Q37

CONSELL DE COL·LEGIS DE METGES CATALUNYA

Good Practice Guide
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TELEMEDICINE

How and when to use it in healthcare practice

Col·legi de Metges de Barcelona

Good Practice **Guide** Q37

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The *Good Practice Guide series* is a periodical publication of the College of Physicians of Barcelona that has been published since 1991 and is characterized by being:

- A continuous medical training tool that promotes the professional development of doctors for the benefit of the public.
- A clinical practice guide that promotes good practice and occupational risk prevention.
- A medicolegal tool that protects both the public and medical professionals.

Contents

Introduction

The practice of medicine poses constant challenges, both in terms of scientific knowledge and clinical reasoning, in the relationship with patients and society and in constant technological transformation. The balance of all these factors supposes a need for continuous adaptation that, in recent years, has accelerated. The relationship between the medical professional and the patient is based on trust and confidentiality. Anamnesis and physical examination represent the basis for good medical practice, from which clinical suspicions are formulated and the remainder of the appointment and the relationship with the patient are planned. The framework of the relationship between patients, professionals and the healthcare system in general is very diverse and the objectives of this interaction (medical act) are also different at every moment of the care process.

Until a few years ago, there were not many ways to address this diversity, but the technological leap of the last decades has allowed the introduction of communication channels that enrich the options and instruments in the doctor–patient relationship.

Telemedicine has been useful and widely accepted by professionals and patients during the COVID-19 crisis

The birth of telemedicine is generally associated with the expansion of information and communications technologies (ICT). Despite this, its Telemedicine has been useful and widely accepted by professionals and patients during the COVID-19 crisis origins can be traced back to the invention of the telephone by Alexander Graham Bell in 1875. In fact, *The Lancet* published, in 1879, an article that outlined the appropriateness of using the telephone to reduce unnecessary house calls and, that same year, an anonymous doctor used it to listen to a cough and reassure a mother mistakenly convinced that her son had whooping cough.

Telemedicine had already become a useful tool in healthcare practice in the era before COVID-19, although change management, regulatory demands and technological needs meant that its implementation was advancing slowly. The health crisis caused by COVID-19 has led to the increased use of ICT in the healthcare field, in this case to avoid crowds in the waiting rooms of healthcare centres and infections of vulnerable patients. Telemedicine has proven to be a good instrument and a mechanism that has allowed the follow-up of patients and care processes and, at the same time, has been sufficiently accepted by healthcare professionals, healthcare organizations and patients.

A study on the impact of COVID-19 on the health of doctors revealed that, while before the pandemic only 8% of doctors stated that they provided a significant or high amount of care online, during the months of March, April and May of 2020 (the first wave of the pandemic) this figure was 65%. During the months of July and August, 51% were still providing a significant or high amount of remote healthcare, 34% believed this type of care would increase and 41% that it would be maintained at this level.

Likewise, various studies have demonstrated patient satisfaction with teleconsultation tools, highlighting that they facilitate communication. They have the perception that they have been actively heard, that they have been able to express their uncertainties and that they have been allowed

sufficient time, certainly in a similar way to how communication is evaluated in the face-to-face environment. However, beyond what can be considered a very useful means in exceptional situations, its use in day-to-day care processes must be considered, not only in the exceptional circumstances of a pandemic.

Sometimes, remote communication tools may be the only option, but on other occasions, the simple existence of ICT does not justify their use.

However, patients and their family members are also no strangers to technological advances and the penetration of these into personal relationships and with other organizations leads to expectations of change.

Despite this, the incorporation of such channels must be carefully assessed, also taking into account individual abilities, access to technology and the competences of patients for self-care. Often, however, on the part of the professionals, the ability of certain groups of patients to incorporate changes has been underestimated and this can lead to a loss of opportunities for patients and professionals.

The simple existence of remote communication tools does not justify their use

Either way, non-face-to-face service during the The simple existence of remote communication tools does not justify their use health crisis has demonstrated its benefits and a positive impact on organizations, professionals, patients and even the environment, and has also shown its limitations and aspects that need to be improved.

In this context, healthcare organizations, both in the public and private sectors, must propose strategies for consolidating the application of telemedicine that are agile and that allow new schedule structures to be defined; identify the benefits that can be offered through this care model and prioritize its implementation; adapt the spaces to provide quality care; identify the technological tools that provide security, usability and trust; and, finally, design a change management model that incorporates the training of professionals in this new care model. This activity must be recognized by organizations as an activity carried out by professionals, with associated economic and budgetary implications.

At the clinical level, it is necessary to know in which cases remote appointments add value and in which they do not, or even when they can involve an unacceptable risk if alternatives are available. Therefore, in each area it is important to identify at what points in the care process and for what clinical objectives physical presence is indispensable, and at what others it does not imply an advantage for patients, as well as situations in which the option of remote appointments provides benefits to both patients and the system. Telemedicine should also be assessed as a useful tool for preventive or therapeutic groups when appropriate.

On the other hand, the professional must identify, for each of the clinical processes, which telematic channels are adequate and sufficient for the act that is intended to be carried out, in function of both what is clinically necessary and what is technologically possible.

Telematic communication tools, in order to be used in the healthcare field for appointments, must meet specific technical requirements that guarantee not only quality of communication, but also compliance with legal aspects of confidentiality and security. Therefore, not every technological tool is valid by the simple fact of being available on the market.

In Spain, telemedicine is not subject to specific legal regulations, as is the case in other neighbouring countries such as France, Sweden, Germany or Switzerland. At the moment, it does not seem that this regulation is necessary or, at least, indispensable, since in our legal system, and in the European framework, we find rules that are applicable and that must be observed in the same way in the face-to-face act and in the remote act. Denmark and Israel, leaders in the application of telemedicine, are also without specific legal regulation on the subject.

All this entails the need to create new knowledge that generates guidelines and protocols that help professionals to get to know the stages on which they act. These protocols and guidebooks must come from health professionals and their representative bodies, with the consensus, in any case, of public and private health entities, in order to arrange non-face-to-face care in accordance with legal, professional, ethical, scientific and technological criteria.

This *Good Practice Guide* aims to compile the fundamental aspects of this model of care to guide professionals and organizations when it comes to incorporating it in a prudent and safe way, at a time when it is growing both in the public and private spheres.

1.

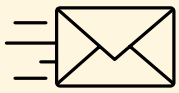
Concept and type of telemedicine

Telemedicine consists of providing healthcare services remotely through information systems and information and communications technologies (ICT).

The use of these technologies can occur in the doctor–patient relationship and is also extendable to the relationship between health professionals within the framework of interdisciplinarity and teamwork, for example, to consult diagnostic criteria or to establish communication that, after all, contributes to the health of patients.

Synchronous, asynchronous and remote monitoring telemedicine

Synchronous telemedicine. The information is transmitted in real time (telephone and videoconference) and takes place when the professional and the patient are available at the same moment, with the advantage of saving time and travel, because there is the opportunity to provide direct interaction, which requires specific technology.



Asynchronous telemedicine. The information is transmitted in non-real time (email, chats, exchanges of images or clinical data). The professional and the patient are not available at the same moment and, in this case, clinical data are collected, stored and transmitted to be interpreted and evaluated later. The advantage is that it is not necessary for both people to be available at the same time or place, although it does not offer the immediacy of direct contact with the patient and presents the difficulty that some images may have insufficient quality and require repeated consultations if the clinical details are not complete enough.

Remote monitoring of the patient can also be considered a type of telemedicine. Device networking via the Internet allows patients to use sensors to measure all kinds of variables: systemic arterial pressure, heart rate, temperature, weight, exercise performed, medication adherence, perceived state of health, etc. This makes it easier for doctors to remotely control the health of a patient in real time, as the information is collected by technological devices and sent to the electronic medical histories of the patients, where it is stored for future evaluation and use.

Remote monitoring has led to the creation of connected health platforms, which allow the telemonitoring of patients with multiple electronic devices that are portable or wearable linked to mobile applications that, starting from the management of data in the cloud, can help to alert healthcare personnel to a possible clinical deterioration and therefore act early.

However, in order for these applications to be effective, it is necessary to promote education about disease, changes in lifestyle and treatment adherence, and patient participation and empowerment must be encouraged, both in the control of chronic diseases (blood pressure, being overweight, diabetes, heart failure, arrhythmias, chronic obstructive pulmonary disease, etc.), as well as in the control of acute diseases (infections

or postoperative processes, in which the use of activity trackers after surgery encourages the patient to walk and has been shown to shorten stays and avoid readmissions).

There is sufficient evidence that telemonitoring improves the health of the population, reduces health costs and improves the patient's experience in the care of their health. For this reason, various scientific societies, such as the American Heart Association, already recommend their use to better control health.

Other ways of constantly monitoring vital signs are, for example, by using contactless remote sensing systems, or by remote photoplethysmography, which can perform continuous, precise long-term monitoring.

2. The doctor–patient relationship and the quality of the medical act in telemedicine

The doctor-patient relationship was masterfully described by Laín Entralgo as a "particular and unique" type of relation between people, asymmetrical and based on a triplicate confidence on the part of the patient: confidence that the medicine can cure, palliate or alleviate their sufferings; confidence in the knowledge of the doctor and confidence in the same doctor as a person. This last point includes all the values that make up the medical profession and that are expressed through prudence, empathy, knowing how to listen and doctor–professional secrecy, among other things.

This relationship is the essence of the exercise of medical practice, as much from the point of view of human relations, which is an important component including the establishment of the therapeutic relationship, from that of the expected outcome (diagnosis, treatment, accompaniment). And, in this relationship model, we must not forget the patient's family, since they are sometimes direct interlocutors with the professionals and, in such cases, have a key role in the relationship model.

The basic principles of the doctor-patient relationship in telemedicine are the same as in the face-to-face appointment

However, the doctor–patient relationship, despite being part of the medical tradition, is neither fixed nor immutable. The substance of the doctor–patient relationship has changed substantially over the years — from the paternalistic model to the incorporation of the patient's values in decision-making — and there have also been profound changes in the manner in which it develops. On the other hand, the introduction of telemedicine as another element of medical practice poses a new challenge in the relationship between the doctor, the patient and the family.

Telemedicine has a clear impact on the framework of the doctor–patient relationship and, although it is advantageous and recommendable in certain circumstances, it must guarantee compliance with good clinical practice, ethical standards and the legal and professional regulations applicable to any medical act and must be presided over by the clinical criteria of the professional. The basic values and principles of the doctor–patient relationship in telemedicine are, simply, the same as in the face-to-face relationship. The appointment or consultation by telematic means should not interfere in

the basic principles of the doctor–patient relationship and, therefore, mutual respect, the independence of clinical judgement, patient autonomy and doctor–patient confidentiality must be observed and considered.

In the practice of telemedicine, special care must be taken with regard to the following aspects:

Clinical criterion

The doctor must assert his or her autonomy to decide whether the patient's appointment should be face-to-face or if it can be done remotely, in any of the modalities. A pre-established care model should not be imposed on top of the clinical criterion.

Confidence

The establishment of a remote relationship between doctor and patient must be by common agreement. It is a matter of trust. The doctor must explore the patient's access to and knowledge of the use of the technology platform that is to be utilized and it must be ensured that the advantages and limits of the procedure, as well as any indications and prescriptions that may be given, are understood.

Caution

The lack of direct visual control of the patient, the impossibility of the usual physical examination and the lack of versatility of a conversation conditioned by the technological platform — some studies show that telephone consultations usually focus solely on concrete symptoms — could neglect a general and complete evaluation. These limitations must increase the caution on the part of the doctor and facilitate a potential conversion to face-to-face mode for an appointment scheduled as remote.

Identification

The doctor must ensure that the consultation is carried out in a safe way, and this includes the prior correct identification of the patient or the person authorized by the patient.

Privacy

The doctor must also ensure the patient's privacy and must take appropriate measures to prevent third parties accessing the appointment without a justified reason, except with the patient's express consent.

Confidentiality

Technological platforms must guarantee the confidentiality of data and information in a manner that can ensure encrypted communication and its security.

Recording in medical history

The remote medical act must also be recorded in the medical history — mentioning the medium that has been used — in the same way that is obligatory for face-to-face medical events (standard 21 of the Spanish Medical Code of Ethics and articles 9 and 10.3 of the Spanish Law 21/2000 of 29 December, on the rights of information concerning the health and autonomy of the patient and clinical documentation). Documentation and communications must be referred to and included in the medical history. In the event that the connection does not occur and, therefore, the remote appointment does not take place, it must also be referred to in the medical history.

Information and communication

Informing and communicating with the patient are essential. The use of telematic means in the process of informing the patient usually has a complementary character, however, at certain times — such as in the case of a pandemic or in situations where the patient has difficulty with mobility — its use allows prompt first appointments and maintenance of follow-up care. The use of these means in the information or follow-up processes entails great advantages, but these aspects must be taken into account:

- The patient must be identified, or the designated reference person in cases where the patient is not in a position to understand the scope of the care intervention.
- The communication must be made via the telephone number or email address that has been indicated.
- The identification data must be checked and recorded in the medical history.

Assess whether the use of telematic means is appropriate when bad news is to be given

The professional must assess the appropriateness of the use of telematic means in cases where bad news, situations of bad prognosis or deaths must be communicated. In these circumstances, face-to-face appointments are preferable, except where this is impossible, in which cases communication strategies must be reinforced.

Informed consent

In accordance with the provisions of Article 6 of the Spanish Law 21/2000, informing and obtaining consent is part of all care processes and, therefore, in acts carried out remotely the information process must also precede the patient's consent.

Informed consent during the COVID-19 pandemic*

During the COVID-19 pandemic, telemedicine has helped to obtain the consent of relatives of patients who were not competent in cases where, for health reasons, the presence of the person who had to give consent was not possible.

In these cases, it is advisable to record the following aspects in the medical history:

a) Time (day and hour when the telematic information process) has been carried out).

b) Identification of the family member or person who has been contacted, including a record of the connection to the patient. It is recommended that this person (if possible) be already identified at the time of the patient's admission.

c) Brief description that explains that the process of information and obtaining consent was not done in writing and the circumstances that have determined this (patient not competent to make decisions, family members quarantined, etc.).

d) The medical necessity of the proposed procedure or medical act.

e) Detail of the content of the information provided (on the care process, general and particular risks for the patient, and therapeutic alternatives).

f) Comments made by the person receiving the information and whether they have understood the process.

g) Agreed decision.

* Document *Consideracions deontològiques en relació amb informació, consentiment i consulta virtual durant la pandèmia de COVID-19*, prepared by the Ethics Commission of the Council of Colleges of Physicians of Catalonia.

Medical prescription

The prescription of medicines must comply with the provisions of the Spanish Royal Decree 1718/2010, of 17 December, on medical prescription and dispensing orders. When an electronic prescription is issued, this must be via an approved platform or application, which must guarantee encrypted communications and allow the dispensing of medication by any pharmacy.

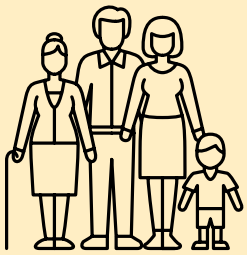
In Catalonia, the electronic prescription system was developed and introduced some years ago in the public sector, and this allows and facilitates prescription in acts carried out through telemedicine. In the private sphere, this development came later, and is slowly being implemented. In the COVID-19 era, the necessity of such a system has become apparent, especially when health insurance companies have recognized its value in their willingness to reimburse this type of activity. Approved platforms exist in the private system through which the prescription must be issued, since a paper medical prescription sent to the patient by email or another similar system is not valid for the purposes of dispensing by a pharmacy. It should be noted that an exception has been made to this rule during the period of the pandemic.

The Council of Colleges of Physicians of Catalonia (CCMC) is analysing the dissemination and implementation of a private electronic prescription system that complies with all requirements.

Evaluation

It is advisable to establish shared objectives for patients and doctors and to be able to carry out periodic evaluations in order to review results and establish instructions and limits for the application of telemedicine.

Basic rights of doctors and patients in telemedicine

Doctors 	• Respect for clinical criteria. • Respect for autonomy in decision-making on the appropriateness of the use of ICT. • Respect for autonomy in the use of the system and platforms that offer the most guarantees. • Respect for working hours. • To be renumerated under the same conditions as for face-to-face appointments.
Patients 	• To guarantee the privacy and confidentiality of clinical information. • To receive information about the care process and to give consent to it. • To receive information on aspects related to telemedicine (how it works, privacy, security, possible deficiencies, contact protocols, medical prescriptions, etc.). • To consent to the processing of their personal data in compliance with data protection regulations. • To give their consent to an appointment in remote mode.

3.

The remote medical appointment

Medicine has traditionally been based on the in-person examination and follow-up care of patients. In its initial conception, telemedicine was influenced by distance and difficulties in patient access to healthcare services. Currently, however, it is recognized as a model of communication in non-face-to-face care in which technologies of information and communication (ICT) are an instrument in the service of professionals and patients in the medical act.

The use of ICT must be tailored to the care process and its requirements and it is the professional who must assess whether, through these means, he or she is in a position to make appropriate clinical and therapeutic decisions, without it being considered a substitute for in-person care in a systematic manner.

The objective of telemedicine is not to replace the traditional model nor the face-to-face act, but to provide instruments for relationship-building and communication to the benefit of the participants in the care relationship. It is up to the profession and professionals to set limits on the use of telematic systems for patient care.

It is up to the medical profession to set limits on the use of telematic systems for patient care

It is necessary to respect the autonomy of the professional in the decision on the appropriateness of the use and application of such systems, as well as on the use of the systems that offer the necessary security guarantees in the medical act.

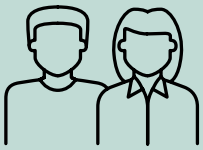
The doctor must be aware that telemedicine cannot replace or enable the omission of the personal examination of the patient when necessary and, therefore, telemedicine should be limited to cases where it is considered possible and appropriate and provided that this circumstance does not imply a limitation or difficulty in the guidance or indications that must be given to the patient. The doctor must fulfil his or her ethical and professional obligations in the same way as in the face-to-face relationship and, therefore, the medical attention must be of good quality in both the human and technical senses.

If the circumstances determine, the medical act must be transformed into a face-to-face appointment or performed in this modality from the beginning, especially in cases in which:

It is necessary to treat or address the presented clinical situation in person.
The patient presents warning signs.
Doubts are raised regarding the diagnosis that could be resolved with a physical examination.
The patient's state or condition poses difficulties in communication and understanding.
A sensitive situation or bad prognosis is to be communicated.
It is not possible to guarantee the confidentiality or privacy of the medical act.

Advantages and limitations of telemedicine

Advantages



Technological aspect

- It allows remote medical appointments.
- It facilitates equity in access to care services, independently of geographical location.
- It facilitates accessibility to healthcare professionals.
- It allows the addressing of problems of low complexity with less time than in face-to-face appointments.
- It enables remote consultations between levels of care (primary care and referral hospital), avoiding patient travel and reducing the number of referrals.
- It allows remote monitoring of patients.
- It provides new organizational and networking environments.

Human aspect

- It avoids travel and avoids or reduces waiting times.
- It contributes to prompt contact between doctor and patient.
- In exceptional situations, it helps to prevent the risk of contagion and the maintenance of continuity of care and transmits increased peace of mind to patients.
- It allows a first assessment of the patient and, if deemed appropriate, gives the option of arranging a subsequent in-person appointment.
- It reduces waiting list times for care, new patient appointments and monitoring.
- The professional does not need to be physically in the workplace, but can connect from any other place (in this case, access to the medical history must be provided).
- It facilitates care for patients who live in remote areas or who have difficulty with mobility.
- It has a good and growing acceptance and satisfaction among professionals and patients.
- It optimizes time and, therefore, facilitates life management for patients and especially for professionals.

Economic aspect

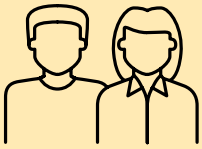
- Procedures are optimized that imply an improvement in the efficiency of the provision of health services.

Advantages and limitations of telemedicine

Limitations

Technological aspect

- More attention needs to be given to the security of the systems that are used, to the privacy of the patient and to the confidentiality of the medical act and to complying with data protection regulations and computer security.
- The net does not always ensure good coverage everywhere nor high enough quality in terms of image and sound.
- Risk of encouraging the increase in inequalities (due to economic, age, social and/or cultural factors) and the digital divide.
- Reluctance and/or difficulties to introduce technologies that imply the redesign of the care model and the corresponding need for training.
- Many of the available solutions do not foresee the possibility of interoperability.



Human aspect

- It hinders emotional connection and the perception of physical expressions of the body and face that can provide clinical information.
- It generates more uncertainty in complex situations.
- Difficulties in the expressing and/or understanding of the information provided to the patient, especially in the case of pathologies linked to mental health or cognitive difficulties.
- More difficulty for the professional to detect lack of agreement or understanding on the part of the patient.
- Internal resistance to change.
- A minimum skill level is needed to operate in digital environments.
- Launching it represents a new workload.
- Leadership is needed to catalyse and properly manage the digital transformation.

Economic aspect

- The centres have to meet the initial financing of the project, the cost and the sustainability.
- Voluntary healthcare insurance entities must recognise the remote appointment as a medical act reimbursable in the ordinary manner, equivalent to the face-to-face appointment.

4.

How to approach the remote medical appointment

Communication is a fundamental part of the doctor–patient relationship, with an impact on key elements of the care process such as the establishment of the therapeutic relationship, therapeutic compliance and trust.

In telemedicine, communication and interaction with patients and families are, simply, different, so strategies are needed to allow them to be good and fluid. The professional must strive to maintain the ceremony and all the values of the medical act and to prevent it being denatured or depersonalized by the use of information and communications (ICT) technology.

Considerations and practical tips for remote medical appointments by videoconference

Regarding devices

- Ensuring that the devices (support, cameras, speakers, etc.) are adequate in terms of quality and enable a secure connection.
- Avoid using devices intended for private use, if possible.

Regarding preparation

- Make the appointment (video or telephone consultation) and note it on the schedule, in the same way as for face-to-face appointments, to make it easier for the patient to be in a comfortable space that guarantees the privacy of the medical act.
- Avoid consultations that have not been scheduled.
- As in any medical act, review the medical history of the patient.
- Before starting the consultation, share with the patient the instructions for the remote appointment and ensure readiness to access and carry it out.
- Ensure the quality of sound, image and lighting.
- The contact with the patient must be made through the telephone number or email address that he or she has provided, or after previous identification if another medium is used. It is necessary to check the name and other details, such as the date of birth, the health card number, the ID card, etc.
- It is necessary to have the patient's telephone number at hand, in order to call if the video consultation is interrupted.
- Ensure access to the patient's clinical information and the resources necessary to carry out the medical act in an appropriate manner.
- Make the doctor's credentials available to the patient.

Regarding clothing and surroundings

Considerations and practical tips for remote medical appointments by videoconference

- Maintain a respectable presence, with appropriate clothing. Wearing a white coat can be a way of transmitting confidence to the patient.
- Ensure that the video or telephone consultation is carried out in a private and quiet space (as if it were a physical consultation).
- The background should be neutral or even institutional, to avoid possible distractions for the patient.
- Be motivated by the task at hand, to transmit positivity.
- If the consultation takes place in an environment that is not a workplace (e.g. at home), it is necessary to inform the patient of this.

Regarding the course of the appointment

- Inform the patient that the appointment will be private and confidential, and offer the possibility that it can take place at another time if the privacy of the conversation cannot be guaranteed.
- Allow the patient to explain his or herself without interruptions.
- The speed of speech must be slower than in the face-to-face appointment and pauses must be left so that the patient can interrupt the conversation if he or she considers it necessary.
- The tone of voice must be reassuring. It is necessary to transmit security and trust.
- If the consultation is carried out in the video consultation modality:
  - Look at the camera to convey a connection with the patient and keep the eyes at the same level.
  - Frame a good perspective that transmits proximity (neither very close to nor too far from the camera).
  - Avoid excessive gesticulation and physical or verbal habits (previous self-recording allows these to be detected and corrected).
  - Be yourself to convey honesty in front of the camera.
  - If another professional is present, the patient must be informed of this.
- If anything needs to be noted down in the medical history, it is necessary to inform the patient so that he or she does not think that communication has been cut off.
- Provide information on the health problem, the action plan, the proposed treatment, the foreseeable evolution, the warning signs and the action to be taken if they present.
- At the end of the appointment, allow the patient to be the one who terminates the connection, after asking whether he or she has any questions and verifying that he or she has understood everything.

5.

The provision of remote healthcare services

It must be understood that the provision of healthcare services in non-contact settings is considered to be carried out in the state where the doctor — or the organization for which he or she works — is legally established, so the regulations of the place of establishment are those governing the health activity, even though the beneficiaries of the care may be located outside this area.

In this way, doctors legally established in Spain, to the extent that they are subject to Spanish professional body, local, regional and state legislation, must inform the recipients of the services of their place of establishment and, at the same time, they must know where these recipients are and the environmental, health and legal peculiarities of their location, in order to be able to refer them to the corresponding health services in the area in emergencies or if it is impossible to provide the required assistance.

Doctors who provide their services from a Spanish establishment must be in possession of a degree or title in Medicine issued by the competent authority or a corresponding homologation or recognition of the degree, and be registered at the college of physicians of the area where they carry out their main or only activity.

Whatever the mode of providing the service — as an employee or as a self-employed person — a doctor must comply with his or her tax and social security obligations (registration and contributions to social security or alternative mutual society) and, at the same time, must take out corresponding professional liability cover, unless his or her services are provided on another's behalf.

The establishment from which the services are provided must have the corresponding authorization. Decree 151/2017, of 17 October, establishes the requirements, common technical and health guarantees and procedures for the authorization and registration of health centres and services in the territory of Catalonia.

The provision of health services in non-face-to-face environments must guarantee, in accordance with Law 34/2002, of 11 July, on public information services and electronic commerce, that the recipients of the services and the competent bodies can access the following information by electronic means permanently, easily, directly and free of charge:

- Name or corporate name
- Residence or domicile, or, if unavailable, address of a permanent establishment in Spain
- Email address or any address that allows communication to be established in a direct and effective way
- Registration data in the Mercantile Registry or in the Register of Professionals Companies
- Administrative health authorization data
- Identification of the competent supervisory body (Healthcare Inspection of the Department of Health)
- Fiscal identification number
- Price of the service (clearly and accurately, indicating whether or not taxes or shipping costs are included)
- Codes of conduct (indicating whether one applies and how it can be consulted)
- Details of the professional body to which he or she is registered
- Collegiate number
- Academic degree and the EU state in which it was issued, or, where needed, homologation or recognition of the title
- Professional standards applicable to the exercise of the profession, with access facilitated to the same (including by electronic means)

6. Technical requirements for security and data protection

In telemedicine, the owner of the activity, to the extent that he or she is responsible for the processing of the personal data of patients and employees, must also comply with the regulations in force regarding data protection: Spanish Regulation 2016/679, of 27 April 2016, on the protection of individuals with regard to the processing of personal data and the free movement of such data (GDPR), and Spanish Organic Law 3/2018, of 5 December, on the protection of personal data and guarantee of digital rights (LOPDGDD). Likewise, special care must be taken when implementing the security measures of these tools taking into account the risks that the processing of health data may entail; such data are considered special category personal data, which also implies specific compliance requirements and a need to remain in accordance with the principle of proactive responsibility of the person responsible for data processing.

(See further information in the Annex, page 28)

7. Professional civil liability

QWhen the use of telemedicine is accepted, physicians assume the professional responsibility of this medical act and everything derived from it, especially with regard to diagnosis, guidance, therapeutic options and direct medical interventions, as well as the need for a referral to a face-to-face consultation. In this sense, it is necessary for physicians to receive adequate training to prevent possible situations from which medical professional liability could arise.

Professional civil liability consists of the obligation of doctors to repair the consequences of their professional acts and the omissions and errors made in the exercise of their profession that has caused damage or harm, provided that the necessary means have not been put in place or due care has not been taken in the treatment of a patient, either by negligence in conduct or by breach of the *lex artis*.

Telemedicine requires planning and predevised protocols that facilitate clinical safety

When a medical act is carried out via information and communications technologies (ICT), it is done with all its legal consequences, also in terms of professional responsibility. Despite this, it should be remembered that the responsibility of doctors is not linked to results, but to the fact that they have not provided the appropriate means according to the circumstances and risks inherent in each procedure.

Telemedicine requires adequate planning, so it is recommended to use standardized protocols of the checklist type that facilitate basic aspects of clinical safety. The identification of the participants in telemedicine must be clear and unequivocal, and must be stated in the clinical history. The physician who provides medical care via telemedicine must have direct access to the patient's clinical history, and must state in writing all care deviations, as well as the planned treatment and recommendations given. A complete medical history is a measure of legal safeguard in the event of a claim. Doctors, in order to issue a diagnosis or make a pharmacological prescription or recommendations, must ensure that they possess sufficient data and the quality of the same.

At this point, it should be remembered that the inherent limitations of telemedicine can determine, in some cases, that a face-to-face consultation is necessary to complement the medical act carried out via telemedicine. In these cases, the professional must refer the patient to this face-to-face consultation.

The limitations of telemedicine may make a complementary face-to-face consultation necessary

Many professional civil liability policies do not include, specifically, the coverage of medical acts carried out through telematic means or remotely. However, when unequivocally carrying out a medical act, in accordance with the instructions in this document, it must be understood that such acts are included in coverage, unless expressly excluded. In any case, it is advisable to verify that the insurance in fact provides coverage, especially when patients established outside Spanish territory consult a doctor established in Spain.

On the other hand, the various health administrations, the main drivers of telemedicine, as well as private provision centres, must guarantee the implementation of non-face-to-face activity in a consensual and orderly manner in the various healthcare settings, with the introduction of clear and concise criteria that involve the recognition and control of non-face-to-face activity. They must also guarantee the patients' correct access to healthcare, ensuring the privacy of communication, and must promote and facilitate the training of professionals and patients on the use of remote care platforms, as well as observing the correct functioning of these, improving and facilitating the accessibility of communication networks.

8. Experience in the public health system of Catalonia

The public health system of Catalonia is made up of more than 160 different health providers, both publicly and privately owned, which make up an integrated care network for public use. The multiplicity of providers has led to a large proportion of these organizations and centres having their own information systems specifically tailored to their concrete needs.

The use of information and communications technology (ICT) systems such as the shared medical history in Catalonia (HC3), plus the standards of integration and interoperability that make them compatible, enables the possession of a unique shared medical history of the patient focused on health. This establishes a common model of access to the records of the various systems of clinical information, respecting the differences between providers and entities. Despite the complexity of the Catalan healthcare model, its public health system has identified the care processes, the different interoperability scenarios and the most relevant actors involved in the exchange of clinical information.

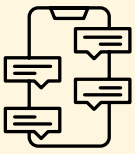
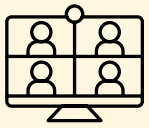
Throughout its recent history, the Catalan healthcare system has been able to implement cutting-edge initiatives in the use of ICT for the benefit of members of the public and professionals, who have facilitated the integration and sharing of clinical information between the different health providers. Examples include the Central User Registry (RCA) and the individual health card, the Primary Care Clinical Station (ECAP), the massive implementation of advanced hospital management in all hospitals in the country, the electronic prescription for pharmaceutical provision, health information

and documentation exchange systems, the HC3, the interoperability platform (iS3), the digitization of the medical image (SIMDECAT) and the member of the public's health file (La Meva Salut, which translates as My Health).

Thanks to these efforts, the dynamics of care and organizational development have enabled valuable initiatives of territorial integration founded in new models of shared care, which are very expensive to accompany from the point of view of technological support due to the lack of standardization of information systems between system providers. The analysis of international trends shows that, in the systems that value and enhance the autonomy of local management with multiple providers, a tendency exists to incorporate general governance, reduce the number of technological solutions and, above all, use standards that enable all the information of the members of the public to be made available for the entire chain of provision of services in a unique longitudinal health history. Therefore, the CatSalut Information Systems Master Plan is working on the development of an electronic health history and on the modalities of integration in the existing systems park, within a more global technological architecture, which is made available to the Public Health System of Catalonia (SISCAT). This repository will progressively replace the current systems, based on interoperability and the sending of records through multiple circuits.

In recent years, possible remote appointment models have been deployed in SISCAT, in primary care and also in other areas such as in outpatient clinics in hospitals or for mental health, to give current examples, which have provided coverage for the following types of relationship:

Between the doctor and the patient	
	**Telephone support**. Classic and widely deployed communication model, both in primary care and in the hospital setting, and which during the COVID-19 crisis has been an essential channel between healthcare professionals and members of the public to avoid travel.
	**eConsultation**. It is an asynchronous non-face-to-face consultation tool. It is an agile communication channel that requires neither the professional nor the patient to share time and space and that guarantees secure communication. It is integrated in La Meva Salut and facilitates members of the public's access to the healthcare system, as it allows the initiation of conversations with written messages between the member of the public and the professional. Each eConsultation generates an entry in the professional's schedule and allows both the professional and the member of the public to also attach information in PDF format or images. Currently, this service is deployed in virtually all primary care settings and is expanding in the SISCAT public hospitals.
	**Video consultation**. It is a synchronous non-face-to-face consultation tool. This is a service that was implemented during the COVID-19 pandemic in primary care and is being rolled out to the remaining levels of care (hospital, social and health care, mental health and addictions). It allows healthcare professionals and members of the public to simultaneously attend a face-to-face appointment with eye contact and voice. It is a widely used service in the private healthcare system and is just being rolled out in the public system, in order to enrich the model of non-face-to-face care and offer an additional channel of relationship between health professionals and members of the public. It avoids unnecessary travel in cases in which in-person attendance is not required for the care to be delivered

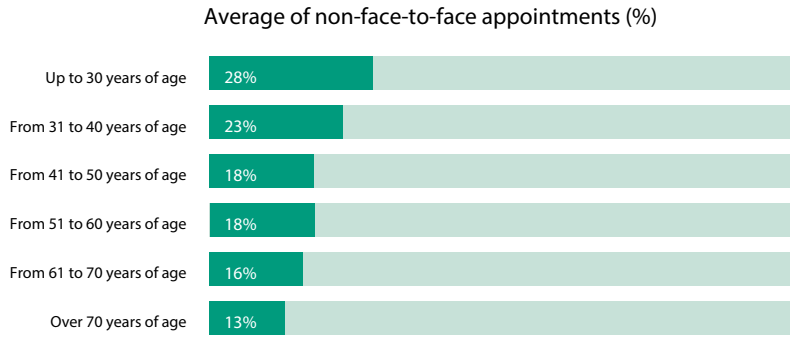
Between professionals	
	**Interconsultations without patient presence or virtual meetings between levels of care**. SISCAT possesses interoperable transferrable platforms, such as HC3 and iS3, which allow different healthcare providers working with different information systems to be able to make referrals between levels of care and that the information is integrated into each workstation, both the sender and the receiver. This allows referrals between different care levels without the need for physical movement of members of the public, sharing the clinical information and documentation required for the interconsultation between the two areas of care and giving a more efficient solution to clinical processes that do not require face-to-face consultations. It is a broad relationship model used in the public health system and is currently avoiding much unnecessary travel for members of the public, as it allows the resolution of cases in the area of care closest to the patient.
	**XatSalut** (***Health Chat***). This is a secure exclusive instant messaging tool for communication between SISCAT professionals. It can be considered an alternative to WhatsApp that guarantees the security and privacy of data. All data, files and folders are encrypted when saved, both on the handset and on the servers. Messages, videos, pictures and voice notes can be shared, and it can be used on various devices. It is a tool that allows the improvement of the relationship between levels of care by also incorporating groups of professionals. It is currently available to SISCAT professionals and its use among the different healthcare providers is being deployed.
	**Video consultation between professionals**. This is a new communication service between professionals that, in the second half of 2020, began to be deployed in SISCAT. It allows the establishment of communications for video call between professionals and will be integrated into XatSalut itself.

9.

Implementation of digital health in private consultation

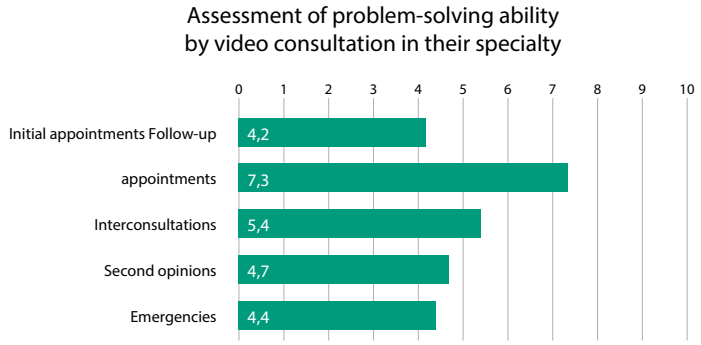
The Council of Colleges of Physicians of Catalonia (CCMC) has carried out a study to find out about the state of the digitization of surgeries and medical centres, aimed at Catalan members who practise medicine in the private sector. These professionals were sent an online questionnaire, between 9 March 2021 and 12 April 2021, from which 568 responses were obtained (sample error: 4.01%).

Regarding teleconsultation, 64% of respondents were conducting non-face-to-face appointments in the period of their response. These non-face-to-face appointments represent an average of 17.5% of the total appointments conducted. Younger doctors conduct, proportionally, more non-face-to-face appointments.

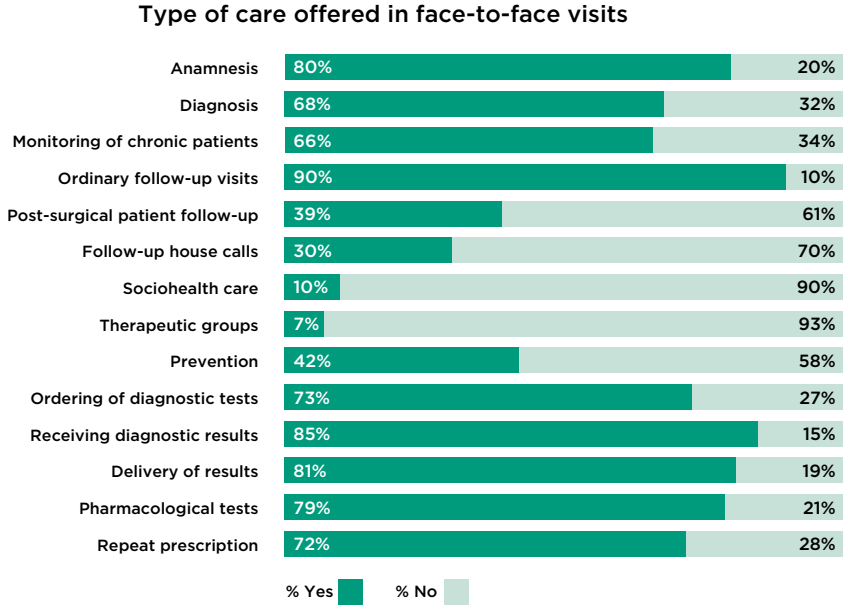


Of the professionals who make non-face-to-face appointments, 97% make them by phone and, for the most part, they are paid. The other main channel for non-face-to-face appointments is email (70%), however, in this case, a low percentage are paid. When non-face-to-face appointments are paid for this is, for the most part, by mutual societies and health insurers.

The type of appointments that are mostly realised in a non-face-to-face way are follow-up appointments, which are the most valued in terms of resolving problems (7.3 points on average on a scale of 1 to 10).



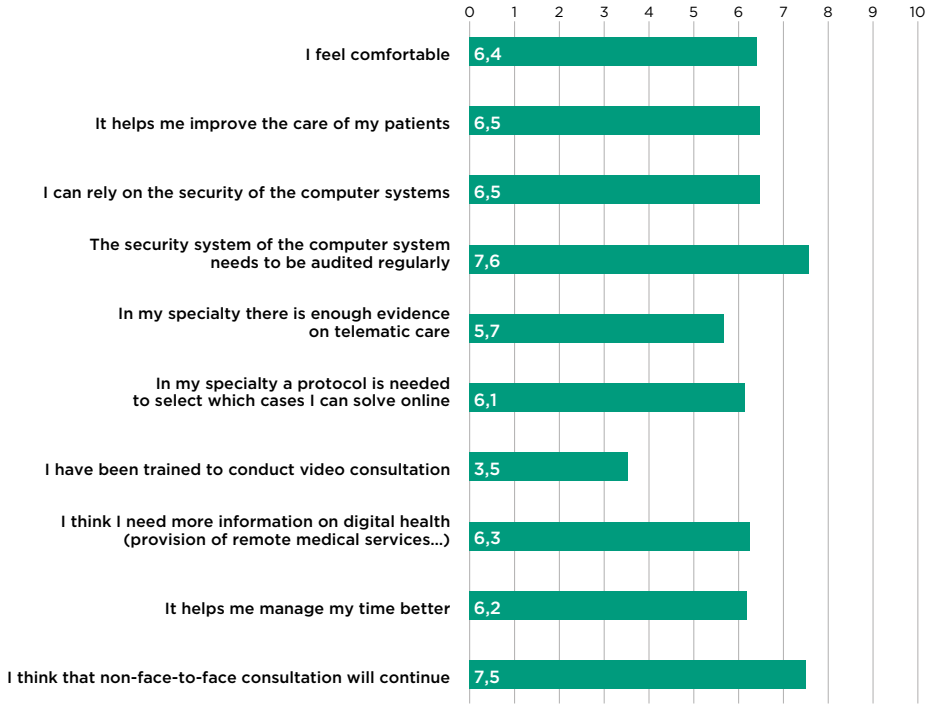
The type of attention offered in non-face-to-face appointments is principally: ordinary monitoring, receiving of diagnostic results, delivery of results, anamnesis and pharmacological prescription.



n = respondents currently carrying out non-face-to-face appointments

Doctors who conduct non-face-to-face appointments rate with an average of 3.5 points out of 10 their agreement that they have received training to deliver this type of care. On the other hand, they substantially agree that the degree of security of the computer system must be regularly verified and that non-face-to-face appointments are likely to continue.

Degree of agreement regarding non-face-to-face visits



The pandemic has represented a great boost in non-face-to-face consultation in the private sector. Whereas before the pandemic only 30% of respondents conducted non-face-to-face appointments (and they represented only an average of 10% of the total appointments), during the first wave of the pandemic, 74% of respondents did so (and they represented an average of 61% of the total appointments).

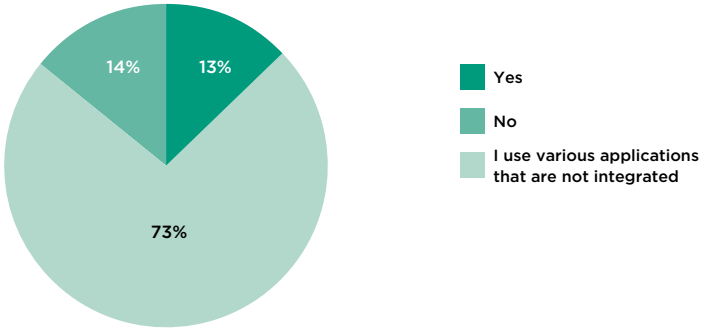
On the other hand, with regard to the patient's medical history, 80% have it computerized, other professionals of the team can access it (80%) and it is connected to other services of the centre (64%).

Only 48% of these professionals have an online schedule and 39% have the possibility of making electronic prescriptions.

Organizations are the main promoters of the implementation of the medical history, as well as the electronic schedule and prescription.

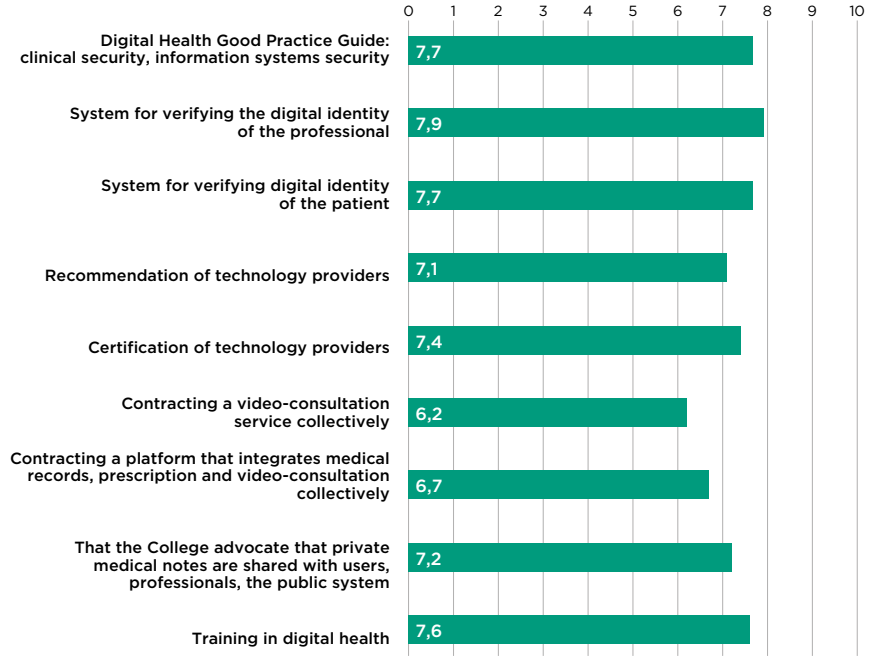
Only 13% have an integrated medical history system, video consultation and prescription on a telemedicine platform, although 63% say that if they had advice and support they would have one. The main reason for not having one is that the centre where they work does not have one, followed by lack of knowledge and the assertion that they do not need it.

An integrated system of medical records, video-consultation and prescription is available in a single telemedicine platform



The purpose of the study was to investigate in which aspects in the field of digital health the colleges could help doctors. The main aspects in which members consider that they can receive support from the colleges are: the system to verify the physical identity of the professional (7.9 points), the system to identify the digital identity of the patient, the guide to good practices in digital health (7.7 points) and training in digital health (7.6 points).

Degree of importance given to aspects with which the college can help



10.
Conclusions

1. Telemedicine is the provision of a health service at distance through the use of information and communication technologies (ICT) that provides a greater diversity of models of communication between the doctor and the patient, without in any case being able to consider it a substitute for the genuine doctor–patient relationship.

2. Telemedicine has shown great potential to help improve patient care, as it provides benefits in terms of life management, accessibility and quality of follow-up.

3. Patients have different characteristics and personal preferences, which is why, in order to maintain a good doctor–patient relationship, the preferred model should be decided together.

4. The professional must have the capacity and autonomy at all times to decide on the most appropriate appointment modality to address the reason for the patient's consultation.

5. The use of virtual consultation or telemedicine should not interfere with the basic principles of the doctor–patient relationship, which are mutual respect, the independence of clinical judgement, the autonomy of the patient and professional secrecy.

6. As a medical act, the choice of telemedicine must guarantee the patient the right of autonomy, professional secrecy, protection of personal data, privacy and confidentiality.

7. It is necessary to record the remote appointment in the medical history.

8. Giving bad news or making complex clinical decisions can require a setting of intimacy and warmth that is sometimes difficult to achieve through telematic tools. Therefore, it is necessary to evaluate the convenience of use in such situations, except in circumstances where there is no alternative and in this case communication strategies need to be strengthened.

9. Telecommunication and telemonitoring tools should be used in a clinical work environment and must comply with regulations on security and data protection.

10. In each field of care, information on the feasibility and security of various medical acts conducted through telecommunication tools and/or telemonitoring, both for clinical control and for the preparation or guidance of diagnoses, must be generated.

11. Healthcare professionals who use telemedicine are subject to the same system of authorizations and regulations as medicine practised in face-to-face environments. It is understood that the service is provided at the place where the professional is established.

12. The responsibility of the professional is always the same, whether in face-to-face or remote appointments. By accepting the use of telemedicine, the physician assumes professional responsibility for this medical act and everything that derives from it, so proper planning is necessary and the use of tools to facilitate the monitoring of the fundamental aspects of clinical safety is recommended.

13. Most professional liability policies do not specifically contain a section on telemedicine, but when a medical act is unequivocally performed, it must be understood that it is covered, unless expressly excluded. In any case, it is advisable to check that, in fact, the insurance provides coverage, especially when patients established outside Spanish territory consult a doctor established in Spain.

14. Public sector health centres and private health centres must guarantee the necessary conditions for the doctor's professional activity via telemedicine to meet the basic requirements that allow it to be carried out with full professional legal certainty. In the case of private medicine, it is also necessary to guarantee that the professional receive a compensation for the activity in the same terms as for face-to-face activity, taking into account the equivalent significance of the medical act.

15. Tools such as HC3 and the longitudinal relationship of patients allow the use of telemedicine within healthcare connectivity and the non-face-to-face intervention of professionals.

Annex

(to section 6)

When choosing the tool to be used in telemedicine, it is necessary to have already filled, if possible, the role of **Data Protection Officer (DPO)**. Health centres and medical premises, with the exception of professionals practising individually, are obliged to appoint a DPO. Among the functions that the General Data Protection Regulation (GDPR) grants to the role of the DPO are those of informing, advising and supervising **the person responsible for the processing of data** that are personal (the owner of the activity) with regard to regulatory compliance in the matter of data protection. In the event that the appointment of a DPO is not mandatory, it is advisable to take legal advice regarding the protection of personal data for this purpose. In any case, the role of these two figures is indispensable at the time of designing the telemedicine tools that are intended to be used.

When choosing a telemedicine provider, it is necessary to take into account whether it will provide a service on behalf of the data controller and will have access to the personal data of patients, within its guidelines. If this is the case, the supplier will have the status of **data processor** and, in addition to the service contract itself, a contract must also be signed to establish the security measures and obligations of both parties. However, there are suppliers, especially the largest ones, who, when their services are engaged, provide contracts with already predetermined clauses that are difficult to modify.

So **what security measures should these telemedicine tools observe to comply with current regulations?**

Unlike the previous regulation, the current one establishes that, taking into account the state of technology and application costs, and the nature, scope, context and purposes of the processing, as well as the variable risks of probability and severity for the rights and freedoms of natural persons, the person responsible and the data controller must apply the appropriate technical and organizational measures to guarantee a suitable level of security against risk that, if applicable, includes, among others:

a) Pseudonymization and encryption of personal data.

b) The ability to guarantee the confidentiality, integrity, availability and permanent resilience of treatment systems and services.

c) The ability to restore access to personal data quickly in the event of physical or technical incidents.

d) A process to regularly verify, evaluate and estimate the effectiveness of the technical and organizational measures established to guarantee the safety of the processing.

It should be remembered that public health centres in Catalonia, as well as privately subsidised centres and services, must comply with, in addition to GDPR and LOPDGDD, the technical instructions on security which — in all areas of the centre — is determined by the **Spanish National Security Scheme (ENS)**, in accordance with Royal Decree 3/2010, of 8 January, regulating the national security scheme in the field of electronic administration, as well as Royal Decree 951/2015, of 23 October, modifying Royal Decree 3/2010, of 8 January, regulating the national security scheme in the field of electronic administration.

Given the complexity of the application of the technical instructions of the ENS, it is recommended, together with the assessment that may be made by the DPO on data protection, to contact advisers specialized in its application and implementation.

Broadly speaking, we can find the use of telemedicine in the following three scenarios:

1. Cases in which the owner of the tool used in telemedicine does not have the status of data processor and, therefore, does not act on behalf of the data controller or under his, her or its guidelines

Example: a professional or health centre that incorporates telemedicine to complement or replace in some cases face-to-face appointments and only as a channel for communication with patients for the purpose of carrying out the appointment, facilitating it remotely through video-conferencing platforms, apps, instant messaging services, telephone or email (Zoom, Microsoft Teams, WhatsApp, Telegram, etc.)

The provider of the tool used is responsible for the security measures that have to be applied. Generally, it only provides a communication channel, without any other access to personal data and with certain determined conditions of use. However, the person responsible for the processing, who is the owner of the health centre, has the responsibility of choosing the communication channel that is the most appropriate and that has the most guarantees for the activity. For example, it should be verified that the platform does not expressly exclude its use in the healthcare field.

The COVID-19 pandemic has led to the proliferation of numerous applications and software, used both in the private and professional spheres, which, in some cases, only need an email address to use them. It should be kept in mind that not all are suitable for telemedicine and care needs to be taken when choosing one, always within the guarantees of current regulations.

In this scenario, two questions are raised:

A) Must the patient be informed again regarding the processing of their personal data (purpose, legitimacy, retention period, recipients, DPO, exercise of rights...) when using telemedicine?

Based on the fact that a previous face-to-face appointment with the patient has taken place, it is understood that he or she has already been duly informed about the processing of his or her personal data, with a written record of this aspect. Therefore, it is not necessary to inform about new processes carried out in relation to existing processing, unless, when introducing telemedicine, the purpose of the processing or any other initial circumstance of the same has been modified.

B) What security measures should be applied?

In accordance with the requirements of GDPR and the LOPDGDD, the main recommendations regarding the security measures to be taken into account in this scenario are the following:

a) Choose tools that incorporate point-to-point information encryption methods to ensure security and confidentiality, preferably TLS (transport layer security) technologies.

b) Avoid instant messaging services — such as WhatsApp or Telegram — for messages with health data, as despite using encryption methods, they do not offer the guarantees required by the regulation in force.

c) Choose suppliers that can guarantee and demonstrate that their tools comply with data protection regulations, with audits or certifications of compliance with ISO standards, to the extent which they are responsible for the processing of personal data in the service they provide.

d) Choose tools that are designed and recommended for use in the healthcare field, and that can be accredited. Some instant messaging or videoconferencing services, for example, expressly warn of the risk of their application in the field of health or telemedicine.

e) In the event of using email with patients, it is necessary to encrypt information that may contain health data in order to avoid improper access.

f) Contract identified and contactable suppliers.

g) Check that the location of the servers is in European Union (EU) territory and verify the identification of the suppliers.

h) Avoid the use of private equipment, such as mobiles, tablets, laptops, etc. taking into account the consequences that may arise in the event of a loss of information or theft of the device, as well as possible accidental access to these devices in the family environment.

2. Cases in which the owner of the tool used in telemedicine holds the status of data controller and, therefore, has access to the personal data of patients on behalf of the person responsible for processing and under his or her guidance.

This scenario, in general, may include the following situations:

1. Contracting a supplier to create software tailor-made for telemedicine and for its implementation.
2. Purchase of the licence of a software in the field of telemedicine that allows its customization or, in some cases, the same provider can carry out some adaptations.

In some cases, the contracted software can also incorporate other services, such as schedule management, medical history and documentation, administrative management or invoicing appointment. However, this guidebook is intended to only address the specific aspects of telemedicine.

In all cases, it is necessary to draw up the corresponding contract for the data processor, as mentioned. It is essential to choose the processor who offers the most guarantees.

These are some issues that can be raised:

A) What information should be provided to the patient or professional who registers on the platform?

It is always necessary to inform the interested parties (patients or professionals who register on the platform) in advance about the processing that will be carried out on their personal data (purpose, legitimacy, retention period, recipients, DPO, exercise of rights, etc.),

in accordance with the provisions of articles 13 and 14 of GDPR. The platform must have the appropriate mechanisms to document that they have been duly informed. The information must be adapted to the purpose of each process, unless the person has already been previously informed about the processing of their personal data.

Likewise, in the case of the legal basis of consent for the processing of personal data, the software must provide means of accrediting that the patient has expressly given consent for the processing.

The means of accrediting that the patient has been duly informed and his or her consent and accreditation, if applicable, has been obtained can be:

- Boxes to be checked via web or apps.
- Voice recordings if over the phone.
- Emails with written declarations that can accredit sending or receipt.
- Recording of videoconferences.

Silence, inaction or pre-marked boxes do not accredit that the patient has given his or her consent.

In the case of websites or apps, they must include, in addition to the corresponding legal notice, the corresponding data protection policy to warn, where appropriate, of the use of the cookies that are deployed.

Occasionally, the information supplied by the software provider to users, as an entity responsible for the processing of personal data (for example, when entering their websites or apps, when personalized tools are not involved), may allow confusion to arise relating to having informed the interested parties about the processing of their personal data by the owner of the healthcare activity. In addition to the information that the provider may supply, in each case it must be evaluated whether it is also necessary to inform the owner of the healthcare activity about the processing, if this has not been done previously.

B) What security measures should be applied?

The main recommendations regarding the security measures to be taken into account in this scenario are as follows:

a) Establish means of identification and authentication of the patient, as well as the identification of the health professional with their professional body membership number, in order to verify their ability to professionally practise, if applicable, and depending on the service provided.

   For telephone service, it is necessary to establish unequivocal identification protocols of the users, such as requesting information from the person that can be compared with existing information, avoiding closed questions that can be answered “yes” or “no”.

b) Check that mechanisms are established for the exercise of patients’ rights and inform them of the contact details of the DPO, if one exists, establishing workflows and/or protocols in this regard.

c) Use point-to-point encryption methods to ensure security and confidentiality, preferably TLS (Transport Layer Security) technologies, and, to the extent possible, include authentication mechanisms by digital certificate.

d) Implement measures to guarantee the availability of data. It is necessary to have backups that guarantee the recovery of the data in the event of a loss of information or unavailability of the system.

e) Establish systems that allow the restoration of availability and access to personal data quickly in the event of a physical or technical incident, so that our work is not affected, by means of service level agreements that guarantee this and that minimize the impact on the service with the establishment of maximum response times and the resolution of technical incidents or system recovery.

f) Determine measures to guarantee the traceability of the data and access to the management of the medical history, if the tool foresees it. If this is possible, the tool should allow the system to integrate the non-face-to-face act directly into the medical history and maintain a change/access record in which the professional, date and time are recorded, saving these accesses for a reasonable period of time (for example, three years, at least).

g) Locate servers in EU territories and at identified providers. It is necessary to check the location, since international transfers of personal data could be made that should be reported and that would need to be managed properly.

h) Establish the recovery or return of the information to which the provider has had access in the event of ending the service or termination by the contractor.

   The recovery of personal data should be included here, in the event that they had been processed by the data controller, in an appropriate format that would allow us to continue our work, especially if the software provides for the safekeeping of the medical history.

i) Limit access by the provider company's staff (for example, in the case of providing technical support to the client) to that which is strictly necessary. Access to health data should be restricted, and, at all times, traceability of accesses should be given.

j) Be attentive to subcontracting chains and define them in the contract of the person in charge of the processing.

k) Check, prior to contracting, the credentials of the providers requesting security certifications or the latest data protection audit. In addition, the person responsible for the processing of personal data can also carry out audits.

l) Establish protocols in relation to security breaches, both with regard to the staff of the same company and those in charge of the processing, in order to be able to comply with the legal requirements in terms of communication to the competent authorities within 72 hours of the knowledge of the breach, if applicable.

3. Cases in which the owner of the health activity, as the person responsible for the processing, creates the telemedicine tool personally or with programmers employed by his or her own organization.

In this scenario, the owner of the centre, when incorporating the telemedicine tool, even if it already complies with data protection regulations, must also ensure that the security measures of this new tool are guaranteed, in accordance with the regulations on data protection in force.

The main issues that can be raised are:

A) Must the patient be informed again regarding the processing of their personal data (purpose, legitimacy, retention period, recipients, DPO, exercise of rights, etc.) when using telemedicine?

As indicated in the first scenario, it is understood that the patient has already been duly informed and, therefore, it is not necessary to inform him or her about new processes carried out in relation to existing processing, unless, when introducing telemedicine, the purpose of the processing or any other initial circumstance of the same has been modified.

B) What security measures should be applied?

The recommendations regarding the security measures to be taken into account with regard to the chosen telemedicine tool are the same as in the previous point.

The person responsible for data processing, within the risk management provided for by GDPR and when choosing a telemedicine tool, must analyse the risks of each one and, with the help of the recommendations gathered, choose the one that offers the most guarantees.

Together with the above recommendations and the technical measures, in accordance with the principle of proactive responsibility governing GDPR, other organizational measures of a preventive nature and risk control can be included, among which the following can be highlighted:

- Incorporate protocols on the implementation of new tools, if not already available. In this sense, important issues such as the exercise of patient rights or security violations would be interesting. In the case of security breaches, if the provider of the tool is in charge of the processing, this must also be incorporated into our protocol. All the staff of the centre must be familiar with these protocols.
- Update the training of the workers of the centre in the new tools and their uses, as well as in the technical and organizational measures that have to be applied.

The security measures and policies adopted in the field of privacy are incorporated into the regulatory compliance obligatory for entities in all areas. These are mechanisms established for the purposes of prevention, detection and management of risks that may arise in their work and that guarantee compliance with them.

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