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Trusting telemedicine: A discussion on risks, safety, legal implications and liability of involved stakeholders

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ABSTRACT

Objectives: The main purpose of the article is to raise awareness among all the involved stakeholders about the risks and legal implications connected to the development and use of modern telemedicine systems. Particular focus is given to the class of "active" telemedicine systems, that imply a real-world, non-mediated, interaction with the final user. A secondary objective is to give an overview of the European legal framework that applies to these systems, in the effort to avoid defensive medicine practices and fears, which might be a barrier to their broader adoption.

Methods: We leverage on the experience gained during two international telemedicine projects, namely MobiGuide (pilot studies conducted in Spain and Italy) and AP@home (clinical trials enrolled patients in Italy, France, the Netherlands, United Kingdom, Austria and Germany), whose development our group has significantly contributed to in the last 4 years, to create a map of the potential criticalities of active telemedicine systems and comment upon the legal framework that applies to them. Two workshops have been organized in December 2015 and March 2016 where the topic has been discussed in round tables with system developers, researchers, physicians, nurses, legal experts, healthcare economists and administrators.

Results: We identified 8 features that generate relevant risks from our example use cases. These features generalize to a broad set of telemedicine applications, and suggest insights on possible risk mitigation strategies. We also discuss the relevant European legal framework that regulate this class of systems, providing pointers to specific norms and highlighting possible liability profiles for involved stakeholders.

Conclusions: Patients are more and more willing to adopt telemedicine systems to improve home care and day-by-day self-management. An essential step towards a broader adoption of these systems consists in increasing their compliance with existing regulations and better defining responsibilities for all the involved stakeholders.

1. Introduction

Over the years a number of different definitions of telemedicine have been proposed [1], but almost all of them share the key elements identified by the American Telemedicine Association: Telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status [2]. This broad definition focuses on the exchange of a specific type of information (health-related), on the means of communication used (electronic) and on the overall goal (improve health status) rather than being very specific about technical details. As a result, telemedicine applications are pretty diverse in terms of specific purposes and implementation. Norris [3] identified 4 main areas where a relevant number of telemedicine applications have focused. These consist in teleconsultation, tele-education, telesurgery and telemonitoring. However, in recent years, telemonitoring systems evolved beyond the simple remote monitoring functionalities empowering active, non-mediated, interactions with the patients. We will refer to these systems as "active" telemedicine systems in the following of the article. Some systems, after physicians have properly set them up, may suggest the patient to perform actions in response to certain events (e.g. take a certain medication if you're experiencing a specific symptom) while others push the automation further beyond and implement a closed loop control of a clinical variable to keep it in a safe range (e.g. blood glucose for

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diabetic patients, controlled using insulin). With the exception of telesurgery, which immediately raised ethical and legal concerns due to its strict connection to risky surgical procedures [4,5], this new generation of active telemedicine systems comprises the systems that more than others pose relevant challenges regarding liability and legal issues due to the risks associated with their development and use.

1.1. Background and related work

Discussion on the legal and ethical implications of remotely exercised medicine started even before specifically designed telemedicine systems were developed. The first applications that involved consultation of a doctor who was not physically present, even using the simplest forms of communication such as telephone or email, already raised concerns about the modification of the doctor-patient relationship [6] and legal jurisdiction to apply in the case of litigation [7]. In the last 10–15 years, telemedicine has become more pervasive and debate about its legal and security implications has arisen in the communities of several clinical domains including telepathology [8], teleradiology [9], chronic diseases management [10,11] and even in the less common application of telepsychiatry [12]. Recently, the growing development of mHealth significantly improved the diffusion of telemedicine. According to the mHealth definition, provided by the World Health Organization (http://www.who.int), mobile devices, such as smartphones, wearable devices or personal digital assistants, are the new way to support the medical and public health practice [13]. As a matter of fact, their rapid expansion definitely reduced technological barriers and costs for the development of telemedicine applications, where the central hub is more often going to be the Smartphone.

The sheer number of available medical or health-related apps have raised debates involving legal implications and security requirements [14,15], highlighting the low level of maturity of this area. The lack of a standard guideline or an official harmonized regulation for mobile apps development and deployment leaves to the developers the overall responsibility concerning safety and quality. Even though both users and developers are getting more aware of this issue, Martinez-Perez et al. [16] highlighted that the current regulations in USA and Europe are still not up to date with latest technology and thus difficult to follow.

A review article by Broens et al. [17] highlighted legislation and policy as one of the five main determinants for successful telemedicine adoption and a similar result was obtained in the analysis of the Information Technology Supplement to the American Hospital Association's 2012 annual survey [18]. As a further testimony to the criticality of the topic, in recent years, centers dedicated to the relationship between ethics, legislation, risk and telemedicine have been established both in Europe and USA [19,20]. Already in 2000 Stanberry [21] pointed out how telemedicine has the potential to create new clinical risks and responsibilities, highlighting the need for better education and guidance for medical professionals about the practical and professional issues that may arise. A risk assessment model for mHealth has been discussed by Lewis and colleagues in a recent paper [22]. The authors suggest classifying mobile medical apps depending on three main dimensions: probability and severity of the potential harm, complexity of the system, and presence of contextual factors that may cause further risks. The proposed model is however directed only to the risk assessment phase and does not provide insights on specific mitigation strategies or details about the relevant regulatory issues and legislation. On the other hand an interesting recent work by Garell et al. [23] proposed a legal framework, in the context of European legislation, to support designers in the development and assessment of digital health services. However, the study addressed the rather broad scope of digital health services at large, thus not focusing on telemedicine application and their peculiarities (e.g. the presence of a set of devices operated directly by patients, dependency from mobile connectivity, etc.). Moreover, the proposed framework is mostly directed to system developers, leaving other stakeholders' perspectives out of scope.

1.2. Motivation and objectives

Modern telemedicine systems involve a wide range of stakeholders, each caring about their own responsibility. Despite the most important role is often attributed to system designers and developers [23] also physicians can be held responsible for malpractice [24] connected to the use of telemedicine. Furthermore also other healthcare professionals like nurses have their responsibilities and workflows changed by the presence of telemedicine [25,26]. The central role of nurses becomes significant especially in telemedicine systems adopted in the homecare settings, where patients have to be introduced to the use of new technology and empowered to perform self-management. Moreover, nurses are often responsible for the daily patients control through the use of remote monitoring systems [27]. Also pharmacists are increasingly acquiring a front-line role in many public health initiatives involving uncomplicated conditions [28,29], with the possibility of being supported by teleconsultation when needed. Finally a frequently overlooked but ethically and legally crucial fact is that home telehealth turns patients (and their significant others) into active co-participants in the delivery of health care [30].

All those issues have been repeatedly tackled over time by the researchers at the Laboratory of Biomedical Informatics of the University of Pavia, which has a long standing record of designing and implementing telemedicine systems. The group started with the remote monitoring of diabetes patients operating through modems over land lines across the turn of the century [31], then moved to using the web [32] and finally switched to mobile applications [33] following the technology evolution. Other experiences have also addressed designing systems for educating patients and improving their compliance to treatments through reminders and notification [34] or even supporting the use of standard protocols by paramedics [35]. More recently, we have been involved in the design and implementation of two major projects, namely MobiGuide and AP@home, funded by the European Union within the 7th Framework Programme; both projects comprised a telemedicine component. We leverage on the problems and perspectives raised by these projects to create a map of the potential criticalities of active telemedicine systems, and provide some insights into the European legal framework that is relevant for them.

The purpose of this article is thus to raise awareness among all the involved stakeholders and avoid defensive medicine practices and fears that might be a barrier to broader adoption in clinical practice of these otherwise very promising systems. We decided to leave issues regarding privacy and confidentiality of health data out of the scope of the present article, which instead primarily focuses on medical liability and on potential risks of harming patients.

2. Methods

We organized two workshops in Pavia in December 2015 and March 2016 where the theme of the potential criticalities of active telemedicine systems has been discussed in a round table with system developers, researchers, physicians, nurses, legal experts, healthcare economists and administrators. As already mentioned, we leveraged on the two European projects MobiGuide and AP@home to trigger the discussion and identify the main features and associated risks of active telemedicine systems. In the following we briefly present an overview of the two systems, namely MobiGuide and AP@home while in the results section we present a detailed list of identified critical points along with some mitigation strategies. Finally, in discussion section we provide insights on the most relevant European regulations that constitute the legal framework for the development and safe usage of active telemedicine applications.

2.1. Mobiguide

The MobiGuide project (www.mobiguide-project.eu) developed a