

Legal & Clinical Risk Assessment Guidelines in Emerging m-Health Systems

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Abstract— Recognising the growing importance of mobile health for providing medical services and improving the quality of life and the right of patients to quality care, this paper presents a guidance on how legal and clinical risk should be addressed and managed when medical practice involves the use of mobile-health systems. To this end, we investigate clinical and legal risks that may result from the application of mobile health systems, looking (a) into the behaviour of healthcare practitioners in the mobile setting, (b) into the management of supporting medical information and data and (c) the effect of the operating environment (context). The objective is to assist those that are involved, use or manage mobile-health systems in exploiting the capabilities of such systems, and in identifying and overcoming their limitations in an operational setting.

INTRODUCTION

IN the recent years, there is a shift in medical services from desktop platforms to wireless and mobile systems. Mobile computing, supported by broadband wireless and terrestrial networks, already allows users to have information and communication outside their homes and workplaces when they are on the move, staying “optimally connected anywhere, anytime”.^{1,2,3,4} This has a significant impact on healthcare delivery, allowing for the provision of health services at distant points of care or even on the move, and by this way making services to patients more flexible and convenient.

Nonetheless, with clinicians free to roam and to utilise

different access devices, new problems arise, mainly due to the inherent risks and limitations of the mobile environment and the need for healthcare practitioners to adopt it as part of their working space. The advent of mobile health (m-health) is causing healthcare to abolish some of its last remaining boundaries, as telemedicine relied mainly on fixed point connectivity, being referred to as “the use of medical information exchanged from one site to another via electronic communication and information technologies to provide medical care at a distance and improve patient care”.

The new paradigm for healthcare delivery calls for global wireless healthcare connectivity to enable the seamless mobility of healthcare practitioners and/or patients. M-health can be defined as the application of emerging mobile communications and network technologies for healthcare systems [1], which involves the use of mobile computing, medical sensor, and communications technologies for healthcare. This represents the evolution of e-health systems from traditional desktop “telemedicine” platforms and applications to wireless and mobile configurations.

M-health enables both the patient and the medical practitioner to be spatially unbound. Indeed, mobile communication technologies help place at the service of clinicians the tools and applications needed to work, either remotely or on the move. Equipped with PDAs, mobile phones etc, clinicians can collect critical supporting information (e.g. patient records, reference material, etc) or communicate with medical experts from wherever they are. Coupled with the advances in the research and development of portable medical devices, especially sensing and diagnostic means (e.g. vital sign monitoring, auscultation and endoscopic devices etc), any remote place can potentially be transformed into a point-of-care. This facilitates new forms of healthcare, such as homecare, emergency care. Moreover m-health also allows for the consumer of medical services (patients or healthy people under medical supervision) to be on the move. The recipient of care and the attending medical practitioner can be at a distance from each other, either in direct contact (e.g. a case of remote consultation) or following an alarming medical reading taken by means of remote sensing devices (e.g. a case of remote monitoring). This facilitates the real-time health-monitoring of chronically ill (e.g. cases of as diabetes, asthma, and respiratory and cardiovascular disorders) or vulnerable individuals (e.g. disabled and elderly people), of healthy people at risk (e.g. airline pilots).

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¹ http://www.emobility.eu.org/research_agenda.html

² <http://europa.eu.int>

³ http://europa.eu.int/comm/research/future/index_en.html

⁴ <http://www.cordis.lu/ist>

⁴ <http://www.wirelesshealthcare.co.uk/wh/news/wk22-0001.htm>

⁴ http://www.medes.fr/home_fr/telemedecine/projets/i_discare.html

⁴ <http://www.mobilalarm-eu.org/>

Emerging technologies promise to make the remote medical monitoring, consulting, and healthcare more flexible and convenient. The classical medical paradigm, which was more or less valid in the case of telemedicine, assumes a one-to-one (or more) relationship between patients and medical practitioners when making a medical diagnosis or a decision concerning therapy or prevention [3]. M-health, boosted by the advances in medical decision-making systems, is challenging this reality, envisaging a future where the consultation of a medical expert will not always be required. Nonetheless, even in this case a concrete set of procedures will be needed, backed by appropriate policy measures, so as to guarantee that all risks associated with an action recommended by the autonomous m-health system are controlled and that the health and safety of the patient are by no means jeopardised. Mobility in healthcare introduces new responsibilities for clinicians and implies the need for an “official” standard of mobile care with clear rules regarding operational procedures, responsibilities and negligence, fraud and abuse etc. In developing this framework, it is of paramount importance to take into consideration the limitations and inherent risks of information and communication infrastructures, given that, the vision of “seamless connectivity”, “ubiquitous access” etc is still far not being fully realised, despite the progress of ICT in the recent decades.

This is the setting for, the present paper, which investigates legal and clinical risks that exist when healthcare practitioners use mobile health systems for the remote exchange and delivery of medical diagnosis, consultation and information (doctor-to-doctor and doctor-to-patient). Aim of the paper is to present guidance on how these should be addressed so that m-health services are used in a consistent, responsible and clinically appropriate manner. The discussion of risks associated with the application of medical decision support or decision making systems falls beyond the scope of this paper.

I. APPROACH

The guidance contained in this paper is intended to assist those that are involved, use or manage mobile-health systems in an operational setting.

We tried to understand the legal and clinical risk management issues that may arise from the use of mobile-health systems by doctors and medical staff. Our motivation comes from the fact that there is an increase in the research and development of mobile-health systems^{5,6,7}, as also in their adoption in everyday clinical practice, subsequently generating the need to establish a solid framework of legal and risk management procedures.

Apart from a thorough study of related literature, on the

⁵ <http://www.medaship.com/>

⁶ http://www.esa.int/esaCP/ESACZSTHN6D_Benefits_0.html

⁷ www.healthservice24.com/cms/index.asp?healthservice24

basis of the present document lie information and feedback collected from the participation in international telemedicine research projects (MEDASHIP [5], EMISPHER [4] and GALENOS [6]), including the results of a qualitative survey with the participation of medical experts.

II. RISKS IN M-HEALTH.

Regardless of the means or the delivery channels employed for healthcare provision, the established standard of care needs to be attained at all times: patients have the right to quality healthcare, whether this is delivered face-to-face or by means of modern ICT technologies. In the context of m-health, three critical sources of risk in clinical praxis are identified, namely the **medical expertise** of healthcare practitioners, the availability of valid **supporting information** (clinical data, patient records, best practice information, medical literature etc) and the **context** within which the medical procedure takes place. When making a diagnosis of illness or deciding on the optimal treatment, clinicians need first to have a good overview of the case (i.e. “sufficient” information) and then to utilise their professional skills and abilities to make an accurate decision unaffected by the environment where this process takes place. In the following sections we investigate these potential sources of risk and their effect on clinical performance.

A. *Lacking skills & professional expertise (the “human factor”)*

Traditionally, being a healthcare professional entails possessing the skill and the qualification to perform a number of medical tasks. By law health professionals are required to exercise the care and skill of a reasonable professional and achieve a “standard of care”. This standard of care is that, not of the “best” or most experienced specialist, but of a reasonable specialist. Failing to reach that standard is considered negligence. In the case of technology-assisted care provision, in addition to possessing the standard medical qualifications, professionals will also be expected to have a certain degree of extra knowledge and skill that will enable them to use technology safely and effectively (e.g. the skill to operate portable medical devices, to use communication devices etc). Nonetheless, setting qualifications standards for ICT-knowledgeable healthcare professionals remains a challenge. Yet, it is commonly agreed that all healthcare workers need to be trained in the use of modern healthcare technologies and be aware of the technical limitations that such systems place upon their work. Whenever healthcare professionals make a clinical judgment by means of such systems, they must be satisfied that they have sufficient information to form such a judgment and that the information itself is of appropriate quality and reliability.

B. Supporting information & expert knowledge

The management of information emerges as an important challenge. Key to the successful implementation of m-health is to make available the right information at the right place, at the right time and in the correct form. With medical practitioners and patients free to roam and to utilise different access devices (in terms of both display and processing capabilities and of communication characteristics), new problems arise regarding the delivery of information, from a variety of sources and in a multitude of formats (ranging from plain messages to multimedia content) in a secure and reliable way. Critical to the successful handling of supporting information are monitoring devices, healthcare databases, communication networks and access devices.

1) Communication networks

The variety and complexity of m-health application scenarios calls for the combined use of wireless technologies (both short- and wide-range), wired communication backbones and the Internet in a seamless, secure and reliable way. The employed wireless technologies include Bluetooth, wLAN, WiFi, GSM/GPRS, UMTS and satellite communications (VSAT, DVB-RCS). The difficulty of achieving operational compatibility between the telecommunication services, terminals and devices continues to be a challenge for m-health applications.

Although high-speed digital communication infrastructures are gradually gaining ground, it is often the case that the regions that would benefit the most from electronically delivered healthcare are mostly underserved in terms of telecommunication capabilities. High speed communication networks are still far from being a reality in many remote rural areas in Europe. This limits the options for telemedicine and the involved medical staff, as many services can only function well under specific conditions, in terms of communication capabilities. Many telehealth applications rely on high-speed broadband IP networks to deliver a high quality, timely and converged voice, video, and data.

2) Access devices

M-health employs a multitude of both wired and wireless access devices, e.g. portable PCs, cellular phones, Personal Digital Assistants (PDAs) etc. Each one of these appliances has its own limitations in terms of screen size, processor power, memory, and bandwidth, battery life etc. Depending on these characteristics the service capabilities of the device are conditioned.

Clinicians should be particularly aware of the limitations of the access devices employed, what amount of information they can provide and how well they can display it. One important aspect to this, are the limitations of screen sizes and digital imaging technologies in some highly visual telemedicine applications, such as teleradiology, teledermatology and telepathology. The technologies

currently available provide excellent pixel density and resolution with a high rate of diagnostic agreement demonstrated in the scientific literature between digital and real images.

There is clinical risk of a wrong or missed diagnosis being made on the basis of a digital image which is of insufficient detail or contains too little clinical information or because of the alteration or corruption of an image due to technical reasons (e.g. the limitations of the store-and-forward approach adopted). Clinician called to make a diagnosis, should be aware of this underlying risk. [2].

To the benefit of telemedicine and m-health is the definition of a medical information transmission protocol (DICOM - Digital Image Communication) and its growing adoption by medical equipment manufacturers.

3) Monitoring devices

Nowadays a lot of effort is being placed on the development of portable and networked devices for the measurement and monitoring of patient vital-signs. With the help of pervasive and wearable technologies, critical health statistics of the patient can be measured, stored and transmitted to a database during daily routines, emergencies, hospital stays or the treatment of chronic illnesses. Wireless Body Area Networks (WBAN) represent an important step in the evolution of monitoring devices. They consist of lightweight and small size sensor platforms that allow for the continuous monitoring of multiple parameters in ambulatory settings.

4) Unification of information sources

Ideally, the entire medical profile of a patient (medical history, results of laboratory testing etc) should be retrievable at the point-of-care at the touch of a button. Yet, the decentralised multi-actor nature of healthcare and the wide distribution of relevant data sources has produced a patchwork of diverse and heterogeneous, in terms of content, database implementations, that makes access to and retrieval of data from repositories a challenging area. Consequently one of the major challenges for mobile health applications is the integration and exploitation of heterogeneous scientific information databases in a seamless way, so as to enable the storage, updating, search and retrieval of useful information.

The effective employment and exploitation of structured information requires a cross mapping and standardisation of the different coding schemes and medical terminologies used in the healthcare sector. Semantic representations can help the process of converting data into different formats, thus helping to understand and effectively analyse this information.

Furthermore, in many cases the access to medical information or the exchange of data among healthcare providers is hindered due to the non-interoperability of the different information systems in place, calling for the adoption of common standards or the development of communication interfaces.

Table I. summarises critical issues related to the mobile care provision. The aforementioned factors that are potential sources of risk for

TABLE I
RISKS ASSOCIATED WITH THE PROVISION OF SUPPORTING INFORMATION IN M-HEALTH ENVIRONMENTS

Factor	Description	Critical issues
monitoring devices	On location measurement and monitoring of vital-signs of the patient (portable devices, pervasive and wearable technologies)	<ul style="list-style-type: none"> - Reliability of measurement - product liability - configuration: setting levels of alert
information sources	<ul style="list-style-type: none"> - Patient related information : medical profile, results of clinical examination etc (health records) - medical literature - pharmaceutical information etc 	Storage, updating, search and retrieval of useful information is hindered by the lack of unification of information sources: <ul style="list-style-type: none"> - multiple and geographically dispersed repositories - heterogeneous data (in terms of format, coding scheme etc) - non-interoperable information systems
communication networks & access devices	Enabling access to information and remote collaboration among healthcare practitioners. Prerequisites: <ul style="list-style-type: none"> - Seamless integration of underlying communication infrastructures. - End-to-end secure and reliable communication. 	Service capabilities conditioned by: <ul style="list-style-type: none"> - the existence of underserved in terms telecommunication capabilities regions - the inherent differences of communication technologies (transmission rates, on-demand linkage or permanent connection etc) - the limitations of the access devices (screen size, processor power, memory, and bandwidth, battery life etc)

A. Operational context

Scholars have predicted that the future will be ‘mobile’ and that we will use our mobile devices anytime anywhere, being always online. “Mobility” has already become a trend in telecommunications, with people using mobile communication appliances in a variety of settings, e.g. walking down a high street someone can notice numerous people using mobile telephones, PDA’s etc. This interaction with the physical environment is often overlooked in studies regarding the application and usage of technology [8], [9].

The present investigation demonstrated that the context of service delivery (i.e. the special conditions that exist at the point-of-care) is a variable that has to be taken into account when examining the quality of a medical service. For example, there is a difference between medical examinations that take place in a hospital, onboard a ship or in an airplane. Following these concerns, medical activities that take place in remote areas or in mobility situations have to report of mistakes and problems effecting patient safety, regarding the physical environment, the convenience and accessibility of services and the appropriateness and timeliness of the whole episode of care.

Therefore the environment in which a healthcare service is going to be delivered could affect its performance and for this reason should be taken into consideration when designing or managing the service.

III. DISCUSSION: GUARANTEEING QUALITY AND CONTROLLING RISK

Quality should be at the heart of all telemedicine health systems, whether mobile or not, in order to guarantee a high level of care for patients. Due the complexity of the operating environment, a strong risk management and quality assurance system is required, when designing an m-health service.

This should ensure that there are:

- Concrete **action lines** and **response procedures** for the provision of care over networked environments,
- clear lines of **responsibility** and **accountability** for the overall quality of clinical care,
- comprehensive programs of **quality improvement** activities,
- clear policies aimed at **monitoring performance**
- clear procedures for **identifying** and **managing risks**, to which the patient could be exposed,
- procedures for all professional groups to identify and **remedy poor performance**,
- accurate and sufficiently detailed **clinical records** of all m-health activities, to document cases of “good conduct” or “negligence”.

A framework highlighting the most important aspects that should be taken into consideration, when aiming for quality healthcare delivery remotely or on the move, is

illustrated in Figure 1.

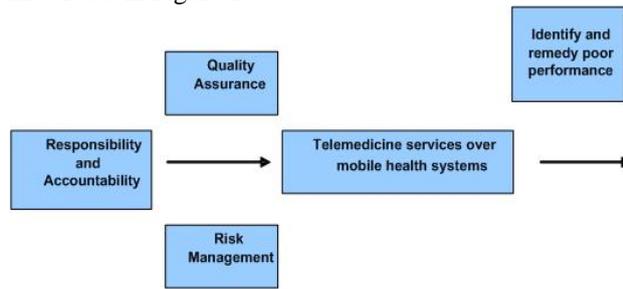


Figure 1: Proposed good practice framework for mobile-health systems

Another important issue that permeates all m-health services is **security** and **confidentiality**. The complex, sensitive and critical nature of healthcare introduces serious security considerations. Mechanisms, policies and procedures are necessary to protect data confidentiality and integrity in each and every phase of the information management process: storage and updating, search and retrieval etc. Access rights to patient records and other private information should be strictly regulated and different healthcare professionals (general practitioners, specialists, care team, pharmacy) should have controlled access to this information and the safe transmission of personal data should be ensured [7]. Provisions should be made for guaranteeing security of electronically transmitted information (protection of the data exchanged over the network, authentication of remote users etc).

To this end, of particular importance is the creation of standardised Electronic Health Records (EHRs) to record in a commonly agreed way data referring to the patient's medical state and history, so as to enable the easy communication of patient information between service providers and/or applications. Any use that may be made of any electronic medical record or any other personally identifiable health information about individuals should have the fully informed consent of patients, who should also have the right to know if such information exists and to review.

One of the most important directions for future research is to tie research into studying the assessments that proposed here. For example, little to no research has addressed the link between quality of medical service and context this takes place.

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REFERENCES

- [1] Istepanian, Robert, Laxminarayan, Swamy, Pattichis, Constantinos S."M-Health: Emerging Mobile Health Systems, Springer-Verlag New York Inc., 2005
- [2] A. Wilson, F. Mann, W. Murphy et al. Diagnostic efficacy of digitized images versus plain films: a study of the joints of the fingers, *Am. J. Radiol.* 158 (1992) 437-441;
- [3] A, M. Skulimowski, The Challenges to the Medical Decision Making System posed by mHealth, IPTS Report, Issue 81, February 2004
- [4] EMISPHER - Euro-Mediterranean Internet-Satellite Platform for Health, medical Education and Research, Project Number : EUMEDIS 110 Project
- [5] MEDASHIP - MEDICAL ASSISTANCE FOR SHIPS, e-Ten Contract n° C27271
- [6] GALENOS - Generic Advanced Low-cost trans-European Network Over Satellite, Contract Number: TEN 45592 (FS)
- [7] General Medical Council. Confidentiality — guidance from the General Medical Council. London: GMC, 1995.
- [8] Davis, F. D. 1989a. Perceived Usefulness, Perceived Ease of Use and User Acceptance of Information Technology. *MIS Quarterly*, 13(3 (September)): 319-340
- [9] Venkatesh, V. & Davis, F. D. 1996. A Model of the Antecedents of Perceived Ease of Use: Development and Test. *Decision Sciences*, 27(3 (Summer)): 451-481.