Applications of Artificial Intelligence in Healthcare as an Example of Innovative Public Governance after the Pandemic Crisis: Regulatory Solutions in the European Union's Integrated Structures

Sebastian Sikorski, Michał Florczak

Abstract: Artificial intelligence (AI) has become a transformative force in the field of healthcare, with the potential to significantly improve the quality of patient care and speed up the process of diagnosis and treatment, resulting in more efficient use of medical staff time. However, it should be emphasized that the application of AI technologies in healthcare is a huge opportunity, but can also be seen as a threat. In the opinion of the authors, in addition to defining the principles of responsibility, an absolutely crucial issue is to regulate the principles of supervision of AI-qualified solutions. When using such solutions in healthcare, the absolute priority should always be to leave the final decision – through the supervision performed – in the hands of a human.

The chapter also formulates a kind of 'working hypothesis' that so-called AI with consciousness is a matter of time and, when it appears, the law will have to cope with it. That is why the authors believe it is so important to react quickly to technological progress by monitoring it. In the case of AI, we are dealing with a situation in which the law laid down will have to keep up with technological progress and not just catch up with it, as is the case in other areas of life.

I. Introduction

Innovation can be looked at from a variety of perspectives – that is, innovations in public governance, in law-making, in resource management. In the context of public administration, innovations of a social nature are often considered, as a response to the changing functions of public administration. However, these trends cannot be viewed without a technological background. In the case of the recent pandemic crisis, it became clear that, in the eyes of decision-makers, solutions of a technological nature should appear not only at the national level, but also at the EU level.

The ageing of the population and the increasing shortage of healthcare professionals in developed countries are encouraging societies to look for new solutions to support healthcare professionals and automate the caring

process. This phenomenon, as well as the recent years of the Covid-19 pandemic, have had a significant impact on the development of new technologies in medicine, which contribute to improved efficiency and, ultimately, better patient care.[1] Artificial intelligence (AI) has become a transformative force in healthcare, with the potential of revolutionizing the way healthcare services are provided and received. AI is a tool that is increasingly used in the healthcare sector. Advanced algorithms, data analysis and machine learning mean that artificial intelligence offers physicians innovative tools, which can significantly improve the quality of patient care and accelerate the diagnostic and treatment process. The use of AI solutions in healthcare can fundamentally improve the quality and accessibility of healthcare services for patients, especially through support in diagnosis and more efficient use of the work time of the healthcare professionals, which became particularly noticeable – and necessary – during the Covid-19 pandemic. However, it should be emphasized that the application of AI technology in healthcare is a huge opportunity, but also a threat, and this is how this matter should be objectively viewed.

The use of deep learning algorithms based on neural networks is emphasized in the literature.[2] AI algorithms were initially most frequently used in radiology for diagnostic imaging purposes, where there has been remarkable progress in image recognition tasks.[3] The discussion is currently focusing on the use of AI for patient consultations, where the support of physicians in analysing symptoms of patients and the results of additional tests during consultations (differential diagnosis) is becoming the challenge. Several tools which can serve this purpose are already available on the market. Infermedica, which facilitates initial medical diagnosis and patient management, can be given here as an example,[4] whereas these algorithms do not yet take into account the analysis of variances found in physical examinations and the results of additional tests (e.g. laboratory test results,

1 Adam Bohr and Kaveh Memarzadeh (eds), *Artificial Intelligence in Healthcare Data* (Academic Press 2020).

2 Kacper Niewęgłowski and others, 'Applications of Artificial Intelligence (AI) in Medicine' (2021) 27 Medycyna Ogólna i Nauki o Zdrowiu 213 <https://doi.org/10.26444/monz/142085> accessed 27 March 2024.

3 Ahmed Hosny and others, 'Artificial Intelligence in Radiology' (2018) 18 Nature Reviews Cancer 500 <https://doi.org/10.1038/s41568-018-0016-5> accessed 27 March 2024.

4 Infermedica.com (2023), available at <https://infermedica.com> accessed 27 March 2024.

ultrasound, etc.). The Glass Digital Notebook, which can significantly help physicians in differential diagnosis and in establishing a treatment plan, is also as an example of another application.[5]

The pandemic crisis provided a particular impetus for the introduction of public management solutions based on modern technology. In many cases, crises have the power to accelerate the development of institutional structures and regulatory solutions. In the following section, the case of artificial intelligence solutions applied to management in the health system will be used as a case study to analyse such processes of the evolution of post-crisis governance.

This section will be divided into two parts as a result of its interdisciplinary nature, whereby the first part illustrates the medical perspective that identifies possible applications of AI technologies, indicating the opportunities and threats. In the second part, the legal part, the analysis will focus on the proposal of a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending certain Union legislative acts (the so-called AI Act),[6] which is of key importance in this area. The discussion will be summarized with conclusions from both areas.[7]

II. The application of artificial intelligence in medicine – searching for innovative solutions

As mentioned in the introduction, significant developments in AI algorithms were made during the Covid-19 pandemic. According to Alberto Gerli et al., ChatGPT became a valuable tool for monitoring the pandemic. ChatGPT's ability to process large amounts of data and provide relevant information means it has the potential to provide precise and timely guidance and support for decision-making processes to reduce the spread and impact of the pandemic. Simultaneously, AI algorithms can also be used in crisis

5 Glass.health (2023), available at <https://glass.health> accessed 27 March 2024.

6 COM (2021) 206 final of 21 April 2021.

7 The section refers to the conclusions of a report commissioned by the Polish medical chamber: Maria Libura, Tomasz Imiela and Dagmara Głód-Śliwińska (eds), *Cyfryzacja zdrowia w interesie społecznym* (Okręgowa Izba Lekarska w Warszawie 2023) <https://izba-lekarska.pl/wp-content/uploads/2023/05/OIL_Cyfryzacja_raport_07042023.pdf> accessed 27 March 2024.

management, which would allow for the better planning of appropriate efforts and resources in the case of future epidemics.[8]

II.1. Exploring technological innovation during the Covid-19 pandemic crisis

During the Covid-19 pandemic, AI started to affect almost every aspect of healthcare, from clinical decision support, through self-treatment of chronic diseases at the patient's home, to drug research. Machine learning algorithms can detect patterns and anomalies in data, which can help diagnose diseases at an early stage, before the patient starts to notice the symptoms. For example, AI systems can help detect susceptibility to diabetes, cancer or heart disease based on an analysis of the patient's data and lifestyle. Its significant contribution to the improvement of efficiency and the automation of many of the processes related to patient care is highlighted, which materially translates into greater time savings.[9] This potential has already been noticed by a number of technology companies, such as Google, Meta, Microsoft, Amazon and Apple, which are investing billions in health research using their proprietary data to understand human diseases, while financing data studies and central nervous system research to support developments in artificial intelligence.[10]

Physicians spend too much time writing out medical records and operating various computer systems during patient consultations.[11] A lack of time devoted to the patient and numerous responsibilities related to creating medical records are common causes of professional burnout among healthcare professionals. Professional burnout among physicians is an insufficiently recognized and under-reported problem, which increased significantly in the era of the Covid-19 pandemic and has frequently contributed to poorer results of treatment. The problem could affect as many as over

8 Alberto G Gerli and others, 'ChatGPT: unlocking the potential of Artificial Intelligence in COVID-19 monitoring and prediction' (2023) 65 Panminerva Medica 461.

9 Thomas Davenport and Ravi Kalakota, 'The potential for artificial intelligence in health-care' (2019) 6 Future Healthcare Journal 94.

10 Paul Webster, 'Big tech companies invest billions in health research' (2023) 29 Nature Medicine 1034.

11 pulsmedycyny.pl (2022), available at <https://pulsmedycyny.pl/biurokracja-kradnie-lekarzom-czas-a-chorzy-czuja-sie-zaniedbani-gdzies-pomiedzy-sa-pielegniarki-raport-1151512> accessed 27 March 2024.

60 % of healthcare professionals. If it is not recognized in time, the costs to the healthcare system could be huge.[12] Therefore, there are high hopes that artificial intelligence technology will improve all aspects of healthcare, including, primarily increasing efficiency by saving time for physicians in individual administrative processes. It is expected that the time that AI helps save can be used to improve the doctor-patient relationship. AI could support the physician in the process of creating medical records based on the medical history previously collected from the patient, in the analysis of additional tests, as well as in the differentiation process. Additionally, support in issuing various documents such as medical certificates or temporary disability certificates or in the prescribing process could be important. The possibility of applying AI solutions in the healthcare system of the EU member states will accelerate governance processes in the health service and has been directly understood as an innovative improvement for many years, as part of the digitizing processes of public administration.

The analysis of medical data and information from the patient's electronic records enable AI systems to suggest personalized treatment plans, recommending appropriate drugs and dosages, taking into account interactions with other drugs, as well as the patient's possible reactions to the substances that are administered. Software supporting physicians is already appearing on the market; this is referred to as 'second diagnosis'. The physician enters the patient's symptoms, variances in the physical examination and additional tests into the system and, on this basis, the computer software formulates a diagnosis and proposes treatment.[13] According to the research, these tools are coping increasingly better with the analysis of large amounts of medical data, on the basis of which they present correct diagnoses. However, the treatment proposed by the AI algorithm does not yet take into account many aspects, such as the guidelines in force in the given EU Member State and psychological issues related to the patient's compliance with the recommendations. It does, however, efficiently analyse the drugs recommended by the physician for possible interactions.[14]

The role of empathy, which directly affects the doctor-patient relationship, as compliance and therefore, long-term results is emphasizsed within

12 Brian E Lacy and Johanna L Chan, 'Physician Burnout: The Hidden Health Care Crisis' (2018) 16 Clinical Gastroenterology and Hepatology 311.

13 Semantic Drug Search Demo (2023), available at <https://chpl-lvm3ln8z3-n1kodem-s-team.vercel.app> accessed 27 March 2024.

14 ibid.

the framework of patient care. Better long-term results mean an improved prognosis and a longer life. Various authors believe software using AI is an important innovation generated through better compliance, as it will allow the physician to develop this relationship through significant time savings. However, the impact of large-scale deployment of AI algorithms in this process is unclear and currently difficult to predict.[15]

In turn, sceptics argue that artificial intelligence could further dehumanize medical practice. AI tools lacking the pluralism of value could encourage a return to paternalism, but this time imposed by AI and not the physician.[16] Even so, the development of telemedicine consultations that took place in the era of the Covid-19 pandemic showed that the lack of a face-to-face relationship with the patient and the short time allocated to consultations can contribute to poorer compliance. Therefore AI tools which optimize the physician's time will allow the physician to build a better relationship with the patient and improve the results of treatment.

Another threat requiring a commentary may be economic pressures. The time AI will save for a physician during a patient's appointment can be used to 'push' more patients through the system, namely a so-called productivity improvement.[17] There is a danger that health centres which use AI models, driven by the desire to achieve better economic efficiency, will want to persuade doctors to see even more patients per hour. This will not translate into a better quality of patient care or the development of personalized medicine, but will contribute to the even greater dehumanization of the treatment process and a greater risk of errors. In such a case, the question should be asked of whether this would be the fault of applying AI or perhaps human nature, which would be driven by the desire to make even greater profits at the expense of the patients themselves. Therefore, the limitations preventing such practices from being implemented systemically should be addressed immediately. A solution to this problem could be the definition of patient paths, specifying the minimum consultation time that a physician should allocate to each type of consultation (e.g. 20 minutes for

15 Olivier Niel and Paul Bastard, 'Artificial Intelligence in Nephrology: Core Concepts, Clinical Applications, and Perspective' (2019) 74 American Journal of Kidney Diseases 803.

16 Aurelia Sauerbrei and others, 'The impact of artificial intelligence on the person-centred, doctor-patient relationship: some problems and solutions' (2023) 23(1) BMC Medical Informatics and Decision Making 73.

17 Robert Sparrow and Joshua Hatherley, 'High Hopes for 'Deep Medicine'? AI, Economics, and the Future of Care' (2020) 50(1) Hastings Center Report 14.

a first appointment, 15 minutes for an infection appointment, 30 minutes for an appointment for a patient with multimorbidity, 20 minutes for a prophylaxis appointment, etc.). The qualification of a patient for a specific type of appointment is an innovative solution which emerged during the Covid-19 pandemic and enabled treatment to start earlier, often while still asymptomatic.

The technology-enabled procedure started in Poland as early as during the process of writing out e-prescriptions. Technology and the lack of effective control enabled so-called 'prescribing machines' to appear on the market during the Covid-19 pandemic, through which patients received an e-prescription without going on an appointment to see a physician, but purely after completing a questionnaire. As a result, a physician could automatically issue dozens of such prescriptions per hour. This activity is currently being generally criticized by numerous organizations, which draw attention to the need to eliminate abuse without denying the positive effects of digital transformation.[18]

In turn, there have been numerous abuses in the USA in the past in the prescription of analgesics, including strong-acting analgesics. The introduction of an e-prescription system in which the prescription is directly sent to pharmacies has significantly reduced the scale of this procedure.[19]

II.2. New trends in patient care

A key aspect of patient-centric care is the involvement of patients in the treatment process and their ability to make decisions about their health. The patient's increasing autonomy through his or her involvement in decision-making processes is a strong objection to the outdated paternalistic model of care.[20] Some AI tools can already contribute to an increase in patient autonomy if only through patient education. AI can be a useful tool in educating patients about their diseases, treatments and ways of staying healthy. Interactive platforms and access to the medical knowledge

18 rx.edu.pl (2023), available at <https://rx.edu.pl/zdalne-wystawianie-e-recept-stanowisko-organizacji-branzowych> accessed 27 March 2024.

19 <www.kaliskleiman.com/are-electronic-prescriptions-safer.html> accessed 27 March 2024.

20 Madison K Kilbride and Steven Joffe, 'The New Age of Patient Autonomy: Implications for the Patient-Physician Relationship' (2018) 320 Journal of the American Medical Association 1973.

base enable patients to better understand their conditions and better cooperate with the physician in the treatment process. According to Milda Žaliauskaite, an effective way of ensuring patient autonomy is to implement legal instruments such as informed consent, advance directives and so-called Ulysses contracts (a term used in medicine, especially with respect to advance directives.[21]

Remote patient monitoring systems using AI tools enable continuous tracking of the health parameters of patients. Devices worn by patients, such as smartwatches, sensors in the form of wristbands or rings and various mobile applications, collect real-time data on vital signs, activity levels and many other parameters. AI algorithms analyse this data to provide valuable information to physicians about the health trends of their patients and early warning signs of potential complications. Remote patient monitoring can enable patients to proactively pursue self-care, while enabling physicians to conduct more proactive tasks based on prophylaxis and early detection of diseases. Personalized patient care provided through telemonitoring is an innovation that evolved in the era of the Covid-19 pandemic and can significantly improve clinical practice, so it can be seen as an innovative solution which modernizes existing forms of governance.

On the one hand, certain devices used for monitoring heart failure, atrial fibrillation and cardiac rehabilitation constitute an inexpensive, non-invasive or minimally invasive approach to long-term monitoring and management in these areas. On the other hand, the availability of big data constitutes a useful tool for predicting the development and outcome of many cardiovascular diseases. In summary, the new targeted therapy enables the physician to quickly provide personalized and tailored treatment, while patients feel safe because they are constantly being monitored, which has a significant psychological effect.[22] However, the doctor-patient relationship should always remain a key element of care.

In addition, mobile apps used by patients for self-monitoring (collecting any form of health data) using AI mechanisms can increase their autonomy,

21 Milda Žaliauskaitė, 'Role of ruler or intruder? Patient's right to autonomy in the age of innovation and technologies' (2021) 36 AI & Society 573 <www.springerprofessional.de/en/role-of-ruler-or-intruder-patient-s-right-to-autonomy-in-the-age/18275722> accessed 27 March 2024.

22 Valeria Visco and others, 'Artificial Intelligence as a Business Partner in Cardiovascular Precision Medicine: An Emerging Approach for Disease Detection and Treatment Optimization' (2021) 28 Current Medicinal Chemistry 6569 <https://doi.org/10.2174/0929867328666201218122633> accessed 27 March 2024.

which contributes to the shift in the doctor-patient relationship towards one in which both parties have a balanced distribution of rights and duties, and therefore an equal input into participation into the decision-making process.[23]

Healthcare organizations have to address a number of challenges to effectively implement AI solutions, including: i) gaining a better understanding of the technology and limitations of the given AI model, ii) defining the strategies for integrating various AI technologies into existing care systems to effectively resolve the most pressing issues currently facing healthcare organizations, iii) quickly filling the shortfall of well-trained professionals for implementing AI, who are lacking in many healthcare entities throughout Europe, iv) fixing the incompatibility of AI technologies with older infrastructure, and v) giving access to good and diverse medical data for training machine-learning algorithms.[24] For example Vishal Sikka claims the lack of well-trained professionals for developing AI algorithms in this context is a major problem. It is estimated that there are only 20,000–30,000 people in the world working on these issues.[25]

Although machine learning has achieved great success in areas using medical imaging and big data, it is not a universal solution. AI is less applicable in cases where multiple aspects need to be taken into account from various areas, e.g. not only data regarding the given specialization, but also other circumstances, such as the patient's preference for a specific type of treatment. This arises from the fact that machine learning relies on computational power and huge amounts of data for identifying superficial patterns and correlations. Therefore, it is unable to take full account of causal relationships or a clear understanding of the full phenomenon being

23 Meghan McDarby and others, 'Mobile Applications for Advance Care Planning: A Comprehensive Review of Features, Quality, Content, and Readability' (2021) 38 American Journal of Hospice and Palliative Care 983 <https://doi.org/10.1177/1049909120959057> accessed 27 March 2024.

24 Mei Chen and Michel Decary, 'AI in Healthcare: From Hype to Impact' (Workshop presented at ITCH 2019: Improving Usability, Safety and Patient Outcomes with Health Information Technology, Victoria, British Columbia, Canada, 14 February 2019) available at <https://de.slideshare.net/MeiChen39/ai-in-healthcarefrom-hype-to-impact> accessed 27 March 2024.

25 <www.zdnet.com/article/ai-experts-are-in-short-supply-thats-making-the-skills-crisis-worse> accessed 27 March 2024.

studied. This process can then lead to errors generated by AI algorithms, which are difficult to reverse.[26]

The American Medical Association defined the role of AI in healthcare as so-called 'augmented intelligence', stating that artificial intelligence will be designed and used to augment and not replace human intelligence. This view emphasizes the human-machine partnership, which has significant implications for the use of artificial intelligence in healthcare.[27]

If a physician works with AI, this does not mean that this tool can be used on its own. The appropriate level of supervision to be exercised by a person over AI must be defined appropriately early. In certain cases, such as the identification of the population of the at-risk groups which should qualify for vaccination or the use of a chat bot to show a patient how to properly administer an insulin injection, the level of automation may be higher (human oversight lower) than for processes in which such supervision should be high (e.g. increasing clinical efficacy in the differential diagnosis process).[28]

III. Legal regulation at the European Union level

We are still currently at the stage of designing the legal regulation of artificial intelligence at the level of European Union law, in the form of a regulation of the European Parliament and of the Council, which will automatically enter into the legal orders of the EU Member States, on the basis of the provision of Article 288 in connection with Article 114 of the Treaty on the Functioning of the European Union.[29] Article 114 TFEU provides for the adoption of measures to ensure the establishment and functioning of the internal market.

The *ratio legis* itself of the adoption of AI legal solutions needs to be especially emphasized at the level of European law. On the one hand, the

26 Mei Chen and Michael Decary, 'Artificial intelligence in healthcare: An essential guide for health leaders', (2020) 33 Healthcare Management Forum 10 <https://doi.org/10.1177/0840470419873123> accessed 27 March 2024.

27 American Medical Association (2023), available at <www.ama-assn.org/press-center/press-releases/ama-adopts-policy-calling-more-oversight-ai-prior-authorization> accessed 27 March 2024.

28 Chen and Decary, 'Artificial intelligence' (n 26).

29 Treaty on the Functioning of the European Union [2016] OJ C202/47, hereinafter: TFEU.

legal framework laid down precisely at the level of the European Union can ensure a level playing field and protection of citizens while, on the other hand, it can strengthen Europe's industrial competitiveness in this area by increasing the power to influence the shape of the AI regulations at global level.[30] It should simultaneously be noted that some EU member states are considering introducing legislation on this at national level, which, as a result, can prevent the free trade of AI-enabled goods and services, cause the fragmentation of the common market and even the loss of competitiveness in this area, especially with respect to the USA and China. Of course, the literature simultaneously also emphasizes the need for cooperation and the exchange of experiences at national levels.[31]

III.1. EU policy strategy for artificial intelligence system

A good example of shaping EU strategies to increase innovation in public management is the Europe's Digital Decade: Digital Targets for 2030 policy programme, which has been proposed at EU level.[32] This programme contains specific targets and objectives for 2030, and will set the direction of Europe's digital transformation. The Commission will pursue these targets and objectives through specific terms, namely projected trajectories at EU and national level, with key performance indicators to track progress in this area.

Strategies of a political nature are embedded in specific legislative initiatives. The act of law of key importance here, and consequently the reference point for further considerations, is the proposed regulation of the European Parliament and of the Council laying down harmonised rules on artificial

30 Karol Rębisz, 'Wybrane zagadnienia prawa cywilnego w propozycjach regulacyjnych dotyczących sztucznej inteligencji w Unii Europejskiej' (2021) 10 Europejski Przegląd Sądowy 22 <https://sip.lex.pl/komentarze-i-publikacje/artykuly/wybrane-zagadnienia-prawa-cywilnego-w-propozycjach-regulacyjnych-151397066> accessed 27 March 2024.

31 Reinhard Busse and others (eds), *Improving healthcare quality in Europe: Characteristics, effectiveness and implementation of different strategies* (World Health Organization 2019).

32 See <https://digital-strategy.ec.europa.eu/en/policies/europes-digital-decade> accessed 27 March 2024.

intelligence (Artificial Intelligence Act) and amending certain Union legislative.[33]

According to the provision of Article 3(1) of the Draft, '"artificial intelligence system" (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with.'

Therefore the wording of Annex I itself is inherent to the definition, stating that 'techniques and approaches' include: '(a) machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning; (b) logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems; (c) statistical approaches, Bayesian estimation, search and optimization methods.'[34]

Such an approach has several implications. First of all, the definition also encompasses machine learning with a distinction between supervised learning, unsupervised learning and learning using a wide range of methods, including deep learning. Given the current state of development of solutions in the healthcare sector, such a broad view can be assessed as being positive. However, the proposed definition already has certain noticeable shortcomings. This is because the indication that its scope also includes 'logic- and knowledge-based approaches' means that a significant amount of software already in use may be included in such solutions.[35] It does not seem as if this was the intention of the drafters. Simultaneously, the definition itself differentiates between supervised and unsupervised machine learning.

Such a definition of artificial intelligence can be considered broad. It includes not only software based on machine learning mechanisms, but also,

33 COM (2021) 206 final, hereinafter: Draft. On July 12, 2024, the Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) was published in [2024] OJ L 1/144.

34 Monika Kupis, 'Stosowanie przepisów Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2017/745 do sztucznej inteligencji' (2022) 4(1) Przegląd Prawa Medycznego 101 <https://przegladprawamedycznego.pl/index.php/ppm/article/view/136> accessed 27 March 2024.

35 ibid 102.

for instance, knowledge bases and search methods, which in themselves do not necessarily have anything to do with artificial intelligence. However, in a way, by including the techniques and approaches specified in Annex I to the Draft, the intention is for the definition of AI to be periodically updated. At this point, it should be assumed that the need for modification will not only apply to the definition itself, but also the holistic view as the technology develops.

Article 3(1) of the Draft stipulates that the artificial intelligence system means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations or decisions influencing the environments they interact with.[36]

Although the matter of supervision is the subject of a separate regulation in Article 14 of the Draft, it is worth pointing out that it would be reasonable to emphasize that ultimate human supervision must be exercised in any solution that is qualified as AI. This aspect is also considered crucial by the European Economic and Social Committee, which emphasizes the need to keep certain decisions exclusively within the responsibility of humans, especially where 'these decisions involve moral aspects and legal consequences or an impact on society,' such as healthcare.[37]

The doctrine distinguishes between narrow AI systems, namely those that can perform one or several specific tasks, and general AI, referred to as superintelligence or self-conscious AI. Indeed, at the current level of technological development, we are dealing with narrow AI solutions. However, it is difficult to agree with the assertion that conscious AI is currently purely a certain hypothesis, and that even such strong AI will perhaps never arise.[38]

36 ibid 101.

37 Opinion of the European Economic and Social Committee on Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts [2021] OJ C517/61, 1.9.

38 Małgorzata Dumkiewicz, Katarzyna Kopaczyńska-Pieczniak and Jerzy Szczotka (eds), *Sto lat polskiego prawa handlowego. Księga jubileuszowa dedykowana Profesorowi Andrzejowi Kidybie* (vol 2, Wolters Kluwer Polska 2020).

III.2. High-risk AI systems

It seems that the question of further development of artificial intelligence is only related to time and not to the question of whether it will happen. In this regard, specific solutions for high-draw AI systems have emerged in the regulatory proposal. The wording of Article 6 of the Draft presents the classification rules for high-risk AI systems, simultaneously – importantly – emphasizing the connection between AI solutions and separate products. The identification of high-risk systems and the classification of AI technology used in the healthcare sector into precisely this group is of particular importance here. This is because it is in this area that the highest values, such as human health and life, are protected. The drafters themselves also point this aspect out in recital 28 of the Draft, emphasizing that AI systems could produce adverse outcomes to health and safety of persons, referring this threat, among other things, to the health sector, 'where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate.'

Taking into account recognized standards or common specifications, the need for event logging in the case of high-risk systems, as specified in Article 12 of the Draft, also needs to be highlighted. By assumption, event logging is also intended to enable the monitoring of the performance of a high-risk artificial intelligence system for situations that can result in an artificial intelligence system posing a risk in the meaning of Article 3(19) of Regulation (EU) 2019/1020.[39] A certain reservation appears here, because the definition contained in this provision refers to a 'product presenting a risk', meaning a potentially adverse effect, among other things, on health. In the context of event logging, it is worth mentioning that the authors of this article already postulated the need to create a public register of AI solutions operating in healthcare at the level of the individual EU Member States in 2019.[40]

39 Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) 765/2008 and (EU) 305/2011 [2019] OJ L169/1.

40 Michał Florczak and Sebastian Sikorski, 'Sztuczna inteligencja w medycynie – nowe wyzwanie w obszarze regulacji administracyjnoprawnej' in Irena Lipowicz, Ewelina Nojszewska and Sebastian Sikorski (eds), *Innowacje w ochronie zdrowia: Aspekty prawne, ekonomiczne i organizacyjne* (Wolters Kluwer Polska 2020).

Article 3(15) of the Draft emphasizes that the instructions for use should 'inform the user, in particular, of an AI system's intended purpose and proper use, inclusive of the specific geographical, behavioural or functional setting.' Article 13 of the Draft contains the requirements for transparency and the provision of information to users. Transparency is intended to enable users to interpret the results of the operation of the system, which is related to specific obligations of the user and the provider. This provision emphasizes the requirement for high-risk AI systems to be accompanied by instructions for use containing 'concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.' This naturally gives rise to the question of the extent to which this assumption will be realistic in practice, given the complexity of AI solutions, which will also be of significance to the scope of responsibility.

In the context of the above comments on the need for human control of AI solutions, the principles of human supervision of AI solutions are of key importance. The wording of recital 48 of the Draft very clearly emphasizes the need to design and develop high-risk AI solutions so that a human can effectively supervise their operation. Therefore, it is up to the provider to specify the appropriate measures in this respect, even before these solutions are placed on the market or put into service. This refers, in particular, to solutions involving 'in-built operational constraints', which AI is unable to bypass on its own and must react to the actions of the system's human operator. A consequence of the supervision described in this way is the wording of the provision in Article 14 of the Draft.

High-risk AI systems are specifically highlighted in Article 14 of the Draft, as their design and development must include appropriate 'human-machine interface tools' which ensure that they can be effectively overseen. This supervision involves the prevention or minimization of risks to health, safety or fundamental rights, under the assumption that the high-risk AI system is used in accordance with its intended purpose or – as should be particularly emphasized – in conditions of reasonably foreseeable misuse.

In this context, it is primarily worth drawing attention to the supervision aspect. The supervision is exercised through the designed and developed solutions mentioned above, i.e. even before the system is placed onto the market or put into service. Simultaneously, the supervision should provide sufficient information to the people exercising this supervision so that they understand the full capabilities and limitations of the high-risk artificial intelligence system that they are supervising and to catch signs of anomalies, malfunctions or unexpected results of operation as quickly as possible

under the given circumstances. The supervisors should be critical of over-reliance on the results of operation of the high-risk artificial intelligence system (so-called automation bias) and should correctly interpret the result of the operation of such a system.

Recital 53 of the Draft specifies the principles of liability, according to which not only is the person who designed or developed the high-risk AI system liable for its placement onto the market or for putting it into service, but so are its suppliers. This is because, according to Article 24 of the Draft, in the case of high-risk AI systems which are related to products to which the acts of law referred to in Annex II, Section A apply, the producer of the product is liable and subject to the same obligations as those imposed on the supplier. In turn, according to Article 26 of the Draft, in the case of these systems, importers must ensure that the conditions of their storage and transportation do not create a threat to their compliance with the specified requirements. The obligations of distributors are specified in Article 27 of the Draft, whereby, in the case of high-risk AI, it is the distributor who is responsible, in particular, for the CE conformity marking, but also for ensuring that the conditions of storage and transportation do not create a threat to the compliance of the system with the requirements specified in the Draft.

In the case of AI solutions in healthcare, it is this aspect that makes liability stricter, which is particularly important because of the subject matter of the protection, i.e. human life and health. The identification of the entities responsible for implementing AI solutions and defining the scope of this responsibility is a key condition of the functioning of these solutions in practice.

An extremely important and simultaneously very interesting solution for the development of AI is the adoption of so-called regulatory sandboxes (Article 53 of the Draft), which should be understood as a 'controlled environment' established by one or more Member States 'that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service.' At this stage, it is the participants of these regulatory sandboxes who are responsible for any damage caused by the experiments being conducted. It is therefore a controlled environment – with defined rules, including rules regarding liability – in which AI solutions can be safely tested. It can be said that such an approach by the European regulator is doubly innovative. This is because, on the one hand, the Draft in question applies to solutions of the

highest IT and technological complexity, which AI solutions are and will be, whereas, on the other, it is a new legislative approach.

IV. Conclusions

AI tools should be an integral component of the patient pathway to clinical decision support at the time of diagnosis. This process will help the physician base the diagnosis on the analysis of a large amount of clinical data that he is currently unable to analyse on his own. This would be an important innovation which would significantly reduce the number of medical errors made by physicians. An example of the use of AI in everyday clinical practice could be the PMcardio application, which physicians use to analyse ECG tests. By uploading an image of the test to the application, the physician very quickly receives a write-up of the test with a proposal of further treatment – in fact, something like a second diagnosis by a physician.[41]

In recent years, certain machine learning algorithms proved to be reliable for detecting and diagnosing diseases. Many such algorithms have received the approval of the U.S. Food and Drug Administration (FDA) for their safe use in healthcare.[42] Furthermore, conduct would be fully in line with the latest EBM guidelines (e.g., in the case of infections of the upper respiratory tract, AI could verify the recommendation of antibiotic therapy in real time). The use of AI solutions would also serve to better optimize costs while maintaining good quality of care.

The development of AI-based or AI-enabled solutions results in the need to prepare an appropriate legal regulation.[43] At European Union level, we have seen increased activity in this area in recent years, as the EU tries to maintain its technological leadership position while ensuring that new technological solutions respect EU principles and values. The result of this activity, which is the subject matter of the analysis, is the proposal of the regulation of the European Parliament and of the Council laying

41 Jelle CL Himmelreich and Ralf E Harskamp, 'Diagnostic accuracy of the PMcardio smartphone application for artificial intelligence-based interpretation of electrocardiograms in primary care (AMSTELHEART-1)' (2023) 4 Cardiovascular Digital Health Journal 80.

42 Bertalan Mesko, 'The Top 10 Health Chatbots' (*The Medical Futurist*, 1 August 2018) <https://medicalfuturist.com/top-10-health-chatbots/> accessed 27 March 2024.

43 Andrzej Matan (ed), *Administracja w demokratycznym państwie prawa: Księga jubileuszowa Profesora Czesława Martysza* (Wolters Kluwer Polska 2022).

down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts. It is precisely from the point of view of this draft that the key issues regarding the regulation of AI in healthcare will be identified. The Covid-19 pandemic perfectly demonstrated the requirement for the application of IT/technological solutions in healthcare. This is because the use of technology will enable the effective use of the potential of healthcare staff. AI solutions can seriously intensify these applications.

The application of AI technology in healthcare is a huge opportunity, but also a threat, and this is how the matter should be objectively viewed. The development of AI-based or AI-enabled solutions results in the need to prepare an appropriate legal regulation. It is very important that the proposed legal solutions are introduced at European Union level, with the intention of ensuring the free trading of goods and services using AI technologies and removing the threat of fragmentation of the common market, which would be the case if different solutions were introduced in individual national legal orders. Therefore, on the one hand, the regulation of AI solutions at EU level is intended to ensure a level playing field and protection for citizens, while, on the other, it should strengthen Europe's industrial competitiveness in this area.

The Draft under review contains a definition of an 'artificial intelligence system', which also encompasses machine learning with a distinction between supervised learning, unsupervised learning and learning using a wide range of methods, including deep learning. However, given the stage of development of the AI solutions which are already operating in the healthcare sector, such a broad view should be considered positive. This proposed definition has some shortcomings, because its scope also includes 'logic- and knowledge-based methods', which can mean that such a solution also includes, to a large extent, software that is already in use, even though this was almost certainly not the objective of the drafters. However, already today, at the stage of designing legal solutions addressed to AI technologies, it should, be accepted that, with the development of technology, the definition of 'artificial intelligence system' – but also the whole of the regulation – will have to be modified, which means that the level of solutions of this technology will have to be monitored.

According to the authors of this article, other than defining the principle of liability, an absolutely fundamental issue is the regulation of the principles of supervision of AI-qualified solutions. This aspect is also especially emphasized by the European Economic and Social Committee, which

highlights the need to keep certain decisions exclusively in the hands of humans, especially where 'these decisions involve moral aspects and legal consequences or an impact on society', which is especially the case in the healthcare sector and the solutions used there.

In this light, the level of risk of individual solutions was very aptly differentiated. As already stated above, recital 48 of the Draft clearly emphasized the need to design and develop high-risk AI solutions so that a human can effectively supervise their operation, which is especially important in the healthcare sector. This is because, in this case, 'where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate.'[44] That is why it is so important to introduce solutions involving 'in-built operational constraints', which AI cannot bypass on its own and must react to the actions of the system's human operator. In the case of high-risk AI systems, the design and development itself must include appropriate 'human-machine interface tools' which ensure that they can be effectively overseen. This is especially justified because this supervision is precisely related to the prevention or minimization of risks to health, safety and fundamental rights. Therefore, the absolute priority is the need to always leave the final decision in the hands of a human through supervision.

At this point, reference should be made to the specific 'working hypothesis' formulated above that the so-called conscious AI is a matter of time and when it appears, the law will have to address it. Of course, it would currently be difficult to design legal regulations so far in advance. That is why it is so important to monitor technological progress in order to quickly address it. This is a situation in which the proposed law in this area will have to keep up with technological progress and not just catch up with it, as is the case in other areas of life.

A very important and simultaneously very innovative solution from the legal and legislative point of view is the adoption of so-called regulatory sandboxes,[45] which should be understood as a 'controlled environment' established by one or more member states 'that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service'. This is how a controlled environment was envisaged – with defined rules, including rules

44 Recital 28 of the Draft.
45 Art 53 of the Draft.

regarding liability – in which AI solutions can be safely tested, which will be very important for the development of AI.

However, AI brings not only opportunities but also threats. At this point, it is worth quoting Stephen Hawking, who stated that 'unless we learn how to prepare for, and avoid, the potential risks, AI could be the worst event in the history of our civilization.'[46] From the point of view of the healthcare sector, concerns are also highlighted in the literature as to whether the value of the research conducted on the basis of AI algorithms will take into account the complexity of the whole of the human body, as well as psychological issues that are extremely important in the doctor-patient relationship.[47] However, it should be accepted that the development of this technology and its application in medicine simply cannot be stopped. Consequently, what is positive in these solutions should be accepted and an attempt should be made to anticipate and eliminate the threats. The proposed legal regulation tries to address this matter.

46 Adam Jezard, 'AI Can Solve Problems – When Will It Tell Us Which Ones Need Solving Most?' (*World Governments Summit,* 11 July 2017) <www.worldgovernmentsummit.org/observer/articles/2017/detail/ai-can-solve-problems-when-will-it-tell-us-which-ones-need-solving-most> accessed 27 March 2024.

47 Johan EH Korteling and others, 'Human – versus Artificial Intelligence' (2021) 4 Frontiers in Artificial Intelligence no 622364 <www.frontiersin.org/articles/10.3389/frai.2021.622364/full> accessed 27 March 2024.