Verification error and supervision error – new types of medical errors resulting from the use of artificial intelligence systems occurring during the provision of health services

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1. Introduction

Artificial intelligence (AI)-based medical devices have been used in the provision of healthcare services for several years, particularly in radiology, urology, cardiology, gynaecology, and psychiatry. Such applications facilitate faster diagnosis and more effective treatment. Medical practitioners are able to analyse a patient’s complex medical data more accurately and in greater detail, and offer treatment methods that are more tailored to the patient’s individual needs.¹ Surgeons utilising the intelligent robot are able to perform procedures with a far higher level of precision compared to conventional methods. However, that does not make all

¹ High-Level Expert Group for Artificial Intelligence, Ethics Guidelines for Trustworthy AI, Brussels, 10 April 2019, p. 43.
procedures successful. A doctor may make a mistake using innovative methods of treatment and diagnosis. Such a mistake will be of a different nature than one made using traditional methods. Changes in the diagnostic and treatment processes have necessitated the identification of new types of medical error, namely verification error and supervision error.

2. The nature and working of artificial intelligence systems

It is fundamental for this study to define the precise scope of the meaning of the term artificial intelligence. The term is not a legal or juridical concept. Attempts to establish what constitutes artificial intelligence have been made by representatives of the psychological, mathematical, computer, and legal sciences. However, this has not led to the development of a common definition. On 14 June 2023, the European Parliament adopted amendments to the draft Artificial Intelligence Act, indicating that an AI system refers to a machine system that is designed to operate with varying levels of autonomy and that can, for explicit or implicit purposes, generate outputs such as predictions, rec-

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ommendations, or decisions affecting physical or virtual environments. In recital 6, the EU legislator highlights that ‘performing tasks with varying levels of autonomy’ implies at least the partial independence of the AI from human control and its ability to operate without human intervention. In contrast, the term ‘machine-based’ refers to the fact that AIs run on machines. In this paper, I will use the definition of an artificial intelligence system as set out in the amendments to the Artificial Intelligence Act of 14 June 2023.

3. Medical error – definition

Medical error constitutes conduct contrary to the generally recognised principles of medical knowledge, manifested in an act or omission harmful to the patient, which could have been avoided by following the rules conforming to the state of medical knowledge. In the US doctrine, it is understood to be any act or omission by a physician during the treatment of a patient that deviates from the norms of conduct accepted in the medical community and causes injury to the patient.

The Polish Supreme Court, in its judgment of 1 April 1955, established that a medical error is an activity (act or omission) of a doctor in the sphere of diagnosis and therapy which is contrary to medical science to the extent available to the doctor. The occurrence of an error is not influenced by the individual characteristics, or inclinations of a particular doctor, or the circumstances under which he or she provided health services. In its decision,
the Supreme Court used the concept of medical malpractice.\textsuperscript{11} In view of this, in this paper I will use the concept of medical error.

The literature distinguishes a variety of classifications of medical errors, with the prevalent division focusing on the criterion of the action taken by the doctor. According to this classification, we distinguish a diagnostic error, an error of prognosis, and a therapeutic error.\textsuperscript{12} Since the scope of activities performed by the doctor in connection with the increasing use of medical devices equipped with artificial intelligence will change, it seems justified to distinguish a new type of medical error, i.e. verification error as a subcategory of diagnostic error and supervision error as a subcategory of therapeutic error.

4. Diagnostic error

A diagnostic error consists in an incorrect evaluation of the patient’s state of health. Diagnosis involves determining the patient’s physical or mental condition, identifying a possible illness, and determining its nature and causes.\textsuperscript{13} Medical literature indicates that a diagnostic error consists in failing to undertake tests necessary for the correct diagnosis of a condition or in incorrectly interpreting the test results obtained.\textsuperscript{14} A positive diagnostic error


\textsuperscript{13} M. Sośnian, \textit{Cywilna odpowiedzialność}, p. 119.

is the recognition of a disease that does not actually exist, whereas a negative diagnostic error is the failure to recognise an actual disease.\textsuperscript{15}

The process of establishing a diagnosis is a two-phased approach: firstly, the collection of data, and secondly, data analysis. IT systems have the capacity to collect and analyse more data than even the most skilful and experienced doctor. However, ‘algorithmic’ analysis of the data collected during the interview and ancillary examinations alone is insufficient to avoid errors in diagnosis.

At this point, it is worth giving an example of a medical device equipped with artificial intelligence for diagnostic testing. The best-known and most widely used artificial intelligence system for cancer diagnosis appears to be IBM Watson for Oncology. The system is currently used by dozens of medical facilities in the US, Asia, and Europe. It is also used in Poland at the Regional Health Centre in Lublin by the ECM Hospitals Group. The equipment is used in cases of doubt about a patient’s diagnosis. Watson for Oncology is a cognitive computing system that uses natural language processing and machine learning\textsuperscript{16} to deliver treatment recommendations. It processes structured\textsuperscript{17} and unstructured\textsuperscript{18} data from medical literature, treatment standards, medical records, imaging, laboratory and pathology reports, and expert opinion from Memorial Sloan Kettering specialists to arrive at a correct cancer diagnosis and then formulate treatment recommendations.\textsuperscript{19}

\textsuperscript{15} K. Bączyk-Rozwadowska, in: System Prawa Medycznego, p. 230.
\textsuperscript{16} The primary technique used to create artificial intelligence systems. It involves identifying patterns in the data available and subsequently applying this knowledge to the new data provided. Data sources include images, texts, sensors, video, sounds, simulations, machines, databases. E.A. Płocha, O pojęciu sztucznej inteligencji i możliwościach jej zastosowania w postępowaniu cywilnym, “Prawo w Dzialeaniu. Sprawy cywilne” 2020, No. 44, p. 279.
\textsuperscript{17} Structured data – all data that can be stored, consulted and processed in an agreed format. See W. Hoogenraad, DUŻE DANE: rodzaje, cechy i zalety, ITpedia, 2017, https://pl.itpedia.nl/2017/08/29/big-data-soorten-kenmerken-en-voordelen/ (access: 30.01.2024).
\textsuperscript{18} Unstructured data – sets of data of unknown shape or structure, they are in an unprocessed or unstructured format. See W. Hoogenraad, DUŻE DANE (access: 31.01.2024).
\textsuperscript{19} S.P. Somashekar, M.J. Sepulveda, A.D. Norden, A. Rauthan, K. Arun, P. Patil, R.Y. Ethadka, R.C. Kumar, Early experience with IBM Watson for On-
In the draft Artificial Intelligence Act, the EU legislator indicates that artificial intelligence systems must be designed and developed in such a manner, including through the integration of appropriate human-machine interface tools, that an appropriately skilled person, in this case a doctor, is able to effectively supervise the AI throughout its life cycle. The AI-enabled tools are required to enable physicians overseeing the system to recognise and sufficiently understand the relevant capabilities and limitations of the AI and to monitor its performance.\textsuperscript{20}

Artificial intelligence is no more than a diagnostic tool used by the doctor. It is the medical professional who mandates a specific procedure, whereas the use of an algorithm is only a diagnostic method that determines further action.\textsuperscript{21} The detection of a condition by the AI system can be read like a starred or bold laboratory result, which signals deviations from an assumed norm.\textsuperscript{22} The diagnosis will also be influenced by cultural and social factors. It is important to note that the course of the disease varies between races and between people living on different continents. The development of the condition may also be influenced by lifestyle: diet, physical activity, and amount of sleep, which vary depending on the region in which the patient lives. Therefore, it may well be that an artificial intelligence developed, tested, and ‘trained’ in the United States will show poor performance in diagnosing diseases in Central and Eastern Europe. The doctor’s role is to take these circumstances into account.

\textsuperscript{20} Article 14(1) of the draft Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain legislative acts of the Union of 21 April 2021, COM(2021) 206 final 2021/0106 (COD), (the ‘Artificial Intelligence Act’).


4.1. Verification error – a subcategory of diagnostic error

Pursuant to Article 4 of the Act on the Professions of Physician and Dentist\(^2\) (henceforth: the A.P.P.D.), a physician is obliged to practice medicine in accordance with the indications of current medical knowledge, methods, and means available to the physician for the prevention, diagnosis, and treatment of diseases. However, a doctor is not equipped to analyse as many scientific publications on possible diseases, to compare as many patients’ medical histories as an ICT programme. Consequently, the use of artificial intelligence will itself constitute correct action in virtually every case. It is still possible for a doctor to make a diagnosis that is different from the one provided by the AI. Moreover, since it is an error to act contrary to medical science to the extent available to the doctor, the failure to use the AI available to the doctor, when it could have diagnosed the disease, will constitute an error, which may incur liability.

The doctor may place trust in the results obtained by the AI, but such trust should be limited. It is not permissible for the doctor to rely entirely on the AI’s diagnosis in the diagnostic process or to fail to verify the results of its actions. The doctor has an obligation to analyse the result presented by the algorithm and to ascertain whether the proposed method is in fact the best way of treatment.\(^2\) The literature indicates that the doctor should be guided by the principle of limited confidence in any previous observation made by another doctor, as well as in his or her own observations.\(^2\) The confidence should decrease in direct proportion to the severity of the potential error. The same principle should


\(^4\) Z. Marek, Błąd medyczny, pp. 76–77.
be applied to artificial intelligence. An error occurs if the current state of medical knowledge makes it possible to conclude that the results of the analysis performed by the AI are incorrect, yet the doctor nevertheless makes a diagnosis in accordance with the AI’s findings. Such an action by the doctor is termed a verification error. If the diagnosis made by the AI follows the rules of formal logic, is not contradictory to the knowledge acquired thus far and to the results of the examinations and consultations performed, then the doctor will be able to trust it without committing a verification error. However, if the diagnosis made by the AI contradicts medical knowledge, the results of examinations or consultations, and thus does not represent a logical conclusion, a verification error will have occurred.

As an argument supporting the need to control the diagnosis made by artificial intelligence, we could also point to the obligation of the doctor commencing treatment to verify the diagnosis made by the previous doctor. When admitting a patient to hospital, the doctor on duty must also carry out what is known as a ‘verification procedure’ in order to clarify the diagnosis, establish indications for surgery, or seek to establish another correct diagnosis. AI is particularly thriving in radiology, hence it is worth giving an example from this field. If an AI, when analysing an X-ray, misses a pathological lesion, and the doctor, when carrying out a diagnostic review, also misreads the image which results in the condition not being diagnosed, a verification error will have occurred. The physician’s fault is a question of whether negligence in the form of failure to exercise diligence has occurred. However, if it was not possible for the diligent radiologist to detect the lesion, this prejudices the absence of his or her fault. If, on the other hand, the AI

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27 Zbigniew Marek defines correct diagnosis as a logical conclusion drawn in accordance with the rules of formal logic, not contradictory to knowledge and to the results of examinations and consultations performed. See Z. Marek, Błąd medyczny, p. 73.
was able to detect the change, but this did not happen for technical reasons outside the scope of medical science, e.g. owing to temporary lack of internet access, lack of system updates, or system suspension, this does not constitute a verification error, because a verification error can only be made by a doctor.

5. Therapeutic error

A therapeutic error occurs in the case of a choice of the wrong method or treatment.\(^{29}\) It involves making the wrong therapeutic decision despite the availability of the right indications.\(^{30}\) The literature points to a particular form of therapeutic error, namely a surgical error. It consists of a wrong medical intervention.\(^{31}\) The wrong procedure may consist in the choice of the wrong means from among those available to the doctor, including medical equipment.\(^{32}\)

5.1. Therapeutic error in supervision made during the conduct of a surgical procedure

The scope of a doctor’s responsibilities when performing surgery with the help of artificial intelligence varies from that of making a diagnosis, a prognosis of disease progression, or in the course of drug therapy. Therefore, it is involved with the risk of making a different type of error.

Doctors have the possibility to use robots to carry out surgical procedures. However, such procedures do not always produce the desired outcome. According to the report ‘Adverse Events in Robotic Surgery, A Retrospective Study of 14 Years of FDA Data’ pre-

\(^{30}\) A. Sieńko, *Błędy medyczne odpowiedzialność lekarza i placówki medycznej*, Warszawa 2018, p. 64.
\(^{32}\) A. Sieńko, *Błędy medyczne*, p. 64.
resented by The Cornell University Library in 2015, 144 people who underwent procedures performed with surgical robots died in the US between the years 2000 and 2013. These deaths were caused by damage to the robots, whose components fell into patients’ bodies, electrical sparks causing tissue burns, and system errors resulting in prolonged procedures. The most widely used robot, da Vinci, is not equipped with an artificial intelligence system, according to the wording of the latest version of the draft Artificial Intelligence Act. However, the (as yet unavailable for mass sale) prototype of the Robin Heart mc2 robot – a three-armed robot that replaces the work of two surgeons and an assistant directing the video track – is equipped with such a system. Moreover, operators use virtual surgical instructors (Virtual Surgery Intelligence). VSI superimposes a computer-generated 3D image on the patient. It produces a comprehensive representation of the patient’s organs, including all anatomical structures that can be easily moved within the surgeon’s field of view. The dynamic development of similar technologies means that it is only a matter of time before a fully autonomous robot emerges and becomes widespread, carrying out the entire procedure autonomously. Even if the national or EU legislator delays the introduction of such robots into the market and the expansion of the services provided by hospitals to include ‘robotic surgery’, it is unlikely that the development of robotics will be restrained.

34 The da Vinci robot is equipped with a system controlled by a system of coupled algorithms that modify the movement of the surgeon’s hands and the image that the operator sees on the screen during the operation, but it itself does not perform any part of the surgery.
35 A Robin Heart robot has been developed at the Institute of Heart Prosthesis in Zabrze. It is the first Polish surgical robot designed for heart surgery. For the moment, it is a prototype, not available for commercial sale. Robot jak Robin Hood, 2020, https://www.gov.pl/web/edukacja-i-nauka/robot-jak-robin-hood (access: 30.01.2024).
A surgical error can be made, not only during the procedure, but also in the pre-operative phase. At this stage, the doctor’s responsibility is to establish the conditions and manner in which the surgery is to be performed. On the basis of the surgeon’s knowledge, experience, examination results, and the diagnosis made by the referring physician, the surgeon is obliged to analyse whether the patient is to undergo surgery and which method should be used. If a surgical robot is available to perform the procedure, the surgeon should assess whether performing the procedure manually or with the help of a robot will be of greater benefit to the patient and which of these methods will carry less risk. The doctor will be committing a therapeutic error by not performing the procedure with the available robot when its use could have produced better results and the risks are no greater than with the traditional form of surgery. An error will also occur if the doctor uses a robot and the results obtained are inferior or the risk of failure is greater than if the procedure were performed without the robot.

The second stage at which a therapeutic surgical error may arise is the surgery itself. When undertaking a surgical procedure, unlike when undertaking other forms of treatment, no prior verification of the correctness of the effects of the AI is possible. The doctor is only able to assess, after making the incisions on the patient’s body, whether they were performed correctly or not. In the case of performing a procedure with a surgical robot, the duty to control whether the blade is guided correctly belongs to the surgeon. In my opinion, the operator should also assess whether the precision of the robot is at least equal to that of a highly skilled surgeon performing the procedure with a scalpel, laparoscope, or any other instrument.

If the doctor is able to use a fully autonomous robot, his or her function will be changed fundamentally. He or she will then be left with only the duty to supervise the surgical robot and take over the conduct of the procedure if irregularities in its operation are observed. In such a case, another type of error may also

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37 M. Sośniak, Cywilna odpowiedzialność, p. 135.
38 Ibidem, p. 136.
arise, i.e. a supervision error. It occurs when a doctor fails to stop an autonomous surgical robot despite the fact that, according to the current state of medical knowledge, its operation is incorrect or the doctor could, with his or her own hands, perform a procedure with greater precision or a procedure resulting in less detriment to the patient’s health. An example of such a situation is the risk of damaging a healthy organ when performing a surgery. It should be noted in this regard that a surgical procedure may have side effects in addition to its health benefits, and therefore, it will be justified to carry out the procedure only if the anticipated benefits outweigh the possible side effects. However, the surgeon’s role is to carry out the procedure in such a way that the negative consequences of the surgery are minimised. Therefore, should the surgeon, observing the procedure performed by the robot, determine that the action of the tool will produce more side effects than the procedure performed by another method, and at the same time the other benefits of the procedure performed by the robot will not compensate for this loss, he or she will be under obligation to continue the procedure using traditional methods. If, on the other hand, the surgeon allows the robot to complete the surgery, a supervision error will occur.

It should be pointed out that the term supervision error was used to describe medical malpractice because of the wording of Article 14(1) of the draft Artificial Intelligence Act, according to which, AI is to be developed in such a way, including through the inclusion of appropriate human-machine interface tools, that systems can be effectively supervised throughout their life cycle by natural persons. These individuals must have a sufficient level of competence in artificial intelligence, including knowledge of basic concepts, and must be competent in how AI works, including the different types of products and their applications, risks, and benefits. In this context, although civil law is familiar with the category of fault in supervision, and it may be confusing to call a medical error a fault in supervision, it seems that consistency with a legal act developed at EU level supports the use of this terminology.
As a third stage, it is important to distinguish the post-operative period, where errors may arise in connection with wound suturing, dressing, etc.\textsuperscript{39} The artificial intelligence system can control the recovery process, wound healing, and the general state of the patient after surgery (in this case, it will not necessarily be an operating robot, but could be another system). At this stage, the doctor’s responsibilities, whether to supervise the fully autonomous robot or to control the correctness of its operation, remain the same. Thus, it seems that also at this stage, it is possible to commit a supervision error.

\textbf{6. Conclusions}

The change in the scope of activities to be performed by a doctor using an artificial intelligence system has resulted in the distinction of two new types of error, i.e. verification error and supervision error. The identification of verification error and supervision error has important consequences in terms of the liability for the harm caused. In the case of culpability, the doctor or, alternatively, the treating entity employing the doctor is liable. This means not accepting an automatic exemption from liability based solely on the fact that a doctor uses AI to perform certain activities when providing healthcare services. The intention is also to impose an obligation on doctors to verify the results of the AI and to supervise its operation. The EU legislator imposes on the AI developers an obligation to develop the AI in such a way that it can be supervised by a human, without obliging its users to supervise its operation or verify the results of its work. In the case of medical practitioners, these obligations should be deduced from the general rules on the civil liability of professionals. Moreover, the doctor is obliged to pursue continuous education and training, not only in medical science, but also in terms of new technologies used in the provision of health services. The proposed distinction between

\textsuperscript{39} Ibidem, p. 137.
a verification error and a supervision error allows a certain link to be created between the doctor’s behaviour and the action of artificial intelligence, which in turn provides the possibility of a comprehensive assessment of a specific case from the point of view of liability, particularly in the case of multiple causal links.

SUMMARY

Verification error and supervision error – new types of medical errors resulting from the use of artificial intelligence systems occurring during the provision of health services

Medical devices based on artificial intelligence have been used to provide health services for several years. Changes in the diagnostic and treatment process have made it necessary to distinguish new types of medical error – verification error as a subcategory of diagnostic error and supervision error as a subcategory of therapeutic error. Artificial intelligence is only a tool used by the physician. A doctor is obliged to verify the correctness of the diagnosis made by the AI. If the medical knowledge allows the physician to conclude that the results of the analysis performed by artificial intelligence are incorrect, and the physician nevertheless makes a diagnosis in accordance with the AI findings, a verification error will occur. When a surgeon is able to use a fully autonomous robot, the activities he or she undertakes will change completely. In such a case, physician will only be obliged to supervise the surgical robot and take over the surgical procedure if any malfunction in its operation is observed. If physician does not stop the autonomous robot although, according to medical knowledge, it does not work properly or the surgeon could perform the surgical procedure with his own hands more precisely, or the surgeon's procedure would result in less damage to health, he will make a supervision error.

Keywords: verification error; supervision error; AI; artificial intelligence; diagnostic error; therapeutic error
STRESZCZENIE

Błąd weryfikacyjny i błąd w nadzorze – nowe rodzaje błędów lekarskich powstałe w wyniku korzystania z systemów sztucznej inteligencji przy udzielaniu świadczeń zdrowotnych

Wyroby medyczne oparte na sztucznej inteligencji od kilku lat wykorzystywane są przy udzielaniu świadczeń zdrowotnych. Zmiany w procesie diagnostycznym i leczniczym spowodowały, że konieczne wydaje się odrębienie nowych rodzajów błędu lekarskiego, tj. błędu weryfikacyjnego jako podkategorii błędu diagnostycznego oraz błędu w nadzorze jako podkategorii błędu terapeutycznego. Sztuczna inteligencja stanowi jedynie narzędzie stosowane przez lekarza. Ma on obowiązek zweryfikowania poprawności diagnozy stawianej przez SI. Jeśli aktualny stan wiedzy medycznej pozwala na stwierdzenie, że wyniki analizy dokonanej przez sztuczną inteligencję są nieprawidłowe, a lekarz mimo to stawia diagnozę zgodnie z rozpoznaniem SI, dojdzie do popełnienia błędu weryfikacyjnego.

W przypadku gdy chirurg będzie mógł korzystać z pełni autonomicznego robota, jego zadania zmienią się całkowicie. Pozostanie mu jedynie obowiązek nadzoru robota chirurgicznego i przejęcia prowadzenia zabiegu w razie zaobserwowania nieprawidłowości w jego działaniu. Jeśli lekarz nie zatrzyma autonomicznego robota, mimo że zgodnie z aktualnym stanem wiedzy medycznej jego działanie jest nieprawidłowe lub mógłby za pomocą własnych rąk wykonać zabieg z większą precyzją bądź zabieg skutkujący mniejszym uszczerbkiem na zdrowiu pacjenta, popełni błąd w nadzorze.

Słowa kluczowe: błąd weryfikacyjny; błąd w nadzorze; SI; sztuczna inteligencja; błąd diagnostyczny; błąd terapeutyczny

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