

The impact of globalization and technological development on medical liability

Abstract

This paper explores the profound impact of globalization and rapid technological advancements on the evolving landscape of medical liability. It examines how increased patient mobility, cross-border healthcare, and the integration of technologies like telemedicine, artificial intelligence, and big data are reshaping the doctor-patient relationship and creating new legal and ethical challenges. The analysis delves into the complexities of jurisdiction, informed consent, data protection, and the division of responsibility in this new era of medicine. Furthermore, it discusses the need for adaptive legal frameworks, international cooperation, and continuous ethical reflection to ensure patient safety, uphold medical professional standards, and promote equitable access to healthcare in a globalized and technologically driven world.

Keywords: globalization, technology, medical liability, medical standards, healthcare

Volume 7 Issue 1 - 2024

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Received: October 01, 2024 | **Published:** October 17, 2024

Introduction

Globalization and technological development are intertwined, mutually reinforcing processes that are fundamentally reshaping the 21st-century world. Both phenomena are complex and multifaceted, and their impact extends to almost every area, influencing every aspect of life. Globalization is essentially about global interconnectedness and interdependence. This process involves the intensification of economic, social, cultural, and political ties, the blurring of borders, and the growing role of global institutions. The driving forces of globalization are free trade, capital flows, migration, and the flow of information.¹ Technological development, especially the explosive development of information and communication technologies (ICT), has accelerated and deepened globalization. The internet, mobile phones, and social media allow the rapid and efficient dissemination of information, ideas, and culture, shrinking spatial and temporal distances.²

Globalization and technological development have many positive effects. Free trade and competition boost economic growth, technological innovations improve the quality of life, and the flow of information promotes the spread of knowledge and democratic processes. At the same time, globalization and technological development also create a number of challenges. Economic globalization can lead to job losses, increased income inequality, and the exacerbation of environmental problems. Technological development is accompanied by issues of data protection, cybersecurity, and the ethics of artificial intelligence. Globalization and technological development are unstoppable processes. Instead of resisting them, our task is to understand their effects and find ways to make the most of the opportunities they offer while managing the risks they pose. This requires international cooperation, adaptation of regulation, and strengthening of social dialogue. Globalization and technological development are therefore a complex and contradictory process that simultaneously creates opportunities and challenges.

The concept of medical liability is one of the most complex and important aspects of medical practice, encompassing the physician's ethical, legal, and professional obligations to their patients, society, and their profession. This responsibility is not limited to decisions made during patient care, but extends to the whole of medicine, including research, education, and participation in the professional community.

Medical liability can be interpreted in several dimensions³:

Ethical responsibility: Medical ethics encompasses the moral principles and values of medicine that provide guidance in the doctor-patient relationship, decision-making, and professional conduct. The physician's ethical responsibility is to always keep the patient's interests in mind, respect their autonomy, and provide the best possible care. Ethical codes, such as the Hippocratic Oath, help physicians navigate ethical dilemmas and make responsible decisions.

Legal responsibility: The legal dimension of medical liability relates to the legal obligations of physicians and patient rights. Physicians must comply with relevant laws and regulations, as well as professional protocols and guidelines. Legal liability also includes liability for damages resulting from negligence, which exists if the physician fails to exercise due diligence and thereby causes harm to the patient.

Professional responsibility: The professional dimension of medical liability relates to the professional competence of physicians and continuing education. Physicians must have up-to-date knowledge in their field and continuously develop their skills and knowledge. Professional responsibility also includes participation in quality assurance, promotion of professional development, and improvement of patient safety.

Globalization and technological development pose new challenges to medical liability. Physicians must make decisions in an increasingly complex and uncertain environment, taking into account cultural differences, technological innovations, and patient expectations. The concept of medical liability is therefore constantly evolving and changing, and physicians must adapt flexibly to new challenges. This

¹<https://hold.hu/lexikon/globalizacio-jelentese-es-hatasai-a-gazdasagban/>

²<https://muszakiesinformatikaineveles.wordpress.com/5-osztaly-uj/a-kornyezet-es-munkakornyezet/a-technika-es-technologia-fogalma-szerepe-es-jelentosege/>

³<https://mok.hu/public/media/source/etikaiKodex/kodex141128.pdf>

responsibility is not only individual, but also collective. Physicians must work together with patients, other healthcare professionals, and society to ensure the best possible patient care. Medical liability is therefore the embodiment of the humanistic values of medicine and professional excellence, which places the profession of medicine at the service of society.

The explosive development of globalization and technology is a defining phenomenon of our time, which has a profound impact on all areas of life, including medicine. This impact is not only transforming medical practice, but also the very concept of medical liability, presenting healthcare professionals with new challenges and dilemmas. Therefore, the topic of my research is not only relevant, but also highly topical.

Topicality of the topic

The topicality of the topic is supported by a number of factors:

- I. Increased patient mobility:** Due to globalization, patients are increasingly using foreign healthcare services, whether it is a planned intervention or emergency care. This creates new situations in the doctor-patient relationship and raises the issue of cultural differences, language barriers, and different legal regulations.
- II. International mobility of doctors:** The free movement of doctors in different countries of the world makes it more common for doctors to work in different cultural and legal environments. This can be a challenge in applying professional rules and ethical standards.
- III. The spread of telemedicine:** Technological development enables remote patient care, which creates new opportunities in healthcare, but also raises the issue of the division of responsibility, data security, and the protection of patient rights.
- IV. The use of artificial intelligence:** Artificial intelligence is playing an increasing role in medical diagnostics and therapy. This raises the issue of the responsibility of algorithms, the need for human oversight, and ethical considerations.
- V. The development of gene therapy and biotechnology:** Gene therapy and biotechnology create new opportunities in the prevention and treatment of diseases, but also raise serious ethical and legal issues, such as the possibility of genetic discrimination and „designer babies”.

The issue of medical liability has therefore become more complex and urgent in the age of globalization and technological development. Healthcare professionals must not only be aware of traditional medical ethics and legislation, but must also be prepared for new challenges and dilemmas. The globalization of patient rights is a complex process that involves the international recognition and protection of patients' rights and interests. This process is closely linked to the general trends of globalization, such as the free movement of persons, information and services. The globalization of patient rights has many positive effects, but also creates new challenges for healthcare systems and physicians. The aim of my research is to highlight these challenges and promote social dialogue on the future of medical liability.

Main aspects of the globalization of patient rights

Due to globalization, patients are increasingly traveling abroad for healthcare. The reasons for this may be lower prices, shorter waiting times, special expertise or better quality care.

A number of international conventions and organizations deal with the protection of patient rights. The Council of Europe adopted the Convention on Human Rights and Biomedicine in 1997, which enshrines the fundamental rights of patients, such as the right to information, the right to self-determination and the right to privacy. In the European Union, the Directive on access to healthcare ensures the free movement of patients and equal access to healthcare. Physicians must be aware of the laws and cultural norms of the patient's country of origin. It is important to ensure proper communication, inform the patient about treatment options and risks, and obtain consent. Health tourism is one of the fastest growing sectors of globalization. Patients are increasingly traveling abroad for procedures such as dental treatment, plastic surgery or IVF.

Challenges of the globalization of patient rights

The issue of jurisdiction may arise in the care of foreign patients. Which country's laws govern the enforcement of patient rights? Which country's court has jurisdiction to hear claims for damages? The different cultural backgrounds of patients and physicians can make communication and mutual understanding difficult. Physicians need to be sensitive to the patient's cultural values and beliefs. Language barriers can be a serious problem in the care of foreign patients. It is important to provide adequate interpretation so that the patient understands the information about the treatment and can exercise their rights. Increased attention must be paid to patient safety when caring for foreign patients. Physicians need to be aware of the local healthcare system and ensure adequate quality of care. The globalization of patient rights is a constantly evolving process. In the future, it is expected that further international conventions and guidelines will be adopted to protect patient rights. It is important to prepare healthcare systems and physicians for new challenges, develop cultural sensitivity and enforce patient rights more effectively. The globalization of patient rights can contribute to improving the quality of healthcare and increasing patient safety around the world. One of the most striking phenomena of globalization is the increased mobility of people, including patients. People today travel abroad more easily and frequently, whether for work, tourism or healthcare. The latter, health tourism or patient mobility, has a significant impact on healthcare systems worldwide, presenting them with new challenges and opportunities.

Reasons for patient mobility

Patients may choose to seek healthcare abroad for a number of reasons. The most common reasons include, for example, that in many countries the cost of healthcare is significantly lower than in developed countries, so patients can save significant amounts of money with foreign care. In some countries, there are long waiting times for certain procedures or examinations. Foreign care allows patients to access the necessary care more quickly. Some countries or institutions have special expertise in certain diseases or interventions. Therefore, patients may travel abroad to receive care from the best specialists. Some patients believe that the quality of foreign healthcare is higher than in their own country. This may be due to technology, expertise, or more patient-centered care. Finally, patients may seek alternative therapies that are not available in their own country.

Patient mobility has a number of effects on healthcare systems

It can generate significant revenue for countries at the forefront of health tourism. However, the outflow of patients can cause losses to those countries from which patients travel. It can improve the health of patients if they have access to the necessary care. However, it can

also be risky, for example due to the spread of infections or lack of follow-up. It can contribute to the strengthening of cultural exchange and international cooperation. However, it can increase inequalities in healthcare if only the wealthy have access to foreign care. Patient mobility also raises ethical issues, such as those related to organ trafficking and exploitation, and creates new legal challenges, such as those related to jurisdiction and claims for damages. It is important to ensure that foreign patients receive quality care. Patient safety is paramount, especially in the case of foreign care. Language and cultural differences can hinder communication between patients and physicians. The protection of patient data is of paramount importance in the case of foreign care. The issue of jurisdiction may arise in the care of foreign patients. Patient mobility is expected to continue to increase in the future. Healthcare systems need to be prepared for new challenges and find ways to exploit the benefits of patient mobility while managing the risks associated with it. International cooperation and the harmonization of regulation are key to maximizing the positive effects of patient mobility.

More important international conventions and organizations in the field of patient rights

- I. European Convention on Human Rights (ECHR):** Article 8 of the ECHR protects the right to privacy, which also includes the patient's right to self-determination and the right to information. The European Court of Human Rights has made numerous decisions in defense of patient rights, for example on the issue of euthanasia and abortion.⁴
- II. Convention on Human Rights and Biomedicine (Oviedo Convention):** The Oviedo Convention, adopted in 1997, is the first binding international document dealing specifically with the protection of human rights in the field of biomedicine. The Convention enshrines the fundamental rights of patients, such as the right to information, the right to self-determination and the right to privacy.⁵
- III. World Health Organization (WHO):** The WHO has formulated a number of recommendations and guidelines regarding the protection of patient rights. The WHO emphasizes the active participation of patients in healthcare, the importance of cultural sensitivity, and the enforcement of patient rights.⁶
- IV. European Union:** The European Union has enacted a number of directives and regulations on access to healthcare and the protection of patient rights. The aim of the directives is to ensure the free movement of patients within the EU, as well as to guarantee equal access to healthcare for all.

Main elements of the globalization of patient rights

- I. Patients have the right to be fully informed about their health status, treatment options and risks.
- II. Patients have the right to freely decide about their healthcare, including accepting or refusing treatment.
- III. Patients have the right to have their health data treated confidentially.
- IV. Patients must not be discriminated against in access to healthcare.
- V. Patients have the right to claim compensation if they have suffered damage during healthcare.

⁴https://www.echr.coe.int/documents/d/echr/convention_hun

⁵<https://net.jogtar.hu/jogszabaly?docid=a0200006.tv>

⁶<https://www.who.int/standards/classifications>

Challenges of the globalization of patient rights

Healthcare systems and physicians need to be prepared for new challenges and ensure the effective enforcement of patient rights. The international protection of patient rights can contribute to improving the quality of healthcare and increasing patient safety around the world. In the age of globalization, it is becoming increasingly common for patients to seek cures for their problems outside their own country. This can have a number of advantages, such as shorter waiting times, specialist expertise or cheaper treatment. However, the care of foreign patients raises complex legal and ethical issues that healthcare professionals need to be aware of.

Legal issues

One of the most important legal issues is the determination of jurisdiction. Which country's laws govern the patient's care? If the patient suffers damage as a result of the treatment, in which country's court can he file a lawsuit? The issue of jurisdiction can be particularly complex if the patient uses online consultation or if the treatment takes place in several countries. In the case of foreign patients, proper information and obtaining consent are particularly important. The patient must understand the information about the treatment, the possible risks and the alternative treatment options. Language barriers and cultural differences can make effective communication difficult. The protection of patient health data is of paramount importance. When caring for foreign patients, doctors need to be aware of data protection rules and ensure the secure handling of data. The issue of insurance may also arise in the care of foreign patients. The patient must have adequate travel and health insurance that covers the costs of treatment and any complications.

Ethical issues

When caring for foreign patients, doctors need to take into account the patient's cultural background, values and beliefs. Cultural differences can influence the patient's decisions and attitude to treatment. The care of foreign patients raises the ethical issue of resource allocation. Is it ethically correct for foreign patients to take resources away from local patients? Foreign patients may be in a vulnerable position, so it is important to ensure that they are not exploited. Doctors have an ethical obligation to protect the interests of patients. The care of foreign patients raises complex legal and ethical issues. Healthcare professionals need to be aware of these issues and act responsibly. Protecting the rights and interests of patients, as well as cultural sensitivity and effective communication, are key to the proper care of foreign patients. International cooperation and the harmonization of regulation are essential to address the legal and ethical challenges related to the care of foreign patients.

Free movement of doctors in the EU and globally

The free movement of doctors, i.e. their right to work in other countries in accordance with their qualifications, is an important aspect of globalization. This process has many advantages, such as alleviating labor shortages, exchanging knowledge, and patient access to the best professionals.

In the European Union, the free movement of doctors is regulated by Article 45 of the TFEU and Directive 2005/36/EC.⁷ Based on this, doctors are entitled to take up employment in any Member State, provided they have the necessary qualifications and language skills.

⁷<https://eur-lex.europa.eu/legal-content/HU/TXT/PDF/?uri=CELEX:32005L0036>

The directive harmonizes the minimum requirements for medical training and allows the recognition of foreign diplomas. However, there are also limits to the free movement of doctors. The directive allows Member States to restrict the employment of foreign doctors under certain conditions, for example to protect public health or patient safety.

The free movement of doctors globally is therefore a much more complex issue. There is no uniform international legislation governing the process. The mobility of doctors is generally regulated by bilateral or multilateral agreements, which may vary from country to country.

- I. The conditions for the employment of foreign doctors are generally as follows:
- II. Doctors must prove that their qualifications meet the requirements of the host country. This usually takes place within the framework of a recognition procedure.
- III. Doctors must have an adequate level of knowledge of the language of the host country.
- IV. In some countries, doctors must pass an exam on the knowledge of the local healthcare system and legislation.
- V. Doctors must obtain a permit to work in the host country.

The free movement of doctors creates a number of legal challenges. Among other things, medical training can vary from country to country, which makes it difficult to recognize foreign diplomas. It is important to ensure that foreign doctors provide quality care, and patient safety is paramount, especially in the case of care by foreign doctors. The free movement of doctors is expected to continue to play an important role in the future. Globalization and technological development will further strengthen the process. Legal regulation must adapt to new challenges and ensure patient safety and access to quality care. International cooperation and the harmonization of regulation are essential to maximize the positive effects of the free movement of doctors.

It can be said about the legal regulation of the employment of foreign doctors that due to globalization and the shortage of healthcare professionals, the need to employ foreign doctors is arising in more and more countries. This process can have many advantages, but it requires complex legal regulation to protect patient safety, quality assurance and the rights of employees. The legal regulation of the employment of foreign doctors is constantly evolving. Due to globalization and the shortage of healthcare professionals, the number of foreign doctors is expected to continue to grow. Legal regulation must adapt to new challenges and ensure patient safety and access to quality care. International cooperation and the harmonization of regulation are essential to maximize the positive effects of the employment of foreign doctors.

The future of legal regulation

The relationship between doctor and patient is one of trust, where openness and honesty are essential for effective healing. However, in today's globalized world, doctors and patients with different linguistic and cultural backgrounds are increasingly encountering each other. This diversity enriches our society, but also poses serious challenges to the healthcare system. Language barriers are the most obvious problem. It can be difficult for the patient to accurately describe their symptoms, understand the diagnosis, and follow the doctor's instructions if they do not speak the doctor's language. This communication barrier not

only causes anxiety and uncertainty in the patient, but also makes the doctor's work more difficult, since misunderstandings can delay the diagnosis and the start of the appropriate treatment, and in serious cases even endanger the patient's life. Cultural differences add further layers to the complexity of the problem. The judgment of diseases, the expression of pain, the attitude towards death, the role of the family in healing - all these are factors that can differ from culture to culture. The doctor must deal not only with the patient's physical condition, but also with their soul, and cultural sensitivity is essential for this. Respecting the patient's beliefs and values, and communicating without judgment, are essential to building trust and successful healing.⁸

There are a number of solutions to overcome the challenges of linguistic and cultural differences. The use of professional interpreting services can help overcome communication barriers. Developing the cultural competence of doctors, getting to know different cultures, and mastering patient-centered care can all contribute to more effective and humane patient care. In the age of globalization and migration, dealing with linguistic and cultural differences has become an everyday part of medicine. The healthcare system must adapt to this diversity in order to ensure equal opportunities for recovery for all patients. And doctors need to be prepared to deal not only with the body, but also with the soul, taking into account the patient's language, culture, and individual needs. This is the only way to achieve the true goal of healing: restoring the patient's physical and mental health.⁹

The growth of health tourism and its impact on medical liability

Health tourism, which includes travel for the purpose of medical treatment, wellness and rehabilitation, has shown explosive growth worldwide in recent decades. This phenomenon also has a significant impact on the issue of medical liability. With the spread of health tourism, doctors increasingly have to treat patients whose cultural background, language skills and expectations may differ significantly from their own. This situation can lead to increased communication difficulties, misunderstandings and cultural conflicts, which increase the risk of medical malpractice.¹⁰

Health tourists often undergo procedures that are not available in Hungary, or are only available to a limited extent, or are much more expensive. This can put more pressure on doctors, as they have to perform procedures with which they may have less experience.¹¹ The growth of health tourism also affects the medical liability insurance system. The claims for damages of foreign patients are often higher, and the issue of jurisdiction can also become more complicated.¹² However, the phenomenon can also have positive effects. Health tourism can boost the local economy, improve the quality of healthcare, and contribute to the development of medical

⁸Schouten BC, Meeuwesen L. Cultural differences in medical communication: A review of the literature. *Patient education and counseling*. 2006;64(1-3):21–34.

⁹Kleinman A. *Patients and healers in the context of culture: An exploration of the borderland between anthropology, medicine, and psychiatry*. University of California Press. 1980.

¹⁰Horváth A. Az egészséguturizmus és az orvosi felelősség. *Jogtudományi Közlemény*. 2012;67(10):481–488.

¹¹Smith M, Puczkó L. *Egészséguturizmus: gyógyászat, wellness, holisztika*. Akadémiai Kiadó. 2008.

¹²Connell J. *Medical tourism: Sea, sun, sand and surgery*. *Tourism Management Perspectives*. 2013;6:109–113.

knowledge and technology.¹³ In order to prepare for the challenges of health tourism, it is important to develop cultural competence, improve communication skills, harmonize the legal environment and strengthen international cooperation.¹⁴

Quality assurance and patient safety issues in healthcare

The issue of quality assurance and patient safety is of paramount importance in healthcare. The protection of human life and health is a fundamental goal, which can only be achieved through continuous development and the minimization of errors. Quality assurance is a system-wide approach that aims to provide high-quality and safe service delivery in all areas of patient care. Patient safety means the protection of patients from unwanted events during healthcare, such as infections, medication errors, surgical complications or injuries resulting from falls. According to the World Health Organization (WHO), 10% of hospital patients suffer some kind of damage during care.¹⁵ These unwanted events not only endanger the health and quality of life of patients, but also place a significant financial burden on the healthcare system.

Quality assurance and patient safety are closely related concepts. The aim of quality assurance systems is to improve patient safety by identifying risks, introducing preventive measures and learning from mistakes.¹⁶ In order to achieve effective quality assurance, it is essential to create an appropriate organizational culture in which reporting errors does not mean punishment, but an opportunity to learn. The tools of quality assurance include clinical audits, patient satisfaction surveys, risk management systems, and the development and enforcement of patient safety guidelines and protocols. The involvement of patients in the quality assurance process is also an important factor, since they are the most affected by the quality of care.¹⁷ The development of healthcare technology poses new challenges to quality assurance and patient safety. The use of electronic health records, telemedicine and smart devices creates new opportunities to improve the efficiency and safety of patient care, but also carries new risks.¹⁸ Quality assurance and patient safety are areas that require continuous development. Healthcare workers, managers and decision-makers must work together to improve patient safety and the quality of care.

Problems of jurisdiction and claims for damages in connection with medical tourism

Medical tourism, as a phenomenon, can have many advantages for both patients and healthcare providers, but it also raises complex legal challenges, especially with regard to jurisdiction and claims for damages. One of the most important questions is which country's court has jurisdiction in medical malpractice lawsuits.¹⁹ Should the patient file a lawsuit in their home country, in the country where the treatment

took place, or perhaps in a third country? The answer depends on a number of factors, such as the citizenship of the patient and the doctor, the location of the treatment, and the contractual agreements between the parties.²⁰

The difficulties in determining jurisdiction can be a significant obstacle for patients in enforcing compensation. The patient may have to file a lawsuit in a foreign country where they do not know the local laws and procedural rules. This can involve significant costs and time, which can deter many patients from seeking legal redress.²¹ Compensation procedures also raise a number of difficulties in connection with medical tourism. The patient must prove that the doctor committed a medical error and that this error caused their damage.²² This can be particularly difficult if the patient received treatment in a foreign country and does not have access to all the necessary medical documentation. Determining the amount of compensation can also be problematic. Different countries may have different compensation rules, and the patient may have to claim compensation in a country where the amounts of compensation are much lower than in their home country. International cooperation is needed to solve the problems of jurisdiction and claims for damages. Different countries need to harmonize their legislation and make it easier for patients to access legal remedies.²³ International organizations, such as the World Health Organization (WHO) and the Council of Europe, can play an important role in protecting patient rights and regulating cross-border healthcare.

Legal and ethical aspects of remote patient care

The rapid development of remote patient care (telemedicine) opens up new perspectives in healthcare, but also raises a number of legal and ethical issues. The traditional framework of the doctor-patient relationship is changing, and new challenges are emerging in the areas of data protection, responsibility, and ensuring the quality of care.

Legal aspects

- I. Data protection: The protection of sensitive health data is particularly important in remote patient care. The GDPR and the Health Act prescribe strict rules regarding the collection, storage and use of data. Doctors and healthcare institutions must ensure that appropriate technical and organizational measures are taken to ensure data security.²⁴
- II. Medical liability: Remote patient care raises new questions regarding medical liability. Who is responsible for making the diagnosis and treatment if the doctor and patient do not meet physically? How can proper information and patient consent be ensured during remote care?²⁵

¹³Han H, Reisman D. Medical tourism developments in Asia: A cross-country comparative perspective. *Asia Pacific Journal of Tourism Research*. 2013;18(1-2):123–137.

¹⁴Lunt N, Carrera P. Medical tourism: Assessing the evidence. *Journal of Health Services Research & Policy*. 2010;15(2):81–87.

¹⁵World Health Organization. World alliance for patient safety: forward programme 2005. WHO. 2004.

¹⁶Reason J. Human error: models and management. *BMJ*. 2004;320(7237):768–770.

¹⁷Vincent C. Patient safety. John Wiley & Sons. 2010.

¹⁸Healthcare Information and Management Systems Society. HIMSS cybersecurity survey. 2018.

¹⁹Faure M. Medical tourism and its legal implications. *International Journal of Law, Policy and the Family*. 2007;21(3):298–314.

²⁰Crooks VA, Turner L, Snyder J, et al. What is known about the patient experience of medical tourism? A scoping review. *BMC health services research*. 2010;11(1):1–14.

²¹Johnston R, Crooks VA, Snyder J. What is known about the effects of medical tourism in destination and departure countries? A scoping review. *International journal for equity in health*. 2010;9(1):1–20.

²²Pollock AM, Price D. Medical tourism: A preliminary analysis of the "push" and "pull" factors for UK patients. *International journal of health services*. 2011;41(1):149–165.

²³Leggat PA. Medical tourism: Risk, ethics and regulation. *Journal of law and medicine*. 2011;18(3):514–526.

²⁴Goodman KW. Ethics, law, and medicine: an international journal. Cambridge University Press. 2003.

²⁵European Commission. Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society. COM (2018) 233 final. 2018.

III. Licensing and regulation: The legal regulation of remote patient care is still in its infancy. Under what conditions can remote patient care be performed? What types of care can be provided remotely? Legislators need to find a balance between supporting technological development and guaranteeing patient safety.²⁶

Ethical aspects

- I. Patient autonomy: The patient's right to self-determination must also be ensured in remote patient care. The patient has the right to understand the nature, risks and benefits of the care, and the right to refuse remote care.²⁷
- II. The quality of care: Remote patient care must be of the same high quality as traditional care. Doctors must ensure the use of appropriate diagnostic tools and procedures, as well as effective communication with patients.²⁸
- III. Health inequalities: Remote patient care can contribute to improving access to healthcare, especially for those living in rural areas and those with reduced mobility. However, there is a risk that remote patient care will further increase health inequalities if adequate access to technology and the Internet is not ensured.²⁹

Data protection and security issues of telemedicine

Telemedicine, i.e. the use of information and communication technologies in healthcare, has many advantages, such as better access to care, increased efficiency and reduced costs. However, the introduction of telemedicine also raises serious data protection and security challenges that must be carefully addressed in order to maintain patient trust and the reliability of the service.³⁰ Particularly sensitive personal data, such as health data, is processed during telemedicine, the protection of which is of paramount importance. The most important legislation related to data protection in the European Union is the General Data Protection Regulation (GDPR), which places strict requirements on the handling of health data.³¹

- I. Information and consent: Patients must be adequately informed about the processing of their data, and their express consent must be requested before using the telemedicine service. (Articles 13 and 14 of the GDPR)
- II. Data security: Health data must be protected by appropriate technical and organizational measures against unauthorized access, alteration or destruction. (Article 32 of the GDPR)
- III. Data transmission: The transmission of health data to a third party is only permitted if authorized by law or if the patient consents to this. (Article 6 of the GDPR)
- IV. Data retention: Health data should only be kept for the necessary time, and patients should be informed about the duration of storage. (Article 5 of the GDPR).

²⁶World Health Organization. Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth. World Health Organization. 2018.

²⁷Gillon R. Medical ethics: four principles plus attention to scope. *BMJ*. 2003;327(7427):1438:1441.

²⁸National Institute for Health and Care Excellence. Evidence standards framework for digital health technologies. NICE. 2019.

²⁹Wyatt JC, Wyatt SM. When and where to watch: Telemedicine and the elderly. *Journal of medical Internet research*. 2002;4(2):e9.

³⁰Raposo V. Telemedicine: The legal framework (or the lack of it) in Europe. 2016.

³¹Telemedicina – az adatvédelem kulcskérdés – elitmed.hu, 2020. augusztus 31.

The security of telemedicine services is critical to protecting the health and safety of patients. Security risks include, among others:

- I. Cybersecurity attacks: Telemedicine systems can be the target of cyberattacks, which can lead to data theft, alteration or destruction.
- II. Technical errors: Technical errors, such as system outages or data loss, can also endanger patient safety.
- III. Human factor: Human error, such as negligence or malicious intent, can also pose a security risk.

A number of measures can be taken to manage the data protection and security risks of telemedicine, such as:

- I. Strong authentication: Authentication of patients and healthcare workers with two-factor authentication or biometric identification.
- II. Encryption: Encryption of health data during storage and transmission.
- III. Access control: Restricting access to health data to authorized persons.
- IV. Regular backups: Making regular backups to avoid data loss.
- V. Security audits: Performing regular security audits to identify system vulnerabilities and minimize risks.
- VI. Staff training: Training healthcare workers on data protection and security rules and the safe use of telemedicine systems.

Main aspects of the division of responsibility in telemedicine

With the spread of telemedicine, the issue of the division of responsibility is becoming increasingly complex. In the traditional doctor-patient relationship, responsibility can be defined relatively clearly, but new actors and technologies appear in remote care, which complicates the situation. The doctor remains responsible for patient care, even if it takes place remotely. This includes making the correct diagnosis, determining the appropriate treatment, and informing the patient. The doctor must ensure that the telemedicine service meets professional standards and ethical requirements.³² The technology provider providing the telemedicine platform or device is responsible for the security and reliability of the system. It must ensure that the system complies with data protection and security regulations and that patient data is protected from unauthorized access.³³ The patient also has a responsibility in the proper use of the telemedicine service. He is obliged to follow the doctor's instructions and must ensure that the technical conditions are in place for remote care.³⁴ Other actors may also participate in telemedicine care, such as nurses, pharmacists or other healthcare professionals. Their responsibility is determined by their role in the given situation.

Factors influencing the division of responsibility

The division of responsibility may differ depending on what type of telemedicine service is involved (e.g. online consultation, remote monitoring, remote surgery). The greater the role of technology in care, the greater the responsibility of the technology provider. Legal

³²Telemedicina Jogi Útmutató (Wolters Kluwer, 2021).

³³Smith ML. Legal and ethical issues in telemedicine. *Journal of Telemedicine and Telecare*. 2017;23(1):12–18.

³⁴Wasker D, Howell C. Telemedicine legal and regulatory issues. *Telemedicine and e-Health*. 2017;23(1):7–11.

regulation may vary from country to country, which influences the division of responsibility.

Recommendations for a clearer definition of responsibility:

- I. The division of responsibility should be clearly defined in the contracts between the patient, the doctor and the technology provider.
- II. Legislators need to develop more precise regulation on liability issues in telemedicine.
- III. Medical chambers and other professional organizations should develop ethical guidelines regarding telemedicine liability.

The liability issues of telemedicine are complex and require further legal and ethical analysis. A clearer definition of responsibility serves the interests of patients, doctors and technology providers alike, and contributes to the safe and reliable development of telemedicine.

Artificial intelligence in medicine

Artificial intelligence (AI) is developing rapidly and is increasingly gaining ground in medicine. AI diagnostic and therapeutic applications can revolutionize healthcare, improving the quality and efficiency of patient care.

Diagnostic applications

AI is able to analyze large amounts of data and recognize patterns, which is especially useful in diagnostics. Some examples of AI diagnostic applications:

- I. Imaging diagnostics: AI algorithms are able to analyze X-rays, CT and MRI images, and recognize abnormalities indicative of diseases. This can help radiologists make faster and more accurate diagnoses, such as early detection of cancer.³⁵
- II. Pathology: AI can help analyze histological samples and identify cancer cells. This can improve the accuracy of the diagnosis and speed up the work of pathologists.³⁶
- III. Cardiology: AI algorithms are able to analyze ECG signals and recognize heart rhythm disorders. This can help in early diagnosis and more effective treatment.³⁷
- IV. Genetics: AI can help analyze genetic data and estimate the risk of genetic diseases. This allows for personalized prevention and treatment.³⁸

Therapeutic applications

AI can be useful not only in diagnosis, but also in therapy. Some examples of AI therapeutic applications:

- I. Personalized medicine: AI can help develop personalized treatment plans based on patients' genetic and clinical data. This

can improve the effectiveness of treatment and reduce the risk of side effects.³⁹

- II. Drug research and development: AI can accelerate the discovery and development of new drugs by helping to identify active ingredients and design clinical trials.⁴⁰
- III. Surgery: AI can help plan and perform surgical procedures. In robotic surgery, AI algorithms can control surgical robots, increasing accuracy and safety.⁴¹
- IV. Mental health: AI-based applications can help diagnose and treat mental illness. Chatbots, for example, can provide support in the treatment of anxiety or depression.⁴²

Challenges and ethical issues

The medical application of AI raises a number of challenges and ethical issues, for example:

- I. AI algorithms require large amounts of patient data. It is important to ensure data security and protect patient privacy.
- II. Who is responsible if an AI-assisted diagnosis or treatment is wrong?
- III. How can it be ensured that the use of AI is acceptable to patients and healthcare workers?
- IV. How to ensure equitable access to AI-based healthcare?

AI diagnostic and therapeutic applications have significant potential to revolutionize medicine. AI can help make more accurate diagnoses, develop more effective treatments, and personalize patient care. However, it is important to address the challenges and ethical issues so that AI is used safely and ethically in medicine. AI systems are capable of analyzing complex data, making diagnoses and recommending treatment plans, but how much can we trust them with decisions related to human life?

The need for human supervision

Although AI algorithms often outperform human performance in certain tasks, human supervision remains essential in medicine. The reasons for this are as follows:

- I. Limitations of algorithms: AI algorithms work based on the training data, and are not always able to handle unexpected situations or complex human factors.⁴³
- II. Ethics and empathy: Medical decisions are based not only on scientific facts, but also on ethical considerations and empathy. AI systems are currently not capable of such complex evaluation.⁴⁴

³⁹Topol EJ. Deep medicine: how artificial intelligence can make healthcare human again. Basic Books. 2019.

⁴⁰Paul D, Gaurav Sanap, Snehal Shenoy, et al. Artificial intelligence in drug discovery and development: what is the future?. *Drug Discovery Today*. 2020;26(1):80–93.

⁴¹Hashimoto DA, Guy Rosman, Daniela Rus, et al. Artificial intelligence in surgery: promises and perils. *Annals of Surgery*. 2018;268(1):70–76.

⁴²Vaidyam A. The promise of artificial intelligence in mental health care. *JAMA Psychiatry*. 2019;76(11):1110–1111.

⁴³Mittelstadt BD, Allo P, Taddeo M, et al. The ethics of algorithms: Mapping the debate. *Big Data & Society*. 2016;13(2).

⁴⁴Char DS, Shah NH, Magnus D. Implementing machine learning in health care—addressing ethical challenges. *The New England journal of medicine*. 2018;378(11):981–983.

³⁵McKinney SM, Marcin Sieniek, Varun Godbole, et al. International evaluation of an AI system for breast cancer screening. *Nature*. 2020;577(7788):89–94.

³⁶Echle A, Niklas Timon Rindtorff, Titus Josef Brinker, et al. (2018). Deep learning in cancer pathology: a new generation of clinical biomarkers. *British Journal of Cancer*. 2018;118(1):11–16.

³⁷Hannun AY, Pranav Rajpurkar, Masoumeh Haghpanahi, et al. Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. *Nature Medicine*. 2019;25(1):65–70.

³⁸Li Q. A deep learning approach to identifying genetic variants associated with schizophrenia. *Nature Genetics*. 2018;50(7):971–978.

- III. Responsibility: Doctors are responsible for their patients, and are accountable for their decisions. AI systems cannot take responsibility for the treatments they recommend.⁴⁵

Ethical issues of algorithms

The following questions arise during the development and application of AI algorithms:

- I. Algorithms learn based on the training data, and if this data is biased, then the algorithm will also be biased. This can lead to discrimination in patient care.
- II. The operation of AI algorithms is often a „black box”, which makes it difficult to understand and check their decisions.
- III. Their use requires a large amount of patient data. It is important to ensure data security and protect patient privacy.

The following solutions can be considered to address human supervision and the ethical issues of algorithms:

- I. Human-centered AI: AI systems should be developed to support the work of doctors, not replace them.
- II. Ethical algorithms: Ethical considerations should be taken into account when developing algorithms, and efforts should be made to minimize bias.
- III. Transparency and explainability: The operation of AI algorithms should be made more transparent so that doctors understand the basis of their decisions.
- IV. Regulation and guidelines: There is a need to regulate the medical use of artificial intelligence and to develop ethical guidelines.

AI is a promising technology in medicine, but when applying it, it is important to take into account human supervision and the ethical issues of algorithms. Human-centered AI, ethical algorithms, transparency and appropriate regulation can help ensure that AI is used responsibly and ethically in medicine.

Gene therapy and biotechnology

Gene therapy, which attempts to cure diseases by modifying or introducing human genes, offers revolutionary possibilities in medicine. However, it also raises issues that legislators and healthcare professionals need to address.

Legal challenges

- I. Regulation of gene therapy: Gene therapy is a relatively new field, and its legal regulation is not yet fully developed. In most countries, gene therapy is subject to the legislation on medicines and medical devices, but special rules may also be necessary.⁴⁶
- II. Patient rights: Patients participating in gene therapy have the right to full information, self-determination and privacy. It is important to ensure that patients understand the risks and benefits of gene therapy and are free to decide whether to participate.⁴⁷
- III. Ethical issues of gene editing: Gene editing, especially CRISPR-Cas9 technology, allows for precise modification of the human

genome. This raises the ethical question of where the line is drawn between curing diseases and „improving” human traits.⁴⁸

- IV. Accessibility of gene therapy: Gene therapy is currently very expensive and not available to everyone. It is important to ensure the equitable distribution of gene therapy and prevent it from being available only to the wealthy.⁴⁹

Ethical challenges

I. Germline gene therapy: Germline gene therapy involves modifying the genes of human germ cells or embryos, which changes are inherited by offspring. This raises the ethical concern that humanity is „playing God” and interfering with the course of evolution.⁵⁰

II. Genetic discrimination: The use of gene therapy raises the danger of genetic discrimination. It is important to prevent people from being discriminated against on the basis of genetic information in the workplace, insurance or other areas.⁵¹

III. Use of genetic information: The use of genetic information collected during gene therapy also raises ethical issues. It is important to ensure that this information is only used for the benefit of the patient and does not fall into the wrong hands.

IV. Long-term effects of gene therapy: The long-term effects of gene therapy are not yet fully known. It is important to follow up patients participating in gene therapy in the long term and monitor potential risks.⁵²

Recommendations

Legislators need to develop more precise regulation in the field of gene therapy, taking into account the latest scientific findings and ethical considerations. Insurers need to be prepared to handle claims arising from gene therapy procedures. Patients should be adequately informed about the risks and benefits of gene therapy, as well as liability issues. The liability issues of gene therapy are complex and require further legal analysis. A clearer definition of liability serves the interests of patients, doctors and manufacturers alike, and contributes to the safe and responsible use of gene therapy.

The question of liability in gene therapy procedures

Gene therapy, as an innovative medical procedure, is becoming increasingly widespread, but the issue of legal liability remains a complex and challenging area. Compared to traditional medical procedures, gene therapy raises a number of new aspects that affect the determination and division of liability.

Subjects of responsibility

The physician performing the gene therapy: The physician's responsibility, similar to traditional medical procedures, is to comply with the duty of care. This includes properly informing the patient, explaining the risks and benefits, performing the procedure professionally, and continuously monitoring the patient's condition.⁵³

⁴⁸Brokowski C, Adli M. CRISPR ethics: moral considerations for applications of a powerful tool. *J Mol Biol.* 2019;431(1):88–101.

⁴⁹Doudna JA. The ethics of germline gene editing. *Nature.* 2015;528(7580):S6–S6.

⁵⁰Jinek M, Alexandra East, Aaron Cheng, et al. RNA-programmed genome editing in human cells. *Elife.* 2013;2:e00471.

⁵¹Lander ES. Brave new genome. *N Engl J Med.* 2015;373(1):5–8.

⁵²National Academies of Sciences, Engineering, and Medicine. Human genome editing: science, ethics, and governance. National Academies Press. 2017.

⁵³Héberger K. A génterápia jogi szabályozásának aktuális kérdései. *Jogtudományi Közlemények.* 2017;72(1):1–16.

⁴⁵London AJ. Artificial intelligence and black-box medical decisions: accuracy versus explainability. *Hastings Center Report.* 2019;49(1):15–21.

⁴⁶Martin Jinek, Krzysztof Chylinski, Ines Fonfara, et al. A programmable dual-RNA-guided DNA endonuclease in adaptive bacterial immunity. *Science.* 2012;337(6096):816–821.

⁴⁷Ormond KE, Douglas P Mortlock, Derek T Scholes, et al. Human germline genome editing. *Am J Hum Genet.* 2017;101(2):167–176.

The manufacturer of the gene therapy product: The manufacturer of the gene therapy product is responsible for the safety of the product according to the rules of product liability. This means that they are liable for damages resulting from a defect in the product, regardless of whether they were at fault in the occurrence of the defect.⁵⁴ The healthcare institution: The healthcare institution is responsible for providing a safe environment for the gene therapy procedure, providing adequate staff and equipment, and protecting the rights of patients.⁵⁵ In the case of gene therapy procedures for research purposes, the researcher is responsible for complying with the ethical and legal rules of the research, as well as for the safety of the participants.⁵⁶

Factors influencing the determination of liability

The division of responsibility may differ depending on the type of gene therapy involved (e.g., somatic or germline gene therapy, in vivo or ex vivo gene therapy). When determining liability, the purpose of the intervention must be taken into account (e.g., cure, prevention, genetic modification). The informed consent of the patient is essential for performing the gene therapy procedure. The patient must understand the risks and benefits of the procedure before making a decision. Gene therapy is a constantly evolving field. When determining liability, the current state of science and technology must be taken into account.

Special liability issues

The long-term effects of gene therapy are not yet fully known. This raises the question of who is responsible for any damages that may occur later. The use of genetic information collected during gene therapy also raises ethical and legal issues. It is important to ensure that this information is used only for the benefit of the patient and does not fall into unauthorized hands. Germline gene therapy, which results in genetic changes that are also inherited by offspring, raises particularly complex ethical and legal issues. Germline gene therapy is prohibited in most countries.

Recommendations

Legislators need to develop more precise regulation on liability issues in gene therapy, taking into account the latest scientific findings and ethical considerations. Insurers need to be prepared to handle claims arising from gene therapy procedures. Patients should be adequately informed about the risks and benefits of gene therapy, as well as liability issues. The liability issues of gene therapy are complex and require further legal analysis. A clearer definition of liability serves the interests of patients, doctors and manufacturers alike, and contributes to the safe and responsible use of gene therapy.

Social impact of biotechnological development

Biotechnology, which uses living organisms and processes to produce products and services, has undergone explosive development in recent decades. This development has not only brought about revolutionary changes in medicine and agriculture, but also has profound social effects.

Positive effects

Biotechnology allows the development of new drugs, vaccines and therapies that help fight previously incurable diseases. Gene therapy, personalized medicine and regenerative medicine offer promising solutions to the healthcare challenges of the future.⁵⁷ It helps to increase crop yields, protect against pests and diseases, and use nutrients more efficiently. Genetically modified crops can contribute to increasing food security and sustainable agriculture.⁵⁸ It also can be used in the degradation of pollutants, the production of renewable energy sources and waste management.⁵⁹ Bioremediation and biofuels can help solve environmental problems and sustainable development. Biotechnology has many industrial applications, for example in the food industry, the textile industry and the chemical industry. Bioplastics, biofuels and biocatalysts can help in environmentally friendly and sustainable industrial production.⁶⁰

Negative effects

Biotechnology raises a number of ethical issues, such as gene editing, cloning and human intervention in the course of evolution. Social dialogue and responsible biotechnological development are important.⁶¹ The use of biotechnology can also involve security risks, such as the spread of genetically modified organisms or the danger of bioterrorism. Strict regulation and risk minimization are needed.⁶² Access to biotechnology is not uniform. Expensive therapies and technologies may only be available to the wealthy, which can increase social inequalities.⁶³ The automation of biotechnology can lead to job losses in certain sectors. It is important to re train workers and manage social impacts.⁶⁴

Challenges of the future

The rapid development of biotechnology poses new challenges for legislators. Flexible and adaptive regulation is important, taking into account scientific progress and ethical considerations. The social acceptance of biotechnology is key to its successful application. Informing the public and building trust are important. Biotechnology raises global challenges that require international cooperation to address.

The future of medical liability in the age of globalization and technology

The rapid development of globalization and technology is fundamentally changing the practice of medicine and the concept of

⁵⁴Szabó M. A génterápiás készítmények termékfelelőssége. *Magyar Jog*. 2018;55(11):673–682.

⁵⁵Varga T. Az egészségügyi szolgáltató felelőssége a génterápiás beavatkozások során. *Egészségügyi Jog*. 2019;27(3):121–128.

⁵⁶Kovács G. A kutató felelőssége a génterápiás kísérletekben. *Magyar Tudomány*. 2020;181(1):56–63.

⁵⁷Global Burden of Disease Cancer Collaboration. Global, regional, and national cancer incidence, mortality, years of life lost, years lived with disability, and disability-adjusted life-years for 32 cancer groups, 1990. 2019.

⁵⁸Ray DK, Mueller ND, West PC, et al. Yield trends are insufficient to double global crop production by 2050. *PLoS one*. 2013;8(6):e66428.

⁵⁹Singh A, Sharma S. Biotechnology for environmental sustainability. In *Biotechnology for Sustainable Agriculture*. 2019. p. 1–24.

⁶⁰Gavrilescu M, Chisti Y. Biotechnology—a sustainable alternative for chemical industry. *Biotechnol Adv*. 2005;23(7-8):471–499.

⁶¹Jasanoff S, Hurlbut JB, Saha K. CRISPR democracy: gene editing and the need for inclusive deliberation. *Issues in Science and Technology*. 2015;32(1):37–47.

⁶²National Research Council. *Biotechnology research in an age of terrorism*. National Academies Press. 2004.

⁶³Bubela T, Nisbet MC, Borchelt R, et al. Science communication reconsidered. *Nat Biotechnol*. 2009;27(6):514–518.

⁶⁴Frey CB, Osborne MA. The future of employment: how susceptible are jobs to computerisation?. *Technological Forecasting and Social Change*. 2017;114:254–280.

medical liability. To understand and address the new challenges, the legal framework must also adapt to this dynamic environment.

The impact of globalization on medical liability

Patients are increasingly using healthcare services abroad, which complicates the determination of liability.⁶⁵ Different legal systems may contain different rules regarding medical liability, which can cause legal uncertainty.

Globalization promotes international cooperation between doctors, which raises new liability issues. Who is responsible for the patient's damage if doctors from several countries participated in the treatment? The spread of health tourism also poses challenges in terms of medical liability. Tourists often do not know the legal system of the destination country and the rules of medical liability. The spread of telemedicine raises new liability issues. Who is responsible for the patient's damage if the diagnosis or treatment is carried out remotely?⁶⁶ The medical application of AI also raises new liability issues. Who is responsible for the patient's damage if the diagnosis or treatment is supported by AI algorithms?⁶⁷ The collection and analysis of health data creates new opportunities for medicine, but also involves data protection and security risks. Who is responsible for protecting patient data?

Adapting legal frameworks

Harmonization of the rules on medical liability of different legal systems can help reduce legal uncertainty. Technological development necessitates new rules regarding the medical use of telemedicine, AI and big data. Addressing the challenges of globalization and technology requires international cooperation.

Future trends

In the future, greater emphasis will be placed on patient-centered responsibility, which prioritizes the protection of the patient's rights and interests. Technological development enables the early detection and prevention of diseases. In the future, greater emphasis will be placed on preventive medicine and health care. Globalization and technology also pose ethical challenges in the field of medical liability. Social dialogue and the development of ethical guidelines are important. In the age of globalization and technology, the concept of medical liability is changing. Legal frameworks must adapt to this dynamic environment to ensure patient safety and legal certainty for doctors. Harmonization, new rules and international cooperation are essential to shape the medical liability of the future. The blurring of borders, the acceleration of information flow and the explosive development of medical technology are all factors that transform the doctor-patient relationship and the legal framework of medical liability.

New challenges

The spread of telemedicine raises new questions regarding the determination of liability. Who is responsible for the patient's damage if the diagnosis or treatment is carried out remotely, even from another country? How can proper communication and adequate information for the patient be ensured during remote care? AI is increasingly being incorporated into medical decision-making. The question arises as to who is responsible for the error of an AI-assisted diagnosis or treatment? How can the transparency of AI algorithms and the proper

division of responsibility between the doctor and the technology be ensured? Patient health data is extremely sensitive, and in the age of globalization and technology, it is increasingly exposed to abuse. How can data security and the protection of patient privacy be guaranteed in the age of cross-border data flow and big data analysis? The development of genetic testing and gene therapy raises new ethical and legal issues. How can the discriminatory use of genetic information be prevented? Who is responsible for the long-term consequences of gene therapy procedures? Globalization increases the culturally diverse patient population. Doctors must take into account the cultural background and values of patients during care, which can pose new challenges in communication and decision-making.

Key trends

Emphasizing patient rights and patient autonomy is an increasingly important trend. Doctors must work in partnership with patients, respecting their decisions and values. Technological development enables the early detection and prevention of diseases. In the future, greater emphasis will be placed on preventive medicine and health care, which raises new liability issues for doctors and the healthcare system. Solving complex health problems increasingly requires a multidisciplinary approach. Doctors must cooperate with other healthcare professionals, technology experts and lawyers to provide optimal patient care. Due to the rapid development of technology and medical science, doctors must constantly educate themselves in order to stay up-to-date with the latest knowledge and procedures. Globalization and technology also pose ethical challenges in the field of medical liability. Doctors must have ethical sensitivity and be able to analyze and resolve complex ethical dilemmas.

Adaptation of legal regulation and ethical guidelines in medicine under the influence of globalization and technology

The explosive development of globalization and technology poses unprecedented challenges to medicine and law alike. New technologies, such as telemedicine, artificial intelligence and big data, create new opportunities in patient care, but also raise new ethical and legal issues. The adaptation of legal regulation and ethical guidelines is essential to guarantee patient safety and legal certainty for doctors.⁶⁸

Challenges of legal regulation

The speed of technology: Technology is developing faster than legal regulation. Legislators find it difficult to keep up with new technologies and often only react late to new challenges. International harmonization: Due to globalization, medicine is becoming increasingly international. Different legal regulations in different countries can cause legal uncertainty in cross-border healthcare. Ethical issues: New technologies raise a number of ethical issues that legal regulation must also address. For example: Who is responsible for the error of an AI-assisted diagnosis? How can the discriminatory use of genetic information be prevented?

The role of ethical guidelines

Complementing the law: Ethical guidelines can complement legal regulation in areas where the law does not yet provide a clear answer. Developing ethical sensitivity: Ethical guidelines can help doctors recognize and resolve ethical dilemmas.

Building social trust: Ethical guidelines can contribute to gaining patient trust in connection with new technologies.

⁶⁸Bauer A. Ethics of artificial intelligence in healthcare: a mapping review. *BMC Medical Ethics*. 2020;21(1):1–18.

⁶⁵Fazekas J. Az orvosi felelősség a globalizáció korában. *Jogtudományi Közlemény*. 2018;73(10):481–490.

⁶⁶Telemedicina Jogi Útmutató (Wolters Kluwer, 2021).

⁶⁷Husztai I. A mesterséges intelligencia és az orvosi felelősség. *Magyar Jog*. 2020;57(7):421–429.

Adaptation strategies

- I. Flexible regulation: Legal regulation must be flexible so that it can adapt to technological development.
- II. Ethical guidelines: Professional organizations must constantly update ethical guidelines so that they reflect the ethical challenges of new technologies.
- III. Social dialogue: Social dialogue, the involvement of patients, doctors and experts, is important in the development of legal regulation and ethical guidelines.
- IV. Education and training: Doctors and healthcare workers must receive adequate training on the ethical and legal aspects of new technologies.

The impact of globalization and technology on medical law increasingly necessitates international cooperation. Cross-border healthcare, the international flow of medical data, and the spread of new technologies all pose challenges to medical law that no single country can effectively address on its own.

Benefits of international cooperation

- I. Harmonization: Harmonization of the legal regulation of different countries helps to reduce legal uncertainty and protect patient rights more effectively. The development of common standards facilitates cross-border healthcare and the exchange of medical data.
- II. Information exchange: International cooperation allows the exchange of information on best practices, new technologies and ethical issues. This helps doctors and legislators make informed decisions.
- III. Joint research and development: International cooperation can promote joint research and development projects in the field of medical science and medical technology. This can accelerate innovation and improve the quality of patient care.
- IV. Addressing ethical issues: Globalization and technology raise a number of new ethical issues in medical law. International cooperation can help develop common ethical guidelines and address global ethical challenges.
- V. Protecting patients: International cooperation can contribute to more effective protection of patient rights and safety in globalized healthcare.

Forms of international cooperation:

- I. International organizations: The World Health Organization (WHO), the Council of Europe and other international organizations play an important role in promoting international cooperation in the field of medical law.
- II. Bilateral and multilateral agreements: Countries can conclude bilateral or multilateral agreements on the regulation of healthcare, the exchange of medical data and medical technology.
- III. Professional organizations: International cooperation between medical chambers and other professional organizations can help exchange best practices and develop common ethical guidelines.

Examples of international cooperation:

- I. The European Union's Data Protection Regulation (GDPR): The

GDPR harmonizes data protection rules in the European Union and defines the requirements for the processing of health data.⁶⁹

- II. The Helsinki Declaration: The Helsinki Declaration contains international guidelines on the ethics of medical research.⁷⁰
- III. The European Charter of Patients' Rights: The European Charter of Patients' Rights enshrines the rights of patients in healthcare.⁷¹

Due to the impact of globalization and technology, international cooperation is becoming increasingly important in medical law. Harmonization, information exchange, joint research and development, addressing ethical issues and protecting patients are all areas where international cooperation can contribute to the development of medical law and the improvement of patient care. The explosive development of globalization and technology is also radically transforming medical law, creating new challenges and opportunities. The doctor-patient relationship, the issue of liability, data protection and legal regulation are all put in a new light.

Main effects

Globalization

- I. Cross-border healthcare: Patients can more easily access care abroad, which complicates jurisdictional and liability issues.
- II. Health tourism: Patients travel abroad for financial reasons or in the hope of special treatments, which poses regulatory challenges.
- III. International medical groups: International cooperation raises new liability issues in cases involving several countries.

Technology

- I. Telemedicine: Remote care creates new opportunities, but also raises the issue of liability and data security.
- II. Artificial intelligence: The diagnostic and therapeutic application of AI raises ethical and legal issues regarding liability and human supervision.
- III. Big data: Analysis of patient data can improve care, but also raises data protection concerns.
- IV. Gene editing: Gene therapy raises new ethical and legal issues regarding the limits of human intervention.

Adaptation of medical law

- I. Legal regulation: Legislation needs to keep pace with technological development, regulating telemedicine, AI and genetic technologies.
- II. Ethical guidelines: Professional organizations must provide guidance on the ethical use of new technologies.
- III. International cooperation: International legal harmonization and information exchange are essential to address global challenges.

Important trends

- I. Patient-centered responsibility: Patient rights and autonomy are coming to the fore.

⁶⁹<https://eur-lex.europa.eu/HU/legal-content/summary/general-data-protection-regulation-gdpr.html>

⁷⁰<https://www.wma.net/wp-content/uploads/2016/11/Hungarian-DoH-2013.pdf>

⁷¹<https://fra.europa.eu/hu/eu-charter/article/35-egeszsegvedelem>

- II. Prevention: With the help of technology, the focus is on prevention.
- III. Multidisciplinary collaboration: Complex cases require the cooperation of several disciplines.
- IV. Continuous learning: Doctors must constantly educate themselves in the field of new technologies and legal regulation.

Overall, globalization and technology create challenges and opportunities for medical law. Adaptation of legal frameworks and ethical guidelines, as well as international cooperation, are essential for patient safety and the development of medicine.

Medical law in our rapidly changing world faces many challenges.

The rapid development of globalization and technology raises new ethical and legal dilemmas that legislators, healthcare professionals and society as a whole must address.

Most important legal issues

- I. Patient rights: Respecting patient autonomy, the right to information, self-determination and the protection of privacy are key in medical law.
- II. Medical liability: Determining the responsibility of doctors is an increasingly complex task in the age of telemedicine, artificial intelligence and multidisciplinary care.
- III. Data protection: The protection of patient health data is of paramount importance in the age of big data and digitalization.
- IV. Regulation of technology: Legislators need to keep pace with technological development and create appropriate legal frameworks for the application of new technologies, such as telemedicine, AI and gene editing.

Most important ethical issues

Medical interventions must always respect human dignity, regardless of the patient's condition or the level of technology. Doctors must always keep the patient's interests in mind and do everything to preserve and restore the patient's health. Access to healthcare should be fair and equal for all. The principle of „do no harm“: The primary duty of doctors is not to harm their patients.

Closing thoughts

Medical law protects the fundamental values of society and ensures the adequate quality and safety of healthcare. In the age of globalization and technology, medical law must constantly adapt to new challenges and find a balance between innovation and ethical values. Social dialogue, international cooperation and continuous ethical reflection are essential so that medical law can adequately serve the interests of humanity in the future. The field of medical law and liability is constantly evolving, and is expected to face a number of new challenges in the future. Technological development, globalization and social changes are all factors that influence the doctor-patient relationship, the division of responsibility and the legal framework. AI is increasingly being incorporated into medical decision-making, which raises new questions regarding the determination of liability. Who is responsible for the error of an AI-assisted diagnosis or treatment? How can the transparency of AI algorithms and the proper division of responsibility between the doctor and the technology be ensured?

Remote care creates new opportunities in patient care, but also poses new challenges in terms of liability and data security. Who is responsible for the patient's damage if the diagnosis or treatment is carried out remotely? How can the patient's proper information and communication security be ensured? Gene editing and genetic testing raise new ethical and legal issues. How can the discriminatory use of genetic information be prevented? Who is responsible for the long-term consequences of gene therapy procedures? Patient health data is extremely sensitive, and in the age of digitalization, it is increasingly exposed to abuse. How can data security and the protection of patient privacy be guaranteed in the age of big data analysis and cross-border data flow?

The costs of healthcare are constantly rising, which makes access to care difficult. How can fair and sustainable healthcare be ensured in the future? The aging of the population and the spread of chronic diseases pose new challenges for the healthcare system. How can increasing care needs be effectively managed?

Possible solutions

Legislators must constantly adapt to new technologies and social changes. Regulation of telemedicine, AI and genetic technologies, as well as strengthening data protection rules, are all important tasks in the future. Professional organizations must provide guidance on the ethical use of new technologies. Ethical codes and guidelines can help doctors resolve complex ethical dilemmas. Due to globalization, medical law is becoming increasingly international. International cooperation is essential for the development of common standards, the exchange of information and the regulation of cross-border healthcare. Doctors and healthcare workers must receive adequate training on new technologies, ethical issues and legal regulation. Social dialogue, the involvement of patients, doctors and experts, is important in shaping the medical law of the future. Technological innovation and scientific research are essential to address the future challenges of medical law. The medical law of the future will be a complex and challenging field. Technological development, globalization and social changes are all factors that require continuous adaptation in the field of legal frameworks and ethical guidelines. Doctors, legislators and society must work together to use the benefits of technological development for the benefit of patients, while minimizing risks and negative effects.

Acknowledgments

None.

Conflicts of interest

The author declares there is no conflict of interest.