Traveling with or without informed consent?

Rethinking patients' rights in cross-border healthcare in the era of Artificial Intelligence in medicine*

Emilia Wesołowska**

Abstract:
L'intelligenza artificiale sta rivoluzionando il campo della medicina e ha un impatto significativo sulla cura dei pazienti e sulle loro decisioni in merito ai servizi sanitari. Di norma, le attuali normative dell'UE tutelano i diritti dei pazienti solo in misura limitata e gli Stati membri dell'Unione europea hanno un ampio potere discrezionale al riguardo. Tuttavia, si prevede che Regolamento sull'intelligenza artificiale (AIA), in fase di approvazione definitiva, apporterà diversi importanti cambiamenti alla portata dei diritti dei pazienti a livello europeo, in particolare relativamente alla nozione di consenso informato. Pertanto, la progressiva europeizzazione dei diritti dei pazienti, determinata dalla Direttiva 2011/24/UE, dal Regolamento generale sulla protezione dei dati (GDPR) e dalle politiche dell'UE in risposta alla pandemia, nonché le implicazioni dell'AIA e lo sviluppo tecnologico giustificano la considerazione delle richieste di promozione di un approccio standardizzato, inclusivo e centrato sul paziente in riferimento al consenso informato. L'articolo si propone di esaminare l'impatto dell'AIA e dello sviluppo tecnologico sulla Direttiva 2011/24/UE nel contesto del diritto dei pazienti al consenso informato. L'Autrice suggerisce di ripensare le condizioni per la validità del consenso informato a livello europeo, ad esempio, propone di introdurre la considerazione dell'individualità del paziente, che comprenda la considerazione dell'identità complessa dei

---

* Contributo sottoposto a revisione tra pari in doppio cieco.

** Ph.D. Student at Interdisciplinary School of Social Sciences, Nicolaus Copernicus University, Toruń, and Ph.D. Student of "Diritto e istituzioni economico-sociali: profili normativi, organizzativi e storico-evolutivi" at Department of Law, University of Naples; emilia.wesolowska@studenti.uniparthenope.it.

ISSN 2611-8882

cittadini europei e dei loro *background* culturali, linguistici e religiosi, così come scelte personali, convinzioni e disposizione degli individui verso le nuove tecnologie. È, quindi, necessario promuovere la fiducia nei servizi sanitari in tutta l'UE e garantire che i pazienti ricevano servizi sanitari di alta qualità, incentrati sul paziente e orientati a principi etici.

Artificial intelligence is revolutionizing the field of medicine and has a significant impact on patients' care as well as their decisions regarding health services. As a rule, current EU regulations cover patients' rights only to a limited extent, hence, the Member States of the European Union have significant discretion in this regard. However, the anticipated EU Artificial Intelligence Act (AIA) is expected to bring several important changes in the scope of patients' rights at the EU level, in particular those regarding the notion of informed consent. Therefore, the progressing Europeization of patients' rights initiated by the Directive 2011/24/EU, and followed by the General Data Protection Regulation (GDPR) applicable in healthcare settings and EU's policies in response to pandemics, as well as implications of the AIA and technological development warrant consideration of calls for promotion of standardized, inclusive and patient-centered approach towards informed consent. The author suggests rethinking conditions for informed consent validity at the EU level, for instance, suggests a prerequisite of patient individualism that covers consideration of EU citizens' complex identity, meaning their multi-layered structure of cultural, linguistic, and religious backgrounds, as well as personal choices, beliefs and disposition of individuals towards new technologies. It is, thus, necessary to foster trust and confidence in healthcare services across the EU and ensure that patients receive ethical, high-quality, and patient-centered health services. Therefore, the paper aims to examine the impact of the anticipated AIA and technological development on Directive 2011/24/EU in the context of patients' right to informed consent.

1. Introduction

The anticipated Artificial Intelligence Act[1] (AIA)[2] aims to establish a framework for the safe and ethical use of artificial intelligence (AI) within the European Union (EU). The new technological advancements are currently revolutionizing EU citizens' everyday lives, and have progressed from medical record-keeping experiments in the 1960s, to clinical decision support systems in the 1990s, to mobile eHealth applications in recent years. Therefore, the Internet of Things (IoT) and Machine Learning ML/AI[3] have a significant impact

[1] The Regulation has been agreed in negotiations in December 2023 and endorsed by MEPs with 523 votes in favor in plenary session March 13th 2024.

[2] Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts - Analysis of the final compromise text with a view to agreement of 26 January 2024. Available [online: https://data.consilium.europa.eu/doc/document/ST-5662-2024-INIT/en/pdf]

[3] G. Cohen argues that the law should impose a necessary disclosure of information regarding AI/ML in healthcare as a part of informed consent giving process, see: I. Glenn Cohen, *Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?*, in *SSRN Electronic Journal*, 2020, https://doi.org/10.2139/ssrn.3529576. pp. 1426

on the efficiency of healthcare services delivery, as well as generative AI demonstrates a strong potential for successful application in healthcare settings[4].

Due to technological advancements, the portability of medical devices, and accessibility to remote health services, it appears that the concept of cross-border healthcare in the EU has become vague. Similarly, the anticipated AIA significantly impacts the ways the patients understand information regarding health services and provide informed consent before undergoing medical interventions. The ethical concerns regarding the process due to the use of AI at an intersection with existing EU regulations on health require further guidelines and clear conditions for informed consent validity. It is, therefore, necessary to examine the impact of new AIA regulations on cross-border healthcare in the EU in the context of patients' right to informed consent. Section 2 outlines the legal framework for informed consent regulation at the EU level as well as explores the conditions for its validity in light of the deployment of AI systems and devices in healthcare. Section 3 explores the condition of patient individualism for informed consent validity. The suggested prerequisite involves consideration of patients' personal choices and beliefs, the disposition of individuals toward new technologies as well as EU citizens' complex identities due to their multitude of cultural, religious, linguistic, and social backgrounds. Section 3 explores the impact of anticipated AIA on the informative procedures (informed consent, informed choice) enshrined in Directive 2011/24/EU. Section 6 provides a conclusion.

Hence, the article seeks to analyze the legal implications of AI deployment in the health sector in the context of informative procedures at the EU level.

2. Regulatory framework and conditions for informed consent validity

Currently, EU bodies encourage the use of AI in the health sector[5], given the wide range of benefits it can bring in diagnosis, treatment, patient care, and many others. However, the most recent studies highlight the ineptness of present EU policies to accommodate the

[4] Peng Zhang and Maged N. Kamel Boulos, *Generative AI in Medicine and Healthcare: Promises, Opportunities and Challenges*, in *Future Internet* 15, no. 9 (24 August 2023): 286, https://doi.org/10.3390/fi15090286.such as OpenAI's ChatGPT, that can be prompted to generate various types of content. In this narrative review, we present a selection of representative examples of generative AI applications in medicine and healthcare. We then briefly discuss some associated issues, such as trust, veracity, clinical safety and reliability, privacy, copyrights, ownership, and opportunities, e.g., AI-driven conversational user interfaces for friendlier human-computer interaction. We conclude that generative AI will play an increasingly important role in medicine and healthcare as it further evolves and gets better tailored to the unique settings and requirements of the medical domain and as the laws, policies and regulatory frameworks surrounding its use start taking shape.","container-title":"Future Internet","DOI":"10.3390/fi15090286","ISSN":"1999-5903","issue":"9","journalAbbreviation":"Future Internet","language":"en","page":"286","source":"DOI.org (Crossref

[5] European Parliament. Directorate General for Parliamentary Research Services., *Artificial Intelligence in Healthcare: Applications, Risks, and Ethical and Societal Impacts*. (LU: Publications Office, 2022), https://data.europa.eu/doi/10.2861/568473.

overall concerns and uncertainties regarding informed consent for medical artificial intelligence. As Van Kolfshooten (2022) notes, the current legal framework for healthcare is not yet well adapted for the extended implementation of new technologies[6]. The problem appears to be especially pronounced in the context of preventing EU patients from risks related to the misuse of AI systems and devices and their opaqueness. The hazardous consequences of the aforementioned can be severe and potentially expert a significant impact on the health and life of patients, their privacy, and dignity or generate other negative patients' experiences. As Delhomme (2020) notices, the legislation regarding health in the EU refers to the general framework regarding the internal market of Article 114 TFEU[7], however, according to Article 168 TFEU, the EU has limited competence to influence the health sector at a national level. However, the interconnection of the necessity of health protection due to technological development and promoting equitable access to healthcare across the EU resulted in the adoption of laws such as the Medical Devices Regulation (MDR)[8], In-vitro Medical Devices Regulation (IVDR)[9], the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare[10] and General Data Protection Regulation (GDPR)[11], as a current regulatory framework for informed consent in healthcare at the EU level[12], requires more attention from legislators in order to ensure the patients with safe and conscious use of the AI-driven medical systems and devices.

Firstly, it should be noted that the Article 168 TFEU in conjunction with Directive 2011/24/EU, demonstrates limited EU competence to shape patients' rights and shifts discretion in this regard to Member States' internal law orders. Therefore, the authors agree that there

[6] H. Van Kolfschooten, *EU Regulation of Artificial Intelligence: Challenges for Patients' Rights*, in *Common Market Law Review* 59, no. Issue 1 (1 February 2022): 81–112.

[7] V. Delhomme, *Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health*, in *European Journal of Risk Regulation* 11, no. 4 (December 2020): 747–56.particularly Article 114 TFEU. The use of internal market powers to conduct EU health policy has given rise to several problems, affecting the legitimacy of EU action and its capacity to adequately protect human health. Only a Treaty change can provide the EU with the clear competence and the solid legislative powers that it needs to tackle the various health challenges that Europe faces and will continue to face.","container-title":"European Journal of Risk Regulation","DOI":"10.1017/err.2020.85","ISSN":"1867-299X, 2190-8249","issue":"4","journalAbbreviation":"Eur. j. risk regul.","language":"en","license":"https://www.cambridge.org/core/terms","page":"747-756","source":"DOI.org (Crossref

[8] 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. vol. 117. 2017.

[9] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. vol. 117. 2017.

[10] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

[11] Regulation (EU) 2016/679 if 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).

[12] Excluding clinical trials, see Article 2 of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

is no comprehensive patients' rights protection system at the EU level[13]. Van Kolfschooten (2022) draws attention to the asymmetry caused by limited EU competence in the area of healthcare and the necessity of protection of patients' rights from hazards related to the use of AI at the EU level[14]. However, the anticipated AIA introduces in consequence significant changes to the EU health law, evoked by the necessary protection of fundamental rights. As asserted by the European Commission, the use of new technologies shall not necessarily imply the need for establishing new values[15], AIA highlights the status and importance of the European set of values in healthcare settings in contrast to the Directive 2011/24/EU, which focusses mainly on accessibility to health services. AIA and the extended use of AI in the medical sector provide thus a solid reason for further convergence of healthcare policies, in particular widely impacted by regulations appear the notion of informed consent.

Historically, informed consent as such has been excluded from the regulatory framework of EU law[16] and has been seen more as a prerogative falling within the discretion of Member States. The right to informed consent is present in various international law documents[17] and is affected by multiple human rights protection instruments such as the European Convention of Human Rights (ECHR) or EU Charter of Fundamental Rights (the Charter). Nevertheless, in the European Union, the concept falls within the competence of Member States' internal law as such. Within the realm of European Union law, the notion of informed consent *per se* as a legal instrument is rather related to clinical trials[18]. However, the notion of informed consent in the no-data-driven realm of medical law in the EU, where the medical services under Directive 2011/24/EU have been provided mostly on-site, already raised several questions regarding the efficiency of human rights protection in cross-border healthcare. The use of AI in medicine demonstrates further challenges to patients' rights, particularly due to the slow transition of health services to the online realm. Campiglio (2024) notices that telemedicine services fall under Articles 56 and 57 TFEU but may mean also 'healthcare service' under Directive 2011/24/EU or 'information society

[13] E. Shuster, *Fifty Years Later: The Significance of the Nuremberg Code*, in *New England Journal of Medicine* 337, no. 20 (13 November 1997): 1436–40.

[14] Kolfschooten, *EU Regulation of Artificial Intelligence*.

[15] European Parliament (2023), 'Ethical aspects of artificial intelligence: Challenges and perspectives (EPRS Briefing). Europan Parliamentary Research Service. Available [online: https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739342/EPRS_BRI(2023)739342_EN.pdf] Access: March 1st 2024.

[16] With an exception for Clinical Trials.

[17] For instance, Declaration of Helsinki (2013), The UNESCO Declaration (2005), The Oviedo Convention (1997).

[18] See article 2 of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC . *'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial;*

service' (ISS) defined by the Directive 2000/31/EC of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market[19]. The shifting landscape due to the modernization of healthcare services raises questions about understanding of cross-border healthcare[20] where, for instance, patients seek medical treatment abroad but use medical devices in their home country or *vice versa*. It should be noted that the use of AI increases the accessibility of healthcare[21], combats workforce shortages[22], reduces costs, and improves the quality of health services[23], but also expands towards telemedicine, enabling remote patient monitoring or diagnosis services in diverse EU countries. According to Article 3 letter e of the Directive, a «'cross-border healthcare' means healthcare provided or prescribed in a Member State other than the Member State of affiliation». Hence, with the advances and free movement of services, as well as remote or portable access to such, the concept of cross-border healthcare become vague. Despite the wide range of benefits of artificial intelligence in medicine (AIM) such as increased accuracy, speed, and cost reduction, it created new challenges to patients' rights protection at the EU level, arising, *inter alia*, from accessibility and ubiquitousness of health services as well as portability of medical devices.

These blurred boundaries of cross-border healthcare and the limited scope of patients' rights expressed in the Directive 2011/24/EU require considering a more patient-centered harmonized approach towards informed consent at the EU level, especially due to the progressing digitalization of health services and the expected augmented use of AI in healthcare settings. The current tendency demonstrates thus a shift from constitutionalization of healthcare, related to a no-data-driven realm and significant autonomy and discretion of Member States in making decisions on healthcare, to what Von Kolfshooten (2022) calls «Europeization of health»[24] due to the expanding EU role in human health followed by *inter alia* the digitalization of health services.

It is worth noticing that informed consent has been also affected by progressing "Europeization". Even though Directive 24/2011/EU leaves the notion under the discretion of internal law orders of Member States, introduces the institution of informed choice provided

[19] C. Campiglio, *EU Cross-border Telemedicine: A Partial Harmonisation of Product and Professional Liability?* Available online: https://www.europeanpapers.eu/it/europeanforum/eu-cross-border-telemedicine-partial-harmonisation-product-professional-liability

[20] According to the Article 3 (e) of the Directive 2011/24/EU: 'cross-border healthcare' means healthcare provided or prescribed in a Member State other than the Member State of affiliation.

[21] R. Bhatia, *Telehealth and COVID-19: using technology to accelerate the curve on access and quality healthcare for citizens in India*, Technol. Soc. 64 (2021), 101465, https://doi.org/10.1016/j.techsoc.2020.101465.

[22] I. *Glenn Cohen* et al., eds., *The Future of Medical Device Regulation: Innovation and Protection*, 1st ed. (Cambridge University Press, 2022), https://doi.org/10.1017/9781108975452.

[23] Han Shi Jocelyn Chew and Palakorn Achananuparp, *Perceptions and Needs of Artificial Intelligence in Health Care to Increase Adoption: Scoping Review*, in *Journal of Medical Internet Research* 24, no. 1 (14 January 2022): e32939, https://doi.org/10.2196/32939.

[24] Kolfschooten, *EU Regulation of Artificial Intelligence*.

by National Contacts Points. In that manner, the health tourists have been facilitated to receive important information regarding medical services in the country of destination. This example of "Europeization" of informed consent at a minimum scale allowed EU patients to make more conscious and informed health choices beyond the borders of their home country. Another important change has been brought about by the enactment of GDPR, which mandates the incorporation of EU rules in providing patients with information on treatment due to the digitalization of healthcare. Hence, Article 4 Paragraph 11 of GDPR[25] along with Article 7 GDPR[26] imply additional conditions for informed consent: it must be therefore freely given (with the right to its withdrawal), specific to the processing purpose, informed (communicated clearly and understandably), and unambiguous meaning affirmative and clear action[27]. It is worth noticing that the aforementioned conditions are not related exclusively to healthcare settings and are dedicated to safeguarding the right to privacy in the first place.

Instead, the 'informed consent' within AIA refers to testing in real-world conditions only[28], which indicates maintaining its regulatory discretion within the purview of the Member States. On the other hand, the use of AI compliant with AIA implies a set of new conditions that contrast with the previous not-interfering approach towards informed consent. These significant steps towards "Europeization" and limited harmonization of informed consent seem to provide sustainable solutions in response to significant challenges evoked by the extended use of AI. In particular, it seems necessary to explore the universal conditions for the validity of informed consent in order to ensure consistency and coherence in the coordination of legal standards across a variety of legal systems within the EU as well as due to practical reasons such as the adaptability of those conditions to AI-driven medical systems and devices during the initial stages of manufacturing processes. The unity of established criteria is expected to facilitate cooperation at the EU level and contribute to ensuring patients' rights protection regardless of their location.

According to the UNESCO Declaration of Bioethics and Human Rights (UDBHR), the rightful process of informed consent giving requires four characteristics to be valid: voluntariness, disclosure, understanding, and capacity[29], however, its form and scope still vary

[25] «'consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her».

[26] «'controller' shall be able to demonstrate that the data subject has consented to process of his or her personal data', 'the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language', 'data subject shall have the right to withdraw his or her consent at any time', 'consent is freely given'».

[27] European Data Protection Board, *Process personal data lawfully,* available [online: https://www.edpb.europa.eu/sme-data-protection-guide/process-personal-data-lawfully_en].

[28] See Article 2 Paragraph 44.

[29] E.Y. Zhang, *Informed Consent*, in *Cross-Cultural and Religious Critiques of Informed Consent*, by J. Tham, A. García Gómez, and M.D. Garasic, 1st ed. (London: Routledge, 2021), 59–70, https://doi.org/10.4324/9781003213215-8.

from the country. Instead, Del Carmen and Joffe (2005) distinguished five conditions for informed consent validity rooted in ethical and legal principles governing informed consent in U.S. law, however, its potential has been also noticed in the literature regarding EU coordination on challenges in cross-border healthcare[30]. The authors therefore distinguish voluntarism, capacity, disclosure, understanding, and decision[31] amongst the validity prerequisites. However, due to the development of new AI human-centered technologies, it seems important to consider also the condition of individualism.

Therefore, voluntarism originally refers to the patient's competence to form his will, free from any manipulation, coercion, or controlling influences[32]. It is worth noticing that these are considered red lines for AI development[33], hence the prerequisite is deemed to increase in significance as a similar approach needs to extend to the overall healthcare interventions. The voluntarism, in this case, shall also mean the right to choose analog technologies over AI-driven medical treatment, respecting the patient's limited trust in new technologies and provision of information about the degree of human surveillance according to Article 14 AIA. It is worth noticing that according to Article 4b AIA, the patients need to receive information according to their technical knowledge, experience, education, training, and the context in which the AI systems are supposed to be used. Thus, the information shall evoke no less than neutral feelings in a patient, avoiding persuading choices and exercising patients' trust toward new technologies. The AI literacy requirement contributes to approaching the condition of capacity by assuming the patients' competence to make a decision followed by understanding the provided information and having sufficient health capacity to understand the consequences of their choices.

Understanding assumes the patient fully comprehends the provided information of the choices and their implications[34]. When AI is involved in consent processes the system or device shall possess features such as explainability (Article 14a), transparency (Article 52 AIA), and accountability (Paragraph 14a, Paragraph 38 AIA). As Molnár-Gábor (2020) notices, black-box medicine, as an effect of the lack of explainability and transparency is threatening patient's autonomy in making informed decisions[35] and Bjerring et Al. (2021)

[30] H. Van Kolfschooten, *EU Coordination of Serious Cross-Border Threats to Health: The Implications for Protection of Informed Consent in National Pandemic Policies*, in *European Journal of Risk Regulation* 10, no. 4 (December 2019): 635–51, https://doi.org/10.1017/err.2019.70.

[31] M.G. Del Carmen and S. Joffe, *Informed Consent for Medical Treatment and Research: A Review*, in *The Oncologist* 10, no. 8 (1 September 2005): 636–41, pp. 638

[32] Van Kolfschooten, *EU Coordination of Serious Cross-Border Threats to Health*.

[33] HLEG, Ethics guidelines for trustworthy AI. Brussels: European Commission; 2019.

[34] Van Kolfschooten, *EU Coordination of Serious Cross-Border Threats to Health*.

[35] F. Molnár-Gábor, *Artificial intelligence in healthcare: doctors, patients and liabilities*. In: Wischmeyer T., T. R, editors. *Regulating artificial intelligence*: Springer; 2020.

argue that it speaks against ideals of patient-centered AIM[36]. Triberti et Al. (2020) instead, distinguishes so-called 'decision paralysis' due to the lack of explainability caused by the trust issues related to the use of AI tools[37]. However, Saubrei et al. (2023) argue that the condition for explainability and transparency can be compromised in favor of fostering the doctor-patient relationship and focusing on the certainty or accuracy offered by the tool, as opposed to high transparency or explainability[38]. As raised in the literature, AIM promises to increase the accuracy, accessibility and efficiency of outcomes[39], therefore it appears vital to consider, whether these benefits have the potential to compromise patients' limited understanding of the algorithms. Hence, Hummel et Al. (2020) propose that as a solution, the ethical AIM should focus on controlling information flows and a necessity of output orientation[40]. However, should be argued that from the patients' perspective, it seems justified the need to be acknowledged input (meaning the type of data shared with a device) and output, meaning the result of the health service provided and its further implications. A condition of disclosure instead, involves providing the patient with all the necessary information in order to fully understand the treatment, including its aim, character, risks benefits, and other available alternative options[41]. The need to provide a patient with information that the treatment will be supported by AI seems to be justified due to a variety of patients' dispositions towards new technologies. Moreover, due to hazardous effects related to the use of AI such as biases leading to discrimination, privacy, and opaqueness of the tools, Article 7 AIA provides necessary risk assessment for the systems and devices. Article 9.1. AIA stipulates that a risk management system shall be established, implemented, documented, and maintained in relation to high-risk AI systems, which includes overall AI-driven medical tools. All AI technologies must be therefore traceable and kept abreast of surveillance throughout its whole lifecycle. The obligation of detecting and reacting to risks is an important step towards the safe use of such systems and devices that ensure trust in new technologies. Hence, should be noted, that in the context of AI healthcare, the condition of disclosure shall involve also unpredictable risks, therefore it is important to highlight the prerequisite of the use of AI as well as inform the patient of the possibility of encountering unpredicted hazards.

[36] J.C. Bjerring and J. Busch, *Artificial Intelligence and Patient-Centered Decision-Making*, in *Philosophy & Technology* 34, no. 2 (June 2021): 349–71.

[37] S. Triberti, I. Durosini, and G. Pravettoni, *A "Third Wheel" Effect in Health Decision Making Involving Artificial Entities: A Psychological Perspective*', in *Frontiers in Public Health* 8 (28 April 2020): 117.

[38] A. Sauerbrei et al., *The Impact of Artificial Intelligence on the Person-Centred, Doctor-Patient Relationship: Some Problems and Solutions*, in *BMC Medical Informatics and Decision Making* 23, no. 1 (20 April 2023): 73.

[39] Amisha et al., *Overview of Artificial Intelligence in Medicine*, in *Journal of Family Medicine and Primary Care* 8, no. 7 (2019): 2328, https://doi.org/10.4103/jfmpc.jfmpc_440_19.

[40] P. Hummel and M. Braun, *Just Data? Solidarity and Justice in Data-Driven Medicine*, in *Life Sciences, Society and Policy* 16, no. 1 (December 2020): 8, https://doi.org/10.1186/s40504-020-00101-7.

[41] Van Kolfschooten, *EU Coordination of Serious Cross-Border Threats to Health*.

3. Individualism as a condition for informed consent AIM

The importance of fundamental rights protection from the risks emerging from the misuse of AI systems and devices or its opaqueness has been highlighted at the very early stages of regulation development and policymaking[42]. Therefore, at the present shape, the AIA, in numerous provisions[43], underscores the significance of human-centered AI. The increased applicability of medical devices that fall under the EU Regulation MDR and the evolving nature of AI raises a pressing need to adapt current regulatory frameworks and patients' rights to the realm of sustainable AI at the level of European Union law. Managing healthcare policies requires a complex approach involving attention and sensitivity to inclusion, diversity, and constant monitoring. Informed consent is considered a fundamental principle for human rights protection in healthcare settings[44]. The Europeization of medical law implies the respect for the EU common European values expressed in Article 2 TEU, such as consideration of individual beliefs and respecting complex EU identity, as well as the support for diversity. The anticipated AIA and the application of AI in medical systems and devices involves prioritization of EU system fundamental rights protection. However, should be highlighted that human rights protection regulations are living instruments and must be interpreted in the time and conditions of present circumstances[45], hence the changes the technological development brought constitute now a set point for assessment of human rights protection performance. Among these, the use of AI leaves challenges the

[42] See for instance: European Comission, *White Paper On Artificial Intelligence - A European approach to excellence and trust* of February 19th 2020. Available [online: https://commission.europa.eu/document/download/d2ec4039-c5be-423a-81ef-b9e44e79825b_en?filename=commission-white-paper-artificial-intelligence-feb2020_en.pdf]

[43] See for instance Articles: 1,1c 6, 7, 9, 10, 14, 29a, 40, 65, 67… AIA.

[44] M. Pallocci et al., *Informed Consent: Legal Obligation or Cornerstone of the Care Relationship?*, in *International Journal of Environmental Research and Public Health* 20, no. 3 (24 January 2023): 2118, https://doi.org/10.3390/ijerph20032118. both in the ethical-deontological field and as a duty of law. The review covered all sentences issued by the 13th section of the Civil Court of Rome during the period January 2016–December 2020. During this period, 156 judgments were found in which a breach of consent was required; in 24 of these, specific liability was proven, and the corresponding compensation liquidated. Moreover, 80% of the cases concerned the lack of information provided. The most involved branches were those related to surgical areas: general surgery, plastic surgery and aesthetic medicine and orthopaedics. The total amount of compensation paid was EUR 287,144.59. The research carried out has highlighted how, in a broad jurisprudential context, the damage caused by the violation of the right related to informed consent is considered, and how it impacts on the economic compensation of damages. Additionally, it showed that the areas most affected by the information deficit are those related to the performance of surgical activities, which are characterized by greater invasiveness and a higher risk of adverse events. The data reported underline the exigency to consider informed consent not as a mere documentary allegation but as an essential moment in the construction of a valid therapeutic alliance, which is also useful for avoiding unnecessary litigation that is becoming increasingly burdensome for healthcare systems all over the world.","container-title":"International Journal of Environmental Research and Public Health","DOI":"10.3390/ijerph20032118","ISSN":"1660-4601","issue":"3","journalAbbreviation":"IJERPH","language":"en","license":"https://creativecommons.org/licenses/by/4.0/","page":"2118","source":"DOI.org (Crossref

[45] 70 years of the European Convention on Human Rights. (2020). Available [online: https://www.coe.int/uk/web/kyiv/-/70-years-of-the-european-convention-on-human-rights].

right to self-determination due to its properties such as opaqueness, black-box medicine, or unpredictability.

Current technological advances indicate the tendency for more personalized healthcare due to its expected augmented accuracy and more satisfactory outcomes[46]. Since 2019, Longoni et Al. (2019) have highlighted the "uniqueness" of patients' circumstances and characteristics and called for more personalized AI healthcare to curb uniqueness neglect[47]. The individualized approach aims to tailor the medical services for the specific needs and characteristics of a patient, therefore not only contributing to better results. It is deemed also to enhance patient-doctor relationships and communication[48]. On the flip side of this coin, however, arises a need to adapt rules governing informed consent to these new conditions. Therefore, a necessity to distinguish individualism as a condition for informed consent validity appears to respond to a part of the challenges resulting from a changing catalogue of risks emerging from the use of AI and personalized medicine. The evolving landscape of regulations on AI require thus individual approach to patients with respect to their individual set of values, preferences, beliefs, and identity**.** A similar approach is already present in Italian Law 219/2017[49], where it takes to consider patients' individual resources, values, fragility, and beliefs[50].

A *rationale* for distinguishing the concept lays resistance towards so-called dehumanization caused by AI, meaning depicting, regarding, or treating less than human or not as human[51]. A study by Formosa et Al. (2022) determined patients' preference to grant competence in decision-making to human practitioners and perceived AI as dehumanizing[52]. To this end, Bender (2024) suggests decentering 'default' or 'unmarked' characteristics, features, or identities (such as language, skin color, education level, economic status, and many others) from AI systems stating: «A system is not accurate if it is not accurate for everybody: If it is failing people of color it is failing»[53]. Moreover, a personalized approach might appear as an effective tool against unnecessary algorithmic bias and contribute to

[46] A. Blasiak, J. Khong and T. Kee, *CURATE.AI: Optimizing Personalized Medicine with Artificial Intelligence*, in*SLAS Technology* 25, no. 2 (April 2020): 95–105.

[47] C. Longoni, A. Bonezzi and C.K Morewedge, *Resistance to Medical Artificial Intelligence*, in *Journal of Consumer Research* 46, no. 4 (1 December 2019): 629–50.

[48] First edition (New York, NY: Basic Books, 2019).

[49] Legge 22 Dicembre 2017 n. 219 "Norme in materia di consenso informato e di disposizioni anticipate di trattamento". Gazzetta Ufficiale della Repubblica Italiana S.G. n. 12, 16 January 2018.

[50] M. Di Paolo, F. Gori, L. Papi *et al.*, A review and analysis of new Italian law 219/2017: 'provisions for informed consent and advance directives treatment'. *BMC Med Ethics* 20, 17 (2019).

[51] M. Kronfeldner, *The Routledge Handbook of Dehumanization*, ed. Maria Kronfeldner, 1st ed. (Abingdon, Oxon ; New York, NY: Routledge, 2021. | Series: Routledge handbooks in philosophy: Routledge, 2021).

[52] P. Formosa et al., *Medical AI and Human Dignity: Contrasting Perceptions of Human and Artificially Intelligent (AI) Decision Making in Diagnostic and Medical Resource Allocation Contexts*, in *Computers in Human Behavior* 133 (August 2022): 107296.

[53] Bender, Emily M. 2024. Resisting Dehumanization in the Age of "AI". Current Directions in Psychological Science 33(2):114-120

the protection of human dignity. Respecting patients' values, beliefs, and preferences, should have continuous character and does not cease with the distribution of a system or device in the market (as it requires post-market surveillance[54]), but also requires continuous surveillance over the process of obtaining informed consent and its eventual consequences. In the case of personalized medicine, the patient's identity is of importance each time obtaining informed consent. For instance, it is worth underlining the complexity of their identity, along with the multitude of cultural, religious, and linguistic backgrounds involved following Article 22 of the Charter. However, following the CJEU judgment C-459/13 claimed a lack of jurisdiction over the Member States' mandate concerning – in this case – consent for vaccination of young children to address its conformity with Charter[55]. Therefore, it should be assumed a probability of undertaking a similar approach in the case of informed consent prerequisites which explains the necessity of establishing common standards at the EU level. Due to the Europeization of medical law, extended use of the AIM regulated, *inter alia*, by anticipated AIA and GDPR patients' individualism condition for informed consent baseline shall thus be explored from the lens of the EU fundamental rights protection landscape and considered already at the stage of the design of a system or a device, eventually during human rights assessment.

Hence, particularly important for the condition of patient individualism are the provisions of the Charter of Fundamental Rights of the European Union, especially Article 3 stating the right of integrity of the person, which safeguards the right to "free informed consent"[56]. No less important in the era of AI are Articles 7 and 8 CFR, stating that the personal data need to be processed under (patient's) consent. At the level of the Council of Europe, Article 3 of the European Convention of Human Rights states that «in the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law». A lack of informed consent can possibly violate also Article 8 of the Convention[57]. With no less importance shall be considered provisions of the European Convention on Human Rights and Biomedicine, where Article 5 states: «An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as its consequences and risks. The person concerned may freely withdraw consent at any time». Therefore, it is important to highlight that the consent un-

[54] AIA, Articles 61 and following.

[55] CJEU judgment C-459/13 *Milica Široká*, §§ 25–27 – ECLI:EU:C:2014:2120.

[56] A de Ruijter, *The Impediment of Health Laws in Values in the Constitutional Setting of the EU*, in TK Hervey et al (eds), *Research Handbook on EU Health Law and Policy* (Cheltenham, Edward Elgar 2017) pp 486–487.

[57] W. Buelens, C. Herijgers, and S. Illegems, *The View of the European Court of Human Rights on Competent Patients' Right of Informed Consent. Research in the Light of Articles 3 and 8 of the European Convention on Human Rights*, in *European Journal of Health Law* 23, no. 5 (28 October 2016): 481–509. pp. 28.

der GDPR stems from Article 8 of the EU Charter of Fundamental Rights. The demonstrated human rights dimension of informed consent requires however further clarification, or as Amini et. Al (2023) indicates, practical and robust ethical guidelines for medical AI[58]. AIA implements, for instance, a requirement for human rights assessment, which refers to the identification and mitigation of risks to assure that AI systems protect and respect fundamental rights[59]. In the context of this study, human rights assessment shall be carried out before a patient provides free, informed consent for the use of AI. At this place, most importantly should be noted that authors draw attention to the multilayered structure of vulnerabilities of the patients and the changing catalog of risks[60]. To mitigate the negative effect of the technology and protect patients' identities it is recommended to advocate for patient-centered, inclusive design of the AIM systems and devices, innovative human rights risk assessments, and also fostering the relationship between patient and medical practitioners.

Hence, Kuran et al. (2020) notice that the vulnerability «stems from various interconnected social processes that lead to multiple dimensions of marginalization». Therefore, particularly important are factors such as gender, ethnicity, health, age, economic status, and other, that require further studies on interconnectedness[61]. Novelli et al. (2023) develop two vulnerabilities in risk assessment within AIA – a generic one, which represents the entitlement to fundamental rights, and a specific one, based on the Article 5 AIA, which considers a patient's age, and physical and mental disability[62]. However, it should be noted that due to EU citizens' complex identity shall be distinguished also the type of vulnerability prone to biases, that manifest in individual beliefs and multilayered cultural, religious, linguistic, and social diversity. Luna (2019) notices that vulnerability needs to be approached as a multi-layered condition[63]. McDougall (2019) adds to that AI-driven machines should be designed with consideration of plurality, which means taking into account patients' personal preferences and priorities. The author finds also a link between the value of plurality and the patient's autonomy[64]. Instead, Norori et Al. (2021), suggest training AI algorithms on representative samples and creating guidelines to make algorithms more inclusive and

[58] M. Amini et al., *Artificial Intelligence Ethics and Challenges in Healthcare Applications: A Comprehensive Review in the Context of the European GDPR Mandate*, in *Machine Learning and Knowledge Extraction* 5, no. 3 (7 August 2023): 1023–35.

[59] AIA, Article 29a.

[60] M. Amini et al., *Artificial Intelligence Ethics and Challenges in Healthcare Applications*.

[61] C.H.A. Kuran et al., 'Vulnerability and Vulnerable Groups from an Intersectionality Perspective', *International Journal of Disaster Risk Reduction* 50 (November 2020): 101826.

[62] C. Novelli, F. Casolari, A. Rotolo, T. Antonino, M. Taddeo and L. Floridi, *AI Risk Assessment: A Scenario-Based*, Proportional Methodology for the AI Act (May 31, 2023). Available at SSRN: https://ssrn.com/abstract=4464783 or http://dx.doi.org/10.2139/ssrn.4464783

[63] F. Luna, *Identifying and evaluating layers of vulnerability - a way forward*. Dev World Bioeth 2019; 19(2):86–95.

[64] RJ. McDougall, *Computer knows best? The need for value-flexibility in medical AI. J Med Ethics*. 2019;45(3):156.

equitable, in particular propose incorporating open science principles into the design and evaluation of AI.

As regards the patient-healthcare provider relationship, due to anticipated extended use of AI, it is supposed that practitioners will have more time to build positive relationships with patients[65] which responds to one of the downsides of AIM - a lack of empathy. Kerasidou (2018) describes empathy as the ability to understand other person's points of view, their experiences of illness, and feeling motivated to help them[66] as well as their values and goals[67], which the technology is able to only imitate. Therefore, there is a need to highlight the values of empathy, trust, and compassion in healthcare[68] out of which Bauchat et Al.(2016) consider empathy as a cornerstone of ethical person-centered care[69]. These claims are supported by several studies[70].

Saurebrei et al. (2023) notice that doctors and patients should therefore engage in meaningful discussions and dedicate time to develop empathy[71]. The above-mentioned approach empowers the patients in decision-making and fulfills the recommendations found in the literature that healthcare practitioners and patients must develop an open dialogue and build trust[72]. At this point it is important to draw attention to compulsory AI literacy of the users, as well as Saurabrei et al. (2023) indicate, a necessity of maintaining the assistive role of AI in healthcare settings and adapting medical education to the AI-assisted realm. Above mentioned solutions altogether are deemed to improve relationships between a patient and doctor[73]. It is also worth noticing that Article 52 states that providers shall ensure that patients are informed that they are interacting with the system. This implies the possibility of refusing treatment options involving the use of AI. It is also important to highlight the continousness of informed consent and changing patient's needs.

---

[65] E.J. Topol and A. Verghese, *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again*, First edition (New York, NY: Basic Books, 2019).

[66] A. Kerasidou, R. Horn, *Empathy in healthcare: the limits and scope of empathy in public and private systems*. In: T. Feiler, J. Hordern, A. Papanikitas, editors. Routledge; 2018.

[67] JR Bauchat, M. Seropian, PR. Jeffries, *Communication and empathy in the patient-centered care model—why simulation-based training is not optional*. Clin Simul Nurs. 2016;12(8):356–9.

[68] A. Kerasidou, *Bull World Health Organ*. 2020;98(4):245–50.

[69] Bauchat JR, Seropian M, Jeffries PR. Communication and empathy in the patient-centered care model—why simulation-based training is not optional. Clin Simul Nurs. 2016;12(8):356–9.

[70] See: J. Moss, MB. Roberts, L. Shea, CW. Jones, H. Kilgannon, DE. Edmondson et al. *Healthcare provider compassion is associated with lower PTSD symptoms among patients with life-threatening medical emergencies: a prospective cohort study*. Intensive Care Med. 2019;45(6):815–22. SS. Kim, S. Kaplowitz, MV. Johnston, *The effects of physician empathy on patient satisfaction and compliance*. Eval Health Prof. 2004;27(3):237–51. M. Hojat, DZ. Louis, FW. Markham, R. Wender, C. Rabinowitz, JS. Gonnella, *Physicians' empathy and clinical outcomes for diabetic patients*. Acad Med. 2011;86(3):359–64. SW. Mercer, M. Neumann, M. Wirtz, B. Fitzpatrick, G. Vojt, General practitioner empathy, patient enablement, and patient-reported outcomes in primary care in an area of high socio-economic deprivation in Scotland—A pilot prospective study using structural equation modeling. Patient Educ Couns. 2008;73(2):240–5.

[71] Sauerbrei et al., *The Impact of Artificial Intelligence on the Person-Centred, Doctor-Patient Relationship*.

[72] JJ. Chin, *Doctor-patient relationship: a covenant of trust*. Singapore Med J. 2001;42(12):579.

[73] Saurebrei et al.

The condition of patient individualism in informed consent means thus the special attention to fundamental rights and empathetic, patient-centered AIM. This condition assumes the complexity of EU citizen identity, individual beliefs, and preferences in order to meet the patient's most complex needs.

4. Impact AIA on Directive 2011/24/EU in the context of informed consent

The AIA appears to demonstrate a significant impact on the Directive 2011/24/EU and the understanding of cross-border healthcare within the EU law. While the economic approach to patients' rights in the Directive has been criticized in Literature[74], one of the most important objectives of the AIA is the ethical use of new technologies with respect to human rights. Another important difference is demonstrated in the fact that the Directive aims to provide rules for facilitating access to services across the EU and promotes cooperation on healthcare at the EU level whilst respecting national competencies in this regard[75], meanwhile, the AIA objectives related to human rights protection and ethical use of AI are supposed to significantly impact Member State's law orders. The solution enables, therefore, more efficient implementation of provisions: Article 2 TEU and Article 6(3) TEU in healthcare settings. However, in order to comprehend the impact of the AIA on Directive 2011/24 EU in the context of obtaining valid informed consent, it is necessary to examine the informative procedures resulting from the Directive.

Presently, EU patients are entitled to two rights regarding information procedures to the treatment on the grounds of Directive 2011/24/EU: informed consent and informed choice. The distinction of the concepts in the context of the regulation is necessary to provide the health tourists with the rights of the EU citizens and consumers respectively. Informed choice is therefore an expansion towards "consumer" patients' rights[76], which is more linked to the quality, range, and prices of medical services but also imposes responsibility for providing all the necessary information related to the treatment. The Directive 2011/24/EU provides informational procedures by the creation of National Contact Points (NCPs). The NCPs are supposed to share healthcare information on medical services in their territory upon patients' request such as information concerning standards and guidelines[77], measures to settle disputes and information on complaints procedures or healthcare pro-

[74] Directive 2011/24/EU, Article 1(2).

[75] See Directive 2011/24/EU Article 1(1).

[76] D. Delnoij and W. Sauter, *Patient Information under the EU Patients' Rights Directive*, in *The European Journal of Public Health* 21, no. 3 (1 June 2011): 271–72, https://doi.org/10.1093/eurpub/ckr053.

[77] See article 4(2) of the Directive 2011/24/EU.

viders and their rights, and any restrictions on medical treatment that exist[78]. Informed choice, following the Directive, includes the information that NCPs provide and other specified information, such as (1) the main aspects of cross-border healthcare (Recital 49) in any of the official languages of the Member State in which the contact points are situated. The information may be also provided in any other language (Recital 48). According to Article 4 of the Directive, the information includes also (2) treatment options, (3) availability, (4) quality and safety of the healthcare they provide in the Member State of treatment, and clear information on (5) invoices and prices, as well as (6) on their authorization or registration status, (7) their insurance cover or other means of personal or collective protection in view of professional liability. There is no research evidence on how NCPs and human rights protection intersect, however, it is worth mentioning that given that NCPs can be valuable intermediaries in providing information, they have a strong potential to contribute to the realization of EU human rights protection objectives, also those included in the AIA. Hence, it is important to stress the importance of AI literacy and engage in dialogues with patients. Therefore, should be noted that anticipated AIA impacts NCPs' duties and imposes additional obligations on them regarding human rights protection. Informed choice, in contrast with informed consent, is a legal institution embedded in EU law. Informed consent, on the other hand, is a prerequisite for medical intervention, rooted in the fundamental right of self-determination[79] as mentioned before, requires voluntariness, disclosure, understanding, capacity[80], and individualism to be valid, including the requirement for understanding the nature of procedure, risks and benefits[81] and needs to be from racial discrimination[82]. The purpose of informed consent is thus to allow a patient to express their free will[83] and exercise their right to self-determination[84]. It is worth noticing that it has also linguistic[85], religious, cultural and social[86] dimensions and allows one to make a choice aligned with the patient's identity. As a rule, the notion

[78] S. Callens, N. Van Gompel, *Guiding Principles and Indicators for the practice of National Contact Points* (NCPs) under the Cross-border Healthcare Directive 2011/24/EU' (2018) [available online: https://health.ec.europa.eu/system/files/201912/2019_ncptoolbox_ncp_guiding_principles_crossborder_en_0.pdf]

[79] Right Docs, *Free, prior and informed consent: a human rights-based approach - Study of the Expert Mechanism on the Rights of Indigenous Peoples*, access online [https://www.right-docs.org/doc/a-hrc-39-62/]

[80] Del Carmen and Joffe, *Informed Consent for Medical Treatment and Research*.

[81] C.P. Selinger *The right to consent: Is it absolute?* British Journal of Medical Practitioners, June 2009 (2/2) pp. 50-54.

[82] Guaranteed by the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights and the International Convention on the Elimination of All Forms of Racial Discrimination.

[83] T. Zürcher, B. Elger & M. Trachsel, *The notion of free will and its ethical relevance for decision-making capacity*. BMC Med Ethics 20, 31 (2019).

[84] J. Katz, *The Silent World of Doctor and Patient* (New York: Free Press, 1984) pp.105.

[85] In France, translation services for healthcare are not covered by the Member State.

[86] Right Docs, *Free (…),* access online [https://www.right-docs.org/doc/a-hrc-39-62/].

of informed consent[87] shall imply the requirement that the medical services are provided respectfully to the autonomy, self-determination, and human dignity of the patient[88]. The above-mentioned is particularly important in the realm of EU citizens' complex identity. Bulton and Parker's (2007) analysis rightfully calls for a more sociological approach to informed consent with consideration of its socially constructed, changing, and multi-layered nature[89]. Linguistic and cultural barriers to informed consent have a significant impact on decision-making and can distort the process of information exchange[90]. Present solutions require the assistance of qualified interpreters to be involved in the informed consent-giving process, especially in the case of disabled and other vulnerable persons[91]. Within the realm of AIM, the level of trust of the users can be influenced also by environmental, cultural, and organizational factors[92].

A progressive Europeization of medical law in the EU, an anticipated increase of significance and implementation of AI in healthcare as well as consequences emerging from the intersection of regulations AIA, MDR, and GDPR imply the need for (limited) harmonization of principles governing informed consent at the EU level in a way that respects complex identity, personal values and preferences of AI citizens. Informed consent shall therefore include a condition of patient individualism rooted in the EU fundamental rights landscape. To facilitate the patients providing informed consent under this condition, it is required to perform a human rights assessment provided by the anticipated AIA, including the ethical, inclusive design of the systems and devices and fostering the patient-healthcare provider relationships, with consideration of patient vulnerability and promoting empathy and inclusion.

5. Conclusions

Prior to concluding it is worth mentioning that this study has certain limitations. Firstly, it is not focused on any particular healthcare service. It is possible that the relevant issues

[87] The concept has long tradition and evolves since the resolution of the Nuremberg Code from 1946, subsequently the Declaration of Helsinki, enacted by the World Medical Association in 1964 and regularly updated ever since.

[88] F. La Rue, UN. Secretary-General, UN. Human Rights Council, Special Rapporteur on the Promotion and Protection of the Right to Freedom of Opinion and Expression, *Promotion and protection of human rights: human rights questions, including alternative approaches for improving the effective enjoyment of human rights and fundamental freedoms* (2012). Available [online: https://digitallibrary.un.org/record/805706].

[89] M. Boulton, M. Parker, *Informed consent*, pp. 2187-2198.

[90] C. Seelman, J. Suurmond, *Shared decision-making in an intercultural context: barriers in the interaction between physicians and immigrant patients*. Patient Educ Couns 60(2/2006) pp. 253–259.

[91] S. Chima, *Language as a Barrier to Informed Consent and Patient Communications in South African Hospitals-A Working Paper*, The Asian Conference on Ethics, Religion & Philosophy (2018). Available [online:https://www.researchgate.net/publication/325381943_Language_as_a_Barrier_to_Informed_Consent_and_Patient_Communications_in_South_African_Hospitals-A_Working_Paper]. Accessed: 17 April 2023.

[92] N.C Benda et al., *Trust in AI: Why We Should Be Designing for APPROPRIATE Reliance*, in *Journal of the American Medical Informatics Association* 29, no. 1 (28 December 2021): 207–12, https://doi.org/10.1093/jamia/ocab238.

may vary from medical use or service. Moreover, debates surrounding the use of AIM are speculative due to the limitations of the implementation of AIM in practice.
The explosion of AI technologies for healthcare has had a significant impact on the legal landscape regarding patients' rights in the EU, in particular the notion of informed consent. At present, Directive 2011/24/EU focuses rather on economic aspects of cross-border healthcare and demonstrates the limited scope of patients' rights. However, the progressing "Europeization" of health caused by digitalization introduces a wide catalogue of patient's rights, present for instance in GDPR and AIA. While the EU aims to respect the ethical choices of Member States and leaves health policies at the discretion of Member States, it is possible to develop standardized conditions for informed consent at the EU level facilitating harmonization and safeguarding patients' rights from violations caused by the misuse of modern technologies. Analyzed in the literature conditions for valid informed consent include voluntarism, capacity, understanding, and decision[93] which are susceptible to the use of AIM. However, in the realm of EU law and extended deployment of AI in the health sector, there should be considered also the condition of patient individualism. The solution is aimed at promoting human-centered AI respecting the individual set of values of each person as well as the preferences, beliefs, and complex identity of EU citizens. Therefore, it is necessary to search for an informed consent model that is immune to sociological variable contexts, with respect to the diversity of EU citizens. The implementation of the condition of individualism should be therefore aligned with the overall of EU fundamental rights landscape and considered during the process of human rights assessment at the early stages of the design of a medical device. Under the influence of technological progress, the new EU laws, policies, and standards require effective further exploration to facilitate the patients' safe and ethical use of AI-driven systems and devices in healthcare settings. It is worth noticing that following Article 168 TFEU «measures setting high standards of quality and safety for medicinal products and devices for medical use» shall be perceived as shared competence with Member States in accordance with Article 4 TEU. Thus, it is worth remembering that a minimum harmonization approach still remains one of the objectives for current policymaking[94], however in case of the informed consent and in view of the consequences the misuse or opaqueness of new technologies can cause it should be concluded that the practical application of AI cannot lead to a situation where patients' rights are being compromised.

[93] Del Carmen and Joffe, *Informed Consent for Medical Treatment and Research*.

[94] European Parliament (2023), 'Ethical ascpects of artificial intelligence: Challenges and perspectives (EPRS Briefing). Europan Parliamentary Research Service. Available [online: https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739342/EPRS_BRI(2023)739342_EN.pdf] Access: March 1st 2024.