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Challenges facing teleradiology services across borders in the European union: A qualitative study

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Abstract
Rationale: This paper aims to identify factors that support or impede the introduction and expansion of teleradiology across borders in the European Union (EU), focusing on both those factors acting within countries and those that are specifically cross-border as well as discussing how the current EU legislation impacts on the provision of this type of services.
Methods: A qualitative study was developed to explore the issues that arise when implementing teleradiology services across European borders. A total of 12 semi-structured interviews with key actors were conducted, recorded and fully transcribed. These were analysed using thematic analysis.
Results: The factors supporting provision of new services in teleradiology were increasing demand for reading images in countries with few radiologists; long waiting lists for MRI reading; and new demand for second and sub-specialized reading of images. The obstacles to the introduction and expansion of teleradiology services included uncertainty about liability in case of malpractice, registration of health care professionals, data security, non-standard contracts and quality reporting systems; and health care system and cultural differences. Radiologists identified as positive experiences the chance to learn and improve their skills in a shorter period of time, having flexibility, and sharing knowledge in a network environment. The most frequently reported negative aspect was the inability to interact with referring clinicians. Language barriers were not identified as a constraint. When asked about policy implications and potential recommendations, participants proposed the introduction of EU wide policies on radiologists' credentials; greater clarity within the EU on data access and sharing; and minimum quality requirements for teleradiology providers.
Conclusion: Teleradiology services face several challenges; most can be overcome if those engaging in this type of collaborations are eager to make it a success. However, it would be beneficial to have a transparent European legal framework that clarifies issues related to the registration and licensing of healthcare professionals; clarifies arrangements for data sharing

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and protection; and specifies liability and means of access to redress. Once this legal framework is in place it should be communicated to regulators, health care professionals and patients in a clear way so that it cannot be undermined or ignored and it truly promotes services of good quality which are beneficial to European citizens.

Introduction

The European regulatory landscape for telemedicine is cumbersome. The European Commission considers telemedicine both a health service and a social information service [1]. As a result, the legal framework involves several directives, which makes the interpretation of the legal environment even more complex. It is further complicated by other sector specific initiatives driven by different European Commission Directorates-General, specifically Health & Consumers, Information Society and Media, and Internal Market and Services [2].

Some clarity was provided by Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, which ruled that, in the case of telemedicine across borders, the Member State responsible is the one where the healthcare provider is established [3]. This is consistent with Internal Market provisions, specifically the EU Electronic Commerce Directive, adopted in 2000, whereby information society services are also, in principle, subject to the law of the Member State in which the service provider is established. Consequently, there is no ambiguity about the nationality of the laws governing the provision of telemedicine [4].

The situation is less clear in relation to processing of personal data related to health, which is regulated under Directive 1995/46/EC on general data protection currently under review. The Commission is seeking to clarify the rules applicable to health-related personal data, specifying requirements relating to confidentiality and security that telemedicine and all other interactive on-line services have to meet in order to safeguard individuals' rights [5]. However, there are still some important unresolved issues, in particular in relation to the use of data for research.

The situation is even less clear in respect of regulation of professionals, for example where a radiologist is reading images in one country and the patient is being treated in another. In principle, given the legislation referred to above, it should be sufficient for the professional to be registered in the Member State in which they physically work, but there is also Directive 2005/36/EC on the recognition of professional qualifications which establishes that qualifications obtained in one Member State are recognised by another [6]. However, this is also under review, in part because of concerns that standards in different countries are not comparable, and there have been demands for physicians to seek registration in all Member States in which their patients are being treated. A further complication is liability if a problem arises, as litigation across borders is inevitably more complicated than when both parties are in the same jurisdiction and both patients and health professionals may have quite different expectations.

Despite this complex legal environment, telemedicine services are already operating in the European Union. The purpose of this paper is to understand and explore the factors that facilitate or impede the operation of such services, with a focus on teleradiology. In preparation, we conducted a systematic review of existing telemedicine initiatives across borders and synthesised the evidence on the factors that hinder or support their implementation [7]. We identified 8 papers that described teleradiology services across borders [8–15]. Four out of the eight papers were pilot studies carried out in the 1990s or early 2000s [9,11,12,14]. Most of the projects were conducted between the USA and other non-European countries [8,9,11–13] and only two were conducted within the European Union [14,15]. One European pilot study, in 1998, involved the Department of Radiology, University of Pisa, Italy and St-Luc University Hospital, Belgium, examining the use of Digital Imaging and Communication image transmission and interactive telediagnosis tools in a daily radiological practice [14]. The second study described two experiences from two partially European Union funded cross-border teleradiology projects – Baltic eHealth and R-Bay. Clinical partners from Czech Republic, Denmark, Estonia, Finland, Lithuania and the Netherlands compared their interpretations of 649 test cases in two different teleradiology projects to develop a shared understanding of diagnostic criteria and reporting systems [15].

None of the teleradiology services identified in the systematic review within Europe are still operating. Consequently, we have undertaken a qualitative study of a contemporary operation to provide much needed evidence in this area, identifying the facilitators and barriers for providing teleradiology services across borders and some of the practical solutions that can overcome any barriers.

Methods

A qualitative study was developed to identify the issues that arise when clinical information such as imaging is read in another country.

Setting

The setting was the Telemedicine Clinic (TMC) in Barcelona. It was selected as it has been established since 2004, thus ensuring adequate time to identify and address issues that might arise. It provides both general and specialist reporting and covers both elective and out of hours services. It has contracts with hospitals in several other countries, but the greatest volume of work is with hospitals in the United Kingdom and Sweden. In the United Kingdom it has provided services to more than 90 NHS Hospital Trusts. It takes advantage of time differences to provide out of hours cover