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### Patients' rights protection and artificial intelligence in the European Union

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UNESCO, Outcome document of the first meeting of the AHEG: first draft of a Recommendation on the Ethics of Neurotechnology (first version) (9 May 2024) SHS/BIO/AHEG-Neuro/2024/1 Rev

UNGA Human Rights Council, ‘Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development’ 53rd session, 19 June–14 July 2023 (21 May 2023) A/HRC/53

WHO, ‘A Declaration on the Promotion of Patients’ Rights in Europe’ (28 June 1994) ICP/HLE 121

WHO Regional Office for Europe, ‘The Rights of Patients. Report on a WHO Consultation (Amsterdam, 28-30 March 1994)’ in: WHO Regional Office for Europe in collaboration with the Health Law Section, University of Amsterdam, *Promotion of the Rights of Patients in Europe* (Kluwer Law International 1995)

WHO, *Ethics and Governance of Artificial Intelligence for Health: WHO Guidance, Executive Summary*, Geneva: WHO (2021)

WHO, *Generating Evidence for Artificial Intelligence Based Medical Devices: A Framework for Training Validation and Evaluation*, Geneva: WHO (2021)

WHO, *Ageism in artificial intelligence for health: WHO policy brief* (WHO 2022)

WHO Regional Office for Europe, *Health and Care Workforce in Europe: Time to Act* (WHO 2022)

WHO, *Regulatory Considerations on Artificial Intelligence for Health* (WHO 2023)

WHO, ‘Global Stakeholders Agree to a New Charter on Patient Safety Rights’ (Geneva, 14 September 2023)

WHO, *Ethics and Governance of Artificial Intelligence for Health: Guidance on large multi-model models* (WHO 2024)

## **Council of Europe**

### **Treaties**

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 Fundamental Freedoms (ETS No. 005) 04/11/1950

European Social Charter (ETS No. 035) 18/10/1961

Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) 28/01/1981

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)

Modernised Convention for the Protection of Individuals with Regard to the Processing of Personal Data, Adopted by the Committee of Ministers at its 128th Session of the Committee of Ministers (Elsinore, 18 May 2018) (Convention 108+)

Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (CETS No. 223) 10/10/2018

Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law (CETS No. 225) 5/IX/2024

### **Other documents**

Ad Hoc Committee on Artificial Intelligence (CAHAI), ‘Feasibility Study’ (Council of Europe 2020) CAHAI(2020) 23

Committee of Experts on Internet Intermediaries (MSI-NET), ‘Algorithms and Human Rights: Study on the Human Rights Dimensions of Automated Data Processing Techniques and Possible Regulatory Implications’ (Council of Europe 2018)

Committee on Artificial Intelligence (CAI), ‘Consolidated Working Draft of the Framework Convention on Artificial Intelligence, Human Rights, Democracy and the Rule of Law’ (Council of Europe 2023) CAI(2023) 18

Parliamentary Assembly, Recommendation 2104 (2017) “Human rights of older persons and their comprehensive care” adopted by the Assembly on 30 May 2017

Parliamentary Assembly, Recommendation 2255 (2023) “Health and social protection of undocumented workers or those in an irregular situation” adopted by the Assembly on 21 June 2023 (17th sitting)

Recommendation Rec(2005)5 of the Committee of Ministers to member states on the Council of Europe Action Plan to promote the rights and full participation of people with disabilities in society: improving the quality of life of people with disabilities in Europe 2006-2015 (Adopted by the Committee of Ministers on 5 April 2006 at the 961st meeting of the Ministers’ Deputies)

# ANNEX I

## INTERVIEW GUIDE

### **First Interview Series: Exploring The Meaning Of AI In Healthcare**

Between January and September 2020, I interviewed 15 individuals from a wide range of stakeholders over Zoom, such as AI developers, medical doctors using AI, and policy advocates. I asked everyone the same set of questions:

- 1. How would you describe AI?*
- 2. Can you give some examples of the use of AI in healthcare?*
- 3. What are the main advantages you see for patients?*
- 4. What are the main challenges you see for patients?*

I used the interviews to identify the issues at play and further refine the scope of my problem statement. Interviews were not recorded and transcribed. All interviews served as background studies and thus no direct references to the interviews were included in this dissertation.

### **Second Interview Series: Healthcare In the AI Act**

Second, I wanted to understand how the healthcare sector was considered in the initial drafting and political negotiation of the AI Act.<sup>1</sup> I went to Brussels two times to conduct in-person semi-structured interviews with five political assistants of members of the European Parliament<sup>2</sup> and six civil servants working on the AI Act or digital health at the European Commission.<sup>3</sup> I asked everyone the same set of broad questions:

- 1. Can you share insights on the negotiation process of the AI Act?*
- 2. What is your opinion on the AI Act Proposal in general?*
- 3. How do you evaluate its implications for the healthcare sector?*
- 4. What is your view on including a right to human oversight?*
- 5. Have you spoken to stakeholders in healthcare in relation to the drafting/negotiation of the AI Act?*
- 6. Are you aware of future legislative or policy initiatives to further regulate AI in healthcare?*

I used the interviews to identify the current state of play on legislation and policy. Interviews were not recorded and transcribed. All interviews served as background studies and thus no direct references to the interviews were included in this dissertation.

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<sup>1</sup> Jan Beyers and others, 'Let's Talk! On the Practice and Method of Interviewing Policy Experts' (2014) 3 Interest Groups & Advocacy 174.

<sup>2</sup> Affiliated with different political parties, namely: Renew Europe (1), EPP (2), S&D (1), and ECR (1).

<sup>3</sup> Within different units of the European Commission: DG SANTE (5) and DG CONNECT (1).

## ANNEX II

### OVERVIEW OF PUBLICATIONS

#### PUBLICATIONS INCLUDED IN DISSERTATION

Hannah **van Kolfshooten**, ‘EU regulation of artificial intelligence: Challenges for patients’ rights’ (2022) 59 (1) *Common Market Law Review*, pp. 81-112, <https://doi.org/10.54648/cola2022005> [published 1 February 2022]

Hannah **van Kolfshooten** & Carmel Shachar\*, ‘The Council of Europe’s AI Convention (2023–2024): Promises and pitfalls for health protection’ (2023) 138 *Health Policy*, 104935, <https://doi.org/10.1016/j.healthpol.2023.104935> [published 30 October 2023]

Hannah **van Kolfshooten**, ‘The AI cycle of health inequity and digital ageism: mitigating biases through the EU regulatory framework on medical devices’ (2023) 10 (2) *Journal of Law and the Biosciences*, lsado31, <https://doi.org/10.1093/jlb/lsado31> [published 7 December 2023]

Hannah **van Kolfshooten**, ‘A Health-Conformant Reading of the GDPR’s Right Not to be Subject to Automated Decision-Making’ (2024) 32 (3) *Medical Law Review*, fwae029, <https://doi.org/10.1093/medlaw/fwae029> [published 9 August 2024]

Hannah **van Kolfshooten**, ‘A human rights-based approach to artificial intelligence in healthcare: A proposal for a patients’ rights impact assessment tool’ in: Philip Czech, Lisa Heschl, Karin Lukas, Manfred Nowak, Gerd Oberleitner (eds.), *European Yearbook on Human Rights 2024* (Brill Publishing 2024), pp. X-Y [published 1 February 2025]

Hannah **van Kolfshooten**, ‘Towards a European Charter of Digital Patients’ Rights in the Age of Artificial Intelligence’ *Digital Society 2025* [in-press, forthcoming]

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\* Van Kolfshooten wrote the original draft. Shachar provided critical review and textual edits.

## OTHER PUBLICATIONS RELATED TO THESIS

### In English

Hannah **van Kolfschooten** & Janneke van Oirschot, 'The EU Artificial Intelligence Act (2024): Implications for Healthcare' (2024) 149 *Health Policy* 105152 <<https://doi.org/10.1016/j.healthpol.2024.105152>>

Hannah **van Kolfschooten** & Astrid Pilottin, 'Reinforcing stereotypes in healthcare through AI-generated images: A call for regulation' (2024) *Mayo Clinic Proceedings: Digital Health*  
<<https://doi.org/10.1016/j.mcpdig.2024.05.004>>

Hannah **van Kolfschooten**, 'The prospects of using AI in euthanasia and physician-assisted suicide: a legal exploration' (2024) *AI and Ethics*  
<<https://doi.org/10.1007/s43681-024-00491-w>>

Hannah **van Kolfschooten**, 'The Council of Europe's Artificial Intelligence Convention: Implications for Health and Patients' (Bill of Health 18 April 2023) <<https://blog.petrieflom.law.harvard.edu/2023/04/18/council-of-europe-artificial-intelligence-convention/>>

Hannah **van Kolfschooten**, 'The mHealth Power Paradox: Improving Data Protection in Health Apps through Self-Regulation in the European Union' in I. G. Cohen, T. Minssen, W. N. Price II, & C. Robertson (eds), *The Future of Medical Device Regulation: Innovation and Protection* (CUP 2022) 63-76  
<<https://doi.org/10.1017/9781108975452.006>>

Hannah **van Kolfschooten** & Sofia Palmieri, 'A Health-Oriented Approach to the Declaration on European Digital Rights and Principles' (2022) *The Digital Constitutionalist* <<https://digi-con.org/a-health-oriented-approach-to-the-declaration-on-european-digital-rights-and-principles/>>

Hannah **van Kolfschooten**, 'Conspicuous by its absence: health in the European Commission's Artificial Intelligence Act' (BMJ Opinion 30 July 2021) <<https://blogs.bmj.com/bmj/2021/07/30/conspicuous-by-its-absence-health-in-the-european-commissions-artificial-intelligence-act/>>

Hannah **van Kolfschooten** & Anniek de Ruijter, 'COVID-19 and privacy in the European Union: A legal perspective on contact tracing' (2020) 41 (3) *Contemporary Security Policy*, 478-491  
<<https://doi.org/10.1080/13523260.2020.1771509>>

## In Dutch

Hannah **van Kolfschooten** & Rolinka Wijne, ‘Diagnosticeren met AI en de aansprakelijkheid van hulpverleners’ (2024) 23 Nederlands Juristenblad 1414, 1760-1773.

Hannah **van Kolfschooten**, ‘Artificiële intelligentie in de ouderenzorg: Een voorstel voor een beoordelingsinstrument voor patiëntenrechten’ in Marco Varkevisser, Erik Schut, Krista Tromp, Jan-Koen Sluijs, Bob van der Kamp & Hannah van Kolfschooten, *VGR Preadvies 2024: Juridische aspecten rondom schaarste in de zorg* (Boom Juridisch 2024).

Hannah **van Kolfschooten** & Bastiaan Wallage, ‘Apps in de gezondheidszorg: een mensenrechtelijk vraagstuk’ in B. Aarrass, K. Albers, & R. Ortlep (eds), *Digitalisering in de rechtsverhouding tussen burger en overheid: Zoeken naar een balans tussen instrumentaliteit en waarborg* (Wolters Kluwer 2022), pp. 245-262.

Hannah **van Kolfschooten**, ‘Eerste stappen in Europese regulering van artificiële intelligentie: algoritmes en patiëntenrechten’ (2021) 45(4) Tijdschrift voor Gezondheidsrecht, 381-389.

Hannah **van Kolfschooten**, ‘Gegevensbescherming in gezondheidscrises in de EU: apps in de strijd tegen COVID-19’ (2021) 70(7/8) *Ars Aequi*, 766-775.

Hannah **van Kolfschooten**, Merel Spaander & Johan Legemaate, ‘Rode draad 70 jaar EVRM: De autonome patiënt na 70 jaar EVRM: Van dwangpsychiatrie naar gentechnologie?’ (2021) 46(2) *Nederlands Tijdschrift voor de Mensenrechten*, 113-130.

Hannah **van Kolfschooten**, ‘Annotatie bij: Rb. Den Haag, 5/02/20 (SyRI wetgeving) ECLI:NL:RBDHA:2020:865’ (2020) 236(25) *AB Rechtspraak Bestuursrecht*, 1510-1539.

Hannah **van Kolfschooten**, ‘Contact tracing’ versus privacy bij ernstige grensoverschrijdende gezondheidsbedreigingen’ (2019) 22(2) *Privacy & Informatie*, 43-48.



## OTHER PUBLICATIONS NOT RELATED TO THESIS

### In English

Angela Hefti, Hannah **van Kolfshooten** & Aminta Ossom, 'A Health-Centric Intersectional Approach to Climate Litigation before the European Court of Human Rights', (2024) 38 Harvard Human Rights Journal 351-378, <https://journals.law.harvard.edu/hrj/wp-content/uploads/sites/83/2024/08/Hefti-van-Kolfshooten-Ossom-Final.pdf>

Hannah **van Kolfshooten** & Angela Hefti, 'Women's Health Rights can Guide International Climate Litigation: KlimaSeniorinnen v. Switzerland before the European Court of Human Rights' (Health and Human Rights Journal Blog, 15 May 2023)  
<<https://www.hhrjournal.org/2023/05/womens-health-rights-can-guide-international-climate-litigation-klimaseniorinnen-v-switzerland-before-the-european-court-of-human-rights/>>

Hannah **van Kolfshooten** & Mirko Faccioli, 'A European Cancer Survivors' Right to be Forgotten?' (Bill of Health 28 September 2023)  
<<https://blog.petrieflom.law.harvard.edu/2023/09/28/a-european-cancer-survivors-right-to-be-forgotten/>>

Hannah **van Kolfshooten**, 'EU Coordination of Serious Cross-Border Threats to Health: The Implications for Protection of Informed Consent in National Pandemic Policies' (2019) 10 (4) European Journal of Risk Regulation, pp. 635-651, <https://doi.org/10.1017/err.2019.70>

### In Dutch

Hannah **van Kolfshooten**, Aniek de Ruijter & Brigit Toebes, 'Voedselregulering als fundamenteel ingrediënt in het gezondheidsrecht' *in: Goed gezondheidsrecht: De maat van Legemaate (Boom Juridisch 2024)* 45-54.

Aniek de Ruijter, Coosje Dijkstra, Bastiaan Wallage, Maartje Poelman, Lianne Bergsma, Hannah **van Kolfshooten**, Margaretha Wewerinke, Tijs Rutgers, Wilma Waterlander, *Tussen mens en ruimte: de (on)gezonde voedselomgeving als omgevingswaarde* (Universiteit van Amsterdam 2023).

Hannah **van Kolfshooten** & Merel Spaander, ‘Annotatie bij: Hof Amsterdam, 4/01/22, ECLI:NL:GHAMS:2022:7 (Dier&Recht/Agractie)’ (2022) 124(14) AB Rechtspraak Bestuursrecht, 1122-1129.

Cathrijn van der Vleuten & Hannah **van Kolfshooten**, ‘Van verplichte geestelijke gezondheidszorg naar verplichte anticonceptie?’ (2022) 97 (10) Nederlands Juristenblad, 739-745.

Hannah **van Kolfshooten**, Richard Neerhof, Anita Nijboer, Anniëk de Ruijter & Marjolein Visser, ‘De gezonde voedselomgeving: Juridische (on)mogelijkheden voor gemeenten’ (2021) 96(8) Nederlands Juristenblad, 586-593.

Hannah **van Kolfshooten**, Richard Neerhof, Anita Nijboer, Anniëk de Ruijter & Marjolein Visser, *Juridisch instrumentarium voor een gezonde voedselomgeving in de stad* (Universiteit van Amsterdam 2021).

## OP-EDS

### In English

Hannah **van Kolfshooten**, ‘The ‘Sarco Suicide Pod’ and Beyond: AI in the Future of End-of-Life Decisions?’ (Bioethics Today 31 October 2024) <<https://bioethicstoday.org/blog/the-sarco-suicide-pod-and-beyond-ai-in-the-future-of-end-of-life-decisions/>>

Hannah **van Kolfshooten**, Janneke van Oirschot & Claudia Nicastro, ‘Five “Big MedTech” Myths about Medical AI Debunked’ (Health Action International 17 April 2023) <<https://haiweb.org/five-big-medtech-myths-about-medical-ai-debunked/>>

Hannah **van Kolfshooten** & Janneke van Oirschot, ‘Health protection is non-negotiable in the AI Act negotiations’ (Euractiv 18 August 2022) <<https://www.euractiv.com/section/digital/opinion/health-protection-is-non-negotiable-in-the-artificial-intelligence-act-negotiations/>>

Jorge Félix Cardoso, Hannah **van Kolfshooten**, Diego Nogueira Leite, Tjasa Petročnik & Hercules Vasconcelos, ‘How the Parliament’s AIDA Report Misdiagnoses the Risks and Benefits of Health AI’ (Euractiv 24 January 2022) <<https://www.euractiv.com/section/digital/opinion/how-the-parliaments-aida-report-misdiagnoses-the-risks-and-benefits-of-health-ai/>>

## In Dutch

Hannah **van Kolfschooten**, ‘AI in de zorg vraagt om richtlijnen, niet om rekensommen’ (Zorgvisie.nl 8 November 2024)

<<https://www.zorgvisie.nl/blog/opinie-ai-in-de-zorg-vraagt-om-richtlijnen-niet-om-rekensommen/>>

Hannah **van Kolfschooten**, ‘Kan AI worden ingezet worden bij euthanasieverzoeken?’ (De Volkskrant 5 November 2024)

<<https://www.volkskrant.nl/columns-opinie/opinie-kan-ai-woorden-ingezet-woorden-bij-euthanasieverzoeken~b4600d21/>>

Anniek de Ruijter, Hannah **van Kolfschooten** & Katrina Pehudoff, ‘De focus op het redden van zoveel mogelijk levens kan de sociale ongelijkheid in Nederland verergeren’ (NRC Handelsblad 25 November 2020)

<<https://www.nrc.nl/nieuws/2020/11/25/denk-bij-coronavaccin-aan-sociaal-kwetsbaren-a4021376>>

Hannah **van Kolfschooten**, ‘Technologische hulp uit China is niet gratis’ (NRC Handelsblad 30 March 2020)

<<https://www.nrc.nl/nieuws/2020/03/30/technologische-hulp-uit-china-is-niet-gratis-a3995326>>

Hannah **van Kolfschooten** & Bastiaan Wallage, ‘Overheid, pas op met gezondheidsdata en het uitvoeren van massasurveillance’ (Het Financieele Dagblad 31 March 2020) <[https://fd.nl/opinie/1339613/overheid-pas-op-met-gezondheidsdata-en-massasurveillance?fbclid=IwARoivt5LsnYIyjgT4YNWaSA3tO12g-ZqQX2FW6C\\_yxNqYP8noD4Qa4nSlXk](https://fd.nl/opinie/1339613/overheid-pas-op-met-gezondheidsdata-en-massasurveillance?fbclid=IwARoivt5LsnYIyjgT4YNWaSA3tO12g-ZqQX2FW6C_yxNqYP8noD4Qa4nSlXk)>

<[https://fd.nl/opinie/1339613/overheid-pas-op-met-gezondheidsdata-en-massasurveillance?fbclid=IwARoivt5LsnYIyjgT4YNWaSA3tO12g-ZqQX2FW6C\\_yxNqYP8noD4Qa4nSlXk](https://fd.nl/opinie/1339613/overheid-pas-op-met-gezondheidsdata-en-massasurveillance?fbclid=IwARoivt5LsnYIyjgT4YNWaSA3tO12g-ZqQX2FW6C_yxNqYP8noD4Qa4nSlXk)>

Hannah **van Kolfschooten** & Anniek de Ruijter, ‘Denk aan rechten bij aanpak Coronavirus’ (NRC Handelsblad 28 January 2020)

<<https://www.nrc.nl/nieuws/2020/01/28/denk-aan-rechten-bij-aanpak-virus-a3988460>>

# ANNEX III

## CURRICULUM VITAE

### EDUCATION

**Ph.D. Program in Law** University of Amsterdam  
**2020-2024**

**LL.M. Information Law** University of Amsterdam  
2018-2019 Obtained 1 July 2019, *cum laude*

**LL.M. Health Law** University of Amsterdam  
2017-2018 Obtained 1 July 2018, *cum laude*

**LL.B. Law** University of Amsterdam  
2013-2017 Obtained 1 July 2017, *valedictorian*  
*Exchange semester at Stellenbosch University, South Africa*

### AFFILIATIONS

**Research Fellow** • Law Centre for Health and Life  
2020 – present • Amsterdam Institute for Global Health &  
Development  
• Amsterdam Centre for European Law &  
Governance

**Research Consultant** Health Action International, non-profit organization  
2022 – present

**Visiting Fellow** Brocher Foundation, Switzerland  
Spring 2024

**Visiting Fellow** University of Verona, Italy  
Summer 2023

**Visiting Fellow** Harvard Law School, USA  
Spring Semester 2023 Petrie-Flom Center for Health Law, Policy, Biotech, and  
Bioethics

## **ACADEMIC TEACHING**

Degree (2021)	<b>University Teaching Qualification (UTQ/BKO)</b>
2024 – present	<b>Coordinator Introduction to Health Law (LL.M)</b> <ul style="list-style-type: none"><li>• Compulsory course in Health Law LL.M., University of Amsterdam (65 students, 6 ECTS)</li><li>• Design and coordination; teaching with ‘active learning’ methods</li></ul>
2024 – present	<b>Member Board of Education</b> <ul style="list-style-type: none"><li>• Advising the Faculty Board on the contents and organisation of the LL.M. Programmes</li></ul>
2020 – present	<b>Co-coordinator mentor programme in Health Law</b> <ul style="list-style-type: none"><li>• Education on academic skills; professional skills and ethics</li><li>• Design and coordination; teaching with ‘active learning’ methods</li></ul>
2019 – present	<b>Student thesis supervision</b> <ul style="list-style-type: none"><li>• Supervising research projects of LL.M. and LL.B. students</li><li>• 46 master theses; 11 bachelor theses (first supervisor)</li><li>• 50+ master thesis; 10+ bachelor theses (second reader)</li></ul>
2019 – 2024	<b>Coordinator International and European Health Law (LL.M)</b> <ul style="list-style-type: none"><li>• Compulsory course in Health Law LL.M., University of Amsterdam (65 students, 6 ECTS)</li><li>• Design and coordination; teaching with ‘active learning’ methods</li></ul>
2019 – 2024	<b>Various guest lectures</b> <ul style="list-style-type: none"><li>• ‘Privacy in Mobile Health Apps: A Legal Perspective’ in: Ethics and law of data protection, <b>University of Verona</b>, Master in Data Sciences (2024)</li><li>• ‘Legal Challenges of AI in Elderly Care: A Human Rights Perspective’ in: Winter school on Ethics and Ageing, <b>University of Basel</b> (2023)</li><li>• ‘Legal Challenges of AI in Healthcare’ in: Basics of Clinical Research &amp; Regulation, <b>VU University</b>, Master in Personalized Medicine (2023)</li></ul>

- ‘Artificial Intelligence in Pharmaceutical Systems: Regulatory Challenges’ in: Pharmaceutical policies in health systems, **Institute of Tropical Medicine Antwerp** (2023)
- ‘Legal and ethical challenges in algorithmic decision-making in healthcare’ in: Neurology, **Amsterdam Medical Centre**, Bachelor of Medicine (2022)

## **MEMBERSHIPS**

Co-chair	<b>Digital Health and Rights Alliance</b>
Co-chair	<b>EU Health Policy Platform Thematic Network: Navigating Health Inequalities in the EU through Artificial Intelligence</b>
Guest author	<b>Bill of Health (Petrie-Flom Center, Harvard Law School)</b>
Member	<b>INSPIRE Digital Health (McGill University)</b>
Member	<b>Alumni Network KU Leuven: Law, Ethics and Policy of Artificial Intelligence</b>
Member	<b>European Association of Health Law (EAHL)</b>
Member	<b>EU Health Governance Research Network (EUHealthGov)</b>
Member	<b>University Association for Contemporary European Studies (UACES)</b>

## **RESEARCH STAYS**

**Harvard Law School**, under the supervision of Prof. Carmel Shachar and Prof. Glenn Cohen (February – June 2023)

**University of Verona**, Department of Law, under the supervision of Prof. Mirko Faccioli (July – August 2023)

**Fondation Brocher**, Hermance, Switzerland (April 2024)

## ACADEMIC TRAINING AND WORKSHOPS

- PhD Programme in Law, **University of Amsterdam**, completed in 2020
- University Teaching Qualification (BKO), **University of Amsterdam**, obtained in 2021
- Summer School Law, Ethics and Policy of Artificial Intelligence, **KU Leuven, Belgium** (28 June – 3 July 2021).
- Winter School Algorithmic State, Market and Society, **University of Florence and European University Institute, Italy** (9-11 February 2022).
- OpenEUdebate Workshop on research outreach, **Luiss Guido Carli University** (7 June 2022)
- Workshop “Storytelling”, **UvA Teaching & Learning Centres (TLC)** (10 and 24 October 2022)
- Workshop Explainable AI in Medicine, **Swiss AI Lab IDSIA USI-SUSPI**, Lugano (2-3 November 2023)
- **UACES** Doctoral Training Academy 2023, Brussels (24 November 2023)

## EVENT ORGANISATION

- Hannah **van Kolfshoeten**, Workshop: ‘Artificial Intelligence in Mobile Health Apps: Ethical, Legal, and Regulatory Challenges’, 17th European Public Health Conference, Lisbon, Portugal (2024)
- Hannah **van Kolfshoeten** & Merel Spaander, Workshop: ‘Controversial Health Issues in the European Court of Human Rights: Recent Developments’, 9th European Conference on Health Law, Warsaw, Poland (2024)
- Pramiti Parwani & Hannah **van Kolfshoeten**, Workshop: ‘PhD workshop for health lawyers’, EU Health Governance: Opportunities for Trust and Solidarity, Amsterdam (2023)
- Hannah **van Kolfshoeten**, Sofia Palmieri, Tjasa Petrocnik, Workshop: ‘HEALTH (DATA) IS WEALTH: The Quest for Effective AI Regulation in Healthcare’, Digital Legal Talks 2022, Utrecht (2022)
- Hannah **van Kolfshoeten**, Katrina Pehudoff & Anniek de Ruijter, Workshop: ‘Mind the gap: The EU-domestic interface and its implications for health lawyers’, 8th European Conference on Health Law, Ghent (2022)

## SEMINARS AND CONFERENCE PRESENTATIONS

### 2024

- ‘Legal, ethical, and societal aspects of AI in mobile apps for public health’, **European Public Health Conference 2024**, Lisbon (November 2024).
- ‘Regulation of Artificial Intelligence: Algorithms and Patients’ Rights’, Workshop McGill University: Use of AI for promoting Health Equity and Equity, Diversity and Inclusion Principles, **Brocher Fondation**, Hermance (October 2024)
- ‘An Intersectional Health Approach to Climate Litigation at the European Court of Human Rights’, 9th European Conference on Health Law, **University of Warsaw**, Poland (September 2024)
- ‘The EU regulatory framework on medical AI tools: the patients’ rights perspective’, 27<sup>o</sup> Cycle of Debates - Nethis/Fiocruz: Artificial Intelligence and Health Inequalities, **Núcleo de Estudos sobre Bioética e Diplomacia em Saúde**, Brasília (June 2024)
- ‘The AI cycle of health inequity and digital ageism’, Prin 2022 ROMA TRE Seminar Series, **Roma Tre University** (June 2024).
- ‘Navigating the Impact of the AI Act on Patient Rights: A Focus on AI in Elderly Care’, Tilburg Institute for Law, Technology, and Society (TILT) seminar, **Tilburg University** (June 2024).
- ‘Regulating Medical Artificial Intelligence: A European Patients’ Rights Perspective’, Les Rendez-Vous de l’IHM, Institut des humanités en médecine CHUV-UNIL, **Université de Lausanne** (May 2024).
- ‘An Intersectional Critique of the Femtech Business Model: The Need For Standards In Reproductive Health Apps,’ Conference on Reproductive Rights: Legal Developments and Challenges, **University of Amsterdam** (May 2024).
- ‘Patients’ Rights in EU Regulation of Medical Artificial Intelligence’, Midi Santé, Institut de droit de la santé, **Université de Neuchâtel** (April 2024)
- ‘EU Regulation of Artificial Intelligence in Healthcare: A Patients’ Rights Perspective’, Brocher Fondation Research Fellows Seminar, **Brocher Fondation**, Hermance (April 2024)
- ‘Artificiële intelligentie in de ouderenzorg: Een voorstel voor een beoordelingsinstrument voor patiëntenrechten’, Jaarvergadering 2024, **Vereniging voor Gezondheidsrecht**, video presentation (April 2024)
- ‘Privacy in Mobile Health Apps: A Legal Perspective’ in: Ethics and law of data protection. **University of Verona** (Italy), Master in Data Sciences (January 2024) (Guest lecture)



## 2023

- ‘Artificial Intelligence in de euthanasiepraktijk’, Jubileumcongres 25 jaar Regionale Toetsingscommissies Euthanasie, **RTE Amsterdam** (December 2023)
- ‘Legal Challenges of AI in Elderly Care: A Human Rights Perspective’ in: Winter school on Ethics and Ageing. **University of Basel** (Switzerland), Institute for Biomedical Ethics (December 2023) (guest lecture)
- ‘Legal Challenges of AI in Healthcare’ in: Basics of Clinical Research & Regulation. **VU University** (Amsterdam, NL), Master in Personalized Medicine (November 2023) (guest lecture)
- ‘The EU’s Hand in Global Health Inequity in the Age of AI: Digital Ethics Dumping and AI Colonialism’, UACES 53rd Annual Conference in Belfast, **Queens University Belfast** (September 2023).
- ‘The EU’s Hand in Global Health Inequity in the Age of AI: Digital Ethics Dumping and AI Colonialism in Africa’, Digital Health: Regulatory and Policy Perspectives, **Warwick University**, Coventry (September 2023)
- ‘Artificial Intelligence in Pharmaceutical Systems: Regulatory Challenges’ in: Pharmaceutical policies in health systems. **Institute of Tropical Medicine Antwerp** (Belgium) (June 2023) (guest lecture)
- ‘The EU's Data Colonialism: Parallels between the EU’s regulation of clinical trials and artificial intelligence’, 16th Annual McGill Graduate Law Conference, **McGill University**, Montréal (May 2023).
- ‘A New Era for Patients' Trust? A Health Law Perspective on Trust and Trustworthiness in EU Risk Regulation of Artificial Intelligence’, EU health governance: An opportunity for trust and solidarity?, **University of Amsterdam** (April 2023).
- ‘Patients’ Rights and Algorithmic Decision-Making in Health: A Legal Perspective on EU Regulation of Artificial Intelligence in Public Health Surveillance’, Harvard Law School VSVR Spring Colloquium, **Harvard University**, Cambridge (March 2023).
- ‘The mHealth Power Paradox: Improving Data Protection in Health Apps through Self-Regulation in the EU’, Foreningen Industriel Retsbeskyttelse (Aippi.dk), **University of Copenhagen**, København (January 2023).

## 2022

- ‘A deep dive into the world of artificial intelligence and what it means for the health sector’, **Webinar** Health Action International: How to realise a health-centric Artificial Intelligence Act (December 2022).
- ‘Health AI and EU Fundamental Rights’, EU Health Policy Platform: 1st Live **Webinar** of the Thematic Network Navigating Health Inequalities in the EU through Artificial Intelligence (December 2022).

- ‘The Quest for Effective AI Regulation in Healthcare: A Patients’ Rights Perspective’, Digital Legal Talks 2022, **Utrecht University** (November 2022).
- ‘Local regulations to limit unhealthy food outlets: a law perspective’, Public Health Law, regulations and public procurement for local food environments, **Wageningen University** (November 2022).
- ‘The New AI Act: Challenges for Patients’ Rights and the European Health Data Space’, Understanding AI webinar series: EU Legislation on AI, **European Patients’ Forum** (October 2022).
- Building Trust in Artificial Intelligence in Medicine: A European Union Legal Perspective, 16th World Congress of Bioethics, **University of Basel** (July 2022).
- ‘Legal and ethical challenges in algorithmic decision-making in healthcare in: Neurology (elective). **Amsterdam Medical Centre** (NL), Bachelor of Medicine (June 2022) (guest lecture)
- ‘How EU Regulation for Trustworthy AI Can Underpin Patients’ Trust in Automated Decision-Making in Health’, 11th Biennial Conference of the SGEU, **Luiss University**, Rome (June 2022).
- ‘Building Trust in Artificial Intelligence in Medicine: A European Union Legal Perspective’, Health Law PhD Workshop Groningen, **Groningen University** (May 2022).
- ‘EU Regulation of Algorithmic Decision-Making in Health: The GDPR as a New Patients’ Rights Instrument?’, Eight European Conference on Health Law, **Ghent University** (April 2022).
- ‘Reflections on the implementation & legal challenges’, AI for Global Health: Decision Support Systems, **Amsterdam Institute for Global Health & Development** and **VU Campus Center for AI & Health**, Amsterdam (March 2022).
- ‘Juridische mogelijkheden regulering lokale voedselomgeving’, Academische Werkplaats Voedsel, **GGD Amsterdam** (March 2022).
- **2021**
- ‘Europese regulering van artificiële intelligentie in de zorg’, **Jaarcongres Gezondheidsrecht**, Utrecht (December 2021).
- Humane Conversations – “Developing AI for Healthcare” with Ivana Išgum and Hannah van Kolschooten, Humane AI Conversations, **Webinar** series from Humane AI (September 2021).
- ‘Juridisch instrumentarium voor gezonde voedselomgeving’, **Webinar** Voedselomgevingen, Gent (March 2021).
- ‘EU regulation of algorithmic decision-making in health’, European Association of Health Law PhD **Online Seminar**, Brussels (January 2021)

## **AWARDS**

- Amsterdam Law Faculty Prize for Best Publication (2023)
- 2<sup>nd</sup> prize for Best Presentation, 16th Annual McGill Graduate Law Conference (2023)

## **FUNDING AND SCHOLARSHIPS**

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# **ANNEX IV**

## **SUMMARY**

### **PATIENTS' RIGHTS PROTECTION AND ARTIFICIAL INTELLIGENCE IN THE EUROPEAN UNION**

The topic of this dissertation is the safeguarding of the rights of patients in the European Union (EU) in light of the increasing use of artificial intelligence (AI) technologies in healthcare, within the context of expanding EU integration through the Digital Single Market. The central aim is to assess whether the current EU legal frameworks adequately protect patients' rights against the algorithmisation of healthcare. Additionally, the research proposes alternative legal approaches to ensure more robust protections for patients in this rapidly evolving sector.

#### **Chapter 1: Introduction**

The introductory Chapter sets the stage by illustrating how AI is transforming healthcare in the EU, focusing on the process of "algorithmisation." This phenomenon refers to the increasing integration of AI into healthcare systems for diagnostic purposes, patient treatment, and hospital administration. Through a fictional but realistic scenario, the chapter provides a glimpse into a future where AI assists in patient diagnosis, monitors health metrics through wearable devices, and aids in surgical procedures. This progression brings both opportunities and risks. The Chapter frames these advancements in the context of the EU's expanding Digital Single Market, where AI technologies play an increasing role. Additionally, it also stresses the legal and ethical concerns arising from this technological shift, especially regarding patient safety, autonomy, privacy, and the transparency of AI decision-making processes.

The Chapter highlights the existing regulatory gaps, questioning whether current EU legal frameworks can adequately protect patients from the risks introduced by AI-driven healthcare. The research question is outlined: How can the rights of patients in the European Union be safeguarded in light of the increasing use of Artificial Intelligence technologies in healthcare in the expanding European Health Union? The Chapter closes by providing an overview of the dissertation's structure, which will examine this issue through

three parts, addressing both theoretical and practical perspectives on patients' rights protection.

## **Chapter 2: Patients' Rights in the Human Rights-Based Approach to Health**

This Chapter introduces the human rights-based approach to health as the normative foundation for the dissertation. It argues that the rights of patients are not merely legal entitlements but critical tools for ensuring human dignity, autonomy, and equity in healthcare. Drawing from international human rights law and principles, the Chapter emphasises the interconnection between health and human rights. It identifies three important links: (1) the right to the highest attainable standard of health is a human right; (2) human rights law can directly influence health outcomes; and (3) health-related laws and policies can, in turn, affect broader human rights.

The Chapter further discusses how patients' rights empower individuals, enhance trust in healthcare systems, and contribute to health equity by protecting vulnerable populations. It focuses on five main categories of patients' rights: (1) the right to access healthcare, (2) the right to autonomy, (3) the right to information, (4) the right to privacy and confidentiality, and (5) the right to an effective remedy. These rights are contextualised within the patient-health professional relationship, where patients are often in a vulnerable position. Through this analysis, the Chapter establishes a framework for evaluating the consequences of AI technologies in healthcare on patients' rights and serves as the theoretical grounding for the chapters that follow, particularly in assessing whether the existing legal protections for patients are sufficient in an AI-driven healthcare environment.

## **Chapter 3: A Common Framework for European Patients' Rights Protection**

Building on the human rights-based approach introduced in Chapter 2, this chapter provides a more concrete conceptualization of patients' rights within the European Union. It examines the shared legal foundations across EU Member States and international agreements that protect patients, identifying a common core of rights applicable in healthcare settings. Despite the lack of a universally accepted list of "European patients' rights", the Chapter traces these rights through various legal sources, including EU law, Council of Europe conventions, and international human rights frameworks.

The Chapter focuses on five categories of rights: access to healthcare, autonomy, information, privacy and confidentiality, and the right to an effective remedy. Within these categories, it identifies fourteen specific rights shared across EU Member States, which include the right to informed consent, access to medical records, and protection against discrimination. This Chapter sets out the parameters for assessing how AI impacts these core rights. It also emphasises that patients' rights exist within a multi-layered legal system, where national laws intersect with EU regulations and international treaties. This normative framework will be applied throughout the dissertation to evaluate AI's impact on healthcare.

#### **Chapter 4: EU Regulation of Artificial Intelligence: Challenges for Patients' Rights**

Chapter 4 examines how the increasing use of AI in medical decision-making challenges the protection of patients' rights. The chapter highlights the vulnerability of patients due to the inherent power imbalances between patients and health professionals, which are exacerbated by the integration of AI into healthcare. While AI can bring benefits such as personalised treatment and more efficient diagnostics, it also raises significant risks related to autonomy, privacy, and informed consent. The Chapter focuses on specific challenges posed by AI, such as its lack of transparency (often referred to as the "black box" problem), the potential for algorithmic bias, and the need for large amounts of sensitive medical data. The Chapter critiques the existing EU regulatory framework, specifically the 2021 proposal for the AI Act, which aims to regulate the use of AI systems across various sectors, including healthcare. It argues that the framework is insufficient for addressing the specific risks AI poses in healthcare, particularly because it does not take into account the unique vulnerabilities of patients. The Chapter concludes that, without specific provisions focused on healthcare, the AI Act risks creating gaps in the protection of patients' rights across EU Member States.

#### **Chapter 5: A Health-Conformant Reading of the GDPR's Right Not to Be Subject to Automated Decision-Making**

This chapter examines the General Data Protection Regulation (GDPR) and its implications for AI in healthcare. The focus is on Article 22 of the GDPR, which grants individuals the right not to be subject to decisions based solely on automated processing. The chapter investigates whether this right can be extended to medical decisions involving AI. AI in healthcare often relies on large datasets of personal information, raising concerns about data privacy,

consent, and control. The chapter argues that patients should have the right to refuse medical treatment based on AI decisions or request human intervention in such processes. The chapter further critiques the GDPR's practical limitations, noting that while it provides a framework for protecting personal data, it does not fully address the complexities of AI in medical decision-making. For instance, the "black box" nature of many AI systems makes it difficult for patients to understand how decisions are made, which undermines informed consent. The chapter proposes a "health-conformant" reading of the GDPR, suggesting that existing legal instruments should be adapted to better protect patients in the context of AI-driven healthcare.

### **Chapter 6: The AI Cycle of Health Inequity and Digital Ageism: Mitigating Biases Through the EU Regulatory Framework on Medical Devices**

Chapter 6 focuses on the issue of discrimination and bias in AI medical devices, particularly as it affects older patients. It introduces the concept of "digital ageism", which refers to the ways in which AI technologies may reinforce or exacerbate age-related discrimination in healthcare. Using AI medical devices as a case study, the Chapter critiques the EU Medical Device Regulation (MDR) and the AI Act for failing to adequately address the risk of bias in AI systems. It highlights how biases can be built into AI systems at multiple stages, from data collection to algorithm design, and how these biases can disproportionately affect older patients. The Chapter introduces the "AI cycle of health inequity", a framework that explains how biases in AI systems can create a reinforcing loop of discrimination and health inequity. It argues that the MDR and AI Act provide some protection against technical biases but do not address contextual biases that arise from the way AI systems are applied in real-world healthcare settings. This is particularly problematic for older patients, who may be excluded from the training datasets used to develop AI systems or may face barriers to accessing AI-driven healthcare due to lower levels of digital literacy.

### **Chapter 7: The Council of Europe's AI Convention: Promises and Pitfalls for Health Protection**

Chapter 7 analyses the Council of Europe's AI Convention and its potential impact on the protection of patients' rights in the EU. The Convention, which aims to regulate AI technologies through a human rights-based framework, represents a significant step toward addressing the ethical and legal challenges posed by AI across various sectors, including healthcare. However,

the Chapter critiques the Convention for taking a sector-neutral approach, which may dilute its effectiveness in addressing the specific risks AI poses in healthcare. The Chapter highlights several shortcomings of the Convention, including its non-binding nature, its exclusion of private-sector AI activities, and its lack of introduction of new human rights specifically tailored to the AI era. While the Convention provides a foundation for regulating AI, it is argued that its current form is insufficient for safeguarding the rights of patients, particularly those in vulnerable populations. The Chapter concludes by advocating for stronger, healthcare-specific regulations that account for the unique risks AI poses in medical settings.

### **Chapter 8: A Human Rights-Based Approach to Artificial Intelligence in Healthcare: A Proposal for a Patients' Rights Impact Assessment Tool**

This chapter introduces a practical solution to address the risks AI poses to patients' rights: the Patients' Rights Impact Assessment Tool. This tool is designed to provide healthcare professionals with guidelines for evaluating the ethical and legal implications of AI technologies before they are deployed in patient care. The chapter argues that healthcare providers often lack clear guidance on how to balance the benefits of AI with the need to protect patient autonomy, privacy, and dignity. The proposed tool offers a self-assessment questionnaire that can be used by healthcare providers to evaluate the impact of a specific AI system on patients' rights. The tool is particularly relevant for elderly care, where the integration of AI technologies is often mixed with informal caregiving. It emphasises the importance of assessing not just the technical aspects of AI but also the social, ethical, and legal consequences of its use. The chapter concludes by stressing that while the tool can help mitigate some of the risks associated with AI in healthcare, it must be supported by robust legal frameworks and regulatory oversight at the EU level.

### **Chapter 9: Towards an EU Charter of Digital Patients' Rights in the Age of Artificial Intelligence**

In Chapter 9, the dissertation proposes the creation of an EU Charter for Digital Patients' Rights, a unified legal instrument that would consolidate and update patients' rights to reflect the new challenges posed by AI in healthcare. The Charter would codify existing rights, such as the right to informed consent and privacy, while introducing new rights tailored to the digital age. The chapter argues that the current legal framework is fragmented, with patients'



rights scattered across various EU and national laws. This fragmentation creates uncertainty about the scope and enforceability of these rights, particularly in the context of AI-driven healthcare. The proposed Charter aims to harmonise patients' rights across EU Member States, ensuring that technological advancements in healthcare do not exacerbate health inequities or undermine patient protection. It also addresses the need for new legal instruments that can adapt to the rapid pace of technological change. The chapter concludes by calling for the EU to take a more active role in regulating AI in healthcare, not only to protect individual patients but also to ensure that the benefits of AI are distributed equitably across society.

## **Chapter 10: Conclusions**

The concluding chapter synthesises the key findings of the dissertation, highlighting four central conclusions: (1) the current portfolio of patients' rights is insufficiently adapted to the challenges posed by AI in healthcare; (2) the use of AI in healthcare disproportionately affects vulnerable populations, exacerbating health inequities; (3) the EU's legal framework on AI does not adequately protect patients' rights; and (4) new legal instruments are needed to safeguard patients in the age of AI. The chapter reflects on the broader implications of AI in healthcare. It also discusses the dynamic regulatory landscape, noting recent developments in the EU's AI Act and the Council of Europe's AI Convention. While these regulatory efforts represent progress, the chapter concludes that they fall short of providing comprehensive protection for patients in an AI-driven healthcare system. The dissertation closes by emphasising the need for a multi-faceted approach to regulation, one that prioritises patient safety, equity, and human dignity amidst the ongoing algorithmisation of healthcare.

## SAMENVATTING

Dit proefschrift gaat over het waarborgen van de rechten van patiënten in de Europese Unie (EU) in het licht van de toenemende toepassing van kunstmatige intelligentie (AI)-technologieën in de gezondheidszorg. Dit wordt onderzocht binnen de context van de groeiende EU-integratie via de digitale interne markt. Het hoofddoel is om te evalueren of de huidige EU-wetgevingskaders voldoende bescherming bieden aan de rechten van patiënten tegen de gevolgen van de algoritmisering van de gezondheidszorg. Daarnaast worden in dit proefschrift alternatieve juridische benaderingen voorgesteld om een sterkere bescherming van patiënten te garanderen in deze snel evoluerende sector.

### **Hoofdstuk 1: Inleiding**

Het inleidende hoofdstuk schetst hoe AI de gezondheidszorg in de EU transformeert, met een specifieke focus op het proces van "algoritmisering". Dit proces verwijst naar de toenemende integratie van AI in gezondheidszorgsystemen voor diagnostiek, patiëntbehandeling en ziekenhuisadministratie. Aan de hand van een fictief maar realistisch scenario schetst het hoofdstuk een toekomst waarin AI een belangrijke rol speelt bij het stellen van diagnoses, het monitoren van gezondheidsgegevens via draagbare apparaten en het uitvoeren van chirurgische ingrepen. Deze technologische vooruitgang biedt zowel kansen als risico's. Het hoofdstuk plaatst deze ontwikkelingen in de bredere context van de groeiende digitale interne markt van de EU, waarin AI-technologieën steeds dominanter worden. Daarnaast worden de juridische en ethische uitdagingen belicht die voortkomen uit deze technologische verschuiving, met name met betrekking tot patiëntveiligheid, autonomie, privacy en de transparantie van AI-besluitvormingsprocessen.

Het hoofdstuk benadrukt de huidige lacunes in regelgeving en stelt kritische vragen over de mate waarin bestaande EU-wetgevingskaders patiënten kunnen beschermen tegen de risico's van AI-gedreven gezondheidszorg. De centrale onderzoeksvraag luidt: hoe kunnen de rechten van patiënten in de EU worden gewaarborgd nu AI een steeds grotere rol speelt in de gezondheidszorg? Het hoofdstuk sluit af met een overzicht van de structuur van het proefschrift, waarin deze kwestie in drie delen wordt onderzocht. Hierbij worden zowel theoretische als praktische perspectieven op de bescherming van patiëntenrechten behandeld.

## **Hoofdstuk 2: Patiëntenrechten in de mensenrechtelijke benadering van gezondheid**

Dit hoofdstuk introduceert de mensenrechtelijke benadering van gezondheid als de normatieve basis voor het proefschrift. Het stelt dat patiëntenrechten essentieel zijn om menselijke waardigheid, autonomie en rechtvaardigheid in de gezondheidszorg te waarborgen. Het hoofdstuk is gebaseerd op internationale mensenrechtenwetgeving en benadrukt de nauwe verwevenheid tussen gezondheid en mensenrechten. Drie belangrijke verbanden worden geïdentificeerd: (1) het recht op de hoogst haalbare gezondheidsstandaard is een fundamenteel mensenrecht; (2) mensenrechtenwetgeving kan directe invloed hebben op gezondheidsresultaten; en (3) gezondheidsgerelateerde wetten en beleid kunnen bredere mensenrechten beïnvloeden.

Daarnaast bespreekt het hoofdstuk hoe patiëntenrechten individuen kunnen versterken, het vertrouwen in zorgsystemen kunnen vergroten en kunnen bijdragen aan gezondheidsrechtvaardigheid door kwetsbare groepen te beschermen. De focus ligt op vijf categorieën van rechten: toegang tot gezondheidszorg, autonomie, informatie, privacy en het recht op een doeltreffende voorziening in rechte. Deze rechten worden geanalyseerd in de context van de relatie tussen patiënt en zorgverlener, waarbij de patiënt zich vaak in een kwetsbare positie bevindt. Door deze analyse biedt het hoofdstuk een kader voor het beoordelen van de impact van AI-technologieën op patiëntenrechten in de gezondheidszorg. Dit kader is tevens de theoretische basis voor de daaropvolgende hoofdstukken, in het bijzonder voor de beoordeling van de vraag of de bestaande wettelijke bescherming van patiënten toereikend is in een door AI gedreven gezondheidszorg.

## **Hoofdstuk 3: Een algemeen kader voor de bescherming van de rechten van Europese patiënten**

Voortbouwend op de mensenrechtenbenadering uit hoofdstuk 2 biedt dit hoofdstuk een concretere conceptualisering van patiëntenrechten binnen de Europese Unie. Het onderzoekt de gemeenschappelijke juridische grondslagen tussen EU-lidstaten en internationale verdragen die patiëntenrechten beschermen en identificeert een gezamenlijke kern van rechten die van toepassing zijn op de gezondheidszorg. Hoewel er geen universeel erkende lijst van "Europese patiëntenrechten" bestaat, worden deze rechten in dit hoofdstuk herleid uit diverse juridische bronnen, waaronder EU-wetgeving, verdragen van de Raad van Europa en internationale mensenrechtenverdragen.

Het hoofdstuk onderscheidt vijf hoofdcategorieën van patiëntenrechten: (1) het recht op toegang tot gezondheidszorg, (2) het recht op autonomie, (3) het recht op informatie, (4) het recht op privacy en vertrouwelijkheid, en (5) het recht op een doeltreffende voorziening in rechte. Binnen deze categorieën worden veertien specifieke rechten geïdentificeerd die in alle EU-lidstaten gedeeld worden, zoals het recht op geïnformeerde toestemming, toegang tot medische dossiers en bescherming tegen discriminatie. Dit hoofdstuk definieert de parameters voor het beoordelen van de invloed van AI op deze kernrechten. Daarnaast benadrukt het dat patiëntenrechten functioneren binnen een gelaagd rechtssysteem, waarin nationale wetten, EU-regelgeving en internationale verdragen elkaar aanvullen en beïnvloeden. Dit normatieve kader vormt de basis voor het gehele proefschrift en wordt toegepast om de impact van AI op de gezondheidszorg en patiëntenrechten te analyseren.

#### **Hoofdstuk 4: EU Regulering van AI: uitdagingen voor patiëntenrechten**

Hoofdstuk 4 onderzoekt hoe het toenemende gebruik van AI in de medische besluitvorming de bescherming van patiëntenrechten op de proef stelt. Het hoofdstuk belicht de kwetsbaarheid van patiënten die ontstaat door de inherente machtsongelijkheid tussen patiënten en zorgverleners en verder wordt versterkt door AI-gedreven gezondheidszorg. Hoewel AI voordelen kan bieden, zoals gepersonaliseerde behandelingen en efficiëntere diagnostiek, brengt het ook aanzienlijke risico's met zich mee op het gebied van autonomie, privacy en geïnformeerde toestemming. Het hoofdstuk richt zich op specifieke uitdagingen die AI met zich meebrengt, zoals het gebrek aan transparantie (vaak aangeduid als het "black box"-probleem), de mogelijkheid van algoritmische vooringenomenheid en de verwerking van grote hoeveelheden gevoelige medische gegevens, wat zorgen baart over privacywaarborging. Het hoofdstuk bekritiseert het bestaande EU-regelgevingskader, met name het voorstel voor de AI verordening van 2021, dat gericht is op de regulering van AI-systemen in diverse sectoren, inclusief de gezondheidszorg. Er wordt betoogd dat het kader ontoereikend is om de specifieke risico's van AI in de gezondheidszorg aan te pakken, met name omdat het geen rekening houdt met de unieke kwetsbaarheden van patiënten. Het hoofdstuk concludeert dat, door het gebrek aan specifieke bepalingen voor de gezondheidszorg, het risico bestaat dat de AI-wet lacunes creëert in de bescherming van patiëntenrechten in EU-lidstaten.

## **Hoofdstuk 5: Een gezondheidsconforme interpretatie van het recht om niet onderworpen te worden aan geautomatiseerde besluitvorming in de AVG**

Dit hoofdstuk bespreekt de Algemene Verordening Gegevensbescherming (AVG) en de implicaties ervan voor AI in de gezondheidszorg. De focus ligt op Artikel 22 van de AVG, dat individuen het recht verleent om niet onderworpen te worden aan beslissingen die uitsluitend gebaseerd zijn op geautomatiseerde verwerking. Het hoofdstuk onderzoekt of dit recht kan worden uitgebreid naar medische beslissingen waarbij AI betrokken is. In de gezondheidszorg is AI vaak afhankelijk van grote datasets van persoonlijke informatie, wat vragen oproept over gegevensbescherming, toestemming en controle.

Het hoofdstuk stelt dat patiënten het recht zouden moeten hebben om een medische behandeling op basis van AI-beslissingen te weigeren of om menselijke tussenkomst in dergelijke processen te verzoeken. Verder geeft het hoofdstuk kritiek op de praktische beperkingen van de GDPR. Hoewel de verordening een kader biedt voor de bescherming van persoonlijke gegevens, houdt het niet volledig rekening met de complexiteit van AI in medische besluitvorming. Het "black box"-probleem van veel AI-systemen maakt het bijvoorbeeld moeilijk voor patiënten om te begrijpen hoe beslissingen worden genomen, wat het principe van geïnformeerde toestemming ondermijnt. In het hoofdstuk wordt een "gezondheidsconforme" interpretatie van de GDPR voorgesteld, die suggereert dat bestaande rechtsinstrumenten moeten worden aangepast om patiënten beter te beschermen in de context van AI-gedreven gezondheidszorg.

## **Hoofdstuk 6: Digitale leeftijdsdiscriminatie en AI-medische hulpmiddelen: het verminderen van biases via het EU-regelgevingskader**

Hoofdstuk 6 richt zich op het probleem van discriminatie en vooroordelen in AI medische hulpmiddelen, in het bijzonder ten aanzien van oudere patiënten. Het introduceert het concept "digitale leeftijdsdiscriminatie", dat verwijst naar de manieren waarop AI-technologieën leeftijdsgerelateerde discriminatie in de gezondheidszorg kunnen versterken of verergeren. Aan de hand van de casestudy van medische AI-apparaten bekritiseert het hoofdstuk de Europese Verordening betreffende Medische Hulpmiddelen (MDR) en de AI-wet, omdat deze er niet in slagen de risico's van bestaande vooroordelen binnen AI-systemen adequaat aan te pakken. Het belicht hoe vooroordelen in AI-systemen geïntegreerd kunnen zijn in meerdere stadia, van gegevensverzameling tot algoritmeontwerp, en hoe deze vooroordelen oudere patiënten onevenredig kunnen treffen.

Het hoofdstuk introduceert de "AI-cyclus van gezondheidsongelijkheid," een kader dat uitlegt hoe vooroordelen in AI-systemen een zichzelf versterkende lus van discriminatie en gezondheidsongelijkheid kunnen creëren. Er wordt beargumenteerd dat de MDR en de AI-wet enige bescherming bieden tegen technische vooroordelen, maar niet ingaan op contextuele vooroordelen die voortkomen uit de manier waarop AI-systemen worden toegepast in de praktijk van de gezondheidszorg. Dit is met name problematisch voor oudere patiënten, die mogelijk worden uitgesloten van de trainingsdatasets die worden gebruikt om AI-systemen te ontwikkelen of te maken krijgen met belemmeringen bij de toegang tot AI-gedreven gezondheidszorg, vanwege een lager niveau van digitale geletterdheid.

## **Hoofdstuk 7: Het AI-Verdrag van de Raad van Europa: beloften en valkuilen voor bescherming van de gezondheid**

Hoofdstuk 7 analyseert het AI-Verdrag van de Raad van Europa en de mogelijke impact ervan op de bescherming van patiëntenrechten in de EU. Het Verdrag, dat AI-technologieën probeert te reguleren vanuit een mensenrechtenperspectief, is een belangrijke stap in de richting van het aanpakken van de ethische en juridische uitdagingen die AI in verschillende sectoren, zoals de gezondheidszorg, met zich meebrengt. In het hoofdstuk wordt echter kritiek geuit op het feit dat het verdrag sectorneutraal is, waardoor het mogelijk minder effectief is in het aanpakken van de specifieke risico's die de toepassing van AI in de gezondheidszorg met zich meebrengt. Het hoofdstuk belicht verschillende tekortkomingen van het verdrag, waaronder het niet-bindende karakter, de uitsluiting van AI-activiteiten in de private sector en het ontbreken van nieuwe mensenrechten die specifiek zijn afgestemd op het AI-tijdperk. Hoewel het verdrag een basis biedt voor het reguleren van AI, wordt betoogd dat het in zijn huidige vorm onvoldoende waarborg biedt voor de rechten van patiënten, met name die van kwetsbare groepen. Het hoofdstuk sluit af met een pleidooi voor sterkere, gezondheidszorgspecifieke regelgeving die rekening houdt met de unieke risico's van AI in medische toepassingen.

## **Hoofdstuk 8: Een mensenrechtenbenadering voor AI in de gezondheidszorg: voorstel voor een beoordelingsinstrument voor patiëntenrechten**

Dit hoofdstuk introduceert een praktische oplossing om de risico's die AI voor patiëntenrechten met zich meebrengt aan te pakken: het

beoordelingsinstrument voor patiëntenrechten. Dit instrument is bedoeld om zorgprofessionals richtlijnen te bieden voor het evalueren van de ethische en juridische implicaties van AI-technologieën, voordat ze worden ingezet in de patiëntenzorg. Het hoofdstuk stelt dat zorgverleners vaak geen duidelijke richtlijnen hebben over hoe ze de voordelen van AI moeten afwegen tegen de noodzaak om de autonomie, privacy en waardigheid van patiënten te beschermen.

De voorgestelde tool biedt een zelfbeoordelingsvragenlijst die zorgverleners kunnen gebruiken om de impact te evalueren van een specifiek AI-systeem op basis van patiëntenrechten. Het beoordelingsinstrument is voornamelijk relevant voor de ouderenzorg, waar de integratie van AI-technologieën vaak wordt gecombineerd met informele zorgverlening. Het benadrukt het belang om niet alleen de technische aspecten van AI te beoordelen, maar ook de sociale, ethische en juridische gevolgen van het gebruik ervan. Het hoofdstuk sluit af door te benadrukken dat het instrument weliswaar kan helpen om sommige risico's van AI in de gezondheidszorg te beperken, maar dat het moet worden ondersteund door robuuste wettelijke kaders en regelgevend toezicht op EU-niveau.

## **Hoofdstuk 9: Naar een EU-Handvest voor digitale patiëntenrechten in het AI-tijdperk**

In hoofdstuk 9 wordt voorgesteld een EU-Handvest voor Digitale Patiëntenrechten op te stellen: een uniform rechtsinstrument dat de rechten van patiënten zou consolideren en actualiseren om de nieuwe uitdagingen van AI in de gezondheidszorg te weerspiegelen. Het Handvest zou bestaande rechten, zoals het recht op geïnformeerde toestemming en privacy, codificeren en tegelijkertijd nieuwe rechten introduceren die zijn afgestemd op het digitale tijdperk.

Het hoofdstuk stelt dat het huidige juridische kader gefragmenteerd is, waarbij patiëntenrechten zijn verspreid over verschillende Europese en nationale wetten. Deze versnippering leidt tot onzekerheid over de reikwijdte en afdwingbaarheid van deze rechten, in het bijzonder in de context van AI-gedreven gezondheidszorg. Het voorgestelde Handvest heeft tot doel de patiëntenrechten in de EU-lidstaten te harmoniseren en te voorkomen dat de technologische vooruitgang in de gezondheidszorg gezondheidsongelijkheden niet vergroot en de bescherming van patiënten niet wordt ondermijnd. Daarnaast gaat het in op de behoefte aan nieuwe juridische instrumenten die kunnen meebewegen met snelle technologische veranderingen. Het hoofdstuk sluit af met een oproep aan de EU om een actievere rol te spelen bij

het reguleren van AI in de gezondheidszorg, niet alleen om individuele patiënten te beschermen, maar ook om ervoor te zorgen dat de voordelen van AI eerlijk over de samenleving worden verdeeld.

## **Hoofdstuk 10: Conclusie**

In het afsluitende hoofdstuk worden de belangrijkste bevindingen van het proefschrift samengevat, waarbij vier centrale conclusies naar voren komen: (1) het huidige portfolio van patiëntenrechten is onvoldoende aangepast aan de uitdagingen van AI in de gezondheidszorg; (2) het gebruik van AI in de gezondheidszorg treft kwetsbare bevolkingsgroepen onevenredig, waardoor gezondheidsongelijkheid toeneemt; (3) het rechtskader van de EU betreffende AI biedt onvoldoende bescherming voor patiëntenrechten; en (4) er zijn nieuwe rechtsinstrumenten nodig om patiënten te beschermen in het tijdperk van AI. Het hoofdstuk reflecteert op de bredere implicaties van AI in de gezondheidszorg en bespreekt het dynamische regelgevende landschap, waarbij recente ontwikkelingen in de EU AI Verordening en het AI-Verdrag van de Raad van Europa worden belicht. Hoewel deze inspanningen op het gebied van regelgeving een vooruitgang betekenen, concludeert het hoofdstuk dat ze tekortschieten in het bieden van uitgebreide bescherming voor patiënten in een AI-gedreven zorgsysteem. Het proefschrift sluit af met een nadruk op de noodzaak van een geïntegreerde benadering van regelgeving, die prioriteit geeft aan patiëntveiligheid, gelijkheid en menselijke waardigheid tegen de achtergrond van voortschrijdende algoritmisering van de gezondheidszorg.