

## THE SIGNIFICANT ROLE OF LEGAL REGULATIONS AND STANDARDISATION IN THE DEVELOPMENT OF TELEMEDICINE IN THE EU

Mikołaj Maśliński

*Adam Mickiewicz University, Poland  
mikolaj.maslinski@amu.edu.pl*

### Abstract

**Purpose** – The main aim of this article is to analyze and evaluate EU policies and legislation concerning telemedicine. Therefore, the article aims to identify the legal instruments which could be implemented to guarantee the development of telemedicine among the Member States of the EU, which will take place with respect to patient welfare and interoperability of healthcare systems.

**Design/methodology/approach** – As for its methodology, this research focuses on the EU policies, legislation and a few recent initiatives that were undertaken by Poland and other EU Member States in the area of telemedicine. This research utilizes qualitative research methods. The textual analysis method has been used to examine the content and meaning of legal texts and other documents as well as their structure.

**Findings** – The phenomenon of telemedicine is an extremely complex issue. This implies that the attempt to provide health services based on such solutions requires a comprehensive approach, taking into account not only the normative material related to the healthcare but also a number of sectoral regulations relating to, for example, personal data protection and cybersecurity rules, patients' rights, or to the provisions governing electronic commerce. On the other hand, most regulations concerning directly telemedicine occur in the area of *soft law*. Due to this fact, there are significant differences in national regulations. Therefore, institutions involved in the EU legislation should focus on implementing general standards in telemedicine, which would guarantee patient welfare. Finally, the significant challenge is to provide interoperability between telemedicine solutions available around the European Union. This is a *sine qua non* condition for a greater utilization of telemedicine solutions by EU citizens.

**Research limitations/implications** – The scope of the research covers the examination of the EU policies and legislation on telemedicine. This article does not cover wide and complex research on sectoral regulations relating to, for example,

personal data protection and cybersecurity rules, patient rights, or finally to the provisions governing electronic commerce. It covers the comparative analysis of telemedicine in Poland and only general analyses concerning different countries, e.g. France or the USA.

**Practical implications** – The findings may give some reference to institutions involved in the EU legislation, especially to the European Commission. Therefore, they can be useful for improving the Member States’ legal frameworks on telemedicine.

**Originality/Value** – Contrary to the majority of papers on telemedicine, this article does not concentrate on the barriers and challenges for the successful implementation of telemedicine but focuses on solutions. What is more, this research covers the latest regulations and publications. Finally, the article presents the current Polish legislation promoting telemedicine solutions, which may prove an interesting case study for researchers from different countries.

**Keywords:** telemedicine, telehealth, teleconsultations, healthcare, eHealth, interoperability

**Research type:** research paper