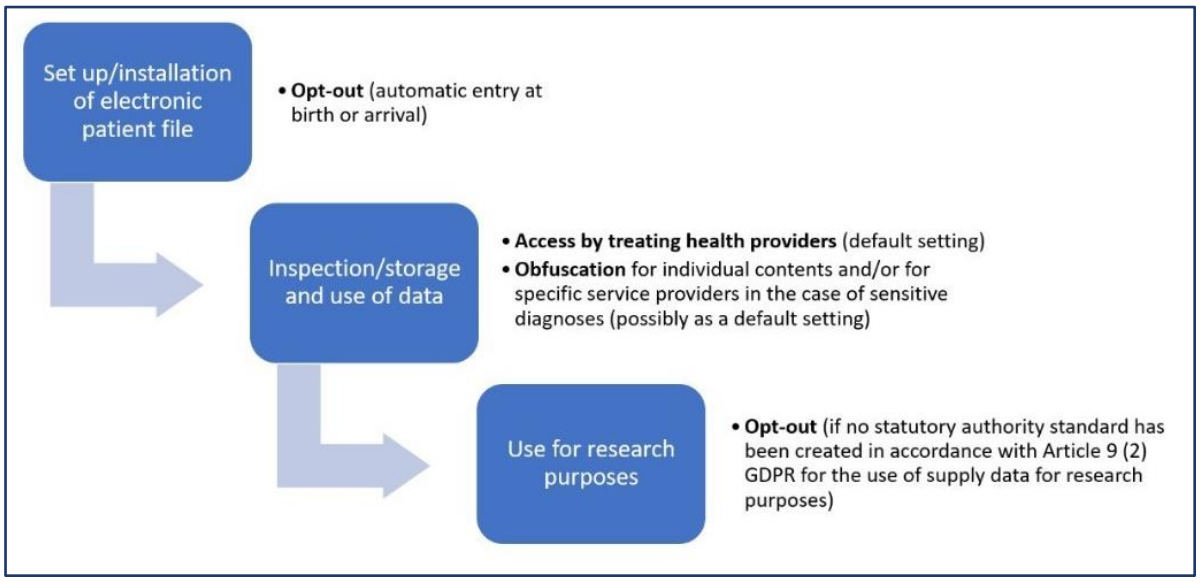

Figure 16: Germany - To account for the immense cost of not using data, new proposals are discussed regarding opt-out processes of data use, own illustration according to: (Gerlach, 2022)

Country – France

3.5 Context

3.5.1 Country profile

On 1st of January, France had 67.8 million inhabitants. In 2O21, there were 738 000 births and 657 000 death, i.e. a natural balance of 81 000 people. The fertility index of France is one of the highest in Europe at 1.83 children per women.

The French population is generally in good health, although there are both socio-economic and geographical disparities. Men have a higher premature mortality rate than women. Thereby, life expectancy at birth is 85.4 years for women and 79.3 for men[43].

The French pyramid of ages was marked by a large number of births during the high economic prosperity period from the 50s to the 70s. This phenomenon, called the "baby-boom" has now given place to the "papy-boom" phenomenon. Indeed, during the last ten years, the aging of the baby-boomers generation constitutes a demographic challenge for the country.[44] The proportion of people over 75 years old will increase from 10% in 2020 to nearly 20% by 2070[45] [46].

Telemedicine, and more broadly eHealth, is viewed in France as a solution to the upcoming challenges facing the French health system : negative evolution of medical demography, territorial disparities to access care, the increasing prevalence of chronic diseases, the aging of the population and care dependency.

3.5.2 Healthcare System

3.5.2.1 Organisation

The French healthcare system is complex, bringing together a private and a public sector. Its organization is defined by a national administration, whose roles and responsibilities are delegated to the territorial administrations, according to the principle of centralization/decentralization and concentration/deconcentration. Thus, the French ministry of health shares or delegates some roles and missions to local authorities (e.g. : Regional Health Agency - ARS) or local communities (e.g. departmental council).

The ministry of health is the main organizer of the French health system. It defines the national health policy and its implementation through the national health strategy. The national health strategy is then rolled out at the regional level by the regional health agencies through the regional health project – PRS. The ministry can rely on organizations or structures with a specific expertise such as the High authority of Health (HAS), the High council of public health (HCSP), the National Agency of Public Health (Santé Publique France) and the National Digital Health Agency (ANS).

[43] INSEE, Bilan démographique 2021 , published on 01/18/2021, available at : https://www.insee.fr/fr/statistiques/6024136?sommaire=6036447 (last access 12/09/2022)
[44] INSEE, Baby-boom et allongement de la durée de vie : quelles contributions au vieillissement ?, published on 09/17/2013 available at : https://www.insee.fr/fr/statistiques/1521327 (last access 12/09/2022)
[45] DREES, Panorama de la DREES, la protection sociale en France et en Europe en 2020, édition 2021, published on 12/15/2021 available at : https://drees.solidarites-sante.gouv.fr/publications-documents-de-reference/panoramas-de-la-drees/la-protection-sociale-en-france-et-en-0 (last access 12/09/2022)
[46] IRDES, Télésanté, santé numérique ou santé connectée - Bibliographie thématique, published on october 2021 available at : https://www.irdes.fr/documentation/syntheses/e-sante.pdf (last access 12/09/2022)

The provisional budget of the healthcare system is proposed by the government according to the economic forecast of the social protection expenditures and incomes and approved by the Parliament. It can be modified during the budget period if necessary.

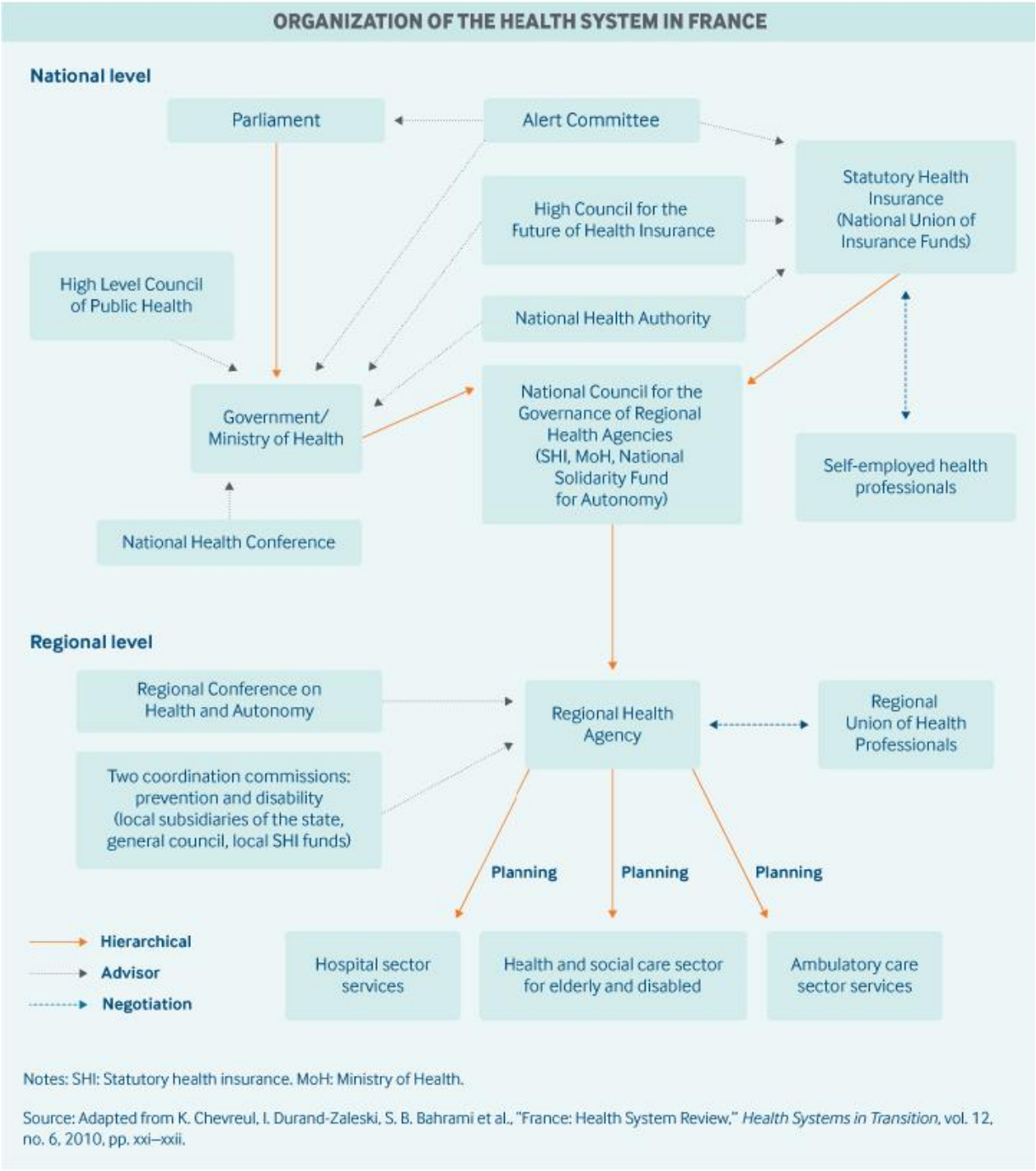

Figure 17: France - : Organisation of the healthcare system[47]

[47] Isabelle Durand-Zaleski, AP-HP and Université Paris-Est, "France" in International Health Care System Profiles edited by Roosa Tikkanen, Robin Osborn, Elias Mossialos, Ana Djordjevic, George A. Wharton, downloaded 21.8.2022 from https://www.commonwealthfund.org/international-health-policy-center/countries/france#:~:text=The%20insurance%20system%20is%20funded,%2C%20hearing%2C%20and%20vision%20care (last access 12/09/2022)

3.5.2.2 Funding/management

The French healthcare system is financed both by a mandatory public national health insurance system called "Assurance Maladie" and by an optional private system, managed by complementary organizations. Both systems are used to finance the care provided by private and public care providers. Reimbursement of care by the national insurance is universal. The amount of reimbursement is fixed by an agreement between health professionals and the national health insurance.

This public system is mainly financed by contributions and taxes. Coinsurance/co-payments rates are applied to all health services and drugs listed in the national benefit package and vary by:

- Type of care:
  - 20 percent for inpatient stays, 30 percent for outpatient doctor and dentist visits.
  - Effectiveness of prescription drugs: highly effective drugs like insulin carry no coinsurance, while rates for all other drugs range from 15 percent to 100 percent, depending on the drug's therapeutic value, whether patients seek a referral from their primary care provider, and whether they seek specialist care or treatments directly without a referral.
- Hospital coinsurance applies only to the first 31 days in hospital, and some surgical interventions are exempt; there are no caps on other coinsurance.
- Safety nets:
  - People with low incomes are entitled to free or discounted health insurance, free vision care, and free dental care. Individuals are considered low-income if they make EUR 8,723 (USD 11,040) or less per year.
  - For households, the qualifying income level increases with each member.

  The total number of low-income beneficiaries is estimated at around 9 percent of the population, with 6 percent receiving means-tested vouchers for VHI and 3percent getting free state-sponsored coverage.[48]

Coinsurance/co-payments are covered by complementary insurance that covers 95% of the population Reimbursement of care by complementary organizations depends on the formula selected by the patient while contracting with the insurance company. Financing of for these complementary organizations is by subscription fees.

3.5.2.3 Healthcare facilities

In France, the care offer is divided into two sectors:

- A public sector composed of hospitals and university hospitals
- A private sector composed of
  - Private hospitals: private for-profit organizations (e.g. medical centre) or private non-profit organizations (Private Health Establishment of Collective Interest – ESPIC)
  - Independent Practitioners: GPs, specialists, other medical professions (dentists, midwives) or paramedics.
    Doctors can both work alone (as an independent) or in a private structure like health centres (group practice). In health centres, doctors can be financed by their own practice, like an independent doctor, or be a salaried employee of the health centre.
  - Some types of facilities such as institutions for dependent elderly people (EHPAD) can sometimes be private or public.

[48] Isabelle Durand-Zaleski, AP-HP and Université Paris-Est, "France" in International Health Care System Profiles edited by Roosa Tikkanen, Robin Osborn, Elias Mossialos, Ana Djordjevic, George A. Wharton, downloaded 21.8.2022 from https://www.commonwealthfund.org/international-health-policy-center/countries/france#:~:text=The%20insurance%20system%20is%20funded,%2C%20hearing%2C%20and%20vision%20care (last access 12/09/2022)

- Ultra-specialized cares requiring a rare expertise or medical treatment, or a highly specialized technical platform are often performed in university hospitals but can also be performed in private hospitals.

City medicine, often called liberal medicine, includes both general practitioners and specialists. City doctors most often practice in the private sector, although they can also, in some cases, be employed by public entities such as departmental councils for example. These doctors can practice either in a group with other health professionals or individually in their own medical office. Historically, GPs mainly practiced as individual. However, in recent years, the trend has changed. Nowadays, GPs and other health professionals often practice in small medical centres.

There is a voluntary "gatekeeping" system for people aged 16 and older, with financial incentives offered to those who opt to register with a GP or specialist as their point of first contact in the system. About 95 percent of the population have chosen a GP as their point of first contact, but specialists can also serve as first contact doctors.

In France, the reimbursement of medical activities of liberal doctors (GPs and specialists) is divided into sectors, according to the agreement between the public National Insurance and the doctors union.

The 3 sectors describe the extent to which doctors bill for their services in accordance with the prices set by the National Insurance Agreement:

- Sector 1 - Doctors who contracted in sector 1 apply the prices set by the national agreement without the possibility of exceeding these fees. Their activities are covered in full by the public health insurance and complementary health insurance.
- Sector 2 - Some additional fees can be applied that are not covered by public health insurance.
- Sector 3 - Doctors are free to apply an unlimited amount of additional fees Complementary insurance can cover part of the excess fees but the rest must be paid by the patient.

GPs can also receive a capitated annual payment to coordinate care for patients with chronic conditions, from 42€ for patients under 80 with chronic conditions, up to 70 € for patients over 80 with chronic conditions [49]

3.5.3 Digitalisation of the health and care system

At the national level, the Ministry Delegation for Digital Health (DNS), is directly linked to the ministry of health, and is responsible for setting the main orientations of the digital health policy. For this, the DNS heavily relies on the expertise of the ANS. The ANS defines the way that digital tools should work, interact together and respect data protection policies in order to organize a coherent framework for eHealth (including telemedicine). ANS helps defining regulation and publishes good practices guides for software publishers.

At the regional level, ARS can rely on regional groups of actors called GRaDES for the development of digital health and the implementation of the information systems master plan (SDSI). GRaDES are consortia of healthcare and medico-social actors (public and private) which act as a support organization for the ARS and assist the ARS in applying the national digital policy at the regional level. GRaDES are also responsible for the implementation of the regional digital health virtual space and are in charge of meeting public health needs by the deployment of regional digital solutions.

[49] https://www.ameli.fr/medecin/exercice-liberal/facturation-remuneration/dispositif-medecin-traitant/forfait-patientele (last access 12/09/2022)

The digitalization of the French health system has been gradual through a succession of plans and programs with variable success and impact. However, since 2012, a voluntarist policy of digitalization of care has been implemented.

As main dates, we can note :

- **2009**: "Hospital Patient Health Territory" (HPST) is an important law introducing the definition of telemedicine.
- **2012 – 2018**: " Digital Hospital" is an important strategic plan for the development and modernization of hospital information systems (SIH) 400 M€[50].
- **2014-2017**: "Digital Healthcare Territory" (TSN) is an investment program of 80M€ spread out in 5 regions aiming to develop innovative patient care organizations strengthened by a package of integrated services [51].
- **2018-2022**: "accelerate the digital shift" is a digital health Roadmap of the Health Ministry, a voluntarist policy to provide an overall vision and global responses to overcome the challenges faced by the French healthcare system with a focus on use of digital technology to improve care[52].
    - **2018 – 2021**: ETAPES, an important telemedicine experimentation to improve patient care with remote monitoring[53].
    - **2019**: HOP'EN, an investment program of €420M to support the evolution of hospital information systems. It is an extension of the "Digital Hospital" program[54].
- **2022**: SEGUR, an investment program of €2Mdrs for the digitalization of the ongoing patient management and to facilitate widespread ease and secure sharing of health data between health professionals and with users to improve prevention and care[55].

The SEGUR digital program is a complementary component of the SEGUR program built in response to the social strike of the public hospitals which was aggravated by the COVID-19 pandemic.

"Accelerate the digital shift" in which the SEGUR program is also part, is based on 5 axes:

1. **Strengthening the governance in digital health** by creating a ministerial delegation for digital health (DNS), directly linked to the Ministry of Health. This delegation is responsible for setting the main guidelines for digital health policy. For this, the DNS relies heavily on the expertise of the ANS (National Digital Health Agency).

2. **Intensify the security and interoperability of health information systems.** This orientation, with the creation of a national cyber surveillance service is a national priority.

[50] DGOS, Bilan du programme hôpital numérique, available at : https://solidarites-sante.gouv.fr/IMG/pdf/dgos_bilan_hn.pdf (last access 12/09/2022)
[51] Ministère de la santé available at : https://solidarites-sante.gouv.fr/systeme-de-sante-et-medico-social/e-sante/sih/tsn/article/le-programme-territoire-de-soins-numerique-tsn (last access 12/09/2022)
[52]Agence du Numérique en Santé available at : https://esante.gouv.fr/virage-numerique/feuille-de-route (last access 12/09/2022)
[53] Ministère de la santé, available at : https://solidarites-sante.gouv.fr/soins-et-maladies/prises-en-charge-specialisees/telesante-pour-l-acces-de-tous-a-des-soins-a-distance/article/la-telesurveillance-etapes (last access 12/09/2022)
[54] Ministère de la santé, available at : https://solidarites-sante.gouv.fr/systeme-de-sante-et-medico-social/e-sante/sih/hopen (last access 12/09/2022)
[55] https://esante.gouv.fr/segur (last access 12/09/2022)

3. **Accelerate the deployment of core services**, i.e.
    - **DMP** (Public Electronic Health Record): It is a national digital health record. It gathers, in a secure space, health information of all patients. This service is free, whether for patients or healthcare professionals. The DMP contains the history of reimbursements from Health insurance, the patient's advance directives, vaccination records, allergies, pathologies, medical treatments and all results of examinations (radiology, biology …) and medical reports (surgery, hospitalization ...) produced by healthcare organisations[56] [57].
    - **MSS : Secure Health Messaging:** It is a secured environment allowing health professionals and medico-social professionals working both in private or public sectors to exchange information in a secure manner. This secured environment is based on the notion of trusted space. This trusted space includes operators whose domain names appear on the ANS white list and healthcare professionals registered in a national health repository. Only members of the trusted space can exchange information with MSS. This means that secure health messaging system can only be used for sending messages and documents to other secure health messaging system and not to public messaging system such as Gmail, Yahoo, Hotmail …
    - **INS : National Health Identity.** This is a unique and permanent health identifier number, used by all health professionals and organisations involved in a patient's care. This identifier improves the safety of care and makes the information exchange more reliable by ensuring the correct identity of patients. The INS includes five identity traits (first name, last name, gender, date and place of birth) in addition to the national social security number.
    - **Pro Santé Connect.** It is a way of authentication and connection to the digital services for healthcare professionals. With Pro Santé Connect, healthcare professionals can be authenticated using their professional card (CPS) or their smartphone with the eCPS (digital professional card) apps. The objectives are both to strengthen security and facilitate access to digital services.
    - **Mon Espace Santé** (My Health Area)**:** it includes 4 main functionalities : a secure mailbox, an upgraded release of public Electronic Health record (DMP), a calendar, a catalogue of digital health services referenced by the Ministry. My Health Area also include referenced public and private digital solutions used by health professionals, patients. Since January 2022, a personal Health Space has been opened automatically for each French citizen, excepted if the citizen deny to have one (Opt-in principle). While opening a personal health, a DMP is also created automatically.

4. **Deployment, of digital health platforms at the national level** for sharing health data and medical records (My Health area) and for innovation and research through the "**Health Data Hub**", a national data storage. It brings together data from several sources such as national health insurance and health establishments.

5. **Support innovation and stakeholder engagement.** The below figure, published by the DNS and revised several times, uses the image of the construction of a house for explaining the development of the French digital health ecosystem. The main message is to build this house on strong foundations based on referential and core services.

[56] arrêté alimentation DMP : https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000045726627 (last access 12/09/2022)
[57] décret contenu DMP : https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043914236 (last access 12/09/2022)

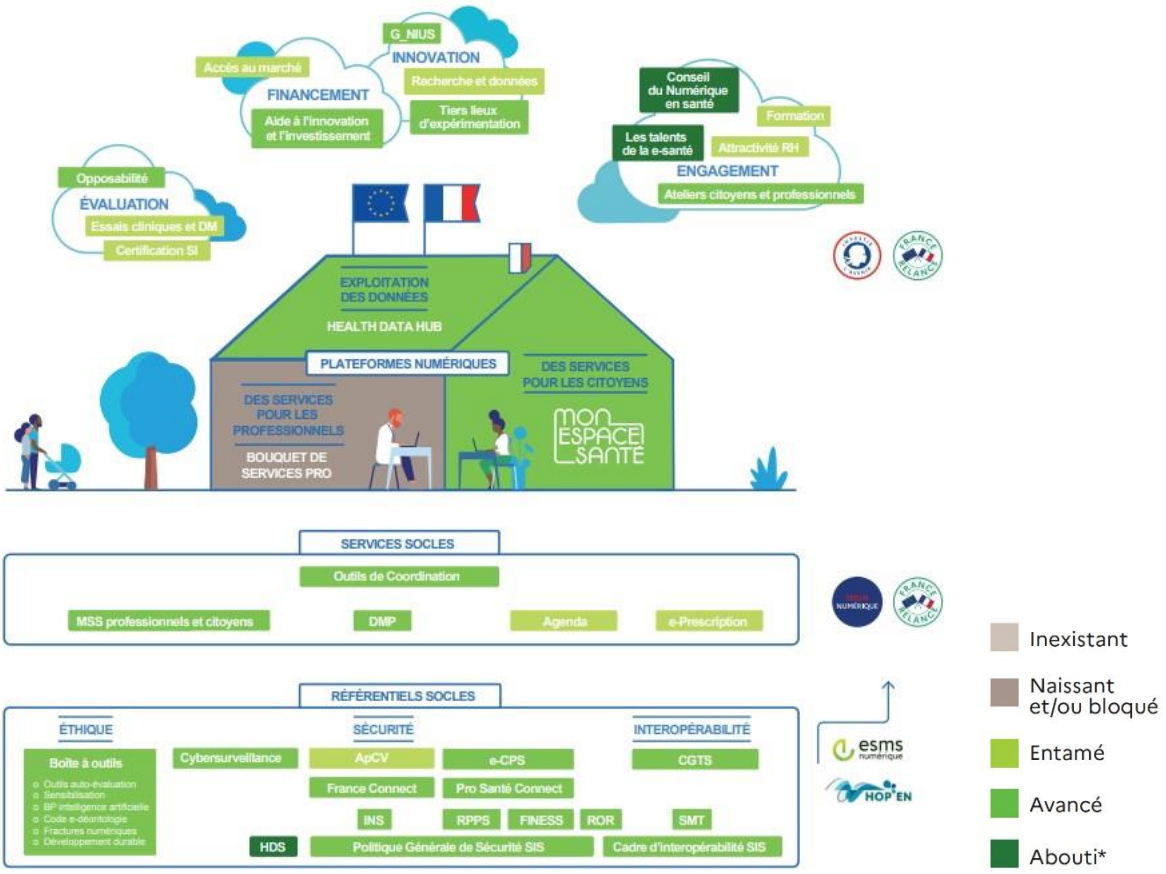

Figure 18: France - Maison de la e-Santé 2022

3.5.4 Cultural aspects

There are multiple cultural obstacles to the development of digital health in France at citizen and health professionals' levels. The slow and laborious deployment of the DMP testifies to this. French people appreciate the close relationship with health professionals which allow more confidential exchanges. This close relationship can sometimes be harder to build with telemedicine. However, this is why a GP cannot perform only teleconsultation. French people are also concerned about the protection of their private data, especially health data. Sometimes, patients don't understand the purpose of certain digital tools and this become an obstacle.

However, the arrival of new actors offering innovative, simple and effective services such as online appointment booking (Doctolib) has significantly changed the situation. In addition, the COVID-19 pandemic has been a tremendous accelerator for the use of digital technologies, with the example of teleconsultation. There were 40 times more teleconsultations between 2019 and 2022 and 142 times more during the COVID-19 pandemic. In 2022, about one million teleconsultations are performed every day. This acceleration can also be observed in the deployment of digital services such as DMP and MSS:

- In 2019 10 million DMPs were open and there is now about 70 million.
- In 2020 2 million of secured messages were exchanged each month with the MSS, to be compared with more than 10 million each month in 2022[58].

[58] DNS, Bilan feuille de route numérique en santé, available at : https://esante.gouv.fr/sites/default/files/media_entity/documents/bilan-feuille-de-route-2022.pdf (last access 12/09/2022)

3.6 Organisational Framework for telemedicine

The organizational framework of telemedicine has been structured in 2009 by the HPST law mentioned under section 3.5.3. It defines 5 types of acts in the public health code:

1. **Teleconsultation**: A doctor performs a distant consultation with a patient through a videoconferencing system. A health professional may be present with the patient and assist the doctor during this act.
2. **Remote monitoring of patient**: A doctor interprets data collected by medical devices for the medical follow-up of patient and, if necessary, makes decisions relating to his care. The data recording and transmission can be automated or carried out by the patient himself or by another healthcare professional.
3. **Tele expertise**: It allows a requesting physician to consult one or more required colleagues regarding a patient's case. It can concern both GPs and specialists. Tele expertise does not require video exchange and can be performed synchronous or asynchronous with a secured messaging system. The requesting physician has to obtain the patient's consent before requesting a consultation about him with a colleague.
4. **Tele assistance**: it enable a caregiver to assist a colleague in carrying out an act remotely. One professional is in contact with the patient while the other is located at distance, helping or leading his colleague.
5. **Medical response**, provided as part of the medical regulation of emergencies or the permanence of care[59]. It is the digital act of linking an emergency doctor with a health professional. This act can be performed by phone or by a digital platform.

Since then the following acts have been added:

6. **Tele-care** when a paramedical professional is performing an act remotely
7. **Guided Teleconsultation** when a patient is consulting a doctor through videoconferencing assisted by a nurse or a pharmacist

The implementation of these acts is framed on the one hand by good practice guides published by the HAS (High Health Authority) and, on the other hand, by the medical agreement signed between the National Medical Insurance and representatives of health professionals. Thus, as an example, the HAS good practice guide for teleconsultations details the requirements for teleconsultation, whether before, during or after it:

- Before the teleconsultation, the health professional must assess the relevance of the use of teleconsultation, inform and obtain the patient's consent.
- During the teleconsultation, the professional must verify the identity of the patient and ensure that the conditions in which the teleconsultation is carried out are favourable to a climate of trust.
- At the end of the teleconsultation, a report must be recorded in the patient's DMP and sent to the doctor's medical software. Technical problems that occurred during the consultation must also be included in the report of the teleconsultation. The report and the medical prescription must be sent securely to the patient.

3.6.1 Telemedicine service implementation

Even if it is defined by law since 2009, the development of telemedicine in France was very gradual and heterogenous. It has been the subject of numerous territorial experimentations, with variable levels of success, from one region to another and from one medical sector to another.

[59] articleR6316-1 du code de la santé publique
https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000043600549/ (last access 12/09/2022)

Nowadays, a large panel of solutions are available and are provided by either Regional Health Agencies or private company. About 104 solutions have been referenced by the Ministry of Health. There is a high level of competition between those providers in all French regions.

Regional telemedicine platforms are mainly optimized for tele-expertise, even if tele-consultation acts can be carried out through these platform. Remote monitoring is carried out through private solutions. The findings of the Pons/Coury report on e-Health[60] in France shows weak coordination between healthcare professionals due to non-interoperable digital services, passive patients who do not have control over his own data and a non-computerized medico-social sector. To accelerate the deployment of digital solutions and basic services, the ANS published digital health guidelines. These guidelines are made available to professionals and software editors. They defines the rules of interoperability, security and ethics that editors with which their solutions must be compliant[61].

3.6.2 Teleradiology implementation:

A medical sector that is more advanced is teleradiology. In this domain, the practice and uses have been developed around telediagnosis and tele-expertise of medical imaging. This sector was included in the priority of the national telemedicine deployment plan of the Ministry of Health since 2012[62].

The professional council of French Radiology, a consortium made up with the College of Radiology Teachers of France (CERF), the National Federation of Medical Radiologists (FNMR), the French Society of Radiology (SFR) and the syndicate of Hospital Radiologists (SRH) published in 2007 a guide for a professional and ethical use of teleradiology. This guide explained the conditions required for the practice of teleradiology such as the medical relevance of the examination and the need of transmitting the results of the examination in a validated format. This guide also explained the conditions for practicing teleradiology, within a formalized framework. For this, an agreement signed between the various partners is settled[63].

3.7 Legislation and regulation for telemedicine

3.7.1 General scope of the services

In France, the practice of medicine is governed by a set of laws and must respect the following obligations and principles :

- Holding a diploma recognized by the national authorities
- Be registered in a professional order for healthcare professionals.
- Holding an insurance covering professional risks.
- Respect the ethics code of the profession
- Respect the principle of free and enlightened consent of the patient

[60] Ma Santé 2022 : Accélérer le virage numérique, Dominique Pons, Annelore Coury ; , available at : https://solidarites-sante.gouv.fr/IMG/pdf/masante2022_rapport_virage_numerique.pdf (last access 12/09/2022)

[61] DNS, Bilan feuille de route numérique en santé, available at : https://esante.gouv.fr/sites/default/files/media_entity/documents/bilan-feuille-de-route-220726-web.pdf (last access 12/09/2022)

[62] DGOS, Guide méthodologique pour l'élaboration du programme régional de télémédecine available at : https://solidarites-sante.gouv.fr/IMG/pdf/guide_methhodologique_elaboration_programme_regional_telemedecine.pdf (last access 12/09/2022)

[63] Organisation de la téléradiologie , Guide pour le bon usage professionnel et déontologique de la téléradiologie, élaboré par le Conseil Professionnel de la Radiologie (G4) et par le Conseil national de l'Ordre des médecins, available at : http://www.sfrnet.org/data/upload/files/teleradiologieg4cnom.pdf (last access 12/09/2022)

- Respect privacy and medical confidentiality
- Respect the rules for sharing information within the medical team
- Respect the European General Data Protection Regulation
- Respect the regulation concerning data storage.

In the context of the practice of telemedicine, a set of more specific rules must also be respected :

- **Free and informed consent of the patient** : Telemedicine acts must be carried out with the free and informed consent of the patient. After obtaining the patient's consent, healthcare professionals can exchange information with information or communication technologies.
- **Conditions for carrying out acts of telemedicine** : Telemedicine acts must be carried out under conditions that guarantee the authentication of healthcare professionals, the identification of the patient and the training and preparation of the patient for the use of the telemedicine device.
- **Respect the rules of keeping the patient's medical record** : At the end of the telemedicine act, a set of information must appear in the patient's medical record such as the report of the performance of the act, the acts done and the prescriptions , the identity of the professionals who took part in the act and, when applicable, the technical incidents that occurred during the act.
- **Duty of training to acquire the technical skills** for the use of telemedicine devices and software: Organizations and liberal health professionals who organize a telemedicine act must ensure that the healthcare professionals who participate have the required technical skills to use the devices.
- **Compliance with the requirements for the personal health data hosting** : Organizations and healthcare professionals using information and communication technologies for the practice of telemedicine must ensure that the use of technologies complies with the interoperability and security standards published by the ANS[64].

3.7.2 Eligibility of professionals, healthcare organizations to provide services

3.7.2.1 Healthcare Organizations

Healthcare institutions can carry out telemedicine acts. These acts are then billed to the National Health Insurance, in the same way as a classic outpatient consultation through the "fee-for-service system" (T2A).

Healthcare organizations can also receive subsidies for setting up telemedicine. This subsidy can take the form of devices (e.g. camera, touch pad, etc.) or digital tools (telemedicine software). This funding can also be paid in the context of experimentations.

3.7.2.2 Professionals

Telemedicine acts can be carried out by medical and paramedical health professionals. In order for their actions to be covered by the National Health Insurance, professionals must sign an agreement. This agreement determines the reimbursable acts and the amount of reimbursement.

In order to have the right to practice (and therefore to perform telemedicine acts), professionals must be registered in a professional order and respect the code of practice of their profession.

[64] Principales conditions s'appliquant aux actes de télémédecine » définies par la HAS en 2019 : https://www.has-sante.fr/upload/docs/application/pdf/2019-07/rapport_delaboration_teleconsultation_et_teleexpertise.pdf (last access 12/09/2022)

The teleconsultations can be carried out at the patient's home or in a pharmacy for people having difficulties to access the internet and who cannot go to the physician's clinic. It is also possible to carry out a teleconsultation with the support of a nurse.

In some rural areas without specialists, teleconsultation booths equipped with medical devices, a screen and a camera with microphone are sometimes used. Healthcare professionals can also equip themselves with medical devices (pulse oximeter, connected blood pressure monitor etc.) but this is not a mandatory prerequisite. Nevertheless, patients must be equipped with this type of medical devices in the case of medical remote monitoring.

3.7.3 Eligibility of patients to receive telemedicine services

Eligibility criteria for patients to receive telemedicine services depend on the performed act :

- Teleconsultation can be used for all types of patients, regardless of the pathology they suffer from. Nevertheless, it is up to the doctor to judge the need to carry out a remote or face-to-face consultation.
    - The patient must have physically consulted his/her attending physician at least one over the last 12 months.
    - The teleconsultation must be a part of a coordinated care and must therefore be performed by the attending physician first. If the patient does not have an attending physician, he will have to get in touch with a local territorial organization such as Health Professional Community (CPTS) or a medical structure providing primary care. These organizations will then have to designate a GP for the long-term follow-up of the patient.
    - Patients aged under 16 can benefit from a teleconsultation insofar as they are not obliged to appoint an attending physician.
    - Patients who do not have attending physician or whose attending physician is not available within a timeframe compatible with their health status can benefit from a teleconsultation.
    - Patients requiring an emergency care can benefit from a teleconsultation.
    - At the end of the teleconsultation, the general practitioner can prescribe medication or additional tests. This prescription can be sent to the patient by electronic transmission via a secured messaging system or a secured information sharing system. The prescription is sent directly from the doctor's business software to a secure health insurance server where other professionals (e.g. pharmacists) can consult it and trace the completion and delivery of the medication.
    - The e-prescription is part of "My Health Area" as a core service. Since July 2019, a national program for rolling out an e-prescription solution has been launched on drugs before being extended to other prescriptions (i.e. exams). In 2022, this program is being scaled up to all medical acts.
- Tele expertise:
    - Any patient can benefit from tele expertise. The use of tele expertise is at the discretion of the requesting healthcare professional and the relevance of its performance is a decision of the requesting doctor.
- Remote monitoring:
    - As part of the ETAPES experimentations, medical remote monitoring concerns patients suffering from chronic diseases. It is limited to five pathologies : patients with cardiac prophesises, diabetics, chronic heart insufficiency, chronic renal insufficiency and chronic respiratory insufficiency.

3.7.4 Security and safety of the service

Exchanges of medical information between healthcare professionals or between a professional and a patient must be performed using a secured channel. This is an essential condition insofar as the information exchanged is by nature sensitive. Therefore, their confidentiality must be protected. Public services such as Skype, WhatsApp, Facetime cannot be used to carry out a telemedicine act.

Moreover, the digital services must meet the technical and regulatory requirements imposed by the ANS. The ANS published a Reference Guide with 3 level of requirements :

- A functional repository for an autonomous patient teleconsultation platform
- A functional repository of accompanied patient teleconsultation platform
- A functional repository of a tele expertise platform

Teleconsultation services must meet a set of technical requirements and include the following functional components:

- Identification and authentication for healthcare professionals
- Identification of healthcare institutions
- Identification and authentication for patients
- Sharing medical records between healthcare professionals
- Sharing medical records between professionals and patients
- Meeting calendar
- A videoconferencing system
- Medical report and prescription editing and sharing system
- Payment system
- Billing system

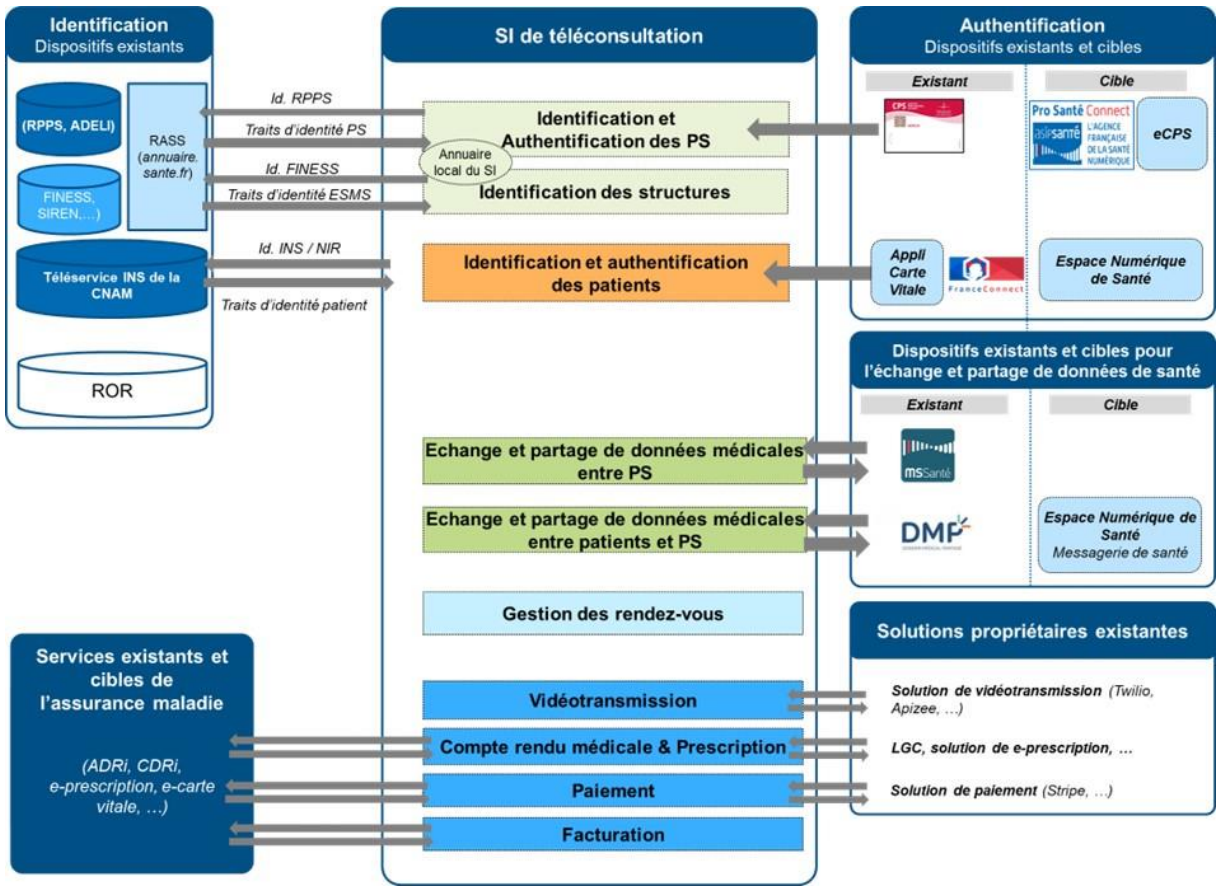

Figure 19: France -Teleconsultation functional components defined by ANS

Telemedicine solutions must also comply with the General Security Policy for Health Information Systems (PGSSI-S) and host their solution on an approved health data hosting server (HDS). The PGSSI-S applies as soon as personal health data is involved. It is made up of standards to be followed by the software editors. The repositories are brought together in a documentary corpus available for free access on the ANS website. Moreover, digital services must respect the European data protection regulation.

3.7.5 Standards of care

The regulatory framework for telemedicine acts, as well as the reference frameworks, have been developed in previous chapters. Based on feedback and medico-economic evaluations of telemedicine uses, professional and organizational standards will be periodically updated by competent authorities of the Ministry of Health to better integrate telemedicine practices into patient life and care.

3.7.6 Reimbursement and Financing

Teleconsultation is billed at the same rate as a physical consultation (25€ for a GP in sector 1), depending on the doctor's specialty and sector of practice, as mentioned before. The coverage rules are the same as for face-to-face consultation, with the same distribution between National Health Insurance and complementary health insurance. A doctor cannot carry out more than 20% of his activity remotely.

Tele expertise is remunerated since 2018. The bill is not invoiced to the patient, but directly to the National Health Insurance by the doctors who performed the act. 20€ are going to the requested doctor and 10€ to the requesting doctor, with a limit of 4 acts per year per doctor per patient. [65]

Modalities of reimbursement and financing **remote monitoring** acts are not yet known. The decree detailing these elements has not yet been published, it was expected by July 2022.

3.7.7 Ethical guidelines Patient consent to be treated with telemedicine

Whatever the patient's clinical situation, the doctor must request and obtain the patient's prior consent before carrying out a teleconsultation.

Within the framework of general practice, teleconsultation must respect the coordinated care plan. Thus, the patient must be known by the doctor before the teleconsultation. A physical consultation must have taken place in the 12 months prior to the teleconsultation. Exceptions to this rule exist, such as patients younger than 16 years old or emergency situations, as detailed before.

General practitioners must not store the videos after finishing a teleconsultation.

Some ethical guidelines are explained in a good practice charter edited by the National Health Insurance and health professionals representatives. The objective of this charter is to make doctors aware of the essential recommendations and obligations regarding the practice of remote activity.

Practice guidelines are edited by the High Authority of Health (HAS) as explained earlier in this chapter.

3.8 Legal and Ethical Challenges to date

One of the main challenges to date concerns the integration of telemedicine in healthcare organizations. Telemedicine is now used by city doctors and some specialists but there still a lot of work for

[65] Convention médicale AMELI : https://www.ameli.fr/medecin/textes-reference/convention-medicale-2016/convention-et-avenants (last access 12/09/2022)

professionals working in organisations to be accustomed to using telemedicine services. The COVID-19 pandemic has in some way accelerate the digital shift but there is still a lot of work needed to integrate telemedicine in daily routine.
Moreover, adoption of new technologies by professionals is an important element considering the aging of healthcare professionals and the evolution of medical demography. To address this challenge, new teaching programs have been recently published to integrate telemedicine in the daily practice of younger professionals.

Another debate concerns the accessibility of digital services for rural territories. These territories are already suffering a lack of care services and can sometimes have difficulties in accessing Internet. The challenge will be for the authorities to ensure that inequalities in the care offer and inequalities in access to telemedicine does not build up, otherwise benefits of telemedicine would be limited.

4 Annexes

4.1 List of Acronyms

4.1.1 Israel

Acronym	Meaning
EMR	Electronic Medical Record
GDP	Gross Domestic Product
GP	General Practitioner
HIE	Health Information Exchange
HMO	Health Maintenance Organization i.e. Health Plan- Insurer and Provider
IT	Information Technology
ITC	Israeli Telemedicine Community
MOH	Ministry of Health
NHS	National Health Service – England
OECD	Organisation for Economic Co-operation and Development
PCP	Primary Care Physician

4.1.2 Germany

Participants & Institutions	Level	Brief description
Politics & Legislation		
Federal Ministry of Health (BMG)	Federal level	**Supreme federal authority** Tasks: Preparation of draft laws, legal ordinances & administrative regulations on health protection, statutory health insurance, etc.
State Ministries of Health	State level	**Part of the state government of the individual federal states** Tasks: Hospital and investment planning, public health service (prevention & health promotion)
Corporations under public law with self-government		
Health Insurance (HI) • **statutory HI (SHI)** • **private HI (PHI)**	Federal level	**Part of the social insurance system** • financed by uniformly fixed contributions = assumption of costs • financed by risk-dependent premiums = reimbursement
Central Association of the Statutory Health insurance (GKV-SV)	Federal level	Task: Conclusion of contracts for care with KBV at federal level (& with German Hospital Association; DKG)
State associations of health insurance companies	State level	Task: Conclusion of contracts with KVs at state level (& with state hospital associations; LKG) e.g. for special treatment program

Federal Association of Statutory Health Insurance Physicians (KBV)	Federal level	Task: Ensures the provision of care by SHI-accredited physicians; conclude federal agreements with the GKV-SV
Association of Statutory Health Insurance Physicians (KV)	State level	Task: Ensures the provision of health care by SHI-accredited physicians at the state level; concludes contracts with the state associations of health insurance companies; redistributes physician remuneration among the individual SHI-accredited physicians
Federal Joint Committee (G-BA)	Federal level	**Central decision-making body of the joint self-government (GKV) in the German healthcare system** Task: Concretization of the entitlement to benefits of the statutorily insured in Germany, the benefit catalog of the health insurance companies Composition: Members of the health insurance companies (GKV), the service providers (DKG, KBV, KZBV), impartial members & patient representation Legal supervision: by the BMG

4.1.3 France

Acronym	Meaning in French	Meaning in English
ARS	Agence Régionale de Santé	Regional Health Agency
ANS	Agence du Numérique en Santé	National Digital Health Agency
CERF	College des Enseignant de Radiologie de France	College of Radiology Teachers of France
CPS		Professional Card for health professionals
CPTS	Communauté Professionnel Territoriale de Santé	Health Professional Territorial Community
DMP	Dossier Médical Partagé	Public Electronic Health Record
DNS	Délégation du Numérique en Santé	Ministry Delegation for Digital Health
eCPS	Carte électronique de Professionnel de Santé	Digital professional card for health professionals
EHPAD	Etablissement d'Hébergement pour Personnes Agées Dépendantes	Institutions for Dependant Elderly People
ESPIC	Etablissement de Santé Privé d'intérêt Collectif	Private Health Establishment of Collective Interest
FNMR	Fédération Nationale des Médecins Radiologues	National Federation of Medical Radiologists
GRADeS	Groupement Régional d'appui au Développement de la e-Santé	Regional Support Group for the Development of e-Health
HAS	Haute Authorité de Santé	High Authoriry of Health
HCSP	Haut Conseil de la Santé Publique	High Council of Public Health
HDS	Hébergeur Données de Santé	Health Data Hosting Server
HPST	Hôpital Patient Santé Territoire	Hospital Patient Health Territory
INS	Identifiant National de Santé	National Health Identity
MSS	Messagerie Sécurisée de Santé	Secure Health Messaging
PGSSI-S	Politique Générale de Sécurité des Systèmes d'Information en Santé	General Security Policy for Health Information System

Acronym	Meaning in French	Meaning in English
SDSI	Schéma Directeur des Systèmes d'Information	IT Systems Master Plan
SFR	Société Française de Radiologie	French Society of Radiology
SRH	Syndicat des Radiologues Hospitaliers	Syndicate of Hospital Radiologists
TSN	Territoire de Santé Numérique	Digital Health Territory
T2A	Tariffication à l'Activité	Activity- Based payment

4.2 Literature

4.2.1 Israel

See footnotes in section 2

4.2.2 Germany

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4.2.3 France

See footnotes in section 4