

The European Union Legal Framework on E-Health, Telemedicine, and Privacy

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INTRODUCTION

The practice of medicine, both in the phase of diagnosis and treatment, necessarily involves the activity of collecting and processing personal data concerning health and genetics of patients. According to the European Union's legislation, such kind of personal data is included in the scope of the patient's fundamental right to informational and communicational self-determination, where it is qualified as sensitive data, therefore deserving greater protection when compared to non-sensitive data. Indeed, personal health data relate to nuclear, inalienable and indispensable dimensions of human dignity privacy or integrity of the person concerned.

Traditionally and in the analog world, the patient rights to privacy and to health data were sufficiently guaranteed by the imposition of duties of professional secrecy on doctors and medical collaborators. In fact, since the origins of the profession, the special relationship of trust that needs to exist between patient and physician has been recognized as one of the main important dimensions of the exercise of medical professions, and the need for doctors to keep confidential any information disclosed to them is codified in the Hippocratic Oath (Whiddett, Hunter, Engelbrecht & Handy, 2007, p. 534).

However, with the growing use of information and communication technologies (ICT), especially the internet, in the practice of medicine, medical informatics and, in particular, telemedicine revealed an enlargement of the circle of people with access to the collected medical data beyond the traditional physician - patient relationship.

Although there is no specific sectorial legislation on the protection of privacy in telemedicine, the European Union has sought to differentially regulate the activity of collecting and processing clinical and health data, through (a) the Directive 95/46/EC of the European Parliament and Council, imposing special requirements for obtaining a special title for collection and treating health data and also the obligation of implementing technical security measures to prevent, among others, the access by unauthorized persons; and (b) also by the Directive 2002/58/EC of the European Parliament and of the Council, on privacy and electronic communications, where it is imposed the adoption of technical measures assuring the inviolability electronic communications.

More than a decade after the approval of the referred directives, technological developments provided the globalization of data flows, the popularization of cloud computing and easy retrieval of massive information through search engines, making it absolutely necessary to update the terms of the legal protection. Considering this necessity, in March 2014, the European Parliament approved a data protection package reinforcing privacy rights in a digital context.

The present chapter aims to expose the rationale for the protection of health data, to describe its particular vulnerability in the context of electronic communications and telemedicine in particular, and to analyze the terms of the current and the proposed European Union legal regime on the matter.

ELECTRONIC HEALTH SERVICES AND DATA PRIVACY

Telemedicine, e-health, telehealth or health telematics are terms often used as synonyms which were coined to describe the provision of healthcare and medical services at a distance. According to the World Health Organization's broad definition of telemedicine, such activities consists in 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. (1998, 10)

However, in a narrow sense, the term 'telemedicine' regards only the provision of clinical services at a distance by the use of medical information exchanged from one site to another through electronic communications regarding the improvement of a patient's clinical health status. The terms e-health and health-telematics are umbrella concepts that cover all the activities involving the provision of remote health care services, clinical or not – like the ones carried out by nurses, social workers or therapists –, tele-education for health or telematics for health services management or health research.

Although the delivery of health care services at a distance is not a new phenomenon, since in the past, in a limited way, some services could be provided by radio, by telephone or by mail, the development of ICT has dramatically increased the possibilities of the use of telemedicine and e-health, putting in evidence their benefits. With the use of ICT, it is possible to provide health care services to patients living in isolated communities and remote regions, home or abroad, to reduce waiting times in health care systems, to monitor chronically ill patients without in-person meetings, or to professionals to easily exchange clinical information without a physical reunion. Electronic health services may consist: (a) in interactive services, where patients and health professionals have real time interactions; (b) in remote monitoring, where physicians are enabled to remotely monitor their patients through the exchange of network-monitoring data; (c) in storing and forwarding data such as diagnostic images or videos with patient data for later evaluation offline.

Regardless the type of e-health or telemedicine, acquiring, recording and transmitting patient's clinical data are their core technological activities.

As it is recognized by the Commission of the European Communities (2008),

privacy and security related aspects are also major components of building trust and confidence in telemedicine systems. The respect of rights and fundamental freedoms, like the fundamental rights to private life and to the protection of personal data, must be guaranteed during the collection and processing of personal data, in particular when relating to health. As any other transmission of personal health-related data, telemedicine can pose a risk to data protection right (in the sense that disclosure of a medical condition or diagnosis could adversely affect an individual's personal and professional life). Data privacy aspects should be systematically assessed whenever telemedicine services are provided.

Maintaining the secrecy of the data is no longer a burden only of the physician or of other clinical professional, but also of all the persons that, in the data network, beyond the relationship clinical professional-patient, directly or indirectly contact with such data, transmitting it, receiving it, assuring its integrity or preventing unauthorized access.

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