Patients' rights protection and artificial intelligence in the European Union

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CHAPTER 4

EU REGULATION OF ARTIFICIAL INTELLIGENCE: CHALLENGES FOR PATIENTS' RIGHTS[1]

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.

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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.[2] AI technologies can be deployed for many aspects of healthcare and public health: from AI software to detect breast cancer in screening mammograms,[3] AI algorithms predicting outbreaks of infectious diseases,[4] AI-powered wearable devices for remote patient monitoring,[5] and fully autonomous robotic surgeons.[6] 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.[7] At the same time, AI can bring about serious risks for individual fundamental rights, such as human dignity, privacy, and non-discrimination.[8] In reaction to these challenges, the European Commission recently put forward a legislative proposal for the regulation of AI: the Artificial Intelligence Act.[9] 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

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[2] Sofia Samoili and others, *AI WATCH. Defining Artificial Intelligence* (Publications Office of the European Union 2020).

[3] Scott Mayer McKinney and others, 'International Evaluation of an AI System for Breast Cancer Screening' (2020) 577 Nature 89.

[4] Becky McCall, 'COVID-19 and Artificial Intelligence: Protecting Health-Care Workers and Curbing the Spread' (2020) 2 The Lancet Digital health e166.

[5] 'FDA Approves Current Health AI-Powered Wearable Solution for Hospital Care' (*NS Medical Devices*, 7 February 2019) <https://www.nsmedicaldevices.com/news/current-health-ai-powered-wearable/> accessed 11 August 2024.

[6] Ghose Aruni, Ghose Amit and Prokar Dasgupta, 'New Surgical Robots on the Horizon and the Potential Role of Artificial Intelligence' (2018) 59 Investigative and clinical urology 221.

[7] Michael Matheny and others, *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril* (National Academies Press 2019).

[8] European Union Agency for Fundamental Rights, 'Data Quality and Artificial Intelligence – Mitigating Bias and Error to Protect Fundamental Rights' (7 June 2019) <http://fra.europa.eu/en/publication/2019/data-quality-and-artificial-intelligence-mitigating-bias-and-error-protect>.

[9] 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.

to regulate AI.[10] 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.[11] 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.[12] 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.[13] 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,

[10] ibid.
[11] Sally Dalton-Brown, 'The Ethics of Medical AI and the Physician-Patient Relationship' (2020) 29 Cambridge quarterly of healthcare ethics 115.
[12] Said Agrebi and Anis Larbi, 'Use of Artificial Intelligence in Infectious Diseases' in Debmalya Barh (ed), *Artificial Intelligence in Precision Health* (Elsevier 2020) 415.
[13] Matheny and others (n 7).

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,[14] and the EU does not have a general competence to take action to protect fundamental rights.[15] As a result, there is no comprehensive legal system for patients' rights protection at the EU level.[16] Most EU legislation in the field of health is based on the internal market legal basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU).[17] The EU legal instruments that do directly regulate health, such as the Medical Device 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.[18] 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?

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[14] Article 168 of the Consolidated version of the Treaty on the Functioning of the European Union [2012] OJ C 326/47 (TFEU); Scott L Greer and others, *Everything You Always Wanted to Know about European Union Health Policies but Were Afraid to Ask* (World Health Organization Regional Office for Europe 2022).

[15] MP Beijer, *The Limits Of Fundamental Rights Protection By The EU. The Scope for the Development of Positive Obligations* (Intersentia 2017).

[16] Evelyne Shuster, 'Fifty Years Later: The Significance of the Nuremberg Code' (1997) 337 New England Journal of Medicine 1436.

[17] Vincent Delhomme, 'Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health' (2020) 11 European journal of risk regulation 747; Sacha Garben, 'Competence Creep Revisited' (2019) 57 Journal of Common Market Studies 205; Case C-376/98 *Germany* v. *European Parliament and Council (tobacco advertising)* ECLI:EU:C:2000:544, [2000] ECR I-8419.

[18] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Medical Device Regulation) (Text with EEA relevance) [2017] OJ L 117/1 (MDR); Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L 119/1 (GDPR); I Glenn Cohen and others, 'The European Artificial Intelligence Strategy: Implications and Challenges for Digital Health' (2020) 2 The Lancet Digital Health e376.

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.[19] The rights of patients are rooted in the notion of human dignity and can be linked to ethical principles and human rights standards.[20] 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.[21] 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

[19] Anniek de Ruijter (ed), 'Institutional Build-up of EU Health Actors' in *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press 2019).
[20] Jonathan Cohen and Tamar Ezer, 'Human Rights in Patient Care: A Theoretical and Practical Framework' (2013) 5 Health and Human Rights Journal.
[21] Joachim Boldt, 'The Concept of Vulnerability in Medical Ethics and Philosophy' (2019) 14 Philosophy, ethics, and humanities in medicine 6.

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.[22] 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.[23] 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,[24] as will be elaborated in section 5.1.[25] 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.[26] 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.[27] 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 States are entitled to.

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[22] Maria Clara Albuquerque and Raquel Roffé, 'The Asymmetrical Relationship between the Health Care Professional and the Patient in Public Hospitals' (2008) 19 Journal International De Bioethique = International Journal of Bioethics 165.
[23] Willy Palm and others, 'Patients' Rights: From Recognition to Implementation' in Anders Anell, Ellen Nolte and Sherry Merkur (eds), *Achieving Person-Centred Health Systems: Evidence, Strategies and Challenges* (Cambridge University Press 2020).
[24] Article 168(7) TFEU; see for more detail on this *infra* section 5.1.
[25] Shuster (n 16).
[26] Palm and others (n 23).
[27] Herman Nys, 'Comparative Health Law and the Harmonization of Patients' Rights in Europe' (2001) 8 European journal of health law 317.

The EU protects patients' rights in relation to specific areas, such as cross-border patient mobility (Cross-Border Patients' Rights Directive).[28] Furthermore, patients' rights are recognized by the Court of Justice of the European Union (ECJ) in relation to fundamental rights, such as health privacy.[29] 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.[30] To illustrate: the EU Charter of Fundamental Rights specifically protects the right to physical and mental integrity (Article 3(1)) and the right to informed consent in the fields of medicine and biology (Article 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.[31] Patients' rights related to access to healthcare and medicines can be derived from the rights to human dignity (Article 1 CFR), prohibition of inhumane treatment (Article 4 CFR), the right to non-discrimination (Articles 20–26 CFR), and the right to access to healthcare (Article 35 CFR).[32] Other legal sources include the European Convention on Human Rights (ECHR) and the Biomedicine Convention (Oviedo Convention) and the general principles of EU law.[33] 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.[34] Finally, patients' rights are protected in non-binding instruments, such as the European Charter of Patients' Rights.[35]

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[28] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (Cross-Border Patients' Rights Directive) [2011] OJ L 88/45.

[29] Case C-101/01 *Bodil Lindqvist* ECLI:EU:C:2003:596, [2003] ECR I-12971.

[30] De Ruijter (n 19).

[31] See further ibid.

[32] Charter of Fundamental Rights of the European Union [2012] OJ C 326/391 (CFR). Also see the ECJ's case law on access to cross-border healthcare: Case C-120/95 *Decker* ECLI:EU:C:1998:167, [1998] ECR I-1831; Case C-158/96 *Kohll* ECLI:EU:C:1998:171, [1998] ECR I-1931; Case C-372/04 *Watts* ECLI:EU:C:2006:325, [2006] ECR I-4325.

[33] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR); 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 (ETS No. 164) 04/04/1997 (Oviedo Convention); Roberto Andorno, 'The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law' (2005) 2 Journal of International Biotechnology Law 133.

[34] Article 6(3) of the Consolidated version of the Treaty on European Union [2012] OJ C 326/13 (TEU).

[35] Active Citizenship Network, *European Charter of Patients' Rights, Basis Document* (Rome, November 2002)

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.[36] 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 Oath.[37] Most EU Member States have codified patients' rights in national legislation, ranging from national constitutions to specific patients' rights laws to civil codes.[38] Many national health laws are supplemented by ethical codes and standards of health practice in order to protect patients' rights.[39] 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.[40] 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.[41] In the standard approach to medical ethics as developed by Beauchamp and

<https://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf>.

[36] Article 6(3) TEU.

[37] Jonathan F Will, 'A Brief Historical and Theoretical Perspective on Patient Autonomy and Medical Decision Making: Part II: The Autonomy Model' (2011) 139 Chest 1491.

[38] David Townend and others, *Patients' Rights in the European Union: Mapping eXercise : Final Report* (Publications Office of the European Union 2016).

[39] Melissa Smith, 'Patients and Doctors: Rights and Responsibilities in the NHS (2)' (2005) 5 Clinical Medicine 501.

[40] Tom L Beauchamp and James F Childress, 'Principles of Biomedical Ethics' (1991) 6 International clinical psychopharmacology 129.

[41] Will (n 37).

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".[42] 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.[43]

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 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.[44] Human dignity is also seen as a central value and overarching principle in international bioethical standards, including the above-mentioned Oviedo Convention.[45] 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,[46] 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.[47] In healthcare, the concept of *interpersonal* trust is crucial for the health professional-patient relationship.[48] In the area of

[42] Beauchamp and Childress (n 40).
[43] ibid.
[44] Explanations relating to the Charter of Fundamental Rights [2007] OJ C 303/17.
[45] Roberto Andorno, 'Human Dignity and Human Rights' in Henk AMJ ten Have and Bert Gordijn (eds), *Handbook of Global Bioethics* (Springer Netherlands 2014).
[46] See Article 2 ECHR and Article 7 CFR.
[47] Onora O'Neill, *Autonomy and Trust in Bioethics* (Cambridge University Press 2002).
[48] BH Gray, 'Trust and Trustworthy Care in the Managed Care Era' (1997) 16 Health Affairs 34.

public health, *social* trust in public institutions plays an essential role.[49] 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.[50] 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 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.[51] However, while

[49] Steven D Pearson and Lisa H Raeke, 'Patients' Trust in Physicians: Many Theories, Few Measures, and Little Data' (2000) 15 Journal of general internal medicine 509.
[50] Townend and others (n 38).
[51] Thomas Davenport and Ravi Kalakota, 'The Potential for Artificial Intelligence in Healthcare' (2019) 6 Future Healthcare Journal 94.

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.[52] AI-driven automated decision-making can be defined as procedures in which decisions are – partially or completely – delegated to an AI system.[53] 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.[54] 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.[55] AI holds the promise to increase accuracy, efficiency, and accessibility of healthcare for patients.[56] 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.[57] 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.[58] AI is also used to improve accessibility, for example in

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[52] Urs J Muehlematter, Paola Daniore and Kerstin N Vokinger, 'Approval of Artificial Intelligence and Machine Learning-Based Medical Devices in the USA and Europe (2015–20): A Comparative Analysis' (2021) 3 The Lancet Digital Health e195.

[53] Based on the definition of Algorithm Watch, available at <algorithmwatch.org/wp-content/uploads/2019/02/Automating_Society_Report_2019.pdf>.

[54] Ethem Alpaydin, *Introduction to Machine Learning* (4th edn, The MIT Press 2020).

[55] Yutong Wang and others, 'Application of Artificial Intelligence to the Diagnosis and Therapy of Colorectal Cancer' (2020) 10 American journal of cancer research 3575.

[56] Paras Malik, Monika Pathania and Vyas Rathaur, 'Overview of Artificial Intelligence in Medicine' (2019) 8 Journal of family medicine and primary care 2328.

[57] Aalto University, 'AI predicts which drug combinations kill cancer cells: A machine learning model developed in Finland can help us treat cancer more effectively' (*Science Daily*, 1 December 2020) <www.sciencedaily.com/releases/2020/12/201201084800.htm> accessed 16 August 2024.

[58] Karin Dembrower and others, 'Effect of Artificial Intelligence-Based Triaging of Breast Cancer Screening Mammograms on Cancer Detection and Radiologist Workload: A Retrospective Simulation Study' (2020) 2 The Lancet Digital health e468.

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.[59] 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.[60]

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.[61] Health is often named as the biggest market opportunity for AI and therefore offers significant socio-economic benefits to the EU internal market.[62] 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 disseminating misinformation.[63] Moreover, because of biases in the training data or algorithm, AI technology can lead to inequality, which may conflict with the prohibition of discrimination.[64] 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.[65]

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[59] 'Vonage Enables AI Chatbot for Spanish Government to Provide Accurate, Updated COVID-19 Information' (*Vonage*, 23 April 2020) <https://www.prnewswire.com/news-releases/vonage-enables-ai-chatbot-for-spanish-government-to-provide-accurate-updated-covid-19-information-301045621.html> accessed 11 August 2024.

[60] Malik, Pathania and Rathaur (n 55); KPMG, 'Inventarisatie AI-toepassingen in gezondheid en zorg in Nederland' (5 October 2020) <https://www.rijksoverheid.nl/documenten/rapporten/2020/10/05/inventarisatie-ai-toepassingen-in-gezondheid-en-zorg-in-nederland>.

[61] European Commission, WHITE PAPER On Artificial Intelligence - A European approach to excellence and trust (COM/2020/65 final).

[62] Davenport and Kalakota (n 50).

[63] 'Getting the Future Right – Artificial Intelligence and Fundamental Rights' (*European Union Agency for Fundamental Rights*, 18 November 2020) <http://fra.europa.eu/en/publication/2020/artificial-intelligence-and-fundamental-rights>.

[64] Philipp Hacker, 'Teaching Fairness to Artificial Intelligence: Existing and Novel Strategies against Algorithmic Discrimination under EU Law' (2018) 55 Common market law review 1143.

[65] Ljupcho Grozdanovski, 'In Search of Effectiveness And Fairness And Fairness in Proving Algorithmic Discrimination in EU Law' (2021) 58 Common market law review 99.

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.[66] 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).[67] 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.[68] 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?[69] 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.[70] The extent of the transformational consequences of health AI will depend on whether AI systems replace, diversify, or complement and expand previous solutions.[71] 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.

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

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66 General Secretariat of the Council, 'European Council Conclusions, 19/10/2017' (19 October 2017) <https://www.consilium.europa.eu/en/press/press-releases/2017/10/20/euco-conclusions-final/>.

67 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 (n 9).

68 Argyro P Karanasiou and Dimitris A Pinotsis, 'A Study into the Layers of Automated Decision-Making: Emergent Normative and Legal Aspects of Deep Learning' (2017) 31 International review of law, computers & technology 170.

69 Mariarosaria Taddeo and Luciano Floridi, 'How AI Can Be a Force for Good' (2018) 361 American Association for the Advancement of Science 751.

70 Max Tegmark, *LIFE 3.0: Being Human in the Age Of Artificial Intelligence* (Knopf 2017)

71 Luciano Floridi, 'AI and Its New Winter: From Myths to Realities' (2020) 33 Philosophy & technology 1.

dependency of patients and the potentially life-threatening effects of inaccurate or dysfunctional AI technology used in the health environment.[72] However, different types of health AI present different degrees of risk.[73] 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.[74] 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).[75] 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

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[72] Agrebi and Larbi (n 12).
[73] Heleen L Janssen, 'An Approach for a Fundamental Rights Impact Assessment to Automated Decision-Making' (2020) 10 International data privacy law 76.
[74] Giulia Claudia Leonelli, 'Acknowledging the Centrality of the Precautionary Principle in Judical Review of EU Risk Regulation: Why it Matters' (2020) 57 Common market law review 1773.
[75] Karanasiou and Pinotsis (n 68).

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.[76] 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.[77] Furthermore, patients are often unaware of the exact extent of personal data processed by health AI.[78] 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.[79]

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.[80] 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

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[76] Rosalind J McDougall, 'Computer Knows Best? The Need for Value-Flexibility in Medical AI' (2019) 45 Journal of Medical Ethics 156.
[77] Thomas Grote and Philipp Berens, 'On the Ethics of Algorithmic Decision-Making in Healthcare' (2020) 46 Journal of Medical Ethics 205.
[78] Hannah van Kolfschooten, 'The mHealth Power Paradox: Improving Data Protection in Health Apps through Self-Regulation in the European Union' in I Glenn Cohen and others (eds), *The Future of Medical Device Regulation: Innovation and Protection* (Cambridge University Press 2022).
[79] Joel Feinberg, 'Autonomy, Sovereignty, and Privacy: Moral Ideals in the Constitution?' (1983) 58 The Notre Dame law review 445.
[80] Karamjit S Gill, 'Prediction Paradigm: The Human Price of Instrumentalism' (2020) 35 AI & society 509.

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.[81] Naturally, the extent of the possible threat of medical AI to the 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.[82]

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 abide by similar values as human health professionals.[83] 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.[84] 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

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[81] McDougall (n 76).
[82] Danielle S Bitterman, Hugo JWL Aerts and Raymond H Mak, 'Approaching Autonomy in Medical Artificial Intelligence' (2020) 2 The Lancet Digital health e447.
[83] Ryosuke Yokoi and others, 'Artificial Intelligence Is Trusted Less than a Doctor in Medical Treatment Decisions: Influence of Perceived Care and Value Similarity' (2021) 37 International journal of human-computer interaction 981.
[84] Andrea Papenmeier, Gwenn Englebienne and Christin Seifert, 'How Model Accuracy and Explanation Fidelity Influence User Trust' (*arXiv*, 26 July 2019) <https://arxiv.org/abs/1907.12652> accessed 11 August 2024.

AI is only as good as the data it uses.[85] 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.[86] 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 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.[87] 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.[88]

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.[89] 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

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[85] 'Data Quality and Artificial Intelligence – Mitigating Bias and Error to Protect Fundamental Rights' (n 8).
[86] Ziad Obermeyer and others, 'Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations' (2019) 366 Science 447.
[87] Cade Metz, 'The Robot Surgeon Will See You Now' *The New York Times* (30 April 2021) <https://www.nytimes.com/2021/04/30/technology/robot-surgery-surgeon.html> accessed 11 August 2024.
[88] European Union Agency for Cybersecurity, 'Artificial Intelligence Cybersecurity Challenges' (15 December 2020) <https://www.enisa.europa.eu/publications/artificial-intelligence-cybersecurity-challenges>.
[89] Romain Cadario, Chiara Longoni and Carey K Morewedge, 'Understanding, Explaining, and Utilizing Medical Artificial Intelligence' (2021) 5 Nature human behaviour 1636.

detection app that analyses a picture of a skin mole) to identify cancerous skin lesions.[90]

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.[91] 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.[92] 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 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.[93] 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.[94] Further uncertainties may arise regarding

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[90] ibid.
[91] Yavar Bathaee, 'The Artificial Intelligence Black Box and the Failure of Intent and Causation' (2018) 31 Harvard journal of law & technology 889.
[92] W Nicholson Price, 'Regulating Black-Box Medicine' (2017) 116 Michigan law review 421.
[93] Bartholome WG, 'Review of Ruth R. Faden and Tom L. Beauchamp: A History and Theory of Informed Consent' (1988) 98 Ethics 605.
[94] Daniel Schiff and Jason Borenstein, 'How Should Clinicians Communicate With Patients About the Roles of Artificially Intelligent Team Members?' (2019) 21 AMA Journal of Ethics 138.

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?[95] 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?[96] 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?[97] 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?[98]

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.[99] 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

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95 I Glenn Cohen, 'Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?' (2020) 108 Georgetown Law Journal 1425.
96 Maximilian Kiener, 'Artificial Intelligence in Medicine and the Disclosure of Risks' (2021) 36 AI & society 705.
97 Sara Gerke, Timo Minssen and Glenn Cohen, 'Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare' (2020) Artificial Intelligence in Healthcare 295.
98 Cohen (n 95).
99 Charline Daelman and Katerina Yordanova, 'AI through a Human Rights Lens. The Role of Human Rights in Fulfilling AI's Potential' in Jan De Bruyne and Cedric Vanleenhove (eds), *Artificial Intelligence and the Law* (Intersentia 2023).

dataset, there is always a risk of re-identification of individuals.[100] This may harm patients' private life, as disclosure of personal health data may negatively affect employment, insurance coverage, and social life.[101]

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.[102] 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.[103] 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 automated decisions?[104] And can patients request the deletion of personal data that has already been aggregated and analysed?[105] The emergence of AI-driven ADM in the context of health is likely to put strains on the patients' right to medical data protection.

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[100] L Rocher, J Hendrickx and YA De Montjoye, 'Estimating the Success of Re-Identifications in Incomplete Datasets Using Generative Models' (2019) 10 Nature.
[101] Price W Nicholson II and I Glenn Cohen, 'Privacy in the Age of Medical Big Data' (2019) 25 Nature medicine 37.
[102] Michael J Rigby, 'Ethical Dimensions of Using Artificial Intelligence in Health Care' (2019) 21 AMA Journal of Ethics 121.
[103] Sartor G, *The Impact of the General Data Protection Regulation (GDPR) on Artificial Intelligence* (European Parliamentary Research Service 2020).
[104] Lilian Edwards and Michael Veale, 'Enslaving the Algorithm: From a "Right to an Explanation" to a "Right to Better Decisions"?' (2018) 16 IEEE security & privacy 46.
[105] Gerke, Minssen and Cohen (n 97).

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,[106] 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.[107] 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.[108] 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",[109] which has powerful effects for health policy and law in the Member States.[110] Second, the EU often resorts to the legal basis of Article 114 TFEU, regarding the integration of the internal market, to justify

[106] Article 3(1) TEU.
[107] Article 168(5) TFEU.
[108] Article 4(2)(k) TFEU; Article 168(4) TFEU.
[109] See Article 6 TFEU.
[110] De Ruijter (n 19); Greer and others (n 14).

regulation of human health.[111] 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.[112] Similarly, the Treaty rules on free movement of services (Arts. 56–62 TFEU), interpreted by the ECJ to apply to healthcare,[113] led to the adoption of the Patients' Rights Directive on Cross-Border Healthcare.[114] The internal market legal basis, however, does not permit limitless legislative harmonization under the flag of health.[115] 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 regulation (e.g. regulations on product liability and unfair commercial practices).[116] 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

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[111] Agrebi and Larbi (n 12); Gareth Davies, 'The Community's Internal Market-Based Competence to Regulate Healthcare: Scope, Strategies and Consequences' (2007) 14 Maastricht journal of European and comparative law 215; Delhomme (n 17).

[112] Kai P Purnhagen and others, 'More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak' (2020) 11 European journal of risk regulation 297.

[113] *Kohll* (n 32); Joined Cases C-286/82 & C-26/83 *Luisi and Carbone* ECLI:EU:C:1984:35, [1984] ECR 377; Case C-157/99 *Geraets-Smits and Peerbooms* ECLI:EU:C:2001:404, [2001] ECR I-5473.

[114] Clemens M Rieder, 'Cross-Border Movement of Patients in the Eu: A Re-Appraisal' (2017) 24 European journal of health law 390.

[115] Stephen 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. *European Parliament and Council (tobacco advertising)* (n 17).

[116] Evas T, *European Framework on Ethical Aspects of Artificial Intelligence, Robotics and Related Technologies* (European Parliamentary Research Service 2020); Gerke, Minssen and Cohen (n 97).

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.[117] The basic premise of the GDPR is that every processing of personal data must be underpinned by a legal basis.[118] Moreover, it imposes duties on data processors and controllers and confers rights on data subjects in order to increase control.[119] Data subjects' rights include the right to information,[120] the right to access,[121] and the right to withdraw consent.[122] 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.[123] 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.[124]

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;[125] data subject rights such as transparency rights are not always useful, as the algorithm is difficult to understand for

[117] Article 4 GDPR.
[118] Article 6 GDPR.
[119] Chapter III GDPR.
[120] Articles 12–13 GDPR.
[121] Article 15 GDPR.
[122] Article 7(3) GDPR.
[123] Case C-362/14 *Schrems* ECLI:EU:C:2015:650; *Khelili* v. *Switzerland* App no 16188/07 (ECtHR, 18 October 2011).
[124] Van Kolfschooten (n 78).
[125] Article 5 GDPR.

patients; and erasure rights are practically impossible to comply with because the personal data is often already aggregated.[126] Another issue is the substantial list of exceptions the GDPR provides for the general prohibition on the processing of health data.[127] 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.[128] Moreover, informed consent is not necessary when, for example, the personal data has been made public by the data subject[129] (i.e. medical images on online medical forums), processing is necessary for public health purposes[130] (i.e. medical contact tracing apps), or for scientific purposes (i.e. research into AI applications for medical diagnosis).[131] 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.[132]

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.[133] 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.[134] 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",

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126 Edwards and Veale (n 104).
127 Article 9 GDPR.
128 Article 7 GDPR.
129 Article 9(2)(e) GDPR.
130 Article 9(2)(i) GDPR.
131 Article 9(2)(j) GDPR.
132 Mélanie Bourassa Forcier and others, 'Integrating Artificial Intelligence into Health Care through Data Access: Can the GDPR Act as a Beacon for Policymakers?' (2019) 6 Journal of Law and the Biosciences 317.
133 Recital 26 GDPR.
134 Oliver Diaz and others, 'Data Preparation for Artificial Intelligence in Medical Imaging: A Comprehensive Guide to Open-Access Platforms and Tools' (2021) 83 Physica medica 25.

and thus data subjects are entitled to multiple rights with regard to the use of this data.[135] The common misunderstandings about anonymization of health data in the context of health AI may threaten patients' rights to data protection.[136]

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.[137] 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.[138] 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.[139] In addition, patients should be informed of the logic involved in the algorithmic decision.[140] It is, however, questionable whether it is practically possible always to provide patients with an individualized explanation of the decision.[141] 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 Device Regulation

At the EU level, health technology is mainly regulated through regulation of medical devices under the MDR.[142] The MDR can be seen as an instrument to ensure quality of medical devices rather than a patients'

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[135] Rocher, Hendrickx and De Montjoye (n 99).
[136] European Data Protection Supervisor, 'AEPD-EDPS Joint Paper on 10 Misunderstandings Related to Anonymisation' (27 April 2021) <https://www.edps.europa.eu/data-protection/our-work/publications/papers/aepd-edps-joint-paper-10-misunderstandings-related_en>.
[137] Articles 13(2)(f) and 14(2)(g) GDPR.
[138] Article 22(1) and (2) GDPR.
[139] Article 22(3) GDPR.
[140] Articles 13(2)(f) and 14(2)(g) GDPR.
[141] Edwards and Veale (n 104).
[142] Note that as of May 2021, Regulation (EU) 2017/745 on Medical devices (MDR) (n 18) replaced Directive 93/42/EEC.

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, 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, …".[143]

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.[144]

The MDR specifically excludes software intended for general purposes, and lifestyle and well-being purposes, even when used in the treatment relationship.[145] 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.[146] 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.[147] 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.[148] Due to the limited consideration of health-specific issues and patients' rights protection, the current EU legal framework surrounding health AI seems

[143] Article 2(1) MDR.
[144] Cohen IG and others (eds), 'Volume Introduction' in *the Future of Medical Device Regulation: Innovation and Protection* (Cambridge University Press 2022).
[145] Recital 19 MDR.
[146] Annex VIII MDR.
[147] Annex I, Chapter I and III MDR.
[148] Articles 109–110 MDR.

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.[149] 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".[150] 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.[151] With the input of the AI HLEG and the European AI Alliance, the Commission published the White Paper on Artificial Intelligence in February 2020,[152] accompanied by a Communication[153]and a Report;[154] 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.[155] On 21 April 2021, the Commission published the long-awaited legislative proposal on artificial intelligence: the Artificial Intelligence Act (AIA).[156] 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,

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[149] 'European Council Conclusions, 19/10/2017' (n 66).

[150] Commission Staff Working Document Liability for emerging digital technologies Accompanying the document Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions Artificial intelligence for Europe (SWD(2018) 137 final).

[151] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Artificial Intelligence for Europe' (COM(2018) 237 final).

[152] WHITE PAPER On Artificial Intelligence - A European approach to excellence and trust (n 61).

[153] 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 (COM(2020) 66 final).

[154] 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 (COM(2020) 64 final).

[155] Council of the European Union, 'Presidency conclusions - The Charter of Fundamental Rights in the context of Artificial Intelligence and Digital Change' (21 October 2020) <https://www.consilium.europa.eu/media/46496/st11481-en20.pdf>.

[156] 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 (n 9).

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".[157] 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.[158] The AIA bans a number of uses because of unacceptable risks to people's security, livelihoods and rights, such as algorithmic social credit systems that rate citizens based on behaviour.[159] "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.[160] This means that all medical devices that fall under the MDR are classified as "high risk" under the AIA.[161] 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.[162] AI systems designed to interact with humans, such as chatbots, qualify as "limited risk".[163] The AIA lays down rules for applications with a high or limited risk, while AI applications with a minimal risk are not regulated.

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[157] Article 3 AIA.
[158] Leonelli (n 74).
[159] Article 5 AIA.
[160] Article 6 AIA.
[161] Recitals 30–31 AIA.
[162] Article 6(2) and Annex III AIA.
[163] Article 52 AIA.

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.[164] For AI systems with a high risk, there must be an adequate system for risk assessment and mitigation;[165] the quality of the datasets must be high;[166] the operation of the system must be sufficiently transparent for users; and there is an obligation to provide information.[167] 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.[168] 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.[169] Monitoring and enforcement are the responsibility of national market surveillance authorities. In addition, a European Artificial Intelligence Board is introduced.[170] For AI applications with a limited risk, only a transparency obligation applies under the AIA.[171] To this end, the Commission commits to facilitate voluntary codes of conduct.[172]

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.[173] 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

[164] Article 16 AIA.
[165] Article 9 AIA.
[166] Article 10 AIA.
[167] Article 13 AIA.
[168] Articles 14–15 AIA.
[169] Articles 11-12, 51, 60 AIA.
[170] Articles 56–59 AIA.
[171] Article 52 AIA.
[172] Article 69 AIA.
[173] 'AlgorithmWatch's Response to the European Commission's Proposed Regulation on Artificial Intelligence – A Major Step with Major Gaps' (*AlgorithmWatch,* 22 April 2021) <https://algorithmwatch.org/en/response-to-eu-ai-regulation-proposal-2021/> accessed 11 August 2024.

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.[174] 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).[175] 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.

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

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[174] European Commission, 'The European Artificial Intelligence Landscape' (18 April 2018) <https://digital-strategy.ec.europa.eu/en/library/european-artificial-intelligence-landscape>.
[175] See e.g. Articles 4 and 5 of the Cross-Border Patients' Rights Directive and Article 5 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (General Product Safety Directive) (Text with EEA relevance) [2002] OJ L 11/4.

as the right to erasure of personal data.[176] 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.[177] 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.[178] 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.[179] 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.[180] 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" and are therefore minimally regulated under the AIA. While the Commission seems to have

[176] Article 17 GDPR.
[177] ibid.
[178] Article 5(b) Cross-Border Patients' Rights Directive.
[179] Article 5 AIA.
[180] Annex III AIA.

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.[181] 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.[182] 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.[183] 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.[184] The AIA proposal seems to disregard these risks.

The AIA aims to complement the existing data protection framework[185] 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

[181] Recital 19 MDR.
[182] Article 5 AIA.
[183] Stephen Cave and others, 'Using AI Ethically to Tackle Covid-19' (2021) 372 BMJ.
[184] Hannah van Kolfschooten and Anniek de Ruijter, 'COVID-19 and Privacy in the European Union: A Legal Perspective on Contact Tracing' (2020) 41 Contemporary security policy 478.
[185] AIA at para 1.2.

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 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,[186] this dimension of trust does not necessarily support the conceptualization of trust that connects to human dignity and autonomy, and underpins fundamental patients' rights.[187] 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.[188] 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

[186] WHITE PAPER On Artificial Intelligence - A European approach to excellence and trust (n 61).
[187] Jonathan Tallant and Donatella Donati, 'Trust: From the Philosophical to the Commercial' (2020) 19 Philosophy of management 3; Andreas Fuchs, Sigrid Gürgens and Carsten Rudolph, 'A Formal Notion of Trust – Enabling Reasoning about Security Properties' (Springer Berlin Heidelberg 2010).
[188] Yokoi and others (n 83).

cross-border healthcare.[189] 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.[190]

Automated health decision-making challenges the foundational principles of autonomy, human dignity, and trust, and puts a strain 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 develop into a global leader in AI while building on EU values and fundamental rights,[191] 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.[192] This constitutional asymmetry caused by the EU's limited legislative competence in areas outside the internal market[193] 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

[189] See Case C-120/95 *Decker* ECLI:EU:C:1998:167, [1998] ECR I-1831, and *Kohll* (n 32).
[190] Article 10 AIA.
[191] WHITE PAPER On Artificial Intelligence - A European approach to excellence and trust (n 61).
[192] Tamara K Hervey and Jean V McHale, *European Union Health Law : Themes and Implications* (Cambridge University Press 2015).
[193] FW Scharpf, 'The Asymmetry of European Integration, or Why the EU Cannot Be a "Social Market Economy"' (2010) 8 Socio-economic review 211.

only way Europe can fully reap the benefits of the algorithmic turn in health, as patients' rights are 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 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.

CHAPTER 5

A HEALTH-CONFORMANT READING OF THE GDPR'S RIGHT NOT TO BE SUBJECT TO AUTOMATED DECISION-MAKING [1]

ABSTRACT

As the use of Artificial Intelligence (AI) technologies in healthcare is expanding, patients in the EU are increasingly subjected to automated medical decision-making. This development poses challenges to the protection of patients' rights. A specific *patients' right to not be subject to automated medical decision-making* is not considered part of the traditional portfolio of patients' rights. The EU AI Act also does not contain such a right. The GDPR does however provide for the right "not to be subject to a decision based solely on automated processing" in Article 22. At the same time, this provision has been severely critiqued in legal scholarship because of its lack of practical effectiveness. However, in December 2023, the Court of Justice of the EU first provided an interpretation of this right in C-634/21 (SCHUFA) – although in the context of credit scoring. Against this background, this paper provides a critical analysis of the application of Article 22 GDPR to the medical context. The objective of this paper is to evaluate whether Article 22 GDPR may provide patients with the right to refuse automated medical decision-making. It builds on its shortcomings to propose a health-conformant reading to strengthen patients' rights in the EU.

[1] Originally published as: Hannah van Kolfschooten, 'A Health-Conformant Reading of The GDPR's Right Not to Be Subject to Automated Decision-Making' (2024) 32 Medical Law Review 3 373-391, https://doi.org/10.1093/medlaw/fwae029.

1. INTRODUCTION

The importance of Artificial Intelligence (AI) technologies in medical decision-making is steadily increasing and paves the way for the embedding of *automated medical decision-making* in regular health services. AI-powered medical applications - such as triage chatbots, automatic thermal screening cameras, ultrasound diagnostic devices, and post-surgery image analysis apps - use algorithms to construct knowledge from large datasets and make medical decisions based on the processing of the patient's personal data or profile. This automation of medical decision-making could enhance the quality and efficiency of healthcare services in the European Union (EU),[2] but at the same time raises concerns for the protection of human rights, and individual patients' rights in particular.

One problem is that current national health laws in the EU Member States are not necessarily adapted to algorithmic developments,[3] since they have not made their architecture of patients' rights fit for the digital age. In fact, although being rooted in the EU and international human rights framework, individual patients' rights are mainly regulated at the level of the EU Member States. With some intra-national variations, all Member States protect the core patients' right to health privacy, encompassing the rights to (1) respect for patients' autonomy; (2) medical data protection; and (3) physical integrity. If the regulatory framework is not updated, these rights are threatened by the implementation of automated decision-making in healthcare.[4]

In the context of medical ethics, some have argued that a *patients' right to not be subject to automated medical decision-making* would be beneficial for the protection of patients.[5] However, considered from a

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[2] Karim Lekadir and others, *Artificial Intelligence in Healthcare: Applications, Risks, and Ethical and Societal Impacts* (European Parliamentary Research Service, Scientific Foresight Unit 2022).
[3] Charlotte Högberg and Stefan Larsson, 'AI and Patients' Rights: Transparency and Information Flows as Situated Principles in Public Health Care' in Katja de Vries and Mattias Dahlberg (eds), *De Lege – Yearbook Uppsala Faculty of Law 2021* (Iustus förlag 2022).
[4] Hannah van Kolfschooten, 'EU Regulation of Artificial Intelligence: Challenges for Patients' Rights' (2022) 59 Common Market Law Review.
[5] Thomas Ploug and Søren Holm, 'The Right to Refuse Diagnostics and Treatment Planning by Artificial Intelligence' (2020) 23 Medicine, Health Care and Philosophy 107; Thomas Ploug and Søren Holm, 'The Four Dimensions of Contestable AI Diagnostics - A Patient-Centric Approach to Explainable AI' (2020) 107 Artificial Intelligence in Medicine 101901.

legal perspective, such a right is not part of the traditional portfolio of patients' rights, and legal scholars have not yet addressed the question how such a right could be implemented. Current national health laws in the EU Member States do not directly equip patients with the legal means to *refuse* medical procedures based on decisions taken with the aid of assisting AI (e.g. diagnostics or treatment selection) and medical procedures that make use of partially and fully automated decision-making (e.g. AI cardiac monitoring or precision medicines).[6] The EU's AI strategy could have offered a suitable platform to introduce this right, but this was not the case. Indeed, the EU AI Act only provides for one individual right for persons affected by AI applications, namely in Article 86: the right to explanation of individual decision-making. However, this right explicitly excludes explanations of decisions made with the use of AI medical devices.[7] Similarly, the proposed European Health Data Space (EDHS) does confer individual rights upon patients to control how their electronic health data is used by healthcare providers, but it does not provide for a right to *refuse* automated medical decision-making.[8]

In the absence of a direct reference to a *patients' right to not be subject to automated medical decision-making* in the law, the General Data Protection Regulation (GDPR) may provide a possible pathway to protect the same interest that this right would safeguard.[9] Indeed, Article 22 GDPR provides individuals with the right "not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her". Deploying the GDPR has two key advantages. First, it is often easier for patients to invoke than some patients' rights

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[6] European Commission, *Study on eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the European Union. Lot 2: Artificial Intelligence for Health and Care in the EU. Final Study Report* (Publications Office of the European Union 2021).

[7] Article 86 of the Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance) [2024] OJ L 2024/1689 (AI Act).

[8] European Commission, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space (COM/2022/197 final) Chapter II, Section 1.

[9] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L 119/1 (GDPR).

protections enshrined elsewhere in the legal system because of its established enforcement mechanisms and harmonised legal nature, and second, the GDPR requires to provide the patient with adequate (organisational and/or technical) tools to meaningfully exercise their rights, preferably built into the system.

Whether Article 22 could be added to the architecture of patients' rights in order to protect *right to not be subject to automated medical decision-making* is however moot. The interpretation of this provision has been extensively debated in legal scholarship, mainly in relation to the scope of application,[10] the (in)effectiveness of rights and safeguards provided in the GDPR in connection to Article 22,[11] and unclarity about the existence of a "right to explanation" of automated decisions in the GDPR.[12] However, in December 2023, the Court of Justice of the EU (CJEU) first provided an interpretation of Article 22 in C-634/21 (SCHUFA) in the context of credit scoring.[13] This case provides insights into interpreting this legal provision in practice. Indeed, it may also clarify the application of Article 22 to medical decision-making.

By examining whether Article 22 GDPR could add an extra layer of health privacy protection if invoked as an *individual patients' right* in the context of automated medical decision-making, this paper makes two key contributions to the existing literature: (1) It problematizes automated decision-making in healthcare from an EU patients' rights perspective; and (2) It provides a critical analysis of the application of Article 22 GDPR to the medical context following the recent SCHUFA judgment, offering new insights into the practical effectiveness of this heavily debated provision. While this paper focusses on the EU context, its considerations

[10] Lee A Bygrave, 'Minding the Machine v2.0: The EU General Data Protection Regulation and Automated Decision-Making' in Karen Yeung and Martin Lodge (eds), *Algorithmic Regulation* (Oxford University Press 2019); Maja Brkan, 'Do Algorithms Rule the World? Algorithmic Decision-Making and Data Protection in the Framework of the GDPR and Beyond' (2019) 27 International Journal of Law and Information Technology, 91–121.

[11] Margot Kaminski, 'The Right to Explanation, Explained' (2019) 34 Berkeley Technology Law Journal; Filip Geburczyk, 'Automated Administrative Decision-Making under the Influence of the GDPR – Early Reflections and Upcoming Challenges' (2021) 41 Computer Law & Security Review 105538.

[12] Andrew D Selbst and Julia Powles, 'Meaningful Information and the Right to Explanation' (2017) 4 International Data Privacy Law, 233–42; Sandra Wachter, Brent Mittelstadt and Luciano Floridi, 'Why a Right to Explanation of Automated Decision-Making Does Not Exist in the General Data Protection Regulation' (2017) 2 International Data Privacy Law, 76–99.

[13] C-634/21 *SCHUFA Holding (Scoring)* ECLI:EU:C:2023:957.

are useful outside of the EU, as generally patients' rights are derived from similar international human rights and medical-ethical standards.

This paper proceeds as follows. Section II provides an overview of recent developments in automated medical decision-making and highlights its potential threats to patients' rights - especially the right to health privacy. Section III explains that some of these threats could be mitigated by having a patients' right to not be subject to automated medical decision-making, which is - however - currently missing. Sections IV and V conduct a legal case study on the application of Article 22 GDPR to automated medical decision-making following the SCHUFA ruling and the contribution of its accompanying safeguards and rights to patients' rights protection. Section VI proposes the outlines of a health-conformant reading of Article 22 GDPR and draws conclusions.

2. AUTOMATED MEDICAL DECISION-MAKING: NEW THREATS TO PATIENTS' RIGHTS

AI technologies in healthcare have the capability to construct knowledge from large datasets, which can be deployed for both virtual (i.e. diagnosis software) and physical (i.e. robot surgeons) applications.[14] Automated decision-making in the healthcare sector differs from automated decision-making in other sectors (i.e. credit scoring) because these decisions can directly impact the body, health, and life of the patient involved. Experts expect the level of automation in medical decision-making to gradually increase in the next years, which brings about new risks for the protection of individual patients' rights.[15] Patients' rights are a subset of human rights specific to the context of healthcare centred around the patient-health professional relationship, derived from the notion of human dignity and rooted in the EU and international human rights framework and medical-ethical principles.[16] Patients' rights deserve specific protection because of patients' position of vulnerability

[14] Eduard Fosch-Villaronga and others, 'Accounting for Diversity in AI for Medicine' (2022) 47 Computer Law & Security Review 105735.
[15] Kun-Hsing Yu, Andrew L Beam and Isaac S Kohane, 'Artificial Intelligence in Healthcare' (2018) 2 Nature Biomedical Engineering 719.
[16] Jonathan Cohen and Tamar Ezer, 'Human Rights in Patient Care: A Theoretical and Practical Framework' (2013) 15 Health and Human Rights Journal.

and dependency when in need of healthcare.[17] *The right to health privacy* is a core patients' right and compromises several entitlements, rights, and obligations. However, at the moment, a *specific* right for patients' not to be subject to automated medical decision-making cannot be derived from the traditional framework portfolio of patients' rights.[18]

This Section highlights the threats of medical automated decision-making to patients' rights. It first describes the outlines of the right to health privacy. Subsequently, it presents real-world examples of AI tools of different automation level and their application. Finally, it illustrates the risks AI tools present in relation to health privacy.

2.1 Components of The Patients' Right to Health Privacy

Privacy scholars generally distinguish between different dimensions of privacy, most commonly informational (the protection of personal data), decisional (the protection from heteronomous influence in individual decisions), and locational privacy (the protection of the physical living space).[19] In the health context, all three dimensions of privacy come into play, and they significantly impact the conceptualization and outreach of some key patients' rights that are protected in all EU Member States. These collectively characterize what can be considered a right to health privacy and consist of: (1) respect for patients' autonomy; (2) medical data protection; and (3) physical integrity.[20] These rights are safeguarded at various levels in the legal order applicable to many European states (i.e. national laws and policies, EU fundamental rights law, and Council of Europe instruments), and a specific framework for protection of personal data is provided for in the GDPR. Despite regulating the processing of data (and protection therefrom) in all sectors, the GDPR is also particularly relevant for the medical context and as a legal instrument contributing to the safeguarding of health privacy. This set of rights – whose implementation is fundamental for the protection of

[17] Joachim Boldt, 'The Concept of Vulnerability in Medical Ethics and Philosophy' (2019) 14 Philosophy, Ethics, and Humanities in Medicine.
[18] Högberg and Larsson (n 3).
[19] Beate Roessler, *The Value of Privacy* (Polity 2005).
[20] David Townend and others, Patients' Rights in the European Union: Mapping eXercise: Final Report (European Commission 2018).

health privacy – is however seriously challenged by the increasing use of automated medical decision-making.[21]

2.2 Different Levels of Automation: Assisting AI, Partial Automation, and Full Automation

The most basic AI tools are *assisting AI systems* (sometimes referred to as AI clinical decision support systems). These can aid health professionals to make a medical decision about an individual patient by providing suggestions. In general, such AI systems automatically process personal data to come to a medical decision, and the health professional can choose whether to take over the suggestion in their provision of patient care. An example of an assisting AI system is an image-based AI tool for skin cancer diagnosis.[22] The application classifies an image of an individual patient's skin lesion as benign or malignant. The idea is that health professionals can look both at the original image and at the classification made by the tool, to then make a diagnostic decision about an individual patient.[23] Similar AI tools exist for treatment recommendations, where the system processes individual patient data (e.g. electronic health records and self-reported systems) to evaluate the prognosis of certain treatments for the specific patient, such as AI breast cancer therapy selection.[24]

Stepping up one level in terms of automation, there are *Partially automated medical decisions systems*. These consist of AI systems that take the medical decision, but ask for human input in certain instances. A first example is AI semi-automated diagnosis: the system classifies images in diagnostic categories (positive/negative), and the original image is only presented to the health professional in borderline cases.[25] Another example is AI for clinical trial selection. By scanning through a large database of patient data (e.g. electronic health records and medical

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[21] Van Kolfschooten (n 4).
[22] Abdulrahman Takiddin and others, 'Artificial Intelligence for Skin Cancer Detection: Scoping Review' (2021) 23 Journal of Medical Internet Research e22934.
[23] OT Jones and others, 'Artificial Intelligence and Machine Learning Algorithms for Early Detection of Skin Cancer in Community and Primary Care Settings: A Systematic Review' (2022) 4 The Lancet Digital Health e466.
[24] Chiara Corti and others, 'Artificial Intelligence for Prediction of Treatment Outcomes in Breast Cancer: Systematic Review of Design, Reporting Standards, and Bias' (2022) 108 Cancer Treatment Reviews 102410.
[25] Fang Liu and others, 'Fully Automated Diagnosis of Anterior Cruciate Ligament Tears on Knee MR Images by Using Deep Learning' (2019) 1 Radiology: Artificial Intelligence 180091.

images), the process of identifying patients who are eligible for a specific clinical trial is automated.[26] The actual selection still depends on a human decision. A third example is AI monitoring of cardiac patients. This tool automatically analyses personalized heart rate data collected by a wearable or implantable device. It detects arrhythmias and automatically transmits the relevant information to the patient's cardiologist.[27]

Finally, *Fully automated medical decisions systems* are those AI tools where the system alone makes choices without – in principle – any human involvement. While full automation is still not entirely possible – it could for example be developed for AI insulin systems.[28] In non-AI automated insulin systems, patients need to provide the system with personal data about food intake and exercise, in order to calculate the level of insulin the wearable insulin pump automatically delivers.[29] In AI insulin systems, sensor data is combined with other data sources, such as activity data from a fitness tracker, geolocation on the smartphone, and hand-gesture sensing. Over time, it can recognize certain patterns in the individual behaviour and automatically deliver insulin accordingly. Another example is autonomous surgical robots, where an AI system can locate a tumour through image analysis and sensors, then decides on the best location to make an incision in the body, and sometimes autonomously perform the surgery.[30] A third example is AI precision medicine in oncology, where AI is used to detect patterns in large datasets in order to identify a specific patient's molecular profile to match with a specific cancer medicine.[31]

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[26] Ronald Chow and others, 'Use of Artificial Intelligence for Cancer Clinical Trial Enrollment: A Systematic Review and Meta-Analysis' (2023) 115 Journal of the National Cancer Institute 365.
[27] Fabio Quartieri and others, 'Artificial Intelligence Augments Detection Accuracy of Cardiac Insertable Cardiac Monitors: Results from a Pilot Prospective Observational Study' (2022) 3 Cardiovascular Digital Health Journal 201.
[28] At the moment, automated closed-loop systems do not provide a full solution. However, the movement of technology-savvy people with type 1 diabetes have been developing open-source "Do It Yourself" systems that enable automated insulin delivery which may further push this development, see for example: Amy E Morrison and others, 'A Scoping Review of Do-It-Yourself Automated Insulin Delivery System (DIY AID) Use in People with Type 1 Diabetes' (2022) 17 PloS One e0271096.
[29] Sophie Templer, 'Closed-Loop Insulin Delivery Systems: Past, Present, and Future Directions' (2022) 13 Frontiers in Endocrinology.
[30] Robert A Vigersky, 'Artificial Intelligence: The Next Frontier in Diabetes Therapy' (2021) Nature.
[31] Pedro J Ballester and Javier Carmona, 'Artificial Intelligence for the next Generation of Precision Oncology' (2021) 5 Precision Oncology 1.

2.3 Divergent Risks for Patients: From Errors, to Access, to Autonomy

Regardless of the level of automation, a general threat that the use of AI system poses to health privacy concerns the fact that AI development (and application) depends on high-quality data. However, high-quality health data is difficult to obtain, as it is often inaccurate (errors in medical records), and/or biased (lack of inclusive clinical data).[32] This can lead to errors in the AI systems, and thus also in the medical decision-making they contribute to, potentially resulting in physical harm, and thus also a threat to physical integrity – one interest safeguarded by health privacy. Another issue is that AI is prone to biases that can lead to discriminatory health outcomes. AI tools for skin cancer diagnosis may for instance perform better for white people than black people because black people were underrepresented in the training dataset.[33] In general, marginalized groups are more prone to the health risks of automated medical decision-making, challenging their autonomous decision-making powers.[34] Automated medical decision-making can create new barriers to access to healthcare. For example, for AI cardiac monitoring, patients are required to have a wearable or smartphone. Digital divide factors such as low levels of digital literacy or access to technology impact overall access to healthcare – preventing patients from autonomously deciding on the care they need.[35] Some AI tools can also bring about trust issues because of their common lack of transparency for example in the case of autonomous surgical robots. The difficulty to establish patients' trust and acceptance may deter some patients from seeking healthcare.[36] Along the same lines, automated decision-making in health challenges human dignity. Increasing use of AI may depersonalize interactions in patient care and

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[32] Eduard Fosch-Villaronga and others, 'Implementing AI in Healthcare: An Ethical and Legal Analysis Based on Case Studies' in Dara Hallinan, Ronald Leenes and Paul de Hert (eds), *Data protection and artificial intelligence: Computers, privacy, and data protection* (Hart Publishing 2021).

[33] Isabel Straw, 'The Automation of Bias in Medical Artificial Intelligence (AI): Decoding the Past to Create a Better Future' (2020) 110 Artificial Intelligence in Medicine 101965.

[34] Hannah van Kolfschooten, Pin Lean Lau and Janneke Van Oirschot, 'AI Can Threaten Health Equity for Marginalised Populations: The EU Must Act Now' (*Health Action International*, 13 June 2023) <https://haiweb.org/ai-can-threaten-health-equity-for-marginalised-populations/> accessed 16 June 2023.

[35] Himabindu Reddy and others, 'A Critical Review of Global Digital Divide and the Role of Technology in Healthcare' (2022) 14 Cureus.

[36] Jinpei Han and others, 'A Systematic Review of Robotic Surgery: From Supervised Paradigms to Fully Autonomous Robotic Approaches' (2022) 18 The International Journal of Medical Robotics and Computer Assisted Surgery e2358.

neglect individual human characteristics.[37] In general, empathy and empathic communication are important factors in healthcare, and as AI is (still) incapable of empathy, automated decision-making risks reducing humans to numbers – impacting the core values of patients' rights.[38]

As AI systems collect, share, and combine large amounts of personal data – often sensitive health data – they introduce new risks to the privacy of patients. New risks for disclosures of personal data are first caused by the increased involvement of commercial third parties – such as tech developers and data storage companies - in the realm of healthcare. This pushes principles such as purpose limitation to their boundaries, thus threatening individual self-determination. Moreover, because of the need for enormous amounts of personal data to create AI systems, AI developers are incentivized to push legal and ethical boundaries to maximize personal data collection. The "blending" of different sources of personal data, for example in the development of AI insulin systems, leads to the creation of an elaborate "health profile" of the patient, which contains sensitive details about their personal life and health status. This information can also be used to influence or manipulate personal decisions, such as purchasing decisions.[39] If the data security of the AI tools is not guaranteed, for example with AI cardiac monitoring, confidential personal health data be revealed and used for the wrong purposes, such as commercial targeting or law enforcement. If personal data is processed by and transferred to multiple parties, the right of patients to data protection is challenged, as it becomes difficult to exercise meaningful control over their personal data.

Additionally, there is usually a lack of explainability in medical AI systems: systems are 'black boxes' and do not always allow for identification and adequate understanding of the relevant parameters of the system and their significance for a certain decision.[40] This is often

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[37] Paul Formosa and others, 'Medical AI and Human Dignity: Contrasting Perceptions of Human and Artificially Intelligent (AI) Decision Making in Diagnostic and Medical Resource Allocation Contexts' (2022) 133 Computers in Human Behavior 107296.

[38] Luciano Floridi, 'On Human Dignity as a Foundation for the Right to Privacy' (2016) 29 Philosophy & Technology 307.

[39] Karl Manheim and Lyric Kaplan, 'Artificial Intelligence: Risks to Privacy and Democracy' (2019) 21 Yale Journal of Law and Technology 106.

[40] Julia Amann and others, 'Explainability for Artificial Intelligence in Healthcare: A Multidisciplinary Perspective' (2020) 20 BMC Medical Informatics and Decision Making 310.

inherent to the specific system, for example, because the choice was made to prioritise effectiveness over interpretability, which is frequently the case in the field of healthcare.[41] Current post-hoc explainability methods, such as saliency maps, do not necessarily provide the information needed for human understanding.[42] The lack of explainability makes it difficult for both health professionals and patients to understand how the system reached a certain medical conclusion. This is for example problematic in the context of AI precision medicine, where often the final decision of the AI system is based on thousands of variables. This may impair patient autonomy, as the information they would need to make an informed decision would not always be available.[43] In this respect, it may also become difficult for patients to provide valid informed consent to automated medical decision-making, as (1) health professionals may not be required to disclose the use of AI in every step of the medical decision-making process, and (2) alternative, non-AI treatment may not always be available.[44] When the AI decision has direct effects on the patient's body, such as with AI insulin systems, this may also affect the patient's physical integrity.

Considering these risks, bioethics scholars suggested that a *right not to be subject to automated medical decision-making* can help to avoid health privacy being considerably compromised. [45] Such a right entails that – under certain circumstances – patients should have the right to refuse medical procedures based on decisions taken with the aid of assisting AI (e.g. diagnostics or treatment selection) and from the use of partially and fully automated decision-making (e.g. AI cardiac monitoring or precision medicines) as part of their individual medical treatment.[46] However, as we show in the next Section, such a right is currently absent in the EU patients' rights framework.

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[41] Line Farah and others, 'Assessment of Performance, Interpretability, and Explainability in Artificial Intelligence–Based Health Technologies: What Healthcare Stakeholders Need to Know' (2023) 1 Mayo Clinic Proceedings: Digital Health 120.
[42] Marzyeh Ghassemi, Luke Oakden-Rayner and Andrew L Beam, 'The False Hope of Current Approaches to Explainable Artificial Intelligence in Health Care' (2021) 3 The Lancet Digital Health e745.
[43] Thomas Grote and Philipp Berens, 'On the Ethics of Algorithmic Decision-Making in Healthcare' (2020) 46 Journal of Medical Ethics 205.
[44] I Glenn Cohen, 'Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?' (2019) 108 Georgetown Law Journal 1425.
[45] Ploug and Holm, 'The Right to Refuse Diagnostics' (n 5).
[46] ibid.

3. LACK OF A PATIENTS' RIGHT NOT TO BE SUBJECT TO AUTOMATED *MEDICAL* DECISION-MAKING

The right to health privacy as implemented in current law does not necessarily encompass a right *not to be subject to automated medical decision-making*. Indeed, both at the level of the EU and the Council of Europe, no such right is explicitly recognised. Moreover, also national interpretations of core patients' rights and related policies do not explicitly specify the rights of patients in relation to automated medical decision-making. For example, it is unclear whether it can be derived from the right to adequate information that health professionals are required to disclose the use of AI in every step of the medical decision-making process. If no such duty exists, this can cause problems for health privacy, since not disclosing to patients that AI was used in the decision-making process has direct consequences for the right to self-determination, as patients cannot approve or refuse the use of an AI system, if they are not aware of its use.[47]

Whilst not present explicitly in the European regulatory framework, it seems also difficult to implicitly derive a right not to be subject to automated medical decision-making from other legally relevant sources composing the patients' right framework. For example, it can hardly be derived from medical confidentiality obligations. These do not protect the patient from being subject to automated medical decision-making, as they allow health professionals to discuss patient information with other health professionals in the treatment team without informing the patient. The same exception may apply when the patient's information is shared and processed by the assisting AI tool.[48] The general right to physical integrity may also be a potential candidate to derive a right not to be subject to automated medical decision-making. Indeed, it does enable patients to refuse to be subjected to automated medical decisions, such as autonomous robot surgeries or partially automated diagnostics. However, it does not encompass *a right to human intervention*, nor does it guarantee patients *access to alternative, non-AI treatment*. If no alternative non-AI treatment is available, this impacts the patient's right

[47] I Glenn Cohen (n 44).
[48] Colin Mitchell and Corrette Ploem, 'Legal Challenges for the Implementation of Advanced Clinical Digital Decision Support Systems in Europe' (2018) 3 Journal of Clinical and Translational Research 424.

to access healthcare, rendering the right useless in practice.[49] In sum: it seems that at the moment, a *specific* right not to be subject to automated medical decision-making is not part of explicit European regulation, nor can it be derived from the traditional framework portfolio of patients' rights.[50]

However, while not specifically addressing the medical decisions, Article 22 GDPR provides individuals with the right "not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her". In this sense, Article 22 GDPR puts forward a *general right* not to be subject to automated decision-making. In theory, a nuanced interpretation of this provision may provide the missing puzzle piece for the protection of patients against the detrimental effects of AI in healthcare, and indirectly grants a similar level of protection for health privacy as an *explicit* right not to be subject to automated medical decision making would.

While it would be possible to explore other legal pathways to enforce this right,[51] the nature of the GDPR offers some procedural benefits. First, in some cases, the GDPR is easier for patients to invoke than some patients' rights protections enshrined elsewhere in the legal system, because of the existence of both independent national data protection authorities and data protection officers in healthcare institutions. It is however important to note that the GDPR was not intended as a health law instrument nor is it focused on the protection of the rights of patients as such. Indeed, if evaluated from a patients' rights perspective, the main challenge of the GDPR seems to be its interplay with national patients' rights, health data rules, and medical ethics. All EU Member States have long had their own laws and policies on health data protection in place based on the principle of medical confidentiality.[52] At the same time, the harmonized nature of the GDPR may be of added value to smoothen the "patchwork" of

[49] Ploug and Holm 'The Right to Refuse Diagnostics' (n 5).
[50] Högberg and Larsson (n 3).
[51] See for example on contract law and tort law: Philipp Hacker and others, 'Explainable AI under Contract and Tort Law: Legal Incentives and Technical Challenges' (2020) 28 Artificial Intelligence and Law 415.
[52] Johan Hansen and others, *Assessment of the EU Member States' Rules on Health Data in the Light of the GDPR* (Publications office of the European Union 2021) 262.

patients' rights in the Member States, often consisting of both legal instruments, ethical codes, and professional protocols.

Second, Article 22 GDPR introduces individual rights that could be invoked by patients subjected to medical automated decision-making. The most useful effect of the individual rights introduced in Article 22 GDPR for patients seems to be the requirement to provide the patient with adequate (organisational and/or technical) tools to meaningfully exercise their rights as part of the decision-making process. The situating of this right within the GDPR – which also promotes the accessible exercise of rights, preferably built into the system ("privacy-by-design"), supports the implementation of rights within the system itself: in some way, a "rights-by-design". For instance, in the case of AI insulin systems, the system could record the exact grounds on which a certain decision was based (i.e. food intake or activity), connected to a system where the patient could request further information about the decision. In this way, an additional layer of protection for patients could be created: on top of the patients' rights flowing from the relationship with the health professional, patients may be equipped with rights towards the AI tool itself. This could take away potential burdens to exercise rights, particularly in case of lengthy legal procedures. Finally, the default prohibition of automated decision-making in Article 22 GDPR may prevent particularly harmful decision-making practices in the medical context, for example, an automated decision to refuse a patient access to emergency care based on their medical history.

However, the interpretation of Article 22 GDPR has been a topic of debate in legal scholarship. The next Section provides a critical analysis of the application of Article 22 GDPR to the medical context, using the recent ruling of the CJEU on its interpretation.[53] While this case concerned the context of credit scoring, it may also clarify the application to medical decision-making.

[53] SCHUFA Holding (Scoring) (n 13).

4. POST-SCHUFA: THE RIGHT NOT TO BE SUBJECT TO AUTOMATED *MEDICAL* DECISION-MAKING IN THE GDPR

Article 22 of the GDPR protects the right not to be subject to decision-making based solely on the automated processing of personal data. The predecessor of the GDPR, the Data Protection Directive already contained a right similar to the GDPR's Article 22, namely a right not to be subject to a decision based on the automated processing of personal data intended to evaluate certain personal aspects relating to the data subject.[54] This right was accompanied by an access right to knowledge of the logic involved in any automatic processing of data concerning him.[55] By adding this provision to the directive, the European Commission aimed to safeguard individual people's capacity to influence decision-making processes that affect them,[56] and prevent human decision-makers from escaping responsibility by shifting it to machines.[57] Another reason for adoption was the prevention of objectification of individuals and the protection of human dignity.[58] Under the GDPR, Article 22 was introduced for similar reasons – although slightly broadened – specifically because of concerns about possible technical deficits and unfair discrimination.[59] Authors have argued that the right provided by this article is based on the three pillars of transparency, contestability, and accountability.[60] But to what extent is Article 22 GDPR applicable in the medical context? The recent SCHUFA ruling may clarify its scope of applicability.[61]

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[54] Article 15 of the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Data Protection Directive) [1995] OJ L 281/31 (DPD).
[55] Article 12(a) and Recital 41 DPD.
[56] Lee A Bygrave, 'Automated profiling. Minding the Machine: Article 15 of the EC Data Protection Directive and Automated Profiling' (2001) 17 Computer Law & Security Review 17.
[57] Commission of the European Communities, Amended proposal for a Council Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data (COM/92/422 final) 26.
[58] Bygrave, 'Automated profiling' (n 56).
[59] Kaminski (n 11).
[60] Paul De Hert and Guillermo Lazcoz Moratinos, 'Radical Rewriting of Article 22 GDPR on Machine Decisions in the AI Era' (*European Law Blog*, 13 October 2021) <https://europeanlawblog.eu/2021/10/13/radical-rewriting-of-article-22-gdpr-on-machine-decisions-in-the-ai-era/> accessed 7 August 2024.
[61] SCHUFA Holding (Scoring) (n 13).

4.1 A Brief Introduction to Automated Decision-Making in Article 22

Article 22 GDPR states that "The data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her".

Paragraph 2 of Article 22 contains three exemptions to this right:
(1) if the decision is "necessary for entering into, or performance of, a contract between the data subject and a data controller";
(2) if the decision is "authorised by Union or Member State law to which the controller is subject and which also lays down suitable measures to safeguard the data subject's rights and freedoms and legitimate interests"; and
(3) if the decision "is based on the data subject's explicit consent".

Paragraph 3 of Article 22 stipulates that – in case of exemption (1) and (3) – the data controller must adopt suitable measures to protect the data subject. Minimum safeguards are (1) the right to obtain human intervention on the part of the controller, (2) the right to express his or her point of view and (3) the right to contest the decision. Recital 71 adds the following safeguards: (4) to provide specific information to the data subject and (5) the right to obtain an explanation of the decision. Paragraph 4 of Article 22 prohibits decision-making based on special categories of personal data as protected under Article 9(1) GDPR, "unless point (a) or (g) of Article 9(2) applies and suitable measures to safeguard the data subject's rights and freedoms and legitimate interests are in place." Thus, automated decision-making can be based on the processing of personal data if the decision is based on explicit or if processing is necessary to protect public interest, and suitable protective measures are in place.

Article 22 is accompanied by other transparency requirements in the GDPR. Data controllers must always be able to demonstrate that personal data are processed in a transparent manner in relation to the data subject.[62] Articles 13 and 14 GDPR introduce general information

[62] Article 5(2) GDPR.

obligations for data processing to guarantee transparency.[63] Data controllers have specific transparency obligations when it comes to automated decision-making: information obligations under Article 13(2)(f) and Article 14 (2)(g) GDPR and a data access right under Article 15(1)(h) GDPR. Data subjects should be informed about the existence of automated decision-making and receive meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.[64] According to the EDPB, the data subject must be given generic information that is also helpful for him or her to contest the decision, specifically on the deliberations in the decision-making process, and on their respective weight on a general level.[65]

4.2 Applicability of Article 22 GDPR in the Medical Context

The applicability of Article 22 GDPR depends on three cumulative conditions: (1) there must be a 'decision'; (2) that decision must be 'based solely on automated processing, including profiling', and, (3) it must produce 'legal effects concerning [the interested party]' or 'similarly significantly [affect] him or her'.[66] Recently, the CJEU explicated these conditions in a preliminary ruling on the situation where a private company (SCHUFA) provided its clients with information on the creditworthiness of certain individuals (for example a prognosis on whether a person will repay a loan), by calculating a probability value or 'credit score' on the basis of certain characteristics of the individual. Clients use these credit scores to decide whether to grant a loan to the individual applicant.[67]

In the SCHUFA case, the CJEU has confirmed that the concept of 'decision' has a broad scope, and also includes 'measures' or 'acts', such as the automatic refusal of a request without human intervention (e.g. an online credit application).[68] A probability value that predicts an

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[63] Article 29 Working Party, Guidelines on transparency under Regulation 2016/679 (wp260rev.01) (adopted 29 November 2017, revised 11 April 2018).
[64] Article 13(2)(f), 14(2)(g) and 15(1)(h) GDPR.
[65] Stefanie Hänold, 'Profiling and Automated Decision-Making: Legal Implications and Shortcomings' in Marcelo Corrales, Mark Fenwick and Nikolaus Forgó (eds), *Robotics, AI and the Future of Law* (Springer 2018).
[66] SCHUFA Holding (Scoring) (n 13) para 43.
[67] SCHUFA Holding (Scoring) (n 13) para 14-16.
[68] SCHUFA Holding (Scoring) (n 13) para 45-46. Also see Recital 71 GDPR.

individual's behaviour (e.g. in relation to creditworthiness) can also be seen as a 'decision' in this sense.[69] All AI tools used for medical decision-making make use of automated processing of personal data and will (at some point, and depending on the level of AI automation) result in a medical decision regarding an individual patient. In the case of full automation, it can be argued that the AI's outcome equals the 'decision', similar to the automatic refusal of an online credit application. The CJEU's rejection of the narrow interpretation of what constitutes a 'decision', also opens the door to medical AI with lower levels of automation, for example, AI systems advising on the eligibility of a patient to participate in a clinical trial. This advice can also be seen as a 'decision', even though the health professional makes the final decision on the selection of clinical trial participants. In this light, the A-G has argued that if there is a significant and decisive influence of the AI's output on the final decision regarding the individual, "the fact that a third party takes the final decision" does not change that this decision is "based on automated processing". The A-G adds that a narrow interpretation would undermine the objective of the GDPR to protect individuals against automation with transparency rights, as these only apply to "decisions based on automated processing".[70]

The second condition is that the decision 'is based solely on automated processing, including profiling'. The word "solely" indicates a very limited scope of application, whereby any human involvement in the decision-making process nullifies the prohibition. However, the EDPB has interpreted the scope of Article 22 more broadly by explaining that human involvement must be 'meaningful'.[71] The involvement must be performed by a competent person who is also competent to change the decision.[72] In the case of full automation, it can be argued that there is no meaningful human involvement in the decision-making process. However, when the decision is only partially automated or assisting, such

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[69] SCHUFA Holding (Scoring) (n 13) para 46. Also see: Francesca Palmiotto Ettorre, 'Is Credit Scoring an Automated Decision? – The Opinion of the AG Pikamäe in the Case C-634/21 — The Digital Constitutionalist' (*The Digital Constitutionalist*, 17 March 2023) <https://digi-con.org/is-credit-scoring-an-automated-decision-the-opinion-of-the-ag-pikamae-in-the-case-c-634-21/> accessed 21 June 2023.

[70] SCHUFA Holding (Scoring) (n 13) and Joined Cases C-26/22 and C-64/22 SCHUFA Holding and Others (Discharge from remaining debts) ECLI:EU:C:2023:957, Opinion of A-G Pikamäe.

[71] Guidelines on transparency under Regulation 2016/679 (n 63) 24.

[72] ibid.

as the use of AI tools for the diagnosis of skin cancer, it is doubtful whether this would qualify as *solely* automated decision-making in the sense of Article 22 GDPR because of uncertainties about the actual weight the health professional assigns to the AI's diagnosis. On the one hand, it could be argued that it is in fact the health professional that makes the central decision that has effects on the patient. The diagnosis provided by the AI tool is just advice and the health professional can decide not to follow it. On the other hand, there is increasing evidence that health professionals are likely to act upon the decision of an AI device because of "automation bias" or "overtrusting technology"[73]: trusting the AI's diagnosis of a specific patient's skin lesion more than their own.[74] In this light, it is questionable whether one could consider the health professional's involvement meaningful. Here, the SCHUFA judgment does not necessarily provide any new insights, since the Court rules that there is no doubt that the situation at hand ("the automated establishment of a probability value based on personal data relating to a person and concerning that person's ability to repay a loan in the future") meets the definition of "profiling" in the GDPR.[75] However, given the broad definition assigned to 'decision' by the Court, a similar interpretation of this criterium is not unthinkable.

Finally, the decision must produce 'legal effects concerning [the interested party]' or 'similarly significantly [affect] him or her'. While the decision itself does not constitute any *legal effects*, many examples of automated medical decisions will *significantly affect* the patient, since AI tools either have direct effects on the body (e.g. AI insulin systems or autonomous surgery robots) or make decisions that indirectly affect the health status of the patient. For example, it is fair to assume that a skin cancer diagnosis or breast cancer treatment selection has a significant, prolonged, or permanent impact on the patient involved.[76] Both a correct diagnostic of the skin lesion as benign or maleficent, and a diagnostic error, have significant effects on the patient's life, as further important

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[73] Alexander M Aroyo and others, 'Overtrusting Robots: Setting a Research Agenda to Mitigate Overtrust in Automation' (2021) 12 Paladyn, Journal of Behavioral Robotics 423.
[74] Patricia L Hardré, 'Chapter 5 - When, How, and Why Do We Trust Technology Too Much?' in Sharon Y Tettegah and Dorothy L Espelage (eds), *Emotions, Technology, and Behaviors* (Academic Press 2016).
[75] *SCHUFA Holding (Scoring)* (n 13) para 47. Also see Article 4(4) GDPR.
[76] SCHUFA Holding (Scoring) (n 13) para 21.

medical treatment decisions are based on this. However, whether these effects are realized depends – again – on how much weight the health professional assigns to the AI's diagnosis. In the SCHUFA case, the Court explained that the probability value (the 'decision') has significant effects on the consumer applying for a loan because empirical research shows that "an insufficient probability value leads, in almost all cases, to the refusal of that bank to grant the loan applied for".[77] For fully automated medical decisions, the same argument will apply. However, generally, for assisting AI tools, the impact on the final medical decision is less evident. While empirical research gives us reason to believe that AI technology has stronger effects on human behaviour than non-AI technology,[78] healthcare professionals do not necessarily 'blindly follow' the AI's advice.

Thus, the applicability of Article 22 GDPR depends on the following unresolved question: when making use of AI tools for medical decision-making, what is the meaning of the health professional's involvement in the decision-making process? This probably needs to be determined on a case-to-case basis. At the same time, the SCHUFA ruling seems to open the door to a broad interpretation of the scope of application of Article 22 GDPR – in favour of individuals.

5. RIGHTS AND SAFEGUARDS AGAINST AUTOMATED *MEDICAL* DECISION-MAKING IN THE GDPR

It follows from the above that the scope of application of Article 22 for automated medical decisions is still uncertain. If applicable, however, the corollaries of this article and other rules in the GDPR provide for more rights and safeguards against automated decision-making. Article 22(3) GDPR provides individuals with several minimum rights when subjected to automated decision-making: the right to human intervention, expressing points of view, contesting the decision, and explanation of the decision. Article 22(4) GDPR stipulates that automated decision-making based on *health* data is only allowed under specific conditions. On top of the condition of a valid legal ground for the processing of the health data

[77] SCHUFA Holding (Scoring) (n 13) para 48.
[78] Max Schemmer and others, 'On the Influence of Explainable AI on Automation Bias' (*arXiv*, 19 April 2022) <https://arxiv.org/abs/2204.08859> accessed 7 August 2024.

to be used in the automated decision, the decision-making needs to be either (1) strictly necessary for contractual purposes, (2) authorised by law by Member States or the EU or (3) explicitly consented to.[79] This Section evaluates these rights and safeguards from a patients' rights perspective and health privacy perspective.

5.1 The Safeguard of "Explicit Consent" for Patients

Article 22(2) GDPR proposes explicit consent to automated decision-making as a safeguard. In the GDPR, consent means the freely given, specific, informed, and unambiguous indication of the data subject's agreement, expressed by a statement or a clear affirmative action.[80] Consent requires 'real choice' and should be 'granular' and 'specific'. The term 'explicit' implies that the data subject must give an "*express* statement of consent": the "ticking of boxes" is not sufficient.[81]

There is however a discrepancy between the right to informed consent as understood in health law, and informed consent in data protection law.[82] The health professional has the ethical and legal responsibility to enable a specific patient to make an informed decision about medical treatment by exchanging information about the benefits and risks of the course of treatment, potential alternatives, and consequences of the patient's decision. The patient's right to information is not absolute but requires the health professional to strike a balance between under-informing and information-overload, tailored to the specific patient.[83] In this line of thought, informed consent to medical decisions is vital for the protection of patient autonomy, self-determination, and physical integrity.[84] In data protection law, on the contrary, consent does not serve as a general safeguard or right but as a legal basis for the processing of personal data, among other legal bases. The GDPR, for example, states in articles 6 and

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[79] See Article 22(2) GDPR.
[80] Article 4(11) and Recital 32 GDPR.
[81] European Data Protection Board, 'Guidelines 05/2020 on consent under Regulation 2016/679' (Version 1.1, adopted 4 May 2020) 20-22; Article 32 GDPR.
[82] Onora O'Neill, 'Some Limits of Informed Consent' (2003) 29 Journal of Medical Ethics, 4-7.
[83] Johan Bester, Cristie M Cole and Eric Kodish, 'The Limits of Informed Consent for an Overwhelmed Patient: Clinicians' Role in Protecting Patients and Preventing Overwhelm' (2016) 18 AMA Journal of Ethics 869.
[84] See *Lambert and others v. France* App no 46043/14 (ECHtR, 5 June 2015) para 74; *Pretty v. the United Kingdom* App no 2346/01 (ECtHR, 29 April 2002) para 63; *Trocellier v. France* App no 75725/01 (ECtHR, 5 October 2006) para 4; *Y. v. Turkey* App no 648/10 (ECtHR, 17 February 2015) para 68–78; *C.C. v. Spain* App no 1425/06 (ECtHR, 6 October 2009) para 33.

9 that consent is amongst multiple potential legal bases whereupon health data can be processed, but an alternative legal basis for data processing can be found in the existence of a relevant public interest, such as collecting data about infectious disease, or scientific purposes.[85]

However, in the privacy debate, informed consent to processing of personal data is considered the main solution to empower data subjects.[86] This also seems to be the rationale behind the GDPR's regime for sensitive personal data, where the threshold is raised to 'explicit' consent, apparently to add an extra layer of protection. Data protection scholars have however long expressed fundamental concerns about how an individual's (explicit) consent can lead to better protection of (medical) data protection. While the GDPR prescribes the correct requirements for obtaining valid consent, these requirements seem impossible to meet in practice.[87] Hence, firstly there is a de facto *lack of freedom* to give consent in practice, because of power imbalances between patients and health professionals.[88] Further, with respect to health data processing, patients often have no choice if they desire adequate medical treatment. While informed consent in health law requires access to alternative treatment, this is not part of the GDPR.[89] Secondly, there is a *lack of real information* for patients giving consent in practice, as there is an inherent risk of information overload, lack of ability to truly understand, and consent desensitization.[90] For example, in the case of AI tools for precision medicine, the complexity of the tool makes it very difficult for patients to provide valid informed consent. Because of this, in many cases consent on the processing of data is a mere "ticking the boxes"-exercise,

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[85] Andrea Martani and others, 'The Devil Is in the Details: An Analysis of Patient Rights in Swiss Cancer Registries' (2022) 48 Journal of Medical Ethics 1048.
[86] Griet Verhenneman (ed), 'Informed Consent, a Means to Empower the Patient?' in *The Patient, Data Protection and Changing Healthcare Models: The Impact of e-Health on Informed Consent, Anonymisation and Purpose Limitation* (Intersentia 2021).
[87] Gabriela Zanfir, 'Forgetting About Consent. Why The Focus Should Be On "Suitable Safeguards" in Data Protection Law' in Serge Gutwirth, Ronald Leenes and Paul De Hert (eds), *Reloading Data Protection: Multidisciplinary Insights and Contemporary Challenges* (Springer Netherlands 2014).
[88] Benjamin Bergemann, 'The Consent Paradox: Accounting for the Prominent Role of Consent in Data Protection' in Marit Hansen and others (eds), *Privacy and Identity Management. The Smart Revolution* (Springer International Publishing 2018).
[89] I Glenn Cohen (n 44).
[90] Bart W Schermer, Bart Custers and Simone van der Hof, 'The Crisis of Consent: How Stronger Legal Protection May Lead to Weaker Consent in Data Protection' (2014) 16 Ethics and Information Technology 171.

and it can thus be doubted that it provides adequate safeguards for health privacy in respect to AI.

5.2 A Patients' Right to Human Intervention?

Any discussion around the rights and safeguards with respect to the use of AI in medical decision-making also begs a diametrically opposite question: Is there a right to be treated by a human health professional? When health data is processed for automated decision-making, it follows from Article 22(3) GDPR that the involved individual has the right to obtain some form of human intervention. This intervention should likely happen in the final stage of the decision-making process that can either confirm or change the automated decision – as involving a human decision-maker in an earlier stage would render Article 22 inapplicable, since it would turn the decision into one that is not based solely on automation. Human oversight is often advocated as a central ethical value for AI deployment.[91] The rationale of this is that human oversight can function as a safeguard to help ensure that an AI system does not undermine patient autonomy or cause untransparent decision-making, privacy and data protection issues, or discrimination.[92]

In theory, equipping patients with the right to human intervention in automated medical decision-making could contribute to patients' rights and health privacy specifically (especially in relation to self-determination and physical integrity) in several ways. First, including a health professional in the automated decision-making process could soften the negative effects of the "objectivation" of patients or reduction of patients to numbers, bringing back the core condition of human dignity, and bringing moral values into the automated process. This could also contribute to the establishment or maintenance of trust in the patient-health professional relationship, which is an essential prerequisite for patients' access to healthcare. Research also shows how human involvement in medical decision-making – as opposed to full automation – is crucial for empathy and compassion, values that directly

[91] Riikka Koulu, 'Proceduralizing Control and Discretion: Human Oversight in Artificial Intelligence Policy' (2020) 27 Maastricht Journal of European and Comparative Law 720.
[92] Riikka Koulu, 'Human Control over Automation: EU Policy and AI Ethics' (2020) 12 European Journal of Legal Studies 9.

impact health outcomes.[93] Second, in theory, health professionals could use their medical knowledge and expertise to test the accuracy of the automated decision for a specific patient, which may mitigate the risks of physical harm and allow patients to make more autonomous decisions about their bodies and health. For example, when AI tools are used for diagnostics, health professionals could fulfil the role of controller of potential biases in the outcome of the decision (e.g. to account for different symptoms for cardiac arrest in men and women), strengthening the patient's right to physical integrity. Including a health professional could potentially also strengthen the right to adequate information, informational self-determination, and medical data protection, as the health professional is – in addition to the provisions in the GDPR – bound to (1) medical confidentiality and (2) medical informed consent duties.

In practice, it is however questionable how exactly meaningful human oversight can be implemented in automated medical decision-making. First, it is doubtful whether the health professional can fulfil a meaningful role in the decision-making process because of the complexity and opacity of many automated decision-making systems. Sarra argues that, as intelligent systems are deployed to make decisions "because of their inhuman efficiency", it is very difficult for the human involved to understand what went wrong in a specific decision and justify the need to change the automated decision.[94] Moreover, a recent empirical study by Jabbour et. al shows that it is very difficult for clinicians to recognize systematically biased AI models, even when image-based AI model explanations are provided.[95] In this light, the involvement of a health professional in the final stage of the decision-making process will offer little protection against AI-powered decisions causing (physical or mental) harm and may even legitimize them.[96]

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[93] Aurelia Sauerbrei and others, 'The Impact of Artificial Intelligence on the Person-Centred, Doctor-Patient Relationship: Some Problems and Solutions' (2023) 23 BMC Medical Informatics and Decision Making 73.
[94] Claudio Sarra, 'Put Dialectics into the Machine: Protection against Automatic-Decision-Making through a Deeper Understanding of Contestability by Design' (2020) 20 Global Jurist.
[95] Sarah Jabbour and others, 'Measuring the Impact of AI in the Diagnosis of Hospitalized Patients: A Randomized Clinical Vignette Survey Study' (2023) 330 JAMA 2275.
[96] Ben Green and Amba Kak, 'The False Comfort of Human Oversight as an Antidote to A.I. Harm' (*Slate*, 15 June 2021) <https://slate.com/technology/2021/06/human-oversight-artificial-intelligence-laws.html> accessed 30 August 2022.

Second, research from social psychology suggests that humans often over-rely on automated systems. There is an "automation bias": the tendency to follow computer-generated outcomes over human-generated ones. For example, a study on oncologists classifying mammograms in either "further examination required" or "no further examination required" with the aid of computer systems advising on the classification, showed the influence of the computer's decision on the oncologists' behaviour. A significant number of oncologists (1) neglected to take appropriate action when the computer failed to detect the irregularity in the mammogram because of decreasing human vigilance (errors of omission), and (2) for ambiguous mammographs, using the computer's absence of prompts as a reassurance not to invite the patient for further examination.[97] A recent study on automation bias in inexperienced, moderately experienced, and very experienced radiologists when reading mammograms with the aid of AI systems showed that all radiologists are prone to automation bias when being supported by an AI-based system, irrespective of experience level.[98] This over-reliance on AI advice is conceptualized by Strauß as "deep automation bias".[99] Another concern is the occurrence of "selective adherence to algorithmic advice": human decision-makers tend to rely on automated decisions selectively: when their predictions correspond to stereotypes.[100] It is questionable to what extent the phenomenon of automation bias decreases the value of human intervention as a safeguard for patients. It has been argued, for example, that adequate education and training on the use and limitations of AI systems can minimise the occurrence of automation bias.[101] Moreover, as argued by Kostick-Quenet and Gerke, additional user testing of medical AI tools in settings that resemble the intended use, can also minimise the risks of "blind" overreliance on AI by addressing context-related risks at

[97] Eugenio Alberdi and others, 'Effects of Incorrect Computer-Aided Detection (CAD) Output on Human Decision-Making in Mammography' (2004) 11 Academic Radiology 909.
[98] Thomas Dratsch and others, 'Automation Bias in Mammography: The Impact of Artificial Intelligence BI-RADS Suggestions on Reader Performance' (2023) 307 Radiology e222176.
[99] Stefan Strauß, 'Deep Automation Bias: How to Tackle a Wicked Problem of AI?' (2021) 5 Big Data and Cognitive Computing 18.
[100] Saar Alon-Barkat and Madalina Busuioc, 'Human-AI Interactions in Public Sector Decision-Making: "Automation Bias" and "Selective Adherence" to Algorithmic Advice' (2022) 33 Journal of Public Administration Research and Theory.
[101] Tina Nguyen, 'ChatGPT in Medical Education: A Precursor for Automation Bias?' (2024) 10 JMIR Medical Education e50174.

an earlier stage, for example by providing detailed use instructions.[102] Especially for AI tools with lower levels of automation, such as diagnostic tools, human oversight by health professionals with adequate AI skills can function as a safeguard for patients.

However, along the same lines, increasing automation poses risks to the quality of the health professional's medical skills and knowledge levels. When health professionals over-rely on the capacities of AI tools, they may lose the necessary expertise to intervene in an automated medical decision.[103] If "deskilling" of health professionals is a real risk, their involvement in medical decision-making would not be meaningful, and thus patients would not necessarily benefit from a right to human intervention with regard to the protection of their safety. Potentially, overreliance on AI tools could also lead to "loss of self-confidence and affect the willingness of a physician to provide a definitive interpretation or diagnosis".[104] Another issue could be that it is questionable whether health professionals would feel the freedom to challenge the automated decision, because of uncertainties about attribution of responsibility, accountability, and liability, and fear of lawsuits.[105] For example, in the case of fully automated surgery, are human surgeons capable of stepping in and replacing the robot if something goes wrong? The risk of "deskilling" could complicate human intervention in general, but for automation in "microsurgery", for example for tumor removal with very small equipment, surgery "by hand" could be impossible because of the high degree of required precision.[106]

On top of this, the GDPR only provides a right to human intervention in the final decision. This causes two issues for the protection of patients. First, the harm may have already taken place, for example, physical harm caused by autonomous robot surgery or the AI insulin system, or the

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[102] Kristin M Kostick-Quenet and Sara Gerke, 'AI in the Hands of Imperfect Users' (2022) 5 npj Digital Medicine 1.
[103] Nithya Sambasivan and Rajesh Veeraraghavan, 'The Deskilling of Domain Expertise in AI Development' in Simone Barbosa and others (eds), *Proceedings of the 2022 CHI Conference on Human Factors in Computing Systems* (Association for Computing Machinery 2022).
[104] Emanuele Sinagra, Francesca Rossi and Dario Raimondo, 'Use of Artificial Intelligence in Endoscopic Training: Is Deskilling a Real Fear?' (2021) 160 Gastroenterology 2212.
[105] Grote and Berens (n 43).
[106] Fanny Ficuciello and others, 'Autonomy in Surgical Robots and Its Meaningful Human Control' (2019) 10 Paladyn, Journal of Behavioral Robotics 30.

health effects of a delayed correct diagnosis.[107] Intervention in an earlier stage of the decision-making process, where there are still significant other pathways to consider, would be of more use to patients. In this sense, the right does not necessarily strengthen patient autonomy. Second, the GDPR does not give patients a right to human decision-making *instead of* automated decision-making. The human may be included in the automated decision at some point, but at this stage, some harms may have already occurred and are not easy to turn back, for example, the processing of personal data. In order words: the automated processing has already taken place, with potentially detrimental consequences for the protection of medical data protection and informational self-determination. To illustrate, the patient could request human intervention over an AI recommendation for a specific type of cancer treatment, but their personal medical data would already have been processed to generate the decision.

5.3 A Patients' Right to Expressing Points of View and to Contest the Decision?

Article 22(3) GDPR puts forward a right for data subjects to express their point of view. The data controller must implement suitable measures to safeguard this right. The right to expressing points of view seems to relate to expressing views in the case of (1) asking for human intervention or (2) contesting the decision.[108] While in theory, the sharing of views, opinions, and preferences does strengthen patient autonomy as it enhances self-determination and physical integrity, Article 22(3) does not stipulate an obligation for either the AI tool or the involved human to act upon this expression. In that sense, it does not seem to provide any direct extra protection to a patient subjected to automated medical decision-making. On the other hand, the fact that measures must be implemented in the decision-making process in order for patients to exercise this right, may in practice lead to the (voluntary) consideration of patients' opinions.

In addition, data subjects are granted the right to contest the decision resulting from the automated decision-making process. To this end, there

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[107] Dario Amodei and others, 'Concrete Problems in AI Safety' (*arXiv*, 21 June 2016) <https://arxiv.org/abs/1606.06565v2> accessed 22 June 2023.

[108] Claudio Sarra, 'Defenceless? An Analytical Inquiry into The Right to Contest Fully Automated Decisions In the GDPR' in David A Frenkel and Anna Chronopoulou (eds), *An Anthology of Law* (Athens Institute for Education and Research 2020).

must be suitable measures to ensure patients have access to this right. The right to contest the decision is different from the right to human intervention, as requesting human intervention does not equal a request to change the outcome of the automated decision-making process. Similarly, exercising the right to contest the decision does not seem to require the involvement of a human – disputes may also be settled in an automated manner.[109] In any way, the GDPR requires the implementation of a "contestable system", equipping patients with the practical tools to contest the automated decision.[110] The implementation of such a right *within* the system could add an extra layer of protection for patients, in addition to, for example, the patient's right to refuse a specific treatment.[111] However, a key concern about the effects of a right to contest the decision is the patient's lack of information about the decision-making process: it is very difficult to contest a decision without fully understanding how it was taken by the machine. This concern is often linked to "the right to explanation".[112]

5.4 A Patients' Right to Explanation?

The nature of a potential "right to explanation" of automated decisions in the GDPR has been a topic of extensive scholarly debate. Articles 13 and 14 entail specific transparency obligations when it comes to automated decision-making and require data controllers to inform the data subject about the following: (1) the fact that they are engaging in this type of activity; (2) provide meaningful information about the logic involved; and (3) provide information on the significance and envisaged consequences of the processing. The CJEU explains that transparency about personal data processing is important because it is a prerequisite for other rights, such as the right of access to personal data and the right to object to the processing of data.[113] Brkan adds to this that granting data subjects a right to explanation of automated decisions, enables them to "understand the

[109] ibid.
[110] Marco Almada, 'Human Intervention in Automated Decision-Making: Toward the Construction of Contestable Systems' in *Proceedings of the Seventeenth International Conference on Artificial Intelligence and Law* (Association for Computing Machinery 2019).
[111] Isak Mendoza and Lee A Bygrave, 'The Right Not to Be Subject to Automated Decisions Based on Profiling' in Tatiana-Eleni Synodinou and others (eds), *EU Internet Law: Regulation and Enforcement* (Springer International Publishing 2017).
[112] Almada (n 110).
[113] Case C-201/14 *Smaranda Bara and Others* ECLI:EU:C:2015:461, Opinion of Advocate General Cruz Villalon, para 74.

reasons behind the decision and to prevent discriminatory or otherwise legally non-compliant decisions."[114] While some scholars such as Wachter, Mittelstadt and Floridi accept only a very restrictive interpretation of a right to explanation,[115] others such as Goodman and Flaxman,[116] Casey, Farhangi and Vogl[117] confer from Articles 13 and 14 GDPR's "right to meaningful information about the logic involved" a solid "right to explanation" of automated decisions for individuals. Selbst and Powles advocate a "functional and flexible" right, that enables individuals to exercise their autonomy and for example contest an automated decision.[118] There is furthermore discussion about the *type* of information that must be provided and the *time* of provision (*ex-ante* or *ex-post* the automated decision-making).[119] According to the EDPB, the data subject must be given information that is also helpful for him or her to contest the decision, specifically on the deliberations in the decision-making process, and on their respective weight on a general level.[120] Edwards and Veale claim that, even if there was a right to explanation, there would be great difficulty in providing data subjects with meaningful explanations, making it an empty promise in practice.[121]

For the patient involved in automated medical decision-making, information about the decision-making process is a key factor in the protection of their patients' rights and health privacy. Adequate information is essential to enable patients' rights related to health privacy, such as the right to refuse treatment. It is also crucial for the protection of the right to medical data protection to provide information

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[114] Maja Brkan and Grégory Bonnet, 'Legal and Technical Feasibility of the GDPR's Quest for Explanation of Algorithmic Decisions: Of Black Boxes, White Boxes and Fata Morganas' (2020) 11 European Journal of Risk Regulation 18.
[115] Wachter, Mittelstadt and Floridi (n 12).
[116] Bryce Goodman and Seth Flaxman, 'European Union Regulations on Algorithmic Decision-Making and a "Right to Explanation"' (2017) 38 AI Magazine, 50–57.
[117] Bryan Casey, Ashkon Farhangi and Roland Vogl, 'Rethinking Explainable Machines: The GDPR's Right to Explanation Debate and the Rise of Algorithmic Audits in Enterprise' (2019) 34 Berkeley Technology Law Journal.
[118] Selbst and Powles (n 12).
[119] Tiago Sergio Cabral, 'AI and the Right to Explanation: Three Legal Bases under the GDPR' in Dara Hallinan, Ronald Leenes and Paul De Hert (eds), *Data Protection and Privacy: Data Protection and Artificial Intelligence* (Bloomsbury Publishing 2021).
[120] Stefanie Hänold, 'Profiling and Automated Decision-Making: Legal Implications and Shortcomings' in Marcelo Corrales, Mark Fenwick and Nikolaus Forgó (eds), *Robotics, AI and the Future of Law* (Springer 2018).
[121] Lilian Edwards and Michael Veale, 'Slave to the Algorithm? Why a "Right to an Explanation" Is Probably Not the Remedy You Are Looking For' (2017) 16 Duke Law & Technology Review 18.

about data processing for automated medical decision-making. To illustrate, in the case of AI precision medicine, the patient needs certain information to object to the decision to choose a specific medicine (e.g. that it was an automated decision, the grounds for deciding on medicine X instead of Y, etc.). Active information sharing is also an important aspect of human dignity and is essential for building trust. For example, adequate information about the functioning of an AI insulin system can improve patients' trust in the system.

However, the lack of judicial clarification on the nature of the GDPR's "right to explanation", may undermine its effectiveness. The right to informed consent – a long-recognized patients' right – seems to be a much stronger right, as its core elements have been established by both national courts and the ECtHR, and healthcare institutions have procedures in place to guarantee proper understanding of patients, with the aim of enabling patients' autonomy and protecting human dignity. For example, the patient's right to informed consent also requires access to information about alternative treatments, and all medical information must be included in the medical file, which the patient must have access to. In the absence of a uniform interpretation of Articles 13 and 14 GDPR, these provisions will not contribute substantially to the protection of health privacy against automated medical decision-making.

6. CONCLUDING REMARKS: THE GDPR AS A CATALYSATOR FOR PATIENT PROTECTION?

Decision-making processes in the healthcare sector are changing quickly, whilst the legal and regulatory framework struggles to keep up. As is often the case in digital transformations, digital processes are evolving faster than the law can adapt. Because of the novelty of these technologies and the fear of being outdated, regulators often favour introducing new legal provisions or instruments over new interpretations of existing legal frameworks, causing the gap between law and technology to grow even bigger. This effect seems to be even stronger in the context of EU regulation, where the balancing of interests in the different EU institutions and political landscape has always been a lengthy process. As EU integration in health is still limited, not much has been said about

individual rights in relation to medical technology. The EU's formal (direct) involvement in medical technology regulation – including medical automated decision-making – does not extend beyond the regulation of safety and quality of the devices themselves. However, this limitation in EU competency does not prevent general EU legislation – such as the GDPR - and fundamental rights instruments from being applied in the realm of healthcare.

This paper examined the impact of AI on health privacy, and showed how – in the absence of an *explicit* right not to be subject to automated medical decision-making – other provisions (and in particular Art 22 GDPR) can be used to provide an equivalent level of protection of patients' rights and health privacy. It showed that many features of article 22 GDPR can indeed constitute the basis for a satisfying protection of health privacy in respect to developments in medical AI. However, it also showed that the rights and safeguards against automated decision-making provided for in the GDPR do have their limitations when applied in the medical context. At the same time, since a *right not to be subject to automated medical decision-making* is currently missing in other frameworks, the GDPR's provisions surrounding automated decision-making may still provide patients with an extra layer of protection. Therefore, an adequate level of protection for health privacy could be achieved by a reading of Article 22 GDPR that takes into consideration the specificities of the healthcare context. It is important to note that this health-conformant reading does not imply a blanket prohibition of automated decision-making in the medical context, but rather introduces conditional rights and safeguards.

That said, the practical application of the rights recognised in the GDPR – and Article 22 specifically – remains a key issue. Because of the opacity of most automated decision-making systems, it is not always possible for patients to find out whether a decision was (1) automated, and (2), based on their personal data, making it more difficult to exercise their rights. Furthermore, objecting to the use of automation does not guarantee a different outcome in the decision. Thus, while the GDPR offers a theoretical solution, it may not be as useful in practice.

Simply rebranding the GDPR and its right not to be subject to a decision based solely on automated processing as a safeguard for patients' rights

and health privacy is not sufficient. While the EU data protection law framework introduces a regime of individual legal protection that the current health law framework misses, health-conformant interpretation of the GDPR is necessary. If we want the instrument to be useful in the medical context, we need to interpret it in light of the underlying ethical values that have given way to patients' rights as protected in the Member States. The general rules of the GDPR in this way can pave the way for ultimately developing a special EU-wide patients' right not to be subject to automated medical decision-making, which will eventually lead to better protection of patients' health privacy rights.