EU Regulation of Artificial Intelligence: Challenges for Patients' Rights

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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 theorizes the Europeanization 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.

1.   Introduction

The European Union is 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

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1. Cf. The European Commission's High Level Expert Group on Artificial Intelligence, "A definition of AI: Main capabilities and disciplines", (2018) available <ec.europa.eu/futurium/en/system/files/ged/ai_hleg_definition_of_ai_18_december_1.pdf> (all websites last visited 20 Oct. 2021).

to detect breast cancer in screening mammograms,[2] AI algorithms predicting outbreaks of infectious diseases,[3] AI-powered wearable devices for remote patient monitoring,[4] and fully autonomous robotic surgeons.[5] AI holds the promise of saving 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 the 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 the regulation of AI, which 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

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

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 Feb. 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. FRA (European Union Agency for Fundamental Rights), "Data quality and artificial intelligence – mitigating bias and error to protect fundamental rights" (2019).

8. 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.

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 sufficiently adapted to the impact of AI technology on patients. In this regard, the new Artificial Intelligence Act (AIA), which has 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 to patients' rights from health AI 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 regulate health directly. The principles of conferral and of subsidiarity limit the EU's possibilities 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

11. 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", *New York Times*, 21 March 2019.

12. Matheny et al., op. cit. *supra* note 6.

13. Art. 168 TFEU; Greer, Fahy and Rozenblum, *Everything You Always Wanted to Know About European Union Health Policies But Were Afraid to Ask*, 2nd ed. (European Observatory on Health Systems and Policies, 2019).

14. Beijer, *Limits of Fundamental Rights Protection by the EU: The Scope for the Development of Positive Obligations* (Intersentia, 2017), Ch. 8 "EU competences and subsidiarity in fundamental rights protection", 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 EJRR (2020), 747–756; Garben, "Competence creep revisited", 57 JCMS (2019), 205–222; Case C-376/98, *Germany* v. *European Parliament and Council (tobacco advertising)*, EU:C:2000:544.

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 raises the following question: does the European approach to AI provide protection to patients' rights in light of the current legislative framework?

This article examines the ways in which health AI is and will be regulated at the EU level and explores legal challenges through a patients' rights lens. Section 2 outlines the legal framework for patients' rights 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 measures in the area of health. The second part of section 5 evaluates to what extent these challenges to patients' rights are addressed in EU law and policy, and discusses whether forthcoming EU regulation will be sufficient. Section 6 provides a conclusion. Overall, this article seeks to theorize the Europeanization 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 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

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

18.   De Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (OUP, 2019).

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

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 partly 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 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 principles of conferral and subsidiarity limit the EU's powers in the field of healthcare,[23] as will be elaborated in section 5.1.[24] Patients' rights in Europe are determined first and foremost at the national level. However, the patients' rights framework in EU Member States is informed by EU law and policy.[25] At the same time, patients' rights are also protected and promoted at the EU level. 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

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

21. Albuquerque and Roffé, "The asymmetrical relationship between the health care professional and the patient in public hospitals", 19 *Journal International De Bioethique* (2008), 165–179, 205–206.

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. Art. 168(7) TFEU; see for more detail on this *infra* section 5.1.

24. Shuster, op. cit. *supra* note 15, 1436–1440.

25. Palm et al., op. cit. *supra* note 22, pp. 347–386.

26. Nys, "Comparative health law and the harmonization of patients' rights in Europe", 8 *European Journal of Health Law* (2001), 319.

does provide direction as to the minimum standard of rights patients in the EU Member States are entitled to.

The EU protects patients' rights in relation to specific areas, such as cross-border patient mobility (Cross-Border Patients' Rights Directive, 2011/24). Furthermore, patients' rights are recognized by the ECJ in relation to fundamental rights, such as health privacy.[27] The Charter of Fundamental Rights of the EU and the European Convention on Human Rights are therefore the most important legal sources in which patients' rights can be found.[28] To illustrate: the EU Charter of Fundamental Rights specifically protects the right to physical and mental integrity (Art. 3(1)) and the right to informed consent in the fields of medicine and biology (Art. 3(2)), and implicitly protects the rights to refuse medical treatment, the right to information about one's health, and the right to autonomy in medical decision-making.[29] Patients' rights related to access to healthcare and medicines can be derived from the rights to human dignity (Art. 1 CFR), prohibition of inhumane treatment (Art. 4 CFR), the right to non-discrimination (Arts. 20–26 CFR), and the right to access to healthcare (Art. 35 CFR).[30] Other legal sources include the ECHR and the Biomedicine Convention (Oviedo Convention) and the general principles of EU law.[31] The Council of Europe instruments – the 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. Patients' rights vis-à-vis health professionals have their origin in bioethical principles as expressed in the Hippocratic

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27. Case C-101/01, *Lindqvist,* EU:C:2003:596.
28. De Ruijter, op. cit. *supra* note 18.
29. See further ibid.
30. Also see the ECJ's case law on access to cross-border healthcare: Case C-120/95, *Decker*, EU:C:1998:167; Case C-158/96, *Kohll*, EU:C:1998:171; Case C-372/04, *Watts*, EU:C:2006:325.
31. Charter of Fundamental Rights of the European Union, O.J. 2000, 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.

Oath.[35] Most EU Member States have codified patients' rights in national legislation, ranging 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*

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, existing 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 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 [one's] 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 CFR which refers to the absolute inviolability of

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. "Patients' rights in the European Union: Mapping eXercise: Final report" (25 Jan. 2018), available <op.europa.eu/en/publication-detail/-/publication/8f187ea5-024b-11e8-b8f5-01aa75ed71a1/language-en>.

37. Smith, "Patients and doctors: Rights and responsibilities in the NHS", 5 *Clinical Medicine* (2005), 501–502.

38. Beauchamp and Childress, *Principles of Biomedical Ethics* (OUP, 1994).

39. Will, op. cit. *supra* note 35, 1491–1497.

40. Beauchamp and Childress, op. cit. *supra* note 38.

41. Ibid.

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 above-mentioned Oviedo 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 sole foundation of the patient-health professional relationship and patients were expected to trust their health professionals without questions being 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 is important in order 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 basis for several concrete patients' rights in EU Member States. Three core patients' rights can be derived from these underlying 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 must be provided for patients to make autonomous decisions about their bodies and give valid informed consent to medical treatment. The right to

42. Explanations relating to the Charter of Fundamental Rights, O.J. 2007, C 303/17–35.
43. Andorno, "Human dignity and human rights" in Ten Have and Gordijn (Eds.), *Handbook of Global Bioethics* (Springer, 2014).
44. See Art. 2 ECHR and Art. 7 CFR.
45. O'Neill, *Autonomy and Trust in Bioethics* (Cambridge University Press, 2002), pp. 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. "Patients' rights in the European Union: Final report", cited *supra* note 36.

medical data protection relates to both these rights, insofar as 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 affect the translation of the foundational principles into 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 increased significantly.[49] However, while healthcare is one of the leading application sectors in AI research, most products are still in the test and development phase and not yet 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 by which models are trained by analysing (often very large) datasets by finding patterns and drawing 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 preparing 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

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

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, available at <algorithmwatch.org/wp-content/uploads/2019/02/Automating_Society_Report_2019.pdf>.

52. Alpaydin, *Introduction to Machine Learning,* 4th ed. (MIT Press, 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.

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 win a central position in the healthcare sector: a growing number of healthcare institutions are 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 in 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 biggest 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 often used to manipulate people. The right of access to information is also at risk because of the role of algorithms in

55. "AI predicts which drug combinations kill cancer cells: A machine learning model developed in Finland can help us treat cancer more effectively", see <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. Press release, "Vonage enables AI chatbot for Spanish Government to provide accurate, updated COVID-19 information", available at <www.prnewswire.com/news-releases/vonage-enables-ai-chatbot-for-spanish-government-to-provide-accurate-updated-covid-19-information-301045621.html>.

58. Amisha et al., op. cit. *supra* note 54, 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", COM(2020)65 final, 19 Feb. 2020.

60. Davenport and Kalakota, op. cit. *supra* note 49, 94–98.

disseminating misinformation.[61] Moreover, because of biases in the training data or algorithm, AI technology can lead to inequality, which may conflict with the prohibition of discrimination.[62] In addition, the use of AI poses risks to the right to protection of private life and raises problems in relation to the right to an effective remedy and fair trial.[63]

In order to mitigate these risks and prevent different national rules and legal uncertainty from hampering free movement of AI-based goods and services across borders, 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-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 that a rather simple technical solution such as digitization of medical records has had on decision-making, the likely impact of AI-driven automated decision-making (ADM) on health decisions is huge.[68] The extent of the transformational consequences of health AI will depend on whether AI systems replace, diversify, or complement and expand previous solutions.[69] However, it can be expected that the growing presence of AI in the context of health will put pressure on the traditional conceptualization of patients' rights to some extent.

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 CML Rev. (2018), 1143–1186.

63. Grozdanovski, "In search of effectiveness and fairness in proving algorithmic discrimination in EU law", 58 CML Rev. (2021), 99–136.

64. European Council meeting Conclusions, Brussels, 19 Oct. 2017, EUCO 14/17.

65. Artificial Intelligence Act Proposal, cited *supra* note 8.

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), pp. 101–102.

69. Floridi, "AI and its new winter: From myths to realities", 33 *Philosophy & Technology* (2020), 1–3.

4.   Consequences of health AI for patients' rights

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 ADM 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 focused mainly on quality issues and liability problems from the developer's or health professional's point of view, but paid little attention to the legal consequences of AI-driven ADM for the end user's 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 focusing 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 give a thorough analysis of all effects that AI can have on patients, but, instead, to 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 the 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 if 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

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70. Agrebi and Larbi, op. cit. *supra* note 11, 415; Metz and Smith, op. cit. *supra* note 11.
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", 57 CML Rev. (2020), 1773–1818.
73. Karanasiou and Pinotsis, op. cit. *supra* note 66, 170–187.

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, it may rank treatment options for colorectal cancer on the basis of maximizing lifespan instead of minimizing suffering. This could 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, since privacy and data protection rights can be seen as the ability to self-rule 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 autonomously, society may experience a paradigm shift towards a more 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 applications on large amounts of personal data may cause problems for 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 might 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 possible threat of medical AI to the human dignity of patients,

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 Cohen, Minssen, Price, Robertson and Shachar (Eds.), *The Future of Medical Device Regulation: Innovation and Protection* (Cambridge University Press, 2021).

77. Feinberg, "Autonomy, sovereignty, and privacy: Moral ideals in the constitution", 58 *Notre Dame Law Review* (1983), 445.

78. Gill, "Prediction paradigm: The human price of instrumentalism", 35 *AI & SOCIETY* (2020), 509–517.

79. McDougall, op. cit. *supra* note 74, 156–160.

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 crucial for the health professional-patient relationship and protection of patients' rights is important in order to safeguard trust. 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 abide by 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 a 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. 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 when 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

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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", paper for IJCAI Workshop on Explainable Artificial Intelligence (XAI), Macau, China, 2019.

83. FRA Focus Paper, "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.

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 evolve to become more accurate through 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]

A third threat to trust in health AI comes from 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 showed 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. a 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 a particular medical diagnosis, even for the creator.[89] This may be because algorithms rely on rules that are 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 relation to medical treatment. The main principle justifying this right is autonomy, meaning the

85. Metz, "The robot surgeon will see you now", *New York Times*, 30 April 2021.
86. European Union Agency for Cybersecurity, "Artificial Intelligence Cybersecurity Challenges. Threat Landscape for Artificial Intelligence", Dec. 2020.
87. Cadario, Longoni and Morewedge, "Understanding, explaining, and utilizing medical artificial intelligence", (2021) *Nature Human Behaviour*, 1–7.
88. Ibid.
89. Bathaee, "The artificial intelligence black box and the failure of intent and causation", 31 *Harvard Journal of Law & Technology* (2017), 889–938.
90. Price, "Regulating black-box medicine", 116 *Michigan Law Review* (2017), 421–474.

underlying idea that sufficient information has to be provided for patients to make autonomous decisions about their bodies. Informed consent consists 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 if the health professional used 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 inform their patients fully about the steps in the medical decision-making process. Health professionals may be insufficiently knowledgeable and the information presented may be too complex for patients.[92] Further uncertainties may arise regarding which circumstances oblige health professionals to inform their patients of the inclusion 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 datasets?[94] The substantial degree of opaqueness, uncertainty, and lack of knowledge surrounding AI-driven medical decision-making may affect the manner in which patients can be guaranteed 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 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

91. Faden, Beauchamp and King, *A History and Theory of Informed Consent*, 1st ed. (OUP, 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, "Informed consent and medical artificial intelligence: What to tell the patient?", 108 *Georgetown Law Journal* (2020), 1425–1469.

94. Kiener, "Artificial intelligence in medicine and the disclosure of risks", *AI & SOCIETY* (2020).

95. Gerke, Minssen and Cohen, "Ethical and legal challenges of artificial intelligence-driven healthcare", *Artificial Intelligence in Healthcare* (2020), 295–336.

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 cause problems in relation to 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 anonymization 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 dataset, there is always a risk of re-identification of individuals.[98] This may harm patients' private life, as disclosure of personal health data may negatively affect employment, insurance coverage, and social life.[99]

The "data hunger" of AI applications may entail tensions with 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 processors of personal data may not be 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 minimization (limiting data collection to only what is required to fulfil a specific purpose) seems to be in conflict with technology that needs enormous datasets to function and evolve.[101] Other issues arise in relation to individual data protection rights, such as transparency rights and the right to erasure. Is it always possible to provide patients with an individualized explanation of

96. Cohen, op. cit. *supra* note 93, 1425–1469.

97. Daelman, "AI through a human rights lens. The role of human rights in fulfilling AI's potential" in De Bruyne and Vanleenhove (Eds.), *Artificial Intelligence and the Law* (Intersentia, 2021), pp. 123–148.

98. Rocher, Hendrickx and de Montjoye, "Estimating the success of re-identifications in incomplete datasets using generative models", 10 *Nature Communications* (2019), 3069.

99. Price and Cohen, "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 Think Tank, "The impact of the General Data Protection Regulation (GDPR) on artificial intelligence", 2020.

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 Europeanization 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 governing 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 for 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 competences 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] it has limited legislative powers in the area of health. Article 168 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 origin, medicines and medical devices, which fall under shared competence.[106] Article 168(5) TFEU actually excludes the harmonization of the laws and regulations of the Member States regarding serious cross-border threats to health, tobacco and alcohol abuse. Article 168(7) TFEU explicitly recognizes the sovereignty of Member States for

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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 et al., op. cit. *supra* note 95, 295–336.
104. Art. 3(1) TEU.
105. Art. 168(5) TFEU.
106. Art. 4(2)(k) TFEU and Art. 168(4) TFEU.

health policy, health services and medical care Nevertheless, despite the absence of a strong legal basis, the body of EU health law and policy is increasing. The reason for this is twofold. First, the EU extensively uses its complementary competence 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, as long as those measures remove obstacles hindering the internal market. In this way, the internal market dimension of EU law does allow for certain harmonizing measures in the field of public health and healthcare.[110] Similarly, the Treaty rules on free movement of services (Arts. 56–62 TFEU), interpreted by the ECJ to apply to healthcare,[111] led to the adoption of the Patients' Rights Directive on Cross-Border Healthcare.[112] The internal market legal basis, however, does 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 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 CFR and the GDPR); and (4) consumer protection

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107. See Art. 6 TFEU.

108. De Ruijter, op. cit. *supra* note 18; Greer et al., op. cit. *supra* note 13.

109. De Ruijter, op. cit. *supra* note 18; Davies, "The Community's internal market-based competence to regulate healthcare: Scope, strategies and consequences", 14 MJ (2007), 215–238; Delhomme, op. cit. *supra* note 16, 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 EJRR (2020), 297–306.

111. Case C-158/96, *Kohll*; Joined Cases 286/82 & 26/83, *Luisi and Carbone*, EU:C:1984:35; Case C-157/99, *Geraets-Smits and Peerbooms*, EU:C:2001:404.

112. Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, O.J. 2011, L 88/45; see 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'", 12 GLJ (2011), 827; Case C-376/98, *Germany* v. *Parliament and Council*.

regulation (e.g. regulations on product liability and unfair commercial practices).[114] The proposed 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 protect patients adequately 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 take a central position in the legal framework surrounding health AI. However, they are not necessarily adapted to the particular 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 data protection in the EU, including health, 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 ECJ 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

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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 et al., op. cit. *supra* note 95, 295–336.

115. Art. 4 GDPR.

116. Art. 6 GDPR.

117. Chapter III GDPR.

118. Arts. 12–13 GDPR.

119. Art. 15 GDPR.

120. Art. 7(3) GDPR.

121. Case C-362/14, *Schrems*, EU:C:2015:650, para 91; ECtHR, *Khelili* v. *Switzerland*, Appl. No. 16188/07, judgment of 18 Oct. 2011.

122. Van Kolfschooten, op. cit. *supra* note 76.

algorithms;[123] data subject rights such as transparency rights are not always useful, as the algorithm is difficult to understand for 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 such 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 are thus not covered by the GDPR.[132] However, as different datasets might be available in a 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

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123. Art. 5 GDPR.
124. Edwards and Veale, op. cit. *supra* note 102, 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.

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 in the "use" phase. In this phase, the algorithmic model is applied to a particular set of personal data in order to take 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 always to 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: " 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used,

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133. Rocher et al., op. cit. *supra* note 98, 3069.
134. AEPD-EDPS joint paper, "10 misunderstandings related to anonymisation", 2021, <edps.europa.eu/system/files/2021-04/21-04-27_aepd-edps_anonymisation_en_5.pdf>.
135. Arts. 13(2)(f) and 14(2)(g) GDPR.
136. Art. 22(1) and (2) GDPR.
137. Art. 22(3) GDPR.
138. Arts. 13(2)(f) and 14(2)(g) GDPR.
139. Edwards and Veale, op. cit. *supra* note 102, 46–54.
140. Note that as of May 2021, Regulation (EU) 2017/745 on Medical devices (MDR), O.J. 2017, L 117, replaced Directive 93/42/EEC.

alone or in combination, for human beings for one or more of the following specific medical purposes: – 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 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 relate mainly to physical risks.[145] As to privacy and data protection, the MDR protects health privacy primarily by referring to the GDPR (c.q. its predecessor Directive 95/46); it 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. Preparation 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

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141. Art. 2(1) MDR.
142. See Yu, "Regulation of digital health technologies in the EU: Intended versus actual use" in Glenn Cohen, Minssen, Nicholson Price II, Robertson and Shachar (Eds.), *The Future of Medical Device Regulation: Innovation and Protection* (Cambridge University Press, 2022, forthcoming).
143. Recital 19 MDR.
144. Annex VIII MDR.
145. Annex I, Chapter I and III MDR.
146. Arts. 109–110 MDR.
147. European Council meeting cited *supra* note 64.

world leader in the AI revolution".[148] At the same time, a "High-Level Expert Group on Artificial Intelligence" was set up in order to advise the Commission on the new AI policy.[149] With the input of the AI HLEG and the European AI Alliance, the Commission published the White Paper on Artificial Intelligence in February 2020,[150] accompanied by a Communication[151] and a Report;[152] it concluded that the current EU legal framework was insufficiently equipped to address the new challenges posed by AI. The Council also called for more regulation to ensure compatibility with fundamental rights.[153] On 21 April 2021, the Commission published the long-awaited legislative proposal on artificial intelligence: the Artificial Intelligence Act (AIA).[154] The main purpose of the legislation is to improve the functioning of the internal market of AI by laying down rules for development, marketing and use, using 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 deals with AI in general.

5.3.1. *Risk-based approach to AI regulation*

The AIA defines an "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 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

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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 April 2018.

149. European Commission, "Artificial Intelligence for Europe", COM(2018)237.

150. White Paper cited *supra* note 59.

151. European Commission Communication, "A European strategy for data", 19 Feb. 2020, COM(2020)66 final.

152. European Commission, "Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics", 19 Feb. 2020, COM(2020)64 final.

153. Presidency conclusions – The Charter of Fundamental Rights in the context of Artificial Intelligence and Digital Change, 11481/20.

154. Proposal cited *supra* note 8.

155. Art. 3 AIA.

156. Leonelli, op. cit. *supra* note 72, 1773–1818.

people's security, livelihoods and rights, such as algorithmic social credit systems that rate citizens based on behaviour.[157] "High risk" includes AI systems that are 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, such as chatbots, qualify as "limited risk".[161] The AIA 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 conditions 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 is 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 commits to facilitate voluntary codes of conduct.[170]

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157. Art. 5 AIA.
158. Art. 6 AIA.
159. Recitals 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. Arts. 14–15 AIA.
167. Arts. 11–12, 51, 60 AIA.
168. Arts. 56–59 AIA.
169. Art. 52 AIA.
170. Art. 69 AIA.

5.4.   *Artificial Intelligence Act: New guardian of patients' rights?*

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, however, has been criticized by human rights organizations 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 focuses 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 the opposite of 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 AI algorithms. 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 threaten the value of human dignity underpinning all EU patients' rights.

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171. Reinhold, "AlgorithmWatch's response to the European Commission's proposed regulation on Artificial Intelligence – A major step with major gaps", 22 April 2021, <algorithmwatch.org/en/response-to-eu-ai-regulation-proposal-2021/>.

172. European Commission – Directorate-General for Communications Networks, Content and Technology, "The European AI Landscape – Workshop Report", 2018.

173. See e.g. Arts. 4 and 5 of the Cross-Border Patients' Rights Directive 2011/24, and Art. 5 of the General Product Safety Directive, 2001/95, O.J. 2002, L 11/4.

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 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 if the general practitioner makes use of an AI-powered diagnosis chatbot; this limits the patients' rights to refuse treatment and informed consent. In addition, the AIA also fails to defer the responsibility for patients' rights protection to Member States, as the Cross-Border Patients' Rights Directive does for the patients' rights to access 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, as it sets the additional requirement that the systems must cause physical or psychological damage or have the capability of doing so.[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 the MDR are considered to pose "limited risk"

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174. Art. 17 GDPR.
175. Ibid.
176. Art. 5(b) Cross-Border Patients' Rights Directive 2011/24.
177. Art. 5 AIA.
178. Annex III AIA.

and are 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 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 direct and indirect effects on the human body, or the use of sensitive health data. To illustrate, mobile pregnancy apps offering AI-powered recommendations will likely influence the (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 of the extent to which 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 for the right to medical data protection. During the COVID-19 pandemic, enormous amounts of sensitive data were processed in the interest of public health, therefore causing problems for 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 the 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

179. Recital 19 MDR.
180. Art. 5 AIA.
181. Cave et al., "Using AI ethically to tackle Covid-19", (2021) *British Medical Journal*, 372.
182. Van Kolfschooten and Ruijter, "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.

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 protection, and can actually disadvantage patients. The concept of patients as sources of data rather than human beings with intrinsic worth threatens 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 conceptualization 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 their 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 increase the risk of objectification of patients. This can have consequences for patients' trust in the health professional or healthcare in general when ADM is used in the health context. Furthermore, because the individual needs of end users are not put at the centre, the right to informed consent may come under pressure. In comparison, the EU does take into account the personal circumstances of patients in relation to cross-border healthcare.[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 these rules, 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 a strain on the core patients'

184. European Commission, White Paper cited *supra* note 59.
185. Tallant and Donati, "Trust: From the philosophical to the commercial", (2019) *Philosophy of Management*; Fuchs, Gürgens and Rudolph, "A formal notion of trust – Enabling reasoning about security properties" in Nishigaki et al. (Eds.), *Trust Management IV* (Springer, 2010).
186. Yokoi et al., op. cit. *supra* note 81, 981–990.
187. See Case C-120/95, *Decker*, and Case C-158/96, *Kohll*.
188. Art. 10 AIA.

rights to information, informed consent, and medical data protection. Although the EU seeks to create an environment in which the EU can develop into a global leader in AI while building on EU values and fundamental rights,[189] the current approach does not deliver on this promise, as 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 depends on national practices and laws.[190] This constitutional asymmetry caused by the EU's limited legislative competence in areas outside the internal market[191] is highly visible in the context of health AI. The EU facilitates and encourages the introduction of health AI onto the internal market, but provides only limited safeguards to the rights of patients as end users, with a resulting asymmetry. This regulatory mismatch trickles down to the (proposed) legal framework governing health AI. In order to protect patients' rights adequately 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. In spite of the limited attention for the healthcare sector, the AIA will have a major impact on patients in Europe. Analysed from a patients' rights perspective, current Europeanization 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

189. European Commission, White Paper cited *supra* note 59.
190. Hervey and McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2015), pp. 160–164, p. 188.
191. Scharpf, "The asymmetry of European integration or why the EU cannot be a 'social market economy'", (2010) *Socio Economic Review*, 211.

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-centred 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 Board? An additional provision in the AIA? Or does the 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 EU competence to legislate in the area of health. Furthermore, this research area is in need of empirical legal research on patients' experiences with health AI in practice in order to determine the best course of action for protecting trust and patients' rights following the algorithmic turn in health. The cause of EU patients' rights protection in the health AI revolution, however, is not lost: the Commission has only taken its first steps on the – presumably – long road to AI regulation. The key ingredients are present: the EU's focus on trust and fundamental rights protection have set the stage for further patients' rights protection with regard to health AI. In the meantime, the risks that AI applications can pose to patients' rights should not be ignored.