AI IN MEDICINE AND THE STANDARD OF CARE

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Abstract: The rapid integration of artificial intelligence (AI) into clinical practice raises pressing legal and ethical questions, including those in relation to the professional standard of care. While international legal instruments, most notably the Convention on Human Rights and Biomedicine, require that all medical interventions be conducted in accordance with relevant professional obligations and standards, the nature of these standards is evolving in response to new technologies. This paper explores how AI affects the legal and regulatory framework surrounding the provision of healthcare, focusing on international law, European Union regulations (especially the AI Act and Medical Device Regulation), and national legal norms.

We argue that although current AI systems mostly function in assistive roles and do not alter the ultimate legal responsibility of healthcare professionals, their use is increasingly shaping expectations around good clinical practice. The standard of care is being redefined not only by legislation and guidelines but also through unwritten norms and expert opinion. As AI systems potentially become more autonomous and widespread, the allocation of legal duties might shift, potentially away from individual practitioners toward manufacturers and system providers. Nevertheless, until such systems reach general and reliable autonomy, human oversight remains essential, and compliance with evolving professional standards will be the key to ensuring lawful and ethical AI deployment in medicine.

Resumé: Rychlá integrace umělé inteligence (AI) do klinické praxe vyvolává naléhavé právní a etické otázky, mj. i ve vztahu k profesionálnímu standardu péče. Mezinárodní právní nástroje, především Úmluva o lidských právech a biomedicíně, vyžadují, aby veškeré lékařské zákroky probíhaly v souladu s příslušnými profesními povinnostmi a standardy. Povaha těchto standardů se však v reakci na nové technologie proměňuje. V tomto článku se zaměřujeme na otázku, jak AI ovlivňuje právní a regulační rámec poskytování zdravotní péče, a to se zaměřením na mezinárodní právo, právo Evropské unie (zejména nařízení o umělé inteligenci a nařízení o zdravotnických prostředcích) a národní právní úpravu.

Ačkoli současné systémy AI většinou fungují v asistivní roli a nemění právní odpovědnost zdravotnických pracovníků, jejich používání čím dál více ovlivňuje očekávání ohledně dobré klinické praxe. Standard péče je přetvářen nejen prostřednictvím legislativy a odborných pokynů, ale také pomocí nepsaných norem a znaleckých posudků. S tím, jak potenciálně narůstá míra autonomie AI systémů i jejich rozšíření v klinické praxi, může docházet k přesunu právních povinností, pravděpodobně od jednotlivých lékařů směrem k výrobcům a poskytovatelům systémů. Dokud však tyto systémy nedosáhnou obecné autonomie při vysoké úrovni spolehlivosti, zůstává lidský dohled nezbytný a dodržování vyvíjejících se profesních standardů bude klíčem k zákonnému a etickému využívání AI v medicíně.

Key words: AI in medicine, standard of care, AI legal regulation, medical devices regulation, Convention on Human Rights and Biomedicine, medical law, health law

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Introduction

The rise of artificial intelligence (AI) permeates many areas of human endeavour, including healthcare. Based on current research and empirical evidence,[1] it seems very likely that AI will increase the effectiveness of diagnostic, therapeutic, and preventive methods, as well as contribute to the development of new medicines. Various legal problems arise in this context, many of them are closely related to fundamental rights and other objects of international law protection. Many patient rights can be affected by the use of AI in medicine, from the right to access to healthcare to the protection of health in the broader sense, to personal data protection, to the issue of just compensation in case of the occurrence of harm.

In this paper, we focus on effects of AI on a particular but crucial aspect of healthcare provision: the standard of medical care. It is a requirement of law (including the Convention on Human Rights and Biomedicine) that every medical procedure is carried out in accordance with professional standards and the rules of science, in one word, the professional standard of care. However, where does the use of medical AI stand today in relation to the professional standard in medicine? What developments can be expected in this area and how will they relate to the advancing autonomy of AI systems?

1. Standard of care in international law

While the standard of care seems at the first sight to be an internal matter of medical profession, its importance reaches much further. As an integral part of the right to the protection of health and other related fundamental rights (such as the right to the protection of private life), it is encompassed in various international law instruments.

Article 4 of the Convention on Human Rights and Biomedicine[2] states that *"[a]ny intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards."* According to the Explanatory Report to this Convention, the term intervention is understood broadly as *"all medical acts"*, both in the clinical and research context.[3] The standards themselves represent a very diverse category, encompassing not only legal regulations but also codes of medical conduct, medical ethics documents, and other sources, including unwritten rules.[4] These rules are not limited to

[1] Among a fast-growing body of literature, see for example the first study documenting real life-saving effect of an AI system: LIN, Chin-Sheng, LIU, Wei-Ting, TSAI, Dung-Jang (eds.). AI-enabled electrocardiography alert intervention and all-cause mortality: a pragmatic randomized clinical trial. *Nature Medicine*. (2024, Vol. 30, Issue 5), pp. 1461–1470. doi: /10.1038/s41591-024-02961-4.

[2] The Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.

[3] See Explanatory Report to the Convention on Human Rights and Biomedicine, par. 29.

[4] See ibid., par. 30.

physicians but apply to all professionals participating in medical acts.[5] While the exact content of such sources differs among jurisdictions, *"the fundamental principles of the practice of medicine apply in all countries"*.[6]

The Explanatory Report to the Convention on Human Rights and Biomedicine aptly describes the science-based and ever-developing nature of the standard of care: *"The current state of the art determines the professional standard and skill to be expected of health care professionals in the performance of their work. In following the progress of medicine, it changes with new developments and eliminates methods which do not reflect the state of the art. Nevertheless, it is accepted that professional standards do not necessarily prescribe one line of action as being the only one possible: recognised medical practice may, indeed, allow several possible forms of intervention, thus leaving some freedom of choice as to methods or techniques."*[7]

Medical standard of care is also referred to in various other international treaties and documents, even though not as directly as in the Convention on Human Rights and Biomedicine. For example, several international instruments set out the obligation of the State parties to recognize the right to the enjoyment of the highest attainable standard of physical and mental health, or otherwise defined quality healthcare (see especially the United Nations instruments such as Article 12 of the International Covenant on Economic, Social and Cultural Rights; Article 25 of the Convention on the Rights of Persons with Disabilities; Article 24 of the Convention on the Rights of the Child; Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women; Article 25 of the Universal Declaration of Human Rights).

To a lesser extent, this also holds true for the Council of Europe human rights protection system (see Article 11 of the European Social Charter, and indirectly also the right to respect for private and family life under Article 8 of the European Convention on Human Rights or, in cases of extreme systemic neglect,[8] the right to life under Article 2 therein). Similar obligations are also to be found in the law of the European Union (see for example Article 35 of the Charter of Fundamental Rights of the European Union; Principle 16 of the European Pillar of Social Rights; Article 4 of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare).

In spite of being rather implicit and vague, these obligations encompass the duty to safeguard the provision of healthcare in accordance with a proper standard of care. Otherwise, it is not possible to secure a reasonable quality of healthcare or equal and non-discriminatory access to it. Defining, maintaining, and enforcing the professional standard of care is, therefore, a direct requirement of international law, both on the global and European level. Nevertheless, the provisions of these instruments are mostly addressed to

5 See ibid., par. 31.

6 Ibid. par. 31.

7 Ibid., par. 32.

8 See for example *Mehmet Şentürk and Bekir Şentürk v. Turkey* (App. No. 13423/09), ECtHR, Second Section, Judgment of 9 April 2013; or *Aydoğdu v. Turkey* (App. No. 40448/06), ECtHR, Second Section, Judgment of 30 August 2016. For a *general* definition of exceptional circumstances under which the violation of Article 2 of the European Convention on Human Rights might occur, see *Lopes de Sousa Fernandes v. Portugal* (App. No. 56080/13), ECtHR, Grand Chamber, Judgment of 19 December 2017, § 191-192.

the individual states with the aim to influence their policies,[9] and can hardly be applied directly to regulate AI in medical care.

2. Emerging AI-related obligations in medicine

The introduction of AI systems into medical practice will inevitably bring about new obligations imposed on the relevant subjects, especially healthcare providers and health professionals. What are these duties going to be? In accordance with the Explanatory Report to the Convention on Human Rights and Biomedicine, we should recall that they consist of legal regulation, professional standards set within the self-regulatory systems of health-related professions, and unwritten rules.

2.1 AI Act and MDR

The **Artificial Intelligence Act (AI Act)**[10] is today the most complex regulation on AI in the world. Its approach stems from the distinction of four risk categories, while each AI system is categorised within one of these tiers. For AI systems intended for clinical use in medicine, the high-risk category is typical, meaning that the most comprehensive set of duties applies to their deployers, providers, manufacturers, importers, distributors, and other relevant subjects. It is important to note that AI Act applies to AI systems regardless of whether they are certified as medical devices or not.[11]

Among the most relevant obligations in the context of this paper is the provider's duty to, for example, design the AI system so that it allows for the automatic recording of events (logs) over its lifetime and enables effective human oversight, to use quality data to train the system, to establish a risk management system, and to ensure that the operation of the AI system is sufficiently transparent.

Even more important in the context of this paper are obligations imposed on the AI system's deployer, who will, as a rule, be the healthcare provider applying the system to clinical practice. Among other duties, they must take appropriate technical and organisational measures to ensure they use AI systems in accordance with the instructions for use, assign human oversight to competent natural persons, ensure that input data is relevant and sufficiently representative, and monitor the AI system operation.

Many AI systems used in clinical settings will be certified as medical devices under the **Medical Device Regulation (MDR)**[12]. In the last two years, several systems of Czech provenance[13] have already achieved the certification. This brings about a set of specific

[9] For a somewhat different context but with similar conclusions see parts 1.2 and 1.3 of HOLČAPEK, Tomáš. Protection of Particularly Vulnerable Patients in Telemedicine, in this volume of the *Czech Yearbook of International Public & Private Law.* Vol 16 (2025).

[10] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

[11] See Article 6(1) in connection with Annex I and Article 6(3) of the AI Act.

[12] 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.

[13] Such as Carebot or Kardi-AI. See Nová expertní skupina pomáhá zavést AI do české medicíny [A new expert group helps introduce AI into Czech medicine]. *Medical Tribune* [online]. 22.1.2025 [2025-07-31]. Available

obligations, as such systems are simultaneously regulated by MDR and other relevant legal norms (such as the Czech Act No. 375/2022 Coll., on Medical Devices and In Vitro Diagnostic Medical Devices). On the other hand, medical device certification also provides the relevant subjects with a certain degree of legal certainty since i) it makes it undeniably clear that there is public law approval for the use of the particular AI system, and ii) it clarifies certain obligations of the said subjects.

MDR distinguishes four risk categories (I, IIa, IIb, and III). So far, the certification process seems to be fully applicable to AI systems with no need to establish special norms in this regard.[14] Each medical device is accompanied by robust documentation, including the instructions for use, which will form the basis for the standard of care in handling such a device. Therefore, while healthcare providers and health professionals who use AI systems certified as medical devices must comply with additional obligations, they are also partly protected by these very same duties: compliance with them can be used as a relatively strong legal defence.

AI models used to support clinical decision-making will mostly fall under the IIa class, which can be described as medium-risk systems. For this class, a wide range of duties is imposed on various subjects such as the healthcare provider, manufacturer, importer, or distributor.

In case of a legal dispute or criminal proceeding, compliance with the relevant obligations would demonstrate due care. It might enable the healthcare provider or another party to prevent their legal liability or even to exonerate themselves from strict liability where it would be applicable. In this sense, the said obligations can be understood as part of the standard of care in the broader meaning.

Nevertheless, it seems inevitable that some AI systems used in clinical practice will not be certified as medical devices. We believe that the use of general-purpose AI systems (especially widely popular large language models such as ChatGPT) is not legally relevant: they may be used as a source of complementary information or for a quick "consult", but they do not alter legal liability in any manner. The health professional (and, in extension, their employer) will bear full legal liability for the decision they will make based on chatting with such a system.

On the other hand, it is feasible that the use of AI systems specifically designed for medical purposes (or even for a particular medical field such as radiology or cardiology) will represent a part of a medical method in the legal sense. The standard of care will then apply to this use, covering individual steps within the procedure as well as the decision to utilise the AI system and subsequent handling of its outputs. The particular process of its use will reflect professional medical standards as well as unwritten rules of professional conduct, as they are described in the following sub-chapters.

2.2 Professional Medical Standards

In Czech national law, the standard of care in medicine is defined under Section 4(5) of Act No. 372/2011 Coll., on Health Services and Conditions of Their Provision, as the set of three criteria:[15]

at: <https://www.tribune.cz/medisekce/digitalni-medicina/ai-v-medicine/nova-expertni-skupina-pomaha-zavest-ai-do-ceske-mediciny-medi/#>.

[14] See ZIKMUNDOVÁ, Klára. Artificial Intelligence and Medical Devices: Do We Need New Regulation? *Časopis pro právní vědu a praxi*. [*Journal of Jurisprudence and Legal Practice*]. (2023, Vol. 31, Issue 2), p. 390.

[15] See also HOLČAPEK, Tomáš, ŠOLC, Martin, ŠUSTEK, Petr. Telemedicine and the standard of care: a call

– conformity with scientific knowledge and recognised medical practices;
– respect for the individuality of the patient; and
– consideration of the specific circumstances and objective possibilities under which the care is provided.

The first mentioned criterion might be called *objective*[16] – it encompasses the standard of care in its narrower form. Nevertheless, it may be further divided into two sub-categories. Recognised medical procedures are at least somewhat formalised: they are embodied in guidelines and other similar documents. This requires that such a procedure must already exist in a sufficiently established form and be recognised by at least an important part of the professional public in the given field.

There have not yet been many AI-specific guidelines issued for clinical practice. Nevertheless, first AI-specific guidelines have arisen in recent years, mainly in the fields of radiology,[17] cardiology,[18] and gastroenterology.[19] As a rule, these guidelines *do not require* the use of AI systems but rather explicitly identify proper circumstances under which it *can be used* and the right manner of doing so. In this way, AI is already a part of the standard of care, since in many cases, its use is a professionally valid option, even though it is not yet a requirement. As of today, the failure to work with AI can hardly be considered a breach of professional duty. However, this may change dramatically in the future: unless a crucial setback in AI effectiveness and safety occurs, it seems almost certain that its use will become a necessary part of the standard of care, at least in many procedures.

Nevertheless, a health professional may encounter a situation when they feel the need to apply a procedure that has not yet been proven. The objective part of the standard of care enables such innovative approach, given that it is in line with scientific knowledge. This condition should be understood in a rather broad manner as the general rules of science, known physiological, chemical and mechanical functioning of the human body, diseases,

for a new approach? *Frontiers in Public Health*. (2023, Vol. 11, Article no. 1184971), pp. 2–3. doi: 10.3389/fpubh.2023.1184971.

16 See HOLČAPEK, Tomáš, ŠOLC, Martin, ŠUSTEK, Petr. Telemedicine and the standard of care: a call for a new approach? *Frontiers in Public Health*. (2023, Vol. 11, Article no. 1184971), pp. 2–3. doi: 10.3389/fpubh.2023.1184971; or ŠOLC, Martin. *Nové metody v medicíně a právo*. [*New Medical Methods and the Law*.] Praha: Wolters Kluwer, 2022, p. 94.

17 See KOTTER, Elmar, AKINCI D'ANTONOLI, Tugba, CUOCOLO, Renato, European Society of Radiology (ESR) (eds.). Guiding AI in radiology: ESR's recommendations for effective implementation of the European AI Act. *Insights into Imaging*. (2025, Vol. 16, Article no. 33). doi: 10.1186/s13244-025-01905-x; The Royal College of Radiologists. *AI deployment fundamentals for medical imaging*. (2024).

18 See SVENNBERG, Emma, HAN, Janet K., CAIANI, Enrico G. (eds.). State of the Art of Artificial Intelligence in Clinical Electrophysiology in 2025: A Scientific Statement of the European Heart Rhythm Association (EHRA) of the ESC, the Heart Rhythm Society (HRS), and the ESC Working Group on E-Cardiology. *EP Europace*. (2025, Vol. 27, Issue 5). doi: 10.1093/europace/euaf071; ARMOUNDAS, Antonis A., NARAYAN, Sanjiv M., ARNETT, Donna K. (eds.). Use of Artificial Intelligence in Improving Outcomes in Heart Disease: A Scientific Statement from the American Heart Association. *Circulation*. (2024, Vol. 149, Issue 14). doi: 10.1161/CIR.0000000000001201.

19 See BRETTHAUER, Michael, AHMED, Jabed, ANTONELLI, Giulio (eds.). Use of computer-assisted detection (CADe) colonoscopy in colorectal cancer screening and surveillance: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement. *Endoscopy*. (2025, Vol. 57, Issue 6), pp. 667-673. doi: 10.1055/a-2543-0370; SULTAN, Shahnaz, SHUNG, Dennis L., KOLB, Jennifer M. (eds.). AGA Living Clinical Practice Guideline in Computer-Aided Detection-Assisted Colonoscopy. The American Gastroenterological Association. *Gastroenterology*. (2025, Vol. 168, Issue 4), pp. 691-700. doi: 10.1053/j.gastro.2025.01.002.

possible medical interventions, and fundamental scientific reasoning. In analogy with engineering, we may say that a physician can base their course of action on the understanding of the first principles of how the human body, its disease, and used instruments work.

This scientific justification might be evaluated less strictly when the intervention is carried out in a state of necessity [20] but should always be required.[21] Otherwise, the patient might not only lose trust in the health system but also be used by the physician for the advancement of science, with no respect for their own intrinsic value as a human person. That would be in stark contrast with the very basic interpretative principle of the Convention on Human Rights and Biomedicine, formulated in its Article 2, according to which *"[t]he interests and welfare of the human being shall prevail over the sole interest of society or science"*.

Provided care must, however, not follow the formalised procedures blindly. It must always consider individual traits of the patient on all levels: biological, psychological, social, and spiritual. It can be reasonably expected that medical AI will contribute to the advancement of personalised medicine, further closing the gap between general guidelines and unique needs of each patient.

2.3 Unwritten Rules

In medical negligence cases in court, it is in fact the expert witness who crucially informs the opinion of the court on whether or not the standard of care was violated. Even if the conduct of a health professional in accordance with the standard of care is a question of law, not a question of fact, and as such can only be answered by the court, judges base their decision on various factual questions as these are answered by expert witnesses.[22] For this reason, expert opinions are, as a rule, critical for the outcome of medical negligence cases.

In turn, an expert witness is influenced not only by written professional standards but also by unwritten rules that are shared among the experts in the relevant medical field. These rules suggest what is considered to be rational, prudent, and overall reflective of good clinical practice. Since they are not written, they may not be explicitly mentioned in the expert opinion. However, it would be a mistake to underestimate their practical importance.

It is therefore important to take into account how AI systems and their use are *perceived* by the professional community in the relevant field of medicine. It can be expected that the more scientific studies and professional guidelines are issued on the matter, the more accepted AI will become in the realm of unwritten expert rules, too. However, personal biases might have a strong impact on some expert opinions, especially when it comes to the question of indication of the use of AI systems and their reliability. The overall "AI hype" penetrating society might prove to be a double-edged weapon, which on the one hand tends to normalise AI use in the public's perception, but on the other hand might provoke intuitive resistance in some people. In the context of medical negligence cases, it will be an important role of attorneys to keep the debate related to hard scientific data and not let it slip into personal opinions and prejudice.

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[20] See ŠOLC, Martin. *Nové metody v medicíně a právo*. [*New Medical Methods and the Law*.] Praha: Wolters Kluwer, 2022, p. 102.

[21] See ibid., p. 102.

[22] See JIRÁSKOVÁ, Kateřina. Znalecké posudky. [Expert Opinions.] In ŠUSTEK, Petr, HOLČAPEK, Tomáš (eds.). *Zdravotnické právo*. [*Medical Law*.] Praha: Wolters Kluwer, 2016, pp. 283-285.

3. Levels of autonomy and the appropriate care

In the literature, we may encounter various classifications of AI autonomy. For example, Bitterman, Aerts and Mak create two broader categories of medical AI systems – assistive and autonomous AI algorithms – that cumulatively contain five levels of capabilities.

- Assistive systems consist of:
  1) AI-assisted data presentation (e.g., an AI system highlighting high-risk regions in a mammogram for a radiologist to check) and
  2) clinical decision-support systems (e.g., an AI system providing a risk score to be interpreted by a clinician, who is still the only one responsible for the clinical decision).
- Autonomous systems consist of:
  3) conditional automation (AI analyses data and makes recommendations; the clinician is always available as backup),
  4) high automation (AI generates recommendations without the human clinician being "present" as a fallback), and
  5) full automation (the same as high automation but intended for general use in all populations and systems).[23]

In this classification, liability is meant to be borne by the clinician for the use of assistive systems, while it is distributed on a case-by-case basis in conditional automation and borne by the AI developer in the two most advanced categories.[24]

Today's AI systems used in medicine mostly pertain to assistive systems. The clinical decision is made by a human health professional. This means that the use of AI represents another partial skill within the clinician's qualification. As it does not replace human qualification and work, it cannot truly alleviate their legal liability either.

Festor et al. provide a specific categorisation of clinical decision support AI systems:

- Level 0 denotes the baseline for the next levels, i.e., the standard of care without any AI involvement. It serves as a reference for the systems' effectiveness and safety.
- Level 1 systems offer outputs to human clinicians who may or may not consider them.
- On Level 2, an AI system acts directly on the environment, but it is continuously monitored by a human expert who may at any moment take the lead. This level would even encompass a system that provides treatment recommendations directly to the patient, provided that there is a human physician reviewing the system's outputs.
- On Level 3, the AI system is not continuously monitored by a human. On the contrary, it is up to the system to ask for a human input when needed (e.g., an AI system routinely administering drugs to a patient that is capable of identifying uncertain or otherwise problematic cases and report them to a physician, or a software autonomously adapting parameters of a mechanical ventilator capable of alerting the staff in case of uncertainty).

[23] See BITTERMAN, Danielle S., AERTS, Hugo J. W. L., MAK, Raymond H. Approaching Autonomy in Medical Artificial Intelligence. *The Lancet Digital Health*. (2020, Vol. 2, Issue 9), pp. 447-449. doi: 10.1016/S2589-7500(20)30187-4.

[24] See ibid.

- Level 4 describes complete autonomy of a system that handles all situations on its own, a category that remains hypothetical as of today.[25]

Similar scales can also be found in the context of medical robotics. Lee, Baker, Bederson and Rapoport classify surgical robots into the following five categories:

- robot assistance (e.g. tremor filtration or haptic feedback),
- task autonomy (autonomous performance of a particular task with parameters provided by a surgeon),
- conditional autonomy (the surgeon selects from strategies proposed by the system; the selected strategy is then carried out autonomously),
- high-level autonomy (the system selects the plan while it still requires the surgeon's approval), and
- full autonomy (no human approval needed).[26]

According to these authors, today's most advanced robots fit into the third category – they have reached conditional autonomy.[27]

It can be assumed that in general, the standard of care will apply to any human involvement in the functioning of medical AI systems, regardless of their level of autonomy, as long as a human in involved in the loop. The standard of care will cover both the input and output stages. On the input, health professionals will be responsible for the appropriateness and completeness of the data supplied to the AI system and perhaps for the manner in which they make their request (prompt engineering). On the output, they will be responsible for appropriate verification of the system's results, as well as for the professionally appropriate way of applying these results to the case at hand. A part of the standard of care may consist of evaluating whether the use of AI is indicated (or perhaps even contraindicated) in the particular case. Nevertheless, the use of AI as such will usually not result in a breach of the standard of care, since its results may always be disregarded by the physician at the output stage (another problem, however, might regard the protection of patient's personal data).

As stated above, the medical profession will in the near future stand before a formidable task to incorporate AI use into their guidelines, clinical algorithms, and other self-regulatory documents. Current guidelines will be iterated, while new documents, both field-specific and general (such as ethical codes of conduct), will need to be formulated.

The changes in the standard of care will inevitably relate both to particular procedures and to the subjects of relevant duties. For lower autonomy levels (up to continuing human monitoring), legal responsibility will be primarily borne by the healthcare provider (or an individual health professional). The standard of care will not, in principle, be drastically different from what it looks like today: it will guide the relevant processes taken by health professionals in the course of healthcare provision. If the autonomy increases and AI systems

[25] See FESTOR, Paul, HABLI, Ibrahim, JIA, Yan, GORDON, Anthony, FAISAL, A. Aldo, KOMOROWSKI, Matthieu. Levels of Autonomy and Safety Assurance for AI-Based Clinical Decision Systems. In HABLI, Ibrahim, SUJAN, Mark, GERASIMOU, Simos, SCHOITSCH, Erwin, BITSCH, Friedemann (eds.). *Computer Safety, Reliability, and Security. SAFECOMP 2021 Workshops. Lecture Notes in Computer Science, Vol. 12853*. Springer Nature Switzerland, 2021, pp. 292-294. doi: 10.1007/978-3-030-83906-2_24.

[26] See LEE, Audrey, BAKER, Turner S., BEDERSON, Joshua B., RAPOPORT, Benjamin A. Levels of Autonomy in FDA-Cleared Surgical Robots: A Systematic Review. *npj Digital Medicine*. (2024, Vol. 7, Art. no. 103), pp. 3, 7. doi: 10.1038/s41746-024-01102-y.

[27] See ibid., p. 4.

make clinically relevant decisions without the constant need for human approval or oversight (for example, reaching the high automation category within the nomenclature proposed by Bitterman et al.[28]), the clinical standard of care will only have limited significance, and the relevant duties will shift more towards other subjects in the supply chain, mostly to the systems' providers and manufacturers. This trend will continue with the hypothetical introduction of AI systems pertaining to the highest autonomy category, i.e. systems capable of fully autonomous operation within all systemic settings, for all patient populations, etc.

The rise of the so-called super artificial general intelligence – systems that will be better than all professionals in all economically relevant tasks – might render the human-centred standard of care obsolete. However, this remains a distant vision, with a high level of uncertainty as to whether it will ever be realised. Until that time, the standard of care will remain a crucial aspect of the use of medical AI.

Conclusion

International law, notably the Convention on Human Rights and Biomedicine, affirms that all medical interventions must be carried out in accordance with relevant professional obligations and standards. As AI becomes embedded in clinical practice, these standards must evolve to reflect both technological innovation and enduring legal and ethical imperatives, such as the primacy of the interests and welfare of the human being over the sole interest of society and science.[29]

The regulatory landscape, especially the EU's AI Act and Medical Device Regulation (MDR), already imposes specific duties on various subjects, particularly on healthcare providers who deploy AI systems in clinical environments. These novel frameworks, on the one hand, add new duties to the legal and administrative burden already borne by the relevant stakeholders, but on the other hand, provide them with a certain level of legal certainty, since compliance with said obligations may be used as a legal defence.

Crucially, the professional standard of care is not shaped by legislation alone. It also derives from clinical guidelines, ethical codes, and unwritten norms of good medical practice, all of which are gradually absorbing AI-related considerations. The level of autonomy of AI systems will play a decisive role in determining who bears legal responsibility and how the standard of care is defined. For now, human professionals remain central actors, responsible for using complete and correct data, verifying AI outputs, and ensuring that their use aligns with scientific knowledge and patient-centred care.

As AI capabilities increase, a significant transformation in medical standards is likely. However, until the day truly autonomous systems become both reliable and widely accepted, the legal system must continue to anchor liability and accountability in the actions of human professionals. It is through a cautious but adaptive interpretation of the standard of care, grounded in science, ethics, and international norms, that medicine can harness the potential of AI without sacrificing patient safety or professional integrity.

[28] See BITTERMAN, Danielle S., AERTS, Hugo J. W. L., MAK, Raymond H. Approaching Autonomy in Medical Artificial Intelligence. *The Lancet Digital Health*. (2020, Vol. 2, Issue 9), p. 448. doi: 10.1016/S2589-7500(20)30187-4.

[29] See Article 2 of the Convention on Human Rights and Biomedicine.