NEW TECHNOLOGIES USED AS THE EVIDENCE IN HEALTHCARE MALPRACTICE PROSECUTION

Assoc. Prof. Dr. IUR. Olga Sovova, PhD
Police Academy of the Czech Republic in Prague, Czech Republic

ABSTRACT

New technologies and digitalisation in medical procedures and patient communication have made significant progress in the last three years and have become part of everyday life. The paper examines the above facts and how they impact healthcare providers' obligations and patients' rights. The use of digitalisation has changed and will also change the requirements for the documentation of each medical case. Content and communication between the doctor, other healthcare professionals, patient and provider have a qualitatively new character. The paper points out the advantages and risks of digitalisation in health care. The author argues that new recordings of health care will also change the proof of misconduct in court and administrative proceedings. The author explores the examined issues using the desk research method to analyse recent doctrinal views and the case law.

The author underlines specific areas of investigation on which the plaintiff, the administrative authority and the prosecution must focus. In conclusion, the paper introduces Czech legal practice and case law examples.

Keywords: *digitalisation, health care, malpractice, prosecution, desk research, case law*

INTRODUCTION

Digital technologies, Artificial Intelligence (AI), video conferences, and collaborative sharing of ideas have influenced and changed everyday life during the last twenty years. Science is no exception. Natural science, medicine, and social sciences, including law and ethics, underwent substantial changes accelerated by the SARS-COVID-19 pandemic. Face-to-face communication becomes unnecessary and remote access or social media replaces it. Due to lockdowns and distancing, many people have entirely moved to social networks and the online world. Now they are afraid to make a simple phone call. [1]

However, the digitalisation of society progresses, despite its negative impacts. Medicine and healthcare in practice form the most current examples. The development of science and technology in digital medicine is enormous. The implications for healthcare delivery's ethical and legal issues are immense, as the legal regulation always delays the practice.

The online world and digitalisation have fundamentally changed communication and relationship between healthcare professionals, providers, and patients. Many services moved online. Telemedicine became very popular and even overused during the pandemic. It avoids direct contact between the doctor and the patient, using electronic communications and software for remote consultations and medication management. Supporting and surveillant systems, known as telehealth, facilitated the clinicians' and other healthcare professionals' exchange of patient data and information. Nevertheless, the sensitivity of generated and transferred health-related data and latent risks of misuse or cyber-attacks pose serious challenges. The patients cannot retain control over their data due to the scale, scope and complexity of systems that create, aggregate, and analyse personal health. [2]

Health care professionals and providers face the employees' negligence in data protection and severe threads of blocking intranet and web communications or data thefts. The healthcare services, especially the public, were and are still considered untouchable and impregnable. That is why providers underestimate cyber security and adequate hardware and software coverage. However, all techniques and technology serve a primary purpose: to provide the required and appropriate health care. The discussion about proper technology use and whether any misconduct can be proven is thus becoming a new phenomenon in medicine, ethics, and law.

CHALLENGES OF DIGITAL TECHNOLOGIES IN HEALTHCARE

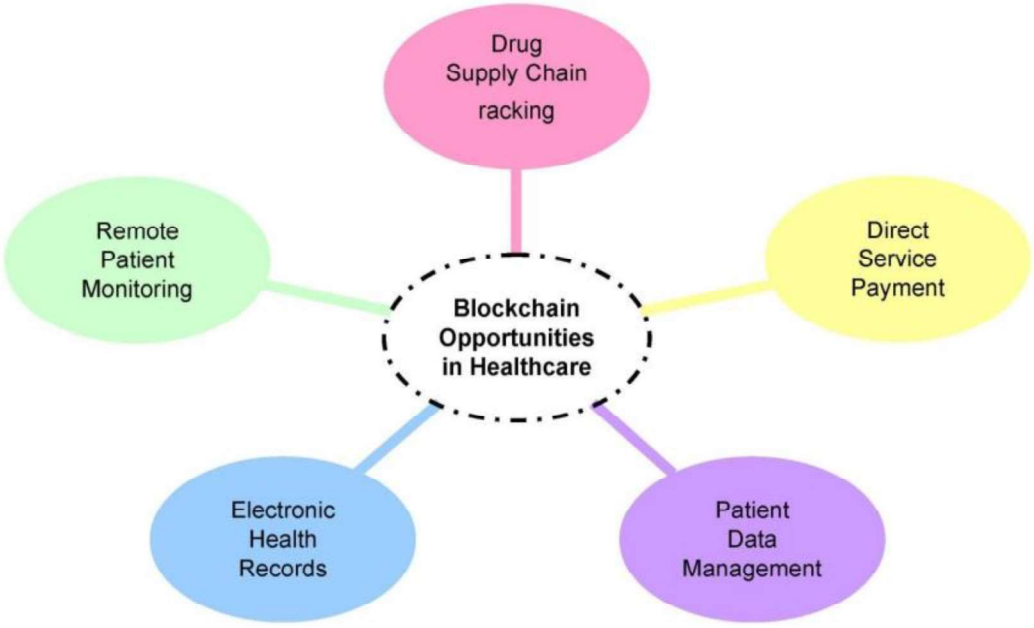
The author has already devoted her research to the benefits and issues of modern technologies in healthcare - see reference [3]. New technologies and artificial intelligence in healthcare and medical services enable the providers to compile, process and share data and information quicker, in more detail and to a much greater extent than heretofore possible. Big data are the future of natural and social sciences, medicine included. AI is not only capable of analysing not only enormous amounts of data in a brief period (big data), but also these processes of analysis are easily improved by machine learning. [3] Modern technologies facilitate progress in operations, genome manipulations or artificial human reproduction.

Nevertheless, all efficient healthcare services depend heavily on information technology. Recording, storing, and exchanging information quickly, efficiently, and economically form the main challenge. If there is a lack of interoperability and limited linkage between the healthcare storage systems, retrieving, transmitting, cleaning, and analysing data becomes difficult. [4] Last but not least, the security, possible changeableness and traceability of originator and user are the conditions without which it is impossible to work with medical data.

Blockchains are becoming the future technology in healthcare delivery. Blockchain-related to and has still been connected with transactions of cryptocurrencies and tracking assets as a shared, immutable ledger. [5] All the parties involved have their data available on a decentralised system. Users can access the storage at any given point in time. Moreover, anyone who tries to tamper with the data can be tracked and located easily. According to research conducted in 2018, the global blockchain in the healthcare market is estimated to amount to $5.61 billion by 2025, witnessing a double-digit growth throughout the forecast period of 2018-2025. [4]

The author argues that blockchains will become a new form of medical documentation and patient surveillance in the coming decade as the European Union strongly supports its introduction in everyday life. Blockchain is a system of recording information in a way that makes it difficult or impossible to manipulate; Distributed ledger technology is a system for recording the transaction details in multiple places simultaneously, with no central data store or administration functionality. These might be used as a new information infrastructure that could support and ensure the safe exchange of information between public administrations, citizens and businesses. [6] Data in a blockchain is ordered chronologically, validated before storage and gets the time-stamp. [7] All this traceability and reliability are significant for both medicine and law.

Fig. 1. *Possible usage of blockchain in healthcare management.*



Source: https://www.mobileappdaily.com/blockchain-in-healthcare

The SARS-COVID-19 pandemic and the need to resolve global health threats connected with local wars, migration or any other epidemiology risks speed up the demand for re-designing concepts of medical care in a broad sense.

Medical professionals trained for personal healthcare delivery and the systems designed for the manual input of information should change their daily practice. The professional becomes a manager of data and information compiled by the AI and stored in the cloud. Face-to-face medicine will apply only in urgent cases.

LEGAL CHALLENGES OF THE DIGITAL EVIDENCE

The current legal doctrine still focuses on individual questions regarding health issues. The above-mentioned substantial changes in healthcare services call for new approaches when discussing and solving legal problems of medical law in the era of digitisation. It is necessary to examine the impact of international instruments, particularly the Convention on Biomedicine [8], the Charter of Fundamental Rights of the European Union (EU), and the EU4Digital Initiative for developing and supporting ehealth platforms.[9] However, remote medical care, data storage, and exchange cross the EU border. The digital evidence is globalised, especially in randomised clinical trials.

The patient's autonomy and the right to self-determination form the basis for any medical intervention and treatment, even under critical or pandemic circumstances. The decision-making autonomy is an essential precondition for the performance of health services, both on the part of the provider and the patient. The specialist determines what treatment and related procedures he will propose to the patient. Based on proper instruction and informed consent, the patient accepts or rejects. Also, each medical data collection requires legal authorisation. However, digitalisation has changed the relationship between the doctor and the patient. There are doctors and medical professionals whom the patient does not even see or know in the background of the treatment. The new doctor, oriented toward the process of experiments on people and armed with new technologies, has replaced the doctor treating people’s illnesses. [10]

The General Data Protection Regulation, 2016 (GDPR) brought a new level of protection and safeguards for protecting health information. Such sensitive information should be collected based on the approval of the data holder or because of legal obligation. Compulsory treatment, vaccination, or emergency are the main reasons for collecting and storing data without a patient's consent. The patient must always get the information on which data, for what purpose and who keeps them. Moreover, healthcare providers and their employees have the duty of confidentiality regarding all the information they obtain because they provide healthcare services. Breaching medical confidentiality whilst wrongfully publishing, communicating a patient's data, or enabling access to another person constitutes unlawful disposal of personal data under the GDPR and in national legal orders. The legal obligation of privacy protection is adequately secured. The main legal challenges are assuring legally valid informed consent when all medical files are digitalised and stored in the cloud, keeping the records topical,

and providing evidence when the medical professional and the provider are subjects of malpractice litigation.

The Supreme Court of the Czech Republic, in its ruling 25 Cdo 1381/2013, defined the legal nature of informed consent as follows: *The term "free and informed consent" means consent given in a situation in which the patient, to whom the purpose, nature, risks and alternatives of the procedure, as well as the consequences of not performing it, have been explained, without coercion and with sufficient time for consideration and with the possibility to supplementary questions, scheduled to undergo the proposed procedure*.

The more extensive the access to personal, often confidential and discreet data, whether on the part of their users, such as insurance companies, pension institutions, or statistical authorities of the state administration, brings the more relative the relationship between doctor and patient. This relativity undoubtedly affects the current practice of informed consent and non-consent, which often become formal documents not meeting the legal and medical requirements of providing care.

Digitisation of consent, when access to documentation will be based on e-identity, an authoritative register of patients and the use of an electronic signature with biometric data, can, on the one hand, lead to more precise and more concrete data. However, on the other hand, some patients, doctors and providers may have a problem with equipment service and internet access. In such a case, on the contrary, the authorised person may not access, but another person under her identity, who gives invalid informed consent or disagreement. Moreover, current legal theory and practice underline that valid consent/disagreement results from the confidential conversation between the doctor and the patient. Written materials serve only as a supplement when clarifying or repeating information. [11] Thus, it can be expected that legal and judicial practice will require the fulfilment of oral and personalised edification. In the digital world, however, this requirement must be tied to the technical possibility of the health service provider and the patient to meet virtually. Furthermore, the doctor must record the procedure in digital documentation. Suppose the documentation, including informed consent/disagreement, will be conducted exclusively in electronic form. This type of data storing can be expected primarily within cross-border healthcare. In that case, it is necessary to resolve the signature of digitised documents by both the patient and the doctor or possibly another healthcare professional, e.g. evaluation of various laboratory examinations or findings. The descriptions of results must also be uniform. Blockchain can enable and guarantee all of this.

Artificial Intelligence could be used for keeping records, as it learns much quicker than a human being. It also can better correct mistakes when evaluating the data collected. A robotic nurse can collect personal and anamnestic data. However, human supervision is always needed, as the medical professional and the provider is responsible. The AI is just an intermediate article.

The pandemic also speeded the judicial transition to remote communication. Nevertheless, the personal interaction and evaluation of nonverbal communication and parties' reaction are principles of the court hearing. In many countries, including the Czech Republic, public authorities, state prosecution and courts are not equipped to hear the virtual evidence. Public digital systems very often do not communicate appropriately with each other or are not able to transfer large amounts s of data or pictures. Moreover, medical picture programmes differ significantly from those used publicly, like png., jpg., or pdf. format.

Based on the above mentioned, the leading legal challenge for the European states is to create a unified platform for collecting and storing medical data, pictures, and files. Digitalised medical documentation could be relevant evidence only if it is reliable, suitable and understandable for patients, doctors, providers, lawyers, public officers and judges.

Blockchain technology could be a solution. Nevertheless, the judicial and public health service systems must transition from individualised, mutually non-communicating systems to self-learning cooperating and easily accessible platforms. Blockchain technology will be adopted if it is economically advantageous, and there will be social pressure to assure a real digitalisation of publicly financed services.

Different digital systems and incompatible hardware and software in courts, state prosecution and public administration significantly delay the attorneys' digitalisation. The companies and private persons are also pretty much better equipped., even if in some regions might the internet connection be slower. Procedural regulations form an obstacle to digitalisation, too. EU offers platforms for e-justice. However, those provide quicker access to the courts in EU countries in business and family cases, where the evidence and the procedure could run without the parties' participation. If any party denies something or the witness or expert should be heard, the process must always be oral and public. Then, hearing the evidence is a crucial issue.

In medical cases, the sustained injury is very often irreparable. Expertise is inevitable; the plaintiff and the defendant provide plenty of medical and legal evidence. Medical files in blockchain comply with the requirement of reliable evidence. Nevertheless, these blockchains are private with restricted access. Procedural parties, experts, and judges need access to the documentation. The Czech legal regulation, Act. No. 372/2012 Coll. The case-law limits access to the patient’s file for necessary information. The Constitutional Court, in its decision No. I. ÚS 2050/14 and I. ÚS 321/06 underlined that only the court summons could grant strictly circumscribed access to the patient's files. Despite the criminal proceedings' public character, the police and prosecution authorities cannot disseminate sensitive data unreasonably. [12]

During the proceedings, the court poses the questions to the expert and parties and determines the scope of browsing the documentation. The court keeps case files in combined form- electronic and paper. Parties can provide their documents in the same way. Access to the case file in any procedural stage is a fundamental right of litigants. The digitalisation of case files and remote access is very slow in EU states. According to the 2021 EU Justice Scoreboard, making blockchain-based tools widely available requires further attention to improve the quality of courts and prosecution services through blockchains and the deployment of AI. [13] In the Czech Republic, only the Constitutional Court enables online viewing for attorneys after registration in an internet application. The Supreme Administrative Court and some public administration authorities send parts of the file on the requirement.

Before the pandemic, Czech courts used video conferences to hear witnesses unable to attend the courtroom due to being on the other continent or very ill. Courts cancelled scheduled hearings at the pandemic's beginning, and the criminal proceedings were limited to urgent matters. Little by little, judges started to organise video court proceedings. Still, the parties provided evidence by email or paper by registered post. The pandemic proved that judiciary digitalisation is at the beginning. The advocates, as private subjects, moved forward much quicker, using cloud storage and remote consultations with clients daily. Nevertheless, the systems are incompatible, and the medical records are still being printed and scanned for online communication. Unprotected data circulate in cyberspace and could be easily misused. So, digital medical evidence becomes unreliable because of its transformation into a paper file. The burden of misconduct and malpractice proof is often moved to the defendant, as the plaintiff considers the healthcare provider (defendant) violated the obligation to maintain medical documentation properly.

CONCLUSION

The transition from voluntary to the compulsory use of AI and web or mobile applications for medical professionals, providers, and patients generates the main risk for privacy protection. Despite this, the diagnosis error rate is almost the same as in the cases of "simple" human evaluation of available information. [14] One of the challenges is that some professionals and patients could be excluded from receiving the appropriate medical care because they could not use modern technologies or simply because of poor mobile network coverage in certain areas. Suppose the health insurance, responsible for health services, is publicly financed. In that case, the public authorities must take care of the internet access and assist users who cannot reach their respective medical care. However, the main issue is and will be, in the next future, the education of medical professionals, public administration, lawyers, patients and their relatives to cope with new problems. The global digital society, as well as new imminent pandemic threats, bring new challenges. The right to health is a fundamental human entitlement, the specific

character determined by the boundaries of the legal regulations and interpretations of all fundamental human rights. [15]

The legal order of current social states must be resilient on the one hand. On the other hand, it must steadily balance the protection of the rights of individual patients and protecting societal health, even under exceptional and, so far, unknown circumstances. The interdisciplinary nature of medical law and the sometimes conflicting interests of the parties involved may cause tension between proponents of traditional approaches in medicine and law and supporters of technological approaches**.** Despite the increasing attention that blockchain, cloud technologies and remote access receive, it will be inevitable to examine the impact on court procedures and the rights of procedural parties. Unless a common trustworthy platform for sharing digital evidence, especially medical records, would not be created, hearing the evidence in medical malpractice cases would be much more the play of medical experts. The judge and the procedural parties will be just the audience with an advisory voice.

REFERENCES

[1] Phone Anxiety in the Age of Coronavirus: Telephone phobia, April 8, 2020. https://www.claritychi.com/phone-anxiety-telephone-phobia-phone-anxiousness/

[2] Mittelstadt, B. Designing the Health-related Internet of Things: Ethical Principles and Guidelines. UK. Information 2017, 8(3), p. 77. https://www.mdpi.com/2078-2489/8/3/77 https://doi.org/10.3390/info8030077.

[3] Sovová, O. Healthcare in the Era of Digitisation: Legal Possibilities, Limits, and Borders' Czech Republic. Common Law Review, 2020, p.33 - 35. HeinOnline. https://heinonline.org/HOL/License. www.commonawreview.cz.

[4] Global Blockchain in Healthcare Market. Focus on Industry Analysis and Opportunity Matrix – Analysis and Forecast, 2018-2025. https://bisresearch.com/industry-report/global-blockchain-in-healthcare-market-2025.html.

[5] What is blockchain technology? https://www.ibm.com/topics/what-is-blockchain.

[6] https://knowledge4policy.ec.europa.eu/foresight/digital-transformation-public-administration-services_en.

[7] Maher A.N. Agi, Ashish Kumar Jha. Blockchain technology in the supply chain: An integrated theoretical perspective of organisational adoption. International Journal of Production Economics, 2022.Vol 247, https://doi.org/10.1016/j.ijpe.2022.108458.

[8] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on

Human Rights and Biomedicine. https://rm.coe.int/CoERMPublicCommon SearchServices/DisplayDCTMContent?documentId=090000168007cf98.

[9] https://eufordigital.eu/wp-content/uploads/2020/09/EU4Digital-eHealth-Factsheet.pdf.

[10] Koutecký, J. Problems and Paradoxes in Medicine at the Turn of the Century. Germany. In: Hofmeister, H. Der Mensch als Subjekt und Objekt der Medizin. Germany, 2000. p. 30. 2000.

[11] Šustek, P., Holčapek, T., et all. Zdravotnické právo. Czech Republic. 2017, pp 232-262.

[12] Available in Czech on www.usoud.cz.

[13] https://ec.europa.eu/info/sites/default/files/eu_justice_scoreboard _2021.pdf

[14] Brdička, R. Artificial intelligence and modern information and communication technologies entering medicine. Czech Republic, Čas.Lék.čes. 158: 2019, p 87.

[15] SOVOVÁ, O. Current Research Issues in Regarding Health as a Fundamental Human Right. Czech Republic Faculty of Law Research Paper No. 2017/III/2. ttps://ssrn.com/abstract=3046484