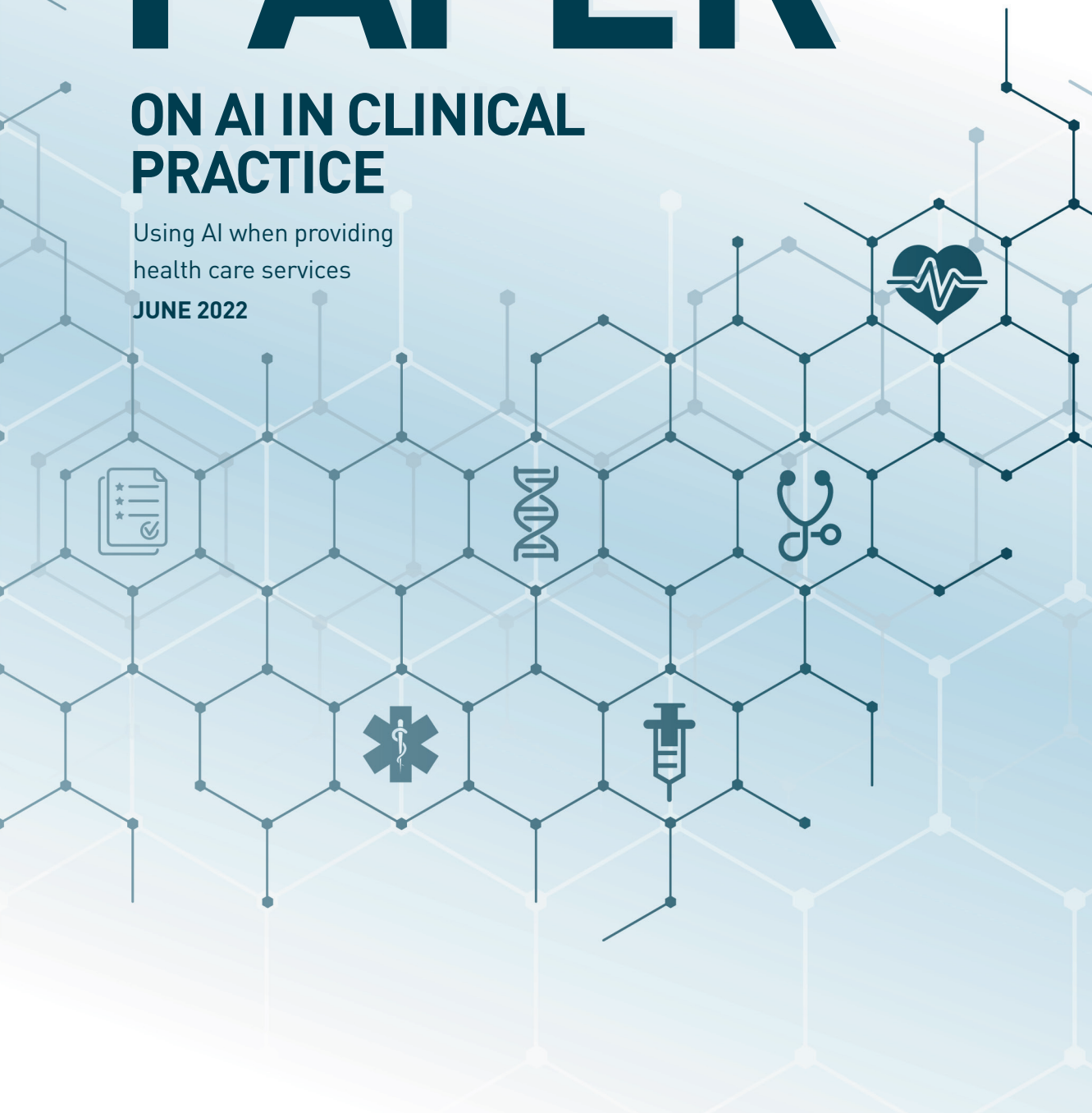
WHITE PAPER

ON AI IN CLINICAL PRACTICE

Using AI when providing health care services

JUNE 2022



Revision 1.0
Warsaw, June 2022
Publisher: wZdrowiu
www.aiwzdrowiu.pl
biuro@aiwzdrowiu.pl

WHITE PAPER

ON AI IN CLINICAL PRACTICE

The development of new technologies is currently very dynamic. **Innovative solutions are often ahead of the applicable regulations** and amendments to the law do not always keep up with them. This is particularly the case in the health sector. For example, less than a decade ago telemedicine was a novelty the legal admissibility of which was a subject of a debate. Today, it is already a legally regulated form of providing health care services widely used in the daily practice of patient care.

Another innovative technology with a potential to revolutionize clinical practice is artificial intelligence (AI). **AI algorithms feature increasing accuracy and effectiveness, thanks to which they can be a real help for health care professionals** (HCPs). This is confirmed by subsequent scientific studies and AI systems provide more and more promising results everyday. At the same time, the process of legal changes that would set the framework for the application of such solutions is still at a relatively early stage. Technology has once again overtaken legislation.

In order to maintain and support the development of AI in the Polish healthcare system under the current conditions, the **AI in Health Coalition** has been established. Bearing in mind the need signaled by the medical community to support responsible use of the potential of AI in the health care system in the current legal environment, which does not contain dedicated regulations in this area, we would like to present this document: the White Paper on AI in Clinical Practice ("White Paper").

The White Paper was written by the best experts in the fields of technology, law and medicine. It has also gone through a public consultation process, in which stakeholders offered their comments and other feedback on the content of the document.

We invite you to read the White Paper and join the discussion on the desirable direction of development of AI in medicine, on which the future of the health care system will depend.

Creators

AI W ZDROWIU

GRAI GRUPA ROBOCZA DS. SZTUCZNEJ INTELIGENCJI

PFSz Polska Federacja Szpitali

Partners

IQVIA

Microsoft

MEDICOVER

GRUPA LUXMED

Abbott

COMARCH Healthcare

Project coordinator:

Ligia Kornowska – leader of the AI in Health Coalition, Leader of the Working Group on AI for health issues, Managing Director of the Polish Hospital Federation

Authors:

Paweł Kaźmierczyk (ed.) – DZP Law Firm
Monika Kupis – DZP Law Firm
Małgorzata Maj – DZP Law Firm

Consultants:

Tomasz Jaworski – Director of Digital Transformation of the Public Sector, Microsoft
Monika Tomaszewska – Director of the Department of Strategy and Medical Innovation, Medical Division, Lux Med Group
Andrzej Osuch – Director for Business Transformation, Lux Med Group
Patryk Kuchta – Group Data Protection Manager, Medicover
Mateusz Łuczko – Associate Data Science & Advanced Analytics Director
Gabriela Sujkowska – Market Access Lead Poland & CEE Abbott Diabetes Care
Piotr Przygodzki – Director of Health Policy and Health Economics
Mateusz Hałdaś – Market Access Manager Poland & CEE
Jan Cybulski – Senior Market Access Specialist
Marcin Wiśniewski – Director of the AI / ML Production Center, Comarch

Scientific Council:

Jarosław J. Fedorowski – President of the Polish Hospital Federation, Chairman of the Scientific Council
Radosław Sierpiński – President of the Medical Research Agency
Paweł Kikosicki – Director of the e-Health Center
Piotr Węcławik – Director of the Innovation Department at the Ministry of Health
Hubert Życiński – Deputy Director of the Department of Innovation at the Ministry of Health
Jakub Adamski – Director of Strategy and Systemic Activities Department at the Office of the Patient Ombudsman
Doctor Artur Drobniak – Vice-President of the Supreme Medical Council
Michał Gontkiewicz – Member of the Regional Medical Chamber in Warsaw
Agnieszka Siennicka – Wroclaw Medical Univesity
Małgorzata Gałązka-Sobotka – Dean of the Center for Postgraduate Education and Director of the Institute of Health Care Management at Lazarski University
Sebastian Irzykowski – Vice-President of the Supreme Chamber of Nurses and Obstetricians
Paweł Krzesiński – Professor at the Department of Cardiology and Internal Diseases of the Military Medical Institute in Warsaw

TABLE OF CONTENTS

1. Executive summary

- AI is not a distant technology of the future but **various solutions available here and now, also for the healthcare sector**. The use of AI in clinical practice can involve many areas and be of diversified nature, provide a number of benefits, including, support and facilitation for medical and non-medical personnel – significantly improving the diagnosis process and accuracy in a shorter time.

- The current legislation does not contain any regulations dedicated to AI. The use of AI, as in the case of other innovative solutions, still raises a number of questions, concerns and uncertainties. **The White Paper identifies the key ones and attempts to answer them**.

1.1. The use of AI in healthcare

- A legal definition of AI has not yet been adopted (although legislative work is underway at the EU level). There are many definitions of AI. In simple terms, it can be assumed that it is a **software** that, based on previously accumulated knowledge and data, performs tasks assigned to it while improving itself on the go.

- **The process of developing a legal framework for the use of AI is underway**. Currently, AI can be legally used in clinical practice, but it should be remembered that the rules resulting from, among others, patient rights and requirements related to the performance of medical professions should be met.

- **Subject to the foregoing principles, AI in health care may be used by a number** of entities including individual medical practices, primary care facilities, clinics and hospitals, as well as research institutes, medical universities or R&D centers. The hitherto experience shows a number of benefits associated with the use of AI for medical staff, facilities and patients, including improvement of diagnostics, substantive support for clinical decisions, time savings for professionals, or better research opportunities.

- **AI is a strategic element of the development of the health care system**. Public policy on the development of AI is formulated at the European and national levels. The European Commission is proposing new rules (in particular the AI Act) to make AI systems used in the EU safe, transparent, ethical, impartial and human-controlled. In Poland, a Policy for the Development of AI is under development, which assumes the use of this technology also in the health care system.

1.2. Using AI with respect for patients' rights

- **When using AI in the patient care process, compliance with the patient's rights must be ensured**. The existing catalog of patients' rights contains key requirements that can be successfully met also in the context of the use of AI.

- The obligation to respect patients' rights applies, inter alia, to HCPs and medical establishments. Although AI can help – for example, in the process of admitting a patient to treatment, choosing its optimal course, or even providing advice to the patient – it cannot replace the doctor, other HCPs or the medical facility. Thus, **it is not the AI that must respect the rights of the patient, but the person who uses it**.

- The patient has the right to be informed, inter alia, about the proposed and possible diagnostic and therapeutic methods and the foreseeable consequences of their use or omission. This means, in particular, **the right to information about the availability and use of AI in the provision of health care services**. However, we should remember that the appropriate degree of adequacy of the information provided should be maintained – not always the use of AI in the treatment process must be disclosed to the patient.

- Similarly, **where the patient's informed consent is required**, there should be no extremes before the patient makes a decision: no information about the use of AI at all (even if it is important) or the opposite – overloading the patient with unnecessary or incomprehensible information (just because it has been generated by a computer program). However, if the patient expects details, they should be provided with as comprehensive and understandable information about AI as possible. If the use of an AI algorithm is only one of the elements of the entire treatment process, and diagnostic and therapeutic decisions are made by an HCP, no separate consent of the patient is required.

- Similarly, **the obligation to keep medical records should be remembered**. Such records should contain information relevant to the patient care process, which has been obtained thanks to an AI system, such as a result or suggestion presented by the algorithm. This will provide an opportunity to better verify the path of patient management and avoid unnecessary repetition of the use of AI.

1.3. The use of AI in accordance with the rules of the performance of medical professions

- **AI should be treated as a tool in the hands of an HCP**, which can support many processes, not only diagnostic and therapeutic, but also scientific-research, organizational or managerial. **AI does not replace an HCP, does not make decisions for them, does not provide health care services on their behalf and does not decide on its own on the patient's health condition**.

- AI used to diagnose or treat patients is, as a rule, a medical device and must meet the applicable requirements including those concerning certification.

- The use of AI solutions recognized as medical devices involves the need to meet the applicable regulatory requirements.

- The provision of health care services using AI systems is subject to **the general rules of caution and diligence required of HCPs**, as well as the principles of professional deontology.

- **AI-enabled software must be used in healthcare with due diligence**, so that this tool provides objective support in achieving the best possible diagnostic or therapeutic goal, while alleviating the risk of adverse side effects, based on current medical knowledge.

- **The state of current medical knowledge related to AI is changing rapidly**. Further work and research are underway both on AI and on its application in the process of patient care. Therefore, it should be checked whether and to what extent a specific AI solution can be successfully used in a given patient for a given purpose and for a specific health problem.

- **From the point of view of legal liability, the use of AI solutions in clinical practice is no different from the use of other medical devices**. The law does not provide for any dedicated sanctions related to the use of AI in this respect. An HCP may incur civil, criminal, occupational or professional liability on a general basis. There is still a discussion on the principles of liability for AI, in the civil one.

- Proper fulfillment of duties in the context of the development of AI will be particularly important and will pose **new challenges for HCPs in terms of preparation for the profession, self-improvement and learning**.

1.4. Protection of patients' medical data

- The use of AI in health care is governed also by the GDPR, which means that **AI systems must meet the personal data protection guidelines** including the principles of transparency, minimal processing and retention period.

- **AI systems do not always need personal data to learn**. However, these rules do not apply to anonymous data that cannot be linked to a specific individual ("natural person").

- **Those who act as personal data controllers must meet all their obligations under the GDPR**, including the duty to carry out risk assessments for the processing involving the use of AI, conclude related outsourcing contracts and ensure transparency with data subjects.

- **An HCP who uses AI should keep in mind their institution's internal procedures and instructions related to the protection of personal data**. Most facilities should have a data protection officer who will provide support in this area and answer questions. Any suspicion of non-conformity or risk to data should also be reported to this person.

1.5. Further regulatory challenges

- In addition to significant opportunities to improve the health care system, AI carries certain risks and new threats. The results provided by AI depend, among other things, on how it was designed, what data it uses and how it is used by humans. **Further regulation of the use of AI, also in healthcare, is necessary and justified**.

- **The development and use of AI is associated with a number of challenges also in other areas**, such as qualification and certification of medical devices, intellectual property rights to AI and its outputs, or medical experiments and clinical trials (involving AI either in the role of data supplier or study subject).

- **In the context of the Polish health care system** attention should be paid to the need to ensure an appropriate process of implementing AI into the public health care system, to design a system of medical records taking account of the development of AI, and to use the potential of AI to improve health care quality. There is also a need for broader education in the use of AI in health care.

- **It is education about AI that is of primary importance from the point of view of development and dissemination of this technology**, because it can potentially drive realistic opinions of HCPs in relation to AI, improve their competences in this area and translate into safer use of the technology.

1.6. Recommendations

- **The development and application of AI in clinical practice should be an increasingly important, or even priority, element of public health policy**. AI has already been recognized in European and national strategy papers as a technology of the future, and there is a need to further intensify work and projects focusing on this area.

- The first legal solutions regarding AI will only be adopted at the EU level and will be of a general rather than sectoral nature. **Current interpretative problems and legal gaps can be solved through "soft" law instruments**, such as guidelines and recommendations published by public authorities, or codes of good practice developed by the industry. **It is reasonable to initiate work of this nature more broadly and quickly**.

- Legal regulations related to access to medical records and individual medical data were not designed with the current challenges related to access to data in mind. It is reasonable to implement **an amendment that will provide clear rules for access to medical data, including in terms of their use in the processes of developing and applying AI systems**.

- Some of the challenges related to the development of AI result from uncertainty about the current rules, in particular those imposed by the GDPR. Also in this respect, **it is reasonable to develop clear guidelines and recommendations with the national supervisory authority regarding, among others, the principles of anonymization of personal data**.

- AI is still a relatively new solution, which is why **special highlights should be placed on activities related to education and awareness raising among patients and HCPs**. HCPs should be prepared and confident to use AI responsibly, and patients should be ready for AI-enabled care.

- **Further public discussion on the directions of AI development in health care is needed, which will take up further, increasingly elaborate, topics related to it**. The very need to support the use of AI does not raise any fundamental objections, but it is necessary to better identify the challenges associated with it both at the strategic level (topics such as certification and public financing of AI) and in everyday practice (e.g., the standard of AI-enabled services).

2. Introduction

2.1. Who are we?

The **AI in Health Coalition** is an independent health care sector's initiative the main goal of which is to take and support measures for quick but responsible development of AI in the Polish healthcare system. It associates several dozen different entities, including key technology and pharmaceutical companies and medical establishments offering medical services on a local and global scale. Individual members of the Coalition use and conduct R&D work on technologies enabling the use of AI in the field of, among others, medical care including telemedicine and advanced diagnostics, healthcare management, clinical trials and development and distribution of medicinal products and medical devices.

The main task of the Coalition is to **create an environment enabling and promoting the use of the latest technological achievements in the process of patient care**, provided that these solutions are proven and safe, in accordance with applicable standards. Our stance is that AI solutions in healthcare should respect **the central role of the HCP** in patient care and inspire patient's trust. The technology is meant to support doctors and other HCPs, not to replace them.

We believe that AI solutions in medicine can create a new quality of health care services, allowing for more effective achievement of the goals of the entire health care system, in particular increasing the effectiveness of patient care. **AI solutions should therefore be as widely available as possible to patients** – they must not be addressed only to a narrow clientele. They should also take into account practical aspects, including issues such as digital exclusion and health literacy, ensure safety of their users and HCPs, and respect patients' rights including the right to privacy.

The values and goals of the Coalition are expressed in the manifesto which all individuals and organizations are expected to sign before joining us. The manifesto can be found on the www.aiwzdrowiu.pl website[1].

One of the areas of the Coalition's activity involves the building of awareness about AI, offering tools promoting its use (taking into account the specificity of the health care sector) and supporting development of sectoral public policies. Therefore, we decided to prepare this publication. **The White Paper is to be the first comprehensive position of the Polish healthcare sector in the discussion on practical challenges arising from the use of AI in healthcare**.

The Working Group on AI (the Health Section), hereinafter referred to as the "Group", is a team of experts established within the Chancellery of the Prime Minister. The group brings together a few dozens of experts from the private and public sectors who deal with issues related to AI in healthcare. The Group's

1 We invite everyone who wishes to actively support the development of AI in the Polish healthcare system. Membership in the AI in Health Coalition is open, subject to acceptance of the Terms and Conditions and submission of the declaration of membership to biuro@aiwzdrowiu.pl.

goal is to **develop legislative solutions enabling effective and safe development and implementation of AI systems in health care**, as well as education and popularization of AI-enabled solutions systems.

2.2. Why did we write the White Paper?

AI is currently undoubtedly one of the most important and promising areas of modern technologies. It raises not only a lively discussion about the numerous benefits and possibilities of using intelligent algorithms, but also about extremely important ethical challenges and legal aspects related to its use. As a technology with potentially very wide applications, AI has serious implications for a number of areas of life and, consequently, also for the existing legal and regulatory framework. The most frequently named areas in which AI can lead to greatest breakthroughs include transport, safety / security, energy and health care. This document focuses exclusively on the health sector in order to best **identify sectoral challenges and difficulties and to discuss possible pathways to address them**.

AI systems can facilitate the work of doctors, improve quality and, at the same time, shorten the duration of treatment, as well as contribute to reducing costs of care and treatment. They make it possible to improve the diagnosis process and increase the likelihood of making an accurate diagnosis in a shorter time. **The implementation of AI is not a distant future but the realities of the present**. Already in Poland there are tools and systems supporting the doctor's work – for example in making decisions, by supporting medical diagnostics and imaging, automation and analysis of medical documentation, or improving the process of patient registration and admission.

Although AI is already used, there are no specific guidelines for its use in healthcare. This is the case not just in Poland – that area has not been regulated in other countries either. The legislative work at EU level is still at a relatively early stage. Medical institutions and HCPs using such solutions therefore have many questions and doubts about how to comply with the current legal principles, including in particular respect for the patient's rights, and the rules of profession and medical activity, while applying various AI-enabled solutions. Some of these questions have not yet been answered.

The lack of detailed regulations does not prevent the use of AI by HCPs. The law sets out general principles from which specific procedures and requirements to be met can be read.

The White Paper is devoted to selected legal issues related to the use of AI in health care by HCPs: doctors, nurses, obstetricians, physiotherapists and other specializations. Its main goal is to identify the most important questions and doubts that arise in the daily practice of using AI. **The document suggests answers and possible solutions that, in our opinion, can contribute to improving safety and quality of the use of AI and, thus, building trust in solutions based on this technology**. It was intended to have a practical dimension and translate into feasible projects.

At the same time, we are fully aware, and we point out, that this is **a voice encouraging discussion on these important subjects**. Our proposals are not intended to definitely settle the matter and present the only acceptable options. They are supposed to inspire reflection on the opportunities and challenges involved in the adoption of AI. Some issues are just mentioned. This is why the AI in Health Coalition wishes to inspire a broader public debate on the key challenges of using AI for medical professions. We hope the White Paper will become one of the first important voices in the discussion on which the future of the development of the health care sector in Poland may depend.

2.3. Who is the addressee of the White Paper?

The White Paper is addressed primarily to **HCPs and medical establishments**. They are the front-line of putting innovation into practice and often have to find answers to questions that many theorists have not yet had time to ask. We wish to help bring the full potential of AI to use by **clarifying legal and ethical doubts associated with the use of this technology**. The use of AI in healthcare can offer a number of benefits, hence we want to encourage it by providing community-accepted guidance related to the dilemmas that HCPs and medical establishments may face[2]. We believe that from the perspective of both HCPs and patients it is necessary to develop rules for the use of AI that would be compliant with the current legislation.

Therefore, the White Paper will be a source of knowledge about AI also for **patients** – about their basic rights, how to enforce them, and about possible infringements. Hence, the patient can be more aware of various considerations around the use of AI in health care and, as a consequence, will be able to more accurately **assess quality of services related to the use of AI**.

The White Paper is also an inducement to a discussion aimed at shaping public policies and regulations in the field of AI in health care. It outlines the main problems and challenges and proposed solutions, without imposing any rigid rules. Therefore, we hope that it will also be a valuable document for **those involved in regulatory activities** in public entities competent in this area.

We want to start a broader public debate so that the use of AI technology is not associated with unnecessary fears or doubts resulting from the legal environment, but with enthusiasm inspired by new opportunities and comfort of moving along a trustworthy path on which we are making the first steps together.

2 The White Paper does not address the use of AI in administrative, organizational or managerial processes in healthcare.

3. The use of AI in healthcare

3.1. How can the concept of AI be understood?

A lot is said and written about AI in different contexts. However, this concept does not have a single definition, either in the technical professional literature or in the doctrine of law. The colloquial understanding of AI is well reflected in the dictionary of the Polish language, which says that AI is "*a branch of computer science that studies the rules governing human mental behavior and creates programs or computer systems that simulate human thinking*[3]".Technical definitions of AI, as a rule, are more complicated and relate directly to the software used. One of the simpler definitions of AI, proposed by one of the first AI researchers, Marvin Minsky, points out that AI is "*the art of teaching machines to do things that, if done by a human, would require the use of intelligence*"[4].

> **What is particularly important in the regulatory context, there is no legal definition of AI in the law yet. However, legislative work in this area is already underway at the EU level. The legal definition of AI was initially proposed in the form of so-called "soft law", i.e. resolutions and communications. The first bill containing the definition of, and regulations on AI – the "AI Act" intended for implementation all the EU states – is currently being processed.**

What is particularly important in the regulatory context, there is no legal definition of AI in the law yet. However, legislative work in this area is already underway at the EU level. The legal definition of AI was initially proposed in the form of so-called "soft law", i.e. resolutions and communications. The first bill containing the definition of, and regulations on AI – the "AI Act" intended for implementation all the EU states – is currently being processed[5].

The definition of AI presented in the bill is very broad. It covers not only software based on machine learning mechanisms but also, for example, knowledge bases and search methods. The proposed definition, by taking into account the techniques and approaches set out in Enclosure I to the bill, is intended to be updated periodically. According to art. 3(1) of the bill, an "AI system" means software developed using one or more of the techniques and approaches listed in Enclosure I, which can, for a given set of human-defined objectives, generate results such as content, predictions, recommendations or decisions affecting the environments with which it interacts. Enclosure I lists the following:

3 *Słownik Języka Polskiego PWN* – https://sjp.pwn.pl/szukaj/sztuczna%20inteligencja.html, accessed on 27/02/2022

4 M. Minsky, (1968) – https://www.britannica.com/biography/marvin-lee-minsky

5 Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM/2021/206 final)

1. **machine learning mechanisms**, including supervised learning, unsupervised machine learning and reinforcement learning, using a wide range of methods, including deep learning;
2. **methods based on logic and knowledge**, including knowledge representation, inductive programming (logical), knowledge bases, inference and deduction engines, reasoning (symbolic) and expert systems;
3. **statistical approaches, Bayesian estimation, search and optimization methods**.

The operation of a learning system can take a variety of forms. It can supply data that can be used in any way (including for further analysis), recommend specific actions (requiring a decision to accept or reject) or, finally, take actions that can possibly be blocked or canceled[6].

Intelligent software gathering knowledge must therefore have the ability to select it and draw conclusions aimed at discovering links between pieces of information – and the discovery of these links must go beyond the solution model originally built into the system. In addition to the machine learning ability, AI should be able to make independent decisions resulting from information processed by the information system.

We would like to draw particular attention to the fact that, nowadays, in practice, the concept of AI is often misinterpreted, and the term "AI" is attributed to "non-intelligent" solutions (such as "smart" ones). Technologies considered to be actually "intelligent" are discussed more extensively in section 3.2.

It is worth emphasizing, however, that sometimes even discrepancies in the different definitions of AI and possible doubts regarding the qualification of a specific solution as "AI" will not be relevant to the recommendations presented in the White Paper regarding clinical practice. Until a specific legal definition of AI comes into force, the challenges and approaches presented in the White Paper can also be successfully applied to software that is not "AI" in the light of narrower or more technical definitions.

3.2. Types of technologies recognized as AI

Algorithms are the basis of programming and their use is much wider than just in AI itself – **not every algorithmic solution can be recognized as AI**.

Below we present technologies that belong to the domain of AI. Note that the following presentation of technologies considered to be AI is not exhaustive and is only intended to outline the technologies we write about in the White Paper. We selected these technologies because of their versatility and growing popularity.

The guidelines we have included in the White Paper can also be applied to non-AI advanced software – the instructions we have presented will work well for many advanced analytical IT tools.

6 L. Lai, M. Świerczyński (ed.): "Prawo sztucznej inteligencji", Warszawa, 2020

Machine learning

As we pointed out above, computer software gathering knowledge is supposed to have the ability to select it and draw conclusions aimed at discovering links between pieces of information, and the discovery of these links is to go beyond the solution model originally built into the system. This is considered to be **machine learning**, which, however, cannot be identical with the concept of AI. The machine learning is, in principle, an element of AI[7]. Systems using machine learning have the ability to draw their own conclusions and improve their abilities based on their own "experiences", but the decisions they make are not always fully autonomous[8].

The use of machine learning allows, for example, to reconstruct mechanisms underlying diseases and better understand their course in individual patients. Algorithms can identify subtle changes in chest X-rays and, in some cases, the level of accuracy in diagnosing medical conditions such as pneumonia is equal to or higher than that of clinicians. Machine learning techniques also help to improve clinical trials. For example, they allow to examine patients' medical records in order to find people who would meet certain qualifying criteria[9]. No less important example of the use of AI is the prediction of non-diagnosing, misdiagnosing or progression of specific diseases. Using patient management pathways and disease histories obtained from hospital systems, along with information about diagnoses, prescriptions, procedures, laboratory tests, and demographics, these solutions are taught to uncover patterns that characterize people at high risk of disease progression[10].

Deep learning

Another technology in the field of AI is **deep learning** which involves the use of **neural networks** with a greater number of neurons, layers and interconnections than in the case of machine learning.

A neural network is a mathematical representation of the human nervous system. The network consists of artificial neurons responsible for the interpretation, modification and further propagation of the input signal.

The main difference in relation to traditional algorithmic programs is the ability of the network to generalize knowledge for new data previously unknown. However, unlike human intelligence, artificial networks are often deprived of the built-in ability to explain the decision-making process – although there are already mechanisms of explainability and interpretability, such as highlighting texts that have influenced the

7 AI includes a number of elements other than machine learning. Examples: simulation methods, heuristics, business rules, etc.

8 Ewa Kurowska-Tober, Łukasz Czynienik, Magdalena Koniarska: "Aspekty prawne sztucznej inteligencji – zarys problematyki" (addendum to *MoP* 21/2019), Xawery Konarski (ed.): "Prawo nowych technologii dane osobowe i cyberbezpieczeństwo, Internet i media, handel elektroniczny, prawo IT, technologie", 2019

9 https://www.nature.com/articles/s41591-020-01197-2, accessed on 13/05/2022

10 https://www.nature.com/articles/s41598-020-67013-6#:~:text=In%20the%20US%2C%20an%20estimated,as%20cirrhosis%20and%20liver%20cancer., accessed on 13/05/202

diagnosis. The deep learning refers to certain types of machine learning methods in which a series of "layers" of simple computing units network in such a way that data entered into the system passes through each of them in turn[11]. For example, if we show an average person a picture of horses, the horses will be recognized even if the person has never seen this particular picture. This person has not memorized this specific representation of horses but simply recognizes a horse based on its obvious attributes. The deep learning can do something similar. This is why it is used in autonomous vehicles, for example.

Deep learning is used, for example, in the detection of diabetic retinopathy, early detection of Alzheimer's disease and ultrasound detection of breast tumors[12].

Natural language processing

Natural language processing (NLP) is a branch of AI that focuses on helping computers understand how people write and speak. The natural language understanding (NLU) is a sub-branch of NLP and deals with these nuances through machine reading with comprehension, not just with the grasp of the literal meaning. The goal of NLP and NLU is to help computers understand human language well enough for them to have a conversation in a natural way.

Examples of the use of NLP and NLU are voice-controlled assistants such as Siri and Alexa, or the generation of natural language for answering questions by customer service chatbots. Examples of the use of NLP specifically for the medical sector include solutions using Name Entity Recognition in combination with the existing clinical literature, thanks to which doctors can extract information faster[13]. In healthcare, NLP combined with medical records can help predict patient outcomes, support hospital administrative systems and generate diagnostic models for detection of chronic diseases at an early stage. NLP can also generate natural language in chatbots, providing patients with an interface to ask questions and access information in chat rooms[14].

Computer vision

Computer vision is a field of AI that enables the acquisition of relevant information from digital images, videos and other visual data – and taking actions or making recommendations based on this information.

Computer vision works similarly to human vision. However, the latter has this advantage that, throughout life, it practices how to distinguish objects, place them in perspective, detect motion and tell whether something in the image does not fit. Computer vision can be trained to do the same much faster using cameras, data, and algorithms. Because a system trained to inspect products or observe production

11 https://course.elementsofai.com/pl/5/1, accessed on 13/05/2022

12 https://research.aimultiple.com/deep-learning-in-healthcare, accessed on 13/05/2022

13 https://www.frontiersin.org/articles/10.3389/fcell.2020.00673/full, accessed on 27/05/2022

14 Saskia Locke, Anthony Bashallb, Sarah Al-Adelyac, John Mooreac, Anthony Wilsonac, Gareth B. Kitchen: "Natural language processing in medicine: a review", *Trends in Anaesthesia and Critical Care*, vol. 38, 2021, https://www.sciencedirect.com/science/article/abs/pii/S2210844021000411, accessed on 27/05/2022

resources can analyze thousands of products or processes per minute, noticing imperceptible flaws or problems, it can quickly surpass human capabilities[15].

Computer vision is used in various areas of health care, supporting mainly imaging diagnostics. Several studies have shown promising results in complex medical diagnostic tasks, also in the field of dermatology. Deep learning-based computer vision models have achieved physician-level accuracy in distinguishing benign skin nevi from melanomas. Deep learning systems can help physicians by marking image areas requiring special attention and verification[16].

Computer vision makes it possible to identify an undesirable situation at a very early stage of the development of a disease. AI can compare an image sample with a large group of reference materials in a short time. This helps HCPs provide patients with prompt and timely treatment. The use of AI in the field of oncology or radiology can help detect cancerous tumors faster using transcriptional profiling on microarrays to obtain information about gene expression.

Researchers use computer vision and machine learning models to increase surgical precision and accuracy of decisions made during complex procedures.

Computer vision and deep learning technologies can also support the reading of 2D scans and transforming them into interactive 3D models. Such image transformation helps HCPs better understand patients' health conditions. This technology assists radiologists in analyzing scans in depth: with a 3D image it is easier to find anomalies without spending a lot of time digging through a pile of materials for analysis.

3.3. What opportunities does AI offer in healthcare?

AI is a technology that has a potential to significantly change the healthcare industry by improving quality and accessibility of health care services[17]. Not only are AI models more accurate than previous symptom-checking software, but in many cases they may now outperform the accuracy of diagnosis by physicians. This is mainly due to the use of methods enabling comparison of huge amounts of data and drawing conclusions from them.

In addition, compared to HCPs, AI does not get tired or stressed and it is not subject to burnout, so it is possible to maximize the use of its resources. AI has no emotions that can affect its work. In addition, AI does not fall into a routine and does not make mistakes because of it, does not compete and has no ambitions or complexes. In other words, software does not experience human problems that HCPs face in the process of providing medical services.

15 https://www.ibm.com/topics/computer-vision, accessed on 13/05/2022

16 https://viso.ai/applications/computer-vision-in-healthcare, accessed on 13/05/2022

17 Example: report "The potential of Artificial Intelligence in the Healthcare Sector" from *Artificial Intelligence Quotient*, vol. 4, presented at the 30th Economic Forum in Karpacz – https://news.microsoft.com/wp-content/uploads/prod/sites/58/2021/09/RAPORT_Sztuczna-Inteligencja-W-Sektorze-Ochrony-Zdrowia-09.2021.pdf, accessed on 27/05/2022

The use of AI in healthcare can extend to many areas and be of diversified nature. Below we mention the basic possibilities related to its use in the context of providing health care services and patient care:

1) **Better diagnosis and clinical decision support**: Studies conducted in independent centers around the world show that machines perform similarly or even better than humans in many aspects. Thanks to AI, among other things, it is possible to mitigate the problem of misdiagnosis. Sometimes AI diagnoses with up to 99% accuracy, eliminating uncertainty and stress after hearing a misdiagnosis, as well as the additional costs of unnecessary biopsies and other tests[18]. In another study, researchers from Babylon Health and University College London compared the accuracy of a state-of-the-art associative diagnostic algorithm and 44 physicians, using a test collection of more than 1,500 clinical vignettes[19]. The doctors achieved an average diagnostic accuracy of 71% and the algorithm 72.5%, ranking at the level of the best 48% of the doctors from the study group[20]. Next, another study on an AI algorithm found a reduction in the number of false negative results in breast cancer screening mammography by almost 10% – the use of an AI system thus opens the way[21].

> **The doctors achieved an average diagnostic accuracy of 71% and the algorithm 72.5%, ranking at the level of the best 48% of the doctors from the study group.**

2) **Time savings for HCPs**: The resources of HCPs are very limited, as the CoViD-19 pandemic has shown very acutely. One of the WHO's key reports on human resources has an overwhelmingly explicit title: "A universal truth: no health without a workforce"[22]. Staff shortages are a serious problem in most countries. According to the EU's estimates, there is a shortage of about one million medical workers in the EU alone, including about 230,000 doctors and 590,000 nurses[23]. Compared to Europe, the situation with medical staff in Poland is dramatic. Poland struggles with one of the lowest in the EU employment

18 According to the American Cancer Society, 12.1 million mammograms are performed every year in the U.S. alone, but a high percentage of these mammograms give false results, leading to 1 in 2 healthy women being told that they have cancer – https://www.wired.co.uk/article/cancer-risk-ai-mammogram, accessed on 27/05/2022 r.

19 Clinical vignettes are a special type of clinical teaching case used primarily to measure trainees' knowledge and clinical reasoning. A vignette can be designed to measure knowledge about a specific diagnosis or clinical situation at the same time as it measures trainees' skills in performing the tasks necessary to diagnose and care for a patient. – https://www.go2itech.org/HTML/CM08/toolkit/tools/vignettes.html, accessed on 27/05/2022

20 https://www.nature.com/articles/s41467-020-17419-7#Sec3, accessed on 13/05/2022

21 https://www.nature.com/articles/s41586-019-1799-6, accessed on 27/05/2022

22 Campbell J, Dussault G, Buchan J, Pozo-Martin F, Guerra Arias M, Leone C, Siyam A, Cometto G. (2013): "A universal truth: no health without a workforce. Forum Report.", *Third Global Forum on Human Resources for Health*, Recife, Brazil. Geneva, Global Health Workforce Alliance and World Health Organization

23 European Union (2012): "EU level Collaboration on Forecasting Health Workforce Needs, Workforce Planning and Health Workforce Trends – A Feasibility Study"

rates in medical professions[24]. The hitherto attempts to solve these problems or improve the existing situation have generally been chaotic. AI can become an important tool that will help relieve HCPs and mitigate organizational and administrative issues related to the provision of health care services.
The first example is the AI-based BrainScan system which enables automatic detection and classification of brain lesions found by computed tomography. It provides doctors with additional information that allows for faster and more efficient interpretation of images[25]. Another example is a machine learning software suite that enables the digitization of highly structured patient medical data and facilitates interaction with patients[26]. Next, we have the Qure.ai software that detects abnormalities in chest X-rays within one minute, separates abnormal scans from normal ones and interprets abnormalities in the lungs, pleura, mediastinum, bones, diaphragm and heart[27].

3) **Clinical trials and R&D work**: Technological developments are also opening new doors for clinical trials. Establishments conducting clinical trials are able to obtain increasing amounts of so-called "real-world data" (RWD)[28]. However, they often lack the expertise and tools needed to use this data effectively. Applying predictive AI models and advanced analytics to RWD can help researchers select candidates for studies, better understand disease mechanisms and build novel tools to support clinical practice. What is more, when combined with an efficient digital infrastructure, clinical trial data can be cleansed, aggregated, coded, stored and processed using AI algorithms[29]. This can help accelerate procedures and refine current standards for conducting clinical trials – statistical models based on artificial neural networks are one of the possibilities for developing tools for detailed simulation of the development of the patient's condition[30]. Using the potential of AI and machine learning in R&D work on new drugs and diagnostic methods makes it possible to significantly shorten the time of looking for molecules and selecting the most promising candidates for clinical trials, reduce research costs and improve the odds for making new effective therapies available to patients. AI can support the planning of clinical trials so that their chances for success are maximized. AI is also applicable at earlier steps – for example during pre-clinical studies – by allowing to reduce the number of animal subjects or to select a minimal number of most promising experiments within a project.

4) **Faster detection of epidemic threats**: Another example of the use of AI is to look for relationships and patterns in data that are simply impossible for humans to analyze. Professor Kamran Khan from the University of Toronto, together with a group of epidemiologists, noticed as early as in December

24 Alicja Domagała: "Fakty i mity na temat braków lekarzy i pielęgniarek w Polsce" – https://izp.wnz.cm.uj.edu.pl/pl/blog/fakty-i-mity-na-temat-brakow-lekarzy-i-pielegniarek-w-polsce/, accessed on 27/05/202

25 https://brainscan.ai/pl#solution, accessed on 13/05/2022

26 https://www.microsoft.com/en-us/research/video/improving-doctor-patient-interaction-with-ml-enabled-clinical-note-taking, accessed on 13/05/2022

27 https://qure.ai/product/qxr/, accessed on 27/05/2022

28 For instance, AI enables identification of HCV patients based on "claims data" from the USA – https://www.iqvia.com/-/media/iqvia/pdfs/library/posters/identifying-undiagnosed-patients-with-hepatitis-c.pdf?_=1647853472923, accessed on 27/05/2022

29 Mohammed Yousef Shaheen: "Applications of Artificial Intelligence (AI) in healthcare: a review" – https://www.scienceopen.com/hosted-document?doi=10.14293/S2199-1006.1.SOR-.PPVRY8K.v1, accessed on 27/05/2022

30 https://www.nature.com/articles/s41598-019-49656-2, accessed on 27/05/2022

2019, thanks to AI, that there were 27 cases of pneumonia with an unclear cause in Wuhan in a relatively short time span, and alerted the WHO. The algorithm created by the researchers browsed through social media, news portals and discussion forums and it was there, and not in hospitals equipped with special databases, that people reported what was happening to them. This is how AI detected abnormal patters[31] that turned out to be the beginning of the SARS-CoV-2 pandemic[32].

The use of AI, as in the case of other innovative solutions, apart from numerous possible benefits, is also associated with certain risks and new threats. AI is not infallible – a wrong data set, design error or lack of human supervision can distort its results in the context of a specific use. This is why it is so important to adopt a standard of handling AI in health care, which will serve its responsible use.

3.4. How can AI support the HCP and the patient?

Intelligent technologies can help HCPs tap into the potential of connectivity and information exchange better than ever before. This will primarily have an impact on relieving administrative duties, increasing the accuracy of diagnosis and treatment, reducing the risk of medical errors and alleviating the problem of the lack of time for patients, which is particularly important from the perspective of combating the growing health debt.

From the perspective of an HCP, AI offers the following benefits:

1) **More time for the patient**: A 2016 study found that, on average, physicians spent 27% of their working days on face-to-face clinical contacts with patients and 49.2% on handling electronic hospital records and desk work. In this study, HCPs were provided with proper documentation support, so they had more time for patients[33]. The use of AI in healthcare has a potential to reduce the amount of administrative work and redirect the time and attention of HCPs to patients.

> **The use of AI in healthcare has a potential to reduce the amount of administrative work and redirect the time and attention of HCPs to patients.**

31 Similarly, thanks to software, it is also possible to strengthen the role of prevention. For example, algorithms analyze data from patient files in order to detect disturbing trends early.

32 https://www.usnews.com/news/best-countries/articles/2020-03-11/how-scientists-are-using-artificial-intelligence-to-track-the-coronavirus, accessed on 13/05/2022

33 C. Sinsky, L. Colligan, L. Li, M. Prgomet, S. Reynolds, L. Goeders, et al.: "Allocation of physician time in ambulatory practice: a time and motion study in 4 specialities", *Ann Intern Med.* 2016, 165:753-60

2) **Valuable hints on the recommended course of action**: In selected applications, AI is able to propose diagnostic methods and treatment methods as accurate as those chosen by HCPs. Systems using the machine learning have the ability to draw conclusions and improve themselves through the use of appropriate technological solutions[34].

3) **Alerting about disturbing changes**: In addition, devices that allow remote access to information allow IT systems to continuously collect data, and integrated AI systems can help analyze this data to detect changes in the patient's health. The use of machine learning, for example, allows for the reconstruction of mechanisms underlying various diseases and a better understanding of specific cases. Algorithms can identify subtle changes in chest X-rays and, in some cases, the level of accuracy in diagnosing medical conditions such as pneumonia is equal to or higher than that of clinicians[35].

4) **A more personalized approach**: AI helps HCPs better identify patients requiring special attention and develop personalized recommendations for them. This translates into an improvement in the quality of services.

5) **Relief from some administrative duties**: HCPs can use AI to take notes, analyze conversations with patients, and input information they need directly into dedicated systems that will collect and analyze patient data and then present the results to HCPs[36].

AI offers a number of benefits for patients and, thanks to the use of AI-enabled solutions, patients can gain:

1) **New options in the process of treatment and prevention**: Thanks to the involvement of AI, the patient will gain access to new tools improving the effectiveness of diagnostic and therapeutic procedures. Deep learning and the NLP have great potential for psychiatry. For example, they can be implemented in intelligent chatbots the contact with which can significantly reduce symptoms of depression and anxiety disorders in patients using them[37]. This is possible because chatbots communicate in the natural human language, providing patients with an interface to ask questions and access information in chat rooms[38]. Another great example is the use of AI in precision oncology. Deep learning models can learn to predict the molecular characteristics of tumor samples, such as

34 Ewa Kurowska-Tober, Łukasz Czynienik, Magdalena Koniarska: "Aspekty prawne sztucznej inteligencji – zarys problematyki" (addendum to *MoP* 21/2019) in Xawery Konarski (ed.): "Prawo nowych technologii dane osobowe i cyberbezpieczeństwo", *Internet i media, handel elektroniczny, prawo IT, technologie*, 2019

35 https://www.nature.com/articles/s41591-020-01197-2, accessed on 13/05/2022

36 Amisha, Paras Malik, Monika Pathania, Vyas Kumar Rathaur: "Overview of artificial intelligence in medicine", 2019 – https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6691444/#ref17

37 https://mental.jmir.org/2017/2/e19/

38 Saskia Lockea, Anthony Bashallb, Sarah Al-Adelyac, John Mooreac, Anthony Wilsonac, Gareth B. Kitchen: "Natural language processing in medicine: a review", *Trends in Anaesthesia and Critical Care*, vol. 38, 2021 https://www.sciencedirect.com/science/article/abs/pii/S2210844021000411

control mutations or histological subtypes, based on the characteristics of histopathological images[39]. Personalization of therapies on this basis translates into better effects.

2) **A sense of safety**: AI will support an HCP by providing them with a second opinion on a specific problem. Therefore, the patient will gain an insight into their health condition. Computer vision standalone is used in various areas of health care, supporting mainly imaging diagnostics. For example, promising results have been shown in complex medical diagnostic tasks, also in the field of dermatology – computer vision models based on deep learning have achieved a human doctor's accuracy in distinguishing benign skin nevi from melanomas.

3) **Quick benefits**: Thanks to the use of AI, the technical and administrative aspects of providing health care services can be handled faster and more effectively, which will translate into the shortening of the time of access to health care services. Thanks to this, HCPs and administrative and technical staff will be able to better focus on patients. In addition, thanks to the use of modern medical devices driven by AI-enabled software, it is possible to deliver therapies at patients' homes. On the other hand, AI systems are able to shorten the time of hospitalization by improving doctor-patient communication, for example by the remote monitoring of temperature (for example in a postoperative wound), heart rate or blood saturation.

4) **Individual approach**: Thanks to the use of AI, it is possible to analyze larger amounts of data than ever before, which leads to a more accurate selection of therapies, identification of dependencies, forecasting the course of events and formulating tailored medication. Thanks to the patient-specific information, AI can also be a valuable tool for patient empowerment, i.e. involvement in the therapeutic process by making informed decisions.

3.5. Is AI used in the Polish healthcare system?

Yes, various AI-enabled solutions are already successfully used in the Polish healthcare system. Therefore, the challenges associated with the use of this technology are not theoretical – they are a part of everyday practice. At the same time, benefits associated with the use of AI can also be seen.

New technologies using complex technical solutions are already being implemented into the healthcare system in a systematic way. The Telemedicine Wristband is an example. The purpose of this project was to assess the performance of primary health care services provided to patients who got over the SARS-CoV-2 disease. The institutions qualified for the program received the wristbands and distributed them to the convalescents. The bands were used to monitor the heart rate and blood oxygen. The wristband had a "911" button marked with Braille, a fall detector, a GPS locator with altimeter, and a voice assistant reminding the patient to take medication and reporting the status of the band[40]. The next similar pilot

39 https://www.nature.com/articles/s41698-021-00216-w, accessed on 13/05/2022

40 https://www.gov.pl/web/zdrowie/rusza-pilotaz-programu-opaska-telemedyczna, accessed on 13/05/2022

project started on January 27, 2022, when primary and ambulatory health care establishments were recruited to experiment with electronic spirometers for emote detection of lung dysfunctions[41].

Another example of implementation of new technologies is the system of continuous glucose monitoring by scanning, currently refunded for children with type 1 and type 3 diabetes. The system measures the concentration of glucose in the intra-tissue fluid using a sensor placed on the arm and sends the result to a smartphone application (or a dedicated reader). It tracks the level and variability of glycemia and alerts about dangerous hypoglycemics by displaying trend arrows. This information can be uploaded to the cloud-based LibreView system, which allows the physician to monitor the situation primarily by viewing ambulatory glycemic profile reports. In addition, the algorithm of insight into the blood sugar trends informs both the patient and the doctor about disturbing developments (hypoglycemia) at selected times of the day. Based on the above information, the diabetologist can make decisions together with the patient and other specialists regarding diet, lifestyle and treatment. At the same time, this system allows for additional education of the patient and supports independent management of the treatment of their disease[42].

Similarly, solutions using AI are implemented in the Polish healthcare system, including the **pilot projects initiated by the Ministry of Health**. The use of electronic stethoscopes in primary care is an example: several dozen institutions qualified for the program received more than a thousand of these devices using AI algorithms and distributed them to patients who gained remote access to advice provided by primary care doctors[43]. In addition, the National Center for R&D (NCBR) together with the National Science Center (NCN) announced the "ARTIQ – Centers of AI Excellence" competition. It provided funding for basic R&D works leading to the implementation of the latest AI-enabled solutions.

The aim of the ARTIQ competition is to strengthen Polish potential in the field of AI by establishing three Centers of AI Excellence (CD AI) in which teams of scientists will carry out projects involving basic, industrial, development and pre-implementation work in the field of AI, leading to commercialization of new solutions[44]. Another thing worth mentioning are the plans of the Medical Research Agency. In 2022 the Agency will offer grants dedicated to development of AI- and telemedicine-enabled solutions. These competitions belong to one of the Agency's priority areas with more than PLN 500 million worth pool of financing[45].

41 http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20220000121, accessed on 13/05/2022

42 https://www.freestylelibre.pl/catalog/product/view/id/682, accessed on 27/05/2022

43 https://www.gov.pl/web/zdrowie/rusza-pilotaz-programu-e-stetoskop, accessed on 13/05/2022

44 https://www.gov.pl/web/ncbr/artiq-wspolne-przedsiewziecie-ncbr-i-ncn-wesprze-rozwoj-sztucznej-inteligencji-w-polsce, accessed on 13/05/2022

45 https://abm.gov.pl/pl/aktualnosci/1184,Agencja-Badan-Medycznych-podsumowala-dotychczasowe-dzialania-i-ogl osila-plany-na.html, accessed on 13/05/2022

> AI is also implemented and successfully used in medical establishments throughout the country on their individual initiatives.

AI is also implemented and successfully used in medical establishments throughout the country on their individual initiatives. For example, the Radom Oncology Center is one the first such institutions in Poland that has reached for AI in imaging diagnostics[46]. Next, the hospital in Ostróda is implementing a voicebot system which is supposed to facilitate the operation of the facility. AI not only answers all incoming calls, but also calls patients and reminds them of their scheduled visits and dates of admission to the hospital[47]. In addition, the project of the Municipal Hospital in Gliwice and the Silesian University of Technology is about to take off. It is an initiative aimed at, among other things, shortening the time of describing CT images to detect clinically unsuspected cases of CoViD-19 and provide additional information to support development of new, or improve existing, diagnostic schemes. This is possible thanks to the use of AI[48]. AI will also support radiology in Brzeg. In the forthcoming months AI models will be trained at the Brzeg's Medical Center, which will be based, among others, on clinical data captured by the clinic[49]. The EVIS X1 system used by the University Hospital in Krakow can detect in real time, thanks to a special application, lesions during colonoscopy. Some abnormalities are imperceptible to the human eye and this is where AI comes in. This technology improves accuracy of diagnosing early cancerous lesions of the gastrointestinal tract[50].

In addition, the development of AI-enabled technologies is also observed in the sector of **newly established med-tech enterprises**. The list of entities implementing AI in the Polish healthcare system is presented in the "Top Disruptors in Healthcare" Report from 2022. The Report presents innovative solutions offered by startups operating in the evolving areas of telemedicine and AI, but also supporting rehabilitation, clinical trials or education[51]. These solutions are already, or will be, used in Polish and foreign therapeutic centers.

In addition, information on further examples of AI implementations in medical establishments can also be found in the "AI is not Sci-fi" review of the AI in Health Coalition[52].

46 https://www.linkedin.com/pulse/sztuczna-inteligencja-ai-w-obrazowaniu-metod%25C4%2585-%25C5%2582ukasz-pruszy%25C5%2584ski/?trackingId=5%2BGZwaoozStrj9NHcYYWSw%3D%3D, accessed on 27/05/2022

47 https://www.cyfrowyszpital.pl/voicebot-rewolucja-w-polskiej-sluzbie-zdrowia, accessed on 13/05/2022

48 https://gliwice.eu/aktualnosci/miasto/sztuczna-inteligencja-pomoze-w-diagnozowaniu-covid-19, accessed on 13/05/2022

49 https://bcm.brzeg-powiat.pl/aktualnosci/sztuczna-inteligencja-pomoze-radiologii-szpital-uruchomi-innowacyjny-system, accessed on 13/05/2022

50 https://www.su.krakow.pl/nasz-szpital/aktualnosci/sztuczna-inteligencja-pomoze-w-rozpoznawaniu-zmian-widocznych-endoskopowo, accessed on 13/05/2022

51 http://www.pfsz.org/wp-content/uploads/2021/06/ENGLISH-Top-Disruptors-in-Healthcare.pdf, accessed on 13/05/2022

52 https://aiwzdrowiu.pl/wp-content/uploads/2022/03/Przegla%CC%A8d-AI-TO-NIE-SCI-FI-Przyklady-wdroz%CC%87en%CC%81-innowacyjnych-w-zdrowiu.pdf, accessed on 13/05/2022

3.6. Is the use of AI in healthcare legally permissible?

AI, understood as systems with specific functionalities, is currently not regulated by dedicated legal provisions, neither at the national level nor in the EU[53]. However, this does not mean that it cannot be used at all or, on the contrary, can be used at will. AI, like any innovative technology, is subject to more general principles of the civil law and sectoral standards, in this case the regulations governing medicine, personal data protection, computerization and cybersecurity. Therefore, **AI can be used today by medical establishments and HCPs in the process of providing health care services** as long as the solutions are consistent with more general legal regulations.

The White Paper focuses on identifying three basic areas of these regulations:

- **Patients' rights** defined by the Act on Patients' Rights, among others. One of such basic rights is the right to give (or refuse) informed consent, which should be preceded by the disclosure of necessary information to the patient, such as concerning the methods and tools to be used by the HCP, which may or may not be AI-enabled.

- **Rules for the performance of medical professions** imposed by a number of occupational regulations including the Act on the Professions of Doctor and Dentist, the Act on the Professions of Nurse and Obstetrician and the Act on the Profession of Physiotherapist. HCPs are obliged, among other things, to act based on current medical knowledge, due diligence and professional ethics, which may restrict the possibility of using some AI-enabled tools.

- **Protection of personal data** pursuant to the GDPR. The operation of AI is based on the analysis of data, much of which is personal. In clinical practice this is particularly sensitive health data.

Therefore, while the use of AI, like any other technology, is governed by the applicable law, it may not always be immediately clear how to interpret the existing regulations, taking into account the novelty of AI. That is why the White Paper tries to identify key matters that may raise doubts, and also proposes and justifies the direction in which, according to the authors, possible solutions should be going.

The issues presented in the White Paper will focus on the use of AI-based tools in clinical practice, rather than on the extremely important process of obtaining medical data for the development of AI. The challenges associated with this have already been presented in the regulatory report entitled "*The use of medical data for the development of AI in Poland and for scientific research. Legal determinants of access to medical data and of their quality.*" developed on behalf of the AI in Health Coalition[54].

53 In this case, work is already underway on a draft regulation on artificial intelligence. However, this is still only a draft that may yet be amended or rejected.

54 https://www.dzp.pl/files/shares/Publikacje/2020_02_03_Raport_AI_v_1_1.pdf, accessed on 13/05/2022

3.7. What is the public policy on the development of AI in healthcare?

AI is a technology that has a potential for triggering a significant qualitative change in healthcare. As such, it is an element of public policy at both EU and national levels. Subsequent strategies and programs take into account its particular importance and the need for further rapid development.

At the EU level, the first attempts to address this subject were made in the European Parliament's resolution of Feb. 16, 2017, containing recommendations for the Commission on civil law regulations on robotics[55]. The resolution calls for a common EU definition of cyber-physical systems, autonomous systems, intelligent autonomous robots and their subcategories, taking into account specific characteristics of intelligent robots, such as the ability to learn based on experience and interactions with the environment[56].

One of the key actions in this regard was taken one year later. The European Commission, in its communication of Apr. 25, 2018, addressed to the European Parliament, the European Council, the European Economic and Social Committee and the Committee of the Regions, entitled *"AI for Europe"*,[57] defined AI as systems that exhibit intelligent behavior by analyzing the environment and taking actions – to some extent autonomously – to achieve specific objectives. The European Commission also presented an AI strategy that into account the socio-economic dimension, increased investment in AI research, innovation and capabilities across the Union, and a coordinated action plan has been agreed with the Member States – so that AI can serve as much as possible with minimal risk[58].

The European Commission has also set up a group of independent experts who published the document entitled *"The Ethical Guidelines for Trustworthy AI"* in April 2019[59]. According to the expert group, such "trustworthy" AI has three features that must characterize the system equipped with it: it should be lawful, that is, comply with all applicable laws and regulations; it should be ethical, ensuring compliance with ethical principles and values; and it should be robust both from a technical and social point of view, as AI systems can cause unintended harm even when used in good faith.

55 European Parliament resolution of Feb. 16, 2017, with recommendations for the commission on civil law rules on robotics (2015/2103(INL)), O.J. C 252 of 18/07/2018, p. 239

56 It is very important to distinguish between the robot (hardware) and the software that controls it. We cite this example of "soft law" due to the reference to the features created by software – which are thus helpful in the analysis of the existing legal environment of AI.

57 Communication on "Artificial Intelligence for Europe" from the Commission of Apr. 25, 2018, to the European Parliament, the European Council, the European Economic and Social Committee and the Committee of the Regions, p. 1 – https://ec.europa.eu/transparency/regdoc/rep/1/2018/PL/COM-2018-237-F1-PL-MAIN-PART-1.PDF, accessed on 27/05/2022

58 Communication on "Coordinated Plan on Artificial Intelligence" from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions A, COM/2018/795 final

59 Guidelines of the independent ethical expert group on trustworthy artificial intelligence, Apr. 8, 2019 – https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai, accessed on 27/05/2022

On Feb. 19, 2020, the European Commission published its *"White Paper on AI"*[60]. The Commission assumes that the new AI framework will be based on criteria of excellence and trust. The development of AI is to be primarily human-oriented, based on respect for European values. According to the Commission, this approach will encourage citizens to use new technologies and inspire businesses to develop them further. The Commission proposes that, as a general rule, the use of AI should be considered to be high-risk if such characterization is justified based on an analysis of whether both the sector and the intended use entail significant risks, in particular from the point of view of the protection of safety, consumer rights and fundamental rights. The White Paper also pointed to the need for creating a regulatory framework for AI and the ongoing legislative work on the draft regulation on AI (the AI Act) responds to this postulate[61]. The development of AI entails far-reaching consequences for the rules of access and data security, hence work is currently underway to regulate this area in the draft Data Act[62], the draft regulation on the *European Health Data Space*[63] and other instruments.

In addition, the European Commission, the Joint Research Center (JRC) and the Directorate General for Communications Networks, Content and Technology (DG CONNECT) have launched the AI Watch initiative to monitor industrial, technological and research potential, policy initiatives in the Member States, the use and technological development of AI and its impact on the economy, society and public services[64]. The AI Watch also provides a number of analyses necessary to monitor and facilitate the implementation of the European AI strategy. The AI Watch published in May 2022 a paper entitled *"AI Watch – a road to the adoption of AI by the public sector*[65]*"*, which aims to make recommendations to policymakers and relevant stakeholders on the sensible adoption and use of AI in the public sector in Europe. The recommendations and actions set out in this guidebook aim to support forward-looking managers, practitioners and innovators throughout the public service chain and at European, national and local governance levels[66].

In Poland, the first steps have already been taken to structure public policy towards the development of AI. The first draft of the formalized public policy, *"The policy for the development of AI in Poland for the years 2019-2027*[67]*"* was subject to public consultations and government pre-consultations in August and September 2019, and in September 2020. This policy was adopted by the Committee of the Council of Ministers for Digitization. It sets out actions and objectives for Poland in the short term (until 2023), in the medium term (until 2027) and in the long term (after 2027). They are divided into six areas: AI and society,

60 White paper on AI: "A European approach to excellence and trust" – https://ec.europa.eu/info/publications/white-paper-artificial-intelligence-european-approach-excellence-and-trust_en, accessed on 27/05/2022

61 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206, accessed on 27/05/2022

62 https://digital-strategy.ec.europa.eu/en/library/data-act-proposal-regulation-harmonised-rules-fair-access-and-use-data, accessed on 27/05/2022

63 https://ec.europa.eu/health/publications/proposal-regulation-european-health-data-space_en, accessed on 27/05/2022

64 https://ai-watch.ec.europa.eu/index_en , accessed on 27/05/2022

65 https://joinup.ec.europa.eu/collection/innovative-public-services/news/ai-watch-road-adoption-artificial-intelligence, accessed on 27/05/2022

66 *Ibid.*

67 "The policy for AI development in Poland since 2020" – https://www.gov.pl/web/govtech/polityka-rozwoju-ai-w-polsce-przyjeta-przez-rade-ministrow-co-dalej, accessed on 27/05/2022

AI and innovative companies, AI and science, AI and education, AI and international cooperation, AI and the public sector. The policy is, by definition, a document that will have to be evaluated, which is to reflect the constantly changing nature of the modern technology sector, in particular AI.

> **In the field of health care, the policy assumes, among others, that in Poland there are favorable conditions for the implementation of various pilot projects and tests of new solutions in the field of health care. It is planned to increase the number of such pilot projects and build demand for AI solutions.**

In the field of health care, the policy assumes, among others, that in Poland there are favorable conditions for the implementation of various pilot projects and tests of new solutions in the field of health care. It is planned to increase the number of such pilot projects and build demand for AI solutions[68]. It is worth noting that pilot programs of medical devices using AI solutions, such as, for example, the electronic stethoscopes, are already being extended[69].

In addition, it is planned to use the research potential embedded in medical data to improve the health of citizens through, among others, pilot projects for the storage of anonymized medical data, support for development of tools and solutions using medical data, including telemedicine and e-health solutions, analysis of data on medical events (medical services), which can improve performance of preventive actions, optimization activities in the health sector based on data analysis such as, inter alia, maps of needs, supply and demand for services, use of resources, data from digital services, sharing of medical data for the development of more effective medicines and treatments[70].

With a view to supporting activities aimed at ensuring appropriate conditions in Poland for development of AI applications in both the private and public sectors, as well as in scientific research, the Working Group on AI has been established. Its aim is to develop recommendations to ensure appropriate conditions for the development of AI applications in Poland, to develop proposals for projects using AI issues and ways to support the development of those already implemented, as well as to develop assumptions for educational campaigns in the field of new technologies. A section dedicated to health issues has been established within the Group.

68 "The policy for AI development in Poland since 2020" – https://www.gov.pl/web/govtech/polityka-rozwoju-ai-w-polsce-przyjeta-przez-rade-ministrow-co-dalej, str.3

69 Regulation of the Minister of Health of Apr. 16, 2021, on the pilot program for the use of electronic stethoscopes in primary healthcare

70 "The policy for AI development in Poland since 2020" – https://www.gov.pl/web/govtech/polityka-rozwoju-ai-w-polsce-przyjeta-przez-rade-ministrow-co-dalej, pp. 70, 71

3.8. Conclusions

- AI is defined differently and comprises various types of technical solutions. AI has not been defined legally. Legislative work is still underway at the EU level related to the adoption of a definition of this concept.

- AI systems can provide valuable support and facilitation for the work of HCPs, improve the diagnosis process and increase the likelihood of making accurate diagnoses in a shorter time. AI should not be seen as an alternative to the HCPs, but as a solution to support them in the process of patient care, thus increasing the efficiency of the health care system.

- AI is not a distant technology of the future – it is available here and now. In Poland, AI-enabled solutions already support the work of HCPs. The AI solutions themselves are so versatile that they can provide both substantive and organizational support.

- The current legal regulations allow the use of AI in the treatment process. However, such tools should be chosen and handled in a manner ensuring observance of the law including patient rights, rules of medical professions and protection of personal data.

- Public policy on the advancement of AI is being developed at the European and national levels. The European Commission is proposing new rules to make AI systems used in the EU safe, transparent, ethical, impartial and human-controlled. Poland is developing its own AI development policy, also for health care applications.

4. AI and patients' rights

4.1. How to use AI with respect for patients' rights?

The use of AI in health care is associated with the need to ensure respect for patients' rights. In order to reduce risks and maximize opportunities associated with the use of AI for health, the WHO has prepared a compilation of the most important principles to ensure that patients' rights are respected[71]. Below we present the most important of them, which, according to the WHO, will enable the use of AI while respecting patients' rights.

- **Control**: AI systems should be kept under human control. In particular, it is a human who should make the final medical decisions.

The legal regulations currently in force in Poland entrust responsibility for patient care to people performing medical professions. Thus, ultimately, it is up to the medical staff to make decisions, in which knowledge generated by AI can help.

- **Confidentiality and protection**: Privacy and confidentiality must be protected and unauthorized access to data prevented.

Legal regulations ensure respect for patients' privacy. A particularly important regulation in the EU, aimed at protecting privacy, is the GDPR, which should be taken into account when using AI-enabled software. We write more about this in chapter V of the White Paper. AI should meet regulatory requirements for safety, accuracy and efficacy for specific use cases or indications. Means must be available to control and improve the quality of AI use.

The safety and security of AI are regulated by a number of legal acts. From the perspective of the use of AI-enabled software in healthcare, the regulations on medical devices establishing the basic principles of verifying and ensuring safety / security of AI solutions recognized as medical devices are particularly important. However, we would like to point out that the regulation of medical devices is not tailored to the specifics of AI-enabled software (see section 7.1.).

- **Transparency, explainability, comprehensibility**: Transparency can be ensured, provided that the implementation of an AI technology is preceded by the collection and publication of as much information as is necessary for consultations and for public debate on the design and use of the technology[72]. Explainability means that users of an AI system should understand where the results presented by the

71 https://www.who.int/news/item/28-06-2021-who-issues-first-global-report-on-ai-in-health-and-six-guiding-principles-for-its-design-and-use, accessed on 27/05/2022

72 https://ethics-of-ai.mooc.fi/chapter-4/2-what-is-transparency, accessed on 27/05/2022

algorithms come from[73]. Finally, comprehensibility means that it must be clear to users of an AI system what makes the system work, which allows users to predict how changes in of circumstances could lead to alternative results[74]. These are important issues in the context of the patient's right to express an informed consent and the HCP's obligation to exercise due diligence.

However, given the complexity of AI technologies, full transparency, explainability and comprehensibility can be very difficult to achieve. This is particularly important from the point of view of information about AI's outputs and the so-called *"black box effect"* with which we deal more extensively in sections 3.5., 3.7. and 4.7.

- **Responsibility**: It is incumbent on those using AI to ensure that the technology is used in the right conditions and in the right way. It is also necessary to ensure effective mechanisms for asking questions and pursuing claims by individuals and groups who have been adversely affected by algorithm-driven decisions.

The Polish legal system already has solutions that can be used to determine liability in the event of misuse of AI-enabled software. We write more about this in chapter V.

- **Inclusivity**: AI in healthcare should be designed in a way that encourages the widest and fairest possible use and access, regardless of age, gender, income, race, ethnicity, sexual orientation, disability or other characteristics protected against discrimination under human rights codes.

Inclusivity is of particular importance from the perspective of the so-called "AI bias". AI-enabled software can be effective as much as the quality, quantity and representativeness of the data used to train models allows. One of the challenges is the under-representation of certain population groups in the data[75]. This translates into bias of AI algorithms, as a result of which an AI model can generate different results for ethnic, gender or age groups underrepresented in the training data set.

- **Responsiveness**: Designers, developers, and users should continuously and transparently evaluate AI applications, in use, to determine whether AI adequately and appropriately responds to expectations and requirements. In our opinion, the responsiveness of AI systems should be the subject of further clarification and standardization.

The catalog of basic patient rights in Poland is regulated by the Act on Patients' Rights and by the Patient Ombudsman. Any use of AI in patient care requires compliance with these regulations. The key questions that this entails, as well as an attempt to determine the right rules of conduct, are presented in the following sections of this chapter.

73 https://www.ibm.com/watson/explainable-ai, accessed on 27/05/2022

74 Daniel S. Weld, Gagan Bansal: "The challenge of crafting intelligible intelligence" – https://arxiv.org/pdf/1803.04263.pdf, accessed on 27/05/2022

75 https://dlaszpitali.pl/nowosci-z-branzy/ai-w-ochronie-zdrowia-czy-jestesmy-na-to-gotowi, accessed on 13/05/2022

4.2. Can AI decide on the admission of a patient?

As can be seen from the previous section, AI supports humans, but does not replace them, In particular, AI does not make decisions regarding the management of the patient. AI can therefore be a tool supporting HCPs in making decisions about accepting a patient, providing them with a health service by a given person, referring to another healthcare provider, etc. However, it should be borne in mind that AI should be treated as an element of support for human decisions during the patient's way through the therapeutic process and cannot fully replace the human factor[76].

> **The use of AI can significantly improve the performance of a medical establishment, support the organizational aspects of referring patients to doctors or departments based on the existing database, or provide HCPs with information about the legitimacy of transferring a patient to another facility. In this respect, AI could be the first point of contact with the healthcare provider and contribute to optimization of the patient registration system, for example through the so-called "symptom checker".**

The use of AI can significantly improve the performance of a medical establishment, support the organizational aspects of referring patients to doctors or departments based on the existing database, or provide HCPs with information about the legitimacy of transferring a patient to another facility. In this respect, AI could be the first point of contact with the healthcare provider and contribute to optimization of the patient registration system, for example through the so-called *"symptom checker"*[77]. AI can also be a tool for the sorting of patients in terms of the urgency of their cases (as in the triage in hospital emergency departments[78]). Bearing in mind the systemic problem of staff shortages in health care and long queues to specialists, AI creates an opportunity to improve the process of registering and admitting patients, thanks to the prior automatic assessment of, among others, the urgency, nature and severity of health problems reported by the patient.

This, of course, raises the issue of responsibility for decisions. The current regulations do not clarify the issue of using such solutions at the patient registration and referral step. In the light of art. 38 of the Act on the Profession of Doctor, the doctor may not undertake, or withdraw from, the treatment of the patient (unless there is an emergency). Then, the HCP is required to give the patient, or their legal representative or a guardian, sufficiently in advance, a notice of the refusal and a referral to another HCP or medical establishment.

76 https://medcitynews.com/2022/03/developing-trustworthy-ai-solutions-for-healthcare, accessed on 13/05/2022

77 However, they carry a risk of not obtaining adequate medical data from the patient, which may significantly affect the algorithm's decision as to the urgency of intervention. – https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7747260/, accessed on 27/05/2022

78 https://itwiz.pl/ai-w-opiece-zdrowotnej-w-polsce-bedziemy-musieli-na-nia-jeszcze-troche-poczekac, accessed on 13/05/2022

Thus, it is possible to imagine a system in which AI makes an initial diagnosis and decides that a visit to a specialist is not yet required and the health problem should first be consulted with a basic health care doctor. While, technically, AI would be able to complete this process, the question of its readiness to make similar assessments in the light of current medical knowledge remains open. According to the current regulations, the responsibility for such decision (assuming that the has been already admitted to the medical establishment and remains under the care of a specialist) rests with the doctor, so the doctor cannot release themselves from it by entrusting the assessment and decision to the machine[79]. Of course, this does not apply, for example, to situations where it is not necessary to involve an HCP when using AI (as when using a smartphone application or a wearable device).

The above considerations do not mean that AI cannot effectively support the process of admitting patients. For example, solutions such as the symptom checker can be used to recommend optimal patient assignment to an available or competent doctor, taking into account additional data previously obtained from the patient.

Another situation is the use of AI by patients who are about to decide whether to use medical services in connection with their symptoms. In this case, AI can collect information about the patient's condition and then provide them with information about possible causes, whether similar cases require medical consultation and, if so, about urgency and the recommended standard procedure. Although AI collects accurate information and provides personalized output, it is important to note that AI does not provide medical advice, and the information can only help the patient make an informed decision about their health.

4.3. When can AI be used in the provision of health care services?

The use of AI in the treatment process is similar to the use of other types of innovative software in medicine. There are no regulations dedicated to this sphere and the existing rules derive from the general principles of medical professions and patients' rights. The HCP must comply with them to use an AI-enabled solution.

HCPs are obliged to practice their professions in accordance with the current medical knowledge, methods and means for the prevention, diagnosis and treatment of diseases, the principles of professional ethics, and with due diligence[80]. Therefore, the doctor is obliged to do everything within the limits of the means available to them (medicinal products, devices, procedures, etc.), and the achievements of medical science, to ease the patient's suffering, improve his health or prevent exacerbation of the disease[81]. One of such measures is the already existing AI algorithms, the availability of which HCPs should not ignore. This means that, while in the light of current medical knowledge a specific AI solution has been verified as effective for use in specific cases, **it should be** just another tool in the hands of an HCP.

79 Note that this liability applies especially to the case when a particular patient is already under the care of a specific HCP. However, if the patient has not yet been cared for, has not been contacted by a HCP in a situation requiring it, liability for this can be attributed to the software manufacturer (see section 5.8.).

80 Art. 4 of the Act on the Profession of Doctor.

81 Art. 4 in: "Commentary to the act on professions of doctor and dentist of Feb. 28, 2020 (*Journal of Laws* 61/2020, item 514)", an editorial study based on *Private Law Liability*, 2021

> ...while in the light of current medical knowledge a specific AI solution has been verified as effective for use in specific cases, it should be just another tool in the hands of an HCP.

There is also the obligation to practice the profession with due diligence which should include, among other things, the duty to obtain sufficient information about the product used, such as AI-enabled software. All IT systems, including AI, thanks to their functionality, become a tool that a modern doctor must know well and use skillfully, which requires them not only to know medicine but also the basic principles of operation of these tools. This should be emphasized especially when the quality of a diagnosis made by an AI system depends on asking correct questions. Particularly critical is the ability to supply AI with reliable data which are a kind of criteria for this software[82].

In addition to the above principles, it is also necessary to take into account the need to ensure compliance with other applicable legal regulations, in particular those concerning patients' rights and personal data protection, which may legally exclude the possibility of applying some solutions that, for example, do not ensure an adequate level of protection of personal data.

Therefore, if, in accordance with the indications of current medical knowledge, the use of an AI-enabled solution available to the doctor is in the best interest of the patient and meets the due diligence criterion and other technical and regulatory requirements, it is allowed to use such software.

4.4. Can AI provide health care services on its own?

We already have software applications that can formulate diagnoses on their own (at least in part). One of them, the EyeDiagnosis, was approved by the FDA (Food and Drug Administration - a US government institution that is part of the United States Department of Health and Human Services) in April 2018[83]. It is the first AI system approved to autonomously perform diagnostic assessments without the supervision of a human specialist. The local system captures images of the patient's eye using a special apparatus that can be operated by anyone, even a layperson, after a short training session. The images are uploaded to a cloud server for analysis by the AI-enabled software. The algorithm can generate a diagnostic interpretation of diabetic retinopathy and generate a report within a few minutes. The software is programmed to give one of two answers: either negative (in which case the report recommends a re-examination in 12 months) or positive (which generates a recommendation to refer the patient to an ophthalmologist who will handle the case).

82 Olga Sitarz, Marcin Sitarz: "Cyfrowe wspomaganie decyzji medycznych w świetle prawa karnego", *Przegląd Prawa Medycznego* N° 3, 2021

83 https://www.eyediagnosis.net/idx-dr, accessed on 13/05/2022

In connection with the emergence of technologies such as the one described above, we may therefore wonder whether it is possible for AI to provide health care services on its own. In the US, the FDA makes the conditions for the acceptance of individual AI systems dependent on a comparison of the degree of dependence of a particular tool on the doctor's decision and the risks to the patient associated with the disease[84]. In the Polish legal system, however, considerations in the context of the possibility of providing health care services independently by AI should begin from the Act on Medical Activity. Pursuant to art. 2(1)(10) of this law, health care services are activities aimed at preserving, saving, restoring or improving health and other medical activities resulting from the treatment process or separate provisions regulating the rules of their performance.

While the above-mentioned definition – literally read – has a relatively wide scope, its systemic significance in the whole medical law should be taken into account. Health care services are provided by healthcare providers, that is, entities carrying out medical activity, individuals who have obtained professional rights to provide health care services and provide them as part of their business activity, and entities active in the field of supply of medical devices[85]. An entity carrying out medical activity within the meaning of the regulations on medical activity means a medical establishment (e.g., a hospital or a clinic operating in the form of a private limited company), doctor, nurse or physiotherapist practicing their profession as part of medical activity as a professional practice[86].

Thus, in the light of the law, a health service is provided by a natural person (for example, a doctor) or by a legal person (for example, a medical establishment). In the latter case, the service is also provided by a definitively specified employee or co-worker, and the attribution of the service to a legal person is intended to extend liability. There is no doubt that AI does not replace the doctor, nor does it replace any other person providing health care services. Therefore, it is just another tool used by HCPs as part of their services. For example, software provides diagnostic information, but it is the doctor who diagnoses.

And we have a similar situation when a patient uses such software without involvement of medical staff – for example, a symptom checker – to learn about possible causes of their condition. Although this system may or should be a certified medical device, the use of the program by a patient without assistance from an HCP cannot be considered as the provision of health care services.

The situation is more complicated in the case of legal persons who are responsible for the health care services provided as part of their business. So, if, for example, an AI system used by a hospital refuse to admit a patient, the patient may make an allegation that the hospital refused to provide them with health care services. However, as can be seen from previous considerations, in the current legal situation, the responsibility for health care services is borne by HCPs and not by the tools used to provide the services.

84 https://www.fda.gov/news-events/press-announcements/fda-releases-artificial-intelligencemachine-learning-action-plan oraz https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

85 Art. 5(41) of the Act on health services financed from public funds

86 Art. 2(4) of the Act on medical activity

Thus, it is not the AI system that provides the health care services, but the doctors using it (even if their role boils down, for example, to authorizing results).

Thus, while the work done by AI may fall within the literally read definition of a health service, the service is provided by a natural person using it, for whose actions a legal person (for example, a hospital) may also be responsible.

The example of AI-enabled software "diagnosing" diabetic retinopathy given in the first paragraph should be perceived in the light of the Polish law as a diagnostic tool that is used under the supervision of a doctor. In the current legal system in force in Poland, such a "detection" of diabetic retinopathy by AI can be treated similarly as the results of laboratory blood tests marked with an asterisk or bold type, which indicate deviations from the norm. This alone is not a diagnosis, but only a diagnostic input that allows the diagnosis to be made.

The example of AI-enabled software "diagnosing" diabetic retinopathy given in the first paragraph should be perceived in the light of the Polish law as a diagnostic tool that is used under the supervision of a doctor. In the current legal system in force in Poland, such a "detection" of diabetic retinopathy by AI can be treated similarly as the results of laboratory blood tests marked with an asterisk or bold type, which indicate deviations from the norm. This alone is not a diagnosis, but only a diagnostic input that allows the diagnosis to be made.

It should be emphasized, however, that it is the HCP who orders a specific procedure, and the algorithm itself is just a diagnostic method determining further proceedings – just like, for example, the results of hormone level tests for thyroid diseases, which the patient can perform on their own and decide whether to visit the doctor to adjust the dose of the drug or stay at the dose already used.

Similarly, if a doctor (or other HCP) informs their patient that, given the negative result reported by the algorithm, the patient should come for a follow-up visit in 12 months, in this case the AI algorithm may work to some extent "independently". It should be emphasized, however, that it is the HCP who orders a specific procedure, and the algorithm itself is just a diagnostic method determining further proceedings – just like, for example, the results of hormone level tests for thyroid diseases, which the patient can perform on their own and decide whether to visit the doctor to adjust the dose of the drug or stay at the dose already used. The results of laboratory tests do not determine whether a patient suffers from Hashimoto's disease but only inform about the values of individual tested parameters. It is the doctor who, based on these results, makes a diagnosis, thus providing health care services to the patient.

4.5. Should the patient's informed consent to the health service be preceded by a disclosure of information about the use of AI?

One of the basic principles of the medical law is the principle of respect for the patient's autonomy, the basic expression of which is the obligation to give the patient an opportunity to give (or withhold) their informed consent to the performance of health care services for them[87]. Among other things, the patient must be able to evaluate the risk of the proposed procedure (such as posed by the tools used during it), which requires understanding of the procedure and the risk it carries. Only such consent of the patient excludes the surmise of illegality of the doctor's intervention. Simply obtaining the patient's formal consent without informing them about the methods, risks and consequences associated with the procedure makes it an "non-informed" consent which, as such, is flawed, in which case the doctor acts without consent and may incur liability. Therefore, this raises the question of how and when to inform the patient about the use of AI when providing health care services.

The principle is to provide the patient with the information defined in art. 9(2) of the Act on Patients' Rights, i.e. information about the patient's health condition, diagnosis, proposed and possible diagnostic and therapeutic methods, foreseeable consequences of their use or omission, treatment results and prognosis. This does not mean that the doctor must give all the information known to them. The task of the information provider is both to select the information to be transmitted and to properly rank the messages according to their rank. This is to provide information adequate to the case – to provide the right holder with a reliable picture of the patient's health condition, thanks to which medical information will become a constructive foundation for further actions: undertake or abandon treatment, choose a specific diagnostic or therapeutic method[88].

87 Beata Janiszewska: "Zgoda na udzielenie świadczenia zdrowotnego. Ujęcie wewnątrzsystemowe.", 2013

88 L. Bosek (ed.): "Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz.", 2020 – comment on art. 9

AI used in the process of diagnosis or treatment can be treated simply as another contribution to the process of reasoning. If we were able to reconstruct the thought process of a doctor deciding what surgical technique or what therapeutic dose of drug to use, we would find a lot of potential inputs. There is no doubt that a physician who does not explain each of these steps of reasoning does not violate the patient's right to express informed consent[89]. The same will be true of the use of AI as one of the many elements of the decision-making process.

> **The HCP has no explicit obligation to inform the patient about the use of AI. Therefore, there is no reason to assume that the use of AI should always be disclosed just because it is AI.**

Therefore, should the provision of a health service using AI be preceded by providing the patient with knowledge on this subject and by obtaining their informed consent to the use of AI? In our opinion, the answer to this question should be similar to the answer to analogous questions about other tools and techniques used in the patient care process. **The HCP has no explicit obligation to inform the patient about the use of AI**. Therefore, there is no reason to assume that the use of AI should always be disclosed just because it is AI. The assessment of whether the patient's informed consent should be preceded by the disclosure of the use of AI depends on the specific case and on the importance of the AI's contribution. If AI were just one of many minor factors in the process (for example, the use of a "smart" thermometer as part of a transplantation procedure), it does not seem necessary to provide information about it, as it should not be a factor influencing the decision for the typical patient. Surgeons do not inform patients what kind of scalpel they will use during the procedure because it is not a kind of information that could be essential to the consent.

However, **the situation is different where AI has a significant impact on the course or nature of the health service provided. Then, the patient should know and understand this impact, otherwise the understanding of their consent may be questioned.** As in the case when the main element of the examination necessary to make a diagnosis is to perform a CT scan, it is necessary to inform the patient about it in order to obtain informed consent, where AI-enabled software is an essential element in the diagnostic or therapeutic process, the HCP must also provide relevant information to the patient so that the patient's consent is informed. Therefore, if it is the AI that decides on the procedure used, and the HCP agrees with it and communicates this decision to the patient, it is reasonable to inform the patient about the role of AI.

89 I. Glenn Cohen: "Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?", Harvard Law School – https://www.law.georgetown.edu/georgetown-law-journal/wp-content/uploads/sites/26/2020/06/Cohen_Informed-Consent-and-Medical-Artificial-Intelligence-What-to-Tell-the-Patient.pdf, accessed on 27/05/2022

A distinction should be made from the above in the case when the patient asks a specific question about the methods of reasoning, diagnosis or treatment. If a patient asked a doctor whether the proposed procedure would be recommended by AI, and the doctor misled the patient by falsely denying, then this would be a violation of the principle of informed consent[90]. It does not matter whether AI is a minor or decisive element for the process of providing health care services.

In the case where output from AI is one of the elements of the decision-making process of an HCP, there may be a situation in which the HCP doubts the accuracy or disagrees with this output. A distinction should be made between the following cases:

- the HCP disagrees with the data used by software – for example, a blood pressure measurement result shows that the patient should be dead while they are OK;
- the HCP has no doubts about the data used by the software but has doubts about the analysis of this data – for example, a blood cell count result provided by the computer is indicative of anemia, while the HCP considers it normal.

If the HCP doubts the veracity of the data used by AI, it is primarily their duty to verify this data by other available methods (see section 5.3.). As in the case of doubts as to the veracity of the results of a laboratory test (which may be false due to errors in the process of collecting or analyzing the material), in the case of doubts as to the veracity of the results presented by the AI, it is necessary to repeat the test in order to obtain the correct result. The patient should be informed of the need to repeat or verify the examination in each case where it is necessary to satisfy the requirement for informed consent, which remains the responsibility of the HCP in the specific factual state.

If, on the other hand, the HCP doubts the veracity of the analysis of the data, their duty arising from the need for due diligence is also primarily to verify this data (see section 5.3.). In the case of using AI, situations can happen when software recognizes certain diseases based on data incomprehensible or unknown to the HCP (see the black box problem described in section 4.7.3.), but also various types of non-conformities that may lead to erroneous analysis cannot be ruled out. The patient should be informed about the need to repeat or verify the examination, which, as in the case presented above, remains the responsibility of the HCP in the specific factual state. In some situations, it will be necessary to report a defect of AI as a medical device to supervisory authorities.

90 *Ibid.*

4.6. Should the patient be informed about the availability of health care services in which AI is used?

Pursuant to art. 31(1) of the Act on the Profession of Doctor, the doctor is obliged to provide the patient or their statutory representative with accessible information about the patient's health condition, diagnosis, proposed and possible diagnostic and therapeutic methods, foreseeable consequences of their use or omission, results of treatment and prognosis. This obligation corresponds to the patient's right to be informed, defined in art. 9(1) and 9(2) of the Act on Patients' Rights.

Importantly, it is assumed that information about "possible diagnostic and therapeutic methods" should cover the spectrum of methods possible in a specific health situation of the patient in general – not only methods that can be used in the medical establishment in which the information is provided. The determinant of the content of the right to obtain information is the patient's health situation, not the human or technical capabilities of a particular facility[91]. It should always be borne in mind that the information provided to the patient about the "possible methods" should be related to the case of the particular patient, taking into account, for example, their age, co-morbidities and the overall situation[92]. At this point, we also point out that the HCP can, of course, verify the factors influencing the provision of information to the patient about possible diagnostic or therapeutic methods, using specific AI solutions that facilitate decision-making (for example by searching for possible treatment methods).

The patient – informed about their condition and prospects for improvement – must be given an opportunity to try to obtain help in a center with a higher degree of referentiality and having professional medical information at their disposal is the starting point for making such attempts. In particular, this applies to methods that are significantly different from those that can be offered to the patient by a particular HCP – if this significantly different method may be more beneficial for the patient. The information obligation provided for in art. 31(1) of the Act on the Profession of Doctor also applies to methods used in other domestic medical centers and, in special situations such as extremely complicated cases, also foreign centers[93].

> **...it is the impact on the patient's condition that counts, not the mere fact of using AI.**

91 L. Bosek (ed.): "Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz.", 2020 – comment on art. 9

92 L. Bosek (ed.): "Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz.", 2020 – comment on art. 9

93 Supreme Court, V CSK 738/14, 24/09/2015

The above raises the question of whether the HCP is obliged to inform their patients about the availability of health care services in which AI is used. In this case, the HCP should proceed as when informing about the availability of other methods – it is the impact on the patient's condition that counts, not the mere fact of using AI. For this reason, it should be assumed that if the HCP is aware of the availability of a better, AI-based, method, it would in principle be recommended to inform the patient – even if the HCP does not intend to use the method.

At this point, it should be emphasized that HCPs cannot be required to know all diagnostic or therapeutic methods, in particular innovative ones. An HCP asked about the possibility of using AI can, of course, honestly answer that they do not know if they are indeed unaware of the existence of such methods. However, the HCP should update their knowledge and contact the patient or suggest other sources of information.

4.7. Does the patient have the right to access information about data from AI systems?

4.7.1. Input data

According to the guidelines of the Medical Device Coordination Group[94], any data fed to software to obtain an output after processing can be considered as input data.

Examples of input data include:

- data input using a human interface device, such as a keyboard, mouse, e-pen, or touch screen or speech recognition application;
- digital documents in general formats (DOC, PDF, JPEG) and files complying with dedicated medical standards (DICOM, ECG, electronic health records);
- unformatted digital documents;
- data pulled from or pushed by devices.

Therefore, if, for example, an AI-enabled application is used for diagnosis, the input data will often be the result of a test or other information about the patient's health, based on which therapeutic decisions can be made. Often it will be information that the patient already knows, such as the results of a blood test. However, we point out that it is important to inform the patient about the information entered into the application in order to obtain results relevant to the diagnosis or treatment process.

At this point, in the context of input data, we emphasize that AI-enabled software should contain elements of data control (e.g., alert the user about the keying in of an extreme value for a parameter), enforce

94 MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, 2019 – https://ec.europa.eu/health/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf

verification before approval (e.g., for a laboratory test result that cannot occur in humans), inform about significant deficiencies in the input data or that the input data are significantly different from the normal ones used in the process of machine learning.

4.7.2. Output data

According to the guidelines of the Medical Device Coordination Group[95], any data produced by software can be considered as output data.

Examples of output data:

- data displayed on screen (such as a layout with numbers, characters, images, etc.);
- printed data (such as a layout with numbers, characters, images, etc.);
- digital documents in general formats (DOC, PDF, JPEG), files complying with dedicated medical standards (DICOM, ECG, electronic health records) and unformatted documents.

> **For this reason, the patient should receive information about the output data but this information may be complemented by a doctor's comment or be part of information to be provided later, if it is not yet relevant to the patient on its own.**

Therefore, if, for example, an AI-enabled application is used to make a diagnosis, the output data from the application will often be the result of a test or other information about the patient's health. For this reason, **the patient should receive information about the output data** from artificial intelligence systems but this information may be complemented by a doctor's comment or be part of information to be provided later, if it is not yet relevant to the patient on its own.

95 MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, 2019 – https://ec.europa.eu/health/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf

If, on the other hand, it is only a part of the doctor's assessment, or concerns marginal issues, it seems that their omission should not be assessed as an error. There is no legal obligation to provide the patient with results produced by AI. However, the obligation to inform the patient about important issues in the context of his self-determination is invoked, and the AI-generated results may be important.

In particular, when an AI system, especially when used as a medical device, presents information unfavorable to the patient as a starting point in the process of treatment or diagnosis, the patient should in principle be informed. This data, of course, can be of a very different nature and reliability, so, if appropriate, they should be accompanied by a comment from an HCP who will explain their meaning in detail. As with other information provided to the patient, it is also important to take into account **the level of significance** of the data. If the baseline data can be relevant to the patient, it should undoubtedly be disclosed. If, on the other hand, it is only a part of the doctor's assessment, or concerns marginal issues, it seems that their omission should not be assessed as an error. **There is no legal obligation to provide the patient with results produced by AI**. However, **the obligation to inform the patient about important issues in the context of his self-determination is invoked, and the AI-generated results may be important** (see section 4.5.).

The exception is the so-called "therapeutic privilege" which seems to include information generated by AI. Exceptionally, a doctor may decide to limit the information provided to a patient based on, and within, the limits of art. 31(4) of the Act on the Profession of Doctor. According to this provision, in exceptional situations, if the prognosis is bad for the patient, the doctor may withhold certain information about the health condition and prognosis if, according to the doctor, it is in the interest of the patient. Therefore, the doctor, guided by the patient's well-being, may restrict the disclosure to a certain extent, which should also include the output data provided by AI, as should be considered due to its purpose. In such cases, the doctor informs the patient's legal representative or a person authorized by the patient. However, if asked by the patient, the doctor is obliged to make the disclosure.

It should be noted here that the obligation to communicate the output data also has its source in the GDPR. If the patient requests this data as the data subject, the data controller is obliged to make the disclosure.

4.7.3. The black box effect

In the context of information about the AI's input and output data, it is necessary to raise the issue of the so-called "black box effect". In computer science, a "black box" is a device, system, or program that allows you to see the input and output, but does not give insight into the processes and interaction taking place

in between. So, in the context of AI, the black box effect means that we do not see how some AI-enabled tools work. In other words, we know the question or input data (e.g., photos of skin lesions). We also know the answer or output data (e.g., skin lesions marked on a diagnostic image as "cancer"). The term "black box effect" describes a situation in which we do not understand how the tool transformed the input data into the output data; what has decided about the result.

> First of all, note that the situation in which an HCP does not fully understand the working of a method is not new in modern medicine.

First of all, note that the situation in which an HCP does not fully understand the working of a method is not new in modern medicine. For example, the mechanisms of action of some drugs with proven effectiveness are not entirely clear – as in the case of drugs for depression. Blood levels of serotonin are measurable – they have been shown to be lower in people suffering from depression – but researchers do not know if the serotonin level in blood corresponds to the level in the brain. It is also unknown whether a decrease in the serotonin level is the cause or effect of depression. Popular antidepressants that affect serotonin levels – selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs) – are thought to suppress symptoms of depression, but their effects are not fully understood[96].

Not every solution in medicine, including AI, will be fully explainable. However, each can be accompanied by a comment or instruction increasing the ability to understand the principles of operation of a particular software suite. As AI becomes more widely used in healthcare, the impact of its decisions is becoming more serious. Given this impact, ignoring the AI black box problem raises ethical concerns – because AI can make mistakes, like humans. AI technology has no moral code. It does not "understand" the results it delivers in the same way as a human being does. If an AI application presents an erroneous result, it will not notice it. Humans must do it and this can be difficult when they cannot understand what reasoning is behind the result.

96 Iwona Patejuk-Mazurek, Katedra Interdyscyplinarnych Studiów nad Niepełnosprawnością APS w Warszawie, Mazowieckie Specjalistyczne Centrum Zdrowia im. prof. J. Mazurkiewicza w Pruszkowie: "Wybrane leki przeciwdepresyjne i o działaniu przeciwlękowym — praktyczne wskazówki stosowania i opisy przypadków", *Via Medica*, vol. 14, N° 3, 135-142, 2017 – https://www.webmd.com/depression/features/serotonin

The black box effect problem in a clinical context is not particularly relevant where studies show that the solution works and is sufficiently effective from the clinical point of view, especially in terms of patient safety. Then, we can trust the solution even without fully understanding the nature of its operation.

This does not mean that a doctor cannot use AI. However, they should, acting with due diligence, understand how it works and know its limitations. For example, if the machine learning data set for an AI system did not take into account patients of a certain gender, age or race, this input data shortage may affect the quality of the system's recommendations[97]. The black box effect problem in a clinical context is not particularly relevant where studies show that the solution works and is sufficiently effective from the clinical point of view, especially in terms of patient safety. Then, we can trust the solution even without fully understanding the nature of its operation. It should also be emphasized that, in the case of limited explainability of AI operation, it will be beneficial to additionally verify the diagnostic information provided by the software using conventional methods. In particular, this may turn out to be necessary where an AI-suggested indication is to be a basis of the therapy. In circumstances where the input data include clinical indicators that are affected by pharmacotherapy, for example, the lack of knowledge about their contribution to the AI-made decision basically means that there is no chance for an adequate intervention. In these types of applications it is particularly important to develop diagnostic standards combining AI solutions with conventional methods for verification of indications. In certain situations, aspects of limitations in the interpretation of AI-made decisions should be part of the patient's informed consent.

4.8. Is entering patient data into an AI system a violation of physician-patient privilege?

A doctor, like any person practicing a medical profession, is obliged to keep confidential information related to the patient and obtained in connection with the performance of the profession. Secrecy therefore applies to all facts and information related to the patient and the treatment, as well as other information (co-morbidities, family, profession, personal relations, sexual contacts or preferences, infertility, etc.)[98].

97 Note that information about training data and the purpose of AI should be provided to medical professionals by the software manufacturer or distributor.

98 L. Ogiegło: "Ustawa o zawodach lekarza i lekarza dentysty. Komentarz.", 2015

> The mere use of an AI system does not mean the disclosure of physician-patient privileged information – just as in the case of using MRI, ultrasound or other medical devices in diagnosis.

The concept of physician-patient privilege includes both the doctor's statements and various documents in which information about the patient is recorded (for example, medical history, records, data entered into the computer)[99]. The physician-patient privilege will therefore cover the data of a specific patient entered into the AI system and the output data concerning the patient. The data may be processed by external entities, such as suppliers of medical devices or IT systems. **This does not mean that the use of AI is unacceptable**. The mere use of an AI system does not mean the disclosure of physician-patient privileged information[100] – just as in the case of using MRI, ultrasound or other medical devices in diagnosis. **As long as this is done in compliance with the applicable legal regulations**, for example based on a contract for entrusting the processing of personal data, **entering patients' data into the AI system does not violate the principles of physician-patient privilege**. However, the risk of violating the privilege increases if the necessary requirements in the field of cybersecurity or protection of medical data are not met.

4.9. May third parties (for example, the patient's family) gain access to information about them generated by an AI system?

In our opinion, important information generated by AI, which significantly affects the diagnostic and therapeutic process (see section 4.7.), should be part of the medical documentation (see section 4.1.). However, this does not apply to the information output from AI, which is only a minor, one of many, elements of the diagnostic process. The entity providing health care services makes medical documentation available only to the patient, their statutory representative or a person authorized by the patient.

Therefore, if the patient does not have a legal representative and has not authorized a family member, then such person may not access information generated by the AI system. The mere fact of being a person close to the patient does not entitle this person to obtain information about the patient's health condition during the patient's lifetime.

99 Apart from the patient's right to access medical records

100 This applies both to the use of data during the creation of a closed AI system and to the subsequent learning by the system, subject to the requirements for the protection of personal data that we discuss in chapter V.

There are some exceptions to this rule. For example, if secrecy may pose a danger to the life or health of the patient or someone else (e.g., if the patient is mentally ill and poses a threat to others or is infected with HIV), the doctor may reveal sensitive information to certain people[101]. Similarly, it seems possible to disclose the results of genetic tests to persons related to the patient where there is a threat to their life or health[102].

However, it should be noted that the doctor can reveal the secret only to those people whose life and health will be endangered as a result of contact with the patient. In the case of HIV, it will undoubtedly be the patient's household members, in particular their partner, but not the patient's whole family. It may also be other medical personnel who have been in contact with infectious material from this patient[103].

> **...sharing patient information with a third party is done in accordance with the applicable law, regardless of whether it concerns information generated by AI or not.**

In summary, sharing patient information with a third party is done in accordance with the applicable law, regardless of whether it concerns information generated by AI or not.

4.10. Should the use of AI be recorded in medical records?

In the light of the current regulations, the catalog of information that may be included in medical documentation is non-exhaustive but, at the same time, the legislator has defined a minimum set of elements necessary in medical documentation[104]. The specification of the scope and types of medical documentation is provided in the regulation of the Minister of Health on the types, scope and forms of medical documentation and methods of its processing. As the use of AI is not yet regulated in detail by the law, the question may arise as to whether and when the use of AI in medical records should be recorded.

101 Art. 40(2)(3) of the Act on the performance of the profession of doctor

102 Dr. Agata Wnukiewicz-Kozłowska, Dr. hab. Leszek Bosek (ed.): "Szczególne świadczenia zdrowotne", *System Prawa Medycznego*, vol. 2 – https://bip.brpo.gov.pl/sprawygeneralne/pdf//2017/7/VII.5002.6.2017/1104442.pdf

103 https://prawalekarzy.pl/artykuly/czy-mozna-powiadomic-rodzine-pacjenta-o-tym-ze-jest-on-nosicielem-wirusa-hiv-26, accessed on 13/05/2022

104 Art. 25 of the Act on Patient's Rights

> The entry of information on the use of AI in medical records is governed by the rules similar to those applicable to the documentation of use of other equipment.

The entry of information on the use of AI in medical records is governed by the rules similar to those applicable to the documentation of use of other equipment.

Firstly, such records document what has happened to the patient so far, what procedures have been used, and what is important for the continuation of the treatment. In that, other people who reach for the records will know the current course of care. This justifies the logging of activities related to the use of important AI tools, so as to avoid, for example, repeating certain procedures.

Secondly, the medical records should contain medically relevant information on the patient management. So, if some important information has been generated by AI, it is worth having it clearly noted. Then, the follow-up doctor will have a more complete knowledge of the previous procedures and, what is more, they will be able to verify whether, for example, the diagnosis proposed by AI has been confirmed by further diagnostic tests.

Thirdly, medical records have an evidentiary function in court proceedings. Thus, documenting the fact of reaching for AI can be used, for example, to demonstrate due diligence on the part of the doctor who used the tool, which is reflected in the documents.

> In view of the above, it must be assumed that the mere fact of using AI does not mean that it must be disclosed in medical records. However, the documentation should include information important for the patient care process, and an annotation about the use of AI can be such information.

In view of the above, it must be assumed that the mere fact of using AI does not mean that it must be disclosed in medical records. However, the documentation should include information important for the patient care process, and an annotation about the use of AI can be such information. This will provide a more precise knowledge of what has been done with the patient. As it has already been mentioned, it is also reasonable to pay attention to **the level of significance of the use of AI**. The more important is its role in the whole process, the more it should be reflected in medical records.

4.11. Conclusions

- The patient has the right to obtain complete and comprehensive information about their health condition, diagnosis, diagnostic and therapeutic methods (including AI), foreseeable consequences of their use or omission, results of treatment and prognosis. On the other hand, the patient may waive this right.

- Under no circumstances should there be any of the extremes before the patient makes an informed decision: no information about the use of AI at all (even if it is important) or the opposite – overloading the patient with unnecessary or incomprehensible information (just because it has been generated by a computer program). In addition, the patient has the right to ask for explanations until the information provided is comprehensible.

- The use of AI itself does not necessarily mean the need to inform, obtain consent or place information in the patient's records. But it is crucial to determine the importance of using AI in the diagnostic and therapeutic process.

- The patient has the right to decide to whom and what information about his health condition can be transferred, which – together with the right to confidentiality – is particularly important in relation to AI which derives its full potential from information. The patient has the right to confidentiality – secrecy of all information related to them, in particular about their health condition, diagnosis, prognosis, examinations and their results. Without the patient's consent, it is forbidden to disclose this information, including the results of the use of AI, to anyone.

- The patient also has the right to services consistent with current medical knowledge. This right is necessarily connected with the above-discussed standard of practicing the profession of a doctor. Proper fulfillment of this patient's right in the context of the development of AI will be particularly important and will pose new challenges for HCPs in terms of self-improvement and learning.

5. AI and the performance of medical professions

5.1. Who can use AI in healthcare?

AI can be used by a number of health care service providers. Firstly, there are **HCPs**, i.e. doctors, dentists, nurses, obstetricians, physiotherapists, paramedics or pharmacists. This catalog may be extended to include other **persons involved in health care services**, i.e. facilitating the provision of health care services within the meaning of art. 24(2) of the Act on Patients' Rights.

Secondly, we have **medical establishments** such as independent health care institutions, entrepreneurs within the meaning of the Act on the Law of Entrepreneurs, research institutes and foundations[105].

Thirdly, there are **investigators** (persons responsible for conducting clinical trials) and **sponsors** (natural persons, legal persons or organizational units without legal personality responsible for undertaking, conducting and financing clinical trials)[106].

Fourthly, there are **universities** – AI can also be effectively used in the process of teaching medical students[107].

AI can also be used outside health care services by **medical establishments** in the field of administration, service and management[108].

5.2. Is the use of AI consistent with current medical knowledge?

According to art. 4 of the Act on the Profession of Doctor, the primary duty of a doctor is to *"practice the profession in accordance with the indications of current medical knowledge, available methods and means for the prevention, diagnosis and treatment of diseases, in accordance with the principles of professional ethics and with due diligence"*. Current medical knowledge is based on the evidence-based medicine system, guidelines and recommendations of scientific societies, which continue to be updated to take account of new developments[109]. It is also based on standards of conduct confirmed by research methods with proven clinical effectiveness[110]. AI can be used to achieve the objective in question[111] – with due caution and taking into account the limitations of AI in health care[112].

105 Art. 4 of the Act on Medical Activity

106 Art. 2 of the Pharmaceutical Law

107 https://www.pwc.com/gx/en/industries/healthcare/publications/ai-robotics-new-health/transforming-healthcare.html, accessed on 23/03/2022

108 https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/transforming-healthcare-with-ai, accessed on 22/02/2022

109 https://prawo.ug.edu.pl/sites/default/files/_nodes/strona-pia/33461/files/38widlak.pdf, accessed on 23/02/2022

110 https://journals.viamedica.pl/folia_cardiologica/article/view/64914, accessed on 23/02/2022

111 https://www.scalablehealth.com/Resources/WP/AI_Changes_Evidence_Based_Medicine.pdf, https://link.springer.com/referenceworkentry/10.1007/978-3-030-58080-3_43-1, accessed on 23/02/2022

112 https://academic.oup.com/ndt/article/35/2/191/5614330, accessed on 23/02/2022

> ...unjustified non-use of new technologies may be considered inconsistent with current medical knowledge.

The possibility of proceeding with the use of the latest technological solutions should always be objectively assessed in accordance with the given clinical case and medical context. Thus, **unjustified non-use of new technologies may be considered inconsistent with current medical knowledge**.

From the perspective of an HCP, it is important to verify whether a given AI solution can, in the light of current medical knowledge, be used for a specific study or treatment. This requires, among other things, careful reading of instructions attached to software, becoming familiar with materials supplied by the manufacturer or distributor, verification of available research results relating to specific software, or finding out about similar software used in the particular context.

Therefore, **the use of AI is consistent with current medical knowledge, as long as there are objective, confirmed by evidence-based medicine, premises confirming the possibility of using AI in a given clinical application**.

5.3. How to use AI with due diligence?

According to art. 4 of the Act on the Profession of Doctor, the doctor is obliged to practice the profession with due diligence. In order to interpret the meaning of "due diligence", it is necessary to refer to art. 355(2) of the Civil Code as a kind of matrix for building a due diligence model. The regulation states that the debtor's due diligence in respect of their business is determined taking into account the professional nature of the business and it is argued that this provision should apply only to contractual liability.

The model of due diligence in the context of this regulation is based on the assumption that certain obligations have been imposed on a professional by operation of law, and solely on the ground that the professional develops their activity in a professional manner[113].

Due diligence is therefore **a model of conduct** that should be followed in the performance of an obligation. The assessment of whether due diligence has been exercised is made by comparing the actual conduct with the model of due conduct[114]. Any deviation for the worse from the model can become a basis for

113 E. Bagińska, K. Bączyk-Rozwadowska, U. Drozdowska et al.: "Komentarz do ustawy o zawodach lekarza i lekarza dentysty of Feb. 28, 2020 (*Journal of Laws* 61/2020, item 514)", editorial study based on *Odpowiedzialność prywatnoprawna*, 2021

114 G. Glanowski: "Należyta staranność udzielenia świadczenia zdrowotnego" [in:] *Umowa o świadczenie zdrowotne*, Warszawa, 2019

considering actions of the professional to be non-compliant, inconsistent with the due diligence model. **Due diligence in the case of medical professions can therefore be understood as taking such actions by an HCP that are aimed at achieving the best for the patient**. These activities are supposed to maximize the odds of achieving the desired results while minimizing the risk of adverse side effects. Exercising due diligence means fulfilling one's obligations in the field of providing health care services. The concept of due diligence refers to the mode of action rather than its outcome. Therefore, due diligence is considered to manifest itself in two basic characteristics of behavior: compliance with the rules of expertise and conscientiousness[115].

According to the judgment of the Supreme Court in case II CR 358/83[116], the concept of due diligence is closely related to current medical knowledge: *The state of medical knowledge must determine the level of requirements in the sphere of diagnosis and therapy. This state of medical knowledge should be understood broadly. It includes not only methods of treatment, but also the use of medicines and medical equipment of health facilities. The question of the use of the best methods of treatment and the best curative and technical means for this purpose comes to the fore.*

> **Therefore, in order to use AI in accordance with due diligence, it should be used in such a way that the use of an AI-based program or tool provides objective support in achieving the best possible diagnostic or therapeutic result for the patient, while securing the risk of adverse side effects, based on current medical knowledge.**

Therefore, **in order to use AI in accordance with due diligence, it should be used in such a way that the use of an AI-based program or tool provides objective support in achieving the best possible diagnostic or therapeutic result for the patient, while securing the risk of adverse side effects, based on current medical knowledge**.

115 *Ibid.*

116 https://sip.lex.pl/orzeczenia-i-pisma-urzedowe/orzeczenia-sadow/ii-cr-358-83-starannosc-lekarzy-i-innego-personelu-521380105, accessed on 23/02/2022

Due diligence means the need for an HCP to take action on two levels. Firstly, the HCP has to consider whether the use of AI is justified in a given case (which is related to the obligation to act in accordance with current medical knowledge). It is therefore appropriate to assess benefits and risks of using AI in a given clinical case. Particular account should be taken of limitations associated with AI systems, as tools and software can primarily support the HCP and cannot completely replace the human factor in the diagnosis and therapy of patients.

Secondly, if the use of an AI tool with due care is permissible, it should be used in accordance with applicable instructions. Improper use of an AI tool or program, such as incorrect data entry or configuration of software parameters, may become a basis for a charge of the lack of due diligence[117]. HCPs should always carefully review operating instructions provided by manufacturers and suppliers of AI tools or software. The aspect of accuracy and reliability of the entered data is important in the case of AI because, in certain solutions, the data can become a part of the machine learning base and, then, errors or carelessness in this area can affect not only the current patient but also all subsequent ones in whom the AI tool will be used. Building awareness of the existence of such relations should be an important element of educating AI users.

> **...we recommend a thorough verification of the software used, including a check whether the software is a medical device (which means that it has already been validated) and whether, according to the instructions, it is intended for the specific medical case.**

So, how should an HCP act in practice to comply with the principle of due diligence? First of all, **we recommend a thorough verification of the software used**, including a check whether the software is a **medical device** (which means that it has already been validated) and whether, **according to the instructions**, it is intended for the specific medical case. It is also worth verifying available research results and legal analyses relevant to the situation.

In addition, the HCP should check whether the available information about the software indicates that it may not be intended or suitable for a given application – for example, **when the data on which the software was trained is significantly different from the clinical case under consideration**. In this context, a very important issue from the perspective of providing health care services with due diligence is the aforementioned problem of the bias of algorithms resulting, among others, from the data fed to them.

117 https://prawo.mp.pl/baza-wiedzy/zawod-lekarza-odpowiedzialnosc/286599,smierc-pacjenta-wywolana-zastosowaniem-sztucznej-inteligencji-w-technologiach-medycznych-analiza-prawnokarna, accessed on 23/02/2022

This bias can involve not only the specificity of the population of "data donors" but also the standards of diagnostic and therapeutic procedures used by the HCPs under whose care these patients remain. This is particularly important in the interpretation of indications of predictive tools using AI methods, which are rarely fed by the data of patients who do not undergo any intervention. It cannot be expected that, for the sake of development of AI algorithms, a recognized therapy will be withheld only to trace the natural course of the disease. Therefore, the AI tool will usually predict the individual patient's condition in the context of "embedding" him in a machine learning database containing information about a number of patients undergoing various therapies.

For example, when using a tool that predicts exacerbation of heart failure in a given patient, one should be aware of whether the AI tool "learned" on a set of patients treated (with intervention) or just passively observed in a similar clinical situation. These two scenarios call for different clinical decisions.

5.4. Is the use of AI in line with professional ethics?

The general criteria for recognizing the performance of the profession of doctor as correct are set out in art. 4 of the Act on the Profession of Doctor. According to this regulation, a doctor should practice their profession in compliance with, inter alia, the principles of professional ethics.

Compliance with the principles set out in the Code of Medical Ethics (KEL) is a part of conduct meeting the requirements of professional ethics. It should be emphasized that, according to art. 1(1) of the Code, the principles of medical ethics are derived from general ethical standards.

The basic principles of Code are fundamentally in line with the whole body of the law. We point out, for example, the principles of due diligence, current medical knowledge, informed consent, and professional secrecy. It should be emphasized, however, that the norms of the Code are not legal regulations falling within the scope of the state administration but are just deontological norms belonging to the field of ethics.

The Code of Medical Ethics does not contain rules that exclude the possibility of using AI by HCPs. To the extent that the use of AI is lawful, it will also be compliant with the Code.

The Code of Medical Ethics does not contain rules that exclude the possibility of using AI by HCPs. To the extent that the use of AI is lawful, it will also be compliant with the Code.

5.5. As an HCP, can I refuse to use AI in the provision of health care services?

The HCP is free to choose the methods of treatment that he considers to be the most effective and consistent with current medical knowledge. The HCP is obliged to exercise due diligence (see section 5.3.).

Performing the profession of a doctor with due diligence involves, among others, the obligation to familiarize oneself with the properties of the means used (both medicines and medical devices), contraindications and warnings from manufacturers. Without this knowledge, the doctor cannot make a reliable decision about the use of treatment and methods[118]. A situation where a doctor does not know the principles of operation of an AI-enabled software application (for example, recognized as a medical device) is similar in some respects to a situation in which a doctor does not know the properties and effects of a particular medicinal product.

Without proper knowledge of the software, the doctor is unable to provide health care services with due diligence. Then, the doctor should refuse to use this particular AI solution.

The situation of refusal to apply a specific solution, for example, due to the impossibility of exercising due diligence, should be distinguished from the situation of refusal to provide health care services as such. Articles 38 and 39 of the Act on the Profession of Doctor introduced into the Polish legal system the HCP's right to refuse to provide health care services, provided that the conditions specified therein are met. The doctor's right to refuse treatment may be exercised in two forms: refusal to provide treatment and refusal to continue (withdrawal from) treatment. The doctor may invoke this right as long as there is no absolute obligation to provide assistance.

A nurse and obstetrician may refuse to comply with a doctor's instruction or otherwise provide a health service if this would be inconsistent with their conscience or the scope of qualifications, immediately giving the reason for the refusal in writing to the doctor or other superior (art. 12 of the Act on the Professions of Nurse and Obstetrician).

There are no specific provisions regarding the possibility or prohibition of refusing to use AI in the provision of health care services. It is therefore necessary to follow the general rules governing the specific medical profession.

118 Court of Appeals in Warsaw, I ACa 515/14, 04/03/2015

5.6. Can the use or non-use of AI be a medical error?

The term "medical error" does not appear directly in the regulations[119]. The definition has been developed by doctrine and judicature. It is assumed **that a medical error is an act (or omission) of a doctor in the field of diagnosis and therapy, inconsistent with the scope of science of medicine known to the doctor**. Hence, for example, a doctor's neglect of their duty to care for the patient and provide them with a safe and hygienic environment is not a medical error[120]. Medical error should be treated strictly as a procedure contrary to the generally recognized principles of medical knowledge. It is an objective category, independent of a person or circumstance.

> **...a failure to use a diagnostic or therapeutic method based on AI where such method should be used in accordance with the current medical standards may be treated as medical error.**

Given that a doctor's failure to order a test (such as an X-ray) or provide a therapy, where available, contrary to current medical knowledge, is recognized as a medical error, also **a failure to use a diagnostic or therapeutic method based on AI where such method should be used in accordance with the current medical standards may be treated as medical error**[121].

In the context of the use of AI by HCPs, irregularities leading to medical error can result from many different technical factors, such as software defects or insufficiency of data. These factors can lead to bodily injury or upset the patient's health. Errors of this nature may occur already at the diagnostic stage. For example, improper spacing of pixels on an image may lead to non-detection or to false detection of a disease[122]. Damage can also be caused by the human factor, for example as a result of misusing a system or insufficient training in the use of specific software.

However, the occurrence of any abnormality in the treatment process **may not be the only cause of a medical error**. Whether the error has occurred or not depends on the answer to the question whether

119 However, there is a "medical event". Pursuant to art. 67a of the Act on patients' rights, a medical event is an event in the form of infection with a biological pathogen, bodily injury, health disorder or death resulting from outdated medical knowledge: (1) diagnosis, if it caused improper treatment or delayed proper treatment, contributing to the development of the disease, (2) treatment, including surgery, (3) the use of a medicinal product or medical device.

120 Supreme Court, IV CR 39/45, 01/04/1955.

121 In this example, for simplicity, we deliberately do not refer to other circumstances in the provision of medical services, such as obtaining or not obtaining consent or the organizational availability of specific methods.

122 K. Bączyk-Rozwadowska: "Odpowiedzialność cywilna za szkody wyrządzone w związku z zastosowaniem sztucznej inteligencji w medycynie", *Przegląd Prawa Medycznego* N° 3, 2021

the conduct of the HCP in the specific situation, taking into account all the circumstances, and in particular the data that the HCP had or could obtain, was consistent with the current medical science and generally accepted practice[123].

In terms of medical errors, the most difficult is the question of how to proceed while using a software application, taking into account that it may be faulty. Two issues need to be discussed in this context.

Firstly, the question whether the doctor has a duty to check the functionality of the system. In general, **the principle of limited trust** is proposed. There is no need for checking the system before each use for functionality, compliance or stability. However, any sign of error (in this case software malfunction) should induce the HCP to refrain from using the system until the problem has been corrected (in accordance with the principles of due diligence)[124].

In the digital world, the choice of tool no longer belongs solely to the doctor (who is primarily responsible for the diagnosis and therapy), so such fault must be viewed not only as the doctor's error (e.g. diagnostic) but also as an error of the health care establishment for which the person who decides to equip the facility with such and not another support system may be held responsible[125].

Secondly, the question whether the doctor is obliged to verify the diagnosis and therapy proposed by the system. In routine practice, the doctor may use only methods which have been positively validated as fit and suitable. The doctor's reliance on digital support may be compared to the necessary mutual trust within a surgical team, the lack of which could be catastrophic[126].

However, this trust must not be absolute and a certain degree of vigilance is dictated by the rules of diligence and prudence. It is assumed that each member of the team is qualified and reliable but the trust lasts until the first sign of a problem.

With regard to an AI-enabled solution recognized as a medical device, the doctor may expect that it is effective, safe and well operated and maintained by the health facility but should always act with due diligence and attention (see the next section).

123 Supreme Court, II KK 124/12 of 12/02/2013, V KK 33/02 of 10/12/2002

124 O. Sitarz, M. Sitarz: "Cyfrowe wspomaganie decyzji medycznych w świetle prawa karnego", *Przegląd Prawa Medycznego* N° 3, 2021

125 *Ibid.*

126 *Ibid.*

5.7. What are the rules of responsibility for the use of AI in healthcare?

The issue of liability for damage caused by the use of AI is the subject of this and following chapters. Due to the extensiveness of the subject, which is certainly worth a separate study, only selected issues that we consider the most important are addressed below.

In order to construe the principles of responsibility for the use of AI, we have used the existing legal acquis. Therefore, the following considerations will focus on the answer to the questions of **to what extent the existing legal regulations are sufficient to regulate liability for the use of AI**, in which areas it is enough to rely on the existing regulations, and which should be amended and how.
We discuss in this White Paper **three basic liability regimes** that can apply to the use of AI in healthcare:

- civil,
- criminal,
- professional.

We ignore the regime of occupational liability of HCPs.

Regarding the principles and basis of liability, some publications suggest that the existing regulations should be revised and certain new rules should be implemented. This often involves proposals to decide whether AI systems can be attributed legal subjectivity (as "electronic persons")[127]. Speaking about the attribution of liability to AI, the European Parliament rightly points out that the responsibility for the use of even autonomous systems should lie with humans[128].

5.8. What are the principles of civil liability in the context of the use of AI in healthcare?

The issue of civil liability for the use of AI is particularly complex. The literature on the subject has just begun to discuss this subject more extensively and the debate concerns mostly the general principles of liability. These, in turn, will only translate into liability in the context of applications in health care, i.e. taking into account the medical law.

We do not present in the following considerations all possible grounds for civil liability in the context of the use of AI in healthcare. We discuss only selected ones that most certainly can apply to health care.

127 K. Bączyk-Rozwadowska: "Odpowiedzialność cywilna za szkody wyrządzone w związku z zastosowaniem sztucznej inteligencji w medycynie", *Przegląd Prawa Medycznego* N° 3, 2021

128 European Parliament resolution of Feb. 16, 2017, with recommendations to the Commission on civil law rules on robotics (2015/2103(INL)), O.J. C 252 of 18/07/2018

5.8.1. Liability of the user

In the context of civil liability, we can consider first of all **the attribution of liability to the user (operator) of an AI system**, that is, an HCP or another person using it. As the European Parliament points out in its resolution of Feb. 16, 2017, users of AI systems should in principle bear a **fault-based liability**[129].

The Polish Civil Code does not establish standards relating to autonomous systems. However, the general formula of tort (art. 415 of the Civil Code) applies in a situation where damage is caused as a result of incorrect or inappropriate use of a robot by the operator.

Pursuant to art. 415 of the Civil Code, the person who through their own fault has caused damage to another person is obliged to remedy it[130]. In order to attribute fault-based liability to the user of an AI system, their act must be culpable, and the resulting material or non-material damage must be in an adequate causal relationship with the doctor's behavior (art. 361 of the Civil Code). For the attribution of blame, it is necessary to state that the HCP would have avoided causing harm if he had exercised due diligence and used all the methods and means available to them in the given circumstances for the diagnosis and treatment of diseases. The lack of diligence alone may not be sufficient to attribute liability if this omission is justified by the circumstances and the possibility of an allegation of misconduct is excluded[131].

For example, fault-based liability for the use of an AI-enabled software application can only be borne by an HCP who knows or should have known about the danger that has been revealed through the use of AI and has not prevented it, although he could have done so. **A violation of the legal obligation to prevent danger is the prerequisite for attributing liability**. The HCP (as a user, an operator of the AI-enabled application) may be held liable if the damage has arisen as a result of the robot's unpredictable behavior (its autonomous decisions) on which the operator did not and could not have any influence[132].

The source of the fault-based liability of an HCP may be a tort or a non-performance or an improper performance of the contract between the parties. The fault should then be assessed taking into account **the objective and abstractly viewed model of a specialist who uses an AI-enabled device**.

As AI solutions in medicine become more popular, it will be necessary to set minimum professional requirements that must be met, for example, by a surgeon using an AI-enabled robot (in this respect, the regulation may also take into account, among others, the obligations of the manufacturer or supplier of specific software in terms of appropriate training of medical personnel). These will be specific requirements

129 *Ibid.*

130 It is worth adding that when a patient and, for example, a dentist were bound by a contract (e.g. for the construction of a prosthesis), contractual liability is based on alleged fault (art. 471 of the Civil Code).

131 Commentary to the Civil Law of 16/09/2020 (*Journal of Laws* of 210/2020, item 1740), editorial study based on: "Odpowiedzialność prywatnoprawna", E. Bagińska (ed.), 2021

132 K. Bączyk-Rozwadowska: "Odpowiedzialność cywilna za szkody wyrządzone w związku z zastosowaniem sztucznej inteligencji w medycynie", *Przegląd Prawa Medycznego* N° 3, 2021

defining what a diligent surgeon should do (or not do) to avoid harming the patient (knowledge of the principles of robot operation, manual skills, ability to react in emergency situations, appropriate training, experience from a certain number of surgeries involving AI-enabled machines)[133].

5.8.2. Liability of the manufacturer

It is also possible to **make the manufacturer remedy the damage** because it is them who have sold the AI solution and earned a profit. According to the doctrine, manufacturers of AI systems should be **liable on a risk basis**[134].

Despite the lack of a dedicated regulation, as in the case of fault-based liability (see section 5.8.1.), other regulations existing in the Polish civil law are sufficiently capacious to be able to cover cases of damage caused in connection with the use of AI. Unfortunately, this is not a simple rendition – this is why we just mention the most important issues related to it in this White Paper.

One possibility is to assign liability for damage caused by AI systems to their manufacturers based on art. 4491 et seq. of the Civil Code. This is the regime of objective liability for damage caused by **dangerous products**, adopted following the implementation of Council Directive 85/374/EEC.

The manufacturer, who controls the risk resulting from the use and development of new technologies, determines the way the device works. For this reason, the manufacturer should provide software that guarantees safe use of the device by both users (operators) and patients. It is noted that if safety standards are not met and damage occurs, the manufacturer should be liable regardless of fault – based on risk. In other words, if a faulty product caused damage, its manufacturer may be liable even if they were not negligent or it was not their fault.

Unfortunately, the definition of a product implemented by the European legislator raises a number of doubts. Article 2 of Council Directive 85/374/EEC provides that "product" means any movable item, with the exception of agricultural raw materials and hunting products, whether or not forming part of another movable or immovable item. In this definition of product, the lawmaker refers to the concept of "movable property" existing in material form. This may lead to the conclusion that the definition of a product proposed in this directive does not cover intellectual goods at all – due to their intangible nature[135]. This problem has not yet been solved.

133 *Ibid.*

134 *Ibid.*

135 For example, W. Katner notes that "it follows from the nature of intangible goods that they cannot be things constituting the principal object of a civil law relationship, since they are not of a material nature". Intangible goods "appearing in circulation exist next to things, which constitute a substrate for these goods, which allows them to be used and, above all, to know their essence. Most often it is about the intangible good and about the *corpus mechanicum* as a material carrier of such a good as a book, picture, compact disc, floppy disk, design documentation, reference product, description of an invention, diagram or a described mathematical formula"; W. Katner in: "System prawa prywatnego, prawo cywilne – część ogólna", edited by prof. dr. hab. Marek Safjan, 2012

On the one hand, it is therefore assumed that a physical object containing software (such as an electronic stethoscope) may be a dangerous product, while the software as such (for example, controlling the stethoscope) may not.

On the other hand, it is assumed that the concept of a product under art. 449[1] et seq. of the Civil Code should be interpreted broadly and, consequently, cover not only tangible objects (within the meaning of art. 45 of the Civil Code) but also intangible goods (such as software). If it is assumed that a computer code in itself is not a product, it may be assumed that the code can be classified as a product where it is a component of the product containing it. Thus, the injured party will have the right to claim compensation if it is shown that the whole system (software and hardware) has the characteristics of a dangerous product[136].

However, even assuming a broad interpretation of the definition of the product, a number of doubts arise:

- Problems arise in connection with the designation of the entity obliged to remedy the damage in a situation where more than one manufacturer is involved. And the situation is even more complicated when the components come from different manufacturers.
- The question arises about the setting of a standard of expectations, which, according to Council Directive 85/374/EEC and the corresponding provisions of the Polish law, should be based on the level of expectations of an average person.
- It may be a problem to establish a causal link between the dangerous properties of the AI system (a specific fault) and the damage caused – for example due to the already mentioned black box problem (see section 4.7.3.).

> **...the objective risk-based liability of manufacturers of AI systems seems to be the optimal solution.**

As we pointed out above, we do not try to answer all the doubts associated with the use of AI in medicine. Regardless of the difficulties identified, resulting to a large extent from the complex nature of AI, **the objective risk-based liability of manufacturers of AI systems seems to be the optimal solution** at the moment due to the wide scope of protection of potentially injured persons[137]. However, perhaps doubts will be dispelled by the intervention of the legislator in this respect.

136 P. Księżak in: "System Prawa Medycznego – organizacja systemu ochrony zdrowia", edited by dr. hab. Dobrochna Bach-Golecka and prof. dr. hab. Rafał Stankiewicz, 2020; K. Bączyk-Rozwadowska: "Odpowiedzialność cywilna za szkody wyrządzone w związku z zastosowaniem sztucznej inteligencji w medycynie", *Przegląd Prawa Medycznego* N° 3, 2021

137 K. Bączyk-Rozwadowska: "Odpowiedzialność cywilna za szkody wyrządzone w związku z zastosowaniem sztucznej inteligencji w medycynie", *Przegląd Prawa Medycznego* N° 3, 2021

5.8.3. Liability of the medical institution

In the context of liability of the medical institution related to the use of AI in health care, we pay attention primarily to liability for **the use of faulty medical equipment**. This liability will be incurred in the absence of proper maintenance of AI-enabled equipment, the responsibility for which rests not on an individual HCP but on the medical institution. Such proper maintenance may consist, for example, in regular installation of updates, providing professional service or taking care of appropriate anti-virus software.

For example, the Supreme Court has found a hospital guilty of the harm suffered by a child during hospitalization due to burns from hot water leaked from a bed warmer in which a gasket ruptured or fell off during heating[138]. In the court's opinion, the hospital was liable regardless of whether more frequent checks of the child by hospital staff (obstetricians and nurses) would have prevented the burns. The infringement consisted of the neglect of the obligation to inspect the equipment that rested with the hospital as an organized entity. Similar liability would apply in the case of AI.

In another ruling given in a similar situation, the Supreme Court concluded that a doctor must not be blamed for harm caused in connection with the use of faulty medical equipment if, with due diligence, he could not notice the fault or know about its previous manifestations. The doctor may legitimately assume that the medical establishment provides them with fault-free, safe and duly maintained equipment[139].

On the other hand, where harm to a patient has been caused by a device malfunction resulting from latent defects arising in the production process (due to design errors, use of unsuitable materials or incorrect assembly), the liability generally rests with the manufacturer (or importer or seller) of the device and is independent of their fault[140].

5.9. What are the principles of criminal liability in the context of the use of AI in healthcare?

Unlike in the Polish civil law, there is no risk-based criminal liability in the criminal law. Criminal liability may only be a consequence of prohibited, unlawful, punishable, gross and culpable acts, and each of these causes has its own precise regulation.

It is clear from the characteristics of criminal liability in Poland that it **cannot apply to AI as such, but only to the legal evaluation of the behavior of human users (individuals or groups)**. Only a person with certain attributes (adult, sane) can be recognized as the perpetrator of a crime and it is their actions that is subject to judgment[141].

138 Supreme Court, IV CR 299/80, 22/08/1980

139 Supreme Court, IV CR 118/83, 11/05/1983

140 Ewa Bagińska (ed.): "Odpowiedzialność prywatnoprawna", *System Prawa Medycznego* vol. 5, 2021

141 Even the existing solution contained in the Act on Criminal Liability of Collective Entities provides for an act of a human being.

Currently, the most accurate approach is to treat AI as a tool in the hands of a human, not a separate subject of rights and obligations. It is the human who, by activating AI, takes on criminal consequences of its use, regardless of whether it will only support a decision-making process or cause effects in a semi-autonomous or autonomous way in the real world[142].

However, none of the prohibited act types defined in the Polish Criminal Code refers directly to AI. The term "AI" does not appear there. However, there are concepts of criminal acts and instruments of crime which can be associated with AI.

For example, art. 165(1)(4) (bringing of a specific danger), art. 268a(1) (thwarting or hindering the use of information), art. 269(1) (destruction of computer data) and art. 287(1) (computer fraud) refers to automated capture, processing or transmission of computer data as the instrument of crime. If an AI system were considered to be a system that automatically processes, collects or transmits computer data, it could be used to commit these crimes[143]. For example, if someone influences the automatic processing or transmission of IT data from an AI system used in a hospital, without authorization, to cause harm, this person will commit the crime defined in art. 287(1).

In the case of any AI-enabled system, **the group of potential entities subject to criminal liability may include the manufacturer, operator or user** (such as an HCP) **and "trainer"** (in charge of system preparation). This means in the language of the criminal law that, for example, any of the foregoing persons may be criminally liable for a fault in AI-enabled software which has caused damage to health or death of a patient. In this study, however, we focused on the responsibility of the doctor.

The regulation which could not be omitted in this context is art. 192 of the Criminal Code: the performance of a medical procedure without the patient's consent[144]. The Supreme Court ruled in case III KK 14 / 15 (Apr. 10, 2015) that the patient's consent to undergo a medical procedure – to be reliable and legitimating the doctor's conduct – must be an expression of the patient's own informed (considering their mental and psychic condition and other essential criteria) and voluntary (error- and coercion-free) decision. The doctor may act on the consent only where the patient's will to undergo the proposed medical procedure has been clearly communicated and raises no doubts[145].

142 Wojciech Filipkowski in: L. Lai, M. Świerczyński (ed.): "Prawo sztucznej inteligencji", Warszawa, 2020

143 Wojciech Filipkowski in: L. Lai, M. Świerczyński (ed.): "Prawo sztucznej inteligencji", Warszawa, 2020

144 Art. 192(1): The person who performs a medical procedure without the patient's consent is subject to a fine, restriction of liberty or imprisonment of up to 2 years; art. 192(2): Prosecution shall take place at the request of the injured party.

145 A. Zoll in: "Kodeks karny. Część szczególna. Tom II. Część I. Komentarz do art. 117-211a.", edited by W. Wróbel, Warszawa, 2017, art. 192

The Supreme Court noted that the absence of any of the foregoing essential characteristics of the consent, or a proof of granting it, should be considered as tantamount to performing the procedure without the patient's consent, which would be the crime defined in art. 192(1). The same rule applies to the use of AI: if the doctor intentionally forces the patient to undergo a medical procedure using AI against the patient's will, the doctor will be liable under art. 192.

Article 155 (manslaughter) may be another example. If a flaw in an AI-enabled system has caused a serious injury and, as a consequence, death of the patient (e.g., as a result of severe internal bleeding caused by interaction of an AI-recommended drug with other medication), we have a manslaughter.

Other crimes particularly important in the context of the use of AI in health care include the unintentional causing of damage to health and the unintentional exposure to the danger of loss of life or serious damage to health (articles 156, 167 and 160). Software as such is not a perpetrator but just a kind of tool in the hands of the doctor. It should be emphasized, however, that the statutory description of the foregoing criminal acts requires the fulfillment of a number of specific conditions – including the neglect of the precautionary rules and, at least, the possibility of envisaging the penalized consequences – which in each case will determine the judgment on criminal liability.

> **...the use or non-use of AI in medicine is not penalized directly in any way.**

In summary, **the use or non-use of AI in medicine is not penalized directly in any way**. This type of liability is currently based on the regulations already in force, which also apply to cases other than the use of AI, such as the lack of the patient's consent or manslaughter.

5.10. What are the principles of professional liability in the context of the use of AI in healthcare?

The professional liability of HCPs is a separate type of legal liability which must be distinguished from the civil, criminal, and administrative liability, as well as from disciplinary responsibility under the labor law. The professional liability of doctors is based on the provisions of the Act on medical chambers[146].

This liability ensues from violation of the principles of medical ethics and regulations related to the performance of the profession of doctor. The Act on Medical Chambers does not contain a closed list of acts triggering professional liability. Potentially, therefore, misuse of AI (or failure to use effective and recognized solutions) can also be a basis for professional liability.

In the context of the use of AI in healthcare, the following examples of irregularities involving professional liability can be identified:

- **Respect for patients' rights**: The main subject of protection is the privacy, intimacy and personal dignity of the patient. In addition, the patient has the right to be fully informed about the treatment process to participate in it consciously. The use of sophisticated AI technology can raise problems with conveying the message to the patient and, consequently, trigger disciplinary liability (see section 4.5.).
- **Physician-patient confidentiality**: The information about the patient and their environment, obtained in connection with professional activities, must be kept secret. Considering that IT/AI systems process very large amounts of data, problems may arise with protecting the physician-patient privilege, leading to disciplinary liability (see section 4.8.).

5.11. Conclusions

- Current medical knowledge is based on the Evidence Based Medicine (EBM) system, guidelines and recommendations of scientific societies, which continue to be updated to take account of new developments. **AI can be used in health care in accordance with the indications of current medical knowledge, with appropriate caution and taking into account the limitations of AI in the health care environment**.

- **AI can be used by a number of health care service providers**. Firstly, there are HCPs, i.e. doctors, dentists, nurses, obstetricians, physiotherapists, paramedics or pharmacists. This catalog may be extended to include other persons involved in health care services.

146 We give this legal act as an example – all considerations in this section are based on the Act on Medical Chambers. However, there are also other grounds for professional liability of HCPs, such as the Act on the Self-Government of Nurses and Obstetricians

- HCPs should treat AI as any other ancillary tool. Outputs produced by AI should be treated as complying with medical standards – they should be accepted as **valid unless proven otherwise**. Although IT systems are becoming increasingly autonomous, HCPs should approach their suggestions **with caution and limited trust.**

- There are several liability regimes that may be important when using AI in healthcare, though there are no regulations in Poland directly defining the principles of liability in the context of AI. Each regime has specific rules governing it. Typically, the principles of liability should be analyzed on the case-to-case basis, but **it is possible to draw conclusions as to the general shape of a particular liability regime based on the general principles of law**.

6. AI and the use of medical data

6.1. What data can be used by AI in healthcare?

The development of AI is based on access to data, which in the context of health care means the need to provide **adequate quantity and quality of medical data**[147] – a particularly sensitive category of data regarding the patient's health. Depending on its type, AI-enabled software can be fed data only once, at the development stage (closed system), or periodically (learning system).

Such systems need access to huge amounts of data, often gathered for years (medical records must be retained, as a rule, for a period of 20 years). Moreover, in order to be used effectively in the process of learning and improving the algorithm, the data must have adequate quality – be reliable, complete and recorded in machine-readable formats.

Medical data may include **data of various types**, such as texts written by HCPs, images and sound or video recordings[148]. **Data sources are homogeneous**: medical databases are used by clinics, pharmacies, research institutes, medical universities, medical registers, etc. Some of the data can be uploaded directly from medical devices used by patients to databases handled by algorithms.

The so-called "**data donation**" which consists in the voluntary transfer of data for research purposes is an increasingly important way of obtaining data for the development of AI and for other purposes. However, the transfer of sensitive health data requires a high degree of trust, which calls for legal and technical safeguards to ensure that data will not be passed on to unauthorized persons. While, formally, the transfer of data is already possible, there are no systemic solutions that would allow stakeholders to transfer data relatively easily in organizational terms or to establish links with potential data receivers[149].

The GDPR explicitly defines health data. Health data in the light of the GDPR is personal data about the physical or mental health of a natural person including the use of health care services (art. 4(15) of the GDPR). Data on the patient's health condition can be structured in such a way it will reveal such information as racial background, sexual orientation or sex life[150]. However, the data controller will not have to guess which types of data they are dealing with are sensitive because all of them are classified as such.

147 We refer to this more extensively in section 4.7.1.

148 Polish legal acts now have a full range of possible relationships between the terms "medical data", "health data" and "personal data".

149 The position of the Polish Hospital Federation – http://www.pfsz.org/2020/09/17/program-otwierania-danych-na-lata-2021-2027-stanowisko-pfsz-i-koalicji-ai-w-zdrowiu, accessed on 27/05/2022

150 Klara Andres, Edyta Bielak-Jomaa, Mariusz Jagielski, Piotr Kawczyński, Monika Krasińska, Paweł Litwiński, Aneta Sieradzka, Kajetan Wojsyk: "Ochrona danych osobowych medycznych", Warszawa, 2018, ch. 1.3., *Legalis*

From the legal point of view, it is crucial to distinguish at least several different categories of data, the collection and further processing of which is regulated by law. These will be, in particular, personal data and individual medical data.

- **Personal data**, in accordance with art. 4(1) of the GDPR, means any information about an identified or identifiable natural person, and an identifiable natural person is a person who can be directly or indirectly identified, in particular based on an identifier such as name, identification number, location data, online identifier or one or more specific factors determining the physical, physiological, genetic, mental, economic, cultural or social identity of a natural person. Personal data will therefore be, for example, information relating to a specific patient stored in the patient's medical records. The rules for the processing of this category of data are regulated primarily by the GDPR.

- **Non-personal data** that do not meet the above definition will constitute non-personal data, the processing of which is not so strictly regulated by the law[151]. Non-personal data includes, for example, information about websites viewed, the number of visits and the time spent there. The processing of non-personal data - capture, recording, storage, sorting, structuring, downloading, viewing, adapting, modifying, using, disclosing by transmission, dissemination or sharing, combining or matching, destroying, restricting or deleting – may be automated or non-automated. Therefore, such data can potentially be easier to obtain and re-use, also in development of AI solutions. Non-personal data include statistical and anonymous data[152].

- The concept of **individual medical data** is used by the Act on IT systems in health care. According to art. 2(7), individual medical data are data of a natural person about health care services used and planned and regarding their health condition, including health prevention and implementation of health programs.

Bearing in mind the need to ensure access to medical data, it should be noted that **the main part of them will be included in medical documentation**, the rules of keeping and making available of which are also regulated by the law. Legal regulations do not contain a definition of medical documentation. However, art. 25 of the Act on Patients' Rights specifies what the medical documentation should contain: information identifying the patient and their health condition.

Electronic medical records is a special type of medical documentation, which, in accordance with art. 2(6) of the Act on IT systems in health care, means documents produced in electronic form with qualified electronic signatures, trusted signatures, personal signatures or authenticated in terms of origin and integrity within the ICT system made available free of charge by the Social Insurance Institution (ZUS), such as prescriptions, referrals and vaccination charts.

151 Which does not mean a complete lack of regulation. Reference should be made, among others, to the Regulation of the European Parliament and of the Council on the framework for the free flow of non-personal data in the European Union. This legal act does not overlap with the GDPR as it covers non-personal data that is not covered by the scope of the GDPR.

152 In practice, it is often questionable whether the effect of a given operation on data allows their classification as non-personal anonymous data or pseudonymised personal data – https://www.dzp.pl/blog/pharma/raport-regulacyjny-dzp, p. 39

The rules for sharing medical documentation are set in art. 23 et seq. of the Act on Patients' Rights. Of course, the patient may access their medical documentation. This is one of the fundamental rights of the patient, which is part of the wider right to be informed (art. 9).

In addition, in accordance with art. 26, the health care establishment makes medical documentation available to the patient's legal representative or to a person (legal or natural) authorized by the patient[153]. Pursuant to art. 26(4), access may be granted, to a necessary extent, to entities listed in the Act: public authorities, courts, the Agency for Health Technology Assessment and Tariff System and the Medical Research Agency.

Article 35 of the Act on IT systems in health care regulates access to individual medical data, without clearly resolving the conflict between access to the data and access to documents in which the data may be contained. In accordance with this provision, the following persons may access personal data or individual medical data of patients:

- the doctor, nurse or obstetrician providing healthcare services to the patient,
- the HCP who has produced an electronic medical record containing personal data or individual medical data of the patient,
- the medical worker practicing a profession with a service provider, who has produced an electronic medical record containing personal data or individual medical data of the patient in connection with the exercise of the medical worker's profession with the service provider, if this is necessary to carry out diagnostics or ensure continuity of treatment[154].

In addition, every medical worker has the right to access the patient's medical records in the event of a threat to the patient's life (art. 35 of the Act on IT systems in health care).

The legislator has made a clear distinction between medical documentation, electronic medical records, information on health status and individual medical data. What is particularly important, the law distinguishes the concept of data from the concept of document which can traditionally be understood as a data carrier (for example printed prescription) or, in the case of a digital environment, as a data set structured according to specific criteria. The law provides for different access rules for these separate conceptual categories.

To sum up, the Polish medical law system uses an extensive terminological network regarding documentation and information about the patient. Although the concepts referred to seem intuitively easy to understand, their mutual scope of meaning in the context of legal terms may raise doubts[155]. Practice shows that the current regulations remain unclear and are interpreted differently, as evidenced, for example, by violations found by the Patient Ombudsman[156].

153 A legal representative of a minor patient may also authorize a third party to take access to the medical records of the patient.

154 There is no reason why administrative and technical staff should have access to patients' medical data other than those required in very specific situations. Even if they need to have access to some of this data, e.g. during patient admission, this does not mean that they should also have access to medical data which is covered by medical confidentiality.

155 https://www.dzp.pl/blog/pharma/raport-regulacyjny-dzp, pp. 47, 48

156 *Ibid.*, p. 50

At the same time, we point out that despite the extensive terminology and doubts regarding data sharing, it is certain that after obtaining the explicit and relevant consent of the patient, it is possible to access and use their data. This consent must be voluntary, specific, informed and unambiguous. The consent can be given in the form of a statement (for example on paper or online) or a confirmative action (for example, moving an object on the tablet screen).

6.2. What is anonymous data and how is it different from pseudonymized data?

As noted in the previous section, some of the data may be anonymous. The colloquial understanding of this concept basically coincides with its legal understanding, according to which this is data based on which we are not able to determine data subjects. However, the matter has become more complicated due to the GDPR, which introduced the concept of pseudonymization. So what is the difference between anonymous data and pseudonymized data? Why is this difference so important in the context of data access for the development of AI?

As defined in art. 4(5) of the GDPR, pseudonymization means the processing of personal data in such a way that they can no longer be attributed to a specific data subject **without the use of additional information**, provided that such additional information is stored separately and is subject to technical and organizational measures that make it impossible to attribute it to an identified or identifiable natural person.

Pseudonymization is therefore, firstly, a certain operation carried out on personal data; it is a kind of data processing. Secondly, in simple terms, it can be said that pseudonymization will create or separate a new set of data and this set – used independently – will not allow to identify a specific natural person (which will make the set similar to anonymous data).

Pseudonymization, however, is **a fully reversible process**. Pseudonymized personal data which can be attributed to a natural person using additional information is therefore traceable to a person. **Pseudonymized data do not lose the nature of personal data**, which is why pseudonymization is considered a security measure rather than an anonymization method[157].

The GDPR defines the concept of the "pseudonymization process", not the "pseudonymized data". To respond to this problem, the European Data Protection Board ("EDPB")[158] recognizes that the GDPR defines pseudonymization as a result and not as the technique in itself[159]. The European Union Agency for Cybersecurity (ENISA) argues that pseudonymization aims to protect personal data by concealing

157 Mariola Więckowska: "UODO. Stosowanie technicznych środków bezpieczeństwa w aspekcie zgłoszeń naruszeń do UODO oraz ocena wagi naruszenie w oparciu o zalecenia Agencji Unii Europejskiej ds. Bezpieczeństwa Sieci i Informacji (ENISA).", 2019 – https://uodo.gov.pl/pl/file/1812

158 The European Data Protection Board is an independent European body that works towards the consistent application of data protection rules across the European Union and promotes cooperation between EU data protection authorities

159 European Data Protection Board, Memorandum on Supplemental Measures Under Schrems II, 2020, p. 3 – https://edpb.europa.eu/sites/default/files/webform/public_consultation_reply/edpb_data_embassy_memorandum_-_11_november_2020.pdf, accessed on 27.5.2022

identities of persons (data subjects) in a data set, for example by replacing one or more personal data identifiers with pseudonyms and adequately protecting the links between pseudonyms and the original identifiers[160]. In addition, the GDPR clearly distinguishes between pseudonymization and data encryption (see art. 6(4)(e) and art. 32(1)(a) of the GDPR), although encryption itself is a technique that may be part of the pseudonymization process[161]. An encrypted text can be an equivalent of a pseudonym and the key needed to decrypt the text can be recognized as the additional information making it possible to reverse the pseudonymization[162].

However, the GDPR does not contain a definition of either the anonymization process or anonymous data. Anonymization is deemed to be the process by which personally identifiable information is irreversibly deleted or altered in such a way that it is no longer possible to directly or indirectly identify the subject of the information, even by the controller acting alone or in cooperation with any other party. In the process of anonymization, information that may constitute personal data within the meaning of the GDPR is deleted or modified, leaving just such information that cannot be traced back to the data subject, but can still be useful for a specific purpose.

The anonymization process must be **permanent and irreversible**. The GDPR does not refer to any specific anonymization technique, so it is up to individual data controllers to decide whether the process chosen by them, with due diligence, is sufficiently robust.

Anonymized data no longer constitutes personal data and is no longer subject to the same requirements and restrictions that apply to the processing of personal data in accordance with the GDPR. However, the anonymized personal data had to be collected and processed in accordance with the applicable standards for keeping the data in a non-traceable format. In this context, the anonymization process, i.e. the processing of personal data in order to achieve anonymization, can be an example of the "further processing", which also must comply with the GDPR[163].

The main legal difference between the process of pseudonymization and anonymization is the fact that pseudonymization, as a reversible process of securing personal data, does not release the controller and processor from the obligations arising from the GDPR and, consequently, the criteria for legal data sharing. The provisions on anonymization and pseudonymization do not sufficiently determine which techniques should be considered as anonymization and which as pseudonymization. In addition, there are no clear guidelines or "soft laws" explaining these issues. For this reason, although anonymization and

160 Deploying Pseudonymisation Techniques, ENISA, p. 9 – https://www.enisa.europa.eu/publications/deploying-pseudonymisation-techniques, accessed on 27/05/2022

161 In this respect, encryption can be regarded as a pseudonymisation technique. It is a security measure designed to protect personal data – https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/encryption/what-is-encryption/, accessed on 27/05/2022

162 A. Sieradzka, M. Wieczorek (ed.): "Monitoring zgodny z RODO. Praktyczny poradnik z wzorami dla sektora publicznego i prywatnego.", Warszawa, 2020

163 Working group's opinion on art. 29 N° 05/2014 of April 10, 2014, concerning anonymisation techniques (WP216), p. 7 – https://archiwum.giodo.gov.pl/pl/1520203/7808

pseudonymization are radically different from each other, it is often difficult to clearly determine which group of techniques will constitute anonymization and which will constitute pseudonymization. Anonymization is sometimes confused with pseudonymization because in both cases there is the context of the principle of minimizing the risk of processing of personal data and in both cases the purpose is to increase the protection of the privacy of the data subject.

Confusing anonymization with pseudonymization can have very serious consequences, which may even result from the failure to apply required data protection rules[164]. The consequences of the issues described above are significant for entities conducting R&D in the field of AI. The inability to precisely determine which data are personal data and which are not poses a significant risk (in the current legal status an indelible legal risk associated with the processing of medical data for scientific research purposes). In addition, due to scientific progress and growing data sets, it can be assumed that the stock of non-personal medical data (especially qualitative) that will be used to conduct scientific research will shrink[165].

6.3. How can medical data be used for the development of AI?

The use of medical data for the development of AI can take very different forms and serve different purposes. However, the common element of this process will be **the stage of obtaining data and finding an adequate legal basis for their further use**.

Data access policies

Data access policies vary depending on the data category and data source. Of course, the safest is to use anonymized data (see section 6.2.) but this does not mean that only such data can be used for the development of AI.

- **Access to individual medical data (medical documentation)**: as we noted above, access to individual medical data is granted to entities listed in art. 35 of the Act on health care services financed from public funds and, in exceptional situations, data included in medical documentation may also be made available to other persons (art. 26 of the Act on Patients' Rights) (see section 5.1.).

- **Access to data contained in medical records**: medical records are a structured set of personal data, including individual medical data. Data contained in medical records may be made available for the purpose of conducting scientific research and for statistical purposes in a form that makes it impossible to associate them with a specific natural person. The entity keeping a medical record is obliged to provide free access to data collected in the register to public entities or noon-public entities carrying out public tasks – by means of electronic communication, as necessary[166].

164 If a technique which is actually pseudonymization is recognized as anonymisation

165 https://www.dzp.pl/blog/pharma/raport-regulacyjny-dzp, str. 41, accessed on 13/05/2022

166 https://www.dzp.pl/files/shares/Publikacje/2020_02_03_Raport_AI_v_1_1.pdf, str. 55, accessed on 13/05/2022

- **Access to other personal data**: In addition to medical data and data from medical records, entities from the medical sector may access other personal data of their patients, users or clients. The GDPR is the key European legal instrument governing access to personal data. According to the GDPR, every natural person should have the right to access data collected concerning this person and should be able to easily exercise this right at reasonable intervals in order to be aware of the process and verify its lawfulness. As we have pointed out, the sharing of personal data with third parties is permissible under the provisions of the GDPR but all procedures must be followed to ensure that the disclosure complies with the regulations.

  Here we refer to the technical method known as "federated learning" (FL), which enables distributed learning without revealing the original training data. This means that, for example, hospitals A, B, and C can train locally their AI models that recognize skin cancer, and then, without passing on inputs A, B, and C (which are patients' personal data), share the model with Hospital D which will use the model to analyze input D.

  Federated learning is an approach to solving data privacy issues in machine learning software, consisting in separating data storage and processing (i.e. local model training) on end-user devices, and in aggregating the global AI model on the service provider's server (i.e. the coordinating server). FL enables you to train your AI model while retaining personal training data on your end-user devices. Only locally trained model parameters – containing the necessary amount of information needed to update the global model – are made available to the coordinating server. However, such model parameters still contain some sensitive elements that can be used to reproduce or infer related personal data[167]. Therefore, the FL system is still subject to GDPR and, in use, has to comply with it.

- **Access to data in the role of a processor**: the processor is an entity that deals with the processing of personal data entrusted to it by the data controller. The entrusting of the processing of personal data consists in that the controller authorizes a third party to process data on the controller's behalf. In the relationship of entrustment we have the controller who commissions the processor to process personal data on behalf and on the terms of the controller. The processor can be a natural person, a legal person, a public authority or other entity. The processor is required to take care of the interests of the data subjects at all times, i.e. at every stage of the processing. Therefore, the processor has to legitimate its actions: meet at least one of the requirements provided for by law for the admissibility of processing, ensure that its conduct will not harm the data subjects, and enable the data subjects to oversee the processing (provide input for making informed decisions)[168].

- **Access to non-personal data**: as explained above (see section 5.1.), access to non-personal data is not regulated by the GDPR. While the GDPR restricts the processing of personal data for its protection (which is as one of the fundamental rights), Regulation (EU) 2018/1807 of the European Parliament

167 Nguyen Truong, Kai Sun, Siyao Wang, Florian Guitton, YiKe Guo: "Privacy preservation in federated learning: an insightful survey from the GDPR perspective", *Computers & Security*, vol. 110, 2021 – https://www.sciencedirect.com/science/article/pii/S0167404821002261#sec0020

168 Klara Andres, Edyta Bielak-Jomaa, Mariusz Jagielski, Piotr Kawczyński, Monika Krasińska, Paweł Litwiński, Aneta Sieradzka, Kajetan Wojsyk: "Ochrona danych osobowych medycznych", Warszawa, 2018, ch. 1.6, *Legalis*

and of the Council of Nov. 14, 2018, on the framework for the free flow of non-personal data in the EU is intended to facilitate the processing of information of a non-personal nature. Respect for the freedom of conducting business as one of the fundamental rights (defined in art. 16 of the Charter of Fundamental Rights) is the essence of this regulation. It is data that drives economic development today and the regulation is supposed to facilitate its use. This is why Regulation 2018/1807 does not impose any additional obligations on private entities, just requiring the EU Member States to lift barriers to the free flow of data and notify the European Commission of each legislative action restricting the free flow of data.

In addition, the European Commission has started work on a new legislative proposal on data: **the Data Act**[169]. The aim of the bill is to ensure fair distribution of data between participants of the data-based economy, also by regulating access to non-personal data in legally regulated B2B (business-to-business) and B2G (business-to-government) contracts. After its entry into force, the Data Act will impose a number of new obligations for protection of non-personal data. For example, it will change the rules for international transfers of non-personal data: data processors will need to take "reasonable" legal, technical and organizational measures, including contractual arrangements, to prevent international transfers or governmental access to non-personal data stored in the EU if such transfer or access would conflict with the law of EU or a Member State. It is currently unknown when the Data Act will take effect.

The recipient of personal data will need a legitimate basis for its further use, i.e. processing. Pursuant to art. 4(2) of the GDPR, the processing of personal data means a transaction or a set of transactions performed on personal data or on sets of personal data, whether or not by automated means, such as gathering, recording, structuring, storing, adapting, altering, retrieving, viewing, using, disclosing by transmission, disseminating or otherwise making available, matching, combining, restricting, removing or erasing.

An entity using personal data may act as a processor or as a controller (or joint controller). In the first case, the data may be used based on a data processing agreement, which should meet the requirements of art. 28 of the GDPR. This may be the case, for example, where a medical device provider processes medical data of patients. The processor has access to the data and processes it based on the agreement. However, it is not the processor who decides about the purposes and methods of processing but the data controller (medical facility) with which the agreement was signed. The data and its processing serve purposes and interests of the controller, not the processor.

In the context of developing AI, being a controller, the decision-maker, offers more opportunities. The controller, having obtained personal data, may continue to use it only in compliance with art. 6 of the GDPR and, for sensitive data, also art. 9. The basic question to be asked is therefore the legal basis for further processing personal data in order to develop AI.

169 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_1113, accessed on 13/05/2022

Further processing

According to art. 5(1)(b) of the GDPR, personal data must be collected for specific, clear and legitimate purposes and may not be processed further in a manner inconsistent with these purposes. Because AI solutions rely on the adaptability depending on data input and the software learning process, further processing may be necessary in order to keep the data useful but has to comply with the GDPR[170]. The concept of further processing is particularly important in the case of medical data supporting scientific research, as it would serve public interest in the development of medicine and health care sector while ensuring an adequate level of protection of personal data.

Further processing of medical data is generally permissible without consent of the data subject, but only if the requirements of art. 6(4) of the GDPR are met, meaning consistency of the original processing and the further processing (the so-called "consistency test"). In the case of AI applications, there are practical problems related to setting goals due to the fact that AI-enabled software can learn.

So, it is possible that AI will learn to process data in a different way than intended and, consequently, generate different results than expected. A practical difficulty encountered in the processing of medical data is that it was not foreseen at the start of its processing that it could be used for other purposes than the original one(s). This leads to a situation where personal data is collected for a single purpose (for example, to treat a patient) and then there is the possibility that it can be used, for example, for scientific research[171].

> **Due to the requirements of the GDPR and the AI service provision model, it may often be necessary to conclude processing agreements, under which the data controller may entrust the processing to a third party.**

Due to the requirements of the GDPR and the AI service provision model, it may often be necessary to conclude processing agreements, under which the data controller may entrust the processing to a third party (see section 6.5.)

170 https://www.dzp.pl/blog/pharma/raport-regulacyjny-dzp, str. 6, accessed on 13/05/2022

171 https://www.dzp.pl/blog/pharma/raport-regulacyjny-dzp, str. 32, accessed on 13/05/2022

6.4. What obligations under the GDPR should be kept in mind when using AI in healthcare?

Although, undoubtedly, one of the main objectives of establishing dedicated personal data protection regulations is to secure the rights and freedoms of the individual in the digital age and protect people against new types of threats resulting from the rapid technological development and globalization of modern IT services, the GDPR and other systematization of personal data protection law impose additional obligations on creators and users of AI, the observance of which may hinder development in this area.

The use of AI-enabled solutions in healthcare, which are based on the processing of personal data, is associated with the need to meet a number of obligations under the GDPR. The exact scope depends on the nature of the data holder who may act as a controller or processor.

Controllers (such as a medical start-up implementing and developing AI using personal data) should keep in mind the following obligations, in particular.

- **Adequate design of the processing**: The principles of data processing concern the way of dealing with personal data and impose quality requirements for the data. Art. 5(1) of the GDPR defines six principles for the processing of personal data:

    1) The principle of lawfulness, fairness and transparency of processing: The data processor is obliged to legitimize its activities, take care of the interests of the data subjects, and keep the data subject harmless at all times, at every stage of the processing.
    2) The principle of limited purpose: Data may be collected only for specific, clearly defined and legitimate purposes and may not be further processed in a manner inconsistent with these purposes.
    3) The principle of data minimization: Only data necessary for the purpose for its achievement can be processed. It is not allowed to gather, store or use data that is not necessary to achieve the purpose of the processing.
    4) The principle of correctness: The administrator is obliged to ensure veracity of the processed data.
    5) The principle of limited storage: Data should be stored in a form that allows identification of the person to whom they relate for no longer than necessary to achieve the purpose(s) of the processing.
    6) The principle of integrity and confidentiality: Appropriate technical and organizational measures should be applied to ensure that the personal data processed is secure[172].

172 K. Andres, E. Bielak-Jomaa, M. Jagielski, P. Kawczyński, M. Krasińska, P. Litwiński, A. Sieradzka, K. Wojsyk: "Ochrona danych osobowych medycznych", Warszawa, 2018, I.1.6, *Legalis*

- **Fulfillment of the information obligations**: The data subject has the right to obtain processing-related information from the controller. The scope of information to be provided depends on whether the controller has obtained data directly from the data subject or from another source. If the data subject exercises their right to demand information, it is them who decides what information is to be provided by submitting a request (art. 13, 14, 15 of the GDPR).

- **Obtaining consents (if applicable)**: Obtaining the data subject's consent is the most widely used basis for the processing of personal data. Such consent is not needed if the use of personal data can be based on other grounds, in particular legal requirements. If the data controller providing or managing medical services strictly complies with the sectoral law, then the patient's consent will not be needed at all. The need to obtain consent will arise only when the controller wants to do something more with the patient's data than allowed under the law applicable to health care. Consent may also be required for the processing of sensitive data. Note that obtaining consents involves all the related consequences under the GDPR. For example, according to art. 7(3), the consent must be revocable, and according to art. 9(2)(g), the consent for the processing of sensitive data must be explicit. This means that it must be clear from the data subject's statement that this person agrees to the processing of their sensitive data[173]. **The consent to the processing of personal data must not be confused with the consent to receive health care services within the meaning of the Act on Patients' Rights because these are two separate statements**. What is more, in principle, the former consent does not mean that the latter one has to be given. In the context of AI-enabled software, we have three different situations:

  a) If the software **is already fully trained** at the time of providing the health service, it is not necessary to obtain an additional consent for the processing, but it may be necessary to obtain the consent to receive health care services.
  b) If the software **is not fully trained** at the time of providing health care services **and it is possible to separate the consent to receive services from the consent to the processing**, it is not necessary to obtain an additional consent to the processing for the purpose of teaching the algorithm if the patient does not want to give the consent, but it is necessary to obtain the consent to receive health care services.
  c) The software **is not fully trained** at the time of providing health care services and **it is impossible to separate the consent to receive services from the consent to the processing**, it is necessary to obtain an additional consent to the processing for the purpose of teaching the algorithm, because it is not possible to use the software without simultaneous data processing and, in addition, it is necessary to obtain consent to receive health care services.

- **Adequate data protection**: Both the data controller (who decides on the purposes and means of processing personal data) and the processor (who has been entrusted the data for processing) are

173 K. Andres, E. Bielak-Jomaa, M. Jagielski, P. Kawczyński, M. Krasińska, P. Litwiński, A. Sieradzka, K. Wojsyk: "Ochrona danych osobowych medycznych", Warszawa, 2018, III.5.3.2, *Legalis*

obliged to apply technical and organizational measures appropriate and adequate for the category of data and threats, in order to protect data against unauthorized processing. The basic step when choosing security measures for medical data is a risk analysis designed to identify and assess risks associated with possible breach or loss of confidentiality, integrity or availability of data. The obligation to complete this analysis is expressed in articles 24, 25 and 32 of the GDPR[174].

- **Keeping a register of processing activities and/or categories of such activities**: Personal data controllers and processors are required to keep such registers. These registers are used to monitor all activities carried out using personal data that are repetitive (not unusual or once-off) but even a once-off activity should be logged if it could cause a breach of the rights and freedoms of a data subject.

- **Ensuring accountability of the processing**: Personal data controllers and processors should not only meet the obligations arising from the regulations, but also must be able to demonstrate that they have done so (art. 5(2) of the GDPR). In case of doubt, the burden of proof will rest on the entity in charge of the data. This is why we recommend careful collection and retention of relevant documents.

- **Ensuring an adequate period of data retention**: – Pursuant to art. 5(1)(e) of the GDPR, personal data should be stored for no longer than is necessary for the purposes for which the data are processed. The data must not be processed indefinitely and, in each case, it should be assessed whether they are necessary in the context of their purpose(s).

- **Appointment of a data protection officer (DPO), if applicable**: The appointment of a data protection officer is mandatory when the processing is carried out by a public authority or entity[175] or where the main activity of the controller or processor consists in processing which, by its nature, scope or purpose, requires regular and systematic monitoring of data subjects on a large scale, or the main activity of the controller or processor consists of large-scale processing of special categories of personal data referred to in art. 9(1) of the GDPR (sensitive data) and personal data relating to convictions and infringements as referred to in art. 10 of the GDPR. Accordingly, **the obligation to appoint a data protection officer applies to numerous health care establishments**, such as hospitals.

> **Even a mere suspicion that data may be processed in breach of the above rules – for example, without adequate protection against unauthorized access – should be immediately reported to the Data Protection Officer or another person in accordance with the in-house rules.**

174 *Ibid.*, IV.2

175 Except for courts within the scope of administering justice

If an HCP uses AI-based solutions, this duty, of course, will not be incumbent on them. The HCP should just act in accordance with the rules of conduct, internal policies and procedures adopted by the medical institution. However, **it is good to be aware of the above obligations under the GDPR because the obligation to act with due diligence in the performance of the profession means, among other things, care for the selection of tools in compliance with the applicable law**. Even a mere suspicion that data may be processed in breach of the above rules – for example, without adequate protection against unauthorized access – should be immediately reported to the Data Protection Officer or another person in accordance with the in-house rules.

The key obligation of each processor is to implement appropriate technical and organizational measures to ensure a level of security corresponding to the identified risk (art. 32 GDPR). In addition, it is important to keep in mind the duties resulting from the obligatory elements of the agreement for entrusting the processing of personal data (see above).

In addition, we emphasize that in certain cases personal data controllers are obliged to disclose the personal data they process. For example, courts have the power to demand anyone, including data controllers, to surrender documents even if the documents contain personal data.

6.5. Should a data processing agreement be concluded where the processor to be outsourced uses AI?

The controller may outsource a third party to do the processing based on an agreement. The agreement may be concluded under a framework contract existing between the parties or as an independent instrument.

> **Such an agreement should be concluded with someone who – within the meaning of the GDPR – will not decide on the purposes and methods of the processing but will just do the processing on behalf of the controller in its interest. As a rule, such a relationship exists between a health care provider (hospital, clinic, individual medical practice) and a supplier of a medical device or other AI-enabled solution.**

Such an agreement should be concluded with someone who – within the meaning of the GDPR – will not decide on the purposes and methods of the processing but will just do the processing on behalf of the controller in its interest. As a rule, such a relationship exists between a health care provider (hospital, clinic,

individual medical practice) and a supplier of a medical device or other AI-enabled solution. For example, if a facility uses a predictive AI-based system, the data input and output serve the interests of the facility – its processing purposes. The AI system supplier only sells its product or service; it does not need either the input or output data. In this situation it would be reasonable to base the mutual relationship and the data processing on a processing agreement. At the same time, the supplier may act as a controller for some data and, for example, store it in a database or feed it to AI algorithms – subject to additional consents of data subjects (patients).

The processing agreement should comply with art. 28 of the GDPR. The agreement must first of all regulate the scope and purpose of entrusting data. However, according to the European Data Protection Board's guidelines of July 2020, the controller must decide on **both the purpose and methods** of processing[176]. The agreement should contain clauses making it clear to the processor what risks to the rights and freedoms of data subjects are involved in the processing.

In the context of the processing of medical data, attention should also be paid to art. 24(5-7) of the Act on Patients' Rights, according to which:

- The performance of this agreement **may not disrupt the provision of health care services** including prompt access to data contained in medical documentation. Thus, the data processing should ensure that the HCP will not lose access to their patient's digital data (for example, the failure or freezing of a system using data from medical documentation should not block access to this documentation).

- The processor is obliged to **keep confidential patient-related information** obtained in connection with the performance of this agreement. This obligation shall survive the patient's death." In the context of AI, this may mean that the statutory obligation of secrecy also extends on generically new patient-related information generated by the algorithm.

- In the event of cessation of the processing of personal data contained in medical documentation by the processor, in particular in connection with its liquidation, **it is obliged to return the data**. This is a limitation of the principle under art. 28 of the GDPR that the processor may return or delete the data (also by anonymization).

The foregoing obligations do not exclude other contractual provisions. Some processors may position themselves as personal data controllers who process personal data for their own purposes and then share output data with HCP's and/or patients. The data resource may stay with the processor even after the end of cooperation with a medical facility. Similarly, it is sometimes possible to use a joint control model that allows more entities to be involved, which may be of particular importance, for example, in the context of conducting clinical trials or R&D using AI.

176 Guidelines 07/2020 concerning the notions of the controller and the processor contained in the GDPR – https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-072020-concepts-controller-and-processor-gdpr_pl, p. 14

Thus, **the processing agreement with a provider of solutions using AI depends on the nature of the processing**, which requires an individual assessment. However, in the context of the use of medical data to support the work of medical personnel, this will in principle be justified, as the purpose of such processing is to support the medic and not to pursue the interest of the AI provider.

6.6. Can data processed as part of AI be processed in a cloud computing environment?

To put it simply, cloud computing is a solution based on sharing computing resources (servers, storage, databases, networks, software, analytics and intelligence) via the Internet to offer faster innovation, flexible resources and economies of scale[177]. There are three basic types of cloud computing services: Infrastructure as a Service (IaaS), Platform as a Service (PaaS) and Software as a Service (SaaS). All these services can be offered in both public and private clouds.

> **Although AI was created much earlier than cloud computing, the latter has been an effective catalyst for the development of AI.**

Although AI was created much earlier than cloud computing, the latter has been an effective catalyst for the development of AI. IaaS provides AI practitioners easy access to infrastructure (CPUs, memory, storage, network, operating system), so they do not waste time waiting for availability of local resources. PaaS helps them use AI and data science-related services, such as user interfaces and data directory services, to easily build next-generation applications. SaaS offers AI services within applications, for example CRM and payment applications, in order to achieve desired effects[178].

The Polish legal system is based on **the principle of technological neutrality**, which implies the requirement for public authorities to treat information and communication technologies equally and to facilitate their fair competition in development of the ICT systems and other competitive products and solutions[179]. The use of cloud computing is therefore permissible, provided that other legal requirements are met, such as those relating to the processing of personal data.

177 https://azure.microsoft.com/pl-pl/overview/what-is-cloud-computing/

178 https://towardsdatascience.com/the-role-of-cloud-computing-in-artificial-intelligence-507ffd68ca46, accessed on 13/05/2022

179 Art. 3(19) of the Act on Computerization of Activities of Entities Performing Public Tasks

> **Similarly, there are no obstacles to processing data in the cloud, using AI algorithms, subject to compliance with legal requirements for cybersecurity and privacy.**

Similarly, **there are no obstacles to processing data in the cloud, using AI algorithms, subject to compliance with legal requirements for cybersecurity and privacy**. In the context of cloud computing, it is worth paying special attention to cross-border data processing because servers of cloud service providers or their subcontractors may be located outside the European Economic Area, which involves additional requirements. Therefore, before choosing a cloud service provider, it should be checked, among other things, where and on what terms data processed in the cloud can be transferred and how it is secured. An additional hint may be the reliance of ISO standards followed by large trusted suppliers[180].

6.7. Conclusions

- The use of data is a key element in the development of AI, which learns thanks to access to data.
- In the current legal situation, when developing AI, there is a need to comply with a number of regulations including the GDPR which will apply until the European legislator writes a separate legal act regarding the use of data by AI. This means, among other things, the need to minimize the processed data and observe the data retention period limitations.
- The regulations on the protection of personal data offer a number of grounds enabling the processing of medical data, but it is worth keeping in mind that voluntary, specific and informed consent to the processing of personal data is the conventional method of legitimating the processing of data by AI.

180 E.g.: ISO 27001, ISO 27018

7. AI and further regulatory challenges

7.1. AI and legal regulations of medical devices – what to look for; which applications can be recognized as medical devices?

7.1.1. Regulation (EU) 2017 / 745 of the European Parliament and of the Council

The definition of a medical device introduced by Regulation (EU) 2017 / 745 of the European Parliament and of the Council (MDR)[181] states explicitly that a software application is a medical device if its developer has provided for its use individually or in combination in humans for at least one of the specific medical purposes listed in Regulation 2017/745:diagnostics and prevention of diseases or examination of a disease process or condition[182]. Importantly, the software application does not have to be intended only for the purposes listed in regulation 2017/745 (art. 2(1) of the MDR).

> **...a software application is a medical device if its developer has provided for its use individually or in combination in humans for at least one of the specific medical purposes listed in Regulation 2017/745:diagnostics and prevention of diseases or examination of a disease process or condition.**

It should be emphasized that **not every software application (SA) used in healthcare can constitute a medical device**. Only an SA that meets at least one of the medical purposes listed exhaustively in the MDR can be classified as a medical device. An SA intended for non-medical purposes (other than listed in Enclosure XVI to the MDR), such as invoicing, obviously does not qualify as a medical device. Similarly, a data retrieval SA with a structuring and library functionality certainly does not qualify as a medical device and is not subject to the rules applicable to it.

In connection with the above, a number of questions arise about which SAs can be actually regarded as medical devices. The MDR classifies software quite restrictively. This is a very significant change from the legal regime of Directive 93/42/EEC in which even advanced SAs calculating doses of cytostatic drugs belonged to Class I[183]. This change in the classification of medical devices is very important because it determines the type of conformity assessment procedure to be carried out by the manufacturer or developer to ensure that the device under assessment meets the essential requirements. The higher the product class, the more restrictive the conformity assessment procedure.

181 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745, accessed on 13/05/2022

182 Art. 2 of the MDR

183 https://www.johner-institute.com/articles/regulatory-affairs/medical-device-regulation, accessed on 13/05/2022

Only SAs intended for the purposes listed in art. 2 of the MDR may be recognized as medical devices. According to art. 2(1), the term "medical device" means a tool, apparatus, device, software application, implant, reagent, material or other article intended by the manufacturer or developer to be used, alone or in combination, in humans for one or more of the following specific medical uses:

- diagnosing, preventing, monitoring, predicting, forecasting, treating or alleviating the disease,
- diagnosing, monitoring, treating, alleviating or compensating for injury or disability,
- examining, replacing or modifying anatomical structure or physiological or disease process or state,
- providing information by in vitro testing of samples taken from the human body, including those taken from donors of organs, blood and tissues,

which does not achieve its essential intended effect by pharmacological, immunological or metabolic means in or on the human body, but the effect of which may be assisted by such means[184].

Rule 11 contained in Enclosure VIII to the MDR is the central criterion for classification of an SA as a medical device[185]. It refers to hardware-independent SAs – software separate from the controlled hardware. As a general rule, SAs intended for diagnosis, monitoring, prognosis or treatment, providing information used in diagnostic or therapeutic decisions are classified as belonging to Class IIa or higher.

Given that this catalog does not encompass all the purposes listed in the definition of the medical device (art. 2(1) of the MDR), SAs intended for other medical purposes will fall within Class I.

Therefore, Class I according to the MDR comprises, for example, SAs intended for disease prevention or prediction but not for supporting diagnostic or therapeutic decisions.

For example, a smartphone SA designed to pacify a patient during a panic attack could end up in Class I. Remote pacification alone does not in any way cure the cause of the panic but may be able to ease it. But, if the same SA used AI to find the best method to reassure the patient – for example, based on machine learning, examining data entered by the patient into the SA – could it still belong in Class I?

Another question that arises in the context of AI is certification – especially important for AI applications classified as medical devices. In this context, attention should be paid to the different situations where

184 The following products are also recognized as medical devices: devices for control or promotion of conception, products specially designed for cleaning, disinfection or sterilisation of devices referred to in art. 1(4) and devices referred to in the first paragraph of art. 1(1).

185 Rule 11: Software intended to provide information used in decision-making for diagnostic or therapeutic purposes belongs in Class IIa, except where the effects of such decisions may result in the death or an irreversible deterioration the health of a person, in which case the software belongs in Class III, or a serious deterioration in the health of the or the need for surgical intervention, in which case the software belongs in Class IIb. Software designed to monitor physiological processes is in Class IIa, except where it is intended to monitor vital physiological parameters where a change in these parameters may cause an imminent danger to the patient, in which case the software is in Class IIb. Other the software is in Class I.

AI-enabled software is introduced as a complete "frozen" or "trained" tool and where such software is intended to continue learning from data obtained while providing health care services. In the first case, we use a ready-made tool. In the second case, decision-making algorithms will further develop during their use, which is a serious challenge from the point of view of the MDR's certification rules. In addition, the "frozen" and "learning" modes may operate in parallel. The use of the incremental knowledge gained through learning would require recertification, as the whole solution would work differently, also in terms of its performance.

A debate is underway on the possibility of verifying AI systems and models in terms of meeting ethical standards and regulatory requirements. It is still necessary to work out the scope or mechanisms of certification. The European legislator is aware of this problem, as the subject of certification of AI systems is reflected in the AI Act (see section 7.1.2.). However, the proposed certification is quite narrow because it refers primarily to the assessment and validation in terms of quality assessment systems and technical documentation.

...the situation in which the software of medical devices developed for health protection is for the first time subject to so many conditions and requirements of the EU law should last as short as possible. It is necessary to formulate transparent and complete explanations, even a "soft law", which will clarify the legal status of AI.

In conclusion, since we have no complete and explicit guidelines on the classification of particular SA types, the changes introduced to the MDR may lead to formal difficulties in developing and marketing new software. In our opinion, the situation in which the software of medical devices developed for health protection is for the first time subject to so many conditions and requirements of the EU law should last as short as possible. It is necessary to formulate transparent and complete explanations, even a "soft law", which will clarify the legal status of AI.

7.1.2. Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on the AI Act

Due to the definition adopted in the draft AI Act, a significant part of software can be considered an AI system (regardless of whether it is "technically" an AI system[186]) and, from the perspective of the principles of classification of AI systems, virtually any such medical device would be a high-risk system.

The proposed AI Act may have significant consequences for developers and manufacturers. For example, for high-risk AI systems, it will be necessary to introduce an additional risk management system (art. 9 of the draft AI Act) or to meet stricter requirements regarding technical documentation (art. 11), registers (art. 12), human oversight (art. 14) and cybersecurity (art. 15).

However, the draft AI Act ignores the fact that an AI-enabled SA recognized as a medical device is usually software classified in Class IIa or higher (Enclosure VIII, chapter III, MDR Rule 11).

To sum up, the draft AI Act requires elaboration in terms of interaction with regulations regarding medical devices, and these also require some clarification and the issuance of explanatory documents in connection with the development of legal regulations in the field of AI.

7.2. AI and intellectual property law – what to look for?

In the light of the intellectual property law, AI poses a number of questions that have not yet been adequately answered. A fundamental question that is also important from the perspective of the White Paper concerns the determination of the threshold from which we will assume the lack of human participation in the creation of a given work.

"Works" created by AI are usually characterized by the fact that no one can demonstrate that their decisions and choices meet the conditions on which the protection of a given work depends in the light of intellectual property law. This raises the question of whether such an AI product is to be protected and, if so, how and who is to be the beneficiary of such protection.

It is difficult to determine who should be the copyright holder of works created by IA: the software developer or the machine? Or maybe there should be no protection at all?

186 The definition of AI used in the draft AI Act is very broad. It includes not only software based on machine learning mechanisms but also, for example, knowledge bases and search methods. In April 2022, a new version of the AI Act appeared, introducing changes in the definition of AI, among others. According to its original wording, such a system means software developed using one or more of the techniques and approaches listed in Enclosure I, which can generate results for a given set of human-defined purposes. A change was proposed according to which the results would not have to be determined by a human. In addition, hypotheses were added to the catalog of potential outcomes of operation of AI systems. – https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/CJ40/PR/2022/05-11/1254442EN.pdf

In support of the first theory – that the owner of the AI will be the rightholder – we can argue that a computer, like a camera or a typewriter, is an instrument capable of functioning only when activated by a human. It is thanks to the element of human creativity that it is possible to create a work[187].

Since the requirement of human authorship has not been questioned in the literature so far, one of the proposals to solve the problem associated with the rights to AI-created products is the concept of indirect authorship. This theory recognizes the granting of copyright to a computer-generated work to the author of the program (programmer), assuming that the user will not have any creative contribution to the work (however, if the work was creatively transformed by the user, one should talk about the creation of a dependent work[188]).

AI-enabled software, through its continuous operation, improves its results which may be initially poor but may get better over time. Sometimes it takes only a minimum of human intervention to create a "work" through the machine. This is confirmed by the European Parliament's report with recommendations for the commission on civil law rules on robotics, which states that robots. *"by developing certain features of autonomy and cognitive ability, such as the ability to learn through experience and the ability to make quasi-independent decisions, increasingly resemble actors who interact with the environment and are capable of changing it in a significant way"*[189].

So far, machines, unlike humans, do not have legal capacity, so it is difficult for them to become the subject of rights including intellectual property rights. Even if AI-generated works meet the criteria of copyright protection, it will not be possible to grant the machine the same rights as to a human because of its lack of awareness, intentionality, emotions, inspiration and creative freedom, etc.

It is often pointed out that imprudently granting the right to a work only to an AI application as the author, or depriving the work of protection could undermine further development of this technology. Without copyrights, including economic rights, what would motivate scientists and developers of algorithms[190]?

We also point out that data used by AI may be protected by one or more intellectual property rights and the use of it by a third party could, of course, require obtaining a license or for the data. However, it would be too far-reaching to attribute copyrights to the provider of data based on which an AI application "created a work".

187 Final Report of the National Commission on New Technology Uses of Copyrighted Works – http://www.digital-law-online.info/CONTU/contu10.html

188 P. P. Juściński: "Prawo autorskie w obliczu rozwoju sztucznej inteligencji", ZNUJ, PPWI 2019, N° 1, p. 5-44

189 The report with recommendations for the Commission on civil law rules on robotics (2015/2103(INL)), cited by A. Konieczna: "Problematyka sztucznej inteligencji w świetle prawa autorskiego", *ZNUJ, PPWI* 2019, N° 4, p. 104-116

190 A. Konieczna: "Problematyka sztucznej inteligencji w świetle prawa autorskiego", ZNUJ, PPWI 2019, N° 4, p. 104-116

> ...data used by AI may be protected by one or more intellectual property rights and the use of it by a third party could, of course, require obtaining a license or for the data. However, it would be too far-reaching to attribute copyrights to the provider of data based on which an AI application "created a work".

In the light of the AI capabilities presented above (see section 3.2. et seq.), we draw attention to the issue of rights to the results of R&D, clinical trials or medical experiments conducted with support from AI. After all, intellectual property is the product of the human mind, and results of creative scientific work often take the form of inventions and industrial or utility designs. At the end of 2018, precedential patent applications were filed at the UK Intellectual Property Office and the European Patent Office. They concerned solutions the author of which, according to the applications, is an AI application called DABUS[191].

The essence of the invention was the way in which DABUS connects huge clusters of neural networks to create and modify links between them, which leads to the production of new ideas. At the same time, the effects of ideas generated by previous setups are being studied. DABUS is the "author" of inventions that solve a technical problem by affecting matter. An example of the solutions "created" by DABUS is a food container that facilitates the heating and cooling of food thanks to the improved design of walls based on fractals. However, the European Patent Office stated that AI-enabled systems and machines do not have any rights because these devices lack legal personality comparable to that of natural and legal persons[192].

In view of these doubts, the European Parliament adopted a resolution on intellectual property rights in October 2020[193]. The resolution makes a distinction between AI-supported human works and products created by AI systems working on their own. It is proposed that in cases where AI is used only as a tool to assist the author in the creative process, the current copyright rules will continue to apply. On the other hand, results of autonomous operation of "artificial agents" or robots do not qualify for copyright protection due to the lack of an author who is a natural person. The resolution also presents an opinion that one should not seek to give legal personality to AI, as this could negatively affect motivational incentives of human creators.

Note that this resolution is not final and does not dispel all doubts related to the development of AI in the context of intellectual property law. Certainly, the law relating to AI will evolve along with the development of the technology, responding to new challenges.

191 DABUS: device for the autonomous bootstrapping of unified sentience

192 I. Bałos: "AI i jej wynalazki - studium przypadku", ZNUJ, PPWI 2020, N° 1, p. 95-115

193 https://www.europarl.europa.eu/doceo/document/TA-9-2020-0277_PL.html, accessed on 13/05/2022

7.3. AI and medical experiments – what to look for?

AI-enabled tools can recognize valuable relationships in raw data. Therefore, they can be used in almost every area of medicine, including development of new drugs and therapies. Typically, the drug development process can take many years, but it happened that an AI application invented a drug within just 12 months[194]. In 2021 it was announced that the invented drug molecules passed on to the first phase of clinical trials in humans[195].

When it comes to studying AI algorithms themselves as part of a medical experiment and a clinical trial, there is a lack of a consistent approach in this respect.

The meaning of the concept of medical experiment on legal grounds has been decided to some extent by the Polish legislator[196]. There are two kinds of medical experiments: therapeutic and scientific[197]. A medical experiment can be carried out to achieve health benefits in the person taking part in the experiment and then a therapeutic experiment takes place. A medical experiment may also be prioritized to expand medical knowledge, in which case it qualifies as a scientific experiment[198].

Like the use of other innovative methods in healthcare, the use of AI, depending on the nature of its application, can sometimes be a medical experiment. This is because we are just getting to know some of these technologies and seeing how they can help modern medicine[199].

One of the conditions for a safe and methodically appropriate experiment is to observe the so-called "rules of careful experimentation". The researchers, although they enter a previously unknown area, do not work in a scientific vacuum. Therefore, they must exercise maximum diligence and design and perform the experiment based on current medical knowledge. For this reason, one of the prerequisites for observing the necessary caution is that the experimenter has necessary qualifications, knowledge and skills[200]. In the case of using AI, this may mean, for example, a proper understanding of the principles of software operation and the acquisition of appropriate software skills.

A very important element of the medical experiment is the consent of its subject. The prerequisites for the effectiveness of the consent to participation in a medical experiment or clinical trial are stricter than in the

194 https://www.bbc.com/news/technology-51315462, accessed on 13/05/2022

195 https://investors.exscientia.ai/press-releases/press-release-details/2021/exscientia-announces-second-molecule-created-using-ai-from-sumitomo-dainippon-pharma-collaboration-to-enter-phase-1-clinical-trial/Default.aspx, accessed on 13/05/2022

196 Art. 21 of the Act on the Profession of Doctor

197 L. Bosek, M. Gałązka: "Szczególne świadczenia zdrowotne", *System Prawa Medycznego*, vol. 2, ed. dr. hab. Leszek Bosek, dr. Agata Wnukiewicz-Kozłowska, 2018

198 R. Kubiak: "Nowe uwarunkowania prawne przeprowadzania eksperymentów medycznych", PS 2021, N° 1, p. 5-26

199 According to the statutory definition, a medical experiment consists, among others, in the introduction of new or only partially tried diagnostic, therapeutic or prophylactic methods in order to achieve direct benefit to the health of the sick person. – art. 21(2) of the Act on the Profession of Doctor

200 R. Kubiak: "Nowe uwarunkowania prawne przeprowadzania eksperymentów medycznych", PS 2021, N° 1, p. 5-26

case of the consent to a standard therapeutic intervention. This is a consequence of additional risks, such as those resulting from the priority of the research goal. The basic condition for the effectiveness of the consent is adequate knowledge of the experiment, e.g. about the AI-enabled software to be used[201]. The consent should be obtained before the start of the medical experiment and may be effectively withdrawn during it.

An AI application recognized as a medical device (see section 7.1.) will generally be evaluated based on clinical trials. A clinical trial consists of checking in the clinical environment whether the medical device meets the criteria of safety, performance and so on in terms of its effect on the patient. While we already have guidelines for conducting clinical trials and clinical evaluation of software, there is still a lack of guidelines on how to ensure reliability and effectiveness of such evaluations conducted on AI-enabled software[202].

AI can be not only the subject of clinical trials but also an element that significantly improves their course, for example, by accelerating the analysis of collected data and, consequently, ensuring faster or more accurate presentation of research results (see section 3.3.). However, there is a lack of guidelines on ensuring reliability and credibility of research conducted using AI.

One of the elements that can significantly improve the conduct of medical experiments is the use of so-called "digital twin" solutions. A digital twin is a virtual model of a physical subject where the two are dynamically linked. This technology used in the healthcare sector could lead to a radical transformation of conventional methods and medical experiments[203].

The use of a digital twin eliminates the need to conduct tests on living tissues or an organism. A medical intervention and its effects can be simulated with a few clicks. Not only individual organs (heart or lungs) can have their virtual representations but also the whole human body. Each patient could have a digital surrogate on which medical experiments can be conducted in virtual space so that, finally, the actual patient could get the maximum benefit from the tested and proven therapy[204].

In a situation where an AI application is leading the way in a clinical trial, one may begin to wonder whether it should not be treated as a researcher: an entity supervising and conducting a clinical trial. However, this is unacceptable under the current law. Art. 2(2) of Regulation 536/2014 defines the investigator as the person responsible for conducting the clinical trial at the clinical trial site (point 15) and the principal investigator as the responsible head of the team of investigators conducting the clinical trial at the clinical

201 L. Bosek, M. Gałązka: "Szczególne świadczenia zdrowotne", *System Prawa Medycznego*, vol. 2, ed. dr. hab. Leszek Bosek, dr. Agata Wnukiewicz-Kozłowska, 2018

202 https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-170921-samd-n41-clinical-evaluation_1.pdf, accessed on 27/05/2022

203 https://genomemedicine.biomedcentral.com/track/pdf/10.1186/s13073-019-0701-3.pdf, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8401029/pdf/jpm-11-00745.pdf, accessed on 27/05/2022

204 https://net4doctor.pl/technologia-w-medycynie/digital-twin-w-medycynie-definicja-i-zastosowanie, accessed on 27/05/2022

trial site (point 16). Art. 2(2a) of the Polish Pharmaceutical Law clarifies the definition of the researcher in terms of specific qualifications required for conducting a study: the practicing of the profession of doctor, dentist or veterinarian requires sufficiently high professional qualifications, scientific knowledge and experience in working with patients[205]. AI-enabled software cannot meet these requirements.

It should be noted that in order to reduce the above-mentioned AI bias in the context of the specificity of machine learning data sets, depending on the specificity of the studied population and diagnostic and therapeutic procedures, it is necessary to strive for implementation of multi-center studies in groups as close as possible to the target population. The numerous exclusion criteria preferred in many scientific studies for AI tools will particularly significantly limit the possibilities of their widespread use in the general population.

The quality and structure of the medical data input is of particular importance in the development of AI tools. Undoubtedly, actions aimed at establishing uniform standards for the data input to information systems will be conducive to development of effective research on AI. Central electronic documentation systems capable of sharing data with AI applications can play a special role in this area.

7.4. AI and the financing of health care services – what to look for?

The implementation of new solutions into the public health care system is a long and complicated process. There are no flexible mechanisms for implementing AI into public health care. The previous examples assume adding a new benefit to the basket, which is the most long-term activity, characterized by the highest cost of system service.

In order to integrate AI solutions into the Polish system of health care services financed from public funds, it is necessary to strengthen the institutions that are to be responsible for the implementation of AI solutions by increasing financial and human resources for performing tasks related to it[206]. In addition, pilot programs, which are a good method of testing innovative solutions in healthcare, should be used more widely and more frequently. The activities described earlier, in the context of intelligent stethoscopes (see section 3.5.), are a good example. However, note that systemic solutions popularizing modern technologies should go hand in hand with a change in public awareness of the potential of AI.

205 J. Haberko, M. Świderska: "Prawo farmaceutyczne", *System Prawa Medycznego*, vol. 4, ed. dr. hab. Joanna Haberko, 2019

206 In this context, note the project of implementing the Hospital-Based HTA (HB-HTA) system – the Hospital Assessment of Innovative Medical Technologies – implemented at Lazarski University. As a result, a system will be created to enable implementation of the HB-HTA to improve self-sufficiency and efficiency of health systems through the use of objective health technology assessment methods aimed at identifying effective and cost-effective health technologies for clinical practice applications under health insurance.

7.5. AI and quality in healthcare – what to look for?

Standards for the use of AI in healthcare are already being developed for example in the United States[207], but AI is unlikely to be used to its fullest extent possible without well-established practices and guidance in the conduct. In order to popularize and authenticate the use of AI, new standards of clinical care, quality, safety, guidelines on abuse and communication, focused on AI, should be developed. There are even attempts to create good practices, for example standards for publishing results from predictive models in the area of AI in healthcare[208].

Such standards and practices are necessary, especially in the context of systematic errors of algorithms (AI bias) that can generate cognitive impairment and deepen the negative effects on data subjects[209]. The implementation of AI techniques must be done with caution, for example by adopting processes in which there is an active debate about software bias and inclusivity during model development. In addition, the ability to continuously monitor a process with built-in AI for efficiency, potential bias and integrity in conjunction with social norms is critical to earning trust of not only patients but also physicians, nurses, insurers, regulators and all stakeholders in our healthcare system[210].

AI-based systems should be seen as a lever for the transformation of the healthcare system, and the evaluation of the value and capabilities of specific AI-enabled software should go beyond technical performance and cost indicators. It is necessary to make a holistic analysis of the value of software in the real context of care and services based on the basic model of health technology assessment **(HTA)** – but adapted to the specifics of AI. AI tools are not just another medical technology, and many specialists find their assessment complex and particularly difficult. For example, the implementation of an AI solution in the healthcare system often takes place quite shortly after its development (months, not years, as in the case of medicines and vaccines), which means that there is not yet as much evidence of their effectiveness and impact as would be required by traditional health technology assessment for many other solutions[211].

Health technology assessment according to Agency for Health Technology Assessment and Tariff System guidelines is an interdisciplinary field of knowledge, used to make evidence-based decisions in the field of health policy and clinical practice[212]. The assessment is therefore used to solve health problems and improve the quality of life of patients. It consists in collecting and summarizing scientific evidence and

207 F. Doshi-Velez, Food and Drug Administration: "Considerations for the Practical Impact of AI in Healthcare" – https://www.fda.gov/media/107792/download

208 https://www.tripod-statement.org/ oraz https://www.tripod-statement.org/wp-content/uploads/2020/01/Tripod-Checlist-Prediction-Model-Development.pdf

209 D. Lubasz: "Projektowanie rozwiązań wykorzystujących sztuczną inteligencję z uwzględnieniem wymogów data protection by design" [in:] "Prawo sztucznej inteligencji i nowych technologii", ed. B. Fischer, A. Pązik, M. Świerczyński, Warszawa, 2021

210 Douglas C. Hague: "Benefits, Pitfalls, and Potential Bias in Health Care AI", *North Carolina Medical Journal*, July 2019, 80 (4) 219-223; DOI: https://doi.org/10.18043/ncm.80.4.219

211 https://www.frontiersin.org/articles/10.3389/frai.2021.736697/full, accessed on 27/05/2022

212 Agencja Oceny Technologii Medycznych i Taryfikacji (2016): "Wytyczne oceny technologii medycznych", rev. 3.0, Warszawa – https://www.aotm.gov.pl/wytyczne-oceny-technologii-medycznych/

information on many aspects of the application of a given medical technology. Among them are health aspects, analyzed at the first stages of the health technology assessment process. It consists of an analysis of the decision-making problem and a clinical analysis, using the principles of so-called "evidence-based medicine"[213]. Health regulators are facing unprecedented complexity in the face of the development of AI: the evaluation and validation of breakthrough technologies requires considering a combination of several aspects. Many studies have described significant technical advances in AI technology but only a few have adopted a holistic viewpoint that would allow them to determine their impact and the associated changes and transformations in health systems. Technical research rarely matches the complexity of AI applications because it ignores context-dependent or customization changes that the implementation and use of AI requires[214].

In the Polish legal system, a project dedicated to improving quality in the health care system has recently appeared: the draft Act on Healthcare Quality and Patient Safety[215]. The project is about quality in healthcare in general; it is not focused on AI. It is planned to introduce a statutory regulation that will ensure that patients, HCPs and health care establishments have access to universal, reliable, objective and comparable information about quality of their services. This is to be done, inter alia, through the implementation of an internal quality and safety assurance system in health care establishments such as hospital services, regardless of the method of financing services.

The changes covered by the proposed Act on Healthcare Quality and Patient Safety will of course also apply to AI solutions. Responsible and effective use of AI-enabled software is likely to become part of the assessments of health care establishments (based on the quality of services they provide). AI can contribute to a significant improvement in quality of diagnosing or monitoring of patients' health, thus translating into better assessments of quality of services provided by AI-enabled entities. Currently, however, it is not clear in what shape the final draft law will enter into force, hence these considerations remain only in the sphere of guesses.

The European legislator is also not indifferent to the issues of ensuring satisfactory quality of AI solutions used in the EU. The draft AI Act[216] focused, among other things, on systems establishing a number of stringent requirements, the fulfillment of which determines the admissibility of using AI systems in the EU. These requirements include, for example, the need to ensure high-quality training, validation and test data sets so that the system works as intended and safely and that it does not become a source of discrimination[217]. In addition, each supplier will have to implement a quality management system,

213 https://izp.wnz.cm.uj.edu.pl/pl/blog/technologie-medyczne-i-ich-ocena-czyli-co-to-wlasciwie-jest-hta, accessed on 27/05/2022

214 Hassane Alami, MScPH, MScHP, PhD, Pascale Lehoux, MSc, PhD, Yannick Auclair, MSc, PhD, Michèle de Guise, MD, IMHL, FRCPC, Marie-Pierre Gagnon, MSc, PhD, James Shaw, PT, PhD, Denis Roy, MD, MPH, MSc, FRCPC, Richard Fleet, MD, PhD, CCFP-EM, Mohamed Ali Ag Ahmed, MD, MPH, PhD, Jean-Paul Fortin, MD, MPH, MBA, FRCPC: "Artificial Intelligence and Health Technology Assessment: Anticipating a New Level of Complexity" – https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7380986

215 https://www.gov.pl/web/krmc/projekt-ustawy-o-jakosci-w-opiece-zdrowotnej-i-bezpieczenstwie-pacjenta, accessed on 13/05/2022. The Act on Quality… did not enter into force on the planned date (Jan. 1, 2022).

216 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206

217 Art. 10 of the draft Artificial Intelligence Act

including techniques and procedures for designing high-risk AI systems and techniques and procedures for the development, quality control and quality assurance[218]. However, as in the case of the draft Act on Healthcare Quality and Patient Safety, the AI Act is currently in the draft phase, hence the above considerations and assessments should not be treated as definitive.

7.6. AI and education in the healthcare sector

In order to achieve optimal use of the potential of AI technology, it is necessary to conduct education, addressed in particular to patients and HCPs, regarding the benefits of responsible use of AI.

Although there have been significant changes in medicine in recent decades, medical education is still largely based on traditional curricula. The length of training varies from country to country but the core competencies contained in these curricula are similar around the world: after the fundamental phase of preclinical didactics, the training focuses mainly on hands-on learning. Meanwhile, education on AI has a potential to drive realistic opinions of HCPs in relation to AI and improve their competence in this area.

Educational activities should take into account, in particular, the involvement of key participants in the health care system, including broadly understood expert bodies, both scientific and industry-specific. Technological development combined with the growing awareness of patients creates a large demand for an educational offer for AI among HCPs. In particular, we see the need to properly update the program of medical other health science studies, provide adequate training and conduct campaigns popularizing the use of AI among practitioners practicing medical personnel, also during residency.

In addition, efforts should be made to break down digital barriers which – for some people, in particular the elderly and the disabled – still hinder or prevent staying remotely in touch with HCPs, and may cause HCPs to be reluctant to enrich their current practice with the use of new IT solutions.

Also, it is necessary to create industry practices and standards that take into account the key role of AI in the development of modern medicine, which can be widely used in clinical practice. Medical universities can use cooperation to lay foundations for effectively equipping medical students with AI knowledge[219], but it will not be possible to use the full potential of AI science without appropriate systemic actions, such as adaptation of curricula of studies.

218 Art. 10 of the draft Artificial Intelligence Act

219 https://journals.sagepub.com/doi/full/10.1177/23821205211036836, accessed on 13/05/2022

7.7. Conclusions

- While AI may still be a novelty in the regulatory environment, there are already a number of standards that apply to this software. It is worth paying attention in particular to the MDR which has changed the way medical devices are regulated in Europe by recognizing a certain type of software applications as medical devices. However, the MDR has many shortcomings that make it difficult to apply it to AI algorithms.

- The development of AI is very important from the perspective of quality in healthcare. The European and Polish legislators pay attention to the aspects of providing high-quality health care services, which translates into drafts of the new laws. In addition, quality in the context of AI is important from the perspective of the nature of the AI-enabled software itself, also in the context of data used to train or validate models.

- Education in the field of AI is of key importance from the perspective of development and popularization of this technology. It can drive realistic opinions of HCPs in relation to AI, improve their competences in this area and translate into increased safety in the use of this technology. It is necessary to take systemic actions leading to the introduction and improvement of education of HCPs and patients in the field of modern technologies.

8. Closing notes

8.1. Why does the White Paper not answer all the questions?

AI is still an innovative technology the evolution and implementation of which has overtaken regulatory changes. Activities aimed at extending the framework for its development began relatively recently, both at the level of the EU and in Poland. **We are only at the initial stage of the discussion on the future of AI and the model of its use in healthcare**. The regulations of national law, including medical law, do not provide for dedicated rules for the use of this type of technology.

> The White Paper is one of the first attempts to analyze and describe the challenges associated with the technological revolution in the development of AI in healthcare.

The White Paper is one of the first attempts to analyze and describe the challenges associated with the technological revolution in the development of AI in healthcare. **We have discussed the key issues in terms of medical law that are not yet regulated or are subject to other, general, regulations that may be interpreted differently**[220].

In this area, as at the moment, there are no clear views in the form of a doctrine or an established line of case-law. The document attempts to answer the key questions to help HCPs find the best course of action. In the case of some questions, we are not yet able to offer explicit answers – we need a wider discussion and new solutions to find them. Note also that further questions and studies on this issue will appear as the technology and legislation evolve.

We hope to start a discussion on changes in the health care sector, thanks to which it will be possible to develop mechanisms for safe and effective implementation of innovative solutions. **We believe that the White Paper, as one of the first such detailed studies on the use of AI in health care in Poland, is only the beginning of the debate**.

220 Note that the White Paper focuses on the aspects of clinical practice regarding the provision of health services. It does not address the use of AI in administrative, organizational or management processes in health care.

8.2. Where can I learn more about AI in healthcare?

New studies on the subject of AI in healthcare are published all the time. In the midst of this plethora of information, we encourage you to look for reliable sources.

First of all, we encourage you to follow the current activities of the **AI in Health Coalition:** https://aiwzdrowiu.pl and of the **section of the Working Group on AI dedicated to health care**, which has been established to propose measures aimed at ensuring appropriate conditions in Poland for the development of AI applications in both the private and public sectors, as well as in conducting scientific research: https://www.gov.pl/web/cyfryzacja/grupa-robocza-ds-sztucznej-inteligencji-grai.

In addition, we encourage you to expand your knowledge and follow the latest news from the world of AI. In particular, we encourage you to follow the following sources:

NGOs:

- http://telemedycyna-raport.pl/#o_fundacji
- http://pfsz.org
- https://aipoland.org/
- https://digitalpoland.org
- https://hl7.org.pl/
- https://www.cybsecurity.org/pl/
- https://panoptykon.org/
- http://piim.org.pl/

Professional portals and magazines:

- https://przegladprawamedycznego.pl/index.php/ppm/index

Polish portals:

- https://www.gov.pl/web/ai
- https://www.sztucznainteligencja.org.pl/
- https://www.cyfrowyszpital.pl/
- https://nafalinauki.pl/
- https://przemyslprzyszlosci.gov.pl/

Foreign portals:

- https://www.aaai.org/
- https://healthitanalytics.com/
- https://ai-med.io/
- https://medicalfuturist.com/
- https://medcitynews.com/
- https://www.ohdsi.org/

9. List of legal acts

9.1. EU law

- **Council Directive 85/374/EEC** of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (*OJ* L. 1985 N° 210, p. 29, as amended)

- **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

- **Regulation (EU) 2016/679** of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC **(General Data Protection Regulation)**

- **Regulation (EU) 2018/1807** of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union

9.2. Soft law

- European Parliament resolution of 20 October 2020 on intellectual property rights for the development of artificial intelligence technologies (2020/2015(INI)).

- European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)), *OJ* C N° 252 of 18/07/2018

9.3. Polish law

- **Civil Code** of Apr. 23, 1964 (*Journal of Laws* 2020, item 1740, as amended)

- **Criminal Code** of June 6, 1997 (*JoL* 2021, item 2345, as amended)

- **Act on Medical Activity** of Apr. 15, 2011 (*JoL* 2022, item 633, as amended)

- **Act on Medical Chambers** of Dec. 2, 2009 (*JoL* 2021, item 1342)

- **Act on Criminal Liability of Collective Entities** of Oct. 28, 2002 (*JoL* 2020, item 358)

- **Act on Patients' Rights and on the Patient Ombudsman** of Nov. 6, 2008 (*JoL* 2020, item 849, as amended)
- **Act on the Law of Entrepreneurs** of March 6, 2018 (*JoL* 2021, item 162, as amended)
- **Act on IT Systems in Health Care** of April 28, 2011 (*JoL* 2021, item 666, as amended)
- **Act on Health care services Financed from Public Funds** of Aug. 27, 2004 (*JoL* 2021, item 1285, as amended)
- **Act on the Professions of Nurse and Obstetrician** of July 15, 2011 (*JoL* 2022, item 551)
- **Act on the Professions of Doctor and Dentist** of Dec. 5, 1996 (*JoL* 2021, item 790, as amended)
- **Pharmaceutical Law** of Sep. 6, 2001 (*JoL* 2021, item 1977, as amended)
- **Act of Feb. 17, 2005, on computerization of the activities of entities performing public tasks** (*JoL* 2021, item 2070, as amended)

9.4. Soft law

- **Resolution 196 of the Council of Ministers** of Dec. 28, 2020, on the establishment of "The Policy for the Development of AI in Poland since 2020" (*Monitor Polski* 2021, item 23).

9.5. Draft legislation

- Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence **(the AI Act)** and amending certain legislative acts of the EU
- Proposal for a Regulation of the European Parliament and of the Council on European data governance **(Data Governance Act)**.
- Proposal for a Regulation of the European Parliament and of the Council on the **European Health Data Space**.
- **Act on Healthcare Quality and Patient Safety** of July 22, 2021

The **AI in Health Coalition** is an initiative intended to harness the full potential of AI in health and support digital transformation. The Coalition aims to drive "The Policy for the development of AI in the Polish Healthcare System". Another aim of the Coalition is to create an environment enabling both fast and widespread use of the latest achievements of AI by the Polish health care system. The Coalition believes that AI solutions in healthcare should respect the central role of the HCPs in patient care and inspire their trust. The Coalition undertakes numerous activities aimed at popularizing AI tools in the Polish healthcare system. Our activities are comprehensive: we operate both on the regulatory side (by proposing sectoral public policies) and on the technological side (by conducting R&D work on technologies enabling the use of AI in health care). The Coalition associates dozens of leading national and global players involved in the development and implementation of AI algorithms. The Coalition is an informal working group. It publishes legal opinions in liaison with a working group in the Chancellery of the Prime Minister, monitors the media and provides information to member organizations. It also arranges for meetings and conducts talks with its public partner. Visit http://aiwzdrowiu.pl to learn more.

The **section of the Working Group on AI dedicated to health care** has been established to propose activities aimed at ensuring appropriate conditions in Poland for the development of AI applications in both the private and public sectors, as well as in conducting scientific research. The Group is composed of experts in the fields of medicine, law and information technology. The Group brings together people and organizations who are interested and actively involved in the development of the potential of AI in the Polish healthcare system.

The **Polish Hospital Federation** (PFSz) is a nationwide organization of hospitals regardless of their ownership structure, size, profile or model of operation. It directly associates more than 250 hospitals and, through agreements with local and sectoral hospital unions, it acts as an umbrella organization for more than 550 hospitals. Another strength of the Federation is a large group of supporting members: major national and international companies, health care system experts and ambassadors of the Federation. The main goal of the Federation is to improve the operating conditions of hospitals. The Federation works for better financing of hospitals, increasing the importance of hospital managers, safety of patients and hospital employees, as well as for good quality, management practices, education and legislation. It is the voice of Polish hospitals on the national, European and global forums. It belongs to the largest multi-branch employers' organization in Poland – Employers of the Republic of Poland. The Federation is also a full member of the European Hospital and Healthcare Federation (HOPE) which brings together over 80% of hospital resources in the EU, as well as the International Hospital Federation (IHF), the only global organization of hospitals. Visit http://www.pfsz.org/ to learn more.

wZdrowiu is a team of experts led by the leader of the AI in Health Coalition, Ligia Kornowska. It hosts the "GDPR and cybersecurity in health" conference, the largest event on the protection of medical data in Poland, bringing together the most significant industry organizations and representatives of the public party. Co-author of the "The Top Disruptors in Healthcare" Report, a compilation of information about innovative Polish medical startups. Since 2021, wZdrowiu has also organized the "AI in Health" conference, the first event on such a large scale in Central and Eastern Europe dedicated to AI and health innovations. The 2021 edition of the event brought together many significant circles and institutions including outstanding panelists from the UK, Hungary and Bulgaria.


AI
W ZDROWIU