ETHICAL AND LEGAL ASPECTS OF THE USE OF ARTIFICIAL INTELLIGENCE IN HEALTH AND NURSING CARE

ETICKÉ A PRÁVNE ASPEKTY POUŽITIA UMELEJ INTELIGENCIE V ZDRAVOTNEJ A OŠETROVATEĽSKEJ STAROSTLIVOSTI

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ABSTRACT

The aim of this paper is to analyse current approaches and perspectives on the development of ethical and legal regulation of artificial intelligence with special regard to its use in health and nursing care. Inextricably linked to this is an analysis of current international and national binding legislation, as well as legally non-binding instruments designed for artificial intelligence developers, manufacturers and users. In addition to the positive benefits of artificial intelligence in health and nursing care, we point out the ethical and legal aspects of its use, such as the legal personality of artificial intelligence, patients' right to privacy, personal data protection and civil liability for damage caused by artificial intelligence. We place the main emphasis on the legislation of the European Union, which has a direct impact on the national legislation of the Slovak Republic.

ABSTRAKT

Cieľom tohto príspevku je analyzovať aktuálne prístupy a pohľady na vývoj etickej a právnej úpravy umelej inteligencie s osobitným zreteľom na jej použitie v zdravotnej a ošetrovateľskej starostlivosti. S tým je neodmysliteľne spojená analýza súčasnej medzinárodnej a vnútroštátnej právne záväznej úpravy, ako aj právne nezáväzných nástrojov, ktoré sú určené pre vývojárov, výrobcov a užívateľov umelej inteligencie. Okrem pozitívneho prínosu umelej inteligencie v zdravotnej a ošetrovateľskej starostlivosti poukážeme na etické a právne aspekty jej použitia, akými sú právna subjektivita umelej inteligencie, právo pacientov na súkromie, ochrana osobných údajov a občianskoprávna zodpovednosť za ujmu spôsobenú umelou inteligenciou. Hlavný dôraz kladieme na právne predpisy Európskej únie, ktoré majú priamy dosah na vnútroštátnu úpravu Slovenskej republiky.

I. INTRODUCTION

Human society is constantly evolving and, increasingly, this development is marked by enormous technical progress. Current development concepts are based on considerable automatization and the introduction of artificial intelligence systems (hereinafter "AI") into our daily lives. This simplifies and streamlines human activities, or even replaces people in performing hazardous work. The introduction of AI therefore has a significant economic, social, demographic and legal impact. A few years ago, we considered autonomous vehicles, intelligent home helpers, robots who assist medical staff in medical procedures, or autonomous weapon systems as part of the scientific fiction. Nowadays, we would not be able

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to imagine the performance of some work without AI. Of particular importance is the use of AI in the field of health and nursing care, whether through robotic surgery[2], the robotic replacement of reduced or lost human organ functions[3], robots for home rehabilitation[4] or care for the elderly[5] or people with disabilities. The United Nations (hereinafter "UN") *World Aging Report* states that the number of people over the age of 60 has tripled since 1950 and that a similar increase is expected by 2050, when more than 2.1 billion people on the planet will have over 60 years.[6] This is directly related to the increase in the volume of provided health and nursing care, which is already confronted with a lack of qualified staff. According to the World Health Organization (hereinafter "WHO"), there will be a global shortage of 18 million health workers by 2030. AI can help reduce this problem by helping physicians diagnose and evaluate patients with degenerative diseases, such as cancer and Parkinson's disease, quickly and effectively.[7] By collecting and analysing data from connected facilities and medical records, healthcare systems will be able to provide proactive and predictive medical care. The possibilities and benefits of AI in this area seem endless. Analysis of health care provision has shown that 75 percent of health care organizations are actively implementing or planning to implement AI strategies.[8] Last but not least, in 2030, AI-powered predictive healthcare networks are expected to help reduce waiting times and take on the ever-increasing administrative burden. Learning from each patient, each diagnosis, and each procedure creates AI experiences that are tailored to professionals and patients.[9] This will have a significant impact on the provision of effective health and nursing care in the future. The importance of the use of AI in health and nursing care has its undeniable advantages, but it should be noted that it is still an area that is only to a small extent regulated by legal norms, whether national or international law.

In the novel *Runaround* (1942), writer Isaac Asimov imagined a world in which human-like robots would behave like servants and whose activities would be regulated by a set of programming rules that would prevent robots from causing harm. Asim's *"Handbook of Robotics"*, which was applied in 2058, contains three rules, namely: 1.) A robot may not injure a human being or, through inaction, allow a human being to come to harm; 2.) A robot must obey orders given it by human beings except where such orders would conflict with the First Law; 3.) A robot must protect its own existence as long as such protection does not conflict with the First or Second Law. Since the publication of these rules, there has been significant technological progress that has changed our view of what robots can look like and how we will interact with them. Therefore, in the recent times, new rules of robotics have been adopted, which reflect the current and partly the future development.

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2 MARKOFF, J.: *New Research Center Aims to Develop Second Generation of Surgical Robots*, The New York Times, 23 October 2014. Online: http://www.nytimes.com/2014/10/23/science/new-research-center-aims-to-developsecond-generation-of-surgical-robots-.html?_r=0.

3 MATARIC, M., OKAMURA, A., CHRISTENSEN, H.: *A Research Roadmap for Medical and Healthcare Robotics*, Workshop „A Research Roadmap for Medical and Healthcare Robotics", Arlington, 2008, p. 6. Online: http://bdml.stanford.edu/twiki/pub/Haptics/HapticsLiterature/CCC-medical-healthcare-v7.pdf.

4 DÍAZ, I., CATALAN, J. M., BADESA, F. J.: *Development of a Robotic Device for Post-Stroke Home Tele-Rehabilitation*, Advances in Mechanical Engineering, Vol. 10, No. 1, 2018.

5 MITZNER, T., TIBERIO, L., KEMP, CH.: *Understanding healthcare providers' perceptions of a personal assistant robot*, Gerontechnology, Vol. 17, No. 1, 2018, p. 48 – 55.

6 United Nations: *World Population Ageing 1950 - 2050,* New York, 2017, p. 2. Online: https://www.un.org/en/development/desa/population/publications/pdf/ageing/WPA2017_Report.pdf.

7 WHO: *Addressing the 18 million health worker shortfall – 35 concrete actions and 6 key messages*, 2019. Online: https://www.who.int/hrh/news/2019/addressing-18million-hw-shortfall-6-key-messages/en/.

8 MORSE, S.: *Artificial Intelligence ROI is coming sooner than you think*, Healthcare Finance, 16 November 2018. Online: https://www.healthcarefinancenews.com/news/artificial-intelligence-roi-coming-sooner-you-think.

9 KRIWET, C.: *Here are 3 ways AI will change healthcare by 2030*, World Economic Forum, 7 January 2020. Online: https://www.weforum.org/agenda/2020/01/future-of-artificial-intelligence-healthcare-delivery/.

The aim of this paper is to analyse current approaches and perspectives on the development of ethical and legal regulation of artificial intelligence with special regard to its use in health and nursing care. Inextricably linked to this is an analysis of current international and national binding legislation, as well as legally non-binding instruments designed for AI developers, manufacturers and users. This is an overview article with a holistic approach, which serves as an introduction to the researched issues. In addition to the positive benefits of AI in health and nursing care, we point out the ethical and legal aspects of its use, such as the legal personality of AI, patients' right to privacy, personal data protection and civil liability for damage caused by AI. We place the main emphasis on the legislation of the European Union (hereinafter "EU"), which has a direct impact on the national legislation of the Slovak Republic.

II. ARTIFICIAL INTELLIGENCE AS A MODERN SUBJECT OF INTERNATIONAL AND NATIONAL LAW

1. Artificial Intelligence - Definition

We encounter the term artificial intelligence or "AI" regularly, whether in the context of scientific research, in discussions on future legislation in this area, but also in the dissemination of technical knowledge, which is important for our daily lives. There are currently several attempts to define the term AI, but there is no clear definition of this term. Both the academic community and the legislative bodies of States, international organizations and non-governmental organizations operating in this field are trying to define this term. *Frankish* and *Ramsey* see AI as "a cross-disciplinary approach to understanding, modelling, and replicating intelligence and cognitive processes by invoking various computational, mathematical, logical, mechanical, and even biological principles and devices."[10] *McCarthy* defines AI as "the science and engineering of making intelligent machines, especially intelligent computer programs. It is related to the similar task of using computers to understand human intelligence, but AI does not have to confine itself to methods that are biologically observable."[11] *Stuart Russell* and *Peter Norvig*, authors of a popular university textbook on AI, summarized eight definitions of AI differentiated according to how they reflect expectations of human thinking and behaviour or rational (machine) thinking and behaviour.[12] Finally, they favoured a rational use approach in which machines operate autonomously, perceive their environment, persist over a long period of time, adapt to change and produce and monitor the best expected result. AI is one of the main examples of an interdisciplinary research space because it combines numerous and diverse disciplines such as computer science, psychology, cognitive science, logic, mathematics and philosophy.[13]

The High Level Expert Group on Artificial Intelligence set up by the European Commission has also come up with its own definition, defining AI as systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their

[10] FRANKISH, K., RAMSEY, W. M.: *The Cambridge Handbook of Artificial Intelligence*. Cambridge, Cambridge University Press, 2014, ISBN: 978-0-521-87142-6, p. 7.

[11] McCARTHY, J.: *What is Artificial Intelligence?* Stanford University, 12 November 2007, p. 2. Online: http://jmc.stanford.edu/articles/whatisai/whatisai.pdf.

[12] RUSSELL, S., NORVIG, P.: *Artificial Intelligence: A Modern Approach*, Third Edition, Pearson Education, New Jersey, 2011, ISBN: 978-0-13-604259-4, p. 1 – 5.

[13] UNESCO: *Report of the World Commission on the Ethics of Scientific Knowledge and Technology on Robotics Ethics*, September 2017, SHS/YES/COMEST-10/17/2 REV., para. 38.
Online: https://unesdoc.unesco.org/ark:/48223/pf0000253952.

previous actions. AI as a scientific discipline includes several approaches and techniques, such as machine learning (specific examples of which are in-depth learning and reinforcement learning), machine derivation (which includes planning, programming, representation and derivaion of knowledge, search and optimization) and robotics (into which include control, perception, sensors and controllers, as well as the integration of all other techniques into cyber-physical systems).[14] The term AI can also include the end product of AI research, i.e. a machine or artifact that embodies some form of "intelligence", i.e. is able to "think" or solve problems in a similar way to human thinking.[15]

There are several different perspectives on both the definition of AI itself and its categorization. Mention may be made, for example, of the *Kurzweil* classification, which proposes an informal classification system based on the "strength" of the basic algorithm or its ultimate effect. On this basis, he classified AI into the so-called "narrow" and "strong".[16] Narrow AI is machine learning algorithms that are designed to perform one particular task, without the prospect of performing anything else. In contrast, a strong AI consists of an algorithm or series of algorithms that could not only narrow down tasks, but also functionally think for themselves and propose solutions to a broader class of problems.[17] On the other hand, *Guihot, Matthew* and *Suzor* consider such a distinction to be unsatisfactory because it is based on different considerations of the power of AI. They therefore suggest that the qualification of AI be based on the risks associated with its use. According to that qualification, the authors defined the various classes of AI on the basis of whether AI poses a low, medium or high risk to society or to human safety or well-being. Such a division is inevitably related to the development of new legal norms that will reflect the individual risks associated with AI.[18]

2. International initiatives in the field of artificial intelligence

The field of AI, its development and regulation, is given considerable attention by a number of States, international intergovernmental as well as non-governmental organizations, expert groups, or the developers, manufacturers and users of AI themselves. These include e.g. the UN, the Organization for Economic Co-operation and Development (hereinafter "OECD"), the Council of Europe (hereinafter "CoE") or the EU. The UN, as a universal international intergovernmental organization, provides an appropriate forum for establishing a common approach to the adoption of adequate ethical and legal standards for AI. The UN Secretary-General's High-Level Panel on Digital Cooperation presented activities that the UN should address as a matter of priority, namely the inclusive digital economy and society, the protection of human rights, trust, security, stability and global digital cooperation. In 2020, we expect "*Global Commitment on Digital Cooperation"* to be adopted, setting out common values, principles, understandings and goals for enhanced global digital cooperation.[19]

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[14] EU: *Ethics Guidelines for Trustworthy AI*, Independent High-Level Expert Group on Artificial Intelligence Set Up by the European Commission, 8 April 2019, Brussels, p. 36. Online:https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/JURI/DV/2019/11-06/Ethics-guaidelines AI_EN.pdf.

[15] UNESCO: *Report of the World Commission on the Ethics of Scientific Knowledge and Technology on Robotics Ethics*, 14 September 2017, SHS/YES/COMEST-10/17/2 REV., para. 43.

[16] KURZWEIL, R.: *The Singularity is Near: When Humans Transcend Biology*, Penguin Books, London, 2005, ISBN: 0-670- 03384-7, p. 206 and 222.

[17] HOROWITZ, M.: *Artificial Intelligence, International Competition and the Balance of Power,* Texas National Security Review, Vol. 1, No. 3 May 2018, ISSN: 2576-1153, p. 42.

[18] GUIHOT, M., MATTHEW, A., SUZOR, N.: *Nudging Robots: Innovative Solutions to Regulate Artificial Intelligence*, Vanderbilt Journal of Entertainment & Technology Law, Vol. 20, No. 2, 2017, p. 393.

[19] United Nations: *The Age of Digital Interdependence*, Report of the UN Secretary-General's High-level Panel on Digital Cooperation, June 2019, p. 2 – 4. Online: https://www.un.org/en/pdfs/HLP%20on%20Digital%20Cooperation%20Report%20Executive%20Summary%20-%20ENG. pdf.

UN specialized agencies also play an active role, in particular the United Nations Educational, Scientific and Cultural Organization (hereinafter "UNESCO"), the WHO and the International Telecommunication Union (hereinafter "ITU"). UNESCO has adopted several documents relevant to AI in recent years, such as Report of the World Commission on the Ethics of Scientific Knowledge and Technology on the *Robotics Ethics*[20], or the *Universal Declaration on Bioethics and Human Rights*[21]. The significance of these documents lies in the effort to define the ethical and legal framework for the use of AI in various areas. In the case of the use of AI, it is necessary, according to the Commission, to apply the following ethical principles and values, namely human dignity, autonomy, privacy, "do no harm" principle, responsibility, beneficence and justice.[22]

With regard to health and nursing care, it is important to mention the *WHO Digital Health* resolution, which urges States to promote the use of digital technologies, including improving access to quality data and monitoring, and to develop data protection legislation and policies on, for example, access to data sharing, informed consent, security, privacy, interoperability and inclusiveness in line with international human rights obligations.[23] The WHO has set up an expert group on Ethics of AI for health and is currently in the process of setting up an expert group on creating framework on Regulations of AI for health.[24] With a view of further development in this area, Focus Group on AI for Health has been established, with the aim of creating a standardized framework for the evaluation of AI-based methods related to health, diagnosis, classification or treatment. AI models are expected to offer improvements over current quality or efficiency practices that are expected to lead to better health outcomes or financial efficiency.[25] The Group works on the premise that a standardized and transparent evaluation of AI methods would benefit from the widespread adoption of AI in the field of health. It should be noted that the group does not intend to specify AI for the health algorithms themselves as an ITU recommendation, nor to standardize medical data formats, nor to set performance criteria for the hardware on which the AI algorithms are based.[26]

In May 2019, OECD member countries adopted the *OECD Principles on Artificial Intelligence* through the *OECD Council Recommendation on Artificial Intelligence*. The recommendation sets out five principles based on the values of responsible stewardship of trustworthy AI, namely: (a) AI should benefit people and the planet through inclusive growth, sustainable development and prosperity; (b) AI systems should be designed to respect the rule of law, human rights, democratic values and diversity, and should include appropriate safeguards - for example, allowing for human intervention if necessary - in order to ensure a just society; (c) there should be transparency and responsible publicity about AI systems to ensure that people understand and can challenge AI-based results; (d) AI systems must operate reliably and safely throughout their life cycles and potential risks should be continuously assessed and managed; (e) organizations and individuals developing,

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[20] UNESCO: *Report of the World Commission on the Ethics of Scientific Knowledge and Technology on Robotics Ethics*, 14 September 2017, SHS/YES/COMEST-10/17/2 REV.

[21] UNESCO: *Universal Declaration on Bioethics and Human Rights*, 19. October 2005, 33 C. Online: http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html.

[22] UNESCO: *Report of the World Commission on the Ethics of Scientific Knowledge and Technology on Robotics Ethics*,14 September 2017, SHS/YES/COMEST-10/17/2 REV, p. 49 – 52.

[23] WHO: *Digital Health,* 26 May 2018, A71/VR/7, para. 7 and 10. Online:https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R7-en.pdf.

[24] ITU: *United Nations Activities on Artificial* Intelligence (AI), 2019, p. 71. Online: https://www.itu.int/dms_pub/itus/opb/gen/S-GEN-UNACT-2019-1-PDF-E.pdf.

[25] WIEGAND, T., KRISHNAMURTHY, R., KUGLITSCH, M.: *WHO and ITU establish benchmarking process for artificialintelligence in health*, The Lancet, March 2019, ISSN: 0140-6736, p. 9 – 10.

[26] SALATHÉ, M., WIEGAND, T., WENZEL, M., KRISHNAMURTHY, R.: *Focus Group on Artificial Intelligence for Health*,2018, pp. 3. Online: https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FG-AI4H_Whitepaper.pdf.

implementing or operating AI systems should be responsible for their proper functioning in accordance with the above principles.[27]

In the field of human rights protection in the use of AI, one of the leading roles has been taken over by the CoE, which in cooperation with the Rathenau Institute published a report *Human Rights in the Robotic Age*. The report addresses the possible negative impact of robotics on a number of human rights issues, including respect for the right to privacy, human dignity, property, security and responsibility, freedom of expression, non-discrimination, access to justice and access to a fair trial. The report recommends the introduction of two new human rights: (1) the right not to be measured, analysed or coached (in relation to possible AI misuse, data collection) and (2) the right to meaningful human contact (in relation to possible misuse, intentional or unintentional, of robots providing care).[28] The authors of this study believe that the public debate on the various dimensions of human rights algorithms lags behind technological developments and needs to be strengthened rapidly to ensure that human rights and individuals' interests are effectively and sustainably protected in accordance with the values set out in the *European Convention on Human Rights and Fundamental Freedoms* and other international human rights treaties. The aim of policy makers must be to ensure that these technologies are used in accordance with the principle of "human superiority" and that our increasingly technology-oriented societies are designed to effectively enforce and exploit the rights of all human beings.[29] In addition to the above-mentioned document, in 2017 the Council of Europe adopted *Guidelines on the Protection of Individuals with regard to the Processing of Personal Data in the World of Big Data*, reiterating its call on Parties to take measures to prevent the potential negative impact of big data on human dignity, human rights and fundamental freedoms, in particular, the protection of personal data.[30]

3. The role of the European Union in the field of artificial intelligence

The European Union is one of the leading international organizations dedicated to supporting the development, implementation as well as legal and ethical regulation of AI. One of the first documents adopted in the EU in the field of AI is the *Declaration on Cooperation on Artificial Intelligence*, which aims, inter alia, to provide an appropriate legal and ethical framework based on the EU's fundamental rights and values, including the right to privacy and personal data protection, as well as the principles of transparency and accountability.[31] Following this document, the Commission announced in April 2018 a strategy for AI[32] that addresses the socio-economic aspects of increasing investment in research, innovation and AI capacity across the EU. The European AI Strategy and the Coordinated Plan show that trust is a prerequisite for ensuring a people-centred approach to AI. In order to achieve trust, it is essential that legal and ethical regulation reflect the existing values on which the EU is

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[27] OECD: *Recommendation of the Council on Artificial Intelligence*, 22 May 2019, OECD/LEGAL/0449, para. 1.1 – 1.5.Online: https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449.

[28] VAN EST, R., GERRITSEN, J.: *Human rights in the robot age: Challenges arising from the use of robotics, artificial intelligence, and virtual and augmented reality*, 28 April 2017, Parliamentary Assembly of the Council of Europe, p. 17 – 46.Online:https://www.rathenau.nl/sites/default/files/2018-02/Human%20Rights%20in%20the%20Robot%20Age-Rathenau %20Instituut-2017.pdf.

[29] Council of Europe: *Study on the Human Rights Dimensions of Automated Data Processing Techniques (in Particular Algorithms) and Possible Regulatory Implications*, DGI(2017)12, 2018, p. 44. Online: https://rm.coe.int/algorithms-and-human-rights-en-rev/16807956b5.

[30] Council of Europe: *Guidelines on the protection of individuals with regard to the processing of personal data in a world of Big Data*, 23 January 2017, T-PD(2017)01. Online: https://rm.coe.int/ CoERMPublic CommonSearch Services/ displayDCTMContent?documentId=09000016806f06d0.

[31] EU: *Declaration on Artificial Intelligence Cooperation*, 10 April 2018. Online: https://ec. europa.eu/jrc/ communities /en/ community/digitranscope/document/eu-declaration-cooperation-artificial- intelligence.

[32] EU: *Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: Artificial Intelligence for Europe*, 25 April 2018, COM/2018/237.

founded. These values include respect for human dignity, freedom, solidarity, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities.[33] The EU, together with Member States, agreed on a coordinated plan[34] to align strategies and, in addition, set up a high-level expert group representing a wide range of stakeholders to task with developing ethical guidelines on AI, as well as preparing a set of recommendations for broader AI policy.

In 2020, several documents were adopted as a further step in the development of EU AI policies, which is inextricably linked to the revision of existing EU legislation. In February, the European Parliament adopted a *Resolution on automated decision-making processes: ensuring consumer protection and free movement of goods and services*, calling on the Commission to put forward proposals to amend EU safety rules for products covered by specific EU legislation laying down harmonized requirements, including Directive on Machinery[35], the Toy Safety Directive[36], the Radio Equipment Directive[37] and the Low Voltage Directive[38], and for "non-harmonized products" covered by the General Product Safety Directive[39], in order to ensure that the new rules are fit for their purpose, users and consumers are protected from harm, manufacturers are clearly aware of their responsibilities and users understood how to use products with automated decision-making capabilities.[40]

The European Parliament further recalls that the existing regulatory framework for services consisting of the Directive on Services in the Internal Market[41], the Professional Qualifications Directive[42], the Proportionality Test Directive[43], the E-Commerce Directive[44] and the General Data Protection Regulation[45] already covers many aspects of services policy, including automated decision-making processes, including rules on consumer protection, ethics and accountability. It notes that such rules should apply to both traditional services and services involving automated decision-making processes.[46] The issue of the use of AI in health and nursing care is addressed in the *European Parliament's resolution on a*

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33 EU: *Charter of Fundamental Rights of the European Union*, OJ C 326, 26 October 2012.

34 EU: *Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: Coordinated Plan on Artificial Intelligence*, 7 December 2018, COM(2018) 795.

35 EU: *Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast),* OJ L 157, 9 June 2006.

36 EU: *Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys*, OJ L 170, 30 June 2009.

37 EU: *Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC*, OJ L 153, 22 May 2014.

38 EU: *Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage*, OJ L 96, 29 March 2014.

39 EU: *Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety*,OJ L 11, 15 January 2002.

40 EU: *Resolution of the European Parliament of 12 February 2020 on automated decision-making processes: ensuring consumer protection and free movement of goods and services*, 12 February 2020, 2019/2915(RSP), para. 6.

41 EU: *Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market*, OJ L 376, 27 December 2006.

42 EU: *Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System*, OJ L 354, 28 December 2013.

43 EU: *Directive (EU) 2018/958 of the European Parliament and of the Council of 28 June 2018 on a proportionality test before adoption of new regulation of professions*, OJ L 173, 9 July 2018.

44 EU: *Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market*, OJ L 178, 17 July 2000.

45 EU: *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)*, OJ L 119, 4 May 2016.

46 EU: *Resolution of the European Parliament of 12 February 2020 on automated decision-making processes: ensuring consumer protection and free movement of goods and services*, 12 February 2020, 2019/2915(RSP), point 9.

comprehensive European industrial policy on artificial intelligence and robotics, which emphasizes that the current system for approving medical devices may not be suitable for AI technologies. It therefore calls on the Commission to monitor closely the progress of these technologies and, if necessary, to propose changes to the regulatory framework in order to establish a framework for determining the respective responsibilities of the user (doctor/specialist), the technology manufacturer and the healthcare facility providing the treatment.[47]

Earlier this year, the Commission published a *White Paper on Artificial Intelligence - A European Approach to Excellence and Trust*, which includes measures to make research more effective, promote cooperation between Member States and increase investment in AI development and implementation. Any changes to the regulatory framework should be limited to clearly identified problems for which realistic solutions exist.[48] AI developers and users are already subject to European legislation on fundamental rights (e.g. data protection, privacy, non-discrimination), consumer protection and product safety and liability. However, the application and enforcement of this legislation may be complicated by some specific features of AI. It is therefore necessary to examine whether the current legislation can cope with the risks of AI and whether it can be effectively enforced, whether it needs to be adapted or whether new legislation is needed.[49]

III. ARTIFICIAL INTELLIGENCE IN HEALTH AND NURSING CARE

The primary purpose of using AI in health and nursing care is to improve the quality of diagnosis and treatment, attempts to increase the independence and social inclusion of vulnerable people such as the elderly and people with disabilities, especially in view of the aging population and the expected shortage of health and nursing staff. The use of robots and AI raises or exacerbates problems typical of healthcare and medical ethics, such as disagreements in treatment decisions, access to healthcare for vulnerable groups, medical errors, and the provision of informed consent.[50] When using any form of AI, whether it is a system that performs only one repetitive activity or system that is able to diagnose and learn on a case-by-case basis, it is essential that ethical principles and values, as well as, relevant legislation are respected. The main motivation for the development of new or revision of existing legislation is to pave the way for the development of the market for products with AI systems and, on the other hand, to protect users from the negative consequences of their use.

1. Ethical aspects of the use of artificial intelligence in health and nursing care

If we want AI to play a beneficial and constructive role in today's and tomorrow's society, then it is essential that these systems operate in accordance with a set of ethical principles and values. There are currently several codes of ethics that find application, whether in the regulation of general AI or AI for the health and nursing care sector. The best-known documents on AI ethical principles include the *Asilomar Artificial Intelligence Principles* [51], the *Montreal Declaration for a Responsible Artificial Intelligence*[52] (hereinafter

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47 EU: *European Parliament resolution of 12 February 2019 on a comprehensive European industrial policy on artificial intelligence and robotics,* 12 February 2019, 2018/2088(INI), point 77.

48 EU: *White Paper On Artificial Intelligence - A European approach to excellence and trust*, European Commission,19 February 2020, COM(2020) 65, p. 11. *Online: https://ec.europa.eu/info/sites/info/files/commission-white-paper artificial-intelligence-feb2020_en.pdf.*

49 Ibid., p. 29.

50 KERR, I., MILLAR, J., CORRIVEAU, N.: *Robots and Artificial Intelligence in Health Care*, Canadian Health Law and Policy, 5th Edition, LexisNexis Canada, Toronto, 2017, ISBN: 9780433490319, p. 267.

51 Future of Life Institute: *Asilomar AI Principles*. Online: https://futureoflife.org/ai-principles/.

52 University of Montreal´s Technosocial Innovation Centre: *Montreal Declaration for a Responsible AI*. Online:https://www.montrealdeclaration-responsibleai.com/.

"Montreal Declaration"), the *Top Ten Principles for Ethical Artificial Intelligence*[53], the World Commission's *Report on Ethics, Scientific Knowledge and Technology on Ethics robotics*, *Ethically Aligned Design: A Vision for Prioritizing Human Well-being with Autonomous and Intelligent Systems*[54] and the *Ethics Guidelines for Trustworthy Artificial Intelligence* (hereinafter "Ethics Guidelines"), adopted under the auspices of the EU. The analysis of the above-mentioned codes of ethics confirms that, despite the number of sources governing AI ethical issues, there is a degree of coherence and overlap from which it can be concluded that there is a set of fundamental principles and values in which society as a whole is interested, namely: (a) respect for human autonomy; (b) prevention of harm; (c) clarity; and (d) justice. As stated by the High Level Expert Group on AI, many of these principles are already largely reflected in existing legal requirements for which mandatory compliance is required.[55]

The provision of health and nursing care is inextricably linked to the principle of respect for human autonomy, which requires that the values and preferences of patients are respected. In order to respect the patient's autonomy, it is necessary to obtain their informed consent to the proposed care. AI systems should not unduly subordinate, coerce, or manipulate people, but should instead design care that enhances, complements, and strengthens human cognitive, social, and cultural skills. The division of functions between people and AI systems should be guided by the principles of human-centred design and leave meaningful opportunities to human decision-making.[56] Applying the principle of autonomy in the context of AI therefore means finding a balance between the decision-making power that we retain ourselves and the power that we delegate to AI.[57]

The principle of prevention of harm is the so-called red line for AI systems.[58] This principle serves to prevent the occurrence of harm, or its increase, and to prevent the misuse of AI systems for other purposes. For instance, the Montreal Declaration requires that every person involved in AI development must exercise caution by anticipating, as far as possible, the adverse consequences of AI systems use and by taking appropriate measures to avoid them.[59] The protection of human dignity, as well as, mental and physical integrity is closely linked to the principle of prevention of harm. AI systems and the environments in which they operate must be secure and protected. Greater attention should be paid to vulnerable people, who should be involved in the development and deployment of AI systems. Particular attention must also be paid to situations in which AI systems could cause or exacerbate adverse effects due to power asymmetries or the availability of information. The principle of prevention of harm must also take into account the natural environment and all living beings.

Given the complexity of the design, construction and programming of AI systems, the central ethical issue is "clarity", i.e. the ability to trace the causes of all past actions (and omissions) of an AI system. For AI with a high level of autonomy, decision-making and learning ability, this requirement of explainability is problematic. This is due to the fact that such robots are not only programmed to perform specific tasks, but to learn and further

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53 UNI Global Union: *Top 10 Principles for Ethical Artificial Intelligence*. Online: http://www.thefuture worldofwork. org/media/35420/uni_ethical_ai.pdf.

54 The Institute of Electrical and Electronics Engineers: *Ethically Aligned Design: A Vision for Prioritizing Human Well-being with Autonomous and Intelligent Systems*. Online: https://standards.ieee.org/content/dam/ieee-standards/standards/web/documents/other/ead1e.pdf.

55 EU: *Ethics Guidelines for Trustworthy AI*, Independent High-Level Expert Group on Artificial Intelligence Set Up by the European Commission, 8 April 2019, Brussels, p. 14.
Online: *https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/JURI/DV/2019/11-06/Ethics-guidelines-AI_EN.pdf.*

56 Ibid., p. 14 – 15.

57 See for instance: *Montreal Declaration Responsible AI*, point 2; *Asilomar AI Principles*, point 6.

58 UNESCO: *Report of the World Commission on the Ethics of Scientific Knowledge and Technology on Robotics Ethics*, 14 September 2017, SHS/YES/COMEST-10/17/2 REV., para. 226.

59 University of Montreal´s Technosocial Innovation Centre: *Montreal Declaration Responsible AI,* point 8.

develop in interaction with their environment, which requires adjustments to current legal and ethical frameworks. It is not always possible to explain why a model produced a particular output or decision (and what combination of input factors contributed to them). These cases are called algorithms "black box" and require special attention.

Justice, as the last of these principles, is usually applied in the context of resource allocation, such as new and experimental treatment options or simply the general availability of conventional health and nursing care. As with other principles already mentioned, interpretations of what justice means as an ethical principle are largely similar, but contain minor differences. In the analysed documents, justice is affected in various ways: (a) the use of AI to correct past wrongs, such as elimination of discrimination; (b) ensuring that the use of AI creates benefits that are shared; and (c) the prevention of new harm, such as undermining of existing social structures.[60] The importance of justice is explicitly stated in the *Montreal Declaration*, which states that the development of AI should promote justice and work to eliminate all forms of discrimination,[61] while the *Asilomar Principles* equate justice with the need for shared benefit and shared prosperity.[62] *Ethics Guidelines* distinguish justice in terms of its substantive and procedural dimension. The substantive dimension entails a commitment to ensure an equal and fair distribution of benefits and costs and to ensure that individuals and groups are not exposed to unfair bias, discrimination and stigmatization. The procedural dimension of justice includes the ability to challenge the decisions of AI systems and the people who run them, and to demand effective redress. To this end, it must be possible to identify the body responsible for the decision and the decision-making processes should be explainable**.**[63]

2. Legal aspects of the use of artificial intelligence in health and nursing care

There are several legal aspects associated with the use of AI in health and nursing care, which are actively addressed by legislators, international organizations and academia. The main legal aspects of the use of AI in the analysed area are the legal status of AI, liability for damage caused by AI, protection of personal data processed by AI, or protection of human rights, especially the right to privacy. Considering the regulation of new technologies, former Australian Supreme Court Justice *Michael Kirby* noted that "normal regulatory bodies often appear powerless."[64] As was the case in other sectors, the AI legislation subsequently responds to changes in society. However, when adopting new legal instruments, it is important to define the definition of AI flexibly enough to take account of technical progress, while being precise enough to provide the necessary legal certainty.[65]

Due to the features of AI systems, we often come across the opinion that AI systems could have a specific legal status, e.g. in the form of an electronic person, the so-called an e-person who will be responsible for compensating for any damage they may cause and, where applicable, applying the electronic personality to cases where they make independent decisions or otherwise communicate independently with third parties.[66] An example is a robot

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60 FLORIDI, L., COWLS, J., BELTRAMETTI, M. (et al.): *AI4People — An Ethical Framework for a Good AI Society: Opportunities, Risks, Principles, and Recommendations*, Minds and Machines, Springer, 2018, ISSN: 1572-8641, p. 698 –699.

61 University of Montreal´s Technosocial Innovation Centre: *Montreal Declaration Responsible AI*, recommendation no. 5

62 Future of Life Institute: *Asilomar AI Principles*, point 14 and 15.

63 EU: *Ethics Guidelines for Trustworthy AI*, Independent High-Level Expert Group on Artificial Intelligence Set Up by the European Commission, 8 April 2019, Brussels, p. 15.

64 KIRBY, M.: *New Frontier: Regulating Technology by Law and "Code",* in: BROWNSWORD, R., YEUNG, K. (eds.): *Regulating Technologies*, Hart Publishing, Portland, 2008, ISBN: 978-1-84113-788-9, p. 367.

65 EU: : *White Paper On Artificial Intelligence - A European approach to excellence and trust*, European Commission, 19 February 2020, COM(2020) 65, p. 18.

66 EU: *European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics*, 18 July 2018, 2015/2103 (INL), OJ C 252, para.59 f).

capable of buying drugs, food or otherwise entering into legal relationships. However, acknowledging the legal personality of AI appears to be problematic for several reasons. According to the UNESCO report on the Robotics Ethics, it is counterproductive to call AI "people" unless they have some of the other characteristics that are usually associated with human persons, such as freedom of will, intentionality, self-awareness or a sense of personal identity.[67] Second, even if the legal personality of the AI were established in a similar way as the legal personality of the legal entity, it would also be an inappropriate solution, as the legal person is also responsible for the action of the natural person, which is not the case for AI.[68] In this context, the European Parliament has made civil law recommendations in the field of robotics, which include a proposal to examine the possibility of introducing so-called e-subjectivity for robots so that they can be held liable under civil law for the damage they cause. However, the European Economic and Social Committee does not share this view and opposes any form of legal status for robots or AI systems, as this creates an unacceptable moral hazard. Civil liability implies a preventive action to change behaviour, which can disappear as soon as the owner no longer bears the risk of liability because it has been transferred to the robot (or AI system). In addition, there is a risk of inappropriate use and abuse of this legal form.[69] Unlike traditional product liability regimes, where a product can be characterized as "defective" due to the manufacturer's negligence, which in turn can be considered to cause harm - in the case of machine learning, there is no equivalent error. This is because AI has not been explicitly programmed to work in a specific way. In many cases, AI developers will not be able to provide a traditional causal explanation of AI behaviour based on their programming inputs. The complexity of large information inputs combined with ever-changing learned behaviour disrupts the traditional occasional connections between programmers' input and system behaviour.[70] It seems that there is usually a "shared" or "distributed" responsibility among robot designers, engineers, programmers, manufacturers, investors, vendors and users. At the same time, this solution weakens the aspect of responsibility. The main challenge is to avoid the possible paralyzing effect of taking and attributing responsibility. One solution to take responsibility may be to develop techniques to anticipate the impacts of robotic development as much as possible.[71] Another solution is to carefully address the necessary occurrence of unexpected consequences by considering the social introduction of robotic technologies as a "social experiment" that needs to be carried out with great care.[72]

Many of the nursing robots currently being tested or used in homes or public institutions are equipped with cameras and other recording devices that monitor the user and store various types of data, in addition to physiological parameters and preferences, habits and user preferences. Thanks to these capabilities, AI can offer very useful information to caregivers and relatives. For example, it could issue warning messages to prevent falls, programming suggestions, reminders or telemedicine services. However, such options can also cause a

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67 UNESCO: *Report of the World Commission on the Ethics of Scientific Knowledge and Technology on Robotics Ethics*, 14 September 2017, Paris, SHS/YES/COMEST-10/17/2 REV., para. 201.

68 O´SULLIVAN, S. (et al.): *Legal, regulatory, and ethical frameworks for development of standards in artificial intelligence (AI) and autonomous robotic surgery*, The International Journal of Medical Robotics and Computer Assisted Surgery, 2019, ISSN: 1478-596X, p. 7.

69 EU: *Opinion of the European Economic and Social Committee on 'Artificial intelligence — The consequences of artificial intelligence on the (digital) single market, production, consumption, employment and society' (own-initiative opinion),* OJ C 288, 31 August 2017, point 3.33.

70 KERR, I., MILLAR, J.: *Delegation, Relinquishment and Responsibility: The Prospect of Robot Experts*, in: CALO, R., FROOMKIN, A. M., KERR, I.: *Robot Law*, Cheltenham, Edward Elgar, 2016, ISBN: 978-1-78347-672-5, p. 106 – 108.

71 WAELBERS, K., SWIERSTRA, T.: *The Family of the Future: How Technologies Can Lead to Moral Change*, in: VAN DEN HOVEN, J., DOORN, J., SWIERSTRA, T. (eds.): *Responsible Innovation*, Springer, Dordrecht, 2014, ISBN: 978-94-017-8956-1, p. 219 – 236.

72 VAN DE POEL: *Why New Technologies Should Be Conceived as Social Experiments*, Ethics, Policy & Environment, Vol. 16, No. 3, 2013, ISSN: 21550085, p. 352 - 355.

problem with the protection of the right to privacy.[73] The right to privacy is guaranteed through a number of international human rights treaties, national legislation or non-legally binding documents. For instance, the *European Convention on Human Rights and Fundamental Freedoms*, which provides for the right to respect for private and family life, home and correspondence.[74] As a possible solution, *Sharkeys* suggests that the robot always make its presence detectable and should seek permission and provide clear indications for recording or monitoring before entering the room.[75] According to *Feil-Seifer* and *Mataric*, another solution could be to distinguish between confidential and non-confidential information, but they express some doubt as to whether the robot would be able to distinguish such information.[76]

AI monitoring and recording capabilities can also cause data breaches. The legal framework for data protection in Europe provides detailed requirements and restrictions on the processing of personal data and contains new provisions on automated decision-making and profiling, which pose interesting challenges for robot developers. Important in this area is therefore the General Data Protection Regulation with regard to the processing of personal data and on the free movement of such data, which gives data subjects the right not to be exposed to decisions based solely on automated processing if the decision has legal effects or similarly affects him or her.[77]

IV. CONCLUSION

Artificial intelligence is and will be an important means of providing effective, human-centred, health and nursing care. AI is increasingly involved in surgical procedures, replacing reduced or lost human organ functions, or providing care to the most vulnerable persons. Although there is no universal definition or categorization of AI to date, this has not affected the interest of States, international intergovernmental and non-governmental organizations or other actors in its development and implementation of AI into everyday life, as well as in adopting adequate ethical and legal regulation. Despite the number of sources governing the ethical issues of AI, there is a degree of coherence and overlap from which it can be inferred that the main ethical principles in the use of AI are respect for human autonomy, principle of prevention of harm, clarity of AI conduct and justice. There are several legal aspects associated with the use of AI in health and nursing care, such as the legal status of AI, liability for damage caused by AI, the protection of personal data processed by AI, or the protection of human rights, in particular the right to privacy. Despite numerous opinions on the introduction of the so-called electronic subjectivity, however, we believe that it would rather serve to relieve of responsibility the developers, programmers and producers of AI. In the provision of nursing care in particular, it is essential to ensure the protection of fundamental rights, in particular the right to privacy, and also to ensure the protection of the data of patients being treated. One way to ensure the protection of the right to privacy is the obligation to obtain informed consent from the patient. At present, AI is insufficiently regulated, which may be due to the fact that it is a new and rapidly evolving area whose impact on the real world and

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[73] SALVINI, P.: *On Ethical, Legal and Social Issues of Care Robots*, in: SAMER, M., MORENO, J., KONG, K., AMIRAT, Y. (eds.): *Intelligent Assistive Robots: Recent Advances in Assistive Robotics for Everyday Activities*, Springer, New York, 2015, ISBN: 978-3-319-12922-8, p. 441.

[74] Council of Europe: *European Convention on Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14*, November 1950, art. 8.

[75] SHARKEY, A., SHARKEY, N.: *Granny and the robots: Ethical issues in robot care for the elderly*, Ethics and Information Technology, Vol. 14, 2012, ISSN: 1572-8439, p. 30 – 31.

[76] FEIL-SEIFER, D. J., MATARIĆ, M. J.: *Ethical Principles for Socially Assistive Robotics*, IEEE Robotics & Automation Magazine, Vol. 18, No. 1, 2011, ISSN: 1070-9932, p. 24 – 31.

[77] EU: *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)*, OJ L 119, 4 May 2016, art. 22.

its legal consequences is difficult to conceptualize and predict. In case of the adoption of new legislation, whether international or national, it is necessary to find a suitable compromise, which would, on the one hand, support the further development of AI, but at the same time would not expose humanity to harm. It is therefore essential to involve all relevant public and private stakeholders. In the future, it will be necessary to ensure that AI continues to serve people and be a driving force for good in the society.

KEY WORDS
Artificial Intelligence, Ethical Aspects, European Law, Health and Nursing Care, Legal Aspects

KĽÚČOVÉ SLOVÁ
Umelá inteligencia, etické aspekty, európske právo, zdravotná starostlivosť a ošetrovateľská starostlivosť, právne aspekty

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