EU Regulation of Artificial Intelligence: Challenges for Patients' Rights

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Abstract: In order to create a well-functioning internal market for Artificial Intelligence (AI)-systems, the European Commission recently proposed the Artificial Intelligence Act. However, this legislative proposal pays limited attention to the health-specific risks the use of AI poses to patients' rights. This article outlines that fundamental rights impacts associated with AI such as discrimination, diminished privacy and opaque decision-making are exacerbated in the context of health and may threaten the protection of foundational values and core patients' rights. However, while the EU is facilitating and promoting the use and availability of AI in the health sector in Europe via the Digital Single Market, it is unclear whether it can provide the concomitant patients' rights protection. This article theorises the Europeanisation of health AI by exploring legal challenges through a patients' rights lens in order to determine if the European regulatory approach for AI provides for sufficient protection to patients' rights.

Keywords: health law, artificial intelligence, patients' rights, fundamental rights, digital single market, EU governance, EU regulation

1. Introduction

The European Union (EU) stands on the brink of an artificial intelligence (AI) revolution in the health sector. AI is the umbrella term for systems designed by humans that display rational behaviour by analysing their environment through the collection and interpretation of data and reasoning and processing of information derived from this data, subsequently deciding on the best action to achieve a given goal, and acting accordingly.[1] AI technologies can be deployed for many aspects of healthcare and public health: from AI-software to detect breast cancer in screening mammograms,[2] AI-algorithms predicting outbreaks of infectious

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[1] Independent High Level Expert Group on Artificial Intelligence, A Definition of AI: Main Capabilities and Disciplines, 2019.

[2] McKinney *et al.*, "International evaluation of an AI system for breast cancer screening", 577 *Nature* (2020), 89–94.

diseases,[3] AI-powered wearable devices for remote patient monitoring[4] and fully autonomous robotic surgeons.[5] AI holds the promise to save billions of lives by improving the quality of healthcare, reducing costs, increasing accessibility of healthcare and anticipating health emergency threats.[6] At the same time, AI can bring about serious risks for individual fundamental rights, such as human dignity, privacy and non-discrimination.[7] In reaction to these challenges, the European Commission recently put forward a legislative proposal for regulation of AI: the Artificial Intelligence Act.[8] The central position in the regulation of the EU internal market and the transboundary nature of the building blocks of AI (data, internet) explain the Commission's initiative to regulate AI.[9] The proposal aims to offer a balanced approach to regulation of AI, that ensures effective protection of fundamental rights, without hindering the socio-economic benefits of AI and technological innovation.

The deployment of AI in the context of health may demand even closer attention to its potential detrimental effects for patients. AI-driven technologies are slowly transforming the health sector and will likely change the health professional-patient relationship and affect patients' rights.[10] Potential hazardous effects associated with AI such as discrimination, diminished privacy and opaque decision-making are exacerbated in the context of health and may threaten the protection of core patients' rights and the interconnected principles of autonomy, human dignity and trust. This is due to the vulnerability and dependency of patients when they are in need of healthcare, the potentially life-threatening effects of inaccurate or dysfunctional AI technology used in the health environment, and the problems arising from the nature of AI, such as lack of transparency and the reliance on enormous amounts of personal (health) data.[11] As technology is preceding legal developments, it is doubtful whether the current framework for patients' rights protection in Europe is

[3] McCall, "COVID-19 and artificial intelligence: protecting health-care workers and curbing the spread", 2 *The Lancet Digital Health* (2020), e166–e167.

[4] 'FDA Approves Current Health AI-Powered Wearable Solution for Hospital Care' (*NS Medical Devices*, 7 February 2019).

[5] Aruni, Amit, and Dasgupta, "New surgical robots on the horizon and the potential role of artificial intelligence", 59 *Investigative and Clinical Urology* (2018), 221–222.

[6] Matheny *et al.*, *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril. NAM Special Publication.* (National Academy of Medicine, 2019).

[7] European Union Agency for Fundamental Rights, Data quality and artificial intelligence - mitigating bias and error to protect fundamental rights, 2019.

[8] European Commission, *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*, COM(2021) 206 final.

[9] Ibid.

[10] Dalton-Brown, "The Ethics of Medical AI and the Physician-Patient Relationship", 29 *Cambridge Quarterly of Healthcare Ethics* (2020), 115–121.

[11] Agrebi and Larbi, 'Use of Artificial Intelligence in Infectious Diseases' [2020] Artificial Intelligence in Precision Health 415; *Metz and Smith, C.S.*, Warnings of a Dark Side to A.I. in Health Care, The New York Times, 21/03/2019.

sufficiently adapted to the impact of AI technology on patients. In this regard, the new Artificial Intelligence Act (AIA), with the objective of protecting fundamental rights in general, may contribute to the protection of patients' rights in the context of health AI.

The potential threat of health AI for patients' rights is further compounded by the legal challenges surrounding EU involvement in health-related issues. Creating an EU regulatory and legislative framework in the field of AI is complex: the EU is faced with the difficult task of striking a balance between innovation and individual interests, rights and values.[12] In the case of health AI, the traditional positioning of the EU in the area of health may further complicate adequate regulation. While the EU holds a key position in the regulation of the internal market, therefore facilitating the availability of health AI on the EU market, the EU has limited competence to directly regulate health. The principle of subsidiarity limits the EU's powers in the protection of patients' rights, as healthcare is a national competence, [13] and the EU does not have a general competence to take action to protect fundamental rights.[14] As a result, there is no comprehensive legal system for patients' rights protection at the EU level.[15] Most EU legislation in the field of health is based on the internal market legal basis of Article 114 TFEU.[16] The EU legal instruments that do directly regulate health, such as the Medical Devices Regulation (MDR) and the General Data Protection Regulation (GDPR), are not necessarily adapted to the specific challenges AI brings about and do not provide a complete solution to its threats for patients.[17] In the context of health AI, these limitations seem to lead to a disconnect. The EU is facilitating and promoting the use and availability of AI in the health sector in Europe, but it is unclear whether it can provide the concomitant protections for patients' rights. This legal gap may lead to the neglect of the position of patients in Europe when health AI becomes common practice. This begs the following question: does the European approach for AI provide protection to patients' rights in light of the current legislative framework?

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[12] Matheny *et al.*, *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril. NAM Special Publication.* (National Academy of Medicine, 2019).

[13] Art. 168 TFEU; Scott L. Greer, N. Fahy, and S. Rozenblum, *Everything you always wanted to know about European Union health policies but were afraid to ask*, Second, revised edition. (European Observatory on Health Systems and Policies, 2019).

[14] Beijer, "EU Competences and Subsidiarity in Fundamental Rights Protection" in, *Limits of Fundamental Rights Protection by the EU: The Scope for the Development of Positive Obligations* (Intersentia, 2017), pp. 179–220.

[15] Shuster, "Fifty Years Later: The Significance of the Nuremberg Code", 337 *New England Journal of Medicine* (1997), 1436–1440.

[16] Delhomme, "Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health", 11 *European Journal of Risk Regulation* (2020), 747–756; Garben, "Competence Creep Revisited", 57 *JCMS: Journal of Common Market Studies* (2019), 205–222; Case C-376/98, Germany v. European Parliament and Council (tobacco advertising). Judgment of the Full Court of 5 October 2000, [2000] ECR I-8419.

[17] Cohen, I.G. *et al.*, "The European artificial intelligence strategy: implications and challenges for digital health", 2 *The Lancet Digital Health* (2020), e376–e379.

This article examines the ways health AI is and will be regulated at the EU level and explores legal challenges through a patients' rights lens. Section 2 describes the legal framework for patients' right protection in Europe, which is traditionally situated at the national level and is gradually developing at the EU level. Section 3 explains the nature of health AI and analyses how the role of the EU in AI-driven automated decision-making will change the health landscape. Section 4 explores the patients' rights issues concerned with health AI. Section 5 examines the current state of affairs and potential solutions for EU regulation of AI with a focus on healthcare and public health. In this regard, special attention will be paid to the constitutional basis and limitations for the EU to take legal and policy measures in the area of health. The second part of section 5 evaluates to what extent aforementioned challenges for patients' rights are addressed in EU law and policy and discusses whether and in what form coming EU regulation will suffice. Section 6 concludes. Overall, this article seeks to theorise the Europeanisation of health AI and analyse its effects for patients' rights protection in EU regulation.

2. Patients' Rights Protection in the EU: Rebalancing Power Positions

2.1 Patients' rights: between vulnerability and dependency

Patients' rights aim to protect the individual person's sphere and liberty and empower people within the health system.[18] The rights of patients are rooted in the notion of human dignity and can be linked back to ethical principles and human rights standards.[19] The main reason for the protection of patients' rights is the position of vulnerability and dependency patients are in, when they are in need of healthcare.[20] Patients – in the sense of potential recipients of health services – are in an asymmetrical relationship with healthcare professionals. This requires patients to trust the health professional to use their power in the patient's best interest. The unbalanced relationship is caused by the patients' need for help from healthcare professionals which makes them dependant and therefore more vulnerable. Another cause is the information asymmetry: healthcare professionals are in the possession of sensitive personal information and patients need to rely on professionals to understand their own health status.[21] Granting

[18] De Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press, 2019).

[19] Cohen, J. and Ezer, "Human rights in patient care: A theoretical and practical framework", 2 *Health and Human Rights Journal* (2013).

[20] Boldt, "The concept of vulnerability in medical ethics and philosophy", 14 *Philosophy, Ethics, and Humanities in Medicine : PEHM* (2019).

[21] Albuquerque and Roffé, "The asymmetrical relationship between the health care professional and the patient in public hospitals", 19 *Journal International De Bioethique = International Journal of Bioethics* (2008), 165–179, 205–

patients legal rights in the context of healthcare serves the purpose of rebalancing the uneven patient-health professional relationship. Patients' rights can be seen as a precondition for patient empowerment.[22] Nowadays, patients enjoy a central position in healthcare and benefit from thorough legal protection in the European Union.

2.2 The EU Framework for Patients' Rights: From National to Supranational

The principle of subsidiarity limits the EU's powers in the field of healthcare,[23] as will be elaborated on in Section 5.1.[24] Patients' rights in Europe are foremost determined at the national level. However, the patients' rights framework in EU Member States is substantially informed by EU law and policy.[25] At the same time, patients' rights are protected and promoted at the EU level as well. While there is no general legislation on patients' rights, a supranational framework for patients' rights has developed at the EU level, informed by EU secondary legislation, fundamental rights instruments and ethical and legal traditions in the Member States.[26] While the EU has never had a leading role in protecting patients, and there are slight differences in interpretation between Member States, the EU patients' rights framework does provide direction as to the minimum standard of rights patients in the EU Member Sates are entitled to.

The EU protects patients' rights in relation to specific areas, such as the Patients' Rights Directive in relation to cross-border patient mobility (Cross-Border Patients' Rights Directive). Furthermore, patients' rights are recognised by the CJEU in relation to fundamental rights, such as health privacy.[27] The Charter of Fundamental Rights of the EU (CFREU) and the European Convention on Human Rights (ECHR) are therefore the most important legal sources in which patients' rights can be found.[28] To illustrate, in Article 3, the CFREU specifically protects the right to bodily and mental integrity (sub 1) and the right to informed consent in the field of medicine and biology (sub 2), and implicitly protects the rights to refuse medical treatment, the right to information about one's health and the right to

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[22] Palm *et al.*, "Patients' rights: from recognition to implementation" in, *Achieving Person-Centred Health Systems: Evidence, Strategies and Challenges* (Cambridge University Press, 2020), pp. 347–386.

[23] Article 168(7) TFEU; See for more detail on this topic §5.1.

[24] Shuster, "Fifty Years Later: The Significance of the Nuremberg Code", 337 *New England Journal of Medicine* (1997), 1436–1440.

[25] Palm *et al.*, "Patients' rights: from recognition to implementation" in, *Achieving Person-Centred Health Systems: Evidence, Strategies and Challenges* (Cambridge University Press, 2020), pp. 347–386.

[26] Nys, 'Comparative Health Law and the Harmonization of Patients' Rights in Europe' (2001) 8 European Journal of Health Law 319.

[27] CJEU 6 November 2003, C-101/01 (*Lindqvist*).

[28] De Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press, Oxford: 2019)

autonomy in medical decision-making.[29] Patients' rights related to access to healthcare and medicines can be derived from the rights to human dignity (Article 1 CFREU), prohibition of inhumane treatment (Article 4 CFREU), the right to non-discrimination (Articles 20-26 CFREU) and the right to access to healthcare (Article 35 CFREU).[30] Other legal sources include the European Convention on Human Rights and Biomedicine (Oviedo Convention) and the general principles of EU law.[31] The Council of Europe's instruments ECHR and the Oviedo Convention make their way into EU law by ways of judicial interpretation, as general principles of EU law and the constitutional traditions of the Member States.[32] Finally, patients' rights are protected in non-binding instruments, such as the 'European Charter of Patients' Rights'.[33]

The EU patients' rights framework is to a large extent inspired by the ethical and legal traditions in the EU Member States, both informally and directly as general principles of law.[34] National legislation often links patients' rights to legal obligations of healthcare professionals, such as the right to informed consent and the duty to inform. Addressing patients' rights to health professionals has its origin in bioethical principles as expressed in the Hippocratic Oath.[35] Most EU Member States have codified patients' rights in national legislation, varying from national constitutions to specific patients' rights laws to civil codes.[36] Many national health laws are supplemented by ethical codes and standards of health practice in order to protect patients' rights.[37] Because national health systems and economic conditions differ, and Member States have unique social, cultural and ethical values, the exact interpretation and hierarchy of patients' rights varies amongst Member States. The core elements of patients' rights are however comparable.

2.3 Foundational Principles and Core Patients' Rights

[29] De Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press, 2019).
[30] Also see the CJEU's case law on access to cross-border healthcare: CJEU 28 April 1998, C-120/95 and C-158/96 (*Decker and Kohll*) and CJEU 16 May 2006, C-372/04 (*Watts*).
[31] Charter of Fundamental Rights of the European Union [2000] OJ C 264/01; Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4 April 1997).
[32] Art 6(3) TEU.
[33] Active Citizenship Network, 'European Charter of Patients' Rights' (2002).
[34] Art 6(3) TEU.
[35] Will, "A Brief Historical and Theoretical Perspective on Patient Autonomy and Medical Decision Making: Part II: The Autonomy Model", 139 *Chest* (2011), 1491–1497.
[36] Publications Office of the European Union 2018 (n 49).
[37] Smith, M., "Patients and doctors: rights and responsibilities in the NHS", 5 *Clin Med* (2005), 501–502.

It can be argued that EU patients' rights are structured on three pillars or fundamental principles: *autonomy, human dignity* and *trust*. In the context of health law, these central principles are interrelated and exist in dynamic connection. *Autonomy* can be seen as the traditional foundation of patients' rights. It entails personal rule of the self.[38] The principle of respect for personal autonomy is regarded as a basic principle in modern medical ethics. The atrocities in research involving human subjects in Germany during World War II gave rise to a movement in moral philosophy to respect patients as autonomous agents and place the value of autonomy at the centre of the health professional-patient relationship.[39] In the standard approach to medical ethics as developed by Beauchamp and Childress, personal autonomy with respect to decision-making is understood in terms of three conditions: one must act (1) "intentionally", (2) "with understanding", and (3) "without controlling influences that determine their action".[40] From this notion of autonomy, several rights can be derived for patients in order to give effect to the autonomy of the person, such as the right to refuse treatment and the right to sufficient information to make an informed choice.[41]

Human dignity as an underlying value can be explained by the fundamental rights character of patients' rights in the EU legal framework. Historically, the principle of human dignity constitutes the foundation of human rights in the EU, as illustrated by article 1 CFREU which refers to the absolute inviolability of human dignity. Human dignity is the notion that all human beings are inherently entitled to the highest standard of respect. This principle justifies the recognition of inalienable equal human rights and fundamental freedoms.[42] Human dignity is also seen as a central value and overarching principle in international bioethical standards, including the Council of Europe's Biomedicine Convention.[43] Patients' rights, when recognized in the context of EU human rights, are based on the same fundamental principle of human dignity. Most patients' rights are protected in relation to the fundamental right to private life,[44] such as rights relating to privacy and medical data protection.

Trust was long considered the only foundation of the patient-health professional relationship and patients were expected to trust their health professionals without questions

[38] Childress and Beauchamp, *Principles of Biomedical Ethics* (1994).
[39] Will, "A Brief Historical and Theoretical Perspective on Patient Autonomy and Medical Decision Making: Part II: The Autonomy Model", 139 *Chest* (2011), 1491–1497.
[40] Childress and Beauchamp, *Principles of Biomedical Ethics* (1994).
[41] Ibid.
[42] Explanations relating to the Charter of Fundamental Rights, OJ C 303, 14.12.2007, p. 17–35
[43] Andorno, 'Human Dignity and Human Rights' in Henk AMJ ten Have and Bert Gordijn (eds), *Handbook of Global Bioethics* (Springer Netherlands 2014).
[44] See Art. 2 ECHR and Art. 7 CFREU.

asked. While this paternalistic notion of trust has been abandoned, trust still plays an important role in the context of health.[45] In healthcare, the concept of *interpersonal* trust is crucial for the health professional-patient relationship.[46] In the area of public health, *social* trust in public institutions plays an essential role.[47] Due to asymmetric power and knowledge in the health professional-patient relationship and health governance, protection of patients' rights are important to safeguard trust. The foundational value of trust is mainly reflected in legislation concerning medical confidentiality and informed consent.

Taken together, autonomy, human dignity and trust can be seen as the meta-values that provide the foundation for several concrete patients' rights in EU Member States. Three core patients' rights can be derived from these foundational principles: (1) the right to information, (2) the right to informed consent and (3) the right to medical data protection. These rights can be found in all EU Member States.[48] The right to information entails the patient's right to reliable and understandable information about the course of treatment (including e.g. possible risks and alternatives) and the health professional's duty to explain. The right to information is closely connected to the right to informed consent. The latter is rooted in the idea that sufficient information has to be provided for patients to make autonomous decisions about their bodies and provide valid informed consent to medical treatment. The right to medical data protection relates to both rights in the sense that patients require meaningful information and control over what happens to their personal data. When the nature of decision-making in health fundamentally changes, this could impact on the translation of the foundational principles in patients' rights.

3. Transforming Health: The Rise of AI-Driven Health Decision Making in the EU

3.1 Automated Decision-Making, Machine Learning and Opportunities for Healthcare

Over the past years, research and development of AI-applications in healthcare in the EU has significantly increased.[49] However, while healthcare is one of the leading application sectors in AI-research, most products are still in the testing and the development phase and not yet

[45] O'Neill, *Autonomy and Trust in Bioethics* (Cambridge University Press 2002), 18-20.
[46] Gray, "Trust And Trustworthy Care In The Managed Care Era", 16 *Health Affairs* (1997), 34–49.
[47] Pearson and Raeke, "Patients' Trust in Physicians: Many Theories, Few Measures, and Little Data", 15 *Journal of General Internal Medicine* (2000), 509–513.
[48] Publications Office of the European Union, 'Patients' Rights in the European Union : Mapping EXercise : Final Report.' (25 January 2018) <https://op.europa.eu:443/en/publication-detail/-/publication/8f187ea5-024b-11e8-b8f5-01aa75ed71a1/language-en>.
[49] Davenport and Kalakota, "The potential for artificial intelligence in healthcare", 6 *Future Healthcare Journal* (2019), 94–98.

publicly available on the EU healthcare market.[50] AI-driven automated decision-making can be defined as procedures in which decisions are – partially or completely – delegated to an AI-system.[51] Generally, AI-driven automated decision-making makes use of *machine learning*-techniques. Machine learning is the process in which models are trained by analysing (often very large) data sets by finding patterns and draw conclusions based on these patterns, without being explicitly programmed to do so. Typically, and in simple words, this process consists of various stages: (1) defining the problem that needs to be solved, (2) gathering and preparation of data, (3) choosing a model, (4) training the model, and (5) evaluation and testing of the model. Once the model is properly trained, it can make predictions in new cases and decide on the best course of action.[52] For example, machine learning-models can be trained to find patterns in large amounts of health and patient data and predict a specific patient's risk of colorectal cancer.[53] AI holds the promise to increase accuracy, efficiency and accessibility of healthcare for patients.[54] An example of an AI-application increasing accuracy is a model developed in Finland that predicts the effects of a certain new drug combination on particular cancer cells. This allows oncologists to choose the best drug treatment to selectively kill cancer cells with specific genetic makeup.[55] In addition, AI can make healthcare more efficient by automating certain tasks. To illustrate, a Swedish study shows that an AI model that determines which mammographs need further radiologist assessment reduces the workload of radiologists.[56] AI is also used to improve accessibility, for example in the form of AI-powered chatbots. A Spanish company has developed an AI chatbot for the Spanish Ministry of Health that is designed to answer the most frequently asked questions about Covid-19 and the coronavirus.[57] AI is expected to conquer a central

[50] Muehlematter, Daniore, and Vokinger, "Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis", 3 *The Lancet Digital Health* (2021), e195–e203.
[51] Based on the definition of Algorithm Watch, see: <https://algorithmwatch.org/wp-content/uploads/2019/02/Automating_Society_Report_2019.pdf>, (last visited 23 March 2021).
[52] Alpaydin, *Introduction to Machine Learning, Fourth Edition* (2020).
[53] Wang *et al.*, "Application of artificial intelligence to the diagnosis and therapy of colorectal cancer", 10 *American Journal of Cancer Research* (2020), 3575–3598.
[54] Amisha *et al.*, "Overview of artificial intelligence in medicine", 8 *Journal of Family Medicine and Primary Care* (2019), 2328–2331.
[55] AI predicts which drug combinations kill cancer cells: A machine learning model developed in Finland can help us treat cancer more effectively, <https://www.sciencedaily.com/releases/2020/12/201201084800.htm>.
[56] Dembrower *et al.*, "Effect of artificial intelligence-based triaging of breast cancer screening mammograms on cancer detection and radiologist workload: a retrospective simulation study", 2 *The Lancet Digital Health* (2020), e468–e474.
[57] Vonage Enables AI Chatbot for Spanish Government to Provide Accurate, Updated COVID-19 Information, <https://www.aithority-67ee47.ingress-bonde.easywp.com/natural-language/chatbots-intelligent-assistants/vonage-enables-ai-chatbot-for-spanish-government-to-provide-accurate-updated-covid-19-information/>, (last visited 23 March 2021).

position in the healthcare sector: a growing number of healthcare institutions is planning to implement these applications in their clinical practice.[58]

3.2 The Necessity to Regulate Risks of AI in the EU

The European Commission welcomes the introduction of AI technology onto the (Digital) Single Market and has expressed the wish for the EU to become a global leader in AI.[59] Health is often named as the largest market opportunity for AI and therefore offers significant socio-economic benefits to the EU internal market.[60] However, in spite of the benefits for healthcare and many other aspects of society, AI can also bring about serious risks for fundamental rights protected by EU law. The lack of transparency about the exact functioning of AI puts EU values such as human dignity and personal autonomy under pressure as AI is regularly used to manipulate people. The right of access to information is also at risk because of the role of algorithms in dissemination misinformation.[61] Moreover, because of biases in the training data or algorithm, AI technology can lead to inequality, which may impact the prohibition of discrimination.[62] In addition, the use of AI poses risks to the right to protection of private life and pressures the right to an effective remedy and fair trial.[63]

In light of mitigating these risks and prevent different national rules and legal uncertainty from hampering free movement of AI-based goods and services cross-border, both the European Parliament and the European Council have demanded legislative action at the EU level.[64] In April 2021, this resulted in the European Commission putting forward a proposal for regulation of AI in the form of the Artificial Intelligence Act (AIA). [65] The objective is to create a well-functioning internal market for AI-systems that adequately protects EU rights and values, without hindering innovation. The proposed AIA uses a risk-

[58] Amisha *et al.*, "Overview of artificial intelligence in medicine", 8 *Journal of Family Medicine and Primary Care* (2019), 2328–2331; *KPMG*, Inventarisatie AI-toepassingen in gezondheid en zorg in Nederland. Onderzoek naar de stand van zaken in 2020, 2020..

[59] European Commission, WHITE PAPER on Artificial Intelligence - A European approach to excellence and trust, 19/02/2020.

[60] Davenport and Kalakota, "The potential for artificial intelligence in healthcare", 6 *Future Healthcare Journal* (2019), 94–98.

[61] FRA, *Getting the future right: Artificial Intelligence and Fundamental Rights* (Publications Office of the European Union, 2020).

[62] Hacker, "Teaching fairness to artificial intelligence: Existing and novel strategies against algorithmic discrimination under EU law", 55 *Common Market Law Review* (2018).

[63] Grozdanovski, "In search of effectiveness and fairness in proving algorithmic discrimination in EU law", 58 *Common Market Law Review* (2021).

[64] European Council meeting (19 October 2017) – Conclusions, Brussels, 19 October 2017, EUCO 14/17.

[65] European Commission, *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*, COM(2021) 206 final.

based approach to regulation of AI: the higher the risk, the stricter the rule.[66] The actual extent of the impact of AI on the area of health remains to be seen. Is AI actually capable of reshaping day-to-day life – and the patient-health professional relationship with it?[67] Considering the effects a rather simple technical solution as digitisation of medical records has had for decision-making, the likely impact of AI-driven ADM on health decisions is huge.[68] The extent of the transformational consequences of health AI will depend on whether AI-systems are going to replace, diversify or complement and expand previous solutions.[69] However, it is to be expected that the growing presence of AI in the context of health will pressure the traditional conceptualisation of patients' rights to some extent.

4. Patients' Rights Consequences of Health AI

With the high stakes involved in the context of health, the use of health AI presents its own challenges. Potential hazards associated with AI are exacerbated in the context of health due to the vulnerability and dependency of patients and the potentially life-threatening effects of inaccurate or dysfunctional AI-technology used in the health environment.[70] However, different types of health AI present different degrees of risk. [71] The degree of risk generally depends on two components: the *severity* of the potential harm or damage and the *probability* that the harm or damage will occur.[72] The first component depends on the type of task AI is deployed for. One can imagine that AI-powered surgical robots can cause more harm or damage (i.e. injury, disability or death) than AI-systems taking over routine computer tasks such as medical appointment management. The second component mainly depends on the degree of automation in the automated decision-making process, according to how much control remains with the human decision-maker: from assisted decision-making (e.g. automated health or fitness recommendations) to full automation (e.g. autonomous robot surgeons).[73] Previous research on the risks of health AI focusses mainly on quality issues and

[66] Karanasiou and Pinotsis, "A study into the layers of automated decision-making: emergent normative and legal aspects of deep learning", 31 *International Review of Law, Computers & Technology* (2017), 170–187.
[67] Taddeo and Floridi, "How AI can be a force for good", 361 *Science* (2018), 751–752.
[68] Tegmark, *Life 3.0: Being Human in the Age of Artificial Intelligence* (Knopf 2017), 101-102.
[69] Floridi, "AI and Its New Winter: from Myths to Realities", 33 *Philosophy & Technology* (2020), 1–3.
[70] Agrebi and Larbi, 'Use of Artificial Intelligence in Infectious Diseases' (2020) Artificial Intelligence in Precision Health 415; Metz and Smith, Warnings of a Dark Side to A.I. in Health Care, The New York Times, 21/03/2019.
[71] Janssen, "An approach for a fundamental rights impact assessment to automated decision-making", 10 *International Data Privacy Law* (2020), 76–106.
[72] Leonelli, "Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why it Matters", *Common Market Law Review* (2020), 1773–1818.
[73] Karanasiou and Pinotsis, "A study into the layers of automated decision-making: emergent normative and legal aspects of deep learning", 31 *International Review of Law, Computers & Technology* (2017), 170–187.

liability problems from the developer's or health professional's point of view but pays little attention to the legal consequences of AI-driven ADM for the end user's patients' rights. The following section analyses relevant AI risks from a patients' rights perspective, first discussing the impact on foundational principles (Section 4.1) and subsequently focussing on the right to informed consent, the related right to information (Section 4.2) and the right to medical data protection (Section 4.3). The objective of this section is not to thoroughly analyse all effects that AI can have on patients, but, instead, provide a general overview of the main challenges health AI presents for traditional patients' rights.

4.1 Dehumanizing Health: Effects for Autonomy, Human Dignity and Trust

Increasing use of AI may present risks to patient autonomy. While in many cases, health AI is said to enhance patient autonomy, it may also result in the exact opposite. Autonomy may be impaired when patients do not understand the nature and consequences of an AI-powered decision in the context of their health, which affects the possibility to make an informed decision. Another concern is that health AI is incapable of incorporating individual patients' wishes, for example in the context of AI-powered treatment recommendations.[74] While modern medicine has shifted towards a model of shared medical decision-making, involving the patient's personal values and preferences in the decision-making process, the AI-system may dictate different values, for example rank treatment options for colorectal cancer on the basis of maximizing lifespan instead of minimizing suffering. This may threaten patient autonomy.[75] Furthermore, patients are often unaware of the exact extent of personal data processed by health AI.[76] This lack of control over personal (medical) data presented by some health AI, may also impair the protection of patient autonomy, as privacy and data protection rights can be seen as the ability to self-rule over one's personal data, and thus as a form of personal autonomy.[77]

Human dignity underpins the protection of fundamental patients' rights. The notion of intrinsic dignity of every human is central to healthcare. However, as AI-applications become smarter and act more autonomous, society may experience a paradigm shift towards a more

[74] McDougall, "Computer knows best? The need for value-flexibility in medical AI", 45 *Journal of Medical Ethics* (2019), 156–160.

[75] Grote and Berens, "On the ethics of algorithmic decision-making in healthcare", 46 *Journal of Medical Ethics* (2020), 205–211.

[76] Van Kolfschooten, 'The mHealth Power Paradox: Improving Data Protection in Health Apps through Self-Regulation in the European Union', in: I. Glenn Cohen, Timo Minssen, W. Nicholson Price II, Christopher Robertson, and Carmel Shachar, *The Future of Medical Device Regulation: Innovation and Protection*, Cambridge: Cambridge University Press 2021.

[77] Feinberg, "Autonomy, Sovereignty, and Privacy: Moral Ideals in the Constitution", 58 *Notre Dame Law Review* (1983), 445.

extrinsic or instrumental valuation of human life for society, putting the very essence of fundamental rights protection at risk.[78] In general, the dependence of AI-application on large amounts of personal data may pressure the notion of human dignity, as humans are valued for their personal data rather than their intrinsic worth. Other concerns for human dignity specific to the context of healthcare include risks of objectivation of the patient, taking out the 'human' and 'individual' or 'subjective' aspect of human health. An AI-powered treatment recommender system may for example be based on a utilitarian calculus, that incorporates values that may threaten the essence of human dignity. Furthermore, an AI treatment recommender system will not always be able to take into account individual values and preferences, therefore neglecting the intrinsic worth of all human beings.[79] Naturally, the extent of the threat medical AI may offer to human dignity of patients, depends on the degree of automation in the decision-making process. Autonomous AI-systems replacing the health professional's primary complex tasks, such as diagnosis, poses more risks to human dignity than AI-systems assisting health professionals in their decisions, such as AI-powered clinical decision support systems informing health professionals about the latest research in a specific field.[80]

Trust is an important prerequisite for the protection of patients' rights. However, empirical research shows that patients are reluctant to trust AI, and therefore hesitant to accept the use of ADM in the medical context. Overall, an AI-system is less trusted than a human health professional, even when the AI-system provided the same care as the health professional. The main factors contributing to distrust in AI-driven ADM are perceived care ability, the lack of ability to feel emotions, the perception that the AI-system will neglect the patient's unique characteristics and symptoms, and the perception that the AI-system does not share similar values as human health professionals.[81] While patients' trust is to a large extent subjective and psychological, some characteristics of AI contribute to the level of distrust in AI-driven medical ADM. First, consistent accuracy of the AI-system is important for patient's trust.[82] However, at this stage of AI development, even the best AI-systems may sometimes make mistakes which will likely reduce trust in AI-driven ADM in the context of health.

[78] Gill, "Prediction paradigm: the human price of instrumentalism", 35 *AI & SOCIETY* (2020), 509–517.
[79] McDougall, "Computer knows best? The need for value-flexibility in medical AI", 45 *Journal of Medical Ethics* (2019), 156–160.
[80] Bitterman, Aerts, and Mak, "Approaching autonomy in medical artificial intelligence", 2 *The Lancet Digital Health* (2020), e447–e449.
[81] Yokoi *et al.*, "Artificial Intelligence Is Trusted Less than a Doctor in Medical Treatment Decisions: Influence of Perceived Care and Value Similarity", 37 *International Journal of Human–Computer Interaction* (2021), 981–990.
[82] *Papenmeier, Englebienne, and Seifert*, How model accuracy and explanation fidelity influence user trust in AI, 2019.

Furthermore, it is often said that AI is only as good as the data it uses.[83] As a result, two main problems may occur, threatening the accuracy of the system. First, the dataset that was used to train the model may be flawed. Poor-quality training data in the context of health AI is often caused by the use of narrow datasets or inaccurate data.[84] Second, even when AI-systems are developed using comprehensive datasets, they will always encounter new situations while used in practice. To illustrate, an AI-powered robotic surgeon is trained on the basis of millions of images and learns from these images. However, after years of use the robot's material has stretched and bent a little bit, which requires the robot to change its movement by millimetres. While human surgeons would unconsciously adapt to these small changes, the decision-making process by an AI-powered robotic surgeon lacks this unconscious adaption to sudden change, chaos and uncertainty.[85] While eventually AI-systems will grow to be more accurate from encountering new situations, this may still lead to errors in the beginning. Lack of protection of sensitive personal (health) data and robust (cyber)security may also cause distrust in health AI.[86] Another threat for trust in health AI is formed by the complex working of AI-driven health decision-making. It is difficult for patients to fully understand how the technology functions and comes to certain medical decisions. Patients' perception that they do not understand how AI makes medical decisions, together with their overestimation of their understanding of human medical decision-making, affects trust in the context of health, as users are less likely to trust technology that they do not understand.[87] For example, empirical research shows that patients are more likely to utilize a healthcare service that relies on a primary care physician, than on a machine learning algorithm (i.e. an skin cancer detection app that analyses a picture of a skin mole) to identify cancerous skin lesions.[88]

4.2 The Black Box-Effect, Information and Consent

The intersection of the use of AI in health and the right to informed consent comes into play when the AI-system is opaque. This is referred to as the "black box-effect" of AI. It is not always possible to tell how an AI-system has come to a certain decision or prediction, such as

[83] European Union Agency for Fundamental Rights, Data quality and artificial intelligence - mitigating bias and error to protect fundamental rights, 2019.
[84] Obermeyer *et al.*, "Dissecting racial bias in an algorithm used to manage the health of populations", 366 *Science* (2019), 447–453.
[85] *Metz*, The Robot Surgeon Will See You Now, The New York Times, 30/04/2021.
[86] European Union Agency for Cybersecurity, AI Cybersecurity Challenges. Threat Landscape for Artificial Intelligence, 12/2020.
[87] Cadario, Longoni, and Morewedge, "Understanding, explaining, and utilizing medical artificial intelligence", *Nature Human Behaviour* (2021), 1–7.
[88] Cadario, Longoni, and Morewedge, "Understanding, explaining, and utilizing medical artificial intelligence", *Nature Human Behaviour* (2021), 1–7.

a particular medical diagnosis, even for the creator.[89] This may be because algorithms rely on rules too complex for human understanding, or because it is impossible to determine exactly what factors were used to come to a decision.[90] This may be problematic for AI-driven ADM in health, especially in the context of patients' rights. Patients have a right to informed consent in the context of medical treatment. The main principle justifying this right is autonomy as the underlying idea is that sufficient information has to be provided for patients to make autonomous decisions about their bodies. Informed consent exists of two components: the right to be informed to an extent that a conscious decision can be made and the right to accept or reject a course of treatment on the basis of that information.[91] The emergence of more opaque AI-systems in the context of health decision-making raises questions about the extent of the information a patient needs to make an informed decision in case the health professional made use of AI in the patient-health professional relationship.

For the "information" component of informed consent, or the general patients' right to information, the obvious consequence is that, given the non-transparent nature of certain AI-systems, it may not always be possible for health professionals to fully inform their patients about the steps in the medical decision-making process. Health professionals may be insufficiently knowledgeable and the presented information may be too complex for patients.[92] Further uncertainties may arise as to under what circumstances health professionals must inform their patients of the participation of AI-systems in the medical decision-making process. Does the patients' right to information require health professionals to disclose the use of AI to patients in all cases, or does this depend on the degree of automation of the decision?[93] And, to what extent are health professionals required to inform their patients of the general risks of the use of AI, such as cyberattacks and biased or flawed data-sets?[94] The substantial degree of opaqueness, uncertainty and lack of knowledge surrounding AI-driven medical decision-making may affect the manner in which patients are ensured informed decision-making about their bodies. The right to informed consent also entails the right of patients to accept or refuse a certain type of treatment. When the health professional makes use of AI in the patient-health professional relationship, this concept may also change. For

[89] Bathaee, "The Artificial Intelligence Black Box and the Failure of Intent and Causation", 31 *Harvard Journal of Law & Technology (Harvard JOLT)* (2017), 889–938.
[90] Price II, "Regulating Black-Box Medicine", 116 *Michigan Law Review* (2017), 421–474.
[91] Faden, Beauchamp, and King, *A History and Theory of Informed Consent*, 1 edition. (Oxford University Press, 1986).
[92] Schiff and Borenstein, "How Should Clinicians Communicate With Patients About the Roles of Artificially Intelligent Team Members?", 21 *AMA Journal of Ethics* (2019), 138–145.
[93] Cohen, I.G., "Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?", (2020), 1425–1469.
[94] Kiener, "Artificial intelligence in medicine and the disclosure of risks", *AI & SOCIETY* (2020).

example, if an AI mobile health app or chatbot is being used as part of the treatment, can the digital user agreement replace the traditional informed consent procedure?[95] And how is the right to informed consent impacted when AI-powered decision-making becomes the norm in the future and there are few alternatives?[96]

4.3 Big Data and Medical Data Protection

Health AI may pressure the patients' right to medical data protection and privacy. Most AI-applications process, collect and analyse personal data, for example to train machine learning models or in the application of those models to personal data of individuals.[97] In the healthcare sector, this often includes sensitive information about patients' health, such as medical records and medical images of the body (i.e. X-ray, CT scan). Effective anonymisation of large datasets consisting of medical records is practically impossible – because of the detailed nature of this type of information and the magnitude of the average data set there is always a theoretical risk of re-identification of individuals.[98] This may harm patients' private life as disclosure of personal health data may negatively impact employment, insurance coverage and social life.[99]

The 'data hunger' of AI-applications may pressure the traditional understanding of patients' rights concerning health privacy, such as patient-health professional confidentiality and medical data protection. While healthcare professionals are subject to the responsibilities of medical confidentiality, potential third-party processers of personal data may not bound by the same legal duties. This may require a new perspective on confidentiality in the health professional-patient relationship.[100] Some guiding principles in EU data protection law seem to be incompatible with the dependency of AI-driven ADM on big data. For example, the principle of data minimisation (limiting data collection to only what is required to fulfil a specific purpose) seems to be in conflict with technology that needs enormous data sets to function and evolve.[101] Other issues rise in relation to individual data protection rights, such as

[95] Gerke, Minssen, and Cohen, G., "Ethical and legal challenges of artificial intelligence-driven healthcare", *Artificial Intelligence in Healthcare* (2020), 295–336.
[96] Cohen, I.G., "Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?", (2020), 1425–1469.
[97] Daelman, "AI through a Human Rights Lens. The Role of Human Rights in Fulfulling AI's Potential." in De Bruyne and Vanleenhove (Eds.), *Artificial Intelligence and the Law* (Intersentia, 2021), pp. 123–148.
[98] Rocher, Hendrickx, and Montjoye, de, "Estimating the success of re-identifications in incomplete datasets using generative models", 10 *Nature Communications* (2019), 3069.
[99] Price and Cohen, I.G., "Privacy in the age of medical big data", 25 *Nature Medicine* (2019), 37–43.
[100] Rigby, "Ethical Dimensions of Using Artificial Intelligence in Health Care", 21 *AMA Journal of Ethics* (2019), 121–124.
[101] European Parliament, *The impact of the General Data Protection Regulation (GDPR) on artificial intelligence*, Brussels: European Union 2020.

the transparency rights and the right to erasure. Is it always possible to provide patients with an individualised explanation of automated decisions?[102] And can patients request the deletion of personal data that has already been aggregated and analysed?[103] The emergence of AI-driven ADM in the context of health is likely to put strains on the patients' right to medical data protection.

5. The Europeanisation of Health AI: Legal Vacuums in EU Regulation

It is clear from the above that traditional patients' rights and underlying values are threatened when health AI is used. While some of these challenges are addressed at the EU level, the following section shows that the current legal framework that governs health AI does not suffice to solve these problems. This leads to a disconnect between the EU's interference in the regulation of health – AI-powered decision-making included – and its involvement in patients' rights protection. The EU is facilitating and promoting the use and availability of AI in the health sector in Europe but provides limited safeguards to the rights of patients as end users. The proposed Artificial Intelligence Act does not seem to solve the shortcomings for patients' rights in the current legal framework. This legal gap may lead to the neglect of the position of patients in Europe when health AI becomes common practice.

5.1 Limited Competencies but Increasing Impact on Health

Given its central position in the regulation of the internal market, the EU plays a key role in the legal framework that governs the introduction of AI in the health sector. However, while the protection of human health is an objective of the EU,[104] the EU has limited legislative powers in the area of health. Article 168 of the Treaty on the Functioning of the EU (TFEU) offers little possibilities for legislative harmonization with regard to health and public health.[105] In terms of legislation, Article 168 TFEU only allows for harmonizing measures regulating quality and safety, such as substances of human origins, medicines and medical devices, which fall under the shared competency.[106] Nevertheless, despite the absence of a strong legal basis, the body of EU health law and policy is increasing. The reason for this is

[102] Edwards and Veale, "Enslaving the Algorithm: From a "Right to an Explanation" to a "Right to Better Decisions"?", 16 *IEEE Security & Privacy* (2018), 46–54.
[103] Gerke, Minssen, and Cohen, G., "Ethical and legal challenges of artificial intelligence-driven healthcare", *Artificial Intelligence in Healthcare* (2020), 295–336.
[104] Art. 3(1) TEU.
[105] Art. 168(5) TFEU.
[106] Art. 4(2)(k) TFEU and Art. 168(4) TFEU.

twofold. First, the EU extensively uses its complementary competency to "carry out actions to support, coordinate or supplement the actions of the Member states,"[107] which has powerful effects for health policy and law in the Member States.[108] Second, the EU often resorts to the legal basis of Article 114 TFEU, regarding the integration of the internal market, to justify regulation of human health.[109] Article 114 TFEU provides the EU with the opportunity to adopt measures to protect health, so long as those measures remove obstacles hindering the internal market. In this way, the internal market dimension of EU law allows for harmonizing measures in the field of public health and healthcare.[110] Similarly, the Treaty rules on free movement of services (Articles 56-62 TFEU), interpreted by the CJEU to apply to healthcare,[111] led to the adoption of the Patients' Rights Directive on Cross-Border Healthcare.[112] The internal market legal basis does however not permit limitless legislative harmonization under the flag of health.[113] Inevitably, EU health law and policy is highly scattered through different laws, policy instruments and institutions.

5.2 Shortcomings of the Current Legal Framework

This complex web of law and policy is also visible with regard to regard to current EU law and policy on AI-driven automated decision-making in health. The current legal framework for health AI at the EU level takes place at multiple tiers and consists of (1) health technology-specific regulation (e.g. regulations on medical devices), (2) regulation specific to technology-related issues (e.g. legislation related to the digital single market), (3) fundamental rights regulation (e.g. the CFREU and the GDPR) and (4) consumer protection regulation (e.g. regulations on product liability and unfair commercial practices).[114] The proposed

[107] See Art. 6 TFEU.

[108] De Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press 2019); Scott L. Greer, N. Fahy, and S. Rozenblum, *Everything you always wanted to know about European Union health policies but were afraid to ask*, Second, revised edition. (European Observatory on Health Systems and Policies, 2019).

[109] De Ruijter (n 70); Davies, 'The Community's Internal Market-Based Comptenece to Regulate Healthcare: Scope, Strategies and Consequences', 14 *Maastricht Journal of European and Comparative Law* (2007), 215-238; Delhomme, "Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health", 11 *European Journal of Risk Regulation* (2020), 747–756.

[110] Purnhagen *et al.*, "More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak", 11 *European Journal of Risk Regulation* (2020), 297–306.

[111] CJEU Case C-158/96 (*Kohll*); CJEU C-286/82 and C-36/8 3 (*Luisi and Carbone*); CJEU Case C-157/99 (*Geraets-Smits and Peerbooms*).

[112] Rieder, "Cross-border Movement of Patients in the eu: A Re-Appraisal", 24 *European Journal of Health Law* (2017), 390–413.

[113] Weatherill, 'The Limits of Legislative Harmonization Ten Years after Tobacco Advertising: How the Court's Case Law Has Become a "Drafting Guide"' (2011) 12 German Law Journal 827; Germany v Parliament and Council ('Tobacco Advertising I') (Case C-376/98), EU:C:2000:544, [2000] ECR I-8419, 5 October 2000.

[114] Evas, 'European Framework on Ethical Aspects of Artificial Intelligence, Robotics and Related Technologies. European Added Value Assessment' (European Parliamentary Research Service 2020) PE 654.179; Gerke, Minssen, and Cohen, G., "Ethical and legal challenges of artificial intelligence-driven healthcare", *Artificial Intelligence in*

Artificial Intelligence Act will become part of this regulatory system. While the current EU framework may avert some risks common to AI health decision-making, it seems to be insufficient to adequately protect patients in case of an algorithmic turn in the context of health. EU instruments that do apply to patients' rights issues occurring in the context of health AI, such as the GDPR and the MDR, may come to obtain a central position in the legal framework surrounding health AI. They are however not necessarily adapted to the specific challenges AI brings about and do not provide a complete solution to its specific challenges for patients' rights.

5.2.1 General Data Protection Regulation

The main instrument for (health) data protection in the EU is the GDPR. The GDPR sets rules regarding the use of personal data. Any information concerning an identified or (in)directly identifiable natural person qualifies as personal data.[115] The basic premise of the GDPR is that every processing of personal data must be underpinned by a legal basis.[116] Moreover, it imposes duties on data processors and controllers and confers rights on data subjects in order to increase control.[117] Data subjects' rights include the right to information,[118] the right to access,[119] and the right to withdraw consent.[120] The CJEU has stipulated that the need for effective safeguards for protection of personal data is even bigger when personal data is subjected to automatic processing, which is often the case with health AI.[121] However, while in theory, the GDPR seems to offer adequate protection to medical data protection in the context of health AI, in practice, the GDPR is not fully adapted to the specific challenges AI brings about for patients' privacy.[122]

In some ways, the GDPR seems to be incompatible with the practice of AI. Principles such as data minimization and storage limitation seem meaningless in the context of AI, since enormous datasets are required for the training of algorithms.[123] Data subject rights such as transparency rights are not always useful as the algorithm is difficult to understand for

Healthcare (2020), 295–336.

[115] Art. 4 GDPR.

[116] Art. 6 GDPR.

[117] Chapter III GDPR.

[118] Art. 12–13 GDPR.

[119] Art. 15 GDPR.

[120] Art. 7(3) GDPR.

[121] CJEU C-362/14 (*Schrems*), §91; ECtHR app. No. 16188/07 (*Khelili v. Switserland*).

[122] Van Kolfschooten, 'The mHealth Power Paradox: Improving Data Protection in Health Apps through Self-Regulation in the European Union', in: I. Glenn Cohen, Timo Minssen, W. Nicholson Price II, Christopher Robertson, and Carmel Shachar, *The Future of Medical Device Regulation: Innovation and Protection*, Cambridge: Cambridge University Press 2021.

[123] Art. 5 GDPR.

patients, and erasure rights are practically impossible to comply with, because the personal data is often already aggregated.[124] Another issue is the substantial list of exceptions the GDPR provides for the general prohibition on the processing of health data. [125] The first one is explicit informed consent by the data subject (i.e. the patient). In practice, this proves to be difficult because it is not always possible to contact the specific patient or explain the use of personal data in a manner that the patient is capable of providing valid informed consent.[126] Moreover, informed consent is not necessary when, for example, the personal data has been made public by the data subject[127] (i.e. medical images on online medical forums), processing is necessary for public health purposes[128] (i.e. medical contact tracing apps), or for scientific purposes (i.e. research into AI applications for medical diagnosis).[129] In those cases, patients will not have meaningful control over their personal health data, which may affect their rights to medical data protection and health privacy.[130]

Health AI generally uses personal data in at least two ways. First, AI-applications use personal data in the training phase: the datasets on the basis of which algorithms are trained often contain large amounts of 'anonymous' personal data. Anonymous data is not covered by the GDPR, because it cannot be traced back to an individual.[131] This may lead to a problem in practice: many AI developers, researchers and health professionals claim their datasets containing for example medical images, are anonymized, and will thus not comply with the GDPR.[132] However, as different datasets might be available in different context (i.e. dataset of patients' medical records in a hospital versus anonymized dataset of chest radiographs of patients for research), there is a risk of re-identification when the anonymous data is cross-referenced with other datasets. In that case, training data could also qualify as 'personal data', and thus data subjects are entitled to multiple rights with regard to the use of this data.[133] The common misunderstandings about anonymization of health data in the context of health AI may threaten patients' rights to data protection.[134] Second, health AI processes personal data

[124] Edwards and Veale, "Enslaving the Algorithm: From a "Right to an Explanation" to a "Right to Better Decisions"?", 16 *IEEE Security & Privacy* (2018), 46–54.
[125] Art. 9 GDPR.
[126] Art. 7 GDPR.
[127] Art. 9(2)(e) GDPR.
[128] Art. 9(2)(i) GDPR.
[129] Art. 9(2)(j) GDPR.
[130] Forcier *et al.*, "Integrating artificial intelligence into health care through data access: can the GDPR act as a beacon for policymakers?", 6 *Journal of Law and the Biosciences* (2019), 317–335.
[131] Recital 26 GDPR.
[132] Diaz *et al.*, "Data preparation for artificial intelligence in medical imaging: A comprehensive guide to open-access platforms and tools", 83 *Physica Medica* (2021), 25–37.
[133] Rocher, Hendrickx, and Montjoye, de, "Estimating the success of re-identifications in incomplete datasets using generative models", 10 *Nature Communications* (2019), 3069.
[134] AEPD, "10 misunderstandings related to anonymisation", 2021.

in the 'use' phase. In this phase, the algorithmic model is applied to a particular set of personal data in order to make decisions about a specific person. The GDPR stipulates that data subjects must always be informed about such use of algorithmic decision-making.[135] Decision-making without human intervention which produces legal effects or similarly significantly affects individuals is prohibited under the GDPR, unless this is necessary for the performance of a contract, permitted by law or is based on the explicit consent of the data subject.[136] Most likely, automated health decision-making falls under this prohibition when it poses significant risks to individual health. This means that in that case, patients are entitled to human intervention and have the right to challenge the decision.[137] In addition, patients should be informed of the logic involved in the algorithmic decision.[138] It is however questionable whether it is practically possible to always provide patients with an individualized explanation of the decision.[139] Moreover, notably, the GDPR does not lay down further rules for decisions using AI-applications that *do* involve a health professional, such as AI-powered clinical decision assistance tools, nor for decisions that do not significantly affect the patients involved, such as health apps generating customized dietary recommendations.

5.2.2 Medical Devices Regulation

At the EU level, health technology is mainly regulated through regulation of medical devices under the MDR.[140] The MDR can be seen as an instrument to ensure quality of medical devices rather than a patients' rights instrument. The MDR aims to guarantee a high level of health and safety of medical devices while supporting innovation. In some cases, AI software or technology may qualify as a medical device within the meaning of the MDR: 'any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes', for example, 'diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease'.[141] In short: if the manufacturer intended to use the AI application for a specific medical purpose, the application must comply

[135] Art. 13(2)(f) and 14(2)(g) GDPR.
[136] Artikel 22(1) and 22(2) GDPR.
[137] Artikel 22(3) GDPR.
[138] Artikel 13(2)(f) and 14(2)(g) GDPR.
[139] Edwards and Veale, "Enslaving the Algorithm: From a "Right to an Explanation" to a "Right to Better Decisions"?", 16 *IEEE Security & Privacy* (2018), 46–54.
[140] NB: Regulation (EU) 2017/745 (MDR) replaces Directive 93/42/EEC in May 2021.
[141] Art. 2(1) MDR.

with the requirements of the MDR.[142] The MDR specifically excludes software intended for general purposes and lifestyle and well-being purposes, even when used in the treatment relationship.[143] AI-applications that qualify as a medical device are subject to a conformity assessment. The exact requirements depend on the risk class: the higher the risk to the patient, the higher the class, and the stricter the rules.[144] The MDR mainly sets technical rules with regard to the protection of the physical safety and health of patients, and is less focused on the protection of patients' rights. However, the MDR does require appropriate access to information for users, and manufacturers are obliged to inform users about 'possible residual risks', which can contribute to the problems surrounding AI transparency. Nonetheless, given the purpose of the MDR, this requirement appears to mainly relate to physical risks.[145] As to privacy and data protection, the MDR protects health privacy primarily with reference to the GDPR and does not set additional requirements.[146] Due to the limited consideration of health-specific issues and patients' rights protection, the current EU legal framework surrounding health AI seems to be ill-equipped to deal with the new challenges automated health decision-making brings about for patients' rights.

5.3 Proposal for the Artificial Intelligence Act

In recent years, great hopes for fundamental rights protection have been pinned on the development of a new regulatory framework for AI at the EU level. The preparing of this framework first started in October 2017, when the European Council urged the European Commission to implement a European strategy for AI.[147] In 2018, the European Commission published the 'European approach to AI' and first expressed its wish to 'make the EU a world leader in the AI revolution'.[148] At the same time, a 'High-Level Expert Group on Artificial Intelligence' was introduced in order to advise the Commission on the new AI policy.[149] With the input of AI HLEG and the European AI Alliance, the European Commission published the

[142] See Helen Yu, Regulation of Digital Health Technologies in the EU: Intended versus Actual Use, in The Future of Medical Device Regulation: Innovation and Protection (Carmel Shachar eds., 2021).

[143] Recital 19 MDR.

[144] Annex VIII MDR.

[145] Annex I, Chapter I and III MDR.

[146] Art. 109–10 MDR.

[147] European Council meeting (19 October 2017) – Conclusions, Brussels, 19 October 2017, EUCO 14/17.

[148] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Artificial Intelligence for Europe {SWD(2018) 137 final}, 25/04/2018.

[149] Europese Commissie, *Artificial Intelligence for Europe*, COM(2018) 237.

White Paper On Artificial Intelligence in February 2020,[150] accompanied by a communication[151] and a report,[152] and concluded that the current EU legal framework was insufficiently equipped to address the new challenges posed by AI. The Council of the European Union also called for more regulation to ensure compatibility with fundamental rights.[153] On 21 April 2021, the European Commission published the long-awaited legislative proposal on artificial intelligence (AI): the Artificial Intelligence Act (AIA).[154] The main purpose of the proposal is to improve the functioning of the internal market of AI by laying down rules for development, marketing and use on the basis of article 114 TFEU. The AIA aims to harmonize AI rules and create an ecosystem of trust in AI by aligning its use with European values, fundamental rights and principles. In this context it is important to note that the AIA does not specifically regulate health AI, but focusses on AI in general.

5.3.1 Risk-Based Approach to AI Regulation

The AIA defines 'AI-system' as 'software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with'.[155] Annex I lists specific techniques and methods, including machine learning. Like the MDR, the proposal takes a risk-based approach to regulation of AI: the higher the risk, the stricter the rule. Three risk classes are used: 'unacceptable risk', 'high risk' and 'limited risk'. Generally, the degree of risk generally depends on two components: the *severity* of the potential harm or damage and the *probability* that the harm or damage will occur.[156] The AIA bans a number of uses because of unacceptable risks to people's security, livelihoods and rights, such as algorithmic social credit systems rate citizens based on behaviour.[157] 'High risk' includes AI-systems that are

[150] European Commission, WHITE PAPER on Artificial Intelligence - A European approach to excellence and trust, 19/02/2020.
[151] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A European strategy for data, 19/02/2020.
[152] European Commission, Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, 19/02/2020.
[153] Council of the European Union, *Presidency conclusions - The Charter of Fundamental Rights in the context of Artificial Intelligence and Digital Change*, 11481/20.
[154] 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, COM(2021) 206 final.
[155] Artikel 3 AIA.
[156] Leonelli, "Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why it Matters", *Common Market Law Review* (2020), 1773–1818.
[157] Artikel 5 AIA.

intended to be used in products regulated at the EU level as listed in Annex II, including the MDR.[158] This means that all medical devices that fall under the MDR are classified as 'high risk' under the AIA.[159] The AI systems used in the areas listed in Annex III also qualify as 'high risk', such as critical infrastructure networks and law enforcement. Health or healthcare are not mentioned here.[160] AI-systems designed to interact with humans qualify as 'limited risk', such as chatbots.[161] The regulation lays down rules for applications with a high or limited risk, while AI-applications with a minimal risk are not regulated.

5.3.2 Requirements and Monitoring

Before providers of AI-systems are allowed to introduce their AI-systems on the EU internal market, a number of obligations must be met.[162] For AI-systems with a high risk, there must be an adequate system for risk assessment and mitigation,[163] the quality of the datasets must be high,[164] the operation of the system must be sufficiently transparent for users and there must be an obligation to provide information.[165] In addition, AI-systems must meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art, and allow for human oversight.[166] In order to be able to assess conformity, all information on the system must be extensively documented, the activities of AI-systems must be registered and the system must be included in a European database.[167] Monitoring and enforcement are the responsibility of national market surveillance authorities. In addition, a European Artificial Intelligence Board is introduced.[168] For AI-applications with a limited risk, only a transparency obligation applies under the AIA.[169] To this end, the Commission is committed to facilitate voluntary codes of conduct.[170]

5.4 Artificial Intelligence Act: New Guardian of Patients' Rights?

[158] Artikel 6 AIA.
[159] Recital 30-31 AIA.
[160] Art. 6(2) and Annex III AIA.
[161] Art. 52 AIA.
[162] Art. 16 AIA.
[163] Art. 9 AIA.
[164] Art. 10 AIA.
[165] Art. 13 AIA.
[166] Art. 14-15 AIA.
[167] Art. 11-12, 51, 60 AIA.
[168] Art. 56-59 AIA.
[169] Art. 52 AIA.
[170] Art. 69 AIA.

The proposed AIA aims to offer a balanced approach to regulation of AI, that ensures effective protection of fundamental rights without hindering its socio-economic benefits. The proposal has however been criticized by human rights organisations precisely for falling short on fundamental rights protection.[171] The same argument applies to AI deployed in the context of health. The AIA does not specifically address the use of AI in healthcare and the effects for patients. This is not surprising given the limited powers of the EU in the field of health. Nevertheless, the Act has consequences for the protection of patients because healthcare forms one of the most popular sectors for AI deployment in the EU.[172] However, the AIA does not seem to offer a direct solution to the health-specific challenges faced by patients in the context of AI.

The central shortcoming of the AIA appears to be the lack of a human-centred approach: the proposal centers on *companies* rather than *humans*. While it sets some important rules for developers of high-risk AI-systems (i.e. transparency and information obligations), and allows for companies to self-assess their conformity with regulation, it does not mention the vulnerable position of 'end users' or those affected by AI-powered decisions (i.e. patients). The proposed Act thus ignores the perspective of the 'end-users', or in the case of health AI, patients. This is contradictory to other EU instruments regulating products and services on the internal market, where the position of the end-users is far more central. For example, both the Cross-Border Patients' Rights Directive (aimed at free movement of services) and the General Product Safety Directive (aimed at free movement of goods) take into account the effects of regulation for end-users (e.g. patients and consumers).[173] The AIA's regulatory approach to AI disregards the vulnerability of humans exposed to the AI-algorithm. This is especially harmful in the clinical context, as patients are particularly susceptible to the risks of AI because of the inherent dependency and information asymmetries in the patient-health professional relationship. It therefore poses the risk of objectification of patients, which may pressure the value of human dignity underpinning all EU patients' rights.

Moreover, the AIA fails to empower end-users with effective and enforceable rights. It mainly sets rules for developers and allows for self-assessment of conformity with those rules but does not provide end-users with the resources to guard themselves against the detrimental

[171] F. Reinhold, 'AlgorithmWatch's response to the European Commission's proposed regulation on Artificial Intelligence – A major step with major gaps', *algorithmwatch.org*, 22 April 2021.
[172] European Commission - Directorate-General for Communications Networks, Content and Technology, 'The European AI Landscape – Workshop Report', 2018.
[173] See for example Art. 4 and 5 of the Cross-Border Patients' Rights Directive and Art. 5 of the Generel Product Safety Directive.

effects of AI. In comparison, the EU's GDPR does empower citizens to control how their personal information is used by granting them extensive rights, such as the right to erasure of personal data.[174] The lack of effective rights to control the flow of personal data threatens the patients' right to medical data protection. Furthermore, there is no general right to object to automated decision-making, while the GDPR does include such a right when personal data is processed and there are significant effects.[175] In the case of health AI, this means that patients cannot object to the use of AI in their treatment, for example when the general practitioner makes use of an AI-powered diagnosis chatbot, which limits the patients' rights to refuse treatment and informed consent. Next to this, the AIA also fails to defer the responsibility for patients' rights protection to Member States, like the Cross-Border Patients' Rights Directive does for the patients' rights to access to their own medical data.[176] This further contributes to a legal vacuum in EU patients' rights protection in the context of health AI.

Furthermore, the proposed system of risk classification in the AIA is very rigid: the bar for "unacceptable AI" is high by setting the additional requirement that the systems must (be able to) cause physical or psychological damage.[177] However, while a data leak in an AI-powered app, such as a menstruation tracker, may not directly cause physical or psychological damage, it may well have significant impact on users' private life and limit their right to medical data protection. The AIA does not acknowledge the severity of this potential harm for patients. Another lacuna in the proposal in light of patients' rights, is the silence on the high risks of AI uses in the healthcare sector. The AIA mainly sets rules for AI-systems in the 'high risk' category. The proposal considers as 'high-risk' AI-systems used in specific areas, such as critical infrastructure, education and law enforcement.[178] While the proposal does stipulate that all devices falling under the MDR qualify as 'high-risk', healthcare is conspicuous in its absence from the list of high-risk areas. This is remarkable since healthcare is an inherently risky and sensitive market because it deals with matters of the human body, life and death. In practice, this means that AI-systems in healthcare that do not fall under MDR are considered to pose 'limited risk' and therefore minimally regulated under the AIA. While the Commission seems to have assumed that *all* AI-applications used in the context of health are covered by the MDR, this is not the case: the MDR only covers devices and software with an intended medical purpose, therefore excluding many AI-applications used in the realms of

[174] Article 17 GDPR.
[175] Ibid.
[176] Art. 5(b) Cross-Border Patients' Rights Directive.
[177] Art. 5 AIA.
[178] Annex III AIA.

health, such as many health apps and chatbots.[179] These applications may however still present new challenges and possible risks to patients, because of the (in)direct effects on the human body, or the use of sensitive health data. To illustrate, mobile pregnancy apps offering AI-powered recommendations will likely influence (reproductive) health of users and process sensitive data on health and life choices. This poses risks to the autonomy of patients, as access to information leading to informed consent may be constrained and control over personal data may be limited, which in turn affects the rights to informed consent and medical data protection. Nonetheless, they are not considered 'high-risk' under the proposed AIA. The omission of healthcare in the 'high risk'-category does not do justice to the vulnerable position of patients exposed to AI. In addition, many of the proposed rules provide for exceptions in case of use for public safety aims.[180] In the context of patients' rights, this raises the question to what extent the Commission intends to regulate AI-systems for public health, particularly considering the rise of AI-applications for purposes of public health and safety since the Covid-19-pandemic.[181] When AI-applications for public health are not regulated, this poses additional risks to the right to medical data protection. In the Covid-19-pandemic, enormous amounts of sensitive data were processed in the interest of public health, therefore pressuring patients' control over use of their personal data and exposing users to cybersecurity vulnerabilities in AI systems.[182] The AIA-proposal seems to disregard these risks.

The AIA aims to complement the existing data protection framework[183] but does not provide for the necessary additional protection. For example, the AIA neglects the limitations of the GDPR in case of algorithmic decisions that *do* involve a health professional and decisions that do not 'significantly affect' those involved, such as AI-powered clinical decision assistance tools and health apps generating customized dietary recommendations. In these cases, neither the GDPR nor the AIA provides the data subject with a 'right to object', while these applications may still significantly affect patients' rights to informed consent (using AI in the course of medical treatment) and medical data protection (meaningful control over the use of personal data). In addition, the proposal does not pay attention to the issue of data protection within the broader context of privacy: the tendency to collect as much personal data as possible is inconsistent with the GDPR's objective and the principles of data

[179] Recital 19 MDR.
[180] Art. 5 AIA.
[181] S. Cave et. al., 'Using AI ethically to tackle Covid-19', *BMJ* 2021, 372.
[182] Kolfschooten, van and Ruijter, A. de, "COVID-19 and privacy in the European Union: A legal perspective on contact tracing", 41 *Contemporary Security Policy* (2020), 478–491.
[183] AIA at para. 1.2.

protection and can actually disadvantage patients. The concept of patients as sources of data rather than human beings with intrinsic worth pressures the notion of human dignity, may disrupt trust in the healthcare system, and limits the right to medical data protection.

Further, while the European Commission has put forward "trustworthy AI" as the main policy aim in EU regulation of AI,[184] this dimension of trust does not necessarily support the conceptualisation of trust that connects to human dignity and autonomy and underpins fundamental patients' rights.[185] One of the reasons for patients to distrust health AI, is the perception that the AI-system will neglect the patient's unique characteristics and symptoms.[186] The AIA does not address this issue, because it does not focus on the end-user (e.g. the patient) and its individual preferences. For example, some patients may experience extra disadvantages in the use of health AI, for example due to the risks of bias in datasets, or differences in digital literacy. Therefore, the equal and intrinsic worth of every human being is not necessarily acknowledged which may lead to the risk of objectification of patients. This may have consequences for patients' trust in the health professional or healthcare in general when ADM is used in the health context. Furthermore, by not centralising the individual needs of end-users, the right to informed consent may be pressured. In comparison, the EU does take into account the personal circumstances of patients in relation to cross-border health care.[187] Finally, the question is to what extent the Commission's definition of AI is future-proof: by limiting the scope of application to specific techniques and methods, future innovations in the field of AI could fall outside the regulation, and developers of health AI may escape the requirements that do indirectly protect patients, such as the requirement to use high-quality datasets.[188]

Automated health decision-making challenges the foundational principles of autonomy, human dignity and trust and puts strains on the core patients' rights to information, informed consent and medical data protection. Although the EU seeks to create an environment in which the EU can grow to be a global leader in AI while building on EU values and fundamental rights,[189] the current approach does not deliver on this promise, as

[184] European Commission, WHITE PAPER on Artificial Intelligence - A European approach to excellence and trust, 19/02/2020.
[185] Jonathan Tallant and Donatella Donati, 'Trust: From the Philosophical to the Commercial' [2019] Philosophy of Management; Andreas Fuchs, Sigrid Gürgens and Carsten Rudolph, 'A Formal Notion of Trust – Enabling Reasoning about Security Properties' in Masakatsu Nishigaki and others (eds), *Trust Management IV* (Springer 2010).
[186] Yokoi *et al.*, "Artificial Intelligence Is Trusted Less than a Doctor in Medical Treatment Decisions: Influence of Perceived Care and Value Similarity", 37 *International Journal of Human–Computer Interaction* (2021), 981–990.
[187] See C-120/95 and C-158/96 (*Decker and Kohll*).
[188] Art. 10 AIA.
[189] European Commission, WHITE PAPER on Artificial Intelligence - A European approach to excellence and trust, 19/02/2020.

health-specific issues are not taken into account and patients' rights are not explicitly considered. Moreover, in the context of health AI, two further regulatory issues arise: (1) the EU's limited competence to regulate health and (2) the EU's marginalized position in protection of patients' rights. While the EU has a responsibility in protecting fundamental rights in general, patients' rights protection mainly takes place at the national level. At the EU level, there is no comprehensive regulation of patients' rights, and indirect protection of patients' rights through fundamental rights instruments still depend on national practices and laws.[190] This constitutional asymmetry caused by the EU's limited legislative competence in areas outside of the internal market,[191] is also highly visible in the context of health AI. The EU facilitates and encourages the introduction of health AI onto the internal market but provides limited safeguards to the rights of patients as end-users, which causes an asymmetry between the facilitating and the protecting role of the EU. This regulatory mismatch trickles down to the (proposed) legal framework governing health AI. In order to adequately protect patients' rights in the context of health AI, the EU must ensure direct obligations towards patients as end-users and empower those affected by AI-systems with effective and enforceable rights. This is the only way Europe can fully reap the benefits of the algorithmic turn in health, as protection of patients' rights is of vital importance to safeguard trust in the patient-health professional relationship and medical science as a whole.

6. Concluding remarks

The first steps in European regulation of AI have been taken and we now have to wait for consideration of the proposal by the European Parliament and the Council of the European Union. In spite of the limited attention for the healthcare sector, the Artificial Intelligence Act will have a major impact on patients in Europe. Analysed from a patients' rights perspective, current Europeanisation of health AI has a limited focus on the specific challenges AI-driven health decision-making poses to end-users and therefore does not do justice to the vulnerability of patients. This disconnect between the EU's interference in the regulation of health and its involvement in patients' rights protection becomes highly visible in the context of AI regulation. This is partially caused by the lack of a rights-based, human-centric approach in the proposed AIA. The question is whether - and how - the EU will respond to this problem. A new adjustment of the MDR? A guideline from the European Data Protection

[190] Hervey and McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2015) 160-164, 188.

[191] Scharpf, 'The Asymmetry of European Integration or why the EU cannot be a "Social Market Economy"' [2010] Socio Economic Review 211.

Board? An additional provision in the Artificial Intelligence Act? Or does the European Commission believe that protecting individual patients from the dangers of AI is a national matter? Answering these questions requires more research into the extent of the limits of EU competence to legislate in the area of health. Furthermore, this research area is in need of extensive empirical legal research into patients' experiences with health AI in practice in order to determine the best course of action for protecting trust and patients' rights after the algorithmic turn in health. The case of EU patients' rights protection in the health AI revolution is however not lost: the European Commission has only taken its first steps on the – presumably – long road to AI regulation. The key ingredients are there: the EU's focus on trust and fundamental rights protection set the stage for further patients' rights protection with regard to health AI. In any case, in that future there is a marked need for being mindful of the risks that AI-applications can pose to patients' rights in the meantime.