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TECHNOLOGY, MOBILITY AND COMMUNICATIONS

Coronavirus: The expansion of telemedicine and e-health services

According to the website of the Portuguese National Health Service, the number of teleconsultations was already increasing in January and February of this year, compared with 2019. With the mandatory confinement, the recommendations of the Directorate-General of Health (DGS) and the announcement of the ADSE on reimbursements, these numbers will grow significantly.

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Digitalisation is reaching all sectors of activity and, through telemedicine, the healthcare sector is no exception.

The Directorate-General of Health's Guideline no. 010/2010 of 16 March, headed "Infection by SARS-CoV-2 (COVID-19) – Social Distancing and Isolation", recommends precisely that:

"(...) You should avoid travelling to see your doctor and should first contact the health services and find out about alternatives to travelling (e.g. teleconsultation, remote prescription of medications)".

The extension of telemedicine services and, in general, the means of distance communication, have come about as a natural reaction to restrictions arising from the current pandemic emergency

In this note, we will present some issues involved in this way of providing medical care which, although not new, are more important today than they ever were.

1. Some notes on the concepts: what are telemedicine and e-health?

The World Health Organization ("WHO") defines "telemedicine" as the provision of health services through the use of information and communication technologies (ICTs), when distance is a "critical factor".

According to the statement adopted by the 51st World Medical Assembly in Tel Aviv, Israel, in October 1999, there are four forms of telemedicine:

- Teleassistance: an interaction between a doctor and a patient who is in a geographically isolated or hostile environment and has no access to a local doctor. This form is generally restricted to very specific circumstances (e.g. emergencies).

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- Telemonitoring: an interaction between a doctor and a patient, in which medical information is transmitted electronically from the patient to the doctor, who analyses it and monitors relevant medical information (e.g. blood pressure and blood sugar level, among others);
- Teleconsultation: an interaction in which a patient seeks medical advice directly from a doctor using any form of telecommunication, including the internet; and
- Interaction between two doctors: one that is with the patient and another, with special knowledge in a particular area, who assists the former.

Another concept is teleintervention, which consists in performing medical examinations (or even surgery) remotely. With the advent of 5G and the potential it brings, this is an area with great potential for growth, which, in the short term, will certainly change how we see medicine.

The concept of e-health is broader and covers every type of digital service to improve the health promotion, education and management, for example, websites providing information, electronic databases, issuing prescriptions electronically.

Telemedicine is not a recent phenomenon in Portugal. The first experiences date back to the year 1998 and, since 2001, four working groups have been created to study and implement telemedicine in Portugal.

More recently, to strengthen the national strategy to promote telemedicine and the use of ICTs in healthcare, the National Centre for Telehealth (“CNTS”) was set up in 2016 (this concept is not restricted to medical activity and includes all health professionals). The CNTS is integrated into SPMS - Shared Services of the Ministry of Health, EPE (“SPMS”).

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In turn, Decree-Law 69/2017 of 16 June broadened the range of services provided by the former National Health Service Helpline (“Health Line 24”). Its name was changed to the National Health Service Contact Centre (“SNS 24”) and responsibility for it was transferred from the Directorate-General of Health to the SPMS, based on the specific roles of those two bodies.

When it comes to the applicable law, this area is still lacking in regulation.

Under DGS Standard 010/2015 of 15 June, under the heading “Telemedicine; teleconsultation”, addressed to the institutions of the National Health Service, teleconsultations can be scheduled or urgent. Furthermore, patients involved in these consultations must be aware and give their informed consent in writing.

In these consultations, the following electronic records are required: (i) identification of institutions providing the consultation; (ii) identification of professionals involved; (iii) identification and details of the user; (iv) identification of the date and time of the start and definitive closure of the teleconsultation; (v) type of the teleconsultation (scheduled/urgent); (vi) identification of specialisation/skill; (vii) reason for the teleconsultation; (viii) notes/clinical data; (ix) diagnosis; (x) clinical/therapeutic decision; (xi) relevant data of complementary means of diagnosis and therapy (“MCDT”); (xii) identification of the episodes (origin, destination and on time consultation - “CTH”); and (xiii) report file”.

2. Some current telemedicine challenges in a time of pandemic

2.1. Information society services

Telemedicine services are “information society services” within the meaning of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000.

In fact, they are subject to the Legal Framework of E-commerce (“RJCE”), approved by Decree-Law 7/2004 of 7 January, which implemented that Directive into Portuguese law.

In fact:

- The providers of these services established in Portugal are fully subject to the Portuguese law on to their activity, even in relation to services provided in another country of the European Union;

- Service providers must have permanently available online in a way that allows easy and direct access, full identification details that include: (i) the name or trading name; (ii) the geographic address at which it is established and the e-mail address, in terms that enable direct communication; (iii) registrations of the provider in public registers and their registration numbers; and (iv) tax identification number; and
- As we are dealing with regulated professions, it is also necessary to indicate the professional title and the Member State in which it was granted, the professional body where the provider is registered, and the professional rules that regulate access to and engagement in the profession in question.

In this context, it is also important to draw attention to the Code of Ethics of the Portuguese Medical Association (“CDOM”), approved by Medical Ethics Regulation 707/2016 of 21 July, which devotes four articles specifically to this matter.

2.2. The doctor-patient relationship?

Under article 46 of the CDOM, under the heading “Doctor-patient relationship”:

- Telemedicine must respect the doctor-patient relationship and maintain mutual trust, the independence of the doctor’s opinion, the patient’s autonomy, and confidentiality;
- When the patient requests or submits to a telemedicine consultation, this should not replace the doctor-patient relationship. The consultation must be carried out in conditions as close as possible to those of a face-to-face consultation, and it should only be given when the doctor has a clear and justifiable idea of the clinical situation; and

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- Any doctor who uses telemedicine and not does not observe the patient in person must carefully evaluate the information received and can only give opinions, recommendations or make medical decisions if the quality of the information received is sufficient and relevant.

In any case, the patient’s rights must always be ensured, in particular, those laid down in the Health Law, the Hospital Statute and, where applicable, in the Charter of Rights of Access to Healthcare by Users of the National Health Service.

Article 47 of the CDOM also establishes specific rules on medical liability in the context of telemedicine. Under this article:

- Any doctor has the freedom to decide whether to refuse or use telemedicine;
- Any doctor who asks for the opinion of a colleague is responsible for processing and for the decisions and recommendations given by him or her to the patient; and
- The doctor giving the teleconsultation is not obliged to issue an opinion if he or she does not have enough knowledge or patient information to issue a reasoned opinion. However, if the doctor does issue an opinion, he or she is responsible for it (even in situations of urgency).

These rules must be read in conjunction with the rules applicable to contractual and non-contractual (tort) liability.

2.3. Health advice, recommendations and information through social networks

Finally, it is important to mention a practice that is very common nowadays, and particularly so in recent times: the provision of health advice, recommendations and information through social networks, most of the time by people who are not medical professionals.

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Very often, it is difficult to determine accurately who the author of these messages is (because they spread rapidly across social networks). Therefore, the general principle in article 485 of the Civil Code will apply to them. This principle provides that:

- As a rule, the simple advice, recommendations or information do not give rise to liability on the part of anyone who gives them, even if they are negligent;

- Exceptionally, there can be liability: (i) when the person has assumed responsibility for any damage; (ii) when there was the legal duty to give the advice, recommendation or information and the person has acted with negligence or intent to harm; and (iii) when the actions of the person amount to a punishable act.

2.4. Telemedicine and personal data

As in any other area that relies on technology, telemedicine has its risks and limitations.

The main disadvantages include:

- Possible breakdowns in communication between doctor and patient, which may lead to errors in diagnosis;
- Difficulties in obtaining informed consent as required by the CDOM. E-consent using explanatory images, graphics and videos, and reliable methods of authentication and signature may be a good solution; and
- Problems in terms of privacy, information security, and protection of personal data.

As regards the last point, it is important to remember that health data is a special category of personal data ("sensitive data"). Therefore, its processing is subject to special rules set out in article 9 of the General Data Protection Regulation ("GDPR").

Under this article, these data may only be processed (among other situations):

- If the data subject has given explicit consent to the processing of those personal data for one or more specified purposes; or

- o If the processing is required for medical diagnosis, the provision of care, health treatment, or by virtue of a contract with a health professional. Even in these cases, the data may only be processed by or under the responsibility of a professional subject to the obligation of professional secrecy or by another person also subject to an obligation of secrecy.

These rules should be read in conjunction with article 29 of the GDPR National Implementing Law. This law extends the duty of confidentiality to members of corporate bodies, employees and service providers responsible for processing. It also extends the duty to students and researchers in the area of health who have access to these data, and it draws particular attention to the need to adopt security measures appropriate to the risk that this type of processing entails. Under this same Article, the data subject must be notified of any access to their personal data, and the data controller is responsible for ensuring that a traceability and notification mechanism is made available.

Telemedicine and, in general terms, the use of distance communication in the health sector, offers many advantages and great potential. However, the rapidly developing regulatory framework raises many legal issues as it seeks to keep pace with the digital transformation we are witnessing (e.g., robotics, blockchain, and artificial intelligence) and to increase the confidence of its users (both patients and health professionals). ■

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