Health Policy and Technology 000 (2018) 1–6

Contents lists available at ScienceDirect

Health Policy and Technology

journal homepage: www.elsevier.com/locate/hlpt

Telemedicine in daily practice: Addressing legal challenges while waiting for an EU regulatory framework

Carlo Botrugno

Research Unit on Everyday Bioethics and Ethics of Science (RUEBES), L'Altro Diritto Interuniversity Research Centre, Department of Legal Sciences, University of Florence, 35, Via delle Pandette, Firenze 50127, Italy

ARTICLE INFO

Article history:
Available online xxx

Keywords:
Telemedicine
E-health
Information and communication technologies
EU policy
Technological innovation in healthcare
ICTs

ABSTRACT

Telemedicine is revolutionising conventional healthcare thanks to countless technological devices that allow patients to remotely access a huge range of care services. In the coming years, the spread of telemedicine will arguably redesign the geography of EU healthcare, with main repercussions on the organisation of the Member States' health systems and the extent of health protection in the EU. Given the current lack of an EU regulatory framework for telemedicine, this analysis aims to explore the most relevant acts issued in the field of (conventional) healthcare in order to assess their suitability for telemedicine services. In the conclusion, the need for an adequate regulatory framework of telemedicine in the EU will be discussed, in order to sustain its spread in daily practice and to guide patients and healthcare professionals towards a safe use of these innovative services.

Introduction

Healthcare can be considered as the maintenance or improvement of an individual's health via the prevention, diagnosis, or treatment of disease, illness, injury or other physical or mental impairments. Healthcare services are conventionally delivered by licensed professionals who interact face-to-face with their patients in likewise conventional places such as hospital wards or physicians' rooms. Nonetheless, over the last few decades, a radically new means of delivering healthcare services has shown up under the term "telemedicine". Telemedicine comes from the intersection of telematics and medicine, and nowadays encompasses a huge series of services delivered via Information and Communication Technologies (ICTs). Telemedicine has made its first appearance in the 1960s with a series of experiments aimed at assessing the feasibility of remote connections and data transmission between major hospitals and peripheral sites [1]. Throughout the 1990s, technological advancements contributed to the emergence of remote services and applications [2], and telemedicine started to be seen as a fundamental means to deal with some of the major problems affecting contemporary health systems (such as rising costs, accessibility, and quality of care services) [3,4]. Furthermore, in the last decade, reported progress in the miniaturisation of technological devices and the availability of wireless networks have enabled the design of ICT-mediated care services that patients may directly use from their own homes. While these services are revolutionising conventional healthcare practice, their spread entails addressing new ethical and legal questions [5,6] The radical novelty of telemedicine is such that it is showing the inadequacy of the available regulatory framework – i.e. provisions issued for conventional healthcare services. Furthermore, telemedicine boasts an intrinsic vocation to overcoming territorial barriers, including national borders. Thus, we may predict that in the coming years the spread of international telemedicine services will redesign the geography of healthcare, with unavoidable repercussions on the EU health systems, the organisation of which still rests upon the Member States (MSs) (Article 168, par. 7, TFEU).

The main objective of this analysis is to explore available provisions for an EU regulatory framework for telemedicine, and to assess their suitability to regulate remote care services. The analysis will focus on the most relevant acts applicable to conventional healthcare, among which includes Directive 2000/31/EC on the information society services, Regulation 2017/745/EU on medical devices, Directive 2011/24/EU on cross-border healthcare, and Regulation 2016/679/EU on data protection. As will be discussed below, the applicability of the available provisions might be hindered by the existence of a "grey area" in which telemedicine may merge with other wellbeing-targeted (albeit non-medical) ICT-mediated services. In the conclusions, the need for the EU to have an adequate regulatory framework for telemedicine in order to sustain

E-mail address: carlo.botrugno@gmail.com

https://doi.org/10.1016/j.hlpt.2018.04.003
2211-8837/

its effective spread in MS' health systems will be highlighted, coupled with the need to guide patients and healthcare professionals towards a safe use of the new technologies.

From the eHealth Strategy to the Policy for Ageing Well with ICTs: looking for a proper definition of telemedicine

Over the last years, several lexical variations have emerged beside the overarching term "telemedicine": "telecare", "telehealth", "mobile-health", and "telehomecare", among others. Although establishing delimitations in this field is not easy, for the purposes of this work it is worth trying to define which services are to be considered as telemedicine and which are not. According to the well-known definition adopted by the WHO, telemedicine shall be intended 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 interest of advancing the health of individuals and their communities" [7]. Though this definition seems to be complete in itself, it shall be integrated with a relevant specification provided by the Communication of the European Commission (EC) 2008/689, which is exclusively dedicated to telemedicine. This Communication established a useful criterion for distinguishing telemedicine from any other use of ICTs in healthcare: "Telemedicine encompasses a wide variety of services […] teleradiology, telepathology, teledermatology, teleconsultation, telemonitoring, telesurgery and teleophthalmology. Other potential services include call centres/online information centres for patients, remote consultation/e-visits or videoconferences between health professionals. Health information portals, electronic health record systems, electronic transmission of prescriptions or referrals (e-prescription, e-referrals) are not regarded as telemedicine services for the purpose of this Communication" [8]. Following this rationale, telemedicine is mostly intended as an alternative way to exercise medical practice, thus always presuming that a licensed physician is on the other side of the device. Both telemedicine and other ICT uses in healthcare belong to the wider sphere of "eHealth", which stands for "electronic health". eHealth has been the object of a long-lasting strategy launched by the EC in 2004 with the "eHealth Action Plan" [9]. This was conceived as a means to: (i) support EU health systems in dealing with chronic-degenerative diseases; (ii) foster the mobility of EU patients; and (iii) take advantage of the economic opportunities associated to the spread of ICTs in healthcare. The EC's commitment to the promotion of eHealth solutions has continued throughout the past decade, with the establishment of a "European Digital Agenda". This included, among other things, the objective of promoting the spread of telemedicine in the EU health systems before 2020 [10].

In 2012, the European Commission launched a new eHealth Action Plan [11] with the ultimate purpose of removing the major obstacles encountered in the implementation of ICTs in routine healthcare. More recently, the eHealth strategy has been incorporated into the "EU Policy for Ageing Well with ICTs", which is a specific programme adopted within the more general framework of the Digital Single Market. According to this programme, the ICTs would enable EU health systems to achieve a "triple win", namely: (i) improving the quality of healthcare services, (ii) supporting the sustainability and the efficiency of the EU health and social care systems, and (iii) enhancing the competitiveness of EU industries through the opening of new markets and businesses [12,13].

Distinguishing telemedicine within the jungle of mHealth applications

Distinguishing telemedicine from any other ICT use in healthcare has become even more complicated with the emergence of "mobile health" (briefly "mHealth"), which has generated a grey area in which telemedicine is merged with other non-medical ICT-mediated services. In 2014, the European Commission published a Green Paper in which mHealth was defined as a "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" [14]. Thanks to the accessibility of portable devices and miniaturised sensors, nowadays mHealth offers the possibility of remotely monitoring body parameters such as weight, blood pressure, heart frequency, and glycaemic levels. According to the Green Paper, mHealth will assume a significant role in the transformation of contemporary health systems, ensuring better quality and greater accessibility to healthcare services, whilst reducing overall expenditures. Considering the quality of healthcare, mHealth would therefore "contribute to the empowerment of patients as they could manage their health more actively, living more independent lives in their own home environment thanks to self-assessment or remote monitoring solutions and monitoring of environmental factors such as changes in air quality that might influence medical conditions" [14]. With regard to expected savings using mHealth, the Green Paper estimates a saving of 99 billion euros per year for EU health systems [14]. According to recent estimates, in 2013, more than 97 000 mHealth apps have been found as available to download [15], and by 2017, 3.4 billion people worldwide would own a smartphone and half of them would use mHealth apps [14]. As mentioned above, mHealth is thus not only the portable evolution of telemedicine, but also includes a countless series of applications designed to assist users in lifestyle control and wellness practices. The spread of these applications may overturn conventional healthcare practice and contribute to "blurring the distinction between the traditional provision of clinical care and self-administration of care and wellbeing" [14]. Operating by means of algorithms, automated or semi-automated care services collect and process users' data, and the ensuing elaborations return to patients in the form of health alert or advice. However, the EU has not yet adopted criteria for distinguishing wellness apps managed in autonomy from telemedicine services administered by healthcare professionals. An attempt to do so was made with the above-mentioned EC Communication 2008/689, which requires the presence of a physician from the other side of the device in order to classify a remote service as telemedicine. Though this criterion has been often disregarded in the literature on telemedicine, mHealth solutions have also significantly developed over the last decade; this is the reason why it is necessary to resort to more recent provisions, such as those offered by the latest EU Regulation 2017/745 on medical devices, which will be discussed below.

The new EU Regulation on medical devices

The newly issued Regulation 2017/745 on medical devices has repealed former provisions of Directive 93/42/EEC and provided a very detailed framework, including 123 articles and 17 technical annexes. It states that a medical device is "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; providing

Please cite this article as: C. Botrugno, Telemedicine in daily practice: Addressing legal challenges while waiting for an EU regulatory framework, Health Policy and Technology (2018), https://doi.org/10.1016/j.hlpt.2018.04.003