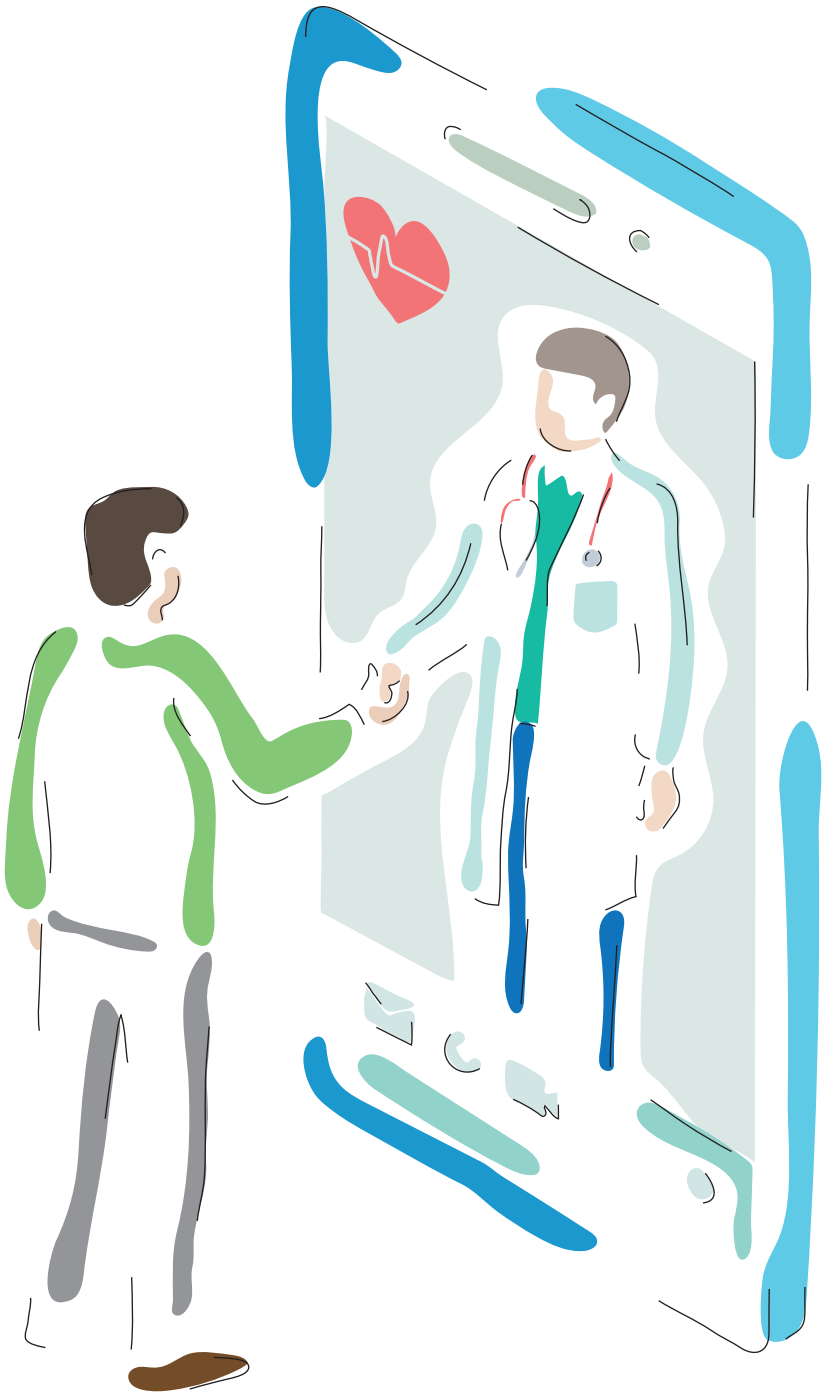
SEEN
Sociedad Española de Endocrinología y Nutrición

TELEMEDICINE AND TELEHEALTH in endocrinology and nutrition in times of the COVID-19 pandemic and beyond



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Rationale

The SARS-Cov-2 pandemic will undoubtedly mark a turning point in the way healthcare activities are carried out and in the development of telemedicine (TM) in Spain. Until now, The use of telemedicine systems in public healthcare systems has been limited to individual projects, and in the private institutions, although they have been more widely implemented, these tools have not had a uniform progress either.

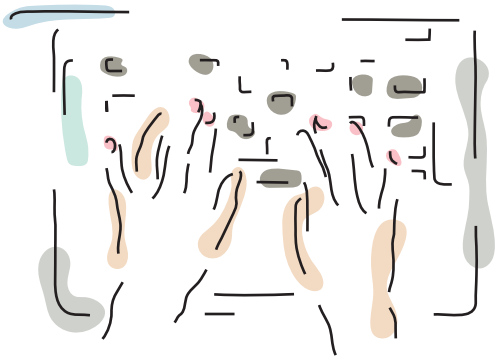
This health crisis has highlighted the need to implement new non-face-to-face care models[1]. According to the survey conducted by the Sociedad Española de Endocrinología y Nutrición (SEEN) [Spanish Society of Endocrinology and Nutrition] of its members in April 2020, only 19.5% used the teleconsultation (TC) format before the crisis. Meanwhile, 77.4% of the rest of the members reported having carried out TC during the weeks of the pandemic, both as an emergency measure and on a previously well stablished basis.

Supporting creativity and innovation in health care services is a constitutive part of the internal mission of health systems in general, and one of the future challenges posed by the SEEN in its "Reflexión Estratégica sobre el futuro de la Especialidad en el período 2018-2022" [Strategic Program on the future of the specialty in the 2018-2022 period][2].

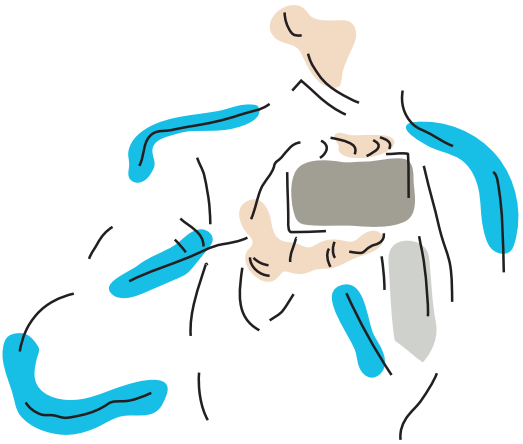
The use of new technologies, including teleconsultation, as part of the clinical practice in our speciality, can improve the quality of clinical care and optimise the use of health resources. These tools, however, must be used following clear guidelines, considering both ethical and legal aspects and from a perspective focused on the benefit for patients.

The aim of this document is to propose updated telemedicine standards that enhance innovative, humane, efficient, and quality healthcare services in virtual health care scenarios.

Contents



Introduction



According to the World Health Organization (WHO), TM is defined as «*the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities*»[3].

Contrary to popular belief, TM is not a new phenomenon. For many centuries, humanity has sought medical help from a distance For example, in ancient Greece and Rome, people who were unable to travel to temples to seek medical care sent messengers describing their symptoms, hoping that they would return with advice on diagnosis and treatment.4 However, the possibilities of an effective implantation of TM have increased exponentially in recent years as a result of technological development, the objective of reducing costs and waiting lists in specialised care, and the need to avoid losses in productivity due to the face-to-face care of patients in health centres.

The COVID-19 pandemic has brought TM to the forefront of healthcare. During this crisis, TC has emerged as a form of healthcare that maintains social distancing and minimises the risk of virus transmission[5]. The health and socio-economic tragedy that this pandemic has generated has paradoxically revealed a resource that was already available in many centres but which suffered from heterogeneity and underuse. The current situation therefore represents an incentive to considerably expand the use of TC for patients that endocrinologists usually attend in person at our office. Digital medicine also offers critically important approaches to improve healthcare access, efficacy, efficiency and cost-effectiveness for people with endocrinology- and nutrition-related diseases.

The use of TM and digitised medicine is likely to allow and facilitate a major reorganisation of health care systems, as the typical visit to the doctor at intervals of 3 to 6 months could potentially be replaced, or increased, through the use of frequent telephone or online communication with the patient. Throughout this pandemic, we have come to realise that certain face-to-face visits by patients (for example, to receive results or routine check-ups) are not necessary.

Of course, there are limitations to TC, which affect patients, doctors, diseases, and health centres[6].

- Patients may have a variable degree of access to new technologies, although in Spain this access is increasingly wide even in elderly populations.
- There may also be physical or mental limitations that make remote care (online or by phone) difficult or impossible.
- Some doctors may be resistant to change, claiming a deterioration in the quality of care, a lack of legal security, a greater workload or simply an inability to adapt to new technologies.
- Some diseases require a physical examination or invasive diagnostic or therapeutic techniques only applicable in face-to-face consultation.

Finally, the Spanish health care system is decentralized. Thus, public and private health care institutions use different information systems, which hinders effective digital communication and data sharing with patients and other health care institutions where this is required (Table 1).

Several questions emerge with the rise of TC[5].

- Is eHealth an option just because the quality of healthcare today is not good enough, or does digital healthcare offer options that traditional healthcare does not?
- Does the paradigm change by transferring part of the responsibility from the health professional to the patient by empowering him/her with information and decision-making support?
- Can we replace most of our patients' face-to-face visits with remote care?

Tabla 1. **SWOT matrix of teleconsultation in Endocrinology and Nutrition.**

WEAKNESSES

- Lack of knowledge and trust in electronic. health solutions among patients, citizens and health professionals.
- Lack of training in medical schools for this type of care.
- Lack of interoperability between eHealth solutions.
- Need for infrastructure (telecommunications and technology) and training in the use of the service, for professionals and patients.
- Lack of teleconsultation standards/process
- Lack of humanisation plan and information for the population.
- More time needed to carry out the consultation (depending on what type of consultations).
- Higher risk in diagnosis due to lack of physical examination and data reported by the patient.
- Obligation to report after each consultation to avoid misinterpretations of diagnosis or treatment.
- Absence of a specific legal framework.
- Decentralisation of the health system.

THREATS

- Ageing population with limited understanding and telephone communication quality.
- Patient commitment: diagnosis and treatment adjustment based on clinical data (weight, blood pressure, glycaemia) recorded and provided by the patient.
- Rejection of the change of care model.
- Negative effect on the doctor-patient relationship.
- Fear of legal problems due to confidentiality problems or diagnostic errors.
- Fear that the public administration will reduce the number of professionals since TM is more efficient.
- Fear that telemedicine enhanced with big data will reduce the doctor to a less relevant role.

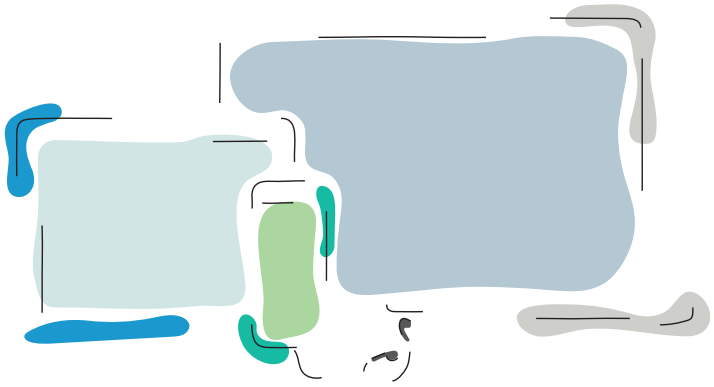
STRENGTHS

- Experience of teleconsultation during the COVID-19 pandemic.
- Current willingness by the health systems to develop this healthcare model.
- It does not require specific premises.
- It can be carried out by different health professionals.
- Possibility to increase the hours of service.
- Specialty with wide scope of care with this system.
- Technical means already available or minimal investment: electronic medical record, telephone/smartphone/tablet for video calls.

OPPORTUNITIES

- Reduction of waiting times: quick access to the specialist.
- Reduction of the geographical gap in care.
- Expand the portfolio of outpatient care services.
- Optimisation of clinical pathways with mixed care models.
- Reduction of travel costs (patient and caregivers).
- Environmental sustainability due to less travel.
- Continuous care: test results received in a short period of time.
- Greater coverage: delivering a timely response to the needs for care and diagnoses in areas where there are no medical specialists or being able to consult with specialists from another centre.
- Avoid admissions/visits to the A&E department
- Risk reduction (in pandemic situations).

Modalities



TM includes a variety of tools and platforms that allow healthcare professionals to connect with each other and with patients[7]. These can be classified into two large groups that are shown in Table 2.

Tabla 2. **TM modalities.**

MODALITY	SUBTYPE	DESCRIPTION
SYNCHRONOUS (can be doctor-patient or doctor-doctor)	Video conference	Real-time communication connecting doctors and patients in different locations
	Teleconference	Real-time audio communication connecting doctors and patients in different locations
	Continuous remote monitoring	Continuous real-time download of remote information (ECG, implantable biosensors...)
ASYNCHRONOUS (can be doctor-patient or doctor-doctor like e-consultation)	Storage and forwarding	Technologies that collect images and data to be forwarded to, and later interpreted by, an expert via web platforms, mobile phones, email, etc.
	Remote patient monitoring	Tools such as blood pressure monitors, continuous glucose monitoring, digital scales, and other portable devices that can download biometric data to digital platforms for later review
	Text messages	Via SMS or web platforms

Modified from Osman MA, *et al.*, 2018

The current paradigm of TM between two health professionals is **e-consultation**[8]. An e-consultation is a written non-face-to-face clinical consultation between professionals from different healthcare settings, which includes the possibility of attaching files such as images and documents. It requires the integration of information systems from different healthcare settings, access to clinical records and complementary tests for primary and hospital care from both levels, and a common electronic prescription module. In addition, the prior establishment of joint protocols for diseases with higher referral frequencies is required.

The main objectives of e-consultation are:

1. Increase resolution capacity.
2. Decrease diagnosis delay.
3. Improve patient accessibility by avoiding unnecessary travel.

It offers a standardised tool for health centres and hospitals of the health system and provides traceability in the electronic medical record.

- Patient's referral to specialized care control allows prioritization of appointments requiring face-to-face or non-face-to-face care. These appointments can easily be adapted depending on patient's or health provider's needs.
- Finally, e-consultation is an educational tool since it allows the specialist to base his/her diagnosis and treatment on the response, so that the primary care doctor can learn from the case and handle similar patients correctly in the future without requiring a referral.

As a local example, within the TM Plan (2014/2018) of Comunidad de Madrid, the deployment of e-consultation is included for all the referral hospitals and health centres of the autonomous community[9].

In a first phase, the task flow circulates from primary care to a service/specialty of a hospital where a specialist will respond to the query made by the primary care doctor. In later phases, this flow may also be established from the hospital to the health centre and from hospital to hospital. Commitments must be established regarding the content of the e-consultation (precise and sufficient clinical information, not using this procedure to bring appointment dates forward), response (generally a maximum period of 72 hours) and management of successive visits in case the patient requires face-to-face visits or

complementary tests. Usually, e-consultation is assigned to one or more doctors and it takes place several days a week to meet the response deadlines.

Regarding TM between doctor and patient, the most widespread modality is remote consultation by **phone call in real time**. The telephone consultation means, for both the patient and the doctor, an optimisation of resources and an improvement in time management. Unnecessary travel, requests for time off work, waiting times prior to consultation and administrative procedures are avoided. Some types of TC may require less time and this would allow us to allocate more time to face-to-face consultations. Each healthcare team must organise its own system for managing TCs, to ensure that the consultations are recorded in the clinical history, are counted as activity and the time needed to conduct them is reserved.

Before the COVID-19 pandemic, these consultations were reserved for reviewing the results of blood tests and other complementary analysis monitoring patients with stable chronic pathologies or solving administrative problems. After the pandemic, most face-to-face consultations have switched to the telephone consultation modality to reduce the risk of infection.

It is recommended at the present time to continue prioritising remote consultation.

- The different services will determine which programmes or services can be considered as mostly remote and provide this information to hospital Administration.
- In these cases, hospital Administration will send a notification (for example, a sms) to every patient asking him/her not to go to the health center and indicating that he/she will be contacted by phone. It should be included in the notification that patients must commit to answering a phone call that will be made within a certain time period.
- A prior review of the appointments schedule is recommended to determine if any of these patients should attend their appointment in person so they can be notified in advance.
- As part of the implementation of remote consultations, access should be given to all national landline and mobile telephone numbers in all offices where a medical consultation is held.
- It is also highly recommended that the doctors who carry out these remote consultations are able to use headphones with microphones or other devices that allow them to have their hands free so that they can note down the information gathered during the interview with the patient.

An improved form of synchronous remote consultation is the video call. For security reasons, it must be end-to-end encrypted.

- Its main advantage is that the healthcare professional can perform a visual examination of the patient.
- In addition, it offers the possibility of group consultations, preferably for training in the correct handling of different devices (sensors, pumps, artificial nutrition, injectable drugs), ensuring therapeutic adherence and monitoring the course of the disease.
- Its main drawback is the need to install specific applications on the computer or the provision of mobile phones with sufficient data or hospital Wi-Fi networks that allow video calls.
- It is also necessary to previously evaluate the technological competence of the patient or caregiver.

In our setting, a mixed modality between video call and e-consultation is the TC call with prisons, which in the future could also be applied to consultations between different hospitals. Inmate patients are a population group that benefit from TC due to the circumstances of isolation that surround them and the types of types of conditions and diseases they suffer that require a close follow-up[10].

- The TC mechanism is based on a videoconference with the hospital specialist at one end and the patient and doctor responsible for their care in the prison at the other.
- In addition, complementary tests carried out in the prison can be examined even before the consultation.
- If the specialist needs to examine the patient, this can be done by the doctor present at the prison, who can report the findings live.
- The videoconference is encrypted through the elaborate security system and the patient's personal data is collected in the electronic medical record, in such a way that there can be no access from other locations.

Another option for non-face-to-face consultation is **asynchronous assessment**, via **mobile phones** or **web platforms**, **text messages**, complementary tests or data generated by biosensors worn by the patient.

- The assessment of data from continuous glucose monitoring or continuous insulin infusion pumps is a good example of this modality, which can also precede a synchronous non-face-to-face consultation with the patient.
- In this scenario, the compatibility of external devices, systems and platforms with the electronic medical record, or having access to them on the same computer we use to manage the medical record, is essential.

Candidate patients

In the current COVID pandemic situation, most patients being followed up in Endocrinology and Nutrition clinics have had to be treated by TC for public health reasons. Over time, the face-to-face activity of the Endocrinology and Nutrition services will gradually recover, but the acceleration in the application of new technologies and the change in care mentality generated by the pandemic will inevitably cause an increase in the use of TM in our consultations.

Candidate and non-candidate patients for TC assessment are summarised in Table 3.

The published experiences in Endocrinology and Nutrition with TM originates mainly from Canada and the USA.

- The general conclusion is that the use of e-consultation improves access to endocrinologists, provides a rapid response, avoids unnecessary referrals and modifies the initial therapeutic attitude of the primary care doctor in a high percentage of cases[11-12].
- The most frequent reasons for e-consultation are thyroid disease and diabetes.
- Similar results have been obtained with e-consultation initiatives implemented in Spain[13].

Several studies have analysed the impact of TC and telemonitoring in diseases related to endocrinology and nutrition, especially diabetes.

- A recent meta-analysis of 42 randomised clinical trials concluded that TM interventions are more effective than usual face-to-face care in the management of diabetes,

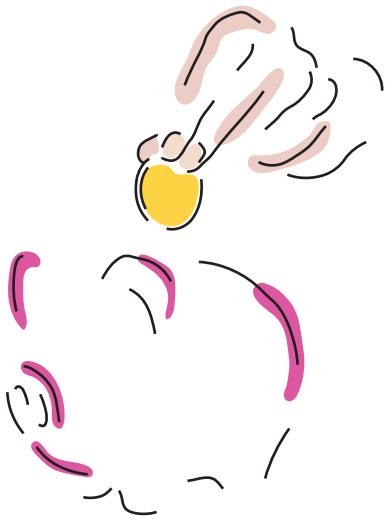
especially type 2 diabetes. In addition, their use in older patients and a longer duration of the intervention provide superior results[14].

- In another meta-analysis of 14 randomised clinical trials, in addition to confirming a favourable effect of TM on glycaemic control, a reduction in the risk of hypoglycaemia was observed[15].

Tabla 3. **Candidate and non-candidate patients for TC care in Endocrinology and Nutrition.**

CANDIDATE PATIENTS	NON-CANDIDATE PATIENTS
• New patients referred through e-consultation. Examples: – consultation with primary care doctor related to laboratory abnormalities – consultations about the treatment of chronic diseases (e.g. hypothyroidism, diabetes) • New patients who can be evaluated without needing a physical examination. Examples: – pregnant women with mild thyroid function abnormalities – type 2 DM patients with suboptimal glycaemic control – overweight or grade 1 obesity • Consultations about test results • Periodic reviews of stable chronic pathologies • Elderly patients with difficulties to travel • Intensive follow-up at hospital discharge (debut of DM1, initiation of artificial nutrition at home, after oncological surgery) • consultations for individual or group training via video call (insulin sensor/pump management, home artificial nutrition, dietary education for obesity, monitoring of bariatric surgery)	• Patients who refuse remote consultation • Patients with sensory limitations or limited language comprehension via telephone or video call • New patients who, due to their complexity, require a physical examination for their evaluation • Unstable patients with a deterioration in their general condition • Patients with physical or mental limitations that make teleconsultation unfeasible • Patients who must go to the hospital for: – diagnostic tests (e.g. thyroid ultrasound with or without FNA, dysphagia test, functional tests) – instrumental procedures (e.g. nasogastric tube placement) – treatments in a clinic or a day hospital (e.g. administration of parenteral drugs) – assessment of functional capacity and body composition – simultaneous assessment in multidisciplinary units (ALS, dysphagia)

Cost effectiveness



- Specialised care represents a significant and growing part of the healthcare cost. TM theoretically reduces the direct costs of the consultation, in terms of work time by the specialist and requests for complementary analysis but it also reduces the indirect costs related to transport and lost working hours. It may also reduce the frequency of complications in some cases as a result of the shorter delay in medical care.
- In a study published in the United States, Medicaid patients who were referred to a specialist through e-consultation had an average cost of $82, significantly lower per patient per month than patients referred to face-to-face consultation[16]. In the case of the endocrinology specialty, the savings were $63 per patient per month.

In a study carried out in Catalonia (Spain) that analysed the differential costs between e-consultation and face-to-face referrals in several specialties in a semi-urban setting, e-consultations saved €780,397 during the period 2011-1917.

- TM was observed to cost approximately €15 less per visit, with the patient being the greatest beneficiary of this saving (85%) in terms of waiting times and travel costs.
- From a health system perspective, TM was efficient in terms of total time spent per patient.

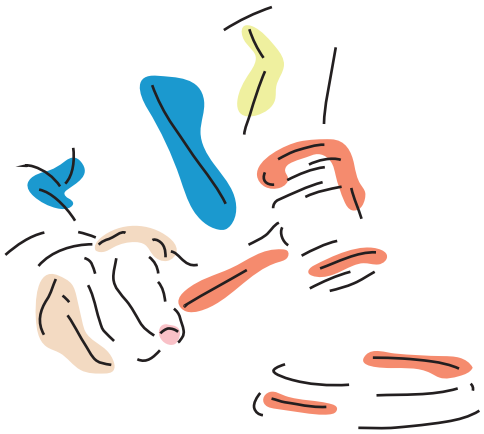
Another study in Catalonia evaluated, between January 2018 and June 2019, the effect of a TM programme on the reduction in atmospheric pollutant emissions as a result of the reduction in the number of visits to the hospital requiring travel by road[18].

- In total, the distance saved was 192,682 kilometres, with a total travel time saving of 3,779 hours and a total fuel reduction of 11,754 litres, with an associated cost of €15,664.
- The study confirmed that TM reduces the environmental impact of atmospheric pollutants emitted by vehicles, by reducing the number of trips made for face-to-face visits and, therefore, contributes to environmental sustainability.

One of the diseases in our specialty where the economic impact of TM has been studied the most is diabetes.

- In a systematic review of 14 studies, it was concluded that the use of TM for screening for diabetic retinopathy was the most cost-effective intervention.
- The use of telemonitoring and telephone reminders were also cost-effective interventions[19].
- The economic savings with TM in diabetic retinopathy has also been confirmed by other systematic reviews[20].

Legal framework



Due to its nature and characteristics, we find that TM is, on the one hand, a health service and, on the other, a feature of the information society, which is why it is governed by the principle of free provision of services, by e-commerce regulations and by the directive on the rights of patients in cross-border healthcare.

1. TM as a health care service is regulated in:
   - Articles 56 and 57 of the Treaty on the Functioning of the European Union (TFEU)[21] since, being a service, it falls within the scope of these articles of the Treaty.
   - Directive 2011/24/EU[22], on the rights of patients in cross-border healthcare. Specifically in articles 3 d), 7.7 and 14.
2. TM as a service of the information society is regulated in:
   - Directive 2000/31/EC[23], on electronic commerce: article 2 a).
   - Directive 98/34/EC[24], on information society services. Article 1.2.

It is a key issue to analyse the situation of the legal regulations at the time of the implementation and development of the TC service. In general, these regulatory aspects are:

1. data protection;
2. the privacy and confidentiality of the data;
3. regulatory aspects related to data responsibility.

There is no exclusive regulation of TM or remote monitoring of European citizens in the European Union, although Directive 2011/24/EU can be applied. This directive relates to the rights of patients in cross-border healthcare, and clarifies the rights of patients to receive healthcare outside our borders, even remotely through TM.

These are 2011 directives that must be adapted to the TM scenario in 2021. In fact, one of the strategic goals of the European Union is to promote TM and improve access to specialised medical care in areas where there are not enough specialists or there are difficulties in accessing healthcare.

In Spain, there is no specific regulation on this matter and it does not help that the responsibilities for healthcare have been transferred to the autonomous communities. This fact does not allow for uniform regulation, although there are certain rules at the national level that must be applied (Table 4).

Tabla 4. **TM regulation.**

- Law 16/2003 on Cohesion and Quality of the National Health System.
- Organic Law 15/1999, of 13 December, on the Protection of Personal Data and Royal Decree 1720/200.
- Law 34/2002 of 11 July, on services of the information society and electronic commerce.
- Law 14/1986, on General Health.
- Law 45/2007, of 13 December, on sustainable development of the rural environment.
- Law 44/2003, of 21 November, on the classification of health professions.
- Law 41/2002, basic law regulating the autonomy of the patient and the rights and obligations regarding information and clinical documentation:
- Law 34/1988, general advertising law; Royal Legislative Decree 1/2007, of the General Law for the Defence of Consumers and Users.
- Royal Decree 81/2014, of 7 February, which establishes rules to guarantee cross-border healthcare.
- Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights.

Informed consent for TC

According to Spanish "Ley de Autonomía del Paciente" (Law on patient autonomy), 41/2002[25] (article 8), any action in the field of a patient's health needs the free and voluntary consent of the patient concerned, who, having received the information provided for in article 4, has assessed the options for their case.

As a general rule, consent will be verbal. However, it will be provided in writing in the following cases: surgical procedures invasive diagnostic and therapeutic procedures and, in general, application of procedures that involve risks or inconveniences with a possible

and foreseeable negative impact on the health of the patient. An attempt will be made to avoid this type of circumstance in the TC model, with verbal consent being sufficient.

In conclusion,

- TM implies the safe transmission of data and medical information through text, sound, images or other forms necessary for the prevention, diagnosis, treatment and monitoring of the patient, and in this sense, the ethical and professional rules related to the provision of this type of service become more relevant.
- Institutions and health care systems must ensure the proper and safe handling of data, providing the necessary technology and establishing specific regulatory conditions for this new care model, agreed with health professionals.
- They must also have a service continuity plan: they must adequately inform about how possible disruptions in services will be addressed, such as failures in communication systems or cybersecurity and data breaches.
- Information on local regulations that should be addressed should be obtained from medical councils, colleges and health care directors/managers. It is also important to check that liability insurance covers medical practice when it is carried out as a TC service.
- In the field of private medicine, the services available must be included on the provider's website for users to read and exercise their right of consent to accept the services and their options. Information should be included on types of care, potential risks and benefits, rights and responsibilities, applicable costs and forms of payment (for different applicable services). Providers must ensure that the technologies and software used can serve their purpose. To do this, they must ensure that the chosen audiovisual system is accepted by the user, and that it meets the requirements in terms of cybersecurity. Along with the structure of the services offered, the person in charge must be identified so that users can contact him/her.
- From a legislative and regulatory point of view, attention will have to be paid to issues of digital health such as the regulation of mobile applications and cybersecurity, the use of public data and the application of the European regulation on digital data protection.

Safety and TM

Patient safety, a key component of the quality of care, has acquired great relevance in recent years both for patients and their families, who want to feel safe and confident in the healthcare received, and for managers and professionals who want to offer safe, effective and efficient care[26]. In the field of TM, safe practices become even more important than in traditional healthcare scenario.

Good practices and recommendations for TC (Table 5[27] and Figure 1)

1. Inform the patient about TC. Before conducting a remote consultation,

- Professionals should ensure that patients understand how the consultation will be carried out.
- The patient should receive information in plain language that allows them to have clear expectations about the type of care they will receive, the other care options available, the associated costs (if applicable) and the day, time and expected duration of the TC.
- In the event that a group video call is offered to the patient, they must also be aware of its characteristics and purpose, as well as be asked for their consent.

2. Evaluate the technological capabilities of the patient (in case of contact via video call) and the correct reception (image and audio) and interpretation of the information.

3. Recommend the following instructions to patients (before and during the consultation):

- Prepare TC in advance, making sure the electronic device has enough battery and adequate internet connection.
- Pretest the connection and the system to be used for the TC.
- If the TC will be carried out via a mobile application, download and install it on your phone or tablet in advance.
- Stay in a place suitable for the TC: if possible somewhere quiet, and with good lighting.
- Write a list of your main symptoms and questions for the professional.
- Have on hand any relevant records (blood glucose, blood pressure, weight, etc.), recent clinical reports and medications you are currently taking. If possible, the data that the patient must report should be previously sent to the healthcare team (by email) or have been uploaded (electronic health record platforms) for prior review by the professional before the consultation.
- Have a pen and paper available to write down instructions and recommendations received during the session.
- Make sure the health care providers have contact information (phone number and postal address) in order for them to be able to text, email or post written instructions.

4. Maintaining the privacy and confidentiality of the patient during TC is a priority. Health professionals should have the necessary resources that will enable them to achieve the same quality standards as face-to-face care, considering the specific privacy risks that exist when using TC.

- It is advisable to corroborate the identity of the patient through a simple mechanism, such as asking them to state their address or ID and date of birth and confirming the data with the available registry, making sure that the contact and address details are up to date.
- When greeting the patient, the professional must introduce himself and indicate his full name, profession and specialty, as well as the institution to which he belongs. Likewise, and as is done in face-to-face sessions, in the case of video calls it is recommended that the identification badge of the treating person is visible for the patient and that health professionals wear their clinical uniform.

- Systems are required to ensure that there are no interruptions in communication, both on the part of the professional and of the patient. It is useful to ask patients for another phone number, to be able to complete the consultation if the connection is interrupted.
- Ensure that patients participating in a TC do so from a private, quiet room where they will not be interrupted.
- Warn other staff members in the vicinity of the professional that a TC is being conducted and ask not be disturbed.
- It is important to register every time that the patient is accompanied (especially in the case of adolescents, elderly patients and people with disabilities) and to obtain their written informed consent to share the private health information with the companion.
- A complete record of care should be made, ideally through the same electronic record of the healthcare centre where the patient is usually seen. In the event that the professional is not in the usual place of care, they must have access to the patient's medical history.
- In addition to the clinical record, copies of all reports and documents generated from the TC should be made and stored.
- If there is a valid and clinically appropriate reason for a TC to be recorded, inform the patient fully and receive their explicit verbal consent after explaining the reason.
- If a consultation is to be recorded, or images or photographs of the care provided are to be recorded, this information must be stored securely, and their privacy and confidentiality must be ensured.
- In addition, if the consultation is recorded, the treating doctor and his team must be able to give the patient a copy of the recording if the patient requests one.

5. If we contact the patient via video call, it is essential to confirm that the platform or application has end-to-end encryption. It is a communication system where only authorised users can read the messages. In principle, it prevents interference by spyware, telecommunications providers, Internet providers and even the communication service provider, from accessing the cryptographic keys necessary to decrypt the conversation.

6. Prior to the consultation, the health professional should review the patient's clinical data to identify situations that would require a face-to-face approach.

Tabla 5. **Safety aspects in TC.**

BEFORE THE CONSULTATION	Information for the patient: day, time, duration, objective, characteristics, costs (if applicable), necessary material and data and consent. Assessment of physical and technological capabilities/limitations. Review of necessary material (landline, mobile phone/tablet, headphones, etc.) Planned TC schedule. Prior history review by the professional (identify patients who require face-to-face consultation).
DURING THE CONSULTATION	Professional and patient/caregiver identification. Suitable place, maintain privacy and confidentiality. Data transmission by the patient. Transmission of information/treatment by the professional. Confirmation of understanding by the patient.
AFTER THE CONSULTATION	Record of data in clinical history. Preparation of report/communication with referring doctor. Treatment prescription/adjustment (electronic prescription). Arranging of next appointment.

Adapted from 27

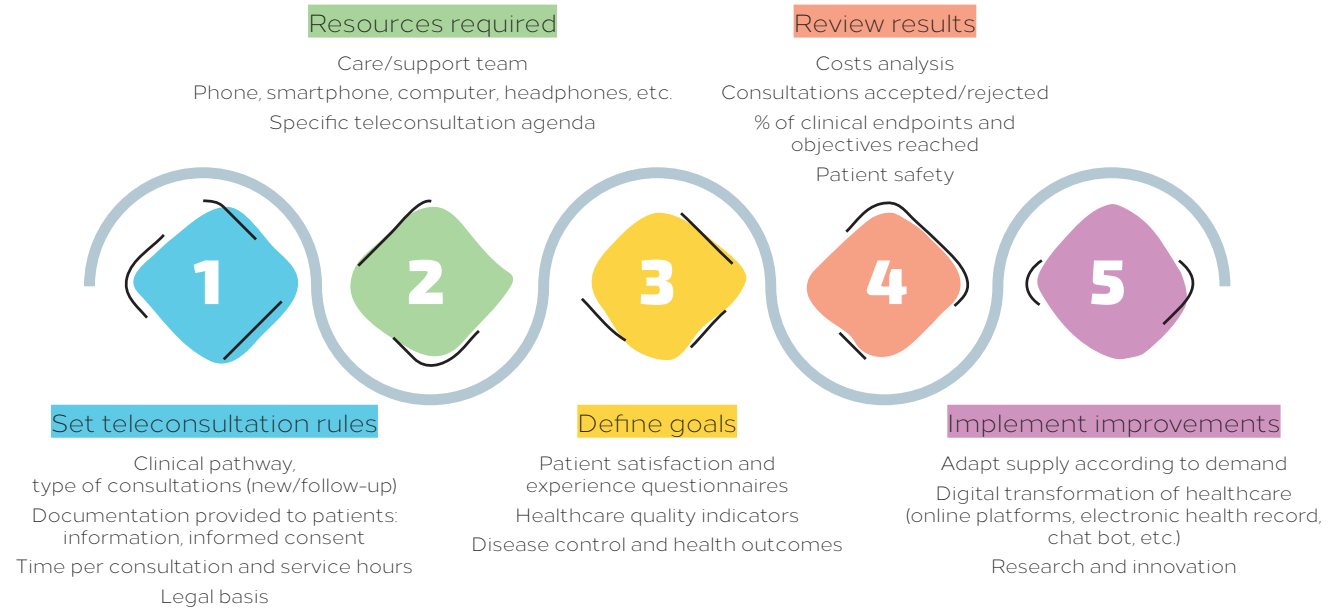


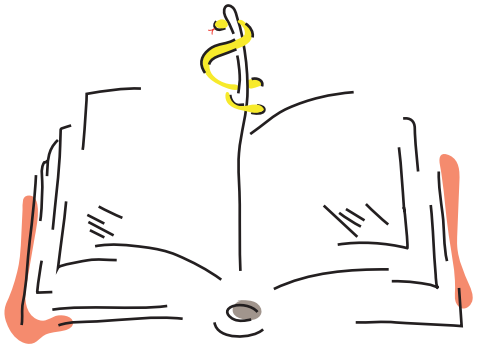
Figure 1. **Teleconsultation implementation process.**

7. As long as the COVID-19 pandemic lasts, we can use every available opportunity to educate on prevention and identify suspected cases of infection. Each interaction between a patient and his/her health team in this period is an opportunity to:

- Educate on the basic recommendations for respiratory and hand hygiene, reinforcing self-care and infection prevention behaviours.
- Gather information in a structured way regarding characteristic symptoms and signs, risk factors and contact identification.
- Refer the patient in a timely manner to the corresponding health care services and intervene in the chain of transmission of COVID-19.

Finally, TC opens up new opportunities to get to know patients in their family or work environment. Without jeopardizing privacy or confidentiality of care, and using good clinical judgment, each TC can be a privileged opportunity to access a space until recently restricted to home care or occupational health. Taking advantage of these opportunities can provide new information for diagnosis, for the development of more comprehensive and timely treatment plans, and for actively involving the patient support network in your city.

Code of ethics and TM



The Organización Médica Colegial (OMC) de España [Spanish Medical Council] promulgated its first Code of Ethics and Medical Deontology in 1978 under the 1978 Constitution, which establishes the recognition of and the need to regulate professional associations and the practice of qualified professionals.

This Code has been updated on four occasions, in 1990, 1999, 2011[28] and in 2018[29]. This last version is still in progress, considering the commitment of the medical profession to the society it serves and the evolution of technical-scientific knowledge. and the rights and responsibilities of doctors and patients.

In relation to the use of TM in the code of ethics, it is mentioned in:

- Article 26.3 of chapter IV (Quality of Medical Attention) of the Code of Medical Ethics of 2011, "The practice of medicine through consultations exclusively by letter, telephone, radio, the press or internet is contrary to deontological norms. Correct action inevitably implies personal and direct contact between the doctor and the patient.»
- In chapter XXV (Information and Communication Technologies) of the new Code of Medical Ethics (2018 draft) two articles should be highlighted:
  - Article 103: «The use of telematic means or other non-face-to-face communication systems intended to aid in decision-making within the professional field is in accordance with medical ethics as long as the identification of those involved is clear, confidentiality is ensured and communication means are used that guarantee the maximum security available.»
  - Article 104: «In the use of telecommunication systems (TM, internet, social networks, computer networks, mobile telephony or other telematic means), the deontological precepts established in this Code will govern, regarding the doctor-patient

relationship, the defence of the rights and safety of the patient, as well as respect for healthcare professionals.»

Hence, for TM to be acceptable, the following must be met:

- The rules and regulations on confidentiality, security and professional secrecy must be scrupulously respected.
- The patient must be informed of the service provided, which includes the identification of the healthcare professional, and must be aware of these conditions, and must authorise and consent to be treated via TM.

Pending the final version of the Code of Medical Ethics 2018, an OMC document has recently been published in which e-consultation, or medical assistance offered through new technologies or communication systems, is recognised as being a true medical act that complements traditional face-to-face patient care, and may have an added value, not only in clinical practice, but also in public health and epidemiological surveillance activities[30]. In addition, it is considered that in any medical act it is a responsibility of the health care practitioner to assess the clinical situation and to decide the most appropriate option for the patient. It should be noted that this non-face-to-face clinical activity should be considered of equal importance as the traditional one, since it requires time and thought from both the physician and the patient in order to prevent errors, considering the shorter time usually available for this type of consultation and with the added difficulty of not being possible to rely on physical examination or non-verbal communication, which are of great important in any medical procedure.

The World Medical Association (WMA) is an international organisation representing medical doctors. It was founded on 18 September 1947, when doctors from 27 different countries met at the First General Assembly of the WMA, in Paris. The organisation was created to ensure the independence of doctors and to serve the highest possible standards of ethical conduct and medical care, at all times. At the 69th General Assembly of the WMA (Reykjavik, October 2018)[31], a statement on TM ethics was presented, including the following ethical standards:

1. The doctor-patient relationship must be based on a personal examination and sufficient knowledge of the patient's medical history.
2. The doctor-patient relationship in TM should be based on mutual trust and respect.

3. Adequate informed consent requires that all the necessary information about the different aspects of TM consultations be fully explained to patients.

4. Doctors should be aware that certain TM technologies may be unaffordable for patients and thus prevent their access to care.

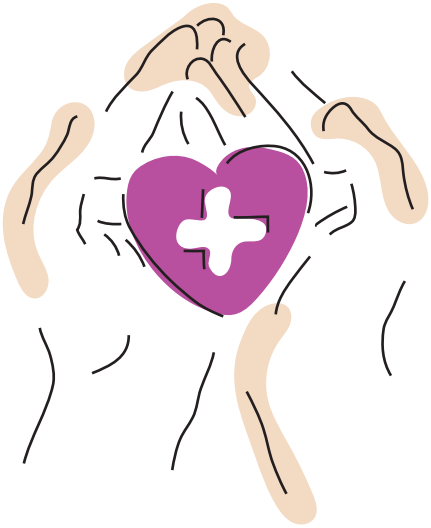
Aspects related to the autonomy, privacy and responsibilities of the doctor and the quality of care are also detailed in the document.

In conclusion,

- From the basic principles of Beauchamp and Childress (Autonomy, Beneficence, Justice and Non-Maleficence), autonomy has become the true revolution in the patient-doctor relationship, considered as the obligation to consider patients capable of making decisions that have an impact on their health and life, after receiving complete information from the doctor.
- The codes of medical ethics include those rules that every doctor must follow to practise his profession in an ethical manner, that is, not only to be a competent doctor (understood from a technical point of view), but also a good doctor (from a technical and human point of view).
- The use of TM should not compromise either the principle of autonomy or the human factor of the medical act. Ideally, TM techniques should contribute to optimising medical care for the general community; they must promote, not undermine the relationship of full trust between doctor and patient.

Telecare has been presented as a necessity and an obligation in pandemic times and now it must be promoted as a complementary healthcare scenario to other more classic ones, without damaging the trust, privacy, or responsibility of the medical act. It must also be accompanied by a commitment to quality of care.

Humanisation of digital healthcare



The humanisation process is a fundamental part of the quality of the service provided. The patient and his/her environment must be taken into account in a comprehensive manner by the health system and its professionals. The need to humanise the health system stems from the existing imbalance between technological innovation and the human aspects of healthcare[32].

In the context of the humanisation of healthcare, two aspects should be highlighted: comprehensive care focused on people and the patient experience.

It is important to develop tools for assessing the incorporation of humanisation in healthcare, including TM. In Catalonia, the experience of using TM in patients with type 2 DM was evaluated, which was found to be satisfactory, but there was also a demand for access and doctor-patient communication to be simple and agile (Rodríguez-Fortúnez P, 2019)[33].

At an international level, there are standardised instruments to measure the patient's experience, such as the CAHPS (*Consumer Assessment of Healthcare Providers and System*) questionnaires[34] that include aspects that users consider important, such as the communication skills of professionals, accessibility to health services, coordination between professionals, etc. There are also other questionnaires such as the *Picker Patient Experience Questionnaire*[35], the *Patient Experience Questionnaire*[36], and the IEXPAC questionnaire[37] for patients with chronic diseases, and others specific to the use of technology such as the SUTAC (*Service User Technology Acceptability Questionnaire*)[38].

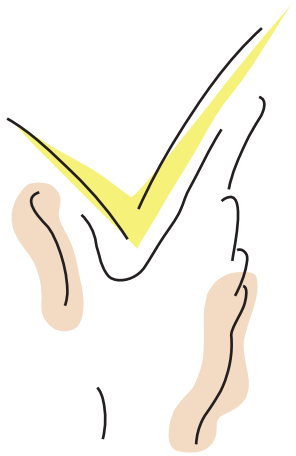
In relation to the experience of patients, there are very important advances with such highly relevant projects such as ICHOM[39] and Beryl Institute[40]. Patient associations can play a fundamental role here, being a relevant point of intersection between public health, health systems, health administrations, health agents and society.

Tools for the humanisation of TC[41,42]

- Take care of the details: the implementation of this type of care model should be accompanied by an information campaign in which users know the reason for these consultations and how they work. Likewise, they should be aware of the possibility to reject this model and that such decision will not affect the follow-up of their pathology. A set of instructions or a welcome guide can be prepared for users, family members/companions and a user guide for professionals.
- Take advantage of creativity and innovation: have a structured approach towards generating creative ideas and innovation in the humanisation of telephone care.
- Care for personal attention: introduction of the health professional at the beginning of the call, verification of adequate connection/audio signal and consent from the patient. Build trust. Protect people's confidentiality and privacy.
- Communication (empathic, assertive and compassionate): availability for active listening, to providing information and advice, promoting the autonomy of the person and shared responsibility in decision-making. Give clear, simple, personalised and understandable information.
- Comfortability: explain and rationalise the care schedule. Patients must know in advance the day and time frame in which they will be called and what data they should have available.
- Share information: provide telephone and digital links of interest, both for the maintenance of health and for the improvement and control of the disease for which the patient is in treatment.
- Include periodic questionnaires to assess the patient's experience.
- Propose a patient forum as a systematised meeting space between patients, professionals and expert personnel to identify areas for improvement.

It should not be forgotten that the objective of the information collected is to clarify the weak points of the care we provide as an organisation, identify the issues that cause the greatest dissatisfaction, and guide decision-making.

Quality management, TC certification



Quality of care is a discipline that has acquired enormous relevance in current healthcare practice.

- We live in an age in which patients 'expertise and autonomy are increasing, professionals more capable and better trained, and medical technology more advanced and decisive.
- These and many other scientific and social factors contribute to enhancing and developing the quality and safety of care provided by health services.

When evaluating the quality of teleconsultation results, two fundamental questions arise[43,44]:

1. What were the effects of teleconsultation on immediate, intermediate and long-term health outcomes compared to the alternatives?

   To answer this question, measures of possible differences in the incidence of physical symptoms can be used; morbidity or mortality rates; the physical, mental or social functioning of the patients measured with scales; health-related behaviours; diagnostic precision; patient satisfaction or patient perceptions of the quality and acceptability of the care received; or, finally, the health outcomes self-perceived by the patients (health-related quality of life).

2. What were the effects of teleconsultation on the care process, compared to the conventional healthcare alternatives?

To answer this question, it is possible to use measures on the differences in the rates of service use, the suitability of the services used, the adequacy of the information accessible to patients and health workers, patients' understanding and compliance, the possible changes in the clinical management of patients, and the technical performance of equipment and the professional team.

Teleconsultation quality standards in Endocrinology and Nutrition[45]

- Models of teleconsultation: the consultation models (first visit, follow-up visits) and the frequency of these should be established in a clinical pathway according to each disease.
- Selection of the patient/disease inclusion and exclusion criteria of this care model will be established in the same way.
- Obtain patient's informed consent. As a general rule, consent will be verbal. Likewise, the patient must know that refusing this type of consultation will not negatively affect the care and follow-up of his/her disease.
- Competent staff: the doctors and health professionals involved in teleconsultation care must be equal in terms of competence, training and experience to those involved in equivalent face-to-face consultations. If the doctor's communication skills are insufficient to adequately encode the non-verbal channel, it could result in obtaining incomplete or biased information about the patient's reality.
- Activity record: care provided via teleconsultation must be recorded in the clinical history and must appear as part of the work activity, with its corresponding schedule.
- The means of communication, either by telephone or by video call, must include adequate security measures. It is important to have agreed protocols, a warning system for any failure in the communication system, and a built-in feedback process.
- Data registry: In addition to complying with the security and privacy standards in legal regulations and professional guidance on the conservation, storage and transfer of patient data, it is important that the patients´ teleconsultation records can be searched by a variety of criteria for audit purposes.
- Audit and quality control. It is vital that each service completes at least one patient survey and one audit each year to assess the quality of the service provided.

- Endpoints must be established on structure (accessibility/availability), process (productivity, performance, use, utilisation and quality) and results, both direct (efficacy/efficiency) and indirect (effectiveness)[46].

Useful evaluation models for TC implementation

- Evaluation of the quality of TM ***services***: when we consider measuring the quality of services, we focus mainly on the measurement of the effect of teleconsultation on immediate, intermediate and long-term health outcomes, in comparison with the alternatives, and in the care process.
- Evaluation of ***access*** to TM services: accessibility refers both to the degree of difficulty – in terms of geographical, economic, architectural, cultural and social barriers – to access the teleconsultation option, as well as the speed in accessing it. From the social point of view, TM should reduce the need to travel and improve the level of satisfaction of communities located in remote areas or with limited healthcare services. Likewise, through TM, not only distance barriers but also those related to quality of care and time could be reduced.
- Evaluation of the ***acceptability*** of TM services: acceptability, in the context of the new health services based on TM, is understood as the ability, both of health personnel and patients, to work in a «friendly» way with ICT. TM services must be user-friendly. This is one of the aspects most frequently evaluated in TM experiences and, in general, it offers high levels of satisfaction. The main tool used to evaluate the acceptability of patients and professionals is questionnaires. Although questionnaires are an adequate tool, it is convenient to ensure that their validity and reliability have been previously determined, as well as to anticipate and try to avoid some common methodological problems such as low response rate and bias towards positive answers.
- Evaluation of the ***cost impact*** of teleconsultation: direct, indirect, intangible, fixed and variable.
- Evaluation in the ***healthcare organisation***: organisational aspects include different levels of evaluation: intra-organisation, inter-organisation and across the healthcare system. At these levels, in addition to staff and patients, there are other players involved such as funders, providers, suppliers, etc., who may have different objectives and expectations regarding health technologies.

Accreditation models

Quality experts have tried to develop models that make life easier for managers and employees. Different models have thus emerged; three of which are of great importance in the health field (ISO standards, the Joint Commission International model and the European Foundation for Quality Management [EFQM] model).

These models do not contemplate the specific evaluation of teleconsultation.

Accreditation of the TC by the Asociación de Investigadores de eSalud (AIES) [Association of eHealth Researchers][47]

The purpose of the Sistema de Acreditación en eSalud (SAeS) [eHealth Accreditation System] for e-consultations is for healthcare professionals to obtain approval, reflected in the Accreditation Document and the Accreditation Seal, both of the appropriate technical and security measures in the equipment, infrastructures and communication methods they use, as well as of their regulatory compliance with the different regulations in force for carrying out remote consultations with their patients, either by telephone or online (e-consultations).

The e-consultation accreditation is based on the domains of security and regulatory compliance. Eight control areas have been established:

- User devices: suitability and security of the professional's equipment. Workstation, computers, operating systems and installed applications are evaluated.
- Infrastructure and network.
- Type and security of communications.
- Health regulations: rules that define user rights, patient safety and quality of healthcare.
- Users: identities, profiles, password management, access management, controls.
- Data: files, security documents, management of storage media, incident management, reports, backup copies, documentary archive, access management and control, medical history.

Conclusions

The scale of the pandemic caused by SARS-CoV-2 is not only testing the real capacity of health systems but also the possibilities of remote clinical care.

The COVID-19 pandemic is proving to be a disruptive element in telemedicine, which is gaining ground by leaps and bounds worldwide. We are probably experiencing one of the biggest and fastest transformations in healthcare in the last decades.

Teleconsultation has been mandatory during COVID-19 pandemic due to the need to limit access to hospitals and the spread of infection, but it is here to stay. There are many advantages that it can offer to professionals and users. Many of regulatory barriers to the development of telemedicine are probably not sufficiently substantiated.

Modern medicine demands that patients go to health centres only when their physical presence is necessary. The time has come to design safe, effective, quality and patient-validated telemedicine care models. These models will complement the traditional consultation model and will result in better clinical care and greater user satisfaction.

Professionals will be able to carry out their activity at the most appropriate time and in the most suitable setting, to treat diseases in an appropriate way. We cannot forget that the doctor-patient relationship implies a high emotional content that cannot be replaced by telemedicine as the exclusive healthcare model, considering that humane treatment resides fundamentally in the health professional.

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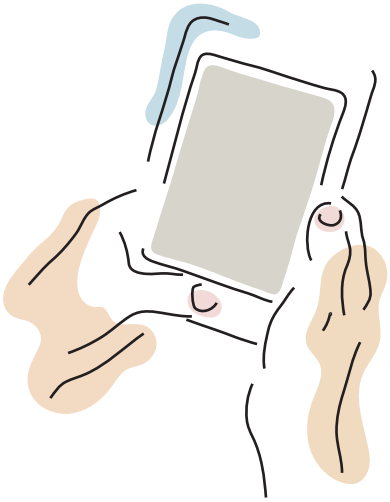

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