Study on the legal and organizational frameworks for delivery of healthcare services on distance
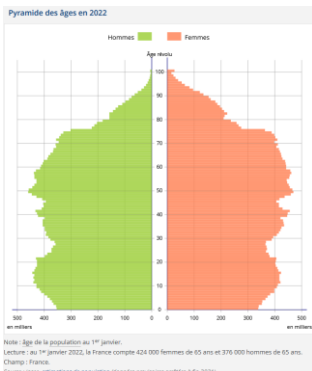
Country Report: **FRANCE, Stéphan Haaz & Maxime Beuzelin**, CATEL

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1. Context (1/3) - Health status of the French population

Good general health although there are significant socio-economic and geographic disparities and premature male mortality. Like many European Countries, the French Healthcare system is challenging by the ageing population, the increase of patients with chronical diseases, the shortage of paramedical and medical staffs and inadequate access to one or more kinds of medical services.

Pyramide des âges en 2022
Hommes | Femmes

Note : âge de la population au 1ᵉʳ janvier.
Lecture : au 1ᵉʳ janvier 2022, la France compte 424 000 femmes de 65 ans et 376 000 hommes de 65 ans.
Champ : France.
Source : Insee, estimations de population (données provisoires arrêtées à fin 2021).

Some figures :

- Life expectancy : 85,4 years (Women) / 79,3 years (Men)

- 738 000 births in 2021 - Cyclical fertility index : 1,8 children per woman

- Around 3% of the French population (1,7 million) are living in high medically underserved areas

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1. Context (2/3) – How the French Healthcare system is organised

Organization / policies	**Administration** Complex, based on a combination of centralization/decentralization and concentration/de-concentration of roles and missions according to a territorial division. Following several successive decentralization changes, the French Health Ministry has shared its power with local authorities managed by elected officials (e.g.: Departmental Councils) • <u>At national level:</u> **Health Ministry** = main organizer of the health system. Defines health policy and its implementation through the National Health Strategy. It relies on advisory and decision support structures (HCSP, Agence Nationale de Santé Publique – SPFrance , **Agence du Numérique en Santé – ANS** …) **The parliament** votes the budget via the Social Security Financing Act (LFFSS) on the basis of projected expenditures and revenues. • <u>At regional level:</u> Regional implementation of the National Health Strategy by the **Regional Health Agencies (ARS)** supported by Regional Support Groups for the Development of e-Health (**GRADES**) The ANS contributes to the implementation of the national digital health strategy. It collaborates on a regional basis with ARS and GRADES for the implementation of this strategy. The ANS has a regulatory role by publishing technical guidelines and operating standards. At regional level, GRADES develop and implement the Information System Master Plan (SDSI). GRADES are responsible for the implementation of the Regional Digital Health Area (ENRS) and respond to digital public health needs through the deployment of regional digital solutions.

Funding / Management	**Public health insurance system** Compulsory Organism : National Social Security Agency (CNAM) <u>Reimbursement:</u> Universal healthcare reimbursement base. Professionals must sign an agreement with the CNAM to allow the beneficiaries to be reimbursed <u>Financing:</u> social contributions and taxes	**Private health insurance system** Optionnal Organism: Mutual insurance companies / insurance companies <u>Reimbursement :</u> according to the member's level of subscription <u>Financing :</u> subcription
Healthcare facilities	**Public Sector** <u>Public hospitals:</u> hospitals and university hospitals Ultra-specialized medical treatments are often performed in university hospitals.	**Private Sector** <u>Private hospital:</u> Profit private organisation (ex : medical center) or non-profit private organization (Private Health Establishment of Collective Interest – ESPIC) <u>Independant Praticians:</u> GPs, specialists, other medical professions (dentists, midwives) or paramedics. Practice grouped within health centers (MSP) or health centers.

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1. Context (3/3) – French policy engagement towards digital transformation

A policy fostering the adoption of digital technology in professional practices since 2014:

- **2019 : "**Hospital Patient Health Territory" (HPST) an important law introducing the definition of telemedicine
- **2014-2017** "Digital Healthcare Territory" (TSN), an investment program of €80M spread out in 5 regions targeting to develop innovative patient care organizations strengthened by a package of integrated services.
- **2018-2022** : Digital health Roadmap of 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 :
  - 2018 – 2021 : ETAPES, an important telemedicine experimentation to improve patient care with remote monitoring
  - 2019 : HOP'EN, an investment program of €420M to support the evolution of hospital information systems.
  - 2022 : SEGUR, an investment program of €2Mdrs for the digitalization of the ongoing patient management and to widespread ease and secure sharing of health data between health professionals and with users to improve prevention and care.

National technical initiatives led by the government:

- Public Electronic Health Record (DMP) : A long and chaotic implementation since 2004 with only 10 million accounts had been opened by January 2021.
- 2022 : Launch of new platform "My Health Area" included an improved release of DMP

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2. Organizational Framework for Telemedicine (1/2)

The public health code (law) has defined 6 types of acts and the methods of implementation were defined by decree :

- **Teleconsultation** when patient is consulting a doctor through videoconference.
- **Remote monitoring** of patient
- **Tele-expertise** when a doctor is asking an advice to a fellow doctor
- **Guided Teleconsultation** when a patient is consulting a doctor through videoconferencing with the support of a nurse or a pharmacist
- **Tele-assistance** = a caregiver assist his colleague in carrying out an act
- **Tele-care** when a paramedical professional is performing an act remotely

The level of telemedicine implementation in the country is heterogeneous

- **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 teleconsultation acts can be carried out through these platform. Remote monitoring are carried out through private solution.

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2. Organizational Framework for Telemedicine (2/2)

The reimbursement terms are defined by the national social security agency through a national convention signed with doctor's unions. The reimbursement conditions made by law are the following :

- *Teleconsultation :* Compliance with the coordinated care pathway with prior referral from the primary care physician and with the respect of a logic of territorial response. Alternating face-to-face consultations and teleconsultations. Same reimbursement rate as in-person consultation
- *Remote monitoring :* it's coming soon
- *Tele expertise :* 4 acts per year by patient with chronic disease (5 pathologies : heart failure, renal insufficiency, respiratory insufficiency, diabetes, implantable cardiac prostheses). 100% reimbursed by National health insurance, no additional fee.
- *Tele care :* Same reimbursement rate as in-person care

=> Limitation : A doctor cannot carry out more than 20% of his activity remotely

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3.   Legislation and regulation for telemedicine (1/3)

- *Since 2019, the French Health Ministry has been carrying a national digital health strategy. It aims to accelerate the exchange and sharing of data by relying on reference documents and core services.*
- *The National Digital Health Agency (ANS) defines the way that digital tools should work, interact together and respect data protection policies in order to organize a coherent framework for telemedicine. It drives 2 priority workshops :*
    - **SEGUR** : To ease, to secure and to scale up the sharing of health data between caregivers and patients to improve the care quality and tackle the disparities of care access
    - **"My Health Area"** : it includes 4 main functionalities : a secure mailbox, an upgraded release of public Electronic Health record (DMP), a calendar, a catalog of digital health services referenced by the Ministry.
- *The ANS publishes a functional repository to define the minimum functionalities expected of a telehealth software.*
- *Telehealth 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)*
https://esante.gouv.fr/produits-services/pgssi-s/corpus-documentaire
https://industriels.esante.gouv.fr/produits-services/telesante

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3.   Legislation and regulation for telemedicine (2/3)

- *Eligibility of patients to receive telemedicine services :*
    - 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.
    - At the end of the teleconsultation, the general practician 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 core service. Since July 2019, a national program for rolling out e-prescription solution has been launched on drugs before being extended to other prescriptions. In 2022, this program is scaled up to all acts.

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3.   Legislation and regulation for telemedicine (3/3)

- *Liability of health professionals when providing TM service and of technical operators such as telemedicine centres*
  - The practitioner must contract with a company providing telehealth services. Thus, the practitioner and the company are bound by a subcontracting agreement. The practitioner must check that several elements are included in the contract.
  - In particular the processing of health data must only be carried out on the instructions of the practitioner, the service provider undertakes to put in place all the required security measures. The provider has to cooperate as the data controller when patients request information about the processing of their data. The provider must also ensure that its staff sign confidentiality agreements and delete or transfer the data at the end of the service.

    https://www.conseil-national.medecin.fr/medecin/exercice/point-teleconsultation

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4.   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.
- **General practician 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 representatives of professionals.**
  - 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)**

https://www.ameli.fr/medecin/exercice-liberal/telemedecine/teleconsultation/charte-de-bonnes-pratiques-de-la-teleconsultation

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Challenges to date

- *Integration of telemedicine in healthcare organizations*
- *Appropriation of technologies by the professionnals*
- *Internet connexion in rural territories*

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