FRENCH NATIONAL PILOT COMMITTEE FOR DIGITAL ETHICS

Reflections and warning points on digital ethics issues in situations of acute health crisis

Ethics Watch Bulletin No. 3

Ethical issues related to digital tools used in telemedicine and telecare in the context of the COVID-19 pandemic

Tuesday July 21, 2020

Right from the start of the lockdown period, there was a sharp rise in telemedicine and telecare procedures: in just three weeks, their number increased 100-fold, from 10,000 per week to almost one million. This greater reliance on teleconsultation when demand rose sharply – mainly due to the lockdown – was possible because the health system was already prepared for it: digital tools for exchanging and sharing reliable information were available (networks, hardware, software, platforms, etc.) and the public authorities took exceptional measures to authorize the practice of telemedicine to facilitate continuity of care.

All of these points are documented in detail in this third Ethics Watch Bulletin of the French National Pilot Committee for Digital Ethics (CNPEN). Because the subject of telemedicine falls within both the digital and health fields, this bulletin was drafted by a working group involving members of the National Consultative Ethics Committee for Health and Life Sciences (CCNE) and the CNPEN. It highlights the merits and complexity of these new medical practices, discusses the issues raised by the combination of medical and digital requirements, and sets out seventeen "vigilance points" that enable these requirements to be taken into account. In particular, it is important to raise awareness among healthcare professionals of the ethical issues involved in the use of digital tools, the need to take account of inequalities in access to telemedicine, and the importance of ensuring that in a healthcare context, only secure data communication tools are used that comply with regulations on the hosting and processing of health data.

The massive use of telemedicine during this epidemic raises questions about the development of this practice as the lockdown is progressively eased, not only in anticipation of future crises, but also in routine practice once the epidemic has been resolved.

Raja Chatila, Laure Coulombel, Christine Froidevaux
Rapporteurs of the working group
Claude Kirchner
Director of the French National Pilot Committee for Digital Ethics

2

CONTENTS

I. Deployment of digital tools in telemedicine and telecare during the COVID-19 crisis

The lockdown during the SARS-CoV-2 epidemic has disrupted care practices and, in particular, access to medical consultation for patients, whether they have mild forms of COVID-19 or other illnesses requiring medical care or monitoring. On the one hand, there was a decline in the activity of medical practices[1] from the moment the lockdown was announced, intensified by the reorganization of hospital services in favor of COVID-19 patients, and on the other hand, there was a significant increase in teleconsultation (in the broad sense), which however only partly compensated for the dramatic fall in patients seeking healthcare.

1. Telemedicine and telecare before the COVID-19 crisis

Within the meaning of Article L6316-1 of the French Public Health Code, *telemedicine* is a form of medical practice performed remotely using information and communication technologies. It includes five acts according to the 2010 decree[2]: teleconsultation, tele-expertise (when a physician remotely seeks the opinion of another physician), telemonitoring (when a medical professional remotely interprets the data needed for the medical care of a patient and, if necessary, takes appropriate decisions), tele-assistance (when a medical professional remotely assists another healthcare professional during the performance of an act), and medical regulation (the "15" emergency telephone number). Its deployment has been accelerating since late 2018, when teleconsultation and tele-expertise became eligible for reimbursement by the French health insurance scheme and were integrated into the coordinated healthcare process (i.e. with a referral by the attending physician)[3].

Telecare is care performed remotely, and is distinct from telemedicine. It was included in the Health Act voted in July 2019, but as of July 17, 2020, not all of its implementing decrees had yet been published. It uses information and communication technologies to put a patient in touch with one or more pharmacists or auxiliary health workers[4] performing their duties[5].

---

[1] A 40% decrease for primary-care medical practices (30% after allowing for teleconsultations). A 70% decrease for specialist practices (CNAM data) – see the July 2020 report to the Minister of Social Security and Parliament on the changes in health insurance expenses and income for 2021 https://assurance-maladie.ameli.fr/sites/default/files/rapport-charges-et-produits-2021.pdf
[2] Decree No. 2010-1229 of October 19, 2010 relating to telemedicine
[3] https://www.ameli.fr/fileadmin/user_upload/documents/Dossier-de-presse_Teleconsultation_12092018.pdf
[4] Nurses, speech therapists, occupational therapists, psychomotor therapists, masseur-physiotherapists https://solidarites-sante.gouv.fr/IMG/pdf/covid-19-telesuivi-infirmier.pdf
[5] The legal framework for telecare acts will be defined in the new Act on the Organization and Transformation of the Health System https://www.senat.fr/rap/l18-524/l18-52419.html

The development of telemedicine has been slower than projected by the French health insurance scheme[6,7] in spite of the experiments carried out over the past several years[8], and its adoption across the country has been uneven (44% of teleconsultations were in Île-de-France).

More recently, a ***strategy for transforming the health system has been implemented***, with a clear ambition to incorporate digital technologies, mainly through the Act of July 24, 2019 on the Organization and Transformation of the Health System[9]. The *Ma Santé 2022* plan thus provides for the deployment of digital tools in the healthcare process, including telemedicine and telecare, the creation of a digital health space for each citizen incorporating his or her shared medical record and enabling secure exchanges with professionals and institutions, and the creation of a health data hub.

Teleconsultation is a medical practice subject to the same ethical rules as care provided in a physician's practice. It should feel the same, even if it involves different ways of questioning and listening to the patient. As with a physical consultation, the physician is responsible for any act or prescription arising from the teleconsultation; in particular, the physician should terminate the teleconsultation and arrange for the patient to visit a local practice, if he or she deems it necessary in order to establish a diagnosis. The teleconsultation may or may not be in the presence of a caregiver, for example when it takes place in a nursing home. It may or may not require use of a connected device, such as a stethoscope or oximeter. A permanent teleconsulting booth with software and connected equipment, installed in various premises, companies or pharmacies, can also be used.

As indicated on the website of the Ministry of Solidarity and Health[10], teleconsultation is highly codified within the framework of the coordinated healthcare process, and the relevance of remote rather than face-to-face care is assessed by the physician, i.e. it is up to the physician to suggest it to the patient, and to discern in which cases it is appropriate or not. The French National Authority for Health (HAS) points out that the use of teleconsultation is a shared decision between the patient and the medical professional who will carry out the teleconsultation[11] and lists a number of eligibility criteria.

---

[6] *La gouvernance de la télémédecine face à l'organisation libérale des soins [The governance of telemedicine in the face of the liberal organization of care].* Florence Gallois, Amandine Rauly. L'Harmattan | *Marché et Organisations* 2020/2 no. 38 | pages 37 to 60

[7] French Court of Auditors, 2018 Annual Public Report, Volume 2: *Les services publics numériques en santé [Digital public health services].* French Court of Auditors, Report on the implementation of the social security financing laws for 2017, Chapter VII, *La télémédecine : une stratégie cohérente à mettre en œuvre [Telemedicine: a coherent strategy to be implemented],* pp.295-330.

[8] The average number of acts was below 200 per week in 2018, 700 in mid-February 2019 and 3,300 in September, for a total of 60,000 teleconsultations by late August 2019. The authorities had anticipated 500,000 teleconsultations in 2019 and 1.3 million in 2021. See documents cited in [1] and [6].

[9] https://solidarites-sante.gouv.fr/IMG/pdf/190425_dossier_presse_masante2022_ok.pdf, et https://www.legifrance.gouv.fr/affichLoiPreparation.do?idDocument=JORFDOLE000038124322&type=general&typeLoi=proj&legislature=15

[10] https://solidarites-sante.gouv.fr/soins-et-maladies/prises-en-charge-specialisees/telemedecine/la-teleconsultation/article/generalites

[11] https://www.has-sante.fr/jcms/c_2844641/fr/qualite-et-securite-des-actes-de-teleconsultation-et-de-teleexpertise

2. Massive use of telemedicine during the crisis

The number of consultations carried out remotely (which in this document we equate to teleconsultations) and reimbursed by the National Health Insurance Fund (CNAM) has increased considerably since the beginning of the lockdown[12], although the analysis of the digital tools used and the medical justifications is still currently unable to distinguish between those that actually used a videotransmission tool (referenced teleconsultations) and those carried out by telephone (which have also been regarded as teleconsultations). Alongside these institutional figures, the Doctolib platform also announced a 100-fold increase in teleconsultation appointments as of April 22, 2020[13]. This increase was also noted by platforms developed by complementary health insurance organizations (MesDocteurs.com)[14].

Several factors have facilitated the use of teleconsultation during the crisis:

- *The COVID-19 epidemic context.* Both physician and patient needed to protect themselves from the risk of contamination, especially where there was a shortage of masks. The screen and distance – previously seen more as obstacles to "human contact", which is essential to the physician-patient relationship – protected against contamination of the physician by the patient, the patient by the physician[15], or one patient by another patient, due to the absence of any clinical examination or contact with other people in a waiting room or while traveling. In the context of the pandemic, remote communication with the physician could be seen as a guarantee of continued access to healthcare, which would otherwise be jeopardized by the fear of contamination during a face-to-face consultation or the lack of availability of the attending physician.
- *The exceptional measures[16] introduced by the health authorities.* These played a fundamental role in facilitating access to remote consultations (teleconsultation and telephone) and encouraging patients to use them. However, these measures only partly mitigated the problem of patients not seeking treatment[17] and failed to offset the decline in consultations for diseases other than COVID-19 from the start of lockdown, particularly with specialists.

---

[12] "80,000 teleconsultations were billed to the French health insurance scheme in the week of March 16, 2020, then 486,369 from March 23 to 29, 2020 and more than one million in early April. The French health insurance scheme counted fewer than 10,000 per week until early March. In April 2020, teleconsultations accounted for more than 11% of all consultations, compared to less than 1% before the crisis".
 See: https://www.ameli.fr/fileadmin/user_upload/documents/20200331_-CP_Teleconsultations_Covid_19.pdf
[13] Press kit of April 22: 2.5 million teleconsultation appointments in one month and an increase from 1,000 consultations per day to over 100,000, with 800,000 patients having had at least one teleconsultation via the site.
[14] "The telemedicine company MesDocteurs saw a 400% increase in registrations from healthcare professionals for its teleconsultation service AvecMonDoc.com during the lockdown period (between March 16 and May 11). The volume of unscheduled teleconsultations grew by '+700%' over the same period. Since the gradual lifting of the lockdown measures, the volume of unscheduled teleconsultations has fallen by 50%". (TicSanté website, June 18, 2020)
[15] The inadvertent transmission of infections by caregivers has been known since the mid-19th century thanks to Ignaz Philipp Semmelweis. This Hungarian obstetrician drastically reduced the mortality rate in maternity wards simply by imposing the practice of hand washing.
[16] Exceptional measures: 100% reimbursement of remote communications, including telephone calls if patients did not have access to digital tools or the Internet, and calls via non-referenced communication tools for the general public; teleconsultation on the patient's initiative and even when not part of the coordinated healthcare process, i.e. when the patient was not already known to the consulting physician.
[17] https://lesgeneralistes-csmf.fr/2020/04/27/attention-a-la-bombe-a-retardement-post-epidemie-les-medecins-face-aux-dommages-collateraux-du-covid-19

- *The diversity and use of digital tools for communication and information sharing.*

Alongside medical teleconsultation, the health authorities also introduced waivers to allow telecare, which in particular enabled regular monitoring of patients with chronic illnesses. Another form of remote care during the crisis was the telemonitoring of COVID-19 patients at home using digital questionnaires (Covidom in Paris, MHLINK in Montpellier or COVIDAPHM in Marseille). Other available applications use self-assessment questionnaires and algorithms for referring potentially infected patients (maladieCoronavirus.fr website).

3. Ethical issues of digital tools used in telemedicine and telecare

The rapid shift towards remote consultation that both patients and physicians have been forced to make in response to the health emergency raises legitimate questions about the benefit-risk ratio of this method of practicing medicine, which differs from traditional consultations held in the physician's practice, especially when digital solutions are used. This debate is all the more important as citizens' attitudes are changing and the widespread use of digital technology is strengthening the trend towards medical consumerism. In addition to scheduled consultations, this is generating demand for rapid medical advice via digital communication tools. This reflection – which goes beyond the scope of this bulletin – is important during the easing of lockdown restrictions, when a discussion on the future of the exceptional measures behind this surge in teleconsultations is ongoing[18,19], and better integration of digital tools in medical practice has been enshrined in the future Health Act.

The first ethical issue relates to caregivers' use of digital solutions likely to entail risks for patients. These solutions call for criteria that are often overlooked, particularly in times of crisis. The French Ministry of Solidarity and Health therefore took urgent action to identify around a hundred available telehealth tools, mainly videotransmission tools (list drawn up on March 18, and updated on May 4), and put forward a list of criteria for selecting them, such as ease of installation and security[20]. Besides choices based on the desired technical features, the use of such digital tools raises ethical issues that we will examine below. For example, risks relating to invasion of privacy and data protection were exacerbated during the crisis due to the exceptional measures.

Aside from the organizational and technical aspects of teleconsultation, the remote consultations carried out during this health crisis have fueled the ethical debate already under way, which arose from the upheaval in care practices facing both caregivers and patients, with the advent of digital tools. This development, sometimes feared as an "industrialization" of healthcare, could weaken the principles of medical ethics and needs to be taken into account. In the post-crisis context, it would be interesting to discuss relevant cases of telemedicine and telecare in medical treatment, and how the use of digital solutions could be adapted to ensure the security of data exchanges while not hindering them.

---

[18] See the report cited in [1]

[19] Société Française de Santé Digitale, *Télésanté « post Covid-19 » en France. Dix préconisations pour accélérer la télésanté [Telehealth in France Post-COVID-19. Ten Recommendations to Accelerate Telehealth] - July 2020 –* https://sfsd-umd.fr/wp-content/uploads/2020/07/Position-Paper-SFSD-10-préconisations-pour-la-télésante-juillet-2020.pdf

[20] https://solidarites-sante.gouv.fr/soins-et-maladies/maladies/maladies-infectieuses/coronavirus/professionnels-de-sante/article/teleconsultation-et-covid-19-qui-peut-pratiquer-a-distance-et-comment

Another major ethical issue is the requirement for quality information on the conditions for using telemedicine and on its benefits and risks to be made available to the patient, to enable him or her to give free and informed consent to these new practices, without risk of discrimination or penalty. Lastly, the crisis has led to the development of private teleconsultation platforms outside the coordinated healthcare process, which could jeopardize the principle of solidarity and pooling of risks, weaken the ongoing physician-patient relationship and have negative consequences for the patient if these platforms are of poor quality.

II.   Vigilance points concerning the deployment of telemedicine and telecare in times of crisis and post-crisis

1. Caregiver training and patient information on teleconsultation

Like tele-expertise, teleconsultation, which is part of the coordinated healthcare process, is a highly codified medical practice[21] that requires training and knowledge of regulatory aspects, certain ethical specificities and technical aspects (in particular, relations with the managers of platforms providing secure digital solutions).

Although there is a large offering available (90 digital teleconsultation solutions identified by the Ministry on June 12, 2020 based on self-reporting by the software companies offering them[22]), the selection criteria may not be known, and institutional communication with stakeholders in the field may not be very effective. Given the low percentage of physicians having tested teleconsultation before the crisis, it can be assumed that a number of caregivers unfamiliar with this medical practice may have been reluctant to use it[23].

According to Nathalie Salles, "the limitations of the democratization of telemedicine are due to a lack of training and support for healthcare professionals" [our translation][24]. It is therefore important to offer training to caregivers to enable them to acquire the knowledge needed to master telemedicine practices in terms of IT and regulations (securing communication channels, data confidentiality, subcontracting contracts with platform managers, etc.), in both normal and crisis situations.

Besides telemedicine, the importance of the requirement for theoretical and practical training on digital technologies during healthcare professionals' university studies cannot be overstated.

According to the Odoxa survey published in January 2020, 29% of patients who have tried teleconsultation are dissatisfied, with technical aspects being the main driver of their satisfaction or dissatisfaction[25]. There is therefore also a need for widespread communication to patients of effective and simple information on the use of teleconsultation.

---

[21] See the good practice guide published by the French National Authority for Health (HAS) in May 2019. Reimbursement is governed by strict rules established by Amendment 6 to the agreement signed by the CNAM (2016). The patient must have already had a physical appointment with the physician within the last twelve months, the teleconsultation must comply with the "healthcare process" in the same way as a conventional consultation, and the technology used must be secure. Remote consultation must always be carried out within the framework of a *"territorial organization"*.

[22] https://solidarites-sante.gouv.fr/soins-et-maladies/maladies/maladies-infectieuses/coronavirus/professionnels-de-sante/article/teleconsultation-et-covid-19-qui-peut-pratiquer-a-distance-et-comment

[23] According to the Odoxa survey published on January 27, 2020, http://www.odoxa.fr/sondage/panorama-telemedecine-aujourdhui-perspectives-lavenir, the technical concerns (sound, image, connection) raised in the answers to its questionnaire undoubtedly explain why teleconsultation is not being integrated more widely in the future practices of healthcare professionals.

[24] Nathalie Salles, Nov. 2019: https://sfgg.org/espace-presse/interviews/que-peut-la-telemedecine-pour-les-patients-ages-par-nathalie-salles-presidente-du-conseil-scientifique-de-la-sfgg-et-presidente-de-la-societe-francaise-de-sante-digitale/

[25] According to the Odoxa survey cited in [23], 80% of French people know what a teleconsultation is, but only 6% have tried one.

1) Offer training in professional telemedicine practices for caregivers, covering the technical aspects and specificities of this new medical practice.

2) Raise awareness among caregivers of the ethical issues related to the use of digital tools.

3) Provide explicit information to patients on teleconsultation arrangements and the ethical issues of these digital tools, and assist them in accessing and using these tools.

2. Respect for patient autonomy and collection of free and informed consent

As with any offer of care, it is important that the patient be informed of the conditions of the teleconsultation and can give free and informed consent when offered this practice. In the case of telemedicine, the patient's consent to care includes his or her acceptance of the medical act and of the fact that it is carried out remotely. The patient therefore accepts that his or her digital data may be shared and processed by different parties, and must therefore be informed of the conditions for processing and protecting these personal data and what happens to them. The physician's ethics and responsibility require him or her to ensure that data transmission is secure and confidentiality is maintained. The patient's consent is essential to the relationship of trust with the physician, which promotes patient adherence to both the diagnosis and the treatment proposed. This relationship of trust, which is customary when it is the attending physician carrying out the teleconsultation, may prove more difficult in the case of a first consultation, or if the teleconsultation involves a physician who does not know the patient (situations which have been enabled by the exceptional measures). It is important to respect the choice of people who do not wish to use a teleconsultation, without this affecting the quality of their medical care, which it must then be possible to provide within the framework of a traditional consultation.
If the patient were to have no other means of access to a physician than via teleconsultation, a lack of confidence, induced for example by the absence of a concrete human relationship, could lead him or her to doubt the relevance of the diagnosis. The refusal to accept any prescription that might follow would then be detrimental to the patient and even to the wider community in the case of a contagious disease.

Vigilance points:

4) Ensure respect for information and free and informed consent of the patient, despite the constraints of the health emergency and the use of remote communication tools. Particular attention should be paid to data collected and stored, even temporarily, on a platform.

5) Raise awareness among all stakeholders of the importance of clearly identifying the conditions and purposes of processing data collected during a teleconsultation or telecare (research objectives, for example) and of ascertaining the quality and status of the associated providers (public, private, national or foreign).

6) Ensure that patients opposed to teleconsultation are not discriminated against or penalized in terms of the quality of their medical care.

3. Equity in access to telemedicine acts

While telemedicine allows easier access to care, its use may be limited or even discriminatory for people who:

- are not, cannot or do not wish to be equipped with computers, or who have obsolete equipment;

- lack the knowledge needed to use their computer system, or to comprehend the information on organizing a teleconsultation;

- live in housing that is too cramped for them to be able to isolate themselves and talk to the physician in conditions of privacy comparable to those of a physician's practice. This problem is aggravated during lockdown and its gradual easing, including as a result of teleworking with the overuse of domestic space;

- rarely see a physician. In the context of the pandemic, it should be remembered that the people most at risk (those suffering from mental illnesses, the economically vulnerable, the socially excluded, migrants, etc.) have greater difficulty than others in establishing a link with medical workers and often do not benefit from any medical monitoring.

The consequences of "digital" exclusion[26] have become even more evident during the COVID-19 epidemic, as the vulnerable populations mentioned above live in a social context where they are particularly exposed to the risks of contamination. The inequalities in access to digital devices combine with social inequalities, thereby compounding health and regional inequalities[27].

Vigilance point:

7)   Inequalities in access to telemedicine are a real ethical issue, especially for economically vulnerable populations. Specific measures could help reduce this disadvantage, for example by developing spaces dedicated to teleconsultation, such as in pharmacies or other local places, and/or by seeking support from local intermediaries accustomed to the use of IT tools, such as certain local authorities, care assistants or associations.

4. Data security, confidentiality and interoperability

Health data are considered "sensitive" and as such they benefit from specific protection, which has been enshrined in particular in the French Data Protection Act (LIL, 1978), the Public Health Code and the European General Data Protection Regulation (GDPR,

---

[26] Regarding access to digital tools, according to INSEE, in France, in 2019, 12% of people aged 15 or over – including 53% of people aged 75 or over – had no Internet access from home (this figure was 34% among people without qualifications or a certificate of primary education (CEP) and 16% among people on the lowest incomes). https://www.insee.fr/fr/statistiques/4241397#consulter

[27] See the Ethics Watch Bulletin No. 1, which presents ethical questions related to the use of digital tools in the framework of fraternity actions: https://www.ccne-ethique.fr/fr/actualites/comite-national-pilote-dethique-du-numerique-bulletin-de-veille-ndeg1

11

transcribed in the amended LIL). On this issue, medical ethics and computer ethics converge around the values of confidentiality and privacy.

The requirements within the teleconsultation framework have been defined[28]: it is important to ensure the confidentiality of the exchange with the physician, as this is necessary to comply with medical secrecy and forge a relationship of trust between the patient and the physician. This means that not only must the patient be able to isolate him or herself for the teleconsultation (or be accompanied by a professional who is bound by confidentiality), but also that the mode of communication used for this teleconsultation is secure.

The Ministry of Solidarity and Health points out that professionals are required to use tools (whether referenced or not) that comply with the regulations on hosting of health data (HDS) and the general policy on the security of health information systems (PGS-SIS). However, if this is not possible, and solely as part of the response to the COVID-19 epidemic, professionals may use other tools (Ministerial Order of 19 March 2020)[29].

Therefore, in order to facilitate continuity of care during the epidemic, if healthcare professionals did not have the equipment needed to use referenced and secure systems, they were given exceptional authorization to hold consultations via digital communication tools for the general public[30]. This broader framework contributed to the increase in the number of teleconsultations. It is important to remember that security and confidentiality must be observed in all circumstances and that only approved and secure systems are allowed. A consultation is currently under way concerning the certification and accreditation of health data hosts[31].

More generally, there is the question of whether to adapt technical tools to emergency situations, where the prompt exchange of data or documents may be vital (e.g. in the case of tele-expertise). This question is particularly relevant to the management of emerging serious diseases, such as acute forms of COVID-19: the exchange of information between practitioners is essential (tele-assistance and tele-expertise), and knowledge of a patient's medical history – which is needed to define criteria relating to seriousness and choose appropriate treatment or actions – is sometimes difficult to reconstruct without access to his or her medical record[32]. The interoperability of information systems is therefore essential.

There is therefore an inevitable tension between the need to secure the transmission of these data – which makes communication more complex for both patients and practitioners – and the risk of abandoning the use of secure tools because of technical difficulties. In a crisis situation, it is customary to strike a balance between the security of communications and the benefit to both the patient's health and public health, and thus to adjust the security requirements according to the urgency and the benefit to the patient or the community.

---

[28] "Have communication tools for the teleconsultation; have IT tools for exchanging, sharing and storing data: secure health messaging and/or access to a secure exchange platform; approved or certified health data host if data are outsourced". (HAS, https://www.has-sante.fr/upload/docs/application/pdf/2019-07/fiche_memo_teleconsultation_et_teleexpertise_mise_en_oeuvre.pdf).

[29] https://solidarites-sante.gouv.fr/soins-et-maladies/maladies/maladies-infectieuses/coronavirus/professionnels-de-sante/article/teleconsultation-et-covid-19-qui-peut-pratiquer-a-distance-et-comment

[30] WhatsApp, Skype, Facetime, telephone and unsecured personal messaging.

[31] https://participez.esante.gouv.fr/project/referentiel-hds-2020/presentation/introduction

[32] This raises the question of the merits of the shared medical record, which is not addressed here because it is not specific to the pandemic crisis.

Confidentiality of data is fundamental, even if they cannot be used to directly identify a person. One example is their possible use for medical research and innovation. In the case of COVID-19, clinical and epidemiological knowledge of this new disease relies on the analysis of patient data. It should be remembered that despite the emergency situation, the use of medical records for research purposes is only permitted in accordance with the GDPR, while complying with the stated purposes and storage period of the data, and maintaining a balance between general interest and respect for the patient's privacy[33].

The following vigilance points are very important and are in line with the framework of the *Accélérer le virage numérique [Accelerating the digital transformation]* roadmap, one of whose five objectives is to intensify the security and interoperability of health information systems[34].

Vigilance points:

8) In all circumstances, when communicating health data, use secure tools that comply with hosting and processing regulations.

9) As of now, provide information on secure digital communication tools currently available for telemedicine and ensure that they are adopted by healthcare professionals and the population.

10) Ensure the development of interoperable information systems, as well as sovereign and secure communication tools and information hosting and processing centers for telemedicine, and subject them to regular independent assessments.

11) Looking beyond the urgency of the health crisis, raise awareness among citizens of the risks associated with the flow of digital data and the use of data collected during teleconsultations carried out with non-secure tools.

---

[33] https://gdpr-info.eu/art-89-gdpr/
[34] https://solidarites-sante.gouv.fr/IMG/pdf/190425_dossier_presse_masante2022_ok.pdf.

5. Principles of solidarity and risk pooling

The greater accessibility of remote consultations due to the exceptional measures during the COVID-19 epidemic has been accompanied by an increased offering of digital solutions by private companies or the insurance sector.

One of the exceptional measures introduced during the COVID-19 crisis enabled full reimbursement of the teleconsultation. This measure also applied to acts outside the coordinated healthcare process[35], which would not normally be fully reimbursed. Online consultation platforms – which have proliferated in recent years[36] – have been very responsive as a result of this greater accessibility, with some offering physicians free use of their services during the COVID-19 crisis. This could be regarded as commercial advertising for healthcare. Some people also fear that this crisis will accelerate these practices, described in a report by the National Council of the Order of Physicians[37] as "the Uberization of health" [our translation]. This mainly relates to the development of teleconsultation platforms funded by complementary health insurance organizations (French people who have taken out a contract can benefit from four to six teleconsultations per year), or commercial platforms that are independent of these complementary organizations and subject to competition. In general, these relate to occasional treatments concerning minor risks, on the patient's initiative. They are not covered by the French health insurance scheme if they do not form part of a territory-based continuous primary care service. However, their role has not been fully clarified and the boundary between tele-advice practices (which are excluded from the telemedicine framework) and teleconsultation practices is still unclear.

Their uncontrolled growth could constitute a parallel offer of private care developing alongside the coordinated healthcare process, which could undermine the principle of solidarity and pooling of risks on which our healthcare and health insurance system is based. This parallel offer could introduce competitive disruption, for example if a platform were to conduct commercial follow-ups or redirect a patient to a caregiver offering teleconsultation – which could be regarded as patient poaching.

A fundamental question here relates to the quality of this care, once it falls outside the coordinated healthcare process.

---

[35] The healthcare process is coordinated by the attending physician; the teleconsultation falls outside this process if it has not been offered to the patient by his or her attending physician or by a physician to whom the patient has been referred by the attending physician, or if it takes place outside the area where the patient normally lives.
[36] Qare, Consulib, Doctoconsult, Hellocare, Doctinet, MédecinDirect, CompuGroup Medical, etc.
[37] Report on *Télémédecine et autres prestations médicales électroniques [Telemedicine and other electronic medical services]*, Feb. 2016 and *La télémédecine face au risque d'ubérisation des prestations médicales : Rappel des positions du Conseil national de l'ordre des médecins [Telemedicine and the risk of Uberization of medical services: Reminder of the positions of the National Council of the Order of Physicians]*, Feb. 2018.

12)   There is an ethical requirement to avoid the uncontrolled development of the health market in order to observe the principle of national solidarity on which our healthcare and health insurance system is based. In particular, it is important to ensure that teleconsultation platforms comply with the ethical and regulatory obligations applicable to medical care.

6. Online questionnaires

What the COVID-19 epidemic also revealed was the usefulness of "home telemonitoring". Faced with the epidemic, hospitals quickly recommended such tools[38] for patients carrying or suspected of carrying coronavirus who did not require hospitalization, or after they had been discharged from hospital. The Paris Public Hospital System (AP-HP) launched the free Covidom solution[39] on March 9. Every day, the isolating patient receives a digital medical questionnaire to answer. Based on his or her responses, the digital application generates alerts, which are picked up by a remote medical monitoring center and sent back to the healthcare team, which adapts the monitoring and care to the patient's needs. Other similar applications have been offered in other parts of France[40]. The Lifen Covid telemonitoring platform[41] enables remote monitoring of patients in cooperation with their attending physician, exchanging health information via a secure messaging system. For all these applications, the validation of a physician is necessary (hospital physician, or attending physician) before the patient can install the application. However, each version of these different applications should be audited and validated to enable physicians and patients to accept the proposals made by the programs used in these systems, in complete confidence.

There are other online questionnaires aimed at helping Internet users assess their state of health in relation to COVID-19, sometimes without any medical guarantees. By answering these questionnaires, users risk being misinformed about their state of health or even, in the event of phishing, communicating their personal health information to service providers whose sole aim is to market these data.

Vigilance points:

13)   Audit and validate online questionnaire applications.

14)   When conducting telemonitoring using digital questionnaires, ensure regular interactive checks between the patient and a caregiver.

15)   Ensure that users are made aware of the risks of misdiagnosis or misuse of their personal data when answering online health questionnaires without the mediation of a physician.

---

[38] https://www.lequotidiendumedecin.fr/actus-medicales/esante/covid-19-des-chu-misent-sur-les-solutions-de-telesuivi
[39] https://www.service-public.fr/particuliers/actualites/A13927
[40] MyCHURennes in Rennes, COVIDAPHM in Marseille, MHLINK in Montpellier (which also offers advice)
[41] https://blog.lifen.fr/posts/fightcovid19-comment-preparer-le-deploiement-de-lifen-covid as at the Saint-Etienne university hospital and the Orléans regional hospital.

7. Ethical issues associated with connected objects

Connected objects have been little used in the context of the COVID-19 epidemic, even though some of them (blood pressure monitors, oximeters, stethoscopes, electrocardiographs, etc.) could have provided additional information to facilitate remote diagnosis or assessment of the severity of the disease while others could have facilitated the management of chronic diseases without risk of contamination.

It should be noted that not all connected objects in healthcare are regarded as medical devices and not all are of certified quality. In late 2016, the HAS published a reference guide of 101 good practices to promote the development of secure, reliable and high-quality connected applications and objects[42], and in 2017, the Healthcare Sector Strategic Committee suggested introducing a certification standard. The HAS pointed out that connected objects regarded as medical devices are required to comply with the GDPR on the protection of personal data[43]. In the case of COVID-19, this relates to data that can be collected by oximeters, for example.

Some of these connected objects can be used by the patient alone, while others require the help of a caregiver, such as a nurse. Some of them can also be used outside the framework of a teleconsultation and transmit the data collected directly to the physician in order to improve patient care, as is already the case. These objects can also be brought together in a teleconsultation booth installed in a pharmacy, for example. Lastly, in addition to the simple collection and transmission of medical data, medical connected objects can be enhanced with algorithmic capabilities to aid diagnosis.

It should be noted that not all caregivers and patients have the same access to these connected objects or are as comfortable with their use, which poses a problem of equity.

Vigilance points:

16) Guarantee the accessibility of connected objects in healthcare of certified quality, offer guidance on their use and ensure the protection of the resulting data.

17) Ensure the robustness, security, transparency, and traceability of the algorithms linked to the connected objects for diagnostic support.

---

[42] https://www.has-sante.fr/jcms/c_2682685/fr/applis-sante-la-has-etablit-101-regles-de-bonne-pratique
[43] https://www.has-sante.fr/jcms/c_2905546/fr/evaluer-les-dispositifs-medicaux-connectes-y-compris-ceux-faisant-appel-a-l-intelligence-artificielle

Conclusion

The significant increase in the use of telemedicine, along with distance learning and teleworking, is evidence of a major change in the way we process and exchange information, particularly in the context of the crisis caused by the SARS-CoV-2 epidemic. The growth in the number of teleconsultations from the beginning of the epidemic and especially during lockdown has revealed ethical issues in the use of digital technology in telemedicine. This Ethics Watch Bulletin shows both the merits and complexity of the combination of medical and digital requirements by highlighting several of these issues and drawing attention to the vigilance points that can enable these requirements to be met.

When this health crisis is over, it would be advisable to revisit these initial vigilance points as part of an in-depth reflection on these ethical issues. Moving beyond the use of telemedicine during the crisis, it also seems necessary to deliberate as openly as possible on the human consequences of medical practices using digital objects. During France's National Consultation on Bioethics (*États généraux de la bioéthique*) in 2018, the CCNE stressed how central these considerations on the place of the human being in the upheaval of the healthcare system were for our fellow citizens[44]. Telemedicine, which is digital by design, is transforming and potentially globalizing health systems worldwide, necessitating a collective reflection on the ethical challenges of this development at national, European and international levels.

[44] Synthesis Report of the CCNE on the National Consultation on Bioethics. pp. 165:
https://www.ccne-ethique.fr/fr/actualites/le-rapport-des-etats-generaux-de-la-bioethique-2018-version-editee-est-en-ligne

17

Summary of vigilance points

1) Offer training in professional telemedicine practices for caregivers, covering the technical aspects and specificities of this new medical practice.

2) Raise awareness among caregivers of the ethical issues related to the use of digital tools.

3) Provide explicit information to patients on teleconsultation arrangements and the ethical issues of these digital tools, and assist them in accessing and using these tools.

4) Ensure respect for information and free and informed consent of the patient, despite the constraints of the health emergency and the use of remote communication tools. Particular attention should be paid to data collected and stored, even temporarily, on a platform.

5) Raise awareness among all stakeholders of the importance of clearly identifying the conditions and purposes of processing data collected during a teleconsultation or telecare (research objectives, for example) and of ascertaining the quality and status of the associated providers (public, private, national or foreign).

6) Ensure that patients opposed to teleconsultation are not discriminated against or penalized in terms of the quality of their medical care.

7) Inequalities in access to telemedicine are a real ethical issue, especially for economically vulnerable populations. Specific measures could help reduce this disadvantage, for example by developing spaces dedicated to teleconsultation, such as in pharmacies or other local places, and/or by calling on local intermediaries accustomed to the use of IT tools, such as certain local authorities, care assistants or associations.

8) In all circumstances, use secure tools for communicating health data, which comply with hosting and processing regulations.

9) As of now, provide information on the secure digital communication tools currently available for telemedicine and ensure that they are adopted by healthcare professionals and the population.

10) Ensure the development of interoperable information systems, as well as sovereign and secure communication tools and information hosting and processing centers for telemedicine, and subject them to regular independent assessments.

11) Looking beyond the urgency of the health crisis, raise awareness among citizens of the risks associated with the flow of digital data and the use of data collected during teleconsultations carried out with non-secure tools.

12) There is an ethical requirement to avoid the uncontrolled development of the health market in order to observe the principle of national solidarity on which our healthcare and health insurance system is based. In particular, it is important to ensure that teleconsultation platforms comply with the ethical and regulatory obligations applicable to medical care.

13) Audit and validate online questionnaire applications.

14) When conducting telemonitoring using digital questionnaires, ensure regular interactive checks between the patient and a caregiver.

15) Ensure that users are made aware of the risks of misdiagnosis or misuse of their personal data when answering online health questionnaires without the mediation of a physician.

16) Guarantee the accessibility of connected objects in healthcare of certified quality, offer guidance on their use and ensure the protection of the resulting data.

17) Ensure the robustness, security, transparency, and traceability of the algorithms linked to the connected objects for diagnostic support.

Annexes

Individuals interviewed

- **Frédéric Adnet,** head of the emergency department at Avicenne hospital and of the Seine-Saint-Denis emergency medical service (SAMU)
- **Ghislaine Alajouanine,** President of the Francophone Academy of Telemedicine
- **Myriam Burdin, Samuel Delafuys, Yann le Douarin**, "Cooperation and Contractualization" Office of the General Directorate for Healthcare Provision, Ministry of Solidarity and Health
- **Dominic Cliche,** Ethics Counselor and **Jocelyn Maclure**, President of the Ethics in Science and Technology Commission of Quebec
- **The Chief Medical Officers François Debrus,** Telemedicine Project Manager for the Armed Forces Directorate of Medicine and **Guillaume Martin**, Head of the Axone Project, Directorate of Information and Digital Services – Ministry of the Armed Forces
- **Alexandre Falzon,** General Manager and **Guillaume Fayolle,** General Manager and Co-founder, Nouveal e-santé, Covidom
- **Jacques Lucas,** President of the French Digital Health Agency
- **Andreas Reis**, Co-Lead of the Global Health Ethics Team in the Division of the Chief Scientist at the World Health Organization
- **Nathalie Salles**, President-elect of the French Society of Telemedicine
- **Jean-François Thébaut**, Vice-President of the French Federation of Diabetics

Members of the working group

CNPEN members – CCNE members* – Members of both committees**

Mounira Amor-Guéret*
Raja Chatila, co-rapporteur
Laure Coulombel**, co-rapporteur
Claude Delpuech*
Laurence Devillers
Karine Dognin-Sauze

Christine Froidevaux, co-rapporteur
David Gruson
Claude Kirchner**
Anne Pellé*
Francis Puech*

Publication of this bulletin was approved on July 8, 2020 during the plenary assembly including Emmanuel Didier (member of the CCNE) as a guest with 14 votes in favor and 2 abstentions.

[Members of the French National Pilot Committee for Digital Ethics](#)

Gilles Adda	Christine Froidevaux	Christophe Lazaro
Raja Chatila	Jean-Gabriel Ganascia	Gwendal Le Grand
Theodore Christakis	Eric Germain	Claire Levallois-Barth
Laure Coulombel	Alexei Grinbaum	Caroline Martin
Jean-François Delfraissy	David Gruson	Tristan Nitot
Laurence Devillers	Emmanuel Hirsch	Jérôme Perrin
Karine Dognin-Sauze	Jeany Jean-Baptiste	Catherine Tessier
Gilles Dowek	Claude Kirchner – Director	Serena Villata
Valeria Faure-Muntian	Augustin Landler	Célia Zolynski

Document translated from the French.

[**Download the original**](#)[45]

Press liaison: communication@comite-ethique.fr

[45] https://www.ccne-ethique.fr/sites/default/files/cnpen-bulletin-telemedecine-2020-07-21.pdf