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AI and the Healthcare sector: Industry, legal and ethical issues

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Abstract

In this modern era, AI systems, robotics and all kinds of technological innovations have prevailed in almost every industry there is. Even though, they provide with several advantages and benefits, such novelties, due to their newly found capacities pose a certain undoubted risk for contemporary societies, unfamiliar yet with the full extent of the perils following these kind of innovations.

This article engages in an examination of one of the industries critically changed and influenceδ by AI technology, the healthcare industry, as it possesses the highest bioethical interest. The article, thus, is divided to four sections. The first is dedicated to novel advancements in the field of health care services and medicine, which include the introduction and/or full deployment of machine learning and robotics. Second, as already mentioned due to the fact that these technologies are accompanied by legal concerns, especially in terms of privacy, a legal analysis of the most relevant and prominent concerns is attempted. The emphasis is given on the European Union's approach on the matter of AI related technology. Both its main bodies are mentioned, the European Parliament and the European Commission, for their procurement of documents related to novel technologies.

In addition, after the legal framework analysis and the more binding in nature legislative efforts, the article proceeds with the presentation of the soft-law related to the AI technological field, as well as the ethics and guidelines developed to mitigate its risks and issues. Lastly, the following analysis is closed by conclusions based on the combination of remarks and resolutions from the above mentioned sections of the article.

Keywords: AI, healthcare, EU law, ethics, guidelines.

Τεχνητή νοημοσύνη και Τομέας Υγείας: Ζητήματα τομέα, νομικά και ηθικά

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Περίληψη

Στη σύγχρονη εποχή, τα συστήματα Τεχνητής Νοημοσύνης, η ρομποτική και κάθε είδους τεχνολογική καινοτομία έχουν επικρατήσει σχεδόν σε κάθε βιομηχανία, που υπάρχει. Αν και παρέχουν αρκετά προτερήματα και προνόμια, τέτοιου είδους νεωτερισμοί, λόγω της νέο-ευρεθείσας δυνατότητας τους, αποτελούν και ένα σίγουρο μη αμφισβητήσιμο ρίσκο για τις σύγχρονες κοινωνίες, μη εξοικειωμένες ακόμα με το πλήρες εύρος των κινδύνων, που ακολουθούν αυτού του είδους τις καινοτομίες.

Αυτό το άρθρο εξετάζει μία από τις βιομηχανίες που αλλάζουν και επηρεάζονται σημαντικά από την τεχνολογία της Τεχνητής Νοημοσύνης, την βιομηχανία υγειονομικής περίθαλψης, καθώς κατέχει και το μεγαλύτερο βιοηθικό ενδιαφέρον. Το άρθρο, συνεπώς, είναι χωρισμένο σε τέσσερις τομείς. Ο πρώτος είναι αφιερωμένος στις νέες προηγμένες τεχνολογίες στον τομέα παροχής υπηρεσιών υγειονομικής και ιατρικής περίθαλψης, που περιλαμβάνουν την εισαγωγή και/ή την πλήρη αξιοποίηση της μηχανικής μάθησης και της ρομποτικής. Δεύτερον, όπως προαναφέρθηκε λόγω του ότι αυτές οι τεχνολογίες συνοδεύονται και από νομικές ανησυχίες, ιδίως σε σχέση με την ιδιωτικότητα, γίνεται προσπάθεια μιας νομικής ανάλυσης των πιο σχετικών και εξεχόντων ανησυχιών. Έμφαση δίνεται στην προσέγγιση της Ευρωπαϊκής Ένωσης στο ζήτημα της Τεχνητής Νοημοσύνης και της σχετικής τεχνολογίας. Και οι δύο βασικές δομές της αναφέρονται, το Ευρωπαϊκό Κοινοβούλιο και Ευρωπαϊκή Επιτροπή, που προμηθεύουν με έγγραφα σχετικά με τις νέες αυτές τεχνολογίες.

Επιπρόσθετα, κατόπιν της ανάλυσης του νομικού πλαισίου και της πιο νομικά δεσμευτικής φύσεως νομοθετικής προσπάθειας, το άρθρο προχωρά στην παρουσίαση των μη δεσμευτικών κανόνων δικαίου, σχετικών με τον τεχνολογικό τομέα της Τεχνητής Νοημοσύνης, των ηθικών αρχών και των κατευθυντήριων γραμμών, που αναπτύχθηκαν για να μετριάσουν τα ρίσκα και τα ζητήματα αυτών των τεχνολογιών. Τέλος, η παρακάτω ανάλυση λήγει με ένα συμπέρασμα βάσει ενός συνδυασμού παρατηρήσεων και διαπιστώσεων, προερχόμενων από τους προαναφερθέντες τομείς του άρθρου.

Λέξεις κλειδιά: Τεχνητή Νοημοσύνη, υγειονομική περίθαλψη, Ευρωπαϊκό δίκαιο, ηθική, κανόνες.

Introduction

Pursuant to the Oxford Dictionary's definition, Artificial Intelligence (hence forth AI) is: "the theory and development of computer systems able to perform tasks normally requiring human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages". As "Big Data" become more prominent and omnipresent in current times, the issues risen from AI technology create reasonable questions, especially in the healthcare sector. For instance, AI, with its ability to detect patterns, process vast amount of data and self-educate, refine and alter its reactions to a case-by-case basis, can become an important contributing factor and aid in the prediction and response of disease predisposition and even in the spread of a disease.[1]

In these turbulent times, amidst a pandemic, on one hand AI and robotics appear to be a promising and revolutionary kind of technology, able to lead humankind to progress. On the other hand, such technological advancements are the source of novel challenges and questions, relevant to their lawful operation, ethical nature and overall economic possibilities. To be more precise, in terms of the healthcare sector, AI has the ability to process a huge amount of patient data and deliver an automatic decision tailor made to each one of them, without a need for close proximity. This can lead to AI being both a facilitating factor in medical diagnosis, and a contributing factor to adding a democratic trait to the process, as more patients will gain access to personalized medicine, especially on the field of oncology.[2]

Nevertheless, with this turning point in the medical field comes a rising concern about the ethical problems deriving from it, such as issues related to informed consent, the capacity to explain to patients the procedure involving AI technology, pursuant to their right to make an informed decision, and last but not least, issues regarding privacy rights and the processing of health-related sensitive information. Naturally, with concern come questions that need to be answered, in order to fully reap the benefits of AI and incorporate it safely in the healthcare sector. To that end, the problematic of AI technology and its applications in the healthcare and medical services industry have become the focal point of legal and ethical discussions and actions.

Industry Issues

AI and its use in robotic science and robotics, generally, has become more apparent in everyday life, as well as a vital part of every industrial sector, with the healthcare and medical one not being an exception. As the field of medicine progresses rapidly and the working life of an adult becomes ever more challenging and frenetic in rhythm, new ways of caring for minors and the elderly emerge not only as a possibility, but also as a need. Currently, in our society, the more innovative approach proposed as a solution, is the incorporation of Personal Care Robots, which possess the ability to look after the abovementioned vulnerable population groups, by supplying them with the much needed assistance, nurturing and anti-stress relief.[3]

Personal care and companion robots can be used in multiple ways. For instance, they can be used as providers of aid in clinical and

[1] Burke T.J, Trazo S, Emerging legal issues in an AI-driven world, Gowling WLG,2019, lexology.com, https://www.lexology.com/library/detail.aspx?g=4284727f-3bec-43e5-b230-fad2742dd4fb (online) accessed: 26 Nov 19.

[2] Furlow, B, IBM Watson Collaboration Aims to Improve Oncology Decision Support Tools, 2015, http://www.cancernetwork.com/mbcc-2016/ibm-watson-collaboration-aims-improve-oncologydecision-support-tools (online) accessed: 26 Nov19.

[3] Alemi, M., Meghdari, A. & Saffari, E, RoMa: A hi-tech robotic mannequin for the fashion industry. Lecture Notes in Computer Science (LNCS): Social Robotics, 2017, 10652, p. 209-219.

rehabilitation services and assistance in memory exercises, as well as act as caretakers with the responsibility of providing the elderly with food and medicine.[4] Innovative robotic caretakers, such as the aforementioned are RI-MAN, PaPeRo, and the Care-O-bot.[5], the design of the last one enables it to move easily around the house and provide assistance in opening doors and the procurement of drinks and beverages.[6] Another example of a care nursing robot is RoBear.[7] It is in an experimental process, but, RoBear, human in size with a teddy-bear like appearance, can lift patients from their beds and place them in wheelchairs.[8]

Besides, though, such kind of robotics, there are also humanoid robots, meaning human like robots. For instance, Advanced Step in Innovative Mobility (ASIMO), Baxter, Compliant Humanoid Platform (COMAN), Exciting Nova on Network (Enon),Humanoid for Open Architecture Platform (HOAP),Humanoid Robotics Project (HRP), iCub, Justin, KHR, MAHRU, Nexi MDS, REEM, Robonaut, Saika, Twenty-One and Wakamaru.[9] But, the above mentioned are all still in an experimental level, created for R&D purposes mostly. In contrast, SoftBank Robotics, in Japan, developed Pepper, a highly sociable and interactive robot, with a complex AI based software, capable of being a provider of physical and cognitive assistance to people in need of it.[10] Even though, Pepper was originally designed for a business-to-business (B2B) application, the increasing global interest around its uses lead to its inclusion into business-to-consumer (B2C), business-to-academics (B2A) and business-to-developers (B2D) sectors, varying in each implementation.[11] Now, it has been made operational and already in use in thousands of homes and schools, while at the same time it has been chosen as the robotic platform for RoboCup@Home,[12] Social Standard Platform League (SSPL) competitions.

Notwithstanding that the Pepper robot has to demonstrate impressive achievements in the area of robotic science, especially when it comes to live interaction, recognition and response to human emotions,[13] legal and ethical issues can be and are expected to be raised. More specifically, a valid concern, from an ethical, legal and social point of view, would be the contradictive relationships formed between a user's commands, privacy rights and the need for being socially accountable and to abide by ethical guidelines, especially regarding minors.[14]

Aside from the above mentioned examples of highly advanced robotic inventions, robotics have been known to be used broadly in the healthcare sector, through the application of prosthetics and most importantly through

[4] Ibidem.
[5] Meghdari, A, Alemi, M, Recent advances in social & cognitive robotics and imminent ethical challenges. Proceedings of the 10th International RAIS Conference on Social Sciences and Humanities organized by Research Association for Interdisciplinary Studies (RAIS) at The Erdman Center at Princeton University, Princeton, New Jersey, United States.Cambridge, MA: The Scientific Press, 2018.
[6] Ibidem.
[7] Wilkinson J, The strong robot with the gentle touch, Riken Research, 2015, http://www.riken.jp/en/pr/press/2015/20150223_2/ (online) accessed: 26 Nov 19.
[8] Ibidem.
[9] Patney AK, Gelin R, A Mass-Produced Sociable Humanoid Robot: Pepper: The First Machine of Its Kind, IEEE Robotics & Automation Magazine, 2018, PP(99):1-1, https://www.researchgate.net/publication/326334563_A_Mass-Produced_Sociable_Humanoid_Robot_Pepper_The_First_Machine_of_Its_Kind , (online) accessed: 22 Dec 2020.
[10] Idem, p.3.
[11] Idem, p2,3.
[12] Idem, p.3 (http://www.robocupathome.org).
[13] Idem, p.4.
[14] Pandey AK, Gelin R, Ruocco M, Monforte M, Siciliano B, When a social robot might learn to support potentially immoral behaviors in the name of privacy: The dilemma of privacy vs. ethics for a socially intelligent robot, in Proc. 2017 Conf. Human-Robot Interaction (Workshop on Privacy-Sensitive Robotics), pp. 1-4.

surgical robots, such as the da Vinci system, designed by Intuitive Surgical Inc.[15] The da Vinci system[16] provides a doctor, through a console, with a 3D image of a patient and with control of four instruments, the forth being a camera, to execute precise, safe and easily/ fluid made moves to perform an operation.[17] However, challenges can still rise in this case, as the operation of such an advanced surgical tool, calls for excessive training and time to master, and the use of 3D imaging, is also immensely different than the experience a doctor is used to, where they can physically interrupt and touch the patient. Besides, accidents have also occurred, such as the one on 8/09/2010 in Japan, when the pancreas of a patient operated for gastric cancer was severely damaged, unfortunately leading to their death a few days later. In the accident, after research that was conducted, there was evidence of not acquiring an informed consent properly, as well as not involving senior surgeons in the process. But, also, from the cameras in the operating room no blame could be directed towards the da Vinci Surgical System, taking in consideration its functions and its capacities as a machinery.[18]

As a result, the incorporation of AI in healthcare has become a central point of discussion and worry, specifically relevant to such services healthcare deprivation of their human factor, if machines were ever to completely replace human contact and general involvement in healthcare. Moreover, a legal problematic and several questions of a legal nature need to be discussed and answered, regarding a more conscious redirection of the sector towards AI applications in it. For example, in terms of prosthetics and surgical robots, the application of specific Directives is quite obvious, such as the Council Directive 93/42/EEC relevant to medical devices (as amended by Directive 2007/47/EC) ("Medical Device Directive"), and the Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices ("AIMDD"), both incorporated to EU Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017.[19] In contrast, the legal framework for care robots has not been clarified. To be more precise, some, judging from the services provided, could be regulated under the provisions of the Regulation for Medical Devices, as they strive to provide medical services (e.g. a reminder to elders to not forget to take their medication), but others with a more broad scope of use, such as the ones providing aid by facilitation of movement, they might not be perceived as a medical device, pursuant to the legal definition, hence they will fall outside of the protective scope of the law. Nevertheless, they need to follow specific international standards, such as the ISO 13482 Robots and robotic devices—Safety requirement for personal care robots.[20]

The principal issue with the aforementioned types of robots and AI technological applications, is that during usage

[15] http://www.intuitivesurgical.com/ (online) accessed: 26 Nov 19

[16] Beasley R.A, Farrokh J.S, Medical Robots: Current Systems and Research Directions, Journal of Robotics, Volume 2012 |Article ID 401613, 1687-9600, https://doi.org/10.1155/2012/401613.

[17] Idem, p.5.

[18] Tanioka, R. , Locsin, R. , Yasuhara, Y. and Tanioka, T, Potential Legal Issues and Care Implications during Care-Prevention Gymnastic Exercises for the Elderly Using Pepper in Long Term Health Care Facilities. Intelligent Control and Automation, 2018, 9, 85-93. doi: 10.4236/ica.2018.93007.

[19] 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, implementation date: 26 May 2020.

[20] Technical Committee : ISO/TC 299 Robotics, ISO 13482:2014 Robots and robotic devices — Safety requirements for personal care robots, 2014-02, 79, https://www.iso.org/standard/53820.html (online) accessed 22 Dec 2020.

by their owner, they consistently collect and process information, regarding that user. The accumulation and saving of such sensitive data (e.g. a patient's medication, health status, biometric information), may be essential for the machine to process and to deploy in its recommendations, or its production of the wanted results, while at the same time such sensitive information could be stored in the cloud, making thus, privacy rights extremely vulnerable to breeching, and safety assurances not feasible.

Aiming to address such concerns, the European Parliament in 2017 has adopted the Civil Law Rules on Robotics, which incorporate specific thoughts and general principles of the Parliament, on how care and medical, but also human repair and enhancement robotics, should be properly handled.[21] In the final text that was adopted, a specific focus is given in terms of maintaining the human factor omnipresent end at center stage, when it comes to care robots, as humans should remain in charge of providing healthcare services, aiming at avoiding replacing the human care and interaction with a complete robotic approach.[22] In terms of medical robots and their use, the framework stresses the need for continuous training, education and familiarization of the surgeons, operating with the aid of these machines, as well as acquiring certifications.[23] Last but not least, pursuant to the Civil Law Rules on Robotics human prosthetic's cause of existence is to enhance the quality of human life and facilitate it, while simultaneously making sure that any mechanism incorporated into the human organism cannot cause harm to its host and that they are accessible to all society's members, in a proper and equal way.[24]

Legal Issues

The EU starting point, regarding regulatory initiatives for AI technology, can be traced back to 2016. A draft report,[25] the "Civil Law Rules on Robotics", was published by the European Parliament's Committee on Legal Affairs (JURI). Not long after, in 2017, the final version of the text proposed was adopted by the European Parliament in 2017 with recommendations to the European Commission.[26] In this final form of the resolution, the European Parliament touched upon many topics, proposing appropriate guiding principles, such as autonomous vehicles,[27] safety standards,[28] education and employment,[29] environmental impact[30] etc. One of the issues addressed, one the stands out among the proposals made for legislative action, is the principals proposed in terms of mitigating the problem of liability. More specifically, liability claims could rise in case of damages caused by a robot or AI system, but the extent of responsibility, the actual responsible person and the causality prerequisites needed all pose equally concerning questions of their own. This is why, a suggestion of the Parliament was the establishing of a legal framework that would require for a mandatory insurance, in order for one to use AI machinery or robotics, regardless of the degree of their autonomy, similar to the one already applying to the lawful operation of automobiles.[31]

[21] European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL).
[22] Idem, principals 31 & 32.
[23] Idem, principals 33,34,35.
[24] Ibidem.

[25] EU Committee on Legal Affairs. (2016). Draft report with recommendations to the Commission on Civil Law Rules on Robotics. May 31.
[26] European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)), http://www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.html (online) accessed: 26 Nov19.
[27] Idem, principals 24-29.
[28] Idem, principals 22,23.
[29] Idem, principals 41-46.
[30] Idem, principals 47,48.
[31] Idem, principle 57.

The last proposal was not adopted by the European Commission, which on February 2020 published a White Paper on Artificial Intelligence (AI), alongside with its complementary report on the security and liability issues regarding AI applications, the Internet of Things (IoT) and robots. In this White Paper, the Commission puts the emphasis on how AI would be perceived by a European perspective, highlighting the fact that it is crucial that European AI is based on the values and fundamental human rights of the EU, such as privacy protection and human dignity.[32]

In terms of privacy and the implications of AI in the medical and healthcare sector, there is a clear problematic, with an entire academic discussion around it, deriving from the General Data Protection Regulation (GDPR). To be more specific, Article 22 of the GDPR incorporates a provision against decisions based solely on automated processing.[33] The objective of Art.22 of the GDPR is to avoid objectification of individuals within a dehumanizing process of fully automated decision making, based and determined entirely by machines. If such an event occurred, and even became the norm, the result would be the loss of personal independence and with it human oversight, monitoring and a sense of duty will also be lost.[34] Thus, Art. 22 §1 GDPR inserts a provision of forbidding of autonomous decision-making without the human factor partaking in the monitoring of the process and the decision outcome ("solely based on automated processing"). Humans should always have the final say.

AI systems that could fall outside the prohibition's scope are the ones who are only supportive in the decision making process. Meaning, the human in the loop retains a high level of authority in the assessment process and is able to influence the result (e.g. a physician reaching a medical decision after taking into consideration AI suggestions). Although, in case the human in the equation does not possess any actual power, so as to dispute the conclusion (e.g. a member of the health care/ nursey personnel, who is required by law to follow the AI recommendations without question), this constitutes the case of a forbidden by Art 22 of the GDPR fully automated decision-making.[35]

An AI-system operating on a completely autonomous way, could be subjected to this prohibition if the outcome of its recommendations entails severe repercussions (of a legal or analogous nature).[36] In terms of AI applications in medical diagnosis or treatment this entry-level will almost undoubtedly be attained, hence medical and healthcare related AI lacking the human factor in the equation constitutes, in general, a forbidden use of this technology, pursuant to the GDPR provisions. Nevertheless, some exceptions do apply in this case. The most crucial exception, regarding the use of medical AI, is the possibility to acquire, through appropriate documentation (e.g. in

[32] European Commission: White Paper On Artificial Intelligence - A European approach to excellence and trust (2020) https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020 en.pdf.

[33] Article 22§1 of the 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 on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation- GDPR).

[34] Bygrave, L.: Minding the machine v2.0. The EU general data protection regulation and automated decision-making. In: Yeung, K., Lodge, M. (eds.) Algorithmic. Regulation, pp. 248-262. Oxford University Press, Oxford (2019). https://doi.org/10.1093/oso/9780198838494.001.0001

[35] Article 29 Data Protection Working Group: Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679,WP251rev.01 (2018)https://ec.europa.eu/newsroom/article29/item-detail.cfm?itemid=612053.

[36] Ibidem.

writing or in electronic form) a direct consent from the "data subject" (the patient), agreeing to have their medical data be processed within a completely automated procedure (this set of data could be related to the physical or mental health of the patient.[37,38]

The right of "informed consent" constitutes (not within the provisions of the GDPR, but incorporated in the Charter of Fundamental Rights of the European Union),[39] one of the foundations of medical law within the EU legal framework, as well as in individual EU Member States Law. There exists only one more exception, regarding the need for an "informed consent" (its interpretation should be narrow), which is: Automated processing of health related data could be made possible, if it serves a substantial public interest, e.g. public health. In the context of this exception, it would, for example, be plausible to point out individuals, demonstrating a particular vulnerability to a pandemic disease, such as COVID-19, by deploying technological innovations like AI fully automated systems. Although, an emphasis should again be given to the fact that, this kind of exception can only apply to cases were a substantial public interest is served and protected. As a result, it cannot possibly be invoked as a general exception to get around the prohibition introduced with the provisions of Art. 22 para GDPR[40,41] (e.g. cases of tax-evasion and fraud).[42]

Apart from the articles of the GDPR that provide with explicit rights, there are also the recitals of the Regulation, serving as complementary guidelines[43] with an interpretative nature. One of those is Recital 71:[44] "The right to obtain an explanation of the decision reached after such assessment", accompanying and shedding some light to the prohibition of fully automated processing. At a primary glance, this kind of explanation incorporated in the recital could be viewed as a right to an explanation. However, as recitals are of non-binding nature and only used as guidelines, this kind of guidance can be perceived as a recommendation and not an obligation. On the other hand, another argument on this debate about the actual existence of a right to an explanation derives from the combined interpretation of Articles 13-15 of the GDPR,[45] Article 22§4 and Recital 71. Without ever being explicitly stated, the conclusion stemming from this combination is that the

[37] Article 22§4 of the 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 on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation- GDPR).

[38] European Data Protection Board: Guidelines 05/2020 on consent under Regulation 2016/679, Version 1.1 (2020) https://edpb.europa.eu/sites/edpb/files/files/file1/edpb guidelines 202005 consent en.pdf.

[39] Charter of Fundamental Rights of the European Union, article 3,para 2(a), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT (online), accessed on: 23 Dec 2020.

[40] Bygrave, L.: Article 22. In: Kuner, C., Bygrave, L., Docksey, C., Drechsler, L. (eds.).
The EU General Data Protection Regulation (GDPR). A Commentary. Oxford University Press, Oxford (2020).

[41] Op.cit.

[42] Recital 71 of 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 on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation- GDPR).

[43] Mendoza, I., Bygrave, L.: The right not to be subject to automated decisions based on profiling. In: Synodinou, T.E., Jougleux, P., Markou, C., Prastitou, T. (eds.).
EU Internet Law. Regulation and Enforcement, pp. 77-98. Springer, Cham (2017). https://doi.org/10.1007/978-3-319-64955-94.

[44] Op.cit. recital 71.

[45] Articles 13§2(f), 14§2(g) & 15§1(h) of 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 on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation- GDPR).

regulator demands (in cases of automated decision- making process) that the data subjected is provided with "meaningful information regarding the strategy deployed and the importance and the predicted results of the relevant processing procedure for the data subject".[46]

The health data controller (the one responsible for the processing of data, either it is a natural or legal person) is at liberty to select the safety measures they consider essential, provided that three fundamental safety precautions are preserved (human intervention made possible, ability of the data subject to communicate their opinion, disputing of the decision), so as to maintain compliance with the Regulation.[47,48] Consequently, the "right to an explanation" only technically does not constitute an obligation, but from the above mentioned interpretation, it is a right that needs to be implemented with level of functionality, at least in the context of good practice, so as to ensure that the data subject is able to fully benefit from the rights provided by the GDPR and its Recitals.[49]

This is why, answering the initial problematic of the existence of a right to an explanation, lies upon the way the term "explanation" is actually defined. On one hand, assuming that "explanation" is perceived as "information about basic system functionality", then the right to an explanation clearly applies, in order to provide the meaningful information that Articles 13-15 of the GDPR require.[50] On the other hand, if the term "explanation" can have a more broad interpretation, in the context of "explaining every single step or/and internal process which is deployed by a complex AI system to reach to a conclusion", then the same right as depicted and interpreted in the aforementioned way, loses its functional purpose and its ability to apply in this case (judging by the already existent simplification of medical information by doctors, so that they provide the essential information in a comprehensive way).

In summary, a clarification of the term could be provided by the European Court of Justice (ECJ), regarding "right to an explanation". A similar approach was followed in the past by the ECJ, regarding the "right to be forgotten", which was basically created due to the Courts interpretation of the Law.[51] Another solution could be the amending of the GDPR itself. If neither of these actions are taken, the right to an explanation will remain vaguely included in the legal framework, dependent by interpretative methods of scholars and legal professionals, and even then its applicability will remain at a minimum level, or worse, it would be perceived in the context of the Recital, remaining a supportive guideline with a non-binding nature.[52]

[46] Selbst AD, Powles J, Meaningful information and the right to explanation, international Data Privacy Law, Volume 7, Issue 4, November 2017, Pages 233-242, https://doi.org/10.1093/idpl/ipx022.

[47] Hacker, P., Krestel, R., Grundmann, S., Naumann, F.: Explainable AI under contract and tort law: legal incentives and technical challenges. Artif. Intell. Law (2020), https://doi.org/10.1007/s10506-020-09260-6.

[48] Wachter, S., Mittelstadt, B., Floridi, L.: Why a right to explanation of automated decision-making does not exist in the general data protection regulation. Int. Data Priv. Law 7, 76-99 (2017), https://doi.org/10.1093/idpl/ipx005.

[49] Op.cit., Article 29 Data Protection Working Group.

[50] Kamarinou D, Millard C, Singh J, 'Machine Learning with Personal Data' (2016) ssrn:2865811 forthcoming in R Leenes and others (eds), Data Protection and Privacy: The Age of Intelligent Machines, Hart, Oxford, UK 2017.

[51] Fosch Villaronga E, Kieseberg, P., Li T.: Humans forget, machines remember:artificial intelligence and the right to be forgotten. Comput. Law Secur. Rev.304-313 (2018). https://doi.org/10.1016/j.clsr.2017.08.007.

[52] Schneeberger D., Stöger K., Holzinger A. (2020) The European Legal Framework for Medical AI. In: Holzinger A., Kieseberg P., Tjoa A., Weippl E. (eds) Machine Learning and Knowledge Extraction. CD-MAKE 2020. Lecture Notes in Computer Science, vol 12279. Springer, Cham. https://doi.org/10.1007/978-3-030-57321-8_12.

Ethical issues

In April 2018 the EU proceeded towards the development of an ethical framework for AI in Europe. The strategy aimed at (according to the agreement of 24 Member States and Norway on AI - European Commission Communication on "Artificial Intelligence for Europe)[53] laying the foundational principles and value, which will be the basis for ethical AI. Part of the initiative was the direct reference to the GDPR and Article 2 of the Treaty on EU, highlighting the humanitarian scope, focusing on justice, non-discrimination and freedom.

Pursuant to the above mentioned European Communication, the Commission initiated two strategic projects. One was the creation of the High - Level Expert Group on AI (AI HLEG)[54] and the second was the launching of the project called AI Alliance.[55] The AI HLEG composed documents regarding ethical principles that ought to regulate the way AI technology should function, alongside a definition for AI itself. Thus, AI HLEG group's first document, on trustworthy AI, accompanied by guidelines for its ethical use, constitutes the "Ethics Guidelines for Trustworthy AI",[56] which was also incorporated in the latest Communication of the EU Commission (Communication: Building Trust in Human-Centric Artificial Intelligence[57] - both their publication being on 8th of April 2019). The recommendations highlighted three crucial factors, essential for establishing a trustworthy AI: a) compliance with the law, b) upholding of ethical principles and c) robustness.

The AI HLEG produced 7 central principles and prerequisites, aside from the three abovementioned key components, the former being instrumental to the achievement of an ethical and trustworthy AI.

These principals are:

1. Human agency and oversight
2. Technical robustness and safety
3. Privacy and data governance
4. Transparency
5. Diversity, non-discrimination, and fairness
6. Societal and Environmental well-being
7. Accountability

In the context of the EU's strategy and launching of initiatives for ethically conducted innovative technology, the same group came up with a proposal for a definition regarding this form of technological advancement, incorporate in the document: "A definition of AI: Main capabilities and scientific disciplines",[58] considering the duality of AI's nature, both as a software and as a scientific field.

The definition introduced with the proposal is as follows: "Artificial intelligence (AI) 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

[53] European Commission https://ec.europa.eu/digital-single-market/en/news/communication-artificial-intelligence-europe (online) accessed: 23 Dec 2020.

[54] AI HLEG https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai (online) accessed: 23 Dec 2020.

[55] AI Alliance https://ec.europa.eu/digital-single-market/en/european-ai-alliance (online) accessed: 23 Dec 2020.

[56] https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai (online) accessed: 24 Dec 2020.

[57] https://ec.europa.eu/digital-single-market/en/news/communication-building-trust-human-centric-artificial-intelligence (online) accessed: 24 Dec 2020.

[58] https://ec.europa.eu/digital-single-market/en/news/definition-artificial-intelligence-main-capabilities-and-scientific-disciplines (online) accessed: 24 Dec 2020.

they can also adapt their behavior by analyzing how the environment is affected by their previous actions. As a scientific discipline, AI includes several approaches and techniques, such as machine learning (of which deep learning and reinforcement learning are specific examples), machine reasoning (which includes planning, scheduling, knowledge representation and reasoning, search, and optimization), and robotics (which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems)".[59]

Last but certainly, not least, there is a more recent development to the EU's approach on ethical AI. A new framework of ethical aspects of artificial intelligence, robotics and related technologies was launched in 2020. On the 20th of October 2020, the European Parliament adopted such a framework with accompanying recommendations to the Commission.[60] The resolution adopted was accompanied by two other, one on civil liability and AI technologies and one regarding the protection of intellectual property rights in the context of AI generated creations. All three were based on previous reports, of the European Parliament's (EP) Committee on Legal Affairs, on the 2nd, 5th and 8th of October 2020.

The most relevant to the ethical aspect of AI technology is the above mentioned framework, adopted by the EP. The rapporteur was Ibán García del Blanco, the Spanish leader of the legislative initiative, which urges the Commission to compose a novel framework with both legal and ethical components, in order to better regulate and control the rapid technologic advancements, such as AI machine learning and robotics. The text adopted, in its very first and opening clause, emphasis on the need for AI related regulation to be human-centric and human-made in its approach.[61]

Moreover, it moves even further in highlighting the necessity of adopting, for a safer and secure use of AI technology, methods such as risk assessment and risk-related strategies, not failing to mention and evoke the "high risk" view point expressed by the European Commission's White paper on AI (see above).[62] More specifically, the approach incorporated with in the document is quite relevant and applicable to health related AI systems. In clause 14,[63] the EP emphasizes the issue of high risk technologies that could potentially harm or severely injure human beings, due to their proximity to them. For instance, wearables and health care robots could potentially fall under the scope of a legal framework on the basis of this proposed principle. In addition, highly related and interesting principles of the text concern the scope of privacy and biometric recognition and data. In that context, the EP in the resolution, highlights the necessity for good governance principles to apply, in such cases, as well as full compliance with the GDPR and the application of the proportionality principle, so as to avoid mass surveillance incidents.[64] The resolution also focuses on the requirement of safety related measures, so as to guarantee the transparency and accountability of AI technology. The latter, needs to be without biases and discrimination, ensuring the safeguarding and respect for human rights.[65]

[59] Op.cit.

[60] Framework of ethical aspects of artificial intelligence, robotics and related technologies, European Parliament resolution with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies (2020/2012(INL)), P9_TA(2020)0275, 20 October 2020, https://www.europarl.europa.eu/doceo/document/A-9-2020-0186_EN.html (online) accessed: 25 Dec 2020.

[61] Idem, clause 1.

[62] Idem, clause 12 to 16, risk assessment.

[63] Idem, clause 14: considered cumulatively;".

[64] Idem, clause 63 to 71, Privacy and biometric recognition.

[65] Idem, clause 17-37.

Conclusions

Undoubtedly, in the modern world the velocity of contemporary advancement leaves the majority of the people in awe, but also as with every novelty, it creates reasonable concern. The current technological growth, especially in the field of modern medicine and health care services provide with an unprecedented opportunity for largely available high quality healthcare. Robotics in surgical procedures, adding value with their precision. Robotic prosthetics and wearables and care robots, personalizing and democratizing the notion of true quality of life for all. Last but not least, AI systems incorporated in medical decision making, provide with the accuracy and speed no human could ever possibly reach. To all wonders and advantages this new exciting era of machine learning and artificial intelligence has to offer, there is also another side, one that calls for caution. All the above mentioned systems are not without safety perils and hazards, especially due to their "high risk" nature, to evoke the White Paper of the EU Commission, and because they could potentially violate fundamental rights, protected by EU law, such as privacy rights.

In that context, the legal frameworks of individual nations, but also those of larger multinational entities, such as the European Union ought to "think" and implement legal strategies ahead of their time. However, as history has proven in the past, the legislators and regulators rarely can keep up and stay relevant with the societal progress. On the other hand, they EU legislature has proven to be quite active, especially to the writing of legal texts concerning AI technology. Nevertheless, the legal texts composed are of a soft-law, non- binding nature. Thus, even though the intention and mentality of the EU's approach to AI is on the right side and quickly catching up to the modern era, it is still highly insufficient, as it fails to provide with the much needed legal foundation, which nations can rely upon.

In terms of ethics, again the EU appears to have made quite the progress in adopting ethical guidelines and principles in the past few years, establishing, hence, itself as a pioneer in the AI regulatory field. The most recent initiative was the resolution adopted by the European Parliament this year, on October 2020, the Framework of ethical aspects of artificial intelligence, robotics and related technologies. Two factors reappearing in texts is the need for AI to be human-centric and protective of privacy and safety rights. In conclusion, there seems indeed to be a convergence of ethical principles and key contributing factors for a trustworthy, human-based AI, but at the same time guidelines by themselves, without the following legislation, cannot provide the certainty and accountability needed to achieve true trustworthiness in the AI and general technological sector.