Book of Abstracts
10th EAHL Conference
Uppsala 2026

Contents

Young Scholars Workshop and 10th EAHL Conference Programs

Wednesday, September 9, 2026

08:00–09:00	Registration
09:00–12:20	Young Scholars* Workshop: "Navigating Health Law in an Evolving Europe from an Early Career Stage" Co-leads: Cato Deprez (Leuven), Tamara Hervey (City, London), Wendy Kwaku Yeboah (Bologna) The program aims to enable the upcoming generation of scholars (primarily PhD students) to navigate the frontiers of their chosen discipline. Details of the program – co-produced by Cato Deprez and Wendy Kwaku Yeboah, early career scholars, and Tamara Hervey, who has been involved in the discipline for several decades – are here. The program is based on 'active learning', and on seeking to 'flatten' distinctions between people at different career stages. All participants are expected to come to the program prepared to participate. Details of advance preparation needed are here. * 'young scholars' refers only to career stage, not biological age
12:20–13:00	Lunch for the attendants of the Young Scholars Workshop
13:00–15:00	City Tour
16:00	Opening ceremony and opening lecture Moderator: Anna Singer, Professor of Family Law at Uppsala University, Sweden Welcome by Uppsala University and the Steering Committee of the EAHL 10th Conference EAHL President, Stefania Negri, Professor of International Law at the University of Salerno, "The 10th EAHL Confrence and 18 Years of the EAHL"

	Opening lecture: Elisabeth Rynning, LL.D., former Chief Parliamentary Ombudsman, Former Judge at the Supreme Administrative Court in Sweden, and former Professor of Medical Law
	"Human rights in biomedicine – revisiting the regulatory toolbox"
	Tom Goffin, Professor of Health Law at Ghent University, Belgium, "EJHL and EAHL"
17:30	Welcome reception by Brill

Thursday, September 10, 2026

08:00–08:30	Registration
08:30–10:00	Keynote lecture Moderator: Tamara Hervey, Jean Monnet Professor of EU Law at The City Law School of City St George's, University of London, UK Timo Minssen, Professor, LL.D., LL.Lic., LL.M., M.I.C.L., Dipl. Jur. Founder and Director, Centre for Advanced Studies in Bioscience Innovation Law (CeBIL), University of Copenhagen, Denmark "Governing the Cutting Edge: Controlling Risks and Enabling Benefits of Emerging Health Technologies" Young Scholar Intervention: Pramiti Parwani, Assistant Professor at Warwick Law School
10:00–10:30	Coffee
10:30–12:00	Parallel session 1 (oral presentations)
12:00–12.30	Lunch A lunch meeting for NCP held at Café Alma 12:00–13:00
12:30–13.00	Poster session and continued lunch
13:00–14:30	Parallel session 2 (oral presentations)
14:30–15:00	Coffee
15:00–16:30	Parallel session 3 (workshops, BRILL book presentation)
16:30–16:45	Group Photo, by Lasse Blom and Dainis Caune
16:45–17:45	General Assembly
19:00–21.30	Conference dinner, held at "Hambergs Festlokal", Nedre Slottsgatan 6, 753 09 Uppsala

Friday, September 11, 2026

8:15–9:15	Plenary Moderator: Carl Fredrik Bergström, Professor of EU Law at Uppsala University, Sweden Keynote lecture: Anniek de Ruijter, Professor of Health Law and Policy and Director of Law for Health and Life, Law Faculty of the University of Amsterdam, the Netherlands. "Renewal of solidarity: health systems and the EU in a changing world order"
9:30–11:00	Parallel session 4 (workshops, oral presentations)
11:00–11:30	Coffee and continued poster session
11:30–13:00	Parallel session 5 (workshops, oral presentations)
13:00–13:30	Lunch
13:30–14:00	Closing

Young Scholars Workshop Keynote

Empowering the Next Generation of Scholars

Tamara Hervey

Abstract

The early career European health law scholars workshop will consider how the upcoming generation of scholars (primarily PhD students) may be enabled to navigate the frontiers of their chosen discipline. The precise modalities of the program will be co-produced by early career scholars and Tamara Hervey, who has been involved in the discipline for several decades. It is likely to include presentations on the craft and art of academic writing; some 'active learning' or reflection; and an opportunity for students to present their work in progress and receive feedback on it, to help them navigate their own ways forward.

Biography

Tamara K Hervey (LLB (Hons) (Glasgow), PhD (Sheffield), Fellow of the Academy of Social Sciences, Principal Fellow of the Higher Education Academy, Honorary Fellow of the Faculty of Public Health) is Jean Monnet Professor of EU Law ad personam at the City Law School, City University, London. She holds visiting positions at the University of Amsterdam, University of Bologna and University of Vienna. Her called-name is Tammy, and her pronouns are she/her.

Tammy's research interests are in European Union health law, comparative health law, equality law, legal research methodologies and legal pedagogy. She is the author of 21 books and over 200 other publications. She is Editor for entries on EU health law in the OUP Online Encyclopaedia of EU law. Tammy works with a large network of academics across Europe and in North America, representing several disciplines. She also regularly co-produces work with third sector entities and with students.

Conference Opening Lecture

Human Rights in Biomedicine – Revisiting the Regulatory Toolbox

Elisabeth Rynning

Abstract

The interaction between ethics and law in the area of biomedicine, between soft law and hard law, at different levels of the diverse European regulatory landscape, is a complex phenomenon with a long history. As we constantly strive to find the best ways to govern this rapidly developing field, in order for biomedicine to benefit society and promote the realisation of fundamental human rights, we need to reflect on the various forms of governance and types of normative systems available to achieve this goal, as well as the roles of different actors involved, at various levels. This includes issues of legitimacy, mandate and competency, of context, impartiality and vested interests.

The aim of this opening lecture is to invite us all to revisit and reflect on the regulatory tools applied to govern biomedicine, interacting and complementing each other, each with their advantages, limitations and drawbacks. As lawyers, we may wish to remind ourselves of the fundamental principles underpinning our legal systems, while still acknowledging that legislation may not always be the answer.

Biography

LL.D., former Chief Parliamentary Ombudsman, Former Judge at the Supreme Administrative Court in Sweden, and former Professor of Medical Law.

Elisabeth Rynning holds an LL.D. in Public Law and was Professor of Medical Law at Uppsala University 2003–2012 (a chair jointly funded by the Faculty of Law and the Faculties of Medicine and Pharmacy). Her research has primarily focussed on issues related to the rights of patients and research subjects, especially privacy, autonomy and the use of new technology in health care and biomedical research. Between 2012 and 2016 she was a Justice of the Supreme Administrative Court, after which she held the position of Chief Parliamentary Ombudsman of Sweden, until the autumn of 2021. She was a Visiting Professor at the Law Faculty of Uppsala University 2022–2023 and, since 2022, chairs the board of the Swedish National Human Rights Institution, https://mrinstitutet.se/.

Conference Keynotes

Governing the Cutting Edge: Controlling Risks and Enabling Benefits of Emerging Health Technologies

Timo Minssen

Abstract

Breakthroughs in health technologies – from AI-driven surgery, diagnostics and precision medicine to neural interfaces, gene editing and synthetic biology – promise transformative gains for health systems and populations. Yet these advances also bring complex risks, such as patient safety, data harms, algorithmic bias, unequal access, regulatory gaps, and shifting lines of accountability. As innovation accelerates, legal and policy frameworks must evolve not only to mitigate harm but also to foster responsible innovation.

This keynote will examine how legal scholars and policymakers can build governance models that are both protective and enabling – responsive to technological change, grounded in rights-based principles, and capable of shaping innovation toward public good. Drawing on recent regulatory developments and interdisciplinary insights, the talk will explore tools such as anticipatory regulation, risk-tiering, regulatory sandboxes, and adaptive oversight. In doing so, it will chart a path forward for law's role in ensuring that emerging health technologies serve society – not the other way around.

Biography

Professor, LL.D., LL.Lic., LL.M., M.I.C.L., Dipl. Jur., Founder and Director, Centre for Advanced Studies in Bioscience Innovation Law (CeBIL), UNESCO Co-Chair in the Right to Science, University of Copenhagen, Denmark

Timo Minssen is Professor of Law, specializing in Health & Life Science Innovation, at the University of Copenhagen (UCPH). He is the Founding Director of UCPH's Center for Advanced Studies in Bioscience Innovation Law (CeBIL). He is also an Inter-CeBIL/PFC affiliate at Harvard Law School, an Associate Member of the Centre of Genomics and Policy at McGill University, and an LML Research Affiliate at the University of Cambridge. His research, supervision, teaching and part-time advisory practice concentrates on Intellectual Property, Competition and Regulatory Law with a special focus on

new technologies, big data and artificial intelligence in the health & life sciences. Timo holds a German law degree from the University of Göttingen, as well as biotech and IP -related LL.M. M.I.C.L., LL.Lic. and LL.D. degrees from Lund and Uppsala University. Moreover, he had been trained in the German Court system, the European Patent Office, law firms & life science start-ups. Timo serves as a member of international committees and as an advisor and facilitator to the OECD, WHO, WIPO, the EU Commission, companies, national governments, and law firms.

Renewal of Solidarity: Health Systems and the EU in a Changing World Order

Anniek de Ruijter

Europe's health systems are under growing strain. Ageing populations, rising healthcare costs, persistent health inequalities, and critical shortages in medicines and personnel are testing the solidaristic foundations of care. Mechanisms like risk-pooling and resource redistribution – once central to post-war social cohesion – are becoming harder to sustain.

At the same time, the geopolitical landscape is shifting. With the development of a European Defence Union and increasing pressure on the EU to assert strategic autonomy, questions arise about the scope and responsibility of European solidarity, also in the realm of health. Should the EU act when a financial crisis shuts down hospitals in one of its Member States? When over 60% of hospital pharmacies report medicine shortages?

While EU law has often been criticized for undermining national health systems, today's complex crises offer a moment to rethink its role. As seen during the COVID-19 pandemic, coordinated EU action – through joint procurement, capacity building, and knowledge sharing – can reinforce health solidarity rather than erode it. In a changing world order, solidarity in health may be as vital to the EU's resilience as defence and energy security.

Biography

Anniek de Ruijter is Professor of Health Law and Policy at the Law Faculty of the University of Amsterdam and Director of Law for Health and Life. Her interdisciplinary research explores how legal frameworks can enhance and protect human health, while also critically examining the legal limits of public and medical authorities in addressing human vulnerability and the aspiration for a healthy life.

De Ruijter's work focuses on the constitutional safeguards for health-specific rights and values, particularly within the context of European Union and global regulatory interactions. She has led various international and interdisciplinary research projects and leads the recently created ELSA Lab AI for Health Equity.

De Ruijter has studied and held visiting positions at Harvard Law School, Columbia University, and the Sorbonne. She serves on the editorial boards of the European Journal of Risk Regulation and The Lancet Regional Health – Europe, and is chair of the Academic Council of the Amsterdam Institute for Global Health and Development.

Oral Presentations

O1: A Comparative Survey of American Health Law: Enforcement, Compensation Structures, and Emerging Compliance Risks

Joseph Wolfe
Hall, Render, Killian, Heath & Lyman, PC, Indianapolis, IN, USA

Abstract

This session would present an analytical overview of the current landscape of American health law, informed directly by my experience representing hospitals, health systems, and physician groups across the United States. The presentation would include findings from a survey of key U.S. health law topics – Stark Law, the Anti-Kickback Statute, fraud and abuse enforcement trends, fair market value and commercial reasonableness developments, and compliance considerations related to value-based care.

The session would also highlight structural differences between the U.S. and European legal frameworks, offering a comparative perspective valuable to policymakers, academics, and practitioners engaged in cross-border discourse. The goal is to provide EAHL participants with practical insights into how American regulatory mechanics shape clinical integration, physician alignment, and system-level compliance strategies – and how these lessons may translate within European contexts.

O2: A Human Right to Genetic Disclosure? Rethinking Confidentiality in the Genomic Era

Róise Connolly
The Open University, Milton Keynes, UK

Abstract

The development of genetic medicine raises novel questions about ensuring access to potentially actionable genetic information. Genetic testing can provide a gateway to earlier, more effective, and in some cases, preventative treatments for Europe's leading causes of premature morbidity and mortality. Indeed, some preventative and early treatment options depend on access to genetic testing, and the information retrieved may be relevant for providing healthcare to genetic relatives. However, the infrastructure for alerting at-risk genetic relatives lags behind the rapidly advancing technology and the default position for healthcare professionals in most European countries is to respect the confidentiality of the proband or index patient. Considering the legal and moral dilemmas faced by healthcare professionals, this article sets out a human rights basis under Article 8 of the European Convention on Human Rights for disclosure-as-default forming part of informed consent processes before genetic testing. The aims of which are to improve access to diagnosis, to allow meaningful treatment choices, and to respect the personal autonomy of patients. This article argues that there is a legal duty to make this information available to at-risk relatives due to the foreseeable health consequences, including access to curative and preventive treatment. Various issues are raised here related to personal autonomy and effective access to diagnostic technology, challenging traditional approaches to confidentiality, disclosure, and informed consent.

O3: A Plea for a European Digital Patients' Rights Charter

Hannah Van Kolfschooten
Centre for Life Sciences Law, University of Basel, Basel, Switzerland

Abstract

Artificial intelligence and other digital health technologies are rapidly transforming healthcare systems across Europe. While these innovations promise improvements in diagnostics, treatment, and efficiency, they also generate new risks for patients' health and fundamental rights. At the same time, the European Union plays an increasingly central role in regulating AI, medical devices, and health data, yet without providing a consolidated framework for patients' rights in this evolving digital landscape.

This contribution examines whether the algorithmisation of healthcare requires the recognition of a coherent canon of patients' rights at the EU level. It argues that the current patchwork of national laws, sector-specific EU legislation, and general human rights instruments leaves significant gaps in protection, particularly in light of AI-related risks such as technical and contextual bias, opacity, automation, and accountability deficits.

A blueprint for an EU Charter of Digital Patients' Rights is outlined. Traditional rights, such as the right to privacy, informed consent, access to healthcare, and effective remedy, are reconsidered in light of AI-driven decision-making. In addition, the blueprint proposes the recognition of novel rights tailored to the digital context, including a right not to be subject to fully automated medical decision-making, a right to meaningful human contact, a right to mental privacy, a right to digital health literacy, and a right to equitable access to new healthcare technologies. By consolidating and modernising patients' rights at EU level, such a Charter could enhance legal clarity, promote more uniform protection across Member States, and strengthen trust in digital healthcare.

O4: Access to Healthcare in the Big Tech Era

Katharina O'Cathaoir
Danish Institute for Human Rights, Copenhagen, Denmark

Abstract

In the age of AI driven healthcare, public healthcare providers face a dilemma: should they respect citizens' rights to data protection, or share patients' health data with Big Tech in exchange for new healthcare services? Big tech is increasingly penetrating all aspects of society, including healthcare. With the growing necessity of cloud storage in healthcare, big tech has infiltrated public infrastructure and become a central partner for public healthcare authorities. AI is aggressively expanding big tech's embeddedness in public healthcare, through terms and conditions that assume permission to reuse data for commercial purposes. The ability of citizens to obtain healthcare or health advice without sharing data with tech companies is thereby dwindling.

Storing health data in cloud computing or using a large language model (LLM) often includes sharing data with a wide range of third parties. This data can be reused for training of the product or other commercial purposes separate from the initial treatment. Even where data is not used for retraining purposes, it can often by accessed in third countries by staff carrying out support functions. Through these practices, patients are subsumed into "surveillance capitalism" when accessing healthcare services.

European data protection authorities have repeatedly held that such practices are contrary to the General Data Protection Regulation. Data controllers have obligations to provide information on data recipients, need a valid legal basis to share data with new data controllers and must carry out a data protection impact assessment before undertaking high risk processing. There are numerous examples of these obligations not being met.

This legal question gives rises to ethical dilemmas in healthcare where citizens are dependent on a public good. Is it legitimate for public health authorities to refuse to engage with Big Tech even where citizens' access to healthcare will be undermined? This presentation will approach this question through the lens of autonomy, arguing that autonomy is substantially undermined in the current big data healthcare context and regulatory context, and thereby inadequate.

O5: AI-Driven Health Care: the Role of EU Conformity Assessment in Safeguarding the Right to Health

Sarah de Heer
Faculty of Law, Lund University, Lund, Sweden

Abstract

My doctoral research examines the extent to which the conformity assessment procedure under the Medical Devices Regulation and the Artificial Intelligence Act ensures the quality under the right to health of AI-driven medical devices in precision medicine. The right to health consists of four interrelated pillars, namely (1) availability, (2) accessibility, (3) acceptability, and (4) quality. While my doctoral project primarily focuses on the pillar of quality, these dimensions cannot be considered in isolation.

Developments in AI and precision medicine may generate both positive and negative effects across all four pillars of the right to health. On the one hand, AI and precision medicine hold considerable potential to strengthen the right to health. AI may enhance the availability and accessibility of healthcare services, while precision medicine can support the development of more tailored medical devices, including for underrepresented populations. On the other hand, both AI and precision medicine may also introduce risks to the right to health. In particular, AI that is characterised by inaccuracy and opacity may negatively affect the pillar 'quality' as healthcare intervention may be unreliable or unsafe. Similar concerns arise in precision medicine, where medical devices are developed on the basis of incomplete or unrepresentative data.

Against this backdrop, my doctoral research examines whether the Medical Devices Regulation and the Artificial Intelligence Act are equipped to ensure that AI-driven medical devices used in precision medicine meet the quality requirements under the right to health.

O6: Are One Health Norms That Disruptive?

Éloïse Gennet
Faculty of Law and Political Science, Aix Marseille Univ, CNRS, DICE, CERIC, Aix-en-Provence, France

Abstract

The Covid-19 pandemic exposed the fragility of siloed approaches to human, animal and environmental health, reigniting interest in the One Health approach. This integrative framework, defined by the UN One Health High Level Expert Panel (OHHLEP) as a holistic approach to optimizing the health of humans, animals and ecosystems, has emerged as a promising response to future global health threats.

Yet, its normative potential remains largely untapped. While One Health is increasingly referenced in international, regional, and national legal instruments, such as the 2025 WHO Pandemic Agreement and the EU's 2022 regulation on cross-border health threats, its legal and ethical implications are still vague, risking its reduction to a rhetorical device rather than a transformative paradigm.

This presentation argues that One Health can only fulfil its promise if it disrupts traditional legal and governance frameworks, and identifies five core disruptive elements that must be addressed to operationalize One Health as a promising normative approach:

(1) Breaking silos: One Health demands the dissolution of disciplinary and sectoral barriers, fostering collaboration across scientific fields (e.g. medicine, environmental science) and legal domains (health, environmental and animal welfare law). Legal systems must evolve to support this interdisciplinary integration.

(2) Challenging anthropocentrism: One Health compels a radical rethinking of legal frameworks by questioning the moral and legal status of non-human entities. Could ecosystems, animals, or microbes be granted rights or legal personality? This shift challenges the human-centric foundations of law.

(3) Deep prevention over crisis management: Current legal frameworks prioritize reactive responses to health crises. One Health advocates for addressing root causes – such as biodiversity loss or climate change – to

prevent spillover events before they occur, requiring a systemic shift in public health law.

(4) Navigating overlapping legal systems: Effective One Health governance requires reconciling global coordination with local adaptation. Legal frameworks must bridge international, regional, and national systems, ensuring coherence while respecting local contexts and subsidiarity.

(5) Reconfiguring democratic governance: One Health necessitates inclusive, multi-stakeholder decision-making, integrating civil society, Indigenous communities, and marginalized groups. This participatory approach disrupts traditional governance models and demands new mechanisms for accountability and representation.

Without addressing these challenges, One Health risks remaining a hollow political priority. The presentation will invite legal scholars and practitioners to consider whether and how these disruptions are or can be implemented to create enforceable norms effectively able to prevent future global health threats.

O7: Balancing Public Interest and Privacy: Transparency of Quality-Related Measures Imposed on Healthcare Professionals

Cato Deprez
Leuven Centre for Public Law, KU Leuven, Leuven, Belgium

Introduction

Transparency about healthcare quality is increasingly viewed as an essential component of modern health systems. As patients take a more active role in treatment decisions, access to reliable information about quality and safety strengthens trust in healthcare professionals. Openness about disciplinary or administrative measures may also promote broader public interests, such as safeguarding patient safety and stimulating continuous quality improvement. At the same time, these disclosures often involve sensitive personal data and may affect the privacy and professional reputation of healthcare providers. This raises a central legal question: To what extent may patients and the public access information about disciplinary sanctions or quality-related interventions imposed on healthcare professionals, and how should transparency be balanced against the rights of those professionals?

Methodology

This study uses doctrinal legal analysis and a comparative examination of Belgian and Dutch legal frameworks. The sources include legislation, parliamentary materials, inspection policies, case law, and relevant soft-law instruments.

Results

Preliminary findings reveal a clear divergence between the Dutch and Belgian approaches to transparency in the governance of healthcare quality. Both systems seek to balance privacy with patient safety, but they do so in markedly different ways. The Netherlands has adopted a broad transparency model. Under

Article 48 of the Individual Healthcare Professions Act (Wet BIG), certain disciplinary and administrative measures are published in a publicly accessible register. Although the register does not include every sanction, it reflects a legislative preference for openness and allows the public to access information relevant to a professional's ability to practise safely.

Belgium, by contrast, does not provide public access to disciplinary or administrative measures affecting healthcare professionals. Instead, Belgian law emphasises transparency for the benefit of individual patients, most notably through the statutory right to free choice of healthcare provider under Article 6 of the Patients' Rights Act. However, this patient-focused transparency does not extend to the general public, leaving such information largely inaccessible beyond the individual care relationship.

Conclusion

The comparison highlights two distinct balancing acts between transparency and privacy. The Dutch model prioritises public disclosure to enhance quality and safety, while the Belgian approach places greater weight on protecting professional privacy. These differences prompt an important policy debate: How should lawmakers balance public interest in healthcare quality with the fundamental rights of healthcare professionals?

O8: Beyond Protection? The European Court of Human Rights and the Future of Mental Health Law in an Evolving Europe

Katarzyna Widlas-Klimsiak
Poznan Human Rights Center, Institute of Law Studies of the Polish Academy of Sciences, Poznan, Poland

Abstract

Mental health law has become one of the most contested frontiers of European health law. As European states confront rising mental health needs, service pressures, and persistent institutional legacies, legal frameworks are increasingly expected to move beyond paternalistic and hospital-centred models of care toward approaches grounded in autonomy, dignity, equality, and community inclusion. This paper asks whether the European Court of Human Rights (ECtHR) has meaningfully contributed to that transformation, or whether it has instead mainly refined a traditional framework of psychiatric control through stronger procedural safeguards.

The paper argues that Strasbourg jurisprudence reveals a mixed trajectory. On the one hand, the Court has strengthened protection under Articles 3, 5, and 8 European Convention of Human Rights (ECHR) by tightening standards for psychiatric detention, extending review to informal and social-care placements, and recognising therapeutic neglect and bodily integrity as human rights concerns. On the other hand, non-consensual treatment is still often approached as an incident of lawful detention, with continuing deference to medical expertise and risk-based reasoning. As a result, autonomy, equal legal capacity, and non-discrimination remain weaker constraints in the Court's doctrine than in the more ambitious standards emerging from the Convention on the Rights of Persons with Disabilities (CRPD).

Methodologically, the paper adopts a doctrinal approach, combining analysis of key ECtHR judgments with the broader normative framework of the Council of Europe, including relevant soft-law developments, read in light of the CRPD. It argues that the significance of the Court's case law extends beyond human rights adjudication narrowly understood: it helps define the legal boundaries of coercion, consent, and patient status within European mental healthcare.

By placing ECtHR jurisprudence in dialogue with the CRPD and wider developments in European mental health governance, the paper shows that the future of mental health law in Europe depends not only on procedural review of coercive measures, but on a deeper legal shift from protection to empowerment, from institutional management to rights-based care, and from formal safeguards to genuine respect for will, preferences, and community-based support.

O9: Biobanks as Trusted Data Holders for the Secondary Use of Health Data Within the Rare Diseases Biomedical Research

Laura Centeno Casado
Applied Ethics Research Group, Institute of Philosophy, Spanish National Research Council (CSIC), Madrid, Spain
Innovation, Law and Technology Research Group, Faculty of Law, University of Murcia, Murcia, Spain

Abstract

Within the framework of the European Health Data Space (EHDS) Regulation, biobanks are positioned as pivotal research infrastructures bridging clinical care and advanced biomedical research. In the context of rare diseases, where data scarcity poses a persistent challenge, biobanks occupy a unique role: they can foster innovation and enhance research capacity through their potential designation as trusted data holders.

Under Regulation (EU) 2025/327, biobank databases are classified within the minimum categories of electronic health data eligible for secondary use (Article 51). This legal recognition effectively transforms biobanks into potential Health Data Holders mandated to make their data available for secondary use, enabling scientific research, innovation, and public health surveillance.

A major development in this legal framework is the creation of the Trusted Health Data Holder (THDH) status under Article 72, which Member States may grant to specific biobanks to streamline data access while maintaining high standards of data protection, security, and ethical oversight. The THDH designation allows biobanks to operate under simplified permit procedures, participate in assessments, provide expert recommendations to national Health Data Access Bodies (HDABs), and exercise enhanced control over their data assets.

This article examines the evolving role of biobanks as trusted intermediaries within the EHDS architecture. It analyses their data governance structures, including cross-country comparisons of relevant frameworks, and the procedures adopted to safeguard patient and donor information. It also evaluates how the concept of the trusted data holder is operationalised under the EHDS, the conditions biobanks must fulfil to obtain the designation, and how national application procedures can ensure consistency with EU-level principles.

Addressing transparency and fragmentation represents another key challenge for biobanks, particularly in the field of rare diseases where local datasets often lack statistical power. The EHDS infrastructure, HealthData@EU, enables the federation of fragmented datasets across Member States, facilitating genotype–phenotype studies central to ending the "diagnostic odyssey" many patients experience. By contributing to cross-border data integration, biobanks can help construct a more coherent and equitable research ecosystem.

The article argues that effective implementation of the EHDS requires a paradigm shift, moving biobanks from passive sample repositories to active data stewards. Through obtaining Trusted Health Data Holder status, biobanks can become foundational pillars of a transparent, secure, and ethically robust environment that maximises the societal and scientific value of health data, particularly in the rare disease domain.

O10: Biotechnology as a Catalyst for a Coherent and Embedded EU Regulation of Bio-Based Products: the Commission's Proposal for an EU Biotech Act

Aurélie Mahalatchimy
UMR 7318 International, Comparative and European laws (DICE) CERIC, CNRS, Aix-Marseille University; Aix-en-Provence, France

Abstract

In March 2024, the European Commission adopted a Communication entitled "Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU", thereby returning biotechnology to the forefront of key policy priorities since its previous Life Sciences strategy dating back to 2002. It paves the way for a possible 'EU Biotech Act', the regulation's proposal for which was adopted in December 2025 with a view to simplifying the regulatory framework and speeding up access to the EU market for biotechnology products.

In that context, we argue that biotechnology appears as a catalyst for a coherent and embedded EU regulation of bio-based products in the health sector.

On the one hand, the proposal for an EU Biotech Act establishes a new material defragmentation (processes by which the substantive or material scope of Union law has the effect of reducing or removing national discretion) of the field. First, it applies to health biotechnology understood widely regarding their types ("any good, technology or activity resulting from the application of biotechnology"), stages of development ("their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities"), and public health objectives (relevance "to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives"). Second, it creates new distributions of rules depending not anymore on products-types or stages of development but on transversal topics based on a refocusing on issues that have been considered the most pressing (Strategic projects, High impact Strategic projects, Accelerators, Centres of Excellence).

On the other hand, the proposal for an EU Biotech Act clarifies and embeds the new material defragmentation it proposes as regards other EU

legislations and policies. Several current legislations (Regulations on clinical trials, advanced therapy medicinal products, substances of human origin, food law, veterinary medicinal products, and strategic Technologies for Europe Platform) are amended while the links with others are considered (Regulations on artificial intelligence, medical devices, medicinal products, chemicals, animals used or scientific purposes). New EU governance bodies should also be created with the aim to ensure efficient coordination and implementation behind common goals.

Overall, the proposal for an EU Biotech Act reflects considerable efforts to strengthen law and policy coordination regarding EU regulation of bio-based products in the health sector, and could have implications beyond this field.

O11: Bridging Regional Human Rights Systems: Inter-American snd European Cooperation of Embryonic Biomedical Research

Gaston Blasi
School of Law, Duke University, Durham, NC, USA

Abstract

Embryonic biomedical research (EBR), which encompasses scientific research on viable surplus embryos and therapeutic heritable genome editing, faces a normatively contested legal landscape in Latin America. The few existing regulatory frameworks are disparate, inadequate and mostly shaped by an embryocentric approach that prioritizes the protection of prenatal life in detriment of scientific progress, healthcare and reproductive autonomy. This combination of legal gap and regulatory fragmentation generates legal uncertainty, leaving governments and scientists without clear guidance.

To overcome this legal deficit, the study argues the necessity of structuring regional cooperation based in human rights law. It evaluates whether the Inter-American and European human rights systems share normative standards capable of informing and converging approaches to EBR governance. The analysis – through an interdisciplinary and comparative methodology – places the jurisprudence of both regional tribunals in dialogue.

In this context, the examination reveals that both systems exhibit functional commitment to proportionality and the balancing of competing rights and interests. In the Inter-American context, the jurisprudence of the Inter-American Court – especially the ruling in *Artavia Murillo v. Costa Rica* – offers the foundation for weighing the rights to health, reproductive autonomy, and access to scientific progress against the protection of prenatal life. Similarly, in Europe, despite there is greater deference to state discretion, the case law together with the Oviedo Convention reflects a comparable engagement with bioethical issues through a proportionality-based approach.

By situating EBR within the *frontiers of health law*, the study contends that these functional similarities provide solid ground for cross-regional normative dialogue. Ultimately, such inter-systemic cooperation can contribute to the development of minimum standards for EBR governance, capable of accommodating competing rights and interests in an evolving global context.

O12: Conceptualising Health Data as a Socio-Technical and Institutional Practice

Anamika Kundu
European University Institute, Fiesole, Italy

Introduction

Health data is often portrayed as a neutral, abundant resource ready for sharing under frameworks such as the European Health Data Space (EHDS) Regulation. This paper challenges that assumption by conceptualising health data as a socio-technical and institutional practice. Drawing on Science and Technology Studies (STS) and Critical Data Studies (CDS), it argues that health data is socially and politically constructed through processes of generation, collection, standardisation, and access, all of which are shaped by law and governance.

Methods

The paper adopts an interdisciplinary framework combining STS, CDS, and socio-legal approaches. It analyses the lifecycle of health data, i.e., generation, collection, access, and (re)use, while incorporating a multidimensional understanding of power. Regulatory power (defining legal categories and permissible uses) and infrastructural power (embedded in technical systems and standards) are used to examine how governance operates and how inequalities are reproduced.

Results

The analysis shows that health data is neither neutral nor evenly distributed. Data generation reflects structural inequalities, including "data poverty," where underrepresented populations are excluded from datasets. Data collection practices, including Real-World Data and platform-based data capture, introduce commercial and ethical tensions. Access to data is shaped by legal, technical, and institutional constraints, meaning that increased access does not automatically produce knowledge or better outcomes. While the EHDS

presumes the availability of interoperable data for secondary use, it overlooks the conditions under which data is produced, standardised, and made meaningful.

Discussion

These findings reveal that health data governance is fundamentally shaped by power relations between actors such as patients, regulators, researchers, and industry. Expanding access without addressing these asymmetries risks reinforcing existing inequalities. Big data practices further complicate governance through issues of data quality, shifts in the context of secondary use, and the significance. Still, often invisible, labour is required to prepare and interpret data.

Conclusion

The paper advances equity and solidarity as key normative principles for health data governance. Equity requires attention to how data burdens, benefits, and value are distributed, rather than merely ensuring access. Solidarity emphasises collective responsibility and the need for inclusive data practices and fair benefit-sharing. Moving beyond narratives of neutrality and innovation, the paper calls for governance frameworks that critically engage with power, address structural inequalities, and promote the public interest in a socially just manner. With the EHDS Regulation being operationalised across the EU, it is more important than ever to analyse the collective models of health data governance.

O13: Connected Objects Usage in Health Care: Current Debates and Future Outlook

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Abstract

Connected objects are increasingly used in the healthcare sector. Heralded as a solution to resource distribution issues and the need to streamline and increase efficiency of care. In a broad sense, connected objects refer to both AI medical devices, and a vast array of wearables, IoT, and wellness tools and applications. These are currently rapid vehicles of AI integration into the healthcare sector.

However, these new developments come with a risk, namely the use of connected objects in an erratic and a spontaneous and inconsistent manner. Meanwhile, the regulatory framework encompassing these technologies is highly complex, continuously evolving and in some sense failing to completely capture the full range of practical opportunities and challenges faced by patients, healthcare professionals and healthcare institutional actors.

Connected objects play a significant role in the provision of healthcare. They not only influence patient interaction and experience but also affect their health outcomes. However, research on medical devices is an area in health law that is traditionally less discussed by health and medical law scholars.

Drawing from the project AICARE recent and ongoing publications, we will explore current and future debates, through the lenses of a forward-looking approach and a legal systematic perspective on connected objects usage in healthcare. During this presentation, we will discuss EU policy directions, ethical considerations, legal framework hurdles, user perceptions and experiences, legal framework hurdles and roadmaps for governance and compliance with the growingly complex intersecting regulatory framework (e.g. MDR, AI Act, GDPR, EHDS, and national law instruments).

O14: Contagion v. 2.0: AI Joins the Fight … Unless the Law Says Otherwise

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Abstract

As the world recovers from the COVID-19 pandemic, it is necessary to remember that the next pandemic is inevitable, and we need smarter tools to identify health threats. Artificial intelligence (AI) is already reshaping how countries track and respond to disease outbreaks. AI disease surveillance systems can combine various sources of information, such as clusters of unusual health counselling contacts and official population registers, to detect early signs of epidemics. They help predict where and when outbreaks occur and tailor responses to the needs of specific communities. As the experience of the COVID-19 pandemic reminds us, responses to identified health threats can be highly invasive, limiting our privacy and freedom of movement.

Developing AI tools to protect public health requires understanding the legal requirements for their use. Under the newly adopted EU AI Act, AI systems are classified into prohibited, high-risk, and non-high-risk categories, with multiple advanced obligations created for high-risk AI. It is important to ask whether AI systems for epidemiological surveillance should be treated as high-risk AI under the EU's AI Act, given their profound influence on public health and human rights, and, accordingly, be held to the highest standards of legal protection with multiple requirements imposed on them.

In our presentation, we introduce a research project, *Explainable and Just AI in Data-Driven Disease Surveillance*. We examine and problematise the ways in which current EU regulation addresses AI for infectious disease surveillance, focusing on the exclusion from the material scope of the AI Act, and highlight the need for clearer regulation.

O15: Different Sources of Persuasive Clinical Medical Standards and Their Impact on Private Law Liability in Comparative Perspective

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Abstract

There is no universal and precise definition of medical standards. However, it is commonly accepted that they are 'signposts' rooted in Evidence-Based Medicine (EBM) that guide medical practitioners in the process of treatment and help them to set realistic goals for a particular patient in a particular condition. According to the criterion of legal significance, they can be divided into *ex-lege* binding standards, the force of which results from a legal provision, and *ex-auctoritate* binding standards, the force of which results from the high esteem of a scientific institution or medical society that created them rather than from law (which should be called persuasive clinical medical standards). In a comparative perspective, there exist centralised and decentralised systems of creation of persuasive clinical medical standards, and they are adopted by different bodies and institutions. Some of them are public institutions, as they have been established by the government or other public entities (e.g. Ministry of Health). The purpose of their establishment is in many situations, *i.a.*, the creation of medical standards. However, in such a situation, even if some of those institutions are established by a legal statute, their recommendations or guidelines do not officially have the binding force in the legal system. Nevertheless, most of the *ex-auctoritate* binding standards are created by strictly private medical organisations or associations. In the decentralised systems of creating medical standards most of those private medical organisations or associations have only limited connections with the state authorities or are not under their strict supervision. Moreover, in most of the European countries those persuasive clinical medical standards exist under many different names and in many different forms, *i.a.*, guidelines (DE: *Leitlinien,* PL: *wytyczne*), recommendations (DE: *Empfehlungen,* PL: *rekomendacje*) or statements (DE: *Stellungnahmen,* PL: *stanowiska*). Regardless of the name, it is commonly accepted that failure to comply with them may determine the existence

of liability in tort law (even though they cannot be formally classified as part of a legal system). They have an impact in court practice on establishing different duties of care of medical professionals. The aim of the paper is to present and categorise different sources of those *ex-auctoritate* binding medical standards in a comparative perspective (based on Austrian, Belgian, English, French, German, Polish and Swiss law) and present their impact on private law liability.

O16: Digital Life and Future Generations: Ethical Dilemmas and Participatory Pathways

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Abstract

The digital environment now constitutes an important part of younger people's lives. The opportunities permitted by new technologies are often tied to a growing expectation – even from a very young age – for constant connectivity, driven by families, schools, peers, and society at large. Coupled with the relentless demands for academic excellence and adaptation to the professional world, digital tools have become nearly impossible to avoid. Consequently, in France, over 80% of 11- to 17-year-olds use at least one major online platform daily, and 44% access social media before the age of 13 (ARCOM, 2025). Online activities raise concerns about children's social, mental, emotional, and physical well-being. The collection and use of personal data – including health data – through social media, connected devices, tracking apps, online games, educational apps, and AI raise issues of privacy, security, transparency, and respect for children's rights. The increasing use of AI-powered chatbots and companions, as well as AI-generated deepfakes intensify existing risks and create new ones. Furthermore, platforms are deliberately designed to maximize time spent and data sharing, yet they provide users with little meaningful opportunity for users to understand those processes or exercise their rights. In this context, there is widespread consensus among policymakers, regulators, civil society, researchers, and educators that existing online protections, safety measures, and respect for children's rights are often insufficient or inadequate. A need to involve children into discussions and decisions is also highlighted. To listen the voice of future generation about their online practices, needs, expectations, and the development of age-appropriate safeguards, workshops including children and young people (10–25 years old) have been set up with a participatory methodology based on children' rights and the ethical and responsibility principles. These workshops are organized in collaboration

with the CNIL (French Data Protection Authority), as part of the 2026 "États généraux de la bioéthique", an initiative led by the French Consultative Ethics Committee for Life and Health Sciences (CCNE) to encourage collective reflection, debate, and public consultation on the ethical implications of scientific, medical, and societal progress. This presentation will showcase key insights from these workshops, revealing participants' strong interest in contributing to the conversation, especially from an ethical standpoint. They also highlighted the rapid pace at which new digital technologies have reshaped our lives and identified both the opportunities and risks these technologies present. The first findings emphasize the critical role of proper education and the need for transparency in setting up algorithms and handling personal data.

O17: EHDS in Practice: the Legal Aspects of Lifecycle of Health Data in the Age of Technological Advancement

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Abstract

The European Health Data Space (EHDS) represents a cornerstone of the European Union's digital and health regulatory framework, closely linked to rapid technological advancement (big data, artificial intelligence, digital health solutions). It seeks to establish a data-driven ecosystem in which the use of health data is reconciled with high standards of data protection and trust (Gellérné, 2025a).

The presentation adopts a lifecycle-based approach to the EHDS, tracing the trajectory of health data from its generation to its secondary use. At the level of primary data sources, particular attention is paid to recruitment, the establishment of cohorts, consent structures, and the management of data collection methods. A central issue concerns the interaction between the legal bases under the GDPR, especially consent and public interest in scientific research, and the partly mandatory data flows introduced by the EHDS, which facilitate broader data reuse in response to technological developments.

The dimension of secondary data use constitutes one of the most innovative elements of the EHDS, introducing new institutional and technical mechanisms for accessing data. Interoperable systems and structured access procedures enable researchers, innovators, and public bodies to access health data for defined purposes, while ensuring that access remains conditional and limited. Member States retain broad discretion in assessing access requests, particularly to safeguard public interest, security, and intellectual property.

A further analytical layer concerns the private law infrastructure underpinning the data economy. The functioning of the EHDS relies on data licence agreements, data sharing arrangements, and data use contracts, which structure data flows in practice. These instruments define access modalities, purpose limitation, and issues of liability and warranties. Models inspired by the ALI–ELI Principles provide a relevant framework for governing contractual relations in the data economy.

The presentation develops the concept of a "data map", situating data as a legal object at the intersection of data protection law, contract law, intellectual property law, and trade secrets. The paper argues that the EHDS is not merely a new regulatory layer but a complex legal ecosystem shaped by technological advancement, redefining the legal nature of data in both EU and national law. The presentation investigates how this emerging data-centric approach increasingly affects fundamental principles of healthcare systems, including universality and accessibility (Gellérné, 2025b).

References

É.L. Gellérné, 'Die Verordnung über den europäischen Raum für Gesundheitsdaten – ein erster Blick auf das Phänomen', in M. Ahrens (ed.), *Deutsch-Ungarisches Kolloquium 2024: Fortschritte – Rückschritte* (Göttingen: Univerlag, 2025a), pp. 127–139, doi: 10.17875/gup-2893.

É.L. Gellérné, 'Health insurance-related rules of EU law and their implementation into Hungarian national law', *Annales Universitatis Scientiarum Budapestinensis De Rolando Eötvös Nominatae Sectio Iuridica* (2025b) 215–236, available at https://www.ajk.elte.hu/dstore/document/166887/annales_elteajk_2024_lxiii_12_215.pdf.

O18: End-of-Life Autonomy in the Face of Structural Constraints: Palliative Care Shortages and Assisted Suicide

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Abstract

Since the beginning of 2022, it has been possible in Austria to establish a declaration for assisted dying ("Sterbeverfügung"), which, if certain requirements are fulfilled, authorizes a person to obtain a lethal substance. In the register, 807 such declarations were recorded between 2022 and 2025, but only 215 deaths were reported. These figures illustrate that even when a wish to die exists, such a substance is sometimes obtained merely as a safeguard to ensure a dignified death, without the immediate intention of executing it. This highlights the importance of adequate and comprehensive palliative care, which can serve precisely this purpose.

However, if palliative and hospice structures are lacking to provide pain relief and palliative care, this results in a restriction of autonomy, as these individuals are confronted with a limitation of possibilities for a dignified death. Practice reports confirm exactly this circumstance. As early as 2021, the WHO reported that only one out of ten people in need of palliative care actually receives appropriate care. In addition, there is an unequal distribution between rural and urban areas. This structural constraints can be observed in many European countries, for example in the United Kingdom, where the financial deficits in the years of 2023 and 2024 led to the closure of several hundred hospice beds. Yet palliative structures themselves are not the only indispensable prerequisite for the exercise of autonomy. Another important component that is repeatedly and regrettably neglected in discussions about palliative care is psychological support. However, structural deficits are also evident in this area, which ultimately come at the expense of the autonomy of the ill or dying person. Psychological counselling and support are scarce and are often available in a timely manner only to private patients. When time is precisely the factor that seriously ill and dying individuals do not have, the urgency of this issue becomes particularly evident. In nursing homes, waiting times for psychological support are often long. In Austria this situation changes once

a wish to establish a declaration for assisted dying is expressed. If a person's autonomy is to be preserved, access to such services must not depend on the expression of a wish to die.

This contribution aims to address precisely this problem, to explain the relationship between autonomy, palliative care and the wish to die, and to demonstrate how important functional structures are for safeguarding the autonomy of those affected.

O19: Endocrine Disrupting Chemicals and Human Procreation: a Human Rights Reading

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Introduction

A growing body of epidemiological evidence documents a marked global decline in human fertility, with deteriorating sperm quality and rising reproductive disorders such as endometriosis, polycystic ovary syndrome and hormone-dependent cancers. Mounting scientific evidence links these trends to EDCs, predominantly man-made compounds ubiquitous in everyday products and the environment, to which virtually the entire global population is exposed (Hilz and Gore, 2023). Yet no international instrument addresses the consequences of EDC exposure on human procreation, leaving their reproductive health dimension unaddressed within IHRL. This contribution asks: to what extent does EDC exposure threaten human rights related to reproductive health?"

Methods

This contribution adopts an interdisciplinary approach combining a review of scientific literature on the procreative effects of EDCs with a substantive analysis of IHRL, identifying zones of tension and priority avenues for action.

Results

First, EDC exposure directly threatens the right to reproductive health, by affecting fertility and undermining the right to decide freely whether and

when to have children. Involuntary EDC exposure also threatens other rights that strongly interact with reproductive rights, notably the right to a healthy environment and the right to food, challenged through contamination of water, soil and food chains (CEDAW, 2022).

Second, drawing on existing IHRL instruments, CESCR General Comments No. 14 and No. 22 recognise that reproductive health encompasses freedom from harmful chemical exposure, under which documented effects on fertility directly fall. CEDAW General Recommendation No. 24 similarly identifies environmental factors affecting women's reproductive health as falling within the substance of their rights.

Discussion

So far, no Treaty Body has issued a recommendation specifically addressing EDCs and human procreation, despite relevant normative material within IHRL. An IHRL reading reframes the issue beyond chemical risk management, enabling the identification of rights affected and giving standing to those exposed. Yet challenges remain: IHRL mechanisms generally engaged with chemical substances where a direct causal link to rights violations was established, standard EDC properties make difficult to meet. The CESCR's General Comment No. 27 (2025) recognises that adherence to the precautionary principle is central in addressing environmental harm affecting economic and social rights (CECSR, 2025). Applying this standard to procreative health in the context of EDC exposure opens an interesting avenue for further reflection.

References

CEDAW, General Recommendation No. 24, 1999; UN GA Res. 76/300 (2022).

CESCR, General Comment No. 27, UN Doc. E/C.12/GC/27 (2025), para. 11.

E.N. Hilz and A.C. Gore, 'Endocrine-Disrupting Chemicals: Science and Policy', *Policy Insights from the Behavioural and Brain Sciences* 10(2) (2023) 142–150.

O20: Ethical and Legal Reflections on the Normative Force of the Hippocratic Oath: the French Case

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Background

The Hippocratic Oath, a foundational symbol of medical ethics, occupies a distinctive place in both the collective imagination and the training of healthcare professionals. Although its relevance has been widely debated – particularly with the rise of North American bioethics after 1945, due to its misuse by Nazi physicians during the Nuremberg trials and its traditionally paternalistic view of the physician–patient relationship – it remains a key reference in the French context. Both physicians and non-physicians invoke it to express the ethical commitments and duties of the profession. In France, medical graduates swear an adapted version endorsed by the Medical Council. While many of its precepts have been incorporated into legal norms, the text itself has evolved alongside legislative changes. Increasing overlap between bioethical norms – especially autonomy and public health – and legal standards raises questions about the Oath's normative force and the scope of its precepts today.

Methods

Drawing on statutory law, bioethics legislation and standards, ethical rules and relevant doctrinal debates, this study explores the tension between the production of norms endogenous to a professional body and exogenous norms, in a context of political recognition of the pluralism of conceptions of the good life, and provides particular attention to the French regulatory framework.

Results

The analysis shows that, after 1945, the medical profession became structured around both internal and external norms, with the rise of a secondary discourse serving as a safeguard against corporatism in a context of rapid technological development. However, recent developments – linked to evolving societal expectations and the integration of bioethical principles into both legislation and the Oath – have been only minimally scrutinized. Revisions introduced by the French Medical Council reflect a broader shift from ethical frameworks toward legal normativity. While legitimate, this evolution does not entail the dissolution of ethics into law, nor can ethics alone suffice given the singular and human nature of medical practice. In the absence of critical examination, this dynamic fosters ambiguity regarding the purpose of medical practice, between art and science, particularly in a context of rapid technological innovation. The Oath's precepts therefore remain relevant alongside legal rules, principles, and clinical guidelines.

Conclusions

This reflection invites a reconsideration of the place of the Hippocratic Oath within the French legal order: not as a binding norm in itself, but as a structuring axiological foundation that contributes to the legitimation and interpretation of the rules applicable to healthcare professionals.

O21: Ethical Challenges of Uterus Transplantation: Beyond the Standards of Bioethics

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Background

Uterus transplantation (UTx) is an innovative procedure enabling women with absolute uterine factor infertility to experience pregnancy and childbirth. Combining organ procurement from a living or deceased donor, transplantation and assisted reproductive technology, it requires subsequent graft removal due to immunosuppression. Since the first successful birth in 2014, UTx has moved closer to clinical practice, although it remains experimental in several countries, including France. Initially focused on technical feasibility and safety, the ethical debate has gradually shifted toward implementation criteria, particularly the assessment of risks and benefits (nonmaleficence). Beyond alleviating infertility-related suffering (beneficence), discussions increasingly address issues of distributive and social justice. As UTx involves a non-vital organ and raises important cultural and symbolic questions about reproduction, it generates ethical and legal challenges that cannot be fully addressed through traditional bioethical principles alone.

Methods

Drawing on philosophical principles, ethical standards, bioethics legislation and doctrinal debates, this study critically reassesses concepts often treated as self-evident in contemporary debates, notably "autonomy", "consent" and their legal interpretation, the invocation of "individual rights" in pluralistic societies, and claims relating to "social justice".

Results

The analysis highlights several ethical tensions surrounding UTx. With regard to donor autonomy, potential intra-family pressures to donate and strong social expectations surrounding motherhood must be considered. From the child's perspective, the donation may also create a form of intergenerational moral debt. Moreover, in a context of limited healthcare resources, reliance on self-determination and utility alone appears insufficient to justify such procedures. Although self-determination increasingly guides medical decision-making, UTx depends on a complex network of relationships between the recipient, the donor, healthcare professionals and society. Social justice therefore cannot be reduced to the mere allocation of resources. More broadly, these technologies raise questions about the symbolic meanings attributed to the body and about social representations of femininity, pregnancy and motherhood. UTx may be interpreted either as enhancing women's reproductive autonomy or as reinforcing normative expectations surrounding biological motherhood. Ultimately, these debates also concern the aims and limits of contemporary medicine.

Conclusion

Concepts such as autonomy, consent and individual rights often structure the debate, yet their legal and philosophical meanings remain contested in pluralistic societies where different conceptions of family, parenthood and the good life coexist. Addressing the ethical issues raised by UTx therefore requires a more nuanced approach combining legal analysis with broader philosophical and social reflection on evolving norms in reproductive medicine.

O22: Ethics and Regulation of Research in Post-Mortem Perfused Whole Human Brains

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Abstract

This paper describes and discusses ethical and legal issues raised by a novel platform for researching brain disease: perfused post-mortem whole human brains. Brains are donated for research by deceased organ donors deemed ineligible to donate organs for transplant. Brains are removed from donors' bodies and attached to perfusion machines which supply them with glucose, oxygen and other substances necessary to maintain basic metabolic function. Neuronal firing in the brains is prevented by several independent means, making consciousness impossible. Candidate brain-disease therapies are tested in diseased and healthy control brains, and data gathered about their metabolization, their on-target effects, their ability to penetrate the blood/brain barrier, etc. Continuing brain/therapy interactions are observed in brain slices after the initial whole-brain perfusion run is complete. Aggregated data from multiple brain runs is used to create digital brain models that can predict responses to new candidate therapies.

The platform is in many ways superior to, and less dangerous than, many models currently used in brain-disease research. Human brains are a better model than animal brains for human brain disease; and donor brains can be used to detect toxicity and other risks from drugs or gene therapy without endangering live human subjects. But the platform also presents some novel ethical and legal questions. Most strikingly, because the brains enter the lab as inert post-mortem tissue, the platform evades regulations governing research on human subjects; but brain perfusion raises the risk that the brains could suffer in some way. The problem is a more urgent version of the issue presented by the development in laboratories of brain organoids which might attain sufficient mental capacity to acquire some kind of moral status--more urgent because in the case of whole human brains, high-level consciousness could appear all at once rather than as a result of stepwise and monitored development "in the dish."

This presentation will examine legal issues raised by the novel platform under US and European law. Issues to be examined include: whether the kind of consent required for post-mortem tissue donation for research is adequate to whole brain donation for perfusion; whether the methods by which consciousness in donated brains can be regulated, scientifically and legally (and whether rules currently being developed for brain organoids might be modified to cover the whole-brain case); and how privacy and security of donor health data, genetic data and perfusion data ought to be maintained.

O23: EU Critical Medicines Act: Can It Facilitate Equal Access to Pharmaceuticals Within the EU?

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Abstract

In March 2025, European Commission presented its proposal for a Regulation laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest (Critical Medicines Act). As stated in its explanatory memorandum, for certain medicines, like orphan medicines, patients' access varies significantly depending on the Member State in which they reside, for various reasons including the market size. According to data from European Federation of Pharmaceutical Industries and Associations (EFPIA) for 2024, around 48% of innovative medicines were not available to patients in Europe, while only 29% were fully available on the national lists of medicines covered (reimbursed) by national social security systems. Median time of availability, meaning time between marketing authorisation and inclusion on national reimbursement list, was 52 days in Germany and 859 days in Lithuania (Newton *et al*., 2024). Such enormous differences cannot be considered acceptable in a Union whose Charter of Fundamental Rights guarantees right to benefit from medical treatment for everyone. The aim of the proposed presentation is to analyse the proposal by the Commission and determine whether its provisions, primarily those on collaborative procurement, are appropriate for facilitating equal access to medicines for EU patients irrespective of their Member State of residence.

The presentation first outlines the state of play regarding differences in access to medicines across the European Union, primarily related to innovative medicines. This part is followed by an analysis of the proposed Critical Medicines Act at its relevant stage of adoption, focusing on its scope and the provisions enabling collaborative procurement of medicines by several Member States. In the end, it presents proposals for facilitating equal access to pharmaceuticals across the Union related to Critical Medicines Act, but

also other potential changes to EU legislation which should be considered for achieving equality of access.

Reference

M. Newton, K. Stoddart, M. Travaglio and P. Troein, *EFPIA Patients WAIT Indicator 2023 Survey* (Brussels: EFPIA, 2024), pp. 2, 9–10.

O24: Forced Paternity in the Use of Assisted Reproductive Technology: Between Procreative Autonomy and Legal Compulsion

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Abstract

Parenthood constitutes a fundamental dimension of human life and remains a central aspiration for many individuals. Statistically, the majority of people worldwide will have at least one child, most often within a heterosexual relationship. If a couple is unable to conceive naturally, they may resort to medically assisted reproduction technology. The distinctive feature of these methods lies in the fact that a considerable period of time – ranging from weeks to months or even years – may elapse between the initiation of the procedure and the transfer of the embryo. During this time, a couple who initially embarked on treatment together may separate, or one partner's reproductive intentions may change. Consequently, a possible problem of so-called "forced paternity," understood as the imposition of legal fatherhood against a man's will in the context of embryo transfer might arise.

The analysis contrasts two competing legal approaches. The first, represented by the *Evans v. the United Kingdom* judgment of the European Court of Human Rights, prioritises the right not to become a parent. In this framework, withdrawal of consent to embryo use is decisive, even if it results in the other party losing the only opportunity to have genetically related offspring. The Court thus elevates negative reproductive autonomy over positive claims to parenthood.

The second approach, exemplified by the Polish legislation and the Israeli Supreme Court ruling in *Nahmani v. Nahmani*, adopts a more pronatalist stance. These frameworks allow, under certain conditions, the override of a man's objection to embryo transfer, thereby enabling the woman to pursue motherhood – even at the cost of imposing fatherhood. Such solutions emphasise the protection of reproductive opportunity, particularly where no alternative means of achieving genetic parenthood exist.

In my opinion both models inadequately balance competing dimensions of procreative autonomy. While forced parenthood constitutes a serious infringement of individual freedom, an absolute veto power may unjustifiably deprive one party of their last realistic chance to reproduce. It is proposed that legal systems should introduce *ex ante* agreements regulating embryo disposition and consider alternative frameworks, such as permitting embryo use without imposing full legal parenthood obligations on the objecting party in the exceptional circumstances.

O25: French Institutions' Perspectives on the Regulatory Adoption of Organoid Technologies

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Abstract

Human organoids are three dimensional structures derived from stem cells that reproduce features of organs that have a great potential for transforming biomedical research and clinical applications. Yet their production, circulation and use raise complex governance questions. This study examines practices of French institutional actors to understand the impact of organoid technologies on their applicable legal frameworks. We seek to identify which regulations are evolving, which are remaining static, and where adaptations are needed to accommodate this emerging technology. By focusing on institutional perspectives, this work contributes to the legal study of organoids, an area still largely underexamined.

This research relies on five qualitative interviews conducted with various institutions, including governmental actors, regulatory agencies, and an ethics committee member. All interviewees are anonymised to ensure confidentiality. Among the several aspects explored during these interviews, this analysis emphasises the regulatory issues associated with the regulation of organoids in accordance with each institutions' role.

Findings reveal that French institutions are closely monitoring the development of organoid technologies and some have already taken a proactive

approach in their regulation. Beyond organoid-specific issues, our interviews reveal deeper systemic issues when dealing with novel boundary-blurring technologies. These include ambiguities with regulatory interpretation and sharing of competence between institutions, organisation of personnel or streamlining of activities.

This work prompts a reflection on how best to accommodate novel technologies, such as organoids, in a preexisting patchwork of legal frameworks and competent institutions. Engaging in this discourse will clarify what needs to be adapted in the applicable legal frameworks, as well as identifying to what extent organoids represent a truly disruptive innovation. Answering these questions will help bringing about the organoid technologies' transformative potential, while also ensuring that they are used in a responsible manner.

O26: From Prohibition to Preservation: Reframing Reproductive Autonomy through Social Freezing in Europe

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Abstract

Social freezing, most notably in the form of oocyte cryopreservation, marks a regulatory frontier in the evolving frameworks of European health law. This paper argues that reproductive autonomy is expanding temporally: it now encompasses not only the decision to have or not to have children, but also the decision to preserve the biological possibility of doing so at a later date.

Against this backdrop, the paper examines the recent judgment of the Austrian Constitutional Court (VfGH G 52/2024), which declared the prohibition of non-medical oocyte cryopreservation to be unconstitutional, and established fertility preservation as a right to private life under Article 8 ECHR. The decision represents a paradigmatic shift from an indication-based, paternalistic model requiring medical necessity to a rights-based framework that foregrounds temporally extended reproductive autonomy irrespective of health status. By closely examining the Court's reasoning, the paper demonstrates how this temporal expansion shifts the focus of the Article 8 ECHR analysis from the permissibility of general regulatory distinctions to the justification of concrete restrictions, thereby placing increased pressure on broad, prophylactic prohibitions in the absence of competing rights.

Considering the jurisprudence of the European Court of Human Rights on procreative decision-making, such as *S.H. and Others v. Austria* (57813/00, 2011) and *Costa and Pavan v. Italy* (54270/10, 2012), and access to assisted reproduction across Europe's diverse legal landscape, the paper contends that social freezing reveals an escalating tension between a broad margin of appreciation

and the growing protection of the individual's right to use reproductive technologies for their own benefit. Recent empirical studies on users, motivations, and success rates further demonstrate how structural factors like partnership patterns and labour market conditions drive the practice, even as clinical outcomes remain sharply age-dependent and uncertain.

Thus, social freezing emerges as an individual solution to a societal problem: an expansion of temporal (individual) autonomy that carries the risk of individualizing responsibility for structural fertility issues, even as it strengthens the legal protection of reproductive self-determination under Article 8 ECHR.

O27: From Restriction to Reproductive Autonomy? The Changing Landscape of Assisted Reproduction Regulation in Lithuania

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Abstract

The regulation of assisted reproduction in Lithuania has long reflected a cautious and restrictive legislative approach shaped by ethical, political, and societal debates. Historically, access to assisted reproductive technologies (ART) has been limited by legal requirements related to family status, eligibility criteria, and the scope of publicly funded services. However, recent developments in constitutional jurisprudence and emerging legislative initiatives suggest that the regulatory landscape may be gradually shifting toward a broader recognition of reproductive autonomy and equality in access to reproductive healthcare.

The analysis focuses on two recent developments: the emerging constitutional discourse on family life and equality, and new legislative initiatives aimed at reforming the existing regulation of assisted reproduction.

Particular attention is given to recent constitutional jurisprudence that has contributed to a broader interpretation of the constitutional concept of family and reinforced the importance of equality and non-discrimination in the enjoyment of family life. These developments have important implications for the regulation of reproductive healthcare, especially in relation to access to assisted reproduction for individuals and couples who may fall outside traditionally recognized family structures.

At the same time, the Lithuanian Ministry of Health has prepared a new draft amendment to the Law on Assisted Reproduction. The proposal aims to respond to Lithuania's demographic challenges and expand opportunities for individuals who wish to have children but face infertility. Under the draft legislation, assisted reproduction would be available to married couples, registered partners, as well as a man and a woman cohabiting for at least one year and intending to form a family relationship, and also to single women. The procedure would be permitted where infertility cannot be medically treated and no contraindications threaten the woman's health or the ability to carry

a pregnancy. Most services would be covered by the public healthcare system, with the exception of gamete, tissue, and embryo preservation and storage.

Despite these efforts to expand access, the proposed reform has already sparked political debate regarding whether the new framework will genuinely reduce discrimination or whether certain restrictions will remain embedded in the regulatory model. By situating these developments within broader European human rights standards and debates on reproductive autonomy, the paper critically assesses whether Lithuania is moving toward a more inclusive and rights-based approach to assisted reproduction, or whether the emerging reforms represent only a partial transformation of an historically restrictive system.

O28: From Rights to Practice: Interdisciplinary Insights into Healthcare Access and Patient Involvement in Rare Disease Governance in Serbia

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Abstract

This paper presents preliminary findings from an ongoing interdisciplinary research project examining access to healthcare and patient involvement in decision-making for people living with rare diseases (PLWRD) in Serbia. Positioned at the intersection of health law, sociology, and anthropology, the study seeks to explore how formal legal guarantees are translated into practice and to identify the structural, institutional, and socio-cultural factors shaping this process. The paper draws on a multi-method research design combining legal and policy analysis with qualitative empirical research. The legal component examines the existing regulatory framework governing access to healthcare and patient rights, including relevant national legislation, strategic documents, and alignment with European standards. This is complemented by qualitative fieldwork, including focus groups with patients, semi-structured interviews with patient organisations and policymakers.

Preliminary findings point to a persistent gap between formally guaranteed rights and their practical realization. While the legal framework provides a basis for access to diagnosis, treatment, and related social rights, its implementation is uneven and often mediated through informal practices, institutional discretion, and varying levels of health literacy. In this context, patients and their families frequently rely on alternative strategies to navigate the system, revealing its limits. The paper further highlights the role of patient organisations as emerging intermediaries in healthcare governance, contributing to advocacy, knowledge production, and policy dialogue. At the same time, it identifies structural constraints on meaningful patient involvement, particularly in key decision-making processes such as resource allocation and access to therapies.

By integrating legal analysis with empirical insights, the paper argues that patient "control" and participation in healthcare systems cannot be understood solely through formal rights frameworks. Instead, they are shaped by a dynamic interaction between law, institutional practices, and social contexts. The findings contribute to ongoing debates on the transformation of health law in Europe, particularly in relation to inclusiveness, governance, and the role of vulnerable groups. The paper reflects on how evolving health systems require new approaches that move beyond formal guarantees toward more context-sensitive and participatory models of healthcare governance.

O29: From the Right to a Healthy Child – Prenatal Genetic Diagnostics from a Legal Perspective

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Abstract

In a time characterized by unprecedented access to medical information and technological possibilities, prospective parents may seek detailed knowledge about the health of their unborn child. Prenatal genetic diagnostics enable the detection of a vast range of genetic conditions during pregnancy and thereby support the desire of prospective parents to have a healthy child. While certain prenatal examinations form part of standard prenatal care, some prospective parents may also request additional diagnostic measures in order to obtain comprehensive information about their unborn child. On the basis of the results of such diagnostics, prospective parents may decide whether to continue the pregnancy or to terminate it in the event of a detected genetic abnormality. In Germany, prenatal genetic diagnostics are permitted within the framework of Paragraph 15 of the German Genetic Diagnosis Act (GenDG).

The interplay between prospective parents' wishes and medical possibilities raises complex legal questions at the intersection of health law, medical law, and fundamental rights in both national and European legal frameworks. Prenatal genetic diagnostics affect several constitutionally protected interests, including the parents' rights to reproductive self-determination and to found a family, as well as the interests of the unborn child, particularly the protection of life and welfare. At the same time, they raise regulatory questions regarding the governance of genetic technologies in healthcare systems.

Against this background, the oral presentation examines prenatal genetic diagnostics from both a German and a European health and medical law perspective. Using the German legal framework as a point of reference, it situates national regulation within the wider European normative context, including human rights standards and evolving approaches to the regulation of genetic testing. Particular attention is given to the implications of prenatal testing for disability discrimination and to the evolving notions of parental responsibility and children's rights in light of expanding genetic knowledge.

O30: Frozen in Time: a Feminist Human Rights Analysis of Social Egg Freezing Time Limits in Austria, Denmark, and the United Kingdom

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Abstract

European States have long regulated the cryostorage of oocytes through fixed time limits, indication-based distinctions, or outright prohibitions. In recent years, Austria, Denmark, and the United Kingdom have each undergone significant legislative change and/or relevant judicial developments in this domain. These reforms raise fundamental questions concerning reproductive autonomy and equality, as temporal restrictions on social (non-medical) oocyte cryopreservation (OC) determine the outer boundaries within which women may plan genetic parenthood.

When do storage periods for social OC constitute unjustified interferences with the right to private and family life under Article 8 ECHR? When does differential treatment of social OC relative to medically indicated freezing, embryo storage, or sperm storage amount to discrimination under Article 14 ECHR? And which regulatory models represent best practice for future European legislation? This work employs a purposive comparative analysis of three jurisdictions representing distinct regulatory approaches: Austria (a statutory ban on social OC, declared unconstitutional by the Austrian Constitutional Court in October 2025), Denmark (a former five-year limit, repealed in January 2024 in favour of an age-linked model), and the United Kingdom (a consent-renewal-based 55-year storage period since 2022). Doctrinal analysis under Article 8 and 14 ECHR is integrated with feminist bioethics as theoretical framework to contextualise human rights norms within the gendered realities of reproductive labour.

All three jurisdictions' former and current regimes constitute interferences with Article 8 (1) ECHR that often resist justification under Article 8 (2) ECHR. Outright prohibitions lack an articulable legitimate aim; short storage periods fail the necessity requirement given the availability of less restrictive alternatives. Under Article 14 ECHR, indication-based, cell-type-based, and

sex-based divergencies in storage rules give rise to direct and indirect discrimination lacking objective and reasonable justification, particularly in the absence of empirical evidence that storage duration affects clinical outcomes. The feminist bioethics integration reveals that restrictive storage limits externalise physical, administrative, and financial burdens disproportionately onto women, perpetuating structural inequality under the guise of moral neutrality. Outright bans and short fixed storage caps for social OC are difficult to sustain under the ECHR and entrench gendered inequalities in reproductive planning. Sound regulatory models permit long-term storage irrespective of medical indication, replacing arbitrary deadlines with periodic consent renewal or clinically grounded age thresholds. The storage period question is therefore a matter of constitutional, not merely technical, significance. Future European legislation must approach fertility preservation as an imperative of reproductive equality rather than a privilege subject to expiry.

O31: Genomic Data, Collective Risks, and the Limits of EU Health Data Governance

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Abstract

By simplifying the sharing of health data for research purposes without implementing appropriate ethical safeguards, the European Union risks enabling research projects that are harmful not only to the individuals included in these datasets but also, more broadly, to European society. Given the specific risks it poses to discrimination and stigmatisation of various communities, the field of genomics provides a suitable context for examining this issue.

Remarkably, this matter has not attracted much scholarly attention in Europe. The most recent regulation aiming to facilitate health data reuse, the European Health Data Space, has sparked a flood of legal scholarship focusing on ensuring its effectiveness while reconciling its goal of data sharing with the pre-existing legal framework. In contrast, few authors have seriously examined the consequences of the research projects enabled by such infrastructures for our societies. The pursuit of science enabled by access to research data is widely represented by legal scholarship and by European institutions as necessarily beneficial to society. The literature on research ethics challenges this assumption, as it is replete with examples of projects involving controversial methods and objectives that have had detrimental consequences for entire communities and for the trust between researchers and the public. In this regard, genomics is a particularly high-risk field. Since genetic data is inherently relational, it provides important information not only about the individuals who provide it, but also about everyone directly or indirectly related to them. Consequently, the harms associated with this type of research can extend far beyond the individual research participants to affect all human beings belonging to the same social or algorithmic group.

The European data governance framework does not appear to adequately address these risks. Indeed, even though the EU applies an ethical framework to the projects it sponsors, it does not, in principle, impose one on research projects which it enables through its legislation, encouraging secondary use of

data. A notable exception is the recent regulation establishing the European Health Data Space, which introduced an embryonic ethical framework whose shortcomings are, unfortunately, apparent.

This oral presentation aims to address this flaw in the legal framework by proposing legal avenues for engaging with communities affected by this type of research to mitigate its risks. These proposals are made with all due caution, since an overly rigid legal framework risks harming the very people it is intended to protect by potentially excessively restricting relevant research.

O32: Governing the EHDS Data Goldmine: Fair Data Governance Amidst Health Data Monetisation and Agentic AI

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Abstract

Article 62 of Regulation (EU) 2025/327 (EHDS), which allows health data access bodies and health data holders to charge fees for making electronic health data available for secondary use, reopens the debate on data monetisation, a divisive topic among privacy scholars who are either in favour or against considering the commodification of health data compatible with the fundamental right to data protection. The rise of agentic AI and large language models, besides casting doubts on whether the distinction between primary and secondary uses of health data remains meaningful, also leaves serious questions unanswered about the ethical use and governance of health data in the development of AI tools that could become medical devices. Thus, in this paper, I argue that debating the payment of fees for the use of health data is a priority if we want the EHDS to function while preventing extractivism. Health data access bodies shall acknowledge that health data holders require innovative cost-accounting procedures to develop sustainable data governance models that improve people's health through prevention and treatment. This reflection supports what is already required by the Health Technology Assessment Regulation 2021/2282, which assesses medical device performance by asking whether the assessed device is better than what is already available, also in terms of cost-efficiency. When, in the near future, AI used for diagnosis and treatment will be considered a medical device, the Medical Device Regulation 2017/745 will require an assessment of whether the device is safe, which will entail evaluating AI trustworthiness and risks, following the logic of the Artificial Intelligence Act 2024/1689. The brief excursus demonstrates the necessity of approaching the issue of the fair use of electronic health records in light of today's agentic AI, which opens great opportunities for advancing scientific research but also requires a new approach to data governance that renders the conceptualisation of EHDS already obsolete. Some concrete examples of applications

already under development or in use for the diagnosis of rare diseases in children and other areas will help us understand why the frontier of AI ethics is moving fast, and how these technological changes are fundamentally reshaping our relationship with digital personal data.

O33: Governing the Secondary Use of Health Data for Healthcare Organization: the Italian Case in the European Landscape

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Abstract

Over the past decade, the Italian public healthcare system has experienced progressive underfunding: between 2012 and 2024, public health expenditure declined by three tenths of a percentage point, reaching 6.3% of GDP in 2024. This trend has been accompanied by a significant increase in out-of-pocket spending and a growing share of the population forgoing necessary care, contributing to widening territorial and socioeconomic inequalities in access to healthcare services.

These pressures call for a rethinking of healthcare organization, with growing attention to network-based models that enhance coordination among hospitals of different sizes, community-based services, and long-term care facilities. Health networks are particularly suited to addressing complex and "wicked" challenges, including multimorbidity and chronic conditions linked to population ageing. Within this framework, big data analytics and artificial intelligence can play a crucial role by enabling the identification of patient clusters, mapping care pathways and mobility, and evaluating the performance of healthcare providers, thereby supporting more effective and evidence-based decision-making in the organizational field.

However, as highlighted by a recent *Lancet* editorial (2025), the potential of digital health data in Italy remains largely untapped due to structural fragmentation, limited interoperability, and governance gaps. Despite the availability of extensive administrative and clinical datasets, their use is still predominantly confined to accounting and reporting purposes. The Italian regulatory framework has contributed to this underuse of health data. Traditionally, it has been characterized by a high level of protection of personal data and privacy, accompanied by specific constraints and procedural requirements. While ensuring strong safeguards, these have in practice limited the use of health data for policy-making purposes and, even more so, for scientific research.

Nevertheless, recent legislative developments, also in anticipation of the European Health Data Space, are fostering greater access to health data, albeit still marked by legal uncertainties and coordination challenges.

Against this background, the paper aims to analyse the legal and organizational conditions for the secondary use of health data, with particular focus on their use for organizational purposes within healthcare systems. The analysis builds on a multidisciplinary research project conducted in 2025–2026 in collaboration with regional health authorities in Piedmont, integrating legal analysis with empirical insights from healthcare data practices. Special attention is devoted to recent developments in national and EU law and to the related challenges in terms of data governance, interoperability, and data protection.

Reference

Editorial, 'The Italian health data system is broken', *Lancet Regional Health Europe* 48 (2025) 101206. doi: 10.1016/j.lanepe.2024.10120

O34: Health Data Governance in Crisis: Rethinking Consent for Sensitive Health Data in the European Health Data Space

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Abstract

This paper investigates whether consent holds as a legal basis under the European Health Data Space (EHDS) Regulation in times of a pandemic or other cross-border health crisis. The aim of the EHDS is to facilitate ethical, cross-border reuse of health data, as identified in Article 53 of the EHDS, includes serving the public interest in public or occupational health, such as protecting against serious cross-border threats to health. According to Recital 52 of the EHDS, Health Data Holders are legally obligated to make specified health data available. As such, making data available under the EHDS relies on a statutory mandate based on the GDPR. However, Article 51 of the EHDS allows Member States to apply stricter safeguards for certain sensitive health data categories, such as data from biobanks or genetic data. One such safeguard might be the requirement to obtain consent from Data Subjects. Although the EHDS generally relies on legal obligation as the basis for secondary use, some categories of health data may only be made available based on consent. In such cases, Member States may rely on derogations from consent under the GDPR, including vital interests or public interest (scientific research) exceptions.

This paper argues that reliance on consent is not justified in cross-border health crises due to the collective and interdependent nature of such risks. Instead, a 'democratically constrained Leviathan model of data governance', in which a strong central authority is empowered to act decisively in crises and

adopt exceptional measures for the public good, can be justified. The EHDS already hints at such a centralized approach through EU-level regulation and the establishment of Health Data Access Bodies. However, the current framework may not be fully crisis-ready. In particular, Article 51 allows consent to remain the legal basis for certain sensitive health data regardless of the purpose of their use, whether for scientific research in normal circumstances or for protecting public health during crises. This lack of distinction may slow data access during emergencies and lead to fragmentation, as Member States may rely on different derogations from consent. To address this, this paper proposes a crisis-specific data governance framework within the EHDS. In such a framework, reliance on legal obligation should replace consent as the legal basis for making sensitive health data available during crises, enabling rapid and coordinated cross-border responses. Under normal circumstances, however, reliance on consent and its derogations would remain appropriate.

O35: Health Data Governance in Europe: Secondary Use, Digital Innovation and Fundamental Rights

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Abstract

The sharing of digital health data for secondary use today requires a rethinking of traditional data protection frameworks, given the expansion of intended purposes, from scientific research to health policymaking. This evolution has fostered increased cooperation between public and private actors, supported by advanced technologies and high levels of interoperability.

Initially, the GDPR marked a move away from viewing privacy as mere protection against external interference, toward a model centred on individual control over personal data, placing the subject in an active role within data exchange contracts.

Today, a further paradigm shift, initiated by the 2020 European Data Strategy, has led to the development of the European Health Data Space (EHDS). Within this framework, access to health data for secondary use is no longer primarily based on the data subject's consent, but on legal bases linked to the pursuit of general interests, implemented through organisational mechanisms and dedicated authorities (Health Data Access Bodies), making a transition from a consent-based model to a proceduralised governance.

However, this shift does not represent a complete rupture, as elements of continuity remain: the GDPR had already promoted data sharing and reuse, while the Data Governance Act maintains a logic of voluntary data sharing, albeit in a solidaristic perspective. Moreover, different access models coexist, including a negotiated model based on contractual or administrative agreements and an intermediated model managed by public bodies.

The emerging trajectory increasingly emphasizes the pursuit of general interests and the collective dimension of health, without overlooking the 'highly sensitive' nature of health data as an expression of personal identity. Even as digitalisation advances, data sharing requires a coherent governance framework that ensures risk minimisation and selective and proportionate access. A case-by-case approach is required to assess the legitimacy of the public interest pursued.

These issues also arise at the national level, requiring coordination between the new European framework and recent domestic legal developments. Relevant aspects include amendments to Article 110 of the Italian Privacy Code, Article 8 of the Italian AI law – which classifies the use of data for training AI systems as a public interest activity – and the development of digital infrastructures such as the Electronic Health Record and the National Telemedicine Platform.

The key challenge is to strike a sustainable balance between innovation, data governance, and the safeguarding of fundamental rights, while avoiding risks of commodification of health data and preserving the centrality of the individual.

O36: Hospitals as AI Deployers: Organisational Failures and Liability Implications

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Abstract

This research investigates the direct liability risk borne by hospitals when they deploy an AI-based medical device, with particular attention to clinical decision support systems. While debates around the liability burden of the physician and of the AI provider have already been analysed by European legal doctrine, the matter of hospital liability is still quite underexplored. This study aims to fill this gap by adopting a socio-technical perspective, analysing the choices that hospitals operate when deploying new medical devices and how they may in turn affect patients' health.

The research first reconstructs the lifecycle of deployment of AI systems by hospitals, through 5 different phases: (1) pre-procurement, (2) procurement, (3) integration and implementation, (4) routine use, and (5) suitability reassessment. Each phase involves critical organisational decisions that may generate foreseeable risks if inadequately performed and thus may lead to direct liability for the hospital. These failures may consist, for example, in inadequate workflow design, lack of training of the staff, and unsuitable integration in the IT infrastructure.

The analysis then extends to the interaction with other parties, namely with AI providers and with physicians. It is highlighted that hospitals and providers both contribute to the creation of the clinical environment, as many of their obligations (set out by the Medical Device Regulation and by the Artificial Intelligence Act) are complimentary. Some of these shared domains include incident management, oversight measures, and updates. When investigating

liability, it is thus important to identify the precise source of the failure between these two actors.

Physicians, conversely, operate within the constraints of said jointly constructed clinical environment. This means that physician responsibility, while of course still relevant, is partially limited by these external boundaries.

By proposing a lifecycle-based framework for identifying organisational failures and mapping how spheres of control of various involved actors interact, this work provides analytical tools to assess hospital liability in AI-assisted healthcare and contributes to a nuanced allocation of responsibility and liability within complex socio-technical systems.

O37: How Pharmaceutical Pay-for-Delay Agreements Have Evolved in Europe by 2026

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Abstract

The regulatory landscape for pharmaceutical patent settlements is undergoing a radical transformation as European authorities move from penalizing direct cash payments to scrutinizing complex commercial arrangements. Recent rulings by the Court of Justice of the European Union (CJEU) have established a rigorous framework for identifying anti-competitive behaviour through four landmark cases:

(1) Generics (UK)/Paroxetine (2020): This case established the fundamental two-part test to determine if parties are potential competitors and if an agreement constitutes a "restriction by object".
(2) Lundbeck/Citalopram (2021): The CJEU confirmed that "buying off" competition is equivalent to a cartel, with a specific focus on direct cash payments used to exclude generic competitors from the market.
(3) Servier/Perindopril (2024): This ruling extended the legal analysis to Article 102 (Abuse of Dominance), scrutinizing "killer acquisitions" and applying a narrow, molecule-level market definition.
(4) Teva/Cephalon/Modafinil (2025): The court applied the framework to complex commercial side deals, confirming a €60.5 million fine for value transfers disguised as API supply agreements and IP licenses that lacked independent economic rationale.

A critical evolution in these rulings is the validation of counterfactual analysis, a methodology that compares a settlement to a hypothetical scenario without restrictive clauses to expose the true intent of side deals. To navigate this environment, firms must now pass the "But-For" test, rigorously documenting whether a commercial deal would have been signed if the patent settlement did not exist.

This European hard line contrasts with the US Federal "Rule of Reason" approach, although California's AB 824 has introduced a stricter presumption

of illegality". Looking ahead, the new frontier for enforcement lies in Biosimilars and ATMPs, where high entry barriers make pay-for-delay tactics attractive to originators, sparking ethical concerns over unmet medical needs. In this era of heightened scrutiny, documenting the independent commercial rationale for every side deal is no longer optional: it is a necessity for survival.

O38: How the Law is Redistributing Clinicians' Responsibilities: a Critical Comparative Analysis

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Abstract

There are a number of professionals that are assuming increasingly significant roles in the provision of clinical care: non-physician clinicians (NPCs). Whether through the creation of new qualifications and roles, through the extension of existing responsibilities or simply through the carving out of exceptions to legal liability, such professionals are now performing clinical tasks that were previously the sole preserve of physicians. The trends buoying this development, both economic and demographic, show no signs of abating, especially when considering the introduction of AI-decision support systems that can contribute their own sophisticated clinical expertise.

While this distribution of responsibilities aims to alleviate strained resources and enhance clinician-patient engagement, it also risks undermining fundamental values; the provision of safe and high-quality medical care and the protection of physicians' occupational freedom. These interests must be balanced through the legal framework. This encompasses a complex array of instruments: from those establishing distinct qualification and reimbursement structures, to those determining the responsible regulators and the allocation of liability.

This presentation views these instruments as an interrelated whole and presents the findings of a comparative project spanning several European jurisdictions. To this end, it systematises the integration of NPCs into different healthcare systems, by highlighting: the nature of the relevant roles, the associated responsibilities and the rationales underlying their development. This allows for the identification of divergent approaches, as well as common trends.

Going further, it evaluates the established frameworks. First, it assesses how the regulation of NPCs is related to the traditional regulation of physicians: are they regulated together or through institutions specially tailored to their competence? Do these align with existing safeguards? From a more targeted standpoint, it analyses whether there is a clear distribution of competences and accountability within healthcare teams. In this regard, the comparison will facilitate the development of a doctrinal distinction between activities that are suitable for substitution (performed without physician input) and those that ought only to be delegated (performed with continued physician oversight).

Second, the analysis turns to the possibility of further strengthening these roles. Simply put, are the regulations of NCPs sufficiently flexible to enable them to assume further clinical tasks as their abilities are augmented through the aforementioned AI-decision support systems? How rigid are existing regulations and what procedures or conditions must be met to develop them? It is hoped that the discussion will provide constructive insights that can be incorporated into the project's development.

O39: Human Dignity as an Unexplained Constraint: What EU Artificial Intelligence Healthcare Regulation Can Learn from EU Biotechnology Patent Law

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Abstract

The European Union's Artificial Intelligence Act (Regulation 2024/1689) classifies AI systems intended for healthcare as 'high-risk'. The Act explicitly anchors itself to the European Union's Charter of Fundamental Rights, including the right to human dignity (Article 1) and the right to integrity of the person (Article 3). It mandates that AI be 'human-centric' and developed in accordance with these fundamental rights. Yet while the Act requires fundamental rights impact assessments for high-risk AI systems (Article 27), it lacks substantive guidance on what dignity requires when applied to AI-mediated clinical decision-making, diagnostics, or triage. Dignity is invoked in the Act's recitals as a value justifying prohibitions and classifications. However, what dignity requires in this context, and how it should be invoked, are questions that will ultimately fall to the Court of Justice of the European Union (CJEU).

This paper argues that EU biotechnology patent law offers a direct and cautionary precedent. Since 1998, the Biotechnology Directive (98/44/EC) has required that patent law respect 'the fundamental principles safeguarding the dignity and integrity of the person' (Recital 16). In *Brüstle v Greenpeace* (C-34/10), the CJEU held that the term 'human embryo' must be understood widely where respect for human dignity could be affected. Yet judicial reasoning on the grounds or requirements of dignity itself was not provided. Rather, dignity was invoked as a constraint but not explained. Three years later, while the CJEU revisited and narrowed this definition in *International Stem Cell Corporation* (C-364/13), the reasoning on dignity remained unexplained.

The challenge is not that dignity remains undefined – as an evolving concept it must retain flexibility to respond to changing societal values and emerging technologies. The problem is that without transparent reasoning, neither

national courts nor the non-judicial actors who will assess dignity at first instance under the AI Act can understand why dignity was invoked in one case and not another.

Drawing on this patent law experience and on interdisciplinary scholarship in bioethics, healthcare access, and intellectual property governance, this paper argues that the CJEU will inevitably face dignity questions arising under the AI Act. When it does, it must provide transparent, explanatory reasoning on why and how dignity is invoked, so that national courts – while respecting their margin of appreciation – can draw on that reasoning as guidance and, over time, develop a coherent body of EU law on dignity as a constraint on artificial intelligence in healthcare.

O40: Intravenous Infusions Between Medicine and Wellness: Regulatory Gaps and Patient Safety

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Background

The global proliferation of elective intravenous (IV) therapies in "wellness clinics," "med-spas," and mobile concierge services has created a complex intersection between standard medical practice and the commercial wellness industry. While aggressively marketed to the public for hydration, anti-aging, hangover relief, and general vitality, these invasive interventions carry inherent clinical risks that are often downplayed or ignored in commercial settings.

Objective

This paper examines the critical regulatory gaps facilitating the unchecked expansion of commercial IV wellness therapies. It evaluates the consequent legal and ethical implications for patient safety, informed consent, medical liability, and the corporate practice of medicine.

Analysis

Through a comparative review of international health regulatory frameworks, medical board guidelines, and recent malpractice cases, this study highlights the legal ambiguities surrounding the classification of wellness infusions. Key areas of legal scrutiny include the scope of practice and credentialing for administering personnel, the compounding and sourcing of off-label vitamin cocktails, and misleading direct-to-consumer marketing practices that routinely bypass traditional healthcare advertising standards.

Findings

Our analysis reveals a fragmented legal landscape where wellness IV businesses frequently operate in a regulatory gray area, circumventing the stringent oversight applied to traditional medical facilities. This regulatory arbitrage fundamentally compromises patient safety. The literature and case law show a concerning rise in preventable adverse events – including severe localized infections, sepsis, electrolyte imbalances, and anaphylaxis – frequently occurring in retail settings that lack adequate emergency response protocols or direct physician oversight.

Conclusion

The commodification of invasive medical procedures under the guise of consumer wellness demands urgent legal and legislative intervention. This paper proposes a modernized, unified regulatory framework that mandates strict facility licensure, enforces rigorous compounding standards, limits the delegation of invasive procedures, and requires transparent marketing guidelines. Bridging this regulatory gap is essential to protecting public health while navigating the evolving boundary between medical treatment and personal wellness.

O41: Keeping Doctors in/on/out the Loop: Human Oversight in Medical AI under the EU AI Act

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Abstract

Artificial intelligence is progressively reshaping clinical decision-making. As medical AI systems gain sophistication, the traditional role of clinicians is reconfigured well before full autonomy is reached. Even at intermediate stages of development, algorithmic outputs may equal or surpass the diagnostic or predictive abilities of individual professionals, raising complex legal and ethical questions about how human oversight should be designed and exercised.

Within the EU, this issue is framed by Articles 14 and 26 of the Artificial Intelligence Act (Regulation (EU) 2024/1689), which govern the oversight of high-risk AI systems, including those used in healthcare delivery. Article 14 imposes obligations on providers to design systems that enable effective human oversight, while Article 26 requires deployers to ensure that such oversight is meaningfully implemented in practice.

This presentation analyses three models of human involvement in AI-supported medical decision-making: human-in-the-loop, human-on-the-loop, and human-out-of-the-loop. The human-in-the-loop model preserves professional autonomy but risks cognitive overload and may reduce oversight to a purely formal step. The human-on-the-loop model grants AI systems greater autonomy, yet increases the danger of automation complacency. Fully removing humans from the loop remains, in most healthcare contexts, ethically and legally untenable.

The presentation argues that effective human–AI collaboration requires interaction models that integrate the strengths of both actors: the speed, scale and pattern-recognition abilities of AI systems with the contextual judgement, ethical reasoning and patient-specific interpretation that clinicians provide. The appropriate degree and configuration of oversight depends on task complexity, risk profile, and technological maturity.

The conclusion advanced is that efficiency and human oversight should not be viewed as competing goals. Instead, they form a continuum of responsible AI integration in medical practice, where the challenge lies in calibrating human involvement to ensure both safety and clinical value.

O42: Legal Certainty and Patient Safety in Healthcare Supervision in Sweden, Finland and the Åland Islands

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Abstract

The possibility of having a complaint regarding healthcare investigated by an impartial, independent supervisory authority is a fundamental prerequisite for the patient's legal certainty and for patient safety. The constitutional control function of healthcare supervision is significant due to the limited access to judicial review and to ensure the regulatory responsibility of states to protect the right to life under the European Convention. This presentation analyses legal certainty in healthcare supervision in Sweden, Finland and the Åland Islands.

In Sweden, the legal position of patients has been significantly weakened during the last 15 years. Previously, almost all patient complaints had to be investigated by the supervisory authority. After a legal reform in 2018, the investigation of complaints decreased significantly to promote risk-based supervision. In most cases, the patient is supposed to turn to the healthcare provider. Only serious misconduct or complaints relating to compulsory care must be investigated by the supervisory authority.

In Finland, everyone has the right to have a complaint directed at authorities or public employees investigated if, for example, it concerns possibly unlawful actions or failure to fulfill obligations. This right is stipulated in the constitution, codified in general administrative law and is included in the general legality control of public administration. Complaints are considered to reveal malpractice in healthcare and constitute a supplementary legal remedy for the individual. Until 1 January 2026, supervision of healthcare was carried out by both regional and central administrative authorities, now only by the central supervisory authority.

The territorial autonomy of the Åland Islands has the right to regulate healthcare and its supervision with some exceptions. Even though patients' complaints are not regulated identically compared to Finland's model, complaints are de facto handled in a similar way due to the constitutional guarantees.

Supervision of healthcare in the Åland Islands is complex, since some aspects such as administrative measures regarding deprivation of liberty and supervision of licensed healthcare staff belongs to Finland's competence. In 2009, the supervision of healthcare carried out by the regional authorities in Finland was however delegated to the Åland Islands. Since 2026 when the regional supervisory authorities were abolished, the central supervisory authority in Finland has regained the responsibility for supervision of all aspects of healthcare in the Åland Islands belonging to Finland's competence. This has resulted in lack of clarity, especially when it comes to complaints regarding healthcare and social care in the Åland Islands.

O43: Legal Challenges of Uterus Transplantation: the French Case

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Background

Uterus transplantation (UTx) is an innovative surgical procedure enabling women with absolute uterine factor infertility to experience pregnancy and childbirth. Unlike other organ transplants, UTx is temporary and intrinsically linked to assisted reproductive technologies (ART). Although the procedure remains experimental in several countries, including France, increasing clinical success suggests that UTx may eventually transition into routine clinical practice. However, its unique reproductive purpose and temporary nature raise complex legal and ethical questions that existing frameworks governing organ transplantation and ART may not fully address.

Methods

This study provides a legal analysis of the French regulatory framework applicable to UTx, examining how current legislation on organ donation and ART might apply to this emerging practice. Particular attention is given to issues concerning donors and recipients, drawing on statutory law, bioethics legislation, and relevant doctrinal debates.

Results

Several legal challenges emerge from the intersection of transplantation law and reproductive medicine. Regarding donors, the legitimacy of uterus procurement from living donors raises questions due to the absence of a life-saving indication for recipients and the surgical risks involved. Additional issues concern the definition of the donor pool, including the role of family members, age limits, intra-couple donations, and the possibility of altruistic donors. Symbolic and psychological implications – particularly in mother–daughter donations – further complicate regulatory considerations.

Recipient-related issues arise primarily from the reproductive aim of UTx. Unlike other organ transplants, UTx culminates in childbirth, raising societal questions about eligibility for motherhood. Aligning recipient criteria with those governing ART may offer regulatory coherence, particularly regarding age limits and access for single women or female couples. Emerging possibilities – such as UTx in transgender women or men – also highlight tensions between technological feasibility and current legal restrictions on ART. Finally, the temporary nature of UTx introduces unique legal concerns, including the obligation to remove the graft after childbearing and the implications of a recipient's refusal to undergo explantation.

Conclusions

UTx challenges traditional distinctions between transplantation and reproductive medicine. Its integration into healthcare systems will likely require specific legal provisions ensuring consistency with existing ART regulations while addressing the distinctive ethical and societal implications of this reproductive transplantation technique.

O44: Legal Issues in Designing and Executing Master Observational Trials

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Abstract

Master observational trials are a cutting-edge trial design that focuses on advancing precision medicine. It is a new master protocol at the core of which is the hybridization of the power of master interventional trials with the richness of real-world data. Substantively, as one of the important facets of such a trial, it combines diverse datasets of differing sensitivity over a long time period, thereby creating significant interferences with the right to privacy.

This contribution examines the legal issues associated with organizing and executing a master observational trial. This includes questions pertaining to the participant's self-determination, data protection, and the use of AI technology. In doing so, it draws on lessons from the PROMOT project, in particular the rare disease-related trials and associated features, such as a limited number of datasets, data transfer outside the EU, and the development of AI for a rare disease patient group.

This work has been supported by the PROMOT project. It has received funding from – the Canadian Institutes of Health Research (CIHR), and in partnership with L'Agence Nationale de la Recherche (France), Health Research Board (Dublin, Ireland), Instituto de Salud Carloss III (Spain), IRSC – IG, Swedish Research Council (Sweden), and Swiss National Science Foundation (Switzerland) – partners of the EJP RD, under grant agreement No 02424-000.

O45: Legal Justification of Ventilator Reallocation in Triage: Patient Autonomy, Criminal Liability, and Health Law Perspectives

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Abstract

The reallocation of ventilators through triage constitutes the discontinuation of a medical treatment or intervention that has already been initiated. In Japan, such acts have traditionally been approached with extreme caution because replacing a ventilator by a physician may constitute, or at least potentially constitute, the crime of homicide under criminal law. Consequently, the legal system has been highly restrictive in recognizing the permissibility of such actions. However, in situations of severe shortages of medical resources, such as those experienced during the COVID-19 pandemic – which forms the central focus of this study – it is evident that discussions on the legal justification of ventilator reallocation are indispensable. Such discussions must consider not only criminal liability but also broader questions of patient autonomy, human dignity, and the legal regulation of scarce medical resources.

This study examines the legal justification of ventilator reallocation (triage decisions) from a health law perspective. When a patient's explicit will cannot be confirmed, the study considers: (1) justification based on a conflict of duties and (2) justification based on necessity. When the patient's will is clearly expressed, the study considers: (3) justification based on withdrawal of treatment and (4) justification based on clinical guidelines. These four theoretical approaches provide a framework for evaluating the legality of triage decisions while balancing physicians' duties with the protection of patients' rights.

With regard to these four theoretical frameworks, the study analyses the current state of medical practice and refers to relevant legal developments, including the German Triage Act (Triage-Gesetz) enacted in November 2022 and the subsequent ruling of the German Federal Constitutional Court in September 2025 declaring the legislation unconstitutional. It also refers to the draft "Joint Guidelines on the Withholding and Withdrawal of Life-Sustaining Treatment in Emergency and Intensive Care," released in February 2026 by

four Japanese academic societies, including the Japanese Society of Intensive Care Medicine.

Based on these analyses, the study proposes a practical legal framework together with a decision-making flowchart that can guide physicians in real clinical situations. By taking into account patient autonomy, the presence or absence of a patient's expressed wishes, and the urgency of medical treatment, the study aims to develop a highly practical model for triage decision-making. Ultimately, the study seeks to clarify under what circumstances and types of decisions physicians would not incur criminal liability when reallocating life-sustaining treatment in conditions of medical scarcity.

O46: Liability of the Manufacturer of Artificial Intelligence-Based Medical Devices Under the Directive (EU) 2024/2853

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Abstract

Directive (EU) 2024/2853 on liability for defective products marks a milestone in adapting the law to technological changes, especially the rise of Artificial Intelligence (AI) in healthcare. This article analyses the liability of AI manufacturer in a clinical setting under this new legal framework, highlighting the framework's main innovations and limitations and considering emerging solutions such as the SafeCaring project.

SafeCaring, funded by the European Regional Development Fund, illustrates the transformative potential of AI in clinical settings. It is an integrated system to support healthcare interventions which, using natural language processing techniques, enables the automation of care records and generates alerts for necessary interventions, helping to reduce the administrative burden on staff and prevent adverse events.

In this context, the Directive attains particular significance by clarifying and broadening the concept of "product", thereby enabling AI-driven software and medical devices (including clinical decision support systems, assisted diagnostic tools and solutions such as SafeCaring) to fall within the scope of strict liability. This entails that manufacturers (including software developers) may be held liable for damages caused to patients regardless of fault.

However, in the medical field, assessing a defect is particularly complex, as the expected safety for AI systems must be measured against high standards of health protection and human life. The dynamic nature of these systems, which are frequently subject to updates and continuous learning processes, raises questions about the temporal limits of liability, especially when the manufacturer maintains control over the system's operation or evolution after it has been placed on the market.

The Directive also strengthens injured persons by easing the burden of proof. It introduces rebuttable presumptions regarding the defect and the causal link. These solutions are particularly relevant in clinical settings, where algorithmic opacity and technical complexity make it challenging to show the origin of harm, especially in cases of AI-assisted diagnostic or therapeutic errors. Furthermore, the expansion of compensable damages (including the loss or corruption of data and certain non-material damages) is vital in a sector where the integrity of clinical information is essential.

Despite these advancements, significant challenges remain, notably regarding the interface between the manufacturer's liability and the liability of healthcare professionals. It is concluded that Directive (EU) 2024/2853 represents a decisive step in protecting patients against the risks of AI use, without, however, fully solving the difficulties inherent in its application within the healthcare domain.

O47: Limits on Interference with Patients' Liberty: Restraints and Involuntary Hospitalization in the Jurisprudence of the European Court of Human Rights

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Abstract

Interference with the liberty of patients, particularly through involuntary hospitalization or the use of restraints, represents one of the most sensitive areas at the intersection of health law and human rights law. Such measures are often justified by the need to protect the patient or others; however, they simultaneously raise serious concerns regarding human dignity, personal autonomy, and physical integrity. This presentation examines the limits placed on such interferences by the jurisprudence of the European Court of Human Rights ("the Court") under the European Convention on Human Rights ("the Convention").

The analysis focuses primarily on the interpretation of Articles 3, 5, and 8 of the Convention. Article 3 establishes an absolute prohibition of torture and inhuman or degrading treatment, which may be relevant in cases involving excessive or disproportionate restraints. Article 5 regulates the lawful deprivation of liberty, including the detention of "persons of unsound mind," and the Court's case-law has developed substantive and procedural conditions that must be satisfied for such detention to be compatible with the Convention. Attention is given to the criteria formulated in the landmark judgment *Winterwerp v. the Netherlands*, which require the existence of a true mental disorder established by objective medical expertise, a disorder of a kind or degree warranting compulsory confinement, and the persistence of that disorder. Article 5 also guarantees procedural safeguards, including the right to judicial review of detention. The analysis further considers Article 2 of Protocol No. 4 to the Convention, which protects freedom of movement and may become relevant in situations where restrictions imposed on patients do not amount to a deprivation of liberty within the meaning of Article 5 but nevertheless significantly limit their ability to move freely. The distinction between "deprivation of liberty" and "restriction of movement" therefore constitutes a key analytical

issue in the Court's jurisprudence, as it determines the applicable level of the Convention protection and the corresponding procedural safeguards.

The analysis is complemented by references to the Convention on Human Rights and Biomedicine, particularly its principles of human dignity, the primacy of the human being, and the requirement of free and informed consent. Building on this framework, the presentation argues that the Court's jurisprudence establishes a multilayered system of substantive and procedural safeguards governing interferences with patients' liberty and clarifies how different levels of coercive practices in healthcare – from restrictions on movement to full deprivation of liberty – should be assessed within the Convention framework.

O48: Medical Populism and Health Law

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Abstract

It might seem that technological and medical advances, the ability to make use of vast amounts of health data to develop diagnostic and therapeutic tools and procedures, and the growth of the biotechnology industry would mean that, in 21st-century Europe, standards for the protection of patients' lives and health would only continue to rise. Meanwhile – paradoxically – widespread access to information and social media or the continuing lack of an effective cure for major diseases (e.g. cancer) have led – alongside medical progress – to the emergence of an increasing number of social movements that openly question the state of current medical knowledge and the established standards of healthcare provision. The COVID-19 pandemic, whilst uniting European countries towards the creation of the European Health Union, has simultaneously acted as a catalyst for the development of such social movements.

These social phenomena, combined with the difficult (on many levels) situation in healthcare systems and widespread fear of diseases or further epidemics, have also led to the emergence of a new phenomenon, which I would call medical populism: the instrumental exploitation of medical (health) law regulations, issues relating to human health and the 'fight against disease', as well as fear of threats to life and health to gain public support, f.e. with the aim of gaining or retaining power. Medical populism is also based on resentment towards the existing legal order and contemporary standards of medical knowledge and practice. Those in authority, politicians or members of smaller social groups: using medical populism: manage and exploit public emotions regarding health and illness to shape social behaviour.

However, the phenomenon of medical populism carries with it significant risks that European countries (and others) must face today: an increased risk to the life or health of people who – following the rhetoric of medical populism – may reject current medical knowledge, difficulties or the inability of public authorities to implement appropriate public health measures and policies, the creation and introduction of health law regulations whose application may

actually create or exacerbate threats to the health of members of society or their fundamental rights and freedoms.

In my presentation, I would like to explore the phenomenon of medical populism, with particular emphasis on how it manifests itself during the drafting, creation and application of medical (health law) legislation and how the legal systems in European countries can currently attempt to respond appropriately and effectively to this phenomenon.

O49: Mental Health Protection: the Perspective of Polish Legal Regulations

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Abstract

The COVID-19 pandemic has revealed catastrophic weaknesses in the international community's ability to respond to the pandemic. The main goal of the presentation will be to find answers to the question of what impact the pandemic had on mental health. For example, on May 13, 2020, the United Nations UN) published a report on the relationship between COVID-19 and mental health. UN experts explain that during the COVID-19 pandemic, many people experienced a feeling of anxiety caused by social isolation, fear of infection, and loss of family members. At the same time, a huge number of people have lost or are at risk of losing their jobs and, consequently, their sources of income.

Legal awareness regarding mental health protection is important. So, what can a lawyer do to positively change the state of psychiatry in Poland? This is just one of many questions I am looking for answers to.

The topic of my speech will be to present the legal aspects of mental health protection in Poland, in particular from the perspective of the rights of patients in a psychiatric hospital. I would like to focus on the patient's right to consent to hospitalization, the patient's right to information and the legality of direct coercion. In addition, I would like to discuss the position and competencies of the Ombudsman for Patients' Rights of the Psychiatric Hospital. In my opinion, it is an interesting institution that supports patients. The main goal of the Ombudsman for Patients' Rights of the Psychiatric Hospital in Poland is to protect the rights of people using health services provided by the psychiatric hospital. During my presentation, I will present the results of my research and analysis of reports of the Polish Patient Ombudsman for 2019–2025 in the mental health field. Because I will analyse data for several years, including during the pandemic, it will be possible to demonstrate existing similarities and differences regarding mental health protection in Poland.

The purpose of my speech is also to contribute to the international discussion about the future of mental health care from a legal point of view. I am a lawyer in Poland, so I will refer to the experience from my country, but I am convinced that the exchange of knowledge and experience with people from other countries can have a positive impact on legal regulations and standards regarding mental health protection.

O50: Navigating Restrictions on Smartphones and Social Media for Children: Balancing Privacy and Mental Health Protection

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Abstract

There is no doubt about the urgent need to promote safer and healthier use of digital tools by children and adolescents, with the protection of their mental health placed at the forefront. With the increasingly widespread use of social media, messaging applications, and chatbots, children and young people are exposed to content harmful to their mental health, as well as to disinformation and online hate. Growing awareness of this phenomenon has sparked discussions on the need to introduce legal restrictions, oversight mechanisms, and protective measures for children and adolescents.

The aim of this presentation is to encourage debate on the positive obligations of states – reconstructed on the basis of international human rights standards – to protect mental health, and to explore optimal legal solutions. The analysis applies the legality–necessity–proportionality test required in the context of limitations on the right to private and family life (protected under Article 8 of the European Convention on Human Rights) and freedom of expression (Article 10 ECHR). This test is used to assess measures designed to reduce risks to mental health, ranging from bans or significant restrictions on smartphone use in schools to statutory minimum age limits for access to social media.

As the presentation will argue, certain factors are particularly relevant to the balancing exercise and the choice of legal response. First, the role of scientific and medical evidence concerning the impact of digital tools and digital environments on the health and well-being of children is crucial. Second, cultural and societal contexts may influence both perceptions of acceptable levels of restriction and the shape of the legal framework. Finally, attention must also be paid to non-legal measures that may – or should – support and complement legal norms.

The analysis will cover recent regulations and legislative proposals, including the Australian "social media minimum age" model, which imposes on platforms an obligation to take "reasonable steps" to prevent individuals under the age of 16 from holding accounts (in force since 10 December 2025), as well as a draft Polish law restricting access to mobile phones and social media.

O51: Non-Pecuniary Damages for Violation of Patient's Rights as an Instrument of Protection of Patient's Autonomy: the Cases of Poland, France and Italy

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Abstract

One of the key issues in contemporary medical law is the possibility of compensating patients for non-pecuniary harm suffered as a result of a violation of their rights. The question is whether a violation of a patient's rights can constitute an independent (unrelated to bodily injury) basis for compensation and how the structure of such a claim affects respect for patient autonomy. These considerations are grounded in a comparative analysis of the legal systems of Poland, France, and Italy. These systems represent three distinct traditions of medical law while sharing a common anchor in the Council of Europe framework and European Union law. A comparison of these systems therefore allows for an assessment of whether legal pluralism across European countries leads to unequal protection of patients, even though they are formally entitled to the same scope of autonomy.

Under Polish law, there is a clear statutory basis for claiming non-pecuniary damages for violations of a patient's rights, even in the absence of bodily injury. Such protection is afforded to the patient through the application of provisions governing the protection of personal rights. In France, case law has given rise to the well-established concept of loss of chance. More recently, the concept of *préjudice moral d'impréparation* has gained prominence; it is designed to compensate for harm resulting from a medical risk that materialised and for which the patient was unable to prepare. In the Italian system, by contrast, in cases of health damage (*danno alla salute*), the patient is required to demonstrate that, had he been properly informed, he would most likely not have consented to the medical intervention. In other cases – concerning damage arising from a violation of the right to self-determination (*danno da violazione del diritto di autodeterminazione*) – the patient must demonstrate that he has suffered

specific harm. The Italian system thus imposes significantly higher evidentiary requirements than its Polish and French counterparts.

The analysis leads to the conclusion that all three systems formally recognise far-reaching patient autonomy as an important legal value. However, they differ considerably in how they enable patients to seek redress for violations of their rights. This presentation will therefore contribute to the broader discussion on how a developing Europe can and should protect patients' rights in cases unrelated to personal injury, and how to reconcile the diversity of legal traditions with the demand for extensive and equal protection of patients across the continent.

O52: One Health Legal Framework: Integrated Governance and Efficiency in Romania's Health System Reform

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Abstract

As Europe faces increasingly complex and interconnected health challenges – from antimicrobial resistance (AMR) to emerging zoonotic diseases and environmental risks – the legal frameworks governing public health must evolve beyond traditional administrative boundaries. The One Health approach, which integrates human, animal, and environmental health governance, has increasingly gained recognition at European level, particularly within the emerging framework of the European Health Union. This paper examines whether the current Romanian legal framework is capable of operationalizing the One Health concept and explores the opportunity and effectiveness of introducing an integrated governance mechanism within the ongoing reform of the national health system. The analysis draws on applied expertise and data collected since 2015 within the "One Health Academician Nicolae Manolescu Strunga" Association, a leading civil society voice in the One Health domain. Using doctrinal legal analysis combined with institutional and policy evaluation, the study examines the structural fragmentation of Romanian legislation governing public health, veterinary health, food safety, and environmental protection. The findings indicate that the coexistence of sectoral regulations, although extensive, does not provide an effective integrated command mechanism capable of addressing cross-sectoral health risks. The institutional isolation of data, limited coordination among authorities, and the absence of a unified governance structure hinder the operationalization of the One Health approach. The reform of Law No. 95/2006 on healthcare is a key opportunity to introduce in Romania mandatory governance standards that would transform One Health from a policy principle into an operational legal framework. The success of this transformation depends on the adoption of imperative legal provisions – mandatory governance standards under the One Health

umbrella – to ensure firmness of implementation both as a transversal policy and an operational standard. Accordingly, the study explores the potential efficiency of a dedicated inter-sectoral coordination mechanism, strategically positioned at a central administrative level to ensure transversal oversight and eliminate institutional silos. The paper supports the need for a dedicated EU One Health Directive, in line with the recommendations of the Scientific Advice Mechanism (SAM), arguing that the transition from soft policy coordination to binding legal obligations is essential to ensure effective implementation and accountability in integrated health governance.

O53: Opt-In or Opt-Out? Secondary Use of Genomic Data Under the European Health Data Space Regulation

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Background

The European Health Data Space (EHDS) Regulation establishes the first EU-wide framework for secondary use of health data, with provisions applying from 2029 and an extended timeline to 2031 for categories deemed particularly sensitive, including genomic, epigenomic, and other -omic data. While the regulation seeks to create a harmonised architecture for secondary use of such data for research, innovation and public health, key elements remain unsettled. Member States retain discretion to impose stricter national safeguards, including the potential for opt-in requirements for genomic data, rather than adopting the opt-out model that applies to other health data under the regulation.

Aim

This study examines the legal scope of Member State discretion to adopt such stricter measures and safeguards, and how different national choices could affect interoperability and cross-border research collaboration within the EHDS secondary-use infrastructure (including HealthData@EU).

Methods

We report on doctrinal analysis of the EHDS Regulation (with emphasis on Articles 51, 53, 68–71 and 105), read alongside the General Data Protection Regulation's (GDPR) rules on special categories of personal data. We also draw on ongoing EU-level implementation work, including TEHDAS2 consultations and draft guidance, to identify governance mechanisms being operationalised and debated (with a focus on the Netherlands as a case study).

Analysis

Three implementation pathways are considered: (1) an opt-out model aligned with the broader secondary use framework; (2) an opt-in model for genomic data and other categories of data deemed sensitive; and (3) hybrid approaches that differentiate consent requirements by data sensitivity (e.g., whole-genome sequencing versus other -omic data) or research context (e.g., public health versus commercial). Each pathway carries distinct consequences: stricter consent requirements may reduce participation and create incomplete datasets, while more permissive opt-out models facilitate scientific and commercial research but could impact public trust and threaten the legitimacy of the secondary-use framework itself. Divergent national choices also risk further fragmentation among Member States, undermining the cross-border interoperability the EHDS is designed to achieve. Emerging insights from EU-level implementation processes, including TEHDAS2 consultations and engagement with policymakers and researchers, further inform how these trade-offs may materialise in practice.

Conclusion

As Member States approach critical decision points of national implementation, choices regarding genomic data consent will shape not only domestic research capacity but the viability of the cross-border data ecosystem the EHDS envisions. Clarifying the available legal options and their trade-offs is essential as Member States prepare to shape genomic research governance in Europe.

O54: Patents over Emerging Health-Technologies & the Right to Science: Reconceptualising Incentives and Access Using a Solidarity-Based Framework

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Abstract

Scientific research has led to development of groundbreaking health-technologies (such as medicines and therapies), with transformative impacts for patient health and lives. Under the contemporary health innovation model, many novel health-technologies will be protected by patents and other intellectual property rights (IPRs). IPRs have an important role in driving scientific development, however, their exclusionary nature means that despite health-technologies being theoretically available to treat certain conditions, in some cases the use of IPRs can contribute to high costs and supply issues. Accordingly, patients may be unable to access these technologies.

Where patients are unable to access the benefits of science this is in direct contravention of the right to science under Article 15 (1)(b) of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 15 (1)(b) provides a right for everyone "[t]o enjoy the benefits of scientific progress and its applications." However, Article 15 (1)(c) provides a right to "benefit from the protection of the moral and material interests resulting from any scientific … production". Thus, there is a tension within Article 15 around the need to protect rightsholders interests in the creation of new health-technologies and the need to enable access to technologies. Focusing on this tension, we argue that whilst there is considerable protection for rightsholders interests, the right to access the benefits of science has received scant attention, and in many cases Article 15 (1)(b) has limited teeth. We argue this is not just in contravention of human rights obligations; it could also jeopardise future and ongoing scientific development. In this context, taking contemporary cell and gene-based therapies as a case study, we argue that public participation including by the altruistic donation of biomaterials, participation in research, and clinical trials

is critical for the development of such therapies. Yet, such participation may be jeopardised if the public feel they cannot access benefits of science.

Against this backdrop, drawing on Prainsack and Buyx's conception of solidarity, critical to which is the notion of reciprocity in the obligations/duties of parties/participants, we examine the extent to which a solidarity based lens could be used to reimagine the current health innovation model in a manner which equitably balances the human rights protected by Article 15 (1)(b) and (c) ICESCR. We argue that applying such a framework may help to inculcate a greater balance between incentives for health innovation and the need for downstream patient access to health innovation.

O55: Patient's Rights in the Nordic Countries

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Abstract

All the Nordic countries have patient rights laid down in their legislation. Finland (1992) was an early adopter with a dedicated act, followed later by Iceland (1997), Norway (1999), and Sweden (2014). In Denmark, patient rights are incorporated into a broader legislative framework ("Sundhedsloven").

A number of issues are addressed in the legislation of all the Nordic countries, such as the right to health services, quality requirements, informed consent, and confidentiality. Nordic legislation partly builds upon one another, and the preparatory works frequently refer to other Nordic countries. Moreover, the Nordic countries share many characteristics in terms of social organization and population. In this respect, a high degree of parallelism in the regulatory frameworks can be expected.

At the same time, there are differences between the regulations, both at a more overarching level and in terms of details. The Norwegian Patients' Rights Act stands out due to numerous amendments and, over time, increasingly detailed provisions. There are also differences related to the scope of application, that is, whether the regulation should encompass patients in a narrow sense or also users of health and care services.

A challenge inherent in all regulation concerns the relationship between concrete provisions and more discretionary terms and expressions, and this is also reflected in patient rights legislation. In all the Nordic countries, the public health care system plays a strong role, but there are differences regarding freedom of choice among private service providers. All the countries regulate information and participation, but there are differences concerning the role of close relatives.

A controversial issue in several of the Nordic countries is access to health care services for individuals without legal residence, where different solutions have been chosen. All the Nordic countries are either members of the EU (Sweden, Denmark, and Finland) or affiliated with the EU through the EEA Agreement (Iceland and Norway). The directive on the application of patients' rights in cross-border healthcare (2011/24/EU) is therefore binding on all the Nordic countries, but has been implemented in different ways. If we look at

the regulation of children, there is considerable variation among the Nordic countries in terms of the age limits chosen and how children are to be included and informed.

Through a comparison of the Nordic countries, the aim is to identify common features and differences, both with regard to the substance of the rules and regulatory techniques.

O56: Pharmaceutical Law Beyond the Product: Rethinking Medicines as Regulatory Ecosystems in the EU

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Abstract

European pharmaceutical law has traditionally been structured around the regulation of medicinal products as clearly defined, discrete objects subject to market authorisation, safety, and quality requirements. This product-centred paradigm has provided a stable foundation for ensuring high standards of public health protection across the European Union. However, it is increasingly challenged by profound transformations in healthcare, biomedical innovation, and digitalisation.

Contemporary medicines are no longer merely physical products but components of complex regulatory ecosystems that integrate multiple layers of governance and functionality. These include health data infrastructures, digital technologies such as artificial intelligence, supply chain dynamics, pricing and reimbursement mechanisms, and interactions between public authorities and private actors. As a result, the traditional boundaries of pharmaceutical law are becoming blurred, revealing growing fragmentation between legal regimes, including pharmaceutical regulation, data protection law, competition law, and national health system governance.

This paper argues that the evolving nature of medicinal products requires a fundamental rethinking of pharmaceutical law in the European Union. It examines how developments such as personalised medicine, advanced therapy medicinal products, and data-driven healthcare challenge existing regulatory categories and expose structural limitations in the current legal framework. Particular attention is paid to the disconnection between EU-level market authorisation and national-level decisions on pricing and reimbursement, which significantly affect patient access to medicines.

The analysis further explores the implications of this transformation for core principles of European health law, including human dignity, patient autonomy, and privacy. It highlights how the increasing reliance on health data and digital tools reshapes the meaning of these principles in practice, while also raising new ethical and legal concerns.

By conceptualising medicines as regulatory ecosystems rather than isolated products, the paper proposes a shift towards a more integrated and systemic approach to pharmaceutical law. Such an approach would enhance regulatory coherence, better align innovation with equitable access, and support the development of resilient and patient-centred health systems in an evolving Europe.

O57: Pregnancy Termination in Cases of Fatal Fetal Abnormalities: Between the Woman's Right to Health Protection and the Child's Right to Dignified Death

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Abstract

Legislation prohibiting the termination of pregnancy on embryopathological grounds aims to protect the right to life of every foetus, however impaired, yet fails to account for foetal life marked by escalating suffering and birth leading swiftly to death. Such suffering is documented in post-mortem examinations, including somatic markers of chronic stress, and is self-evident in conditions such as osteogenesis imperfecta.

A woman's decision to terminate a pregnancy on grounds of foetal abnormality serves not only her mental and physical health but is frequently motivated by the intention to prevent suffering during the foetal period and after birth. To reduce such a decision to convenience or avoidance of responsibility would be a serious distortion. The foetus's capacity to feel pain is routinely cited as an obstacle to termination, yet the suffering caused by congenital defects receives no equivalent consideration. Since many adults prefer a swift death to prolonged painful dying, there is no rational basis for refusing to apply the same reasoning to foetal well-being.

A caesarean section performed to protect maternal health and ensure a healthy birth must be assessed differently from one carried out solely because a child affected by a lethal defect is incapable of natural delivery – a procedure that serves no therapeutic purpose for the child and exposes the woman to risks far greater than an early termination. Failure to weigh these factors appropriately warrants classification as inhumane treatment: the infliction of unnecessary suffering without therapeutic justification.

A woman seeking an abortion thus serves the foetus's interest alongside her own, sparing it suffering that cannot be compensated for by a brief life spent in even greater pain. Restrictive anti-abortion legislation takes none of this into account, remaining indifferent to the suffering of both woman and foetus as it

intensifies in utero. The gestational viability threshold is inapplicable where a lethal defect precludes survival.

Embryopathological abortions may therefore be understood as a humanitarian safeguard against suffering that is medically and humanly unnecessary. If euthanasia of gravely suffering, helpless individuals unable to request it themselves is regarded as an act of mercy subject to appropriate legal safeguards, this reasoning applies with even greater force to the foetus before birth. That interest in protection from unjustified suffering can only be realised by a woman consenting to an intervention that humanely ends foetal life condemned to inevitable death, before the full extent of that suffering is experienced.

O58: Preventive Germline Genome Editing Through the Lens of the European Convention of Human Rights

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Abstract

Germline genome editing (GGE) entails genetic modification of the germline, either through alterations to reproductive cells or to the early embryo. Germline modifications are, in principle, heritable. Because of its heritable and intergenerational character, GGE has long raised profound ethical, legal, and societal concerns, particularly in light of unresolved safety issues. As science progresses, there is an increasing call for a prudent pathway forward in the regulation of GGE techniques.

This presentation focuses on GGE aimed at preventing genetic conditions across successive generations. Scientific advances are most developed with regard to the prevention of monogenic conditions, making this the most likely first safe reproductive application of GGE. Because this application would be directed at improving human health, operate within a limited scope, and typically involve restoration of a wild-type gene rather than introducing novel genetic material, it is less controversial than other potential uses of GGE. These features raise the question whether, once safety is demonstrated, a differentiated regulatory framework compatible with European human rights law could be feasible.

The presentation first proposes a definition of 'preventive GGE'. Building on the 2022 evaluation of Article 13 of the Oviedo Convention, it argues that reference to international, scientific, and peer-reviewed databases can provide a precise and objective delineation of 'genetic condition'. This conceptual clarification helps avoid regulatory arbitrariness and aims to enable consistent identification of the techniques that fall within the preventive scope.

Secondly, the presentation analyses the human-rights implications of preventive GGE and explores the extent to which its future regulatory acceptance could be compatible with the standards of the ECHR. The analysis addresses

both basic research on embryos *in vitro* and potential reproductive applications of preventive GGE, drawing on key doctrines developed in the ECtHR's case law, including the margin of appreciation, evolutive interpretation, and European consensus. It further builds on existing ECtHR jurisprudence from which principles relevant to preventive GGE can be derived, including the Court's approach to State obligations in contexts of scientific uncertainty; an issue of particular relevance when moving from basic research to reproductive use. The presentation also considers the influence of international regulatory instruments, such as the Oviedo Convention and the Clinical Trials Regulation, on the Court's reasoning.

It can be concluded on a preliminary basis that neither a prohibition nor an authorisation of preventive GGE is *a priori* incompatible with the ECHR, provided that specified conditions, discussed in the presentation, are satisfied.

O59: Prioritisation in Times of Scarcity: New Legal Limits on Political Discretion

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Abstract

Today, many European countries are confronted with a persistent and growing imbalance between the high demand for healthcare on the one hand, and the insufficient available resources on the other. An imbalance that can be ascribed to multiple societal changes, including the aging population, the increasing healthcare costs and recurring economic and financial crises. A difficult situation that results in waiting lists growing ever longer.

To address these growing waiting lists, states often adopt prioritisation mechanisms that determine the order in which individuals gain access to the required healthcare. These mechanisms have traditionally been considered as a purely political matter. Consequently, they have largely been excluded from the legal sphere, and legal scholarship on prioritisation mechanisms in healthcare remains scarce. Over the past two decades, however, a noticeable shift has occurred within the judiciary, demonstrating an increasing willingness to review these prioritisation mechanisms. Leading to a judicialisation of this traditionally considered political matter.

This contribution analyses the implications of this judicialisation for the prioritisation of the access to healthcare, trough specifically the judgments, decisions and conclusions of the European Committee of Social Rights (ECSR). Based on the European Social Charter, the ECSR has namely determined situations in which states are obliged to establish prioritisation mechanisms, and developed boundaries that must be respected when designing and implementing these mechanisms.

The core insight of this analysis is that five principles shape the establishment and design of prioritisation mechanisms in the access to healthcare. First, prioritisation cannot completely impede the access to healthcare. This access must namely remain effective and affordable. Second, the omission or establishment of prioritisation may not impair human dignity. Third, when the competence to establish prioritisation mechanisms is decentralised, a reasonable uniformity of treatment must be secured. Fourth, decisions concerning

these mechanisms must be subjectable to appeal before an independent authority. In that regard, free legal aid must be available to persons without resources. Finally the omission or establishment of prioritisation mechanisms cannot result in a discrimination.

Therefore, when addressing the challenge of increasing demand and limited healthcare resources through prioritisation mechanisms, states will only retain their traditionally established discretion if they comply with these five principles.

O60: Prioritization Decisions in Swedish Health Care During Crisis or War

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Abstract

Prioritization is a constant feature of the healthcare system. Neither financial, material nor human resources are infinite. Prioritization is therefore inevitable. However, the need for prioritization becomes particularly evident when something unexpected occurs, leading to a rapid rise in demand for resources that far exceeds the supply. Such situations can be described as crises. Crises can occur both in peacetime and during wartime. In Sweden, the government has in recent years taken several initiatives to strengthen crisis and war healthcare planning in various ways. For example, since 1 January 2026, Swedish legislation requires that in cases of crisis or war, only healthcare necessary for saving the life and health is provided. It is crucial for both society's resilience and for the lives, health, and survival of individuals that the healthcare system is sufficiently prepared to cope with difficult times.

My newly started doctoral project focuses on prioritization decisions in Swedish healthcare during crises or war. By placing the prioritization decisions within this context, the aim is to identify and analyse potential risks related to both an acceptable minimum level of healthcare, and discrimination and disadvantages affecting certain groups. I intend to analyse prioritization decisions at both the regional level, through decisions made by regional policy bodies, and the clinical level, through decisions made by healthcare professionals.

In this presentation, I will focus on the prioritization decisions made at the regional level by either a regional council, a regional executive board or a regional policy committee. I will address questions regarding the definition of a prioritization decision, whether certain typical decisions should or should not be defined as prioritization decisions, and what legal consequences may arise.

O61: Procedural Misalignment and the Burden of Proof in the EU Joint Clinical Assessment

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Introduction

The implementation of the EU Health Technology Assessment Regulation (HTAR 2021/2282) has introduced a "PICO explosion" that threatens the efficiency of the Joint Clinical Assessment (JCA). While the JCA aims to reduce duplication, the lack of a cohesive approach across 27 Member States has resulted in a fragmented scoping phase where a single technology must address a multiplicity of national research questions.

Methods

This research examines the emerging misalignment between the JCA's 100-day compressed timeline and the "dossier explosion" caused by divergent national PICO (Population, Intervention, Comparator, and Outcome) requirements. Drawing on the 2025–2026 implementation wave, the analysis will focus on the "resource burden" placed on Health Technology Developers (HTDs) who must adapt evidence packages at short notice – often within 7 to 30 days – following late-stage scoping adjustments.

Results

The PICO requirements reveal that the JCA's attempt at standardisation is frequently undercut by national HTA bodies, such as Germany's G-BA, which may require supplementary data not captured in the JCA's consolidated PICO scope. This study identifies a critical "scoping gap": while the JCA accepts experimental Indirect Treatment Comparison (ITC) methodologies (e.g., unanchored comparisons), these same methodologies are often rejected outright by conservative national agencies, leading to a double-jeopardy of evidence submission.

Discussion

To mitigate these administrative and legal risks, HTDs must pivot from Clinical Trial Excellence to Regulatory Intelligence Consolidation. I argue that the strategic imperative for 2026 is the early use of PICO Simulation and Joint Scientific Consultations to align EMA trial designs with HTA comparator needs. Without a formal rebuttal phase in the scoping process to ensure the feasibility of PICO definitions, the JCA risks becoming a "dossier trap" that delays rather than expedites patient access across the European Union.

O62: Public Health and Freedom of Speech in the Online Environment: Conflicting Laws in the United States and Europe

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Abstract

On December 23, 2025, the US government prohibited five Europeans from entering the US. Those five individuals included former EC official Thierry Breton, one of the drafters of the EU's Digital Services Act. The other four were leaders of non-governmental organisations working to prevent hate speech and disinformation.

US President Trump's Secretary of State issued a press statement describing those five Europeans as "radical activists," and "agents of the global censorship-industrial complex." In response, European leaders supported the EU's digital rules, and stated that the US was trying to undermine Europe's ability to decide on rules for its digital space.

Both the US and Europe support the general principle of freedom of speech, and both recognize that there must be some exceptions or limitations on that general principle. However, the laws of the US and Europe are very different about where to draw the line on those exceptions, especially in regard to hate speech and disinformation that could harm the public.

Under US law, the First Amendment to the Constitution provides very strong protection for freedom of speech. Even statements that could be described as "hate speech" are protected by the Constitution, unless they fit within one of the narrow exceptions such as incitement to violence. In contrast, the laws of the EU and its Member States criminalise hate speech on the basis of specific grounds such as race, religion, or ethnic origin.

In addition, the EU's Digital Services Act requires large online platforms to remove or limit access to "illegal content." That EU law will promote public health by requiring platforms to remove or limit access to hate speech which falsely blames immigrants for causing or spreading disease. That EU law also requires platforms to identify and mitigate the risk of negative effects on

protection of public health. Mitigating those risks is likely to require removing or labelling disinformation about the safety and effectiveness of vaccines.

The differences between US and European laws are the basis of an ongoing controversy over regulation of large online platforms, which are based in the US and provide services to people in Europe. The evolving regulatory framework will reflect the need to adapt to technological change, while protecting against threats to public health and safeguarding individual rights.

O63: Putting the Child First? Constitutional Silence and the Child's Best Interests in Assisted Reproduction: the Lithuanian Case

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Abstract

This presentation examines how constitutional qualification influences the position of the child in cases concerning assisted reproduction. In Lithuania, on 10 April 2025, the Constitutional Court adopted a ruling addressing this field. In that decision, assisted reproduction is conceptualised primarily as a healthcare service linked to the right of equal access to healthcare. The child who may be born as a result of such procedures is not explicitly addressed as a constitutional subject in the Court's reasoning.

The analysis explores the structural consequences of qualifying assisted reproduction as a healthcare service. Constitutional adjudication does more than resolve disputes; it shapes legal understanding by selecting the categories through which issues are framed. When assisted reproduction is approached mainly as a matter of healthcare and reproductive freedom, the reasoning naturally centres on patients, medical professionals, and the proportionality of regulation. The child remains present only indirectly, as a background figure within a framework focused on adult rights.

An alternative analytical perspective is proposed. Assisted reproduction may also be understood as a legal mechanism participating in the construction of filiation and origin. Unlike most healthcare services, it is intrinsically linked to the emergence of a new legal subject whose identity and parentage are influenced by the regulatory model chosen by the state. From this perspective, the central question is whether constitutional reasoning should recognise that regulation in this field inevitably affects the future child's interests, including the interest in identity.

The analysis outlines the reasoning adopted by the Lithuanian Constitutional Court, examines how the qualification of assisted reproduction as a service structures the scope of constitutional review, and reflects on the notion of constitutional silence and its implications for the principle of the best interests of the child.

More broadly, it asks whether constitutional courts should explicitly incorporate the child's perspective in assisted reproduction cases, even where legislation is primarily articulated in terms of adult rights.

O64: Reforming Disability Care in Times of Budgetary Constraints: Navigating Between Social, Civil and Disability Rights

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Abstract

Driven by the aim of complying with the UN Convention on the Rights of Persons with Disabilities (CRPD), many European countries such as Germany, Belgium and the Netherlands, have introduced personalised budgets and demand-driven forms of disability care.

In Flanders (Belgium), however, this reform has collided with a widespread and growing tendency of limited public resources and budgetary constraints. A trend that creates a mismatch between high demand and insufficient supply, resulting in extremely long waiting lists for access to these budgets.

In response to this problem, Flanders has introduced a new reform designed to provide more people with access to appropriate care, within the limits of existing budgetary realities. However, implementing such a reform without affecting those who already receive a budget or those who will apply for care in the future is impossible.

This contribution uses the challenge encountered in Flanders as a starting point to reflect on the role of fundamental rights and the limits they impose in reforming disability care in times of budgetary constraints. More specifically, it considers social rights (in particular the right to non-regression in the Belgian Constitution), civil rights (notably the right to property and the prohibition of discrimination), and disability rights as they arise from the CRPD.

The key takeaway is that, while the right to non-regression leaves governments some room to introduce reforms that disadvantages the position of both current and future budget beneficiaries, the right to property offers much stronger protection to those already receiving a budget. As a result, reforms may create a two-tier system in which acquired rights are preserved while new applicants face less favourable conditions. This raises questions about the justification for treating persons with similar care needs differently, and, ultimately, about the compatibility of such reforms with the CRPD: can regression affecting persons with disabilities ever be justified?

This contribution is relevant to anyone with a research or policy interest in reforms in the care sector in the broad sense, as it first elaborates the meaning and scope of the social, civil and disability rights at issue. Second, it identifies and analyses the constraints these fundamental rights impose on the reform of disability care. Finally, it emphasises the degree of policy discretion available to the legislature when reforming disability care in times of budgetary constraints.

O65: Restricting Access to One's Health Records: For the Patient's Good?

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Abstract

Many jurisdictions have long-established laws that impose various restrictions on individuals from accessing their own health records. One form of restriction arises where it is considered by a doctor or other healthcare professional that the contents of a health record may pose a risk of serious harm to the patient. Focusing primarily on the jurisdiction of Ireland, this paper critically assesses the legal frameworks imposing access restrictions and in so doing, considers whether it is 'for the patient's good', reflecting a kind of benevolent paternalism that appropriately balances patient autonomy and safety, or instead may imperil the mutual trust, reciprocity, and transparency necessary for the healthcare professional-patient relationship to flourish. In other words, are there really compelling patient safety and ethical considerations to justify this access restriction, or is it an (increasing) anachronism in law that now requires thoughtful and thorough reassessment?

O66: Rethinking Governance Imaginaries for Health-Data-Based Research

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Abstract

Contemporary medical research is increasingly data driven. Development of precision medicine and medical AI require access to vast volumes of health and related data as well as tissue samples for genome sequencing and molecular analyses. The European Union regards data as a core strategic resource and seeks to unlock its full potential through various regulatory frameworks such as the GDPR, the EHDS, the AI Act, and, most recently, the Digital Omnibus proposal. At the same time, the EU also emphasises a human-centric approach, grounded in respect for human dignity and privacy, to ensure trust and accountability.

This paper examines whether existing European regulatory frameworks succeeds to adequately balance these objectives and safeguard the rights and freedoms of data subjects in contemporary medical research. It compares the regulation of traditional biomedical research involving human participants with that of research based solely on health and other data, highlighting discrepancies in ethical oversight, scientific quality assurance, and public engagement. The analyses shows that while data-driven research is often justified by public interest, this concept remains underdefined and insufficiently aligned with patients' and citizens' expectations.

The paper argues that current legal instruments do not fully reflect the broader range of human rights at stake, including dignity, integrity, and protection against discrimination. The paper calls for a recalibration of safeguards and governance mechanisms, including stronger interdisciplinary ethical oversight, clearer criteria for assessing public interests, and mechanisms for meaningful citizen participation. Such recalibration would not only strengthen the protection of data subjects but also better align with existing human rights standards and evolving socio-technical imaginaries, ensuring that health data research advances both scientific progress and societal values.

O67: Bridging Policy and Tradition: The Role of Tort Law and Private Law Theory in Transatlantic Regulation of Medical AI

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Abstract

Governments across the world are taking action to regulate artificial intelligence (AI) technologies. In some places this has led to detailed ex ante rules, whereas other countries or regions are taking a more relaxed approach. Regardless of the chosen framework, the AI regulation toolbox involves elements of both public and private law. The former, because the decision to regulate is taken on a governmental level and may involve governmental regulatory oversight; the latter, because the chosen framework may involve adapting private law rules and if not, the existing private law framework still continues to apply in situations where new technologies are involved. Whereas policy considerations lie at the heart of public law, certain private law theories resist extra-legal arguments, adhering instead to values such as tradition and coherence. Although, in practice, pluralist approaches are often adopted to allow flexible adaptation to contemporary societal attitudes towards justice, tradition and doctrine continue to frame the conceptualization of responsibility. Therefore, while various AI regulations may employ similar language, their embedding in distinct, living frameworks with different path dependencies may, over time, lead to diverging interpretations. For example (and, for brevity, omitting nuance), EU-level regulation is usually based on a policy-oriented rationale, whereas Member State (private) law may rely on a more doctrinal rationale. This creates complexities where EU legislation is interwoven with national law. In the UK, the reluctance to introduce binding AI regulation may place greater emphasis on private (tort) law, which appears to (at least academically) favour doctrinal reasoning, resisting the law-and-economics approaches viewed more favourably in the US. The goal of this project is to analyse (i) the extent to which the AI regulatory landscape in the EU, UK and US depends on or defers to private law rules and, where it does, (ii) how and to what extent it (explicitly or implicitly) relies on concepts influenced by regional differences in private law theory and (iii) what the effects of these are on risk distribution and legal incentives for risk mitigation, specifically for AI used in the healthcare sector.

This important aspect of AI regulation has been underinvestigated, as current research predominantly focuses on effectiveness and gaps of either public law or private law frameworks instead of their interface.

This project runs from March to August 2026. As the first results are expected by midsummer 2026, it would be a great opportunity to discuss those in September at EAHL 2026.

O68: Rethinking Healthcare Providers' Liability for Damages: the Concepts of Anonymous and Organisational Fault

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Abstract

The complexity of the treatment process is constantly increasing. This, however, results in a mismatch between the normative framework of tort liability and the nature of therapeutic practice. In many cases, it is, indeed, difficult to identify the exact perpetrator, which constitutes one of the prerequisites for attributing liability. Consequently, due to evidentiary challenges in this regard, the injured party is often unable to successfully claim compensation for damage caused by improper treatment.

In situations where the perpetrator cannot be identified, certain legal systems, including the Polish one, have introduced the concepts of anonymous fault and organisational fault, or analogous normative frameworks. These concepts allow liability to be attributed to a legal person for damage caused by the acts or omissions of an unnamed member its staff (anonymous fault) or management (organisational fault). They also provide for additional evidentiary facilitations for the claimant (e.g. with regard to the required standard of proof for establishing a causal link), arising from the inability to identify the perpetrator, in order to ensure effective legal protection of the patient.

However, these concepts also give rise to a number of concerns. For example, under Polish law, they lack statutory regulation, which creates uncertainty regarding the scope of the parties' evidentiary obligations in proceedings. As a result, in many cases the expansion of evidentiary facilitation leads to a situation in which the healthcare provider has no real possibility of adducing counter-evidence, resulting in the effective absolutisation of its liability.

This paper aims to present the concepts of anonymous and organisational fault as possible responses to the challenges faced by patients pursuing claims in an era of increasing complexity of the treatment process. It will also highlight the problems stemming from the lack of statutory recognition of these

normative constructions, particularly the lack of clarity concerning the parties' evidentiary obligations, which gives rise to legal uncertainty. Accordingly, the paper seeks to spark discussion on adapting traditional models of attributing tort liability for medical damage to the challenges posed by the development of medicine.

O69: Rethinking Incentives in Medical Innovation

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Abstract

Repurposing and Advanced Therapy Medicinal Products (ATMP's) are areas of drug development in which non-commercial institutions make significant contributions to pharmaceutical innovation. This, first, calls for nuance in the dominant narrative of private industry as the primary innovative force; and second, for reconsideration of how a more diverse innovation ecosystem is sustained, for example in terms of incentives and research infrastructure.

Recent research on repurposing (i.e. exploring new uses of already approved drugs) shows that public research institutions are responsible for a substantial share of innovative activity, including both early- and late-stage clinical trials (Liddicoat *et al.*, 2022). In the domain of ATMPs, public and academic institutions account for a significant proportion of early-phase trials, while private industry continues to sponsor most later-stage development (Priesner and Hildebrandt, 2022). One explanation may be that ATMPs are often highly personalized and/or target ultra-rare diseases. This, in practice, means that administration through pre-marketing authorization routes: such as clinical trials, compassionate use, or hospital exemption: becomes the primary pathway to patients. In this context, non-commercial actors frequently assume roles as innovators, manufacturers and users of these treatments.

This presentation will first review ATMP clinical trials conducted in the European Union (EU), focusing on the relative roles of industry and academic developers across different phases of development. Second, it will consider whether existing theories on the drivers of non-commercial repurposing also apply to non-commercial and academic ATMP development. Finally, it will

explore the implications of academic ATMP development for incentives and regulatory design.

J. Liddicoat, K. Liddell, J. Darrow, M. Aboy, M. Jordan, C. Crespo and T. Minssen, 'Repositioning generic drugs: empirical findings and policy implications', *IIC-International Review of Intellectual Property and Competition Law* 53(9) (2022): 1287–1322.

C. Priesner and M. Hildebrandt. 'Advanced therapy medicinal products and the changing role of academia', *Transfusion Medicine and Hemotherapy* 49(3) (2022): 158–162.

O70: Rethinking Patient Autonomy: the Limits of Informed Consent in AI-Enhanced Healthcare

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Abstract

The integration of artificial intelligence (AI) into healthcare decision-making challenges the traditional legal and ethical foundations of informed consent. Built on assumptions of transparency, comprehensibility, and interpersonal communication, informed consent becomes increasingly difficult to operationalise in contexts where clinical recommendations are shaped by complex, data-driven, and partially opaque systems, whose outputs may resist meaningful explanation and verification within existing clinical and legal standards.

This presentation argues that AI does not merely complicate the process of obtaining consent, but destabilises its underlying normative structure. The distinction between decision-support, advisory, and autonomous AI systems reveals varying degrees of epistemic opacity and shifts in responsibility, thereby exposing a structural tension between the legal requirement of informed decision-making and the practical limits of explainability in AI-assisted medicine, raising questions about what it means for consent to be truly informed and voluntary.

The analysis combines doctrinal and theoretical approaches to European health law, situating these developments within a broader regulatory landscape. Against this backdrop, the challenges posed by AI expose tensions between technological innovation and the protection of fundamental rights, particularly human dignity and autonomy. They also reveal inconsistencies in how existing legal frameworks – including, in particular, data protection regimes and emerging AI regulation at the EU level – address the role of AI in clinical settings.

The presentation proposes a principle-based reconstruction of informed consent that accounts for the epistemic limits introduced by AI while preserving its core protective function. Rather than relying solely on enhanced

disclosure obligations, it advocates for a more relational and context-sensitive model of consent, one that shifts the focus from the quantity of information provided to the conditions under which understanding and trust can be meaningfully established in AI-mediated healthcare. In doing so, it contributes to the ongoing redefinition of patient rights in contemporary European health law.

O71: Rethinking the Governance of Neurodata in Brain-Computer Interfaces: Limits of Consent and Comparative Insights from European and Quebec Law

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Abstract

Brain-computer interfaces (BCIs) rely on the collection and processing of neural data, the unique characteristics of which challenge established legal frameworks for data protection. Situated at the intersection of healthcare, technological innovation, and fundamental rights, this "neurodata" raises specific concerns regarding autonomy, personal integrity, and privacy.

This contribution seeks to analyse the limitations of current legal regimes applicable to neurodata, drawing upon the RE-MOVE project, a Quebec-based research initiative aimed at restoring movement in individuals living with paralysis through the use of neuromodulation technologies, specifically BCIs.

While neurodata may, in principle, be classified as sensitive personal data, its processing remains governed by traditional mechanisms, notably the prior determination of purpose and informed consent. However, these mechanisms appear increasingly inadequate given the evolving applications of BCIs and the inherent specificities of neurodata.

On one hand, the advancing capabilities of decoding technologies make it difficult to exhaustively identify the information that might be extracted from neural signals, including content of which the individual themselves may be unaware. This uncertainty undermines the validity of consent, as it becomes impossible for the individual to make a fully informed decision regarding future and indeterminate uses. On the other hand, risks associated with device security, particularly regarding unauthorised access to data or system control, raise unprecedented challenges affecting both privacy and physical integrity.

Adopting a comparative perspective, this analysis draws on European legal frameworks and brings them into dialogue with legislative and doctrinal developments in Quebec law. It aims to contribute to the discourse on applicable protection mechanisms by proposing governance models better suited to the

evolving, uncertain, and highly sensitive nature of neural data. Specifically, the analysis examines the relevance of more dynamic consent models, such as meta-consent.

Ultimately, this contribution interrogates the necessary balance between the protection of fundamental rights and the individual and collective benefits associated with neuroreadaptation technologies, within a landscape defined by rapid innovation in healthcare.

O72: Shifting Geographic Frontiners of Health Law: the EU as a Global Health Actor in the Pandemic Agreement Negotiations

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Abstract

Years after COVID-19, the political and social desire to move beyond the pandemic is palpable. Yet, the likelihood of more pandemics in the not-so-distant future remains a certainty. In this backdrop, international efforts to strengthen pandemic preparedness have continued at the WHO – most notably through the recently concluded Pandemic Agreement. Negotiations for an annex on pathogen access and benefit sharing (PABS) are still ongoing, leaving critical questions unresolved.

Through a qualitative documentary analysis of the EU's publicly available textual proposals and drafting suggestions, this paper examines its role as a global health actor in the Pandemic Agreement negotiations. While itself not a formal member of the WHO, the EU has played a pivotal role in shaping the Pandemic Agreement. It was instrumental in initiating the call for a binding international instrument on pandemic preparedness and response. Further, it was also able to secure formal participation within the Intergovernmental Negotiating Body set up to draft the agreement. In this context, the EU has been described as an "agenda-setter", expanding its "normative power" by promoting the multilateral order under the WHO framework.

This paper evaluates the EU's negotiating positions against a comprehensive analytical framework, namely its stated objectives under the 2022 Global Health Strategy, its internal health competences, and applicable international human rights law. Central to this analysis is whether the EU's negotiating position in the Pandemic Agreement aligns with its declared objective of improving equitable access. Preliminary findings reveal important tensions. While the EU emphasizes "solidarity and equity, and the respect of human rights" (2022 EU Global Health Strategy), its negotiating positions reflect a market-oriented approach that threatens to undermine global equitable access to medical countermeasures. This is evident, for example, through the EU's push for technology transfer to be limited only to voluntary and mutually agreed

terms, as well as its reluctance to endorse binding benefit-sharing obligations linked to pathogen access.

This paper interrogates the EU's role within the evolving frontiers of health law, with a specific focus on the fast-eroding geographic frontiers of global health law in the context of pandemic preparedness. With the US withdrawing from the WHO, this paper argues, that it is all the more crucial for the EU to reassert its commitment to multilateralism and global health governance to bring about equitable health outcomes.

O73: Structural Injustice, Children's Rights, and Iatrogenic Harm in Anti-FGM Interventions: a Health Law Perspective

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Abstract

Efforts to eradicate female genital mutilation (FGM) are firmly embedded within global health, human rights, and legal frameworks. However, recent scholarship highlights significant unintended consequences of current interventions, raising critical questions for health law. This paper examines how anti-FGM policies and practices may generate structural injustice, undermine children's rights, and produce iatrogenic harm, drawing on three recent studies focusing on Sweden and the broader global context.

The first study analyses genital examinations conducted in Sweden between 1982 and 2022 in cases of suspected FGM. Although grounded in a legal framework designed to protect children, these practices reveal patterns of disproportionate targeting of migrant communities. In many cases, girls undergo invasive examinations without clear medical necessity. While legally sanctioned, such interventions risk violating principles of bodily integrity, proportionality, and non-discrimination, illustrating how lawful decisions can produce structural injustice within healthcare systems.

The second study examines the role of special representatives for children in FGM-related cases, focusing on the child's right to be heard. Despite strong legal protections, children's participatory rights are often constrained in practice. The special representatives – intended to safeguard the child's interests – may instead reinforce procedural formalism, where children's voices are marginalized. This raises important concerns about how children's rights are operationalized, particularly in sensitive and culturally complex contexts.

The third study provides a critical analysis of the global anti-FGM campaign, including approaches that may produce unintended harms. These include the reinforcement of stigmatizing narratives about affected communities, and erosion of trust between patients and healthcare providers. The strategies can silence alternative perspectives and hinder culturally sensitive, harm-reduction-oriented approaches.

Taken together, these studies reveal a tension at the heart of health law: the obligation to protect individuals from harm versus the risk of harm caused by protective interventions themselves. The Swedish case demonstrates how legal mandates can lead to intrusive clinical practices, while the analysis of children's rights exposes gaps between legal ideals and procedural realities. The global perspective further situates these issues within broader patterns of epistemic injustice and policy-driven harm.

The paper argues for a more reflexive and context-sensitive approach. This includes stricter safeguards for medical examinations and stronger implementation of children's participatory rights. By foregrounding the interplay between law, ethics, and clinical practice, this paper contributes to European health law debates on how to design interventions that are legally justified, and also equitable, proportionate, and respectful of the rights and dignity of those they aim to protect.

O74: Telemedicine Advertising and the Country-of-Origin Principle – How Far Does It Reach?

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Abstract

Although digital health services are increasingly crossing national borders, there is still controversy over which rules apply to telemedicine. This also concerns the advertising of these services. In the case of *DrSmile v Austrian Dental Association* (Case C-115/24, 11 September 2025), the ECJ interpreted the second sentence of Article 3(d) of Directive 2011/24/EU on patient rights in cross-border healthcare, in conjunction with Article 3(1). 3(1) of the E-Commerce Directive (2000/31/EC) as a broad country-of-origin rule for telemedicine services. According to this interpretation, cross-border telemedicine is deemed to be provided in the Member State of establishment, and this principle extends beyond reimbursing costs. Before the DrSmile judgment, attempts by the host state to extend advertising rules to foreign service providers were frequently discussed in the context of Article 5(3) of Directive 2005/36/EC on the recognition of professional qualifications, which has a narrow scope of application. Regarding this, the ECJ ruled in the *Konstantinides* case (C-475/11) that it applies only to provisions directly related to the practice of medicine and patient protection. Rules on fees and advertising were considered to fall outside of its scope.

In an Online-Diagnose case, the German Federal Court of Justice (BGH, 26 March 2026, I ZR 118/24) stayed proceedings regarding the German ban on advertising remote treatments, referring the question to the ECJ of whether extending the provision to telemedical services provided by foreign doctors is compatible with Article 56 TFEU. The BGH takes the view that, notwithstanding

the decision in the DrSmile case, advertising regulations in the field of telemedicine are not subject to the provisions of the Patient Mobility Directive. Instead, the provisions of the E-Commerce Directive 2000/31/EC are decisive. Article 3(4)(a), first subparagraph, second indent of this directive provides that Member States may take measures where necessary to protect public health.

Against this background, this presentation will examine the relationship between the two directives in the context of cross-border telemedicine services, exploring whether there remains room for the application of the country-of-destination principle in the context of the freedom to provide services under Article 56 TFEU.

O75: Tensions Between the Health and Human Rights Protection and the Economic Paradigms: the Legal Framework of Surrogacy in Europe

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Abstract

Reproductive rights are among the most debated issues in Europe. While the Court of Justice of the European Union has applied the freedom of movement on reproductive issues contributing to the recognition of "Rainbow Families", Member States claim that these issues are related to national identity and should be left out of the scope of European Union law. Besides, under the principle of conferral, the European Union's competences in the field of health are limited. In this context, the law on surrogacy, like other bioethical issues, is perceived by States as a matter closely connected to the fundamental rights and principles of the legal order. This is why it varies significantly. Most of countries do not authorise surrogacy. Others tolerate surrogacy, that is, in the absence of explicit prohibitions, those who engage in it are not prosecuted and may even be able to establish legal parentage of the child born through surrogacy. Surrogacy is explicitly legal in the United-Kingdom, Portugal, Greece, Cyprus and Ukraine. Because of theses differences, surrogacy often takes place in a cross-border context.

This paper focuses on the laws of France and Greece. France provides a typical example of a State that prohibits surrogacy. Under the French Civil Code, surrogacy agreements are declared null and void. Greece, by contrast, is a State that permits surrogacy and strictly regulates it. In Greece, surrogacy agreements are considered as legal under certain preconditions (the most important being the non-commercial character of a surrogacy arrangement). Although French and Greek law regulate surrogacy differently, both justify their legislation using similar arguments, such as the need to protect human dignity, public order, and public health, as well as the rights of those involved in the surrogacy arrangement, particularly the rights of the child and of the surrogate woman. In addition to that, they are both aiming at preventing the creation of a national or a cross-border surrogacy market and, thus, the commercialisation of the human body and the human reproductive system. This paper examines

whether French and Greek legal frameworks genuinely provide protection against commercialization, as they claim. Addressing this issue requires not only a thorough analysis of both legal frameworks but also consideration of the fact that both states are members of the European Union and that surrogacy arrangements may be regarded as constituting an economic activity. Consequently, surrogacy may fall within the scope of economic freedoms and the principles underlying them.

O76: The Artificial Therapist and the Missing Clinician: Generative Artificial Intelligence and Access to Mental Health Care for Minor Patients

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Abstract

Across Europe, children and teenagers face severe and growing obstacles to accessing professional mental health care: structural shortages of child psychiatrists and clinical psychologists, geographic inequities, and cost barriers leave large numbers of minors without timely support. Into this gap, generative artificial intelligence tools – artificial therapists that simulate empathic understanding and therapeutic continuity – are being deployed with increasing frequency, without clinical supervision, regulatory authorisation, or child-specific safeguards. This paper examines its legal and bioethical dimensions, focusing on the dignity and therapeutic autonomy of the minor and the equal access imperative.

The paper first argues that using generative artificial intelligence as a substitute for inaccessible human mental health care raises equality concerns under European Union non-discrimination law and the positive obligations under Article 8 of the European Convention on Human Rights. These tools do not fill the access gap equitably: they disproportionately replace human care for children from disadvantaged socioeconomic backgrounds, thereby entrenching rather than remedying structural inequality in child mental health protection.

The paper then develops a dignity-based legal argument grounded in Article 1 of the European Union Charter of Fundamental Rights, Article 3 of the European Convention on Human Rights, and the Oviedo Convention on Human Rights and Biomedicine. It contends that an artificial intelligence system simulating empathy without disclosing its non-human nature raises a cognisable legal concern about deception and integrity when the interlocutor is a minor in psychological distress. Basing on relational autonomy theory and the vulnerability doctrine, the paper argues that authentic autonomous choice requires conditions free from manufactured emotional dependency, conditions that current frameworks do not guarantee.

Examining the current European legal framework, the paper identifies four critical gaps: the absence of a child-specific sub-category within the Artificial Intelligence Act's high-risk classification, the inadequacy of generic disclosure obligations in emotionally adaptive contexts, the absence of a justiciable right to human mental health care as a floor entitlement, and the fragmentation of national regulatory approaches.

The paper concludes with the following targeted proposals: a dedicated child mental health conformity assessment pathway under the Artificial Intelligence Act, a prohibition on dependency-engineering design in artificial intelligence tools accessible to minors, recognition of the right to a human clinician, and addressing the dignity and equal access rights of minors in artificial intelligence-mediated health contexts.

O77: The Causality Brake in Health Data: Reconciling the EHDS Access Regime with the CJEU's Evolving Interpretation of Article 15 GDPR

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Abstract

As Europe moves toward a unified European Health Data Space (EHDS), the legal framework for patient data access is undergoing a significant transformation. This paper aims to define the "causality brake" emerging from recent jurisprudence of the Court of Justice of the European Union (CJEU), specifically the Right of Access under Article 15 of the GDPR.

While the EHDS seeks to empower data subjects through enhanced digital portability and seamless access to electronic health records, the CJEU has begun defining limits to the "free of charge" principle when the request's purpose deviates from data protection objectives, such as in medical malpractice litigation. This creates a potential tension between the broad accessibility goals of the EHDS and the restrictive interpretations of the GDPR intended to safeguard the administrative resilience of healthcare providers.

This article explores whether the EHDS truly bestows the data subject with more robust rights, or whether the "causality brake" represents a systemic shift that might restrict the practical exercise of these rights in a pluralistic legal landscape. By analysing this relation in the context of health data access and its possible limitations, this study offers critical insights into the future of health data governance, balancing individual autonomy with the sustainability of European health systems.

O78: The Challenge of Informed Consent in AI-Supported Healthcare

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Abstract

This presentation addresses the demands that AI-assisted clinical decision-making places on the doctrine of informed consent. The latter requires that patients are fully informed about the nature of a medical procedure or intervention, the potential risks and benefits, and any available alternatives. It aims to respect patient autonomy, promote trust in the patient-provider relationship, and safeguard against unethical practices. There are some well-known challenges to achieving genuinely informed consent, including a lack of understanding due, for instance, to the use of complex jargon and varying levels of literacy, and the existence of power asymmetries between patients and providers. Yet the integration of AI into clinical decision-making introduces an additional layer of complexity to these challenges. In many cases, the reasoning behind an AI-generated recommendation is difficult to explain because of the complex computational architectures that underpin these systems. This "black box" problem creates a challenge for informed consent: if clinicians themselves cannot fully understand how a system arrives at a particular recommendation, it becomes difficult to communicate the basis of that recommendation to patients in a meaningful way. The problem is further complicated by the fact that explainability in AI is not always straightforward to achieve. In some contexts, making a model more interpretable may come at the cost of reduced accuracy, potentially leading to worse medical outcomes for patients. Even when developers provide information about their algorithms or offer post hoc explanations, these disclosures may omit key data features or weightings that influence the final output, leaving the underlying reasoning difficult to interpret. As a result, clinicians may face legal and ethical dilemmas when advising patients about the use of AI-assisted recommendations in their care, particularly where the reliability of a system must be justified without a clear understanding of how its outputs are produced. Given this background, the presentation will examine the literature on explainable AI in

order to assess what kinds of explanations current systems can realistically provide and whether these explanations satisfy the requirements of informed consent. The analysis will also consider possible interpretations of the doctrine of informed consent to accommodate the growing role of AI in clinical practice: for instance, by reconsidering the type of information required for consent to be informed, such as providing higher-level information about the reliability or success rates of an AI system rather than detailed explanations of its internal functioning.

O79: The EU and Global Health: Evolution and Recent Developments

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Abstract

The European Health Union is a set of initiatives adopted by the European Union (EU) since 2020 in response to the COVID-19 pandemic aimed at ensuring better protection of citizens' health by strengthening health cooperation among EU Member States. Discussions concerning the European Health Union often focus on the actions taken by the EU at the internal level. These include, for example, measures related to preparedness and response to cross-border health, the reform of pharmaceutical legislation, the EU Beating Cancer Plan and the creation of the European Health Data Space.

Conversely, what has been termed the 'external dimension' of the European Health Union, that is, the strategy outlining the EU's role within the broader context of the global health order, has so far received relatively limited attention. This presentation aims to fill this gap, highlighting how a comprehensive analysis of the European Health Union cannot be separated from an examination, on the one hand, of the global health governance system within which the EU operates, and on the other, of the evolution of European policies regarding the role it intends to play in this context.

My presentation is organised as follows. First, I present the concepts of global health governance and global health law, and their interactions. Second, I focus on the key documents that guide the EU's action in the field of global health, whilst also considering how these have evolved. Third, I examine how the EU engages in global health discussions through its participation in international organisations such as the World Health Organisation (WHO) and political forums such as the G7 and G20, as well as its recent interest in strengthening health cooperation with the African Union. Fourth, I analyse the EU initiatives in response to the COVID-19 pandemic that are relevant to global

health, with particular attention to the Union's proposal to draft an international pandemic treaty. Finally, I offer concluding remarks on the relationship between the EU and the WHO, the possible motivations underlying the current EU approach to global health, and the question of the EU's competencies in the field of health.

O80: The EU and Its Package Reforms: a Healthy Approach for Healthy People?

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Abstract

In its Competitiveness Compass for the EU, the European Commission states that, to secure prosperity, it needs to increase innovation, referring amongst others to accelerated authorisations in a pharmaceutical context and to reducing the burden in the field of medical devices (COM(2025) 30 final, pp. 1, 18). The European Commission argues that innovation is amongst others constrained by regulatory burdens. To reduce these burdens, several new reforms (including so-called Omnibus proposals) have been put forward. However, how does this innovation focus align with the EU's pre-existing health protection aspirations?

This contribution focusses on the new EU Health Package and its interplay with other recent reforms like the Digital Omnibus proposal (COM(2025) 837 final). We posit that these initiatives risk reorienting EU health policy, as amongst others effectuated through digital governance, towards primarily economic aspirations at the expense of other health policy goals, *de facto* hollowing out the indirect health protection aims of the relevant EU laws concerned. The analysis includes a focus on the rules proposed for simplification of the Medical Devices Regulation and the AI Act (COM(2025) 1023 final), and the Biotech Act (COM(2025) 1022 final/2), and discusses these in the context of the digital single market rules, notably the AI Act, the GDPR and the EHDS Regulation.

The EU must ensure a high level of human health protection in defining and implementing its policies and activities (Article 9 TFEU, Article 168 TFEU and Article 35 EU CFR), as also expressed in secondary law (for example in recital 1 of the AI Act). This benchmark allows to verify whether the EU Health Package proposals combined, in the digital context, do not trade off health for the mere sake of innovation, thereby also considering the EU's competence to protect non-market values even in the context of internal market rules (De

Witte 2012). As a way forward, the analysis further explores the role of the 'Health in All Policies' principle as a policy framework for fostering a tighter alignment between innovation and health protection in the regulation of digital health, especially where EU legislation might not provide a sufficiently detailed, or desired, outcome. In short, this contribution aims to assess the impact of the most contemporary regulatory shifts in EU Health Law on EU health values.

O81: The European Health Data Space and Artificial Intelligence: Towards a New Regulatory Architecture of European Health Law

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Abstract

The accelerating use of artificial intelligence in healthcare is profoundly reshaping the role of data in medical research, clinical decision-making, and the organisation of health systems. Within the European Union, this transformation is closely linked to the emergence of the European Health Data Space (EHDS), which aims to establish a common legal framework for the access, sharing, and secondary use of electronic health data across Member States. While much of the current debate focuses on the technological opportunities and regulatory risks associated with artificial intelligence, the structural implications of the EHDS for the evolving architecture of European health law remain largely unexplored. This paper therefore asks how the interaction between the European Health Data Space and the regulation of artificial intelligence is reshaping the regulatory architecture of European health law.

The paper argues that the interaction between the EHDS and the regulation of artificial intelligence reflects a deeper transformation of the regulatory architecture governing health innovation in the European Union. In doing so, the analysis develops a regulatory and constitutional perspective on the EHDS as an emerging legal infrastructure for data-driven health innovation. By creating a structured framework for the secondary use of health data, the EHDS establishes new institutional mechanisms and governance structures that are likely to become central enabling conditions for AI-driven medical research and innovation. At the same time, this development raises fundamental questions concerning governance, accountability, and the protection of fundamental rights within an increasingly integrated European health data ecosystem.

The paper situates the EHDS within the broader evolution of the European Health Union and examines how the governance of health data interacts with other key elements of the EU's regulatory framework, including the General Data Protection Regulation, the Artificial Intelligence Act, and the regulatory

regime for medical devices. Particular attention is paid to the role of Health Data Access Bodies and to the emerging mechanisms governing the secondary use of health data for research and innovation.

From a broader constitutional and systemic perspective, the paper suggests that the EHDS should not be understood merely as a sector-specific data initiative. Rather, it represents a central component in the gradual constitutionalisation of European health governance. By reorganising the governance of health data at the European level, the EHDS contributes to the emergence of a new regulatory architecture that will shape the development and deployment of artificial intelligence within the European Health Union.

O82: The Invisible Architecture of Health Care Systems: Constitutional Guarantees, Administrative Procedures and Organizational Accountability

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Abstract

The right to health care is widely recognized as a fundamental constitutional guarantee in contemporary legal systems. Nevertheless, the practical realization of this right depends not only on its normative recognition, but also on the institutional and procedural frameworks through which it is implemented. While health law scholarship has extensively examined patients' rights, financing structures, and professional liability, comparatively little attention has been paid to the administrative procedures that operationalize these constitutional guarantees, revealing a significant research gap.

This paper examines the relationship between constitutional norms protecting the right to health care and the administrative mechanisms through which these norms are translated into practice. It argues that administrative procedures constitute the "invisible architecture" of health care systems, shaping access to services, determining entitlements, and influencing the effective protection of patients' rights. Building on the concept of procedural justice, the paper highlights the importance of fairness, transparency, and accountability in administrative decision-making processes within health systems.

Beyond procedural aspects, the paper also addresses organizational challenges within health care institutions, including fragmented decision-making structures, unclear allocation of responsibilities, and procedural inconsistencies. Drawing on insights from national practice to illustrate broader structural issues, the analysis demonstrates how such organizational deficiencies may limit the effective realization of the right to health care.

In this context, the paper introduces the concept of organizational accountability in health care, arguing that legal frameworks should move beyond an individualistic understanding of responsibility and more explicitly address systemic and institutional dimensions of governance. By linking constitutional law, administrative procedures, and organizational analysis, the paper

contributes to a more comprehensive understanding of health care systems as complex legal and institutional arrangements, emphasizing the need to strengthen procedural safeguards and address organizational shortcomings in order to ensure the effective protection of health-related rights.

O83: The Legalisation of Oocyte Donation in Switzerland: an Empirical Study with Clinicians

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Abstract

Medically Assisted Reproduction (MAR) is an umbrella term referring a range of treatments offered to overcome infertility. The most common one is In-Vitro-Fertilisation, a procedure whereby the gametes of infertile intended parents are extracted, fertilised in the lab, and then transferred to the uterus of the intended mother. An increasing number of couples need MAR to conceive: in some European countries (e.g. Denmark) up to 10% of all births are achieved through fertility treatment.

Given that MAR involves the creation, selection and use of embryos, it is heavily regulated throughout Europe, with very divergent rules on who can get access to fertility treatments and on what conditions. Even within the diverse European legal landscape, Switzerland represents a unique case. Indeed, not only are most types of fertility treatments not covered by public health insurance, but there are also other significant restrictions. The most notable one is a complete ban on the use of donated oocytes. This means that infertile couples within which the women are unable to use their own gametes (e.g. due to premature ovarian insufficiency or previous cancer treatment) must either forgo treatment, or seek care abroad in jurisdictions where oocyte donation is permitted. To address this issue, the Swiss government announced that oocyte donation will be legalised and a draft of the revised MAR law is in preparation. However, many doubts exist on how the concrete rules on oocyte donation should be designed and on how its legalisation will be implemented by Swiss clinics.

This presentation examines the prospective legalisation of oocyte donation in Switzerland by drawing on preliminary findings of an empirical study with fertility clinics. Using a semi-structured interview guide, interviews with 15 clinicians (as of April 2026) from all language regions of Switzerland (German, French and Italian) have been conducted and additional ones are planned. The interviews explore how physicians working in fertility clinics appraise the current Swiss legal framework for MAR and how they are preparing for the

upcoming legalisation of oocyte donations. Their views on rules about donor anonymity, payment for oocyte donation and the recruitment of donors are being collected and analysed thematically. After reporting the preliminary results of this ongoing empirical legal study, the presentation discusses how the emerging legal framework can be designed to ensure not only the formal legalisation of oocyte donation (law-in-the-books), but also its effective and ethically sound implementation in clinical practice (law-in-action).

O84: The Limits of Consent in AI-Driven Healthcare: a Fundamental Rights and Bioethical Perspective

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Abstract

The concept of consent plays a central yet evolving role in both data protection and healthcare regulation. While the two frameworks approach consent with different doctrinal emphases – fundamental rights protection in data processing and respect for patient autonomy in medical decision-making – they increasingly intersect in data-driven healthcare environments. In particular, the rise of personalised medicine and artificial intelligence (AI) in clinical settings creates situations in which both data protection consent and informed medical consent may be required simultaneously.

This presentation examines under which conditions consent may be considered genuinely valid in the context of experimental AI-assisted treatments. We argue that in situations involving severe or life-threatening condition – such as rare and aggressive cancers – the voluntariness of consent may be more theoretical than real. These patientsThis creates a heightened responsibility for healthcare professionals and researchers to communicate clearly, honestly, and in an accessible manner what is known about the treatment, what remains uncertain, and what risks are involved.

The analysis is enclosed within the EU Charter of Fundamental Rights and Human Rights frameworks applicable in the European context. A balance must be struck between the rights to personal data protection, respect for private life and access to information on the one hand, and freedom of research on the other,

> Particular attention is paid to the duty to inform, especially given the "black box" nature of many AI systems, which may hinder explainability and thus undermine informed decision-making. We explore potential tensions between data protection requirements (such as transparency and intelligibility) and medical law standards for patient information.

The balancing will be done using bioethical principles, namely patient autonomy and the right to self-determination, as constructed both in bioethical and (national) hard-law instruments. The construction of these rights and their application within the specific circumstances of treatment in the case exposed above will in our opinion provide a clearer picture on the safeguard of fundamental rights in cases where genuine consent can be deemed impossible to obtain.

Our key argument is that in AI-driven and high-risk clinical contexts, consent alone cannot bear the full weight of legitimacy: it must be complemented by strengthened duties of care, transparency, and substantive safeguards that genuinely protect patients in situations of profound vulnerability.

O85: The Meaningful Transparency: Rethinking Transparency in Artificial Intelligence-Based Depression Screening

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Abstract

Transparency has become a cornerstone of the EU AI Act. Yet in the context of AI-based depression screening, this commitment may rest on a fundamental misconception. A central question is what should count as "meaningful transparency" for systems that generate probabilistic depression risk scores based on the AI Act. How does this standard interact with information duties under the General Data Protection Regulation (GDPR)? At stake is the assumption, embedded in both frameworks, that AI outputs can be explained in ways that are both understandable to patients and clinicians and epistemically sound.

Consider AI-based systems that infer depression risk from behavioural and linguistic data, such as word choice, response patterns, or self-reported symptoms. The demand for transparency in this setting collides with the nature of psychiatric knowledge itself. Mental health assessment is not based on clear causal mechanisms but on probabilistic inference, interpretation, and context-sensitive judgment. Clinicians routinely rely on tacit knowledge that cannot be fully articulated, and diagnostic categories remain fluid and contested.

This creates a structural mismatch between legal expectations and clinical reality. While the AI Act and the GDPR presume that explanations can make system outputs understandable, depression screening tools produce results whose underlying logic cannot be communicated without either distortion or excessive complexity. In practice, "meaningful transparency" becomes difficult to achieve.

The risks are significant. Misleading explanations may generate unwarranted trust in system outputs, obscure inherent uncertainty, and shape clinical or self-assessment decisions in ways that are difficult to question. At the same time, overly technical disclosures may overwhelm clinicians, disrupt clinical workflows, and reduce the usability of these AI systems. In both scenarios, transparency obligations risk undermining rather than strengthening autonomy, trust, and professional judgment.

In this light, transparency can be better understood as a normative practice that must openly acknowledge epistemic limits rather than conceal them. Instead of prioritising explanation alone, greater emphasis could be placed on calibrated forms of disclosure that communicate uncertainty, enable contestability, and reflect epistemic humility.

O86: The Paradox of Compassionate Use: a Symptom of and a Treatment for the Ailments of Pharmaceutical Law in the European Union

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Abstract

Compassionate use is the administration of medicines that are not effectively in the market outside of clinical trials. It is one of the few exceptions to the MA rule, the keystone of EU Pharmaceutical legislation.

Member States can regulate it through two distinct legal bases: art. 83 of Regulation 726/2004, which is only for groups of patients and tends to be absent of MS legislation, and art. 5 of Directive 2001/83/EC. The legislation, however, varies wildly between MS, not only on requisites for use, but also in the initiator of the process and the (almost insignificant) role of manufacturers and patients. In all cases, it needs to go through a preliminary examination that tests that the patient fulfills the requisites and that the drug is as safe and effective as we can presume in the lack of all data.

The use of art. 5 as the legal basis shifts all regulatory responsibility to the MS, which moves us to the paradigm of health as a service, as we focus on the treatment dimension of the medicine. We, however, forget the product dimension, which creates a fragmented market, contrary to the objectives of the legislation. It is even clearer, as the exception is used to correct inefficacies of the system, in which not all medicines are effectively in the market in all Member States.

This presentation will reflect upon this paradox: the use of the most lenient legal basis lets MS have the most liberty in legislating, which creates a fragmented regulatory landscape and fragments the market. Using materials from the current research on the legislation of nine MS, the presentation explores how the system has created an unsolvable problem, which requires further harmonization.

However, and as this presentation will explore on its last part, the Pharma Package will suppose both a lost opportunity and a step in the wrong direction, as this remains virtually unchanged and the voluntary nature of the few harmonizing dispositions is further highlighted.

O87: The Patients' Rights Implications of Artificial Intelligence as a Decision Aid for Patients and Surrogates: a Scoping Review

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Introduction

Over the past decades, respect for patient autonomy has emerged as a fundamental patients' right and bioethical principle. Artificial intelligence (AI) is increasingly explored as a support to patients and surrogates when making healthcare decisions. AI decision aids (AI DA) can process a person's health or personal data to provide more tailored, accessible information on the benefits and risks of treatment options and help patients reflect on their values and preferences. Examples include models guiding patients through breast cancer treatment options or advance care planning. For patients lacking capacity make their own treatment decisions, AI models have also been suggested to aid surrogates in predicting an incapacitated patients' treatment preferences. Legal scholarship has analysed the potential rights implications of AI DA for clinicians, however less attention has been given to AI DAs for patients and surrogates. This review maps the existing literature, identifying gaps in legal analysis and proposing future research avenues.

Methods

A scoping literature review method was conducted. Included articles were analysed thematically using Atlas.Ti. Issues explicitly framed within European and international human rights frameworks were identified, as well as broader legal, ethical and practical perspectives. Potential implications for international and European patients' rights were derived and narratively summarized.

Results

The review demonstrates a significant gap in the legal literature. Only three articles analysed the use of AI DAs for patients in relation to international or European human rights law. No legal literature addressed the use of AI DAs for surrogates. By contrast, both developments received substantial analysis from medical and bioethical perspectives, particularly employing the principilism framework, raising questions of respect for patient autonomy, privacy and confidentiality, transparency and explainability, bias and impact on the doctor-patient relationship.

Discussion

This presentation will provide a comprehensive mapping of the potential patients' rights opportunities and issues related to the use of AI DA for patients' and surrogate. It highlights that such tools have the potential to further patients' rights to the highest attainable standard of health and self-determination. At the same time, use of AI in this way brings with it risks to, inter alia, confidentiality, privacy, non-discrimination and to gaining a patients' informed consent due to a lack of transparency. Future research avenues within European human rights law will be specifically highlighted, in particular Article 8 ECHR, the Biomedicine Convention and the AI Framework Convention on Artificial Intelligence.

O88: The Right to Be Treated by a Human: Human Rights Challenges in the Era of Medical Automation

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Abstract

The rapid integration of artificial intelligence (AI) into healthcare systems worldwide presents unprecedented opportunities for innovative diagnostics and treatments. However, it also presents critical human rights challenges. This paper explores the emerging discourse on human rights in the Era of AI, particularly examining whether patients are entitled to receive medical care from human professionals amid accelerating medical automation. It examines how algorithmic decision-making in diagnosis, triage, and treatment is related to core rights to autonomy, privacy, equality, and human dignity. Particular focus is given to the European context, where legal scholars and policymakers raise their voices to protect a "right to human care" as a necessary safeguard within digital health ecosystems. The paper analyses the implications of existing legal frameworks, including the EU's General Data Protection Regulation and the new AI Act, for informed consent, explainability, and the right to contest automated decisions. It further examines various legislative proposals and ideas protecting the need for human oversight and face-to-face interaction in healthcare. The study concludes that preserving the therapeutic alliance between doctor and patient is not only a matter of ethical preference, but a fundamental human rights concern requiring urgent regulatory attention.

O89: The Right to Explanation in Medical AI: Comparison and Impact of Existing Proposals

Krzysztof Kaźmierczak

Abstract

The European Union Artificial Intelligence (AI) Act unambiguously introduces the right to explanation concerning AI systems. Its Article 86 obliges the deployers of certain AI systems to provide those affected with clear and meaningful explanations of decisions shaped by these system.

This requirement naturally creates a particular challenge to explain AI in clinical or medical environment, particularly to layperson. The deep integration and complexity of such systems may result in the very relation between the doctor, the patient, and the health issue being affected – when the integration between AI and making decision could be understood to have achieved what is called an "Intimate fusion" where we almost talk about a single entity from the point of view of patient. Explainability

The purpose of the presentation would be to compare several models of explanation to compare them against existing legal requirement and challenges posed by the nature of medical fusage of AI systems, concept of meaningful human oversight and model explainability. Four models will be compared:

(1) Saliency method – which describes the areas (in medical imaging) and data which weighted most heavily for the algorithm;
(2) Feature importance – method which assigns a "weight" value to each input variable and this demonstrates the elements which influenced specific outcome;
(3) Counterfactual explanation – method explaining what value could have resulted in a different decision, on "what-if" basis;
(4) Anchors method – method which determines which conditions that, if met, guarantee a specific outcome of the AI's prediction regardless of other factors.

O90: Transparency as a Regulatory Frontier for Biobanks in the Era of the European Health Data Space

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Abstract

The European Health Data Space (EHDS) establishes enhanced requirements for transparency in the secondary use of health data, positioning it as a central regulatory concern. In this context, transparency extends beyond a mere informational obligation and constitutes a normative boundary at the intersection of data accessibility, privacy protection, and public trust.

Biobanks occupy a pivotal position within this evolving framework, prompting an assessment of the legal and governance mechanisms capable of ensuring effective transparency. Such mechanisms may include the introduction of mandatory data quality and utility labels, designed to standardize and communicate the characteristics, limitations, and fitness for purpose of datasets; the establishment of publicly accessible registers of data use, enabling oversight of data access and purposes of use; and the reinforcement of patients' rights to be informed about the processing of their data, particularly in the context of secondary use.

Furthermore, technical and organizational standards, including ISO norms relating to data quality, information security, and data governance, may contribute to the operationalization of transparency by facilitating auditability, comparability, and accountability. Increased transparency may also have implications for liability, as clearer documentation of data provenance, quality, and use can enable the attribution of responsibility for errors or inaccuracies in datasets.

However, the effectiveness of these instruments depends on their consistent implementation and integration into existing legal frameworks. A review of the current literature reveals significant gaps, particularly with regard to the practical implementation and enforceability of transparency measures.

Transparency thus delineates not only the opportunities but also the structural limitations inherent in the secondary use of health data.

In this regard, biobanks are required to reconsider their institutional role, transitioning from data repositories to entities co-responsible for the implementation and enforcement of transparency within the European health data ecosystem.

O91: Use of AI in Medical Decision-Making: is Trustworthy AI Sufficient to Satisfy the Ethics Principle of Disclosure?

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Background

Artificial Intelligence (AI) is stepping into healthcare in support of medical decision-making. Once AI is used in course of diagnosis or treatment, it inevitably breaks into patient-doctor relationship, and informed consent process, respectively. This raises a question whether trustworthy AI stands ethics principles of informed consent. Normative approach, conceptual analysis and legal pragmatism are used in analysis.

Computer science is concerned with technical quality and ethical responsibility, medical ethics centres on trust in patient-doctor relationship. Information disclosure, comprehension, competence, voluntariness and the consent itself are the five elements forming an ethically valid informed consent. Trustworthy AI is critical in medical research: patient safety and regulatory compliance depend on it. Reproducibility, traceability, explainability and transparency are the key elements trustworthy AI must have. Regulatory transparency requires high-risk AI systems should be "sufficiently transparent to enable deployers to interpret a system's output and use it appropriately" (Article 13.1 AI Act). While technical features are intrinsic in technology, explainability and/or interpretability should enable a human to predict a model's output by comprehending its inner workings. In contrast to interpretability as a general understanding how AI works (input, output, calculations), explainability refers to local post hoc interpretability, namely why AI has made the decision that affects that patient? Explainability closely relates to information disclosure and comprehension in medical ethics and transparency requirements under the GDPR. The data subjects have the "right not to be subject to a decision based solely on automated processing" (Article 22 GDPR) and must be provided with "meaningful information about the logic involved" (Articles 13.2.f; 14.2.g, and 15.1.h GDPR). Two ethics principles on explainability of medical AI evolved: tailoring the levels of explainability to the patient's needs, first, and to the scope of

a medical decision on a patient, second, "The greater the scope of a medical decision for a patient, the more normatively decisive the patient's insight into the factors relevant to this decision and their interpretation in the context of the patient's personal life."

It is to conclude that once AI is involved into medical decision-making, it is ethically binding to disclose the use of AI, as a minimum, and the more invasive and impactful the medical decision is, the more explainability the physician should be able to serve and stay responsible for the final decision.

O92: When Is Consumer Privacy Really a Business Priority? The Case of 23andMe

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Abstract

Our digital world is characterised by rapid technological change and an insatiable need by businesses to collect, share and reuse our personal data. From direct-to-consumer genetic testing (which allow consumers to order DNA tests online), to a wide range of wearable devices (tracking even how well we sleep) and other consumer focussed health offerings, what was once private may now be shared both with and without our knowledge.

Many offerings in the digital space rely on harvesting very sensitive data with businesses wanting to get to know us as intimately as possible. While several areas of law are relevant to the oversight of these industries, the international nature of many of these businesses and their reliance on opaque and lengthy terms and conditions has meant that much consumer focussed healthtech and other related technologies that collect sensitive information fall outside existing governance mechanisms.

While many industries have posed significant risks in terms of data reuse and the potential for data breaches, the 23andMe data breach should serve as a wake up call highlighting how easily things can go wrong, the real need for improving cyber security practices, and the limits in terms of consumer redress when things do go wrong. With the continuing expansion of Artificial Intelligence, there is an increasing likelihood that genetic data and a wide range of data that could be considered health data will be used in generative biology projects where we cannot fully appreciate what future risks this could pose for individuals, their families and larger communities to which they may belong.

This talk builds upon my previous work: 'Owning me, owning you – How private companies acquire rights in our most intimate data' in G Reynolds, A Mogyoros, and T Dagne (eds), *Intellectual Property Futures – Exploring the Global Landscape of IP Law and Policy* (University of Ottawa Press 2025); and the monograph *Buying Your Self on the Internet: Wrap Contracts and Personal*

Genomics (*Edinburgh University Press, Future Law series 2019*). Here, I will use the example of the 23andMe data breach to explore the risks which consumers may face when engaging with this industry and similar industries relying on sensitive data and make suggestions for reform.

O93: When Low Odds Must Be Taken: Probabilistic Risk Standards and the Criminal Liability of Physician-Guarantors in European Health Law

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Abstract

Medical decision-making is inherently probabilistic. Clinicians routinely act under uncertainty, balancing statistical evidence against the irreducible particularity of the individual patient. Yet criminal law has struggled to translate this probabilistic reality into coherent liability standards. This paper addresses one of the most pressing frontier questions at the intersection of criminal health law and risk theory: under what conditions does a low-probability treatment option generate a legally binding obligation to act, and when does failure to pursue it constitute a criminal omission?

The paper centres on the concept of the physician as a guarantor – a role recognized across European criminal law traditions, paradigmatically expressed in omission-liability provisions such as Article 2 of the Polish Criminal Code, but equally embedded in other continental legal frameworks. A guarantor's duty is not unlimited; it is bounded by feasibility, proportionality, and the reasonable standards of care prevailing at the moment of decision. What remains legally undertheorized, however, is the probabilistic threshold that triggers this duty when only a high-risk, low-success-rate intervention remains available.

Drawing on doctrinal analysis, comparative criminal law, and an emerging body of medico-legal scholarship on acceptable risk, this paper asks whether European courts and legislatures have developed – or are capable of developing – a coherent and consistent standard for the evaluation of last-resort medical interventions. The dominant ex ante framework – which assesses physician conduct against knowledge available at the time of decision – is theoretically sound but practically underspecified. It fails to articulate when a treatment with negligible or marginal success rates crosses the threshold from permissible gamble to mandatory attempt.

Through comparative analysis, this paper identifies the key normative factors that any coherent legal standard must engage with – including the severity and irreversibility of the threatened harm, the relative efficacy of available

options, and the state of medical consensus at the time of decision. It further argues that the proliferation of AI-assisted clinical risk-scoring tools across European health systems creates urgent pressure to address these questions, as algorithmic probability outputs increasingly shape – and may distort – both clinical judgment and subsequent criminal attribution.

The paper concludes with *de lege ferenda* recommendations directed at European legislators and the emergent European health law framework, advocating for harmonized guidelines on risk-threshold assessment in criminal proceedings involving medical omission.

O94: Where Does France Stand in the Implementation of the EHDS in 2026

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Abstract

The European Health Data Space (EHDS) marks a major evolution in EU health governance, shifting from theoretical data rights to a fully operational, cross-border digital infrastructure. One year after the EHDS's adoption in March 2026, France has established itself as the leading digital pioneer, thanks to its Doctrine du numérique en santé 2026, which aligns national tools with European requirements.

France's strategy is built on three pillars: reinforcing individual control over health data, enabling secure secondary use for research and policymaking, and creating a unified market for interoperable Electronic Health Record (EHR) systems. For primary data use, France relies on Mon espace santé – now counting more than 24 million active citizen profiles – and Sesali.fr, which gives healthcare professionals seamless access to cross-border Patient Summaries through MyHealth@EU. Secure identity verification is strengthened by the eIDAS-aligned HospiConnect framework.

For secondary data use, the Health Data Hub (HDH) coordinates France's involvement in the HealthData@EU pilot and prepares for the establishment of national Health Data Access Bodies (ORAD) by 2027. A defining strength of the French approach is the integration of EHDS-standardised data into Health Technology Assessment (HTA) processes. This supports faster access to innovative treatments and more robust reimbursement decisions by incorporating high-quality Real-World Evidence (RWE) and Patient Experience Data (PED). The "voir pour payer" ("see to pay") model exemplifies this shift: a performance-based agreement ensuring that public reimbursement for high-cost therapies is tied to demonstrated real-world effectiveness.

Despite clear progress, challenges remain. France must maintain high data quality for clinical assessments, manage the potential impact of citizen opt-outs on data representativeness, and ensure that EHDS processes integrate smoothly with existing regulatory timelines. The national roadmap envisions a phased deployment through 2031, ultimately making data exchanges – such

as e-prescriptions, medical imaging, and laboratory results – mandatory across systems.

France's experience demonstrates how the EHDS can transcend theoretical debates and become the operational foundation for a European health ecosystem driven by transparency, interoperability, and evidence-based decision-making. By rapidly implementing the EHDS infrastructure and linking it to market-access mechanisms, France is not merely complying with EU regulation but actively shaping the future of European health governance and pharmaceutical innovation.

O95: Whistleblower Protection in Healthcare: a Multi-Layered Legal Framework

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Abstract

Integrity and quality scandals in healthcare are not a new phenomenon. Striving for the highest possible quality of care ideally starts with individuals within the institution who are closest to its day-to-day practice. Exposing wrongdoing therefore depends on individuals willing to report misconduct, known as whistleblowers, who often become victims of retaliation. A prominent example is the case of Brigitte Heinisch, a German nurse who reported staff shortages, inadequate hygiene and improperly documented services in her workplace. After her concerns remained unaddressed and she filed a criminal complaint, she was dismissed without notice. In *Heinisch v. Germany* (2011) the European Court of Human Rights recognised her as a whistleblower and ruled that her dismissal was a violation of Article 10 ECHR.

In recent years, legal whistleblower protection gained increasing attention on the European level, which led to a breakthrough in the multi-layered protection of whistleblowers. An emerging international consensus on the need for strong whistleblowing laws and persistent fragmentation among national legislation combined with civil society activism led to the adoption of the EU Whistleblowing Directive, described as the "starting point of an entirely new field of EU law".

Despite this recent wave of legislation, the protection of whistleblowers remains fragmented. While the ECtHR recognises whistleblower protection as an aspect of freedom of expression, the EU perceives whistleblower protection as an instrument for the enforcement of EU law, resulting in different approaches and creating "a normative patchwork". Given the subsidiary role of the ECtHR and the minimum harmonisation by the EU, the effectiveness of whistleblower protection ultimately depends on national legislation. Especially in Belgium, a federal state with a complex division of competences, this fragmentation is further reinforced. Such fragmentation raises questions regarding legal certainty: an essential component of an effective protection

framework as uncertainty may discourage potential whistleblowers and create a chilling effect.

This study adopts a doctrinal research method and examines the multi-layered protection of whistleblowers in healthcare in two steps. First, it analyses the supranational level, focusing on ECtHR case law and the EU Whistleblowing Directive. Second, it examines the implementation of these supranational standards within the Belgian legal framework. Through legal comparative research, a comparison with the Netherlands and the United Kingdom will be conducted. The proposed study aims to identify inconsistencies and problem areas and contributes to the research field by offering a holistic overview of the legal protection of whistleblowers in Belgian healthcare.

O96: Who Controls Health Data? Rethinking Governance Models in AI-Enabled European Healthcare

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Abstract

The rapid development of artificial intelligence (AI)–based systems in healthcare is significantly increasing the importance of data as a foundational resource for medical innovation, while simultaneously raising complex legal, ethical, and institutional questions concerning its control, access, and use. Within the European Union legal framework, health data governance remains fragmented across multiple regulatory regimes, including personal data protection law, AI regulation, and emerging instruments addressing the secondary use of data for research, innovation, and broader societal purposes.

This article examines models of health data governance in the context of the expanding deployment of AI technologies in European healthcare systems. It advances the thesis that the current governance model – primarily grounded in individual control over personal data, as embodied in data protection law – proves insufficient to meet the demands associated with the development and effective functioning of AI systems. These systems require access to large-scale, diverse, and high-quality datasets, which often exceed the practical limits of individual consent-based frameworks.

The analysis highlights the inherent tension between the protection of individual rights, including privacy and autonomy, and the public interest in fostering medical innovation, improving healthcare quality, and enhancing the efficiency of healthcare systems. In response to these challenges, the article examines alternative data governance approaches, such as data-sharing frameworks, data trusts, and institutional mechanisms designed to enable controlled and secure access to health data while maintaining appropriate safeguards.

Drawing on legal-theoretical analysis and comparative perspectives, the article proposes a paradigm shift from a model centred on individual data protection toward a more comprehensive and multidimensional data governance framework. Such a framework should integrate the protection of fundamental

rights with the functional requirements of AI-driven innovation. Particular emphasis is placed on the role of transparency, institutional accountability, and mechanisms ensuring equitable and non-discriminatory access to health data.

In conclusion, the article argues that the development of effective and socially legitimate models of health data governance in the European context requires the integration of legal, technological, and ethical dimensions. Only through such an interdisciplinary and balanced approach can a sustainable equilibrium be achieved between the protection of individual rights and the realization of the full societal and scientific potential of health data.

O97: Who Pays When the Algorithm Fails? Revisiting No Fault Compensation for Medical Adverse Events

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Abstract

Traditional fault-based liability, the prevailing paradigm for compensating medical adverse events, has long been criticised for its protracted adversarial procedures, substantial overhead costs, uncertainty and detrimental impact on the patient-provider relationship. As early as the 1970s, Sweden pioneered an alternative approach, replacing fault-based liability with a no-fault patient insurance scheme – a model subsequently adopted by other Nordic nations and New Zealand.

These no-fault systems share distinctive features: fault is irrelevant as an entitlement criterion; costs are covered by insurance; claims are settled extra-judicially, expeditiously and at no cost to the patient; and prevention is pursued through risk management and clinical transparency rather than deterrence. Nordic patient insurance schemes compensate for iatrogenic injury that could have been prevented by specialised healthcare or an equivalent alternative therapeutic technique. This also applies to injury caused by a medical device or equipment failure or incorrect handling thereof, which is particularly relevant to AI-related injury. New Zealand's Accident Compensation Act goes further, abolishing tort claims for personal injury altogether.

The rapid deployment of artificial intelligence (AI) in healthcare, such as AI Decision Support Systems and robotic surgery – brings forth unprecedented challenges to fault-based liability. The complexity, opacity and autonomous learning capabilities of AI systems make allocating liability among developers, producers, healthcare providers and practitioners exceedingly difficult, if not impossible. The 'black box' problem undermines proof of causation, traditionally the claimant's most significant hurdle.

Recent European legislative developments have not fully addressed these concerns. In February 2025, the European Commission withdrew the proposed AI Liability Directive, which had sought to ease the burden of proof for claimants. Meanwhile, the new Product Liability Directive, though modernised, may

not adequately cover damage suffered by a patient following AI deployment in clinical settings, particularly where the injury results from AI output rather than a specific product defect. Consequently, member states retaining traditional fault-based frameworks may face a 'compensation gap': patients injured by AI-mediated treatment may be left without an effective legal remedy.

In this context, no-fault compensation offers a coherent and compelling framework: it provides a 'one-stop shop' for claims, removes the alleged chilling effect of stringent liability rules on technological innovation, and aligns with a risk-management approach to patient safety. Whilst no-fault systems are not a panacea – they require robust incident reporting and sustainable financing – they represent a balanced, efficient and humane response to the liability challenges posed by artificial intelligence in healthcare.

O98: "Can I Sell 'My' Organoid? Rethinking the Legal Framework for Organoid Commercialisation"

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Abstract

Recent advances in biomedical research have made it possible to develop organoids: three-dimensional, miniature models of organs cultivated from human stem cells or tissue samples. These organoids have significant potential for disease modelling, drug development and personalised medicine. However, the emergence of these technologies also raises a number of complex legal issues. This is because existing legal frameworks were not designed to address such novel biological entities. The legal status and commercialisation of organoids, particularly human embryo models and cerebral organoids, is a contentious issue, especially with regard to concepts such as human dignity and the personality rights of donors whose biological samples are used to generate such models.

The presentation provides an overview of recommendations for the commercialisation of organoids and analyses their potential as products derived from human biological materials. Additional attention will be given to embryo models and cerebroids. The presentation will address three fundamental aspects.

Firstly, it begins by analysing the similarities and differences between biological materials, products thereof and organoids from scientific and legal perspectives.

Secondly, it discusses why organoids should be commercialised.

Thirdly, despite the potential commercialisation of organoids, it puts forward a compelling argument for re-evaluating the commercialisation regime for specific types of organoids, namely embryo models and cerebroids. A thorough rationale is provided to explain why their commercialisation could pose significant legal challenges.

Poster Presentations

P1: A Legal Methodology for Describing the Ethical Issues of Novel Stem Cell Models

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Abstract

The rapid advancement of stem cell models such neural organoids, stem-cell-based embryo models, and chimeras, presents critical ethical and legal challenges. These models demonstrate an ability to model important structural and functional features of the human body. Stem Cell-based Embryo Models (SCBEMs), neural organoids and chimeras raise concerns related respectively to their developmental potential, possible sentience and disruption of the boundary between species. These issues of moral status have been discussed at length in the ethical literature. Yet, there is almost no equivalent discussion in the legal literature on organoids. We are suggesting a conceptual approach to these ethical issues that is geared for critically analysing existing laws, as well as offering a more prospective approach to identify and fill regulatory gaps.

This work proposes a theoretical legal method to address issues of moral status in law. We proceed first by classifying ethical issues among four broad types of values to be protected: (i) intrinsic value of an entity, (ii) its relational value, (iii) its symbolic value and (iv) its instrumental value. These four values highlight the different interests at stake in regulating stem cell models, and which interests are to be balanced with one another. Additionally, each of those stem cell technologies invoke broader ethical notions related to (i) human reproduction, (ii) sentience and (iii) the boundary between species. Understanding how a given legal order deals with each of these notions helps us describe how stem cells models fit in the broader picture of biotechnology regulations. Combining both this value-approach and this notional-approach allows us to anticipate how stem cell models might be regulated in that given legal order.

Applying this method helps clarifying the legal status of novel entities by classifying each issue relating to their moral status, by systematically highlighting discrepancies between issues raised by the literature and those which are

actually regulated. The proposed methodology offers an analytical yet proactive and flexible model for discussing stem cell models regulation. By taking into account ethical dilemmas and diverse stakeholders' interests, it aims to balance scientific progress with societal values. This work is designed to be both theoretically rigorous and practically actionable, which should appeal to legal scholars, policymakers, and scientists alike. While it is designed primarily for analysing organoid regulation, it aims to be transposable to other legal questions concerned with moral status.

P2: AI in Healthcare Decision-Making and the Human Will

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Abstract

AI is increasingly being used in healthcare. It can be used in various ways. For example, you can think of an AI system that predicts when a patient needs to be stabilized based on vital data. Or an AI system that indicates whether a scan shows a tumour. It is even conceivable that an AI system could not only provide information but also carry out the treatment directly. For example a device that automatically administers drugs during surgery or places a suture based on AI data. These may all be great developments, but we wondering what this means for human will in connection with the medical treatment agreement, the informed consent that the patient must give for every medical treatment and the requirement for shared decision-making. Thus far, in the field of health law, the human will has been the determining factor in all decisions made by and for a patient. Prioritizing human will reflects the great importance attached to the right to self-determination. A principle that also serves as a fundamental tenet within health law. In the paper we are currently writing, we explore the importance of human will in medical decision-making and the use of AI. In doing so, we address the following questions:

(1) Whether the introduction of AI into our health care system displaces or undermines the human will?
(2) Why should the human will be protected as the basis for our actions and decisions especially in health care?
(3) Can we overcome problems related to a potential threat to human will when using AI in healthcare? (Consider the safeguards set down in, for example, the AI Act or the Medical Device Regulation)

Given our background: a legal scholar and a philosopher: the article will be interdisciplinary in nature.

P3: Dynamic Consent or Legal Fiction? Rethinking Informed Consent for AI-Driven Neurotechnology in European Health Law

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Abstract

Informed consent remains a cornerstone of European health law, the primary mechanism through which autonomy and human dignity are operationalised, as reflected in the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights. However, the doctrinal foundations of consent are increasingly strained by advances in neurotechnology. AI-integrated active implantable medical devices enable continuous and adaptive interventions, such as closed-loop systems that automatically adjust stimulation parameters in response to real-time physiological or neural data, thereby directly influencing cognition, mood, and behaviour over time, and challenging conventional assumptions about the stability of autonomous decision-making.

This paper argues that prevailing legal models of informed consent are structurally inadequate to address three interrelated limitations. First, a temporal limitation: consent is traditionally a discrete, ex ante authorisation, whereas neurotechnological interventions operate as ongoing processes that evolve across the lifecycle of a device and may require continuous recalibration. Second, a capacity limitation: established legal standards, including those articulated in Montgomery v Lanarkshire Health Board, align with broader European approaches to patient autonomy but presume relatively stable decision-making capacity, notwithstanding the possibility that such technologies may alter the cognitive and affective conditions underpinning autonomy. Third, a regulatory limitation: existing EU frameworks, such as the Medical Device Regulation and the Artificial Intelligence Act, prioritise pre-market conformity, safety, performance, and risk classification, but do not adequately address the persistence, modification, or continuing legal validity of consent over time. This regulatory gap creates a protection vacuum in which the high-risk classification of neurotech under the AI Act fails to translate into actionable, post-market protections for the user's ongoing decisional integrity.

Situated at the intersection of human rights law, medical device regulation, and health law, the paper develops the concept of temporal autonomy to ensure consent remains meaningful and effective throughout an intervention's lifecycle. It argues that existing approaches to dynamic consent provide only a partial response, particularly where interventions may affect the very conditions necessary for autonomous decision-making rather than merely facilitating its exercise.

The paper concludes that AI-driven neurotechnology reveals a structural limitation in the consent doctrine. It calls for a partial reconceptualisation of informed consent in European health law, shifting from static, one-off authorisation towards continuous autonomy protection, the integration of enforceable safeguards within device design and governance, such as mandatory periodic re-consent mechanisms or human-in-the-loop oversight, and heightened legal thresholds for interventions risking material alterations to identity or decision-making capacity.

P4: From Diagnosis to Population Screening: Legal and Ethical Perspectives on Consent and Information in Genetic Testing

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Abstract

The increasing use of biotechnologies in health covering prevention, care, and research raises significant ethical questions and challenges existing legal frameworks. In France, the 2021 revision of bioethics laws has eased the rules governing the analysis of genetic characteristics, in order to accommodate advances in deep sequencing and the use of large-scale data.

This shift in scale introduced by genomics requires reconsidering the balance between individual protection and collective interest. This poster evaluates the adequacy of the current French legal framework in light of these technological advances, with particular attention to the scope of information provided and the modalities of consent for genetic testing.

Based on two projects (INFOGENETIC-FR and PERIGENOMED) we aim to analyse the recognition and reinforcement of individuals 'autonomy undergoing such tests. Through complementary approaches, they explore autonomy at two levels: individual, in the context of diagnosis, and population-based, in the context of neonatal genomic screening tests.

Genetic tests are strictly regulated under French law, particularly with regard to information and consent requirements. However, implementing these rules presents practical challenges. Consent, a fundamental principle grounded in personal autonomy and dignity, requires clear, complete, and

adapted information. The scope of consent depends on the type of genetic testing being performed, in relation to specific issues such as familial implications and incidental findings. For constitutional genetic testing, written and fully informed consent is required, whereas for somatic genetic testing in a diagnostic context, oral consent is generally sufficient on the basis of clear and understandable information. In the case of population-scale screening such as neonatal screening, clear and comprehensive information must be provided to ensure free and informed parental consent. However, challenges remain, particularly concerning the information of potential risks associated with newborn screening, as well as issues of public understanding and acceptability. As a result, in practice, defining and delivering information faces specific constraints in both individual and population-based screening contexts.

Therefore, although consent is a fundamental prerequisite for preserving autonomy in genetic testing, the nature, scope and objectives of consent can differ depending on the context in which it is given. In order to achieve the aforementioned objective, emphasis on a precise and comprehensive information is necessary (its scope and its quality) to comply with national ethical and legal standards and to adapt professional practices in a way that mitigates the impact on families, while at the same time ensuring the safeguarding of individual rights.

P5: Legal Frameworks for Medical Countermeasures and Health Crisis Preparedness

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Abstract

The European Union has significantly strengthened its role in health crisis preparedness in response to recent cross-border health threats. The EU Commission's Health Emergency Preparedness and Response Authority (DG HERA) was established to bolster the European Union's capability to anticipate, prevent, and respond to health crises, thereby ensuring a more coordinated and robust preparedness by developing medical countermeasures and facilitating rapid deployment during emergencies. Central to HERA's mandate is the establishment of new mechanisms aimed at ensuring the availability, accessibility, and timely deployment of medical countermeasures across Member States. These developments reflect a broader shift towards a more proactive and coordinated EU approach to managing public health risks.

This contribution examines key instruments developed within the framework of DG HERA, focusing in particular on EU-level approaches to securing medical countermeasures. It analyses three complementary mechanisms: capacity reservation for existing countermeasures, joint procurement procedures, and the development of EU FAB as a strategic reserve for large-scale manufacturing in the event of emerging health threats, including "pathogen X" scenarios.

Drawing on practice-informed insights, the analysis explores how these instruments operate in practice and assesses their contribution to enhancing preparedness for health crises. Particular attention is given to issues of coordination, flexibility, and the interaction between EU-level mechanisms and national health systems.

The contribution argues that, while these tools represent a significant step forward in strengthening EU preparedness, important legal and governance challenges remain. There are varying levels of Member State engagement,

and uncertainties regarding roles, responsibilities, and accountability in crisis situations. In addition, the analysis highlights the innovative nature of joint procurement as a mechanism for collective action, while also identifying legal and practical challenges related to participation, contractual complexity, and alignment of national priorities.

It further underscores the tension between the need for rapid and flexible responses in emergency contexts and the requirements of legal certainty, transparency, sound financial management and on the other side industry expectations. These tensions are particularly visible in the design and implementation of instruments that must operate across diverse legal and institutional frameworks.

It concludes that further refinement and consolidation of these mechanisms will be essential to ensure an effective and coherent EU approach to future health crises, capable of responding to both known and emerging threats while maintaining a robust and accountable legal framework.

P6: Medical Negligence in the Philippines and Spain: a Comparative Analysis of Civil and Criminal Liability

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Abstract

This paper examines the legal frameworks governing medical negligence in the Philippines and Spain, situating both systems within a shared civil law heritage while highlighting their doctrinal divergence over time. The study traces the historical foundations of both jurisdictions to the Spanish Civil Code of 1889 and the Spanish Criminal Code of 1870, which were extended to the Philippines during the colonial period. Despite the subsequent introduction of American common law elements, particularly in procedural and evidentiary rules, the Philippines retained its civil law foundations, resulting in a hybrid legal system. This continuity is reflected in the New Civil Code of 1950 and the Revised Penal Code, both of which preserve fault-based liability as the core principle governing civil and criminal responsibility.

Using a comparative doctrinal methodology, the paper analyses statutory provisions and jurisprudence from both jurisdictions, focusing on how individual liability for medical negligence is established and enforced. It examines key elements such as standard of care, causation, evidentiary requirements, and the distinction between civil and criminal liability. The analysis is confined to individual medical negligence to enable a focused comparison of professional fault, excluding institutional and vicarious liability except where contextually necessary.

In the Philippines, the absence of a comprehensive medical malpractice statute has led to a jurisprudence-driven framework grounded in general civil and criminal law principles. Courts rely heavily on expert testimony and apply traditional doctrines such as proximate cause and *res ipsa loquitur*, often influenced by American jurisprudence. This approach emphasizes evidentiary certainty but creates challenges in proving causation and accessing expert witnesses.

In contrast, Spain has developed a more differentiated and flexible system. It distinguishes between public and private healthcare liability, incorporates

the *lex artis ad hoc* standard to assess professional conduct, and recognizes the *pérdida de oportunidad* doctrine, which allows compensation for loss of chance in cases of uncertain causation. Spanish courts also demonstrate greater flexibility in evidentiary evaluation, addressing informational asymmetries between patients and medical professionals.

The paper concludes that while both systems share a common legal ancestry and exhibit restraint in imposing criminal liability, they diverge significantly in civil law approaches. The Philippines prioritizes doctrinal consistency and evidentiary rigor, whereas Spain adopts a more adaptive framework that accommodates medical uncertainty through probabilistic reasoning. This comparison underscores how legal systems with shared origins can evolve differently in response to institutional, historical, and policy influences.

P7: Overriding Suffering-Alleviating Treatment Refusal in Detained Patients with Capacity: Is Reform an Illusion of Autonomy?

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Abstract

Recent proposals to reform the Mental Health Act 1983 in England and Wales seek to remove clinicians' power to override a detained but capacitous patient's refusal of treatment solely on the basis of alleviating suffering under Section 62. This represents a significant normative shift towards strengthening patient autonomy, allowing patients to determine the level of suffering they are willing to endure. However, its feasibility is constrained by limitations in assessing capacity in acute settings. Capacity is a conceptually binary determination defined under the Mental Capacity Act 2005, but it can be difficult to establish reliably in emergencies. Challenges include perceived irrationality and contradictory expressed wishes under influences of external pressures or personal beliefs. From the clinician perspective, uncertainty arises in predicting the consequences and distinguishing severe suffering from immediately life-threatening, often within constrained timeframes that limit meaningful facilitation of decision-making. These constraints may result in reliance on legal workarounds that frame intervention in patients' best interests rather than their expressed wishes, creating an illusion of autonomy. Rather than complete abolition of override powers, a more viable approach lies in strengthening safeguards. These include promoting the use of Advance Choice Documents, ensuring statutory weight of the Nominated Person, mandating second opinions where feasible, strengthening documentation and retrospective audits of capacity overrides, and investing in crisis support services to reduce escalation to compulsion. Given persistent uncertainties in capacity assessment and clinical decision-making, a safeguards-based approach will ensure protection of patient autonomy while preserving clinician's ability to intervene in genuine emergencies.

P8: Reassessing the Legal Status of the Embryo in Light of a Combination of New Technologies: A Renewed Debate

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Abstract

Old debates about the legal status of the embryo have been reignited with the rapid advancement of several novel reproductive and genetic technologies. Recent developments such as the challenge of the '14-day rule' for embryo research, Stem Cell-Based Embryo Models (SCBEMs), In Vitro Gametogenesis (IVG), aneuploidy detection, mitochondrial donation and germline modification, urge us to reassess existing legal frameworks surrounding these practices. While each technology has been studied at length by the ethical literature, their combined effect on the embryo's legal status remains underexplored.

Starting from the French context of the bioethics law revision, this study aims to evaluate how these innovations potentially transform the legal status of the embryo through a review of ethical and legal literature, as well as regional and international instruments.

Our findings reveal how long-standing consensuses have been challenged, particularly regarding the '14-day rule', germline modification, and the creation of embryos for research, without a clear vision on how to reach new and updated consensuses. Other technologies, such as SCBEMs, IVG, mitochondrial donation and aneuploidy detection offer promising research and therapeutic pathways but face a high degree of fragmentation among countries. This can

be explained by the important ethical issues raised, each country having to decide on the acceptability of such technologies.

As it will be shown from the French case, these debates impact the legal classification criteria of the embryo as well as rules applicable to assisted reproductive technologies. It requires us to revisit previous prohibitions or enact new ones, and to adapt governance and oversight frameworks. Ultimately, considering the cumulative effect of these technologies on the classical balance struck between the protection of the embryo and the preservation of research freedom adds a whole new dimension to the debate.

P9: The Importance of Health Law Scholarship in the Fight Against Antibiotic Resistance

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Antibiotic Resistance

Antibiotic resistance is one of the most complex heath challenges of our time, responsible for 1.3 million direct deaths annually and disproportionately affecting low- and middle-income countries. Often described as a so-called "wicked problem", antibiotic resistance requires the support and engagement of not only sectors across society (such as healthcare, pharmaceutical firms, civil society, and agriculture) but also from disciplines across academia.

Law Scholarship and Antibiotic Resistance

Domestic and international legal mechanisms can be used to address antibiotic resistance and overcome the governance and political economy challenges that accelerate it. Specific examples of areas where legal scholarship is of particular relevance to AMR are:

(1) Intellectual property law: to tackle antibiotic resistance by either strengthening, or weakening, the protection of pharmaceutical innovation.
(2) Global governance and treaty design: to integrate antibiotic resistance into existing international instruments.
(3) Framework Implementation: learnings from the fifteen years of implementing the WHO International Health Regulations.
(4) Patent rights: How to balance with the public health need for affordable, generic alternatives, especially in low-income countries.
(5) EU legislative and regulatory response to antibiotic resistance: for example, the EC has recently proposed EU pharmaceutical legislation designed to modernize and reinforce the EU's approach to drug regulation, especially in combating antibiotic resistance.
(6) Regulatory frameworks for antibiotic use: how to regulate antibiotic availability, and use in humans. This may also include legislation to prohibit

the use of antibiotics for so-called growth promotion in livestock and stricter regulation of the management of environmental pollution from drug manufacturing waste.

(7) Regulatory frameworks for antibiotic prescription: imposition of additional regulations by states, such as limiting the validity period of prescriptions, mandating diagnostic tests prior to prescribing or restricting the quantities prescribed.

(8) Innovation and economic incentives: mechanisms to drive innovation in new antibiotics, including novel mechanisms that disconnect the revenues of pharmaceutical firms from the number of antibiotics sold by means of new economic and legal models.

(9) Surveillance and compliance: design mechanisms for the surveillance of antibiotic resistance as well as the compliance with standards for testing, data, and antibiotic use across borders

In essence, the promise of legal scholarship in relation to antibiotic resistance is to help translate the medical challenge of antibiotic resistance into a governable social and economic problem, and in making sure that strategies to fight antibiotic resistance are enforceable, fair, and sustainable.

I also plan to present the Uppsala Antibiotic Center, a cross-disciplinary research hub on antibiotic resistance.

P10: The Limits of Presumed Consent: Legal, Institutional, and Social Barriers in the UK Organ Donation System and the Need for Holistic Reform

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Abstract

The United Kingdom continues to face a significant shortage of organs for transplantation, with over 8000 individuals currently on waiting lists despite the introduction of the soft opt-out system across England, Wales, Scotland, and Northern Ireland. Under the Organ Donation (Deemed Consent) Act 2019, consent for organ donation after death is presumed, subject to consultation with family members. However, this reform has not achieved its intended impact, with recent data indicating a decline in donation rates, highlighting the persistence of barriers beyond the legal framework.

This paper argues that the limitations of the current system arise from a combination of legal, institutional, and social constraints. Legal barriers include the continued decisive role of family refusal, structural weakness of the deemed consent model, and the strict prohibition of incentives under the Human Tissue Act 2004 which arguably created disincentives. Institutional challenges involve inconsistent identification and referral of potential donors, limited integration and utilisation of Specialist Nurses for Organ Donations (SNOD), and resource limitations in transplant services. Social barriers persist in the form of low public awareness of the opt-out system, social mistrust, and ongoing socio-cultural disparities and beliefs affecting consent rates.

To address these challenges, the paper proposes a multi-level reform framework. Institutional reforms should focus on improving professional training and communication skills, through professional training, strengthening of clinical guidance and its integration into clinical practice, alongside expanding service capacity. Social reforms should prioritise sustained public education, early engagement at key administrative and healthcare touchpoints, and the promotion of open discussions about donation preferences, supported by collaboration with community and religious leaders. Legal reforms should aim to clarify the role of family in deemed consent, optimise donor registration, and

introduce non-commercial "soft incentives" while preserving the principle of altruism, and the potential of reconceptualising organs as regulated resources and adopting priority allocation to encourage participation.

By addressing barriers across these three domains, this paper argues that a more coherent and ethically balanced framework can improve donation rates while maintaining public trust and respect for individual autonomy.

P11: The Obligation to Present a Personal Identification Document When Registering for or Receiving Medical Treatment in the Republic of Latvia

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Abstract

In the Republic of Latvia, patient identification constitutes a fundamental legal prerequisite for the provision of healthcare services and the protection of patients' rights. According to Section 15, paragraph 4 of the Law on the Rights of Patients when registering in a medical treatment institution or receiving medical treatment, a person shall, upon request of a medical practitioner, present a personal identification document, except when emergency medical care is provided to the patient and he or she is unable to present such document due to his or her state of health. The patient shall present the personal identification document as soon as it is possible. According to Section 15, paragraph 7 of the Law on the Rights of Patients, the requirement to present a personal identification document does not apply to arrested or convicted patients, and the procedure for informing medical treatment institutions about such patients' personal data is regulated by Cabinet of Ministers regulations.

The presentation of a personal identification document is not a formality but a legal obligation aimed at ensuring safe, accurate, and high-quality healthcare. Proper patient identification enables healthcare professionals to verify a patient's legal status, access previous medical records, ensure continuity of treatment, and protect patients' personal data, including special category health data. Incorrect or incomplete patient identification may lead to significant risks, such as medical errors or breaches of patient confidentiality.

Legal challenges arise in situations where a patient does not possess a personal identification document. The applicable identification procedures differ depending on the patient's age and legal capacity. In emergency situations, or when a patient is unable to present an identification document due to health conditions, identification may be carried out using biometric data or other lawful and reasonable means, without delaying the provision of emergency medical care. However, if the patient is not registered in databases or biometric identification is impossible, healthcare professionals must still provide treatment, using other reasonable methods to identify the patient, such as name, personal code, address, or visual records, to ensure access to previous medical information and continuity of care.

The aim of this research is to analyse the legal framework governing the obligation to present a personal identification document in healthcare in the Republic of Latvia, to assess its role in safeguarding patient safety and patients' rights, and to identify practical and legal challenges related to patient identification in both routine and exceptional healthcare situations.

P12: The Right to Health in Emergencies: Legal Challenges of Access to Potable Water in Cholera Epidemic Management in Bukavu, DRC

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Anansoft Foundation, Bukavu, DRC

Introduction/Context

Despite the international recognition of the right to health, universal access to safe drinking water remains a major challenge in many conflict-affected or post-conflict regions. The city of Bukavu, in South Kivu, is regularly faced with devastating cholera epidemics. This situation creates a direct tension between the State's obligation to guarantee the right to health and the realities on the ground where the Anansoft Foundation operates. This poster examines the practical "frontier" where international legal principles collide with failing infrastructure and complex governance structures.

Objectives

This poster aims to analyse the concrete obstacles to the effective implementation of the right to health through the lens of access to safe water in an urban context at high epidemic risk. It explores the crucial, yet often ambiguous, role of local NGOs like Anansoft in supplementing state obligations regarding water, sanitation, and hygiene (WASH).

Methodology/Approach

The analysis is based on a case study of emergency interventions led by the Anansoft Foundation in Bukavu during the most recent outbreak. It examines project documentation, water point mapping, and local coordination mechanisms. This field data is then cross-referenced with international and national legal frameworks (DRC Constitution, Health Code) governing the right to health.

Main Results/Analysis

The findings highlight a paradox where the formal "right" is present, but the material "service" is absent. The analysis reveals that inadequate water access in Bukavu is not merely a logistical problem but a structural violation of the right to health. While essential, the emergency intervention of NGOs raises questions about long-term accountability. The poster proposes a legal analysis framework to redefine the responsibilities of various actors (State, public services, NGOs) in preventing waterborne diseases in fragile environments.

Conclusion/Implications

Guaranteeing the right to health in epidemic-prone urban areas cannot be limited to a medical response. It requires the recognition and legal enforcement of access to safe water as a non-negotiable fundamental right. This poster argues that the "frontiers of health law" must explicitly include WASH infrastructure as a sine qua non condition for dignity and survival in cities like Bukavu.

Workshops

W1: Between Biology and Law: the Moral and Legal Status of Emerging Embryonic and Bodily Entities

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Fredrik Lanner
Professor of Embryonic Stem Cell Biology at Karolinska Institutet, Stockholm, Sweden

Sara J. Fovargue
Professor of Law in the School of Law at the University of Sheffield, Sheffield, UK

Lena Wahlberg
Associate Professor, Law Faculty at Lund University, Lund, Sweden

Göran Collste
Emeritus Professor of Applied Ethics at Linköping University, Linköping, Sweden

Tesi Aschan
Chief Legal Counsel at the Swedish Ethical Review Authority, Uppsala, Sweden

Aim

To examine, comparatively, the moral and legal status of stem cell-based embryo models (SCBEMs), organoids, and bodyoids – asking what they share, where they differ, and whether a coherent European regulatory response is possible.

Expected Content

Advances in stem cell and developmental biology are producing entities that existing law was never designed to govern. At the centre of the discussion are stem cell-based embryo models (SCBEMs): three-dimensional structures

grown from human stem cells that increasingly resemble early human embryos, yet are not created through fertilisation and do not fall within existing legal definitions of the embryo. The frontier extends further. Organoids – stem cell-derived structures modelling specific organs such as the brain or gut – raise overlapping questions about oversight and moral consideration without falling under the reproductive law frameworks that govern embryo research. And now a third category is entering serious scientific and ethical debate: bodyoids, human biological structures developed entirely from stem cells outside the human body, in which brain development is genetically inhibited from the outset, producing entities that are biologically human but lack sentience or the capacity to feel pain. Leading researchers have recently argued that bodyoids, while still facing substantial technical obstacles, are sufficiently plausible to demand immediate ethical and regulatory attention – as a potential source of transplant organs, personalised drug-testing platforms, and a means of radically reducing dependence on animal research.

What unites these entities is not only their novelty, but the way they expose the fragility of the foundational concepts on which European health law is built: person, body, embryo, life. The challenge is not only one of definition. It is about whether capacity-based approaches to regulation – asking what an entity can become or can experience, rather than how it was produced – offer a more robust foundation than the property-based definitions currently in use.

Examples of questions to be addressed: On moral and legal status: what moral and legal status should SCBEMs, organoids, and bodyoids hold – and should they be governed by the same frameworks, or does their different origin, purpose, and developmental potential justify distinct regulatory approaches? Should moral status be understood as a binary threshold, or do these developments favour gradient-based frameworks that track morally relevant properties – such as sentience, developmental capacity, and the potential to give rise to a human being – more closely and dynamically?

On bodyoids specifically: does the existence of entities deliberately developed without consciousness risk eroding the protections we extend to living humans who lack consciousness or have never developed sentience – people in a vegetative state, or those with severe cognitive disabilities? And what does human dignity require when we deliberately engineer the absence of the very properties we typically regard as morally significant?

On consent and donation: a person donating biological material today is unlikely to have envisaged that it could be used to create a human embryo, or a complete human body, subsequently used for research or organ harvesting – how should consent frameworks be redesigned to reflect these qualitatively

new uses, and can consent alone bear the moral weight increasingly placed upon it?

Academic discussion of these questions is only beginning. The goal of this workshop is to ensure that ethicists, legal scholars, and policymakers are engaged before the science forces the question – not after.

Audience Involvement

Participants will engage through open plenary discussion following the panel presentations, with panellists asked to respond to and challenge each other as well as the audience. The format is designed to generate genuine exchange across disciplinary boundaries – between scientists, ethicists, and legal scholars – rather than sequential expert presentations.

W2: Compulsory Care – Where Are We Heading? Human Rights, Expertise and the Future of Mental Health Law

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Anna Nilsson
Faculty of Law, Lund University, Lund, Sweden

Solvita Olsena
Law Office "Solvita Olsena ZAB" Ltd, Riga, Latvia

Aim

Mental health law is currently undergoing significant normative and legal transformation. Developments in international human rights law, particularly in relation to the UN Convention on the Rights of Persons with Disabilities (CRPD), evolving case law from the European Court of Human Rights, and ongoing debates concerning the role of medical expertise and societal protection, raise fundamental questions about the legitimacy, scope and future direction of psychiatric compulsory care.

The workshop aims to explore central questions concerning human rights standards, states' margin of appreciation, the role of medical expertise, and the relationship between law, ethics and clinical practice, and to critically examine whether current legal frameworks remain fit for purpose and to explore possible future directions for mental health law in Europe and beyond.

Expected Content

This two-hour workshop brings together legal scholars working at the intersection of mental health law, human rights, medical ethics, and medical expertise. The workshop will consist of a series of short introductory presentations, followed by an extended moderated discussion aimed at identifying key tensions, emerging trends, and future directions in mental health law.

The introductory presentations will address three interrelated themes:

(1) Anna Nilsson, Associate Professor in Human Rights, Faculty of Law, Lund University, will examine psychiatric compulsory care in light of discrimination concerns and the CRPD, focusing on equality, non-discrimination and the future legitimacy of such coercion targeting persons with psychosocial disabilities.
(2) Moa Dahlin, Associate Professor in Public Law, Faculty of Law, Uppsala University, will discuss the possibility of moving towards a more general framework for coercive care, with particular emphasis on impaired decision-making capacity as a potential legal threshold across psychiatric and somatic healthcare.
(3) Solvita Olsena, Law Office "Solvita Olsena ZAB" Ltd. Attorney at Law, will give a presentation on the recent legislative and judicial processes of the Council of Europe's human rights bodies in relation to mental healthcare. First, she will provide an overview of the draft Additional Protocol to the Oviedo Convention on involuntary placement and treatment in psychiatry, and the draft Recommendation on respect for autonomy in mental healthcare. Secondly, she will discuss the evolving jurisprudence of the European Court of Human Rights.

Together, these contributions will frame a broader discussion on the future of psychiatric compulsory care.

Audience Involvement

The short introductory presentations are followed by an extended, moderated discussion in which all participants are invited to actively engage, aimed at identifying key tensions, emerging trends, and future directions in mental health law.

W3: Data Governance Through Legal Design: An Interactive Workshop on the Implementation of the European Health Data Space

Andrea Martani
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Andrea Parziale
Sant'Anna School of Advanced Studies, Italy

Arianna Rossi
Fit4MedicalRobotics, Sant'Anna School of Advanced Studies, Pisa, Italy

Noemi Conditi
University of Bologna, Bologna, Italy

Aim

This hands-on workshop addresses the legal and implementation challenges arising from the interaction between the European Health Data Space (EHDS) framework and the General Data Protection Regulation (GDPR), with a specific focus on research biobanks and medical registries managing large datasets for secondary use of data. While the EHDS aims to facilitate the secondary use of health data for research and innovation, its implementation raises questions regarding data governance, individual rights (e.g. to opt out), and institutional compliance. The workshop aims to map both the opportunities and tensions embedded in this evolving framework, and to explore how these challenges may be addressed in practice through an exercise of legal design.

Expected Content

The workshop will be structured as a highly interactive session lasting 90 minutes.

It will begin with a short introduction about the objectives, structure, and expected outcomes of the workshop (ca. 5 minutes).

Thereafter, the organisers will hold a preliminary input-presentation (ca. 15 minutes) outlining specific legal and operational challenges at the intersection of EHDS and GDPR in the context of biobanking and medical registries, and in particular with respect to the rules about the secondary use of data and their implementation.

Participants will then be introduced to the concept of legal design (ca. 10 minutes) and guided through a collaborative legal design exercise based on a concrete use-case (ca. 30 minutes). The use-case will concern the implementation of the rules for the re-use of health data set by the EHDS and the GDPR. It will consist in an exercise of translating abstract legal rules (e.g. about individual rights, such as the right to opt-out from secondary use of data) into the concrete policies that biobanks and medical registries need to implement to manage their databases and comply with the law. Working in small groups, participants will engage in a structured activity centred around the concept of legal design. By reflecting on the presented use-case, participants will be guided to prototype potential solutions to the identified challenge of implementing the rules about secondary use of health data.

The session will conclude with a plenary discussion, in which groups briefly present the outputs of their work (ca. 20 minutes), followed by concluding remarks by the organising team (ca. 10 minutes)

Audience Involvement

Active participation is central to the workshop. The proposed format is intended to foster exchange between participants with diverse backgrounds and to encourage collaborative problem-solving. Interactive facilitation, guided tasks, and group presentations will ensure continuous engagement throughout the session. With an organising team of four members, we will be able to manage a group of participants anywhere from a few people up to ca. 20 participants, ensuring that group-work is facilitated by the convenors of the workshop.

W4: From Stethoscope to Decision-Support Tool: Balancing Legal Requirements and Responsibilities of a Physician in the Use of Medical AI

Tom Goffin
University of Ghent, Ghent, Belgium

Griet Verhenneman
University of Ghent, Ghent, Belgium

Sofie Depauw
University of Ghent, Ghent, Belgium

Sylvie Tack
University of Ghent, Ghent, Belgium

Aim

As artificial intelligence is integrated into the clinical environment, the legal parameters defining the physician's role are undergoing a fundamental transformation. What was once a relationship mediated by physical tools is now increasingly governed by algorithmic outputs, raising critical questions regarding the evolution of the lex artis. This workshop provides a rigorous juridical analysis of the shifting responsibilities and liabilities of physicians within the European Union's complex regulatory ecosystem.

Expected Content

The workshop is divided into four thematic pillars, each focusing on the legal dogmatics and regulatory challenges facing the modern practitioner.

Each part starts with a brief (max 2 minutes) video of a healthcare professional identifying the specific topic-related problems that arise in healthcare practice. After the video intro, one of the four organisers gives a 7-minute legal pitch. Each pitch will end with some egal questions that translate the healthcare professional's problems. Over the next 10 minutes, we will organise

a discussion with the audience to try to resolve the legal questions on that specific topic.

We will conclude the workshop with a general conclusion and a call to collaborate further.

(1) Evolution of Professional Duties: Literacy, Autonomy, and Transparency

This session examines the normative shifts in professional conduct. We analyse how the legal standard of care is being redefined to include AI literacy as a prerequisite for clinical competence. From a legal perspective, we explore the tension between reliance on algorithms and the preservation of professional autonomy, investigating the point at which "automation bias" constitutes a breach of professional duty. Finally, we dissect the physician's duty of transparency, assessing the scope of information disclosure required to ensure valid informed consent.

(2) The Regulatory Interplay: Navigating the AIA and MDR

This pillar addresses the intersection of horizontal and sectoral EU legislation. We provide an analysis of the AI Act in conjunction with the Medical Device Regulation. The discussion focuses on the physician's status as a "deployer" under the AI Act and the specific compliance obligations that arise from this classification. We will evaluate the legal mechanisms available to physicians to verify the "trustworthiness" of high-risk AI systems and the resulting obligations regarding post-market surveillance and risk reporting.

(3) Data Governance: Professional secrecy, GDPR, and the EHDS

The use of AI in medicine necessitates a re-evaluation of data protection frameworks. This session explores the legal friction between the data-intensive nature of machine learning and the traditional doctrine of medical secrecy. We analyse the application of the GDPR – specifically the processing of special categories of personal data – alongside the emerging framework of the European Health Data Space (EHDS). We will discuss the legal basis for the secondary use of health data for AI training.

(4) Liability Paradigms: From Negligence to Product Liability

The final session addresses the "accountability gap" created by algorithmic opacity and the phenomenon of "hallucinations." We analyse the attribution of fault when AI outputs lead to patient harm, contrasting traditional medical malpractice (fault-based liability) with the evolving landscape of product liability. The session will specifically examine the impact of the AI Liability Directive and the potential for no-fault liability models to provide redress. We aim to determine the extent to which a physician remains the "legal bottleneck" for liability when using black-box systems.

Audience Involvement

We involve the audience through active discussion to address the specific questions raised on the different topics. We used a similar format at the 9th European Conference on Health Law in Warsaw, with great success and positive audience reactions. The balanced combination of the healthcare professionals' videos, the short pitches, and the audience discussions creates a constructive vibe that should lead to interesting outcomes.

W5: Health Law and Trade: Exploring Coherence Between the European Union's Trade and Pharmaceutical Policies

Giacomo Di Federico
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Jean Monnet Centre of Excellence "New Visions of the European Union's Role in Global Health" (EU4GH), Fisciano, Italy

Flavia Zorzi Giustiniani
Link University of Rome, Rome, Italy
Jean Monnet Centre of Excellence "New Visions of the European Union's Role in Global Health" (EU4GH), Fisciano, Italy

Stefania Negri
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Luciano Bottini Filho
Helena Kennedy Centre for International Justice, Sheffield Hallam University, Sheffield, UK

Emanuele Cesta
Italian Medicines Agency (AIFA), Rome, Italy
European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), Council of Europe, Strasbourg, France

Aim

The workshop is jointly organised by the Italian holders of three Jean Monnet Actions funded by the European Commission and dedicated to EU health law and the European Union's role in global health. The workshop aims to explore and discuss the emerging and most challenging legal/regulatory issues arising from the interplay between health law, intellectual property, trade and access to pharmaceuticals in Europe. The focus is placed on the following core topics:

(1) EU competences and the legal framework governing trade and public health in the European Union's external and internal action;

(2) trade relevant priorities, objectives and lines of action incorporated in the EU Global Health strategy;
(3) possible tensions between trade objectives and public health needs, especially with regard to access to medicines;
(4) the impact on pharmaceutical policy objectives of TRIPS-plus provisions incorporated into bilateral trade agreements;

trade in medicines within the European Union and importation as a tool to mitigate medicine shortages.

Expected Content

The workshop will be chaired by Prof. Dr. Giacomo Di Federico and will include four speakers:

(1) Prof. Dr. Flavia Zorzi Giustiniani will provide the general legal framework governing the European Union's external relations and its bilateral trade policies, focusing on trade rules having an impact on public health and on access to medicines.
(2) Prof. Dr. Stefania Negri will discuss the key trade-related elements within the EU Global Health Strategy: (i) manufacturing diversification (boosting local manufacturing of vaccines and health technologies in partner countries to reduce dependency, using the Global Gateway initiative for infrastructure support); (ii) intellectual property and access to medicines (prioritizing access to health countermeasures through voluntary licensing and technology transfers, ensuring trade rules support health equity); (iii) resilient supply chains (protecting EU supply chains for medicines and medical equipment to handle future pandemics while enhancing international health security); (iv) regulatory cooperation (encouraging, aligned, evidence-based regulatory standards for pharmaceutical products); and (v) support for the WHO (ensuring trade policy and intellectual property mechanisms, such as TRIPS, work in harmony with WHO instruments).
(3) Dr. Luciano Bottini Filho will explore the TRIPS-Plus IP provisions contained in the EU bilateral trade agreements concluded with Canada (2016), Vietnam (2019) Chile and New Zealand (2023), comparing them with the text of more recent agreements where a reassessment of the EU's approach to negotiating pharmaceutical-relevant trade provisions is warranted. He will address the impact of trade agreements on pharmaceutical policy in order to systematically examine the text of the four most recently concluded EU trade agreements, with MERCOSUR, Mexico,

India and Australia respectively. He will discuss the agreements for ten types of provisions and their potential to impact on four pharmaceutical policy objectives: i) access and affordability; (ii) safety, efficacy, and quality; (iii) rational use of medicines, and (iv) local production capacity and health security.

(4) Dr. Emanuele Cesta will explore the role of medicinal imports as a pragmatic and short- to medium-term tool to mitigate medicines shortages, examining the operational, regulatory, and clinical issues arising from shortage situations across different Member States and highlighting the fragmentation of responses and the uneven impact on healthcare providers/facilities and patients. He will also address ongoing policy discussions at EU Commission and Parliamentary level concerning the proposed Critical Medicines Act and the New Pharma Legislation. Exposing real-world shortage management practices with forthcoming regulatory scenarios, he will provide an overview of current challenges and future policy directions to improve the resilience and sustainability of the EU pharmaceutical sector.

Audience Involvement

The workshop will allocate sufficient time for a final Q&A session to stimulate discussion involving the audience.

W6: Implications of Concluding Observations of the CRPD for Health Law in The Netherlands, Belgium and Norway. Is a Revision of Our Legislation Inescapable?

Brenda Frederiks
Department of Health Law, Amsterdam UMC, Amsterdam, The Netherlands

Tim Ogenhaffen
Department of Health Law, Vrije Universiteit Brussel, Brussels, Belgium
Department of Social Welfare Law, KU Leuven, Leuven, Belgium

Willemijn Krugers Dagneaux
Department of Health Law, Rijksuniversiteit Groningen, Groningen, The Netherlands

Henriette Sinding Assen
Department of Law, University of Bergen, Bergen, Norway

Brigit Toebes
Department of Health Law, Rijksuniversiteit Groningen, Groningen, The Netherlands

Aim

The United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) pursues full societal inclusion of persons with disabilities. This objective has significant implications for health law, particularly with respect to access to healthcare, decision-making, and the use of coercion. State parties that have ratified this convention are obliged to align their national legislation the provisions of this convention, with the aim of improving the legal position of people with disabilities (including elderly, people with intellectual disabilities). For almost two decades, the CRPD has therefore functioned as both a catalyst and a benchmark in the field of health law.

The concrete impact of the Convention on health law is most clearly reflected in the concluding observations issued by the UNCRPD in response

to developments at the level of the States Parties. Despite numerous reforms at the level of the States Parties, these concluding observations are frequently marked by substantive concerns.

This contribution draws on the most recent concluding observations concerning the Netherlands, Belgium and Norway to assess the broader impact of the UNCRPD on health law frameworks and practices. We compare the three country reports, the recommendations of the UNCRPD Committee are contextualised and used to identify potential lessons for national reform processes. The analysis focuses on three central elements: the underlying health-law context; the extent to which the CRPD Committee has accurately identified key issues; and the presence of relevant nuances or omissions. Particular attention is paid to supported decision-making, legal capacity, and coercion, as well as to the broader implications of the UNCRPD for the right to health.

Expected Content

The speakers will first reflect on the concluding observations in Norway, Belgium and the Netherlands. In the second part the focus is on the broader impact of the CRPD for health law frameworks.

Audience Involvement

Participants are invited to react to statements but are also invited to give live feedback and bring in their own vision.

W7: Just Ask the Bot? Ethical Medical Dilemmas

Vera Lúcia Raposo
NOVA School of Law, NOVA University of Lisbon, Lisbon, Portugal

Oliver Quick
University of Bristol Law School, Bristol, UK

Barry Solaiman
HMS Center for Bioethics, Boston, MA, USA

Aim

Medicine is rich with complex and deeply entangled ethical dilemmas, from patients refusing life-saving treatment to decisions about terminating a pregnancy based solely on predicted foetal sex. Traditionally, such dilemmas have been examined by multidisciplinary ethics committees composed of clinicians, ethicists, and legal experts, who collaboratively attempt to articulate the most ethically defensible course of action. These processes remain essential, but they are also slow, inconsistent, and subject to human bias and institutional asymmetries.

At a time when AI systems, particularly general-purpose large language models (LLMs), are increasingly integrated into healthcare workflows, a crucial question arises: Can AI meaningfully contribute to ethical deliberation, despite not being specifically designed or trained for bioethical decision-making? And, if so, what are the risks, benefits, and boundaries of such involvement?

This workshop investigates the suitability, limitations, and potential role of generalist LLM-based chatbots in addressing complex clinical-ethical dilemmas. The core aim is to examine whether AI can augment ethical reasoning in healthcare, or whether its outputs risk oversimplification, hallucination, or ethically unsound recommendations.

Expected Content

The workshop is structured around three components:

(1) Presentation of Ethical Scenarios

Participants will be introduced to a series of real-world-inspired medical dilemmas that exemplify the tensions between legal norms, ethical principles, and clinical judgment.

(2) Human vs. AI Ethical Reasoning (Turing-style Exercise)

For each scenario, two anonymised ethical assessments will be presented: one crafted by human experts and one generated exclusively by an LLM.

Without knowing which is which, participants will evaluate the quality, coherence, and ethical grounding of both answers.

(3) Critical Analysis and Thematic Discussion

After the 'reveal', the session will explore recurrent themes such as:

(1) The adequacy of LLM moral reasoning,
(2) The transparency and explainability of AI judgments,
(3) Legal and ethical constraints on using AI in normative decision-making,
(4) Implications for accountability and clinical governance.

Audience Involvement

The workshop is highly interactive. Participants will:IVote live (via cards or digital poll) on which answer they consider ethically superior;

(1) Guess which response is human-generated and which stems from AI;
(2) Engage in facilitated group discussion to justify their choices;
(3) Compare reasoning patterns and identify where AI converges: or diverges: from established ethical frameworks;
(4) Reflect collectively on under what conditions, if any, AI might responsibly support clinical ethics decision-making.

By blending analytical discussion with an engaging Turing-style exercise, this workshop aims to deepen understanding of the promise and pitfalls of AI in bioethics. Ultimately, it seeks to evaluate if, how, and when AI systems might responsibly contribute to clinical ethical deliberation, while making their epistemic, legal, and moral limitations transparent.

W8: Regulating Medical Decision-Making for Minors: Comparative and Clinical Perspectives Across Europe

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Centre for Public Law, Faculty of Law, KU Leuven, Leuven, Belgium
Child and Youth Institute, KU Leuven, Leuven, Belgium

Jaan Toelen
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Ingrid Boone
Child and Youth Institute, KU Leuven, Leuven, Belgium
Institute for Family Law and Juvenile Law, Faculty of Law, KU Leuven, Leuven, Belgium

Aim

This workshop addresses the complexity of medical decision-making involving minors in Europe. Both the European Convention on Human Rights and Biomedicine and the United Nations Convention on the Rights of the Child require that minors be involved in healthcare decisions in accordance with their age and maturity. While these instruments establish a shared normative framework, European states differ significantly in how they regulate the legal position of minors, reflecting different balances between autonomy and protection.

The workshop aims to show how the legal position of minors in medical decision-making is regulated across European jurisdictions and how these are put into practice. By combining a comparative legal analysis, national

perspectives, and empirical insights from paediatricians, the workshop seeks to identify common patterns, divergences, and gaps between law and clinical practice, and to stimulate discussion on shared challenges and harmonisation.

Expected Content

The workshop is structured in four interrelated parts:

(1) Short cases with live polling

Initially five clinical cases that illustrate the topic of the workshop will be presented to the public with live polling. The answers will be used in the subsequent parts of the workshop.

(2) Comparative Legal Analysis

Prof. Dr. Steven Lierman will present the results of an extensive comparative study covering 20 European countries, conducted through a questionnaire completed by national legal experts. The study examines key aspects of minors' healthcare decision-making, including consent to treatment, the assessment of decision-making capacity, and confidentiality. It also addresses specific legal frameworks applicable to different types of medical decisions, such as sexual and reproductive healthcare, mental health treatment, end-of-life decisions, and cosmetic procedures. This comparative analysis identifies key similarities and differences across jurisdictions and distinguishes a range of regulatory approaches, thereby providing a structured framework for the subsequent discussion.

(3) National Perspectives

Building on this comparative framework, a series of brief presentations by national legal experts will explore how these regulatory approaches operate in practice. This part aims to deepen the understanding of how different legal frameworks govern the legal position of minors by moving from a comparative overview to in-depth national perspectives.

The selected countries reflect the diversity of regulatory models identified in the comparative study. Luxembourg has a system where decision-making capacity is assessed on a case-by-case basis. Austria has a model that combines a fixed age threshold of 14 years with additional parental involvement for treatments with potentially serious consequences. Norway has a system with dual age thresholds, while France has an approach linked to the age of majority.

Medical Practice and Professional

The workshop concludes with a presentation by Prof Toelen on how paediatricians across Europe approach decision-making involving minors. The results will be compared with the legal frameworks presented earlier, providing insight into possible discrepancies between law and clinical practice.

Audience Involvement

To ensure an interactive and engaging format, the workshop will actively involve participants throughout:

(1) Live polling: Participants will be invited to respond to short hypothetical cases involving minors in different medical contexts (e.g. contraception, mental health treatment, refusal of treatment). Through live polling, the audience will be asked who should be entitled to decide and whether parental involvement is required. The results will provide an immediate comparison of perspectives across jurisdictions and will serve as a starting point for discussion of the legal frameworks presented during the workshop.
(2) Interactive Q&A moments: Facilitated exchanges will encourage reflection on national experiences and potential best practices.
(3) Plenary discussion: The workshop will conclude with an open debate inviting participants to share insights on whether greater convergence in Europe is desirable or feasible.

The combined use of case studies, structured dialogue, and live-feedback tools will foster meaningful interdisciplinary exchange between legal scholars and healthcare professionals.

W9: Regulating the Commercial Determinants of Health: Towards a National Duty of Care?

Rosalind Turkie
Faculty of Law, University of Amsterdam, Amsterdam, The Netherlands

Katrina Perehudoff
Faculty of Law, University of Amsterdam, Amsterdam, The Netherlands

Aim

Non-communicable diseases (NCDs) account for the majority of premature mortality across Europe, yet their commercial drivers remain underregulated in most Member States. Transnational companies contribute substantially to the NCD burden through the sale, promotion, and marketing of unhealthy commodities (including tobacco, alcohol, and ultra-processed food and drink), shaping the environments in which people live and work, influencing choices through marketing and pricing strategies that undermine public health policies. While the drivers of the NCD burden are complex and multifactorial, the influence of commercial interests in shaping policy environments, markets, and human and planetary health and wellbeing is a major driving force.

This has been termed the commercial determinants of health: the systems, practices, and pathways through which commercial actors shape health outcomes, often to the detriment of equity, sustainability and human rights. Despite growing recognition of this concept by public health practitioners and researchers, the World Health Organisation and the European Union, European health law has yet to develop a coherent legal architecture for holding industry accountable.

This workshop addresses a fundamental and underexplored question: can and should European states bear a duty of care towards their populations in respect of the commercial determinants of NCDs, and what legal instruments could give effect to such a duty?

Expected Content

The 90-minute workshop will be structured around four thematic pillars, each introduced by a short presentation (8–10 minutes) followed by facilitated discussion:

Presentation 1: Tort Law Applied to Pharmaceutical Companies: An Unwritten Duty of Care?

This presentation examines whether the Dutch tort law 'duty of care', applied in 2021 against a private company in *Milieudefensie et al v Royal Dutch Shell*, can be used to regulate pharmaceutical companies, an interpretation which is supported by the international human rights law framework. It explores the limits and potential of this approach in the Netherlands for regulating excessive pricing of pharmaceuticals.

Proposed speaker: Rosalind Turkie

Presentation 2: Legal Pathways Towards Fair Pricing and Access: a Typology for Governing Medicines Price Transparency

Excessive medicines pricing reflects the commercial determinants of health, where regulation, corporate practices and information asymmetries shape prices and access to care. "Transparency" has emerged as a key regulatory response, notably through the World Health Organization's WHA Resolution 72.8. This paper develops a legal typology of disclosure mandates across the pharmaceutical lifecycle, ranging from secrecy to full public disclosure. It shows that fragmented national implementation produces regulatory inconsistency, weakens oversight, and sustains power imbalances. Transparency is thus a normative governance tool, but without coordinated and enforceable legal frameworks, it remains insufficient to address inequities in medicines access.

Proposed speaker: Katrina Perehudoff

Presentation 3: Front-of-Pack Labelling and the State's Right to Regulate

Framing

Examines the legal basis and limits of the state's right to restrict commercial speech in the interest of public health. It considers the right to information as a component of the duty of care, and asks whether a failure to adopt mandatory front-of-pack nutrition labelling or to restrict the marketing of unhealthy

commodities to children could constitute a breach of a state's positive health obligations.

Proposed speakers: TBC, Amandine Garde

Audience Involvement

The second part of the workshop will involve small-group discussions on a hypothetical regulatory scenario (depending on the number of participants, 1–3 scenarios will be proposed on different commercial drivers), requiring participants to assess the legal viability and policy implications of imposing a national duty of care in a given Member State context. Groups will report back in plenary, with one participant feeding back. The session will close with a collective mapping exercise identifying priority gaps in the current European legal framework and potential avenues for reform.

W10: Revisiting European Health Values as a Guide for Current and Future Challenges

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MCI | The Entrepreneurial School®, Innsbruck, Austria

Joaquin Cayon-De las Cuevas
IDIVAL-Universidad de Cantabria, Santander, Spain

André den Exter
Erasmus University Rotterdam, Rotterdam, The Netherlands

Tamara Hervey
City St George's, University of London, London, UK

Anniek de Ruijter
University of Amsterdam, Amsterdam,, The Netherlands

Tomislav Sokol
Zagreb School of Economics and Management, Zagreb, Croatia
European Parliament, Brussels, Belgium

Aim

This workshop critically re-examines the 2006 Council conclusions on common health values and principles against the background of various challenges, such as population ageing, rising chronic and multimorbid conditions, workforce shortages, and geopolitical tensions. Drafted in response to the emerging dynamics of patient mobility and Member States' efforts to retain regulatory authority over healthcare in 2006, the document reflected a specific political and legal settlement. Two decades later, profound transformations in the European health landscape call for renewed assessment. These also include digitalization, demographic ageing, pandemics, environmental pressures, and widening health inequalities. In parallel, the post-Lisbon constitutional framework has reinforced the significance of foundational European Union values, including human dignity, equality, and solidarity. Against the backdrop of the policy concept of the European Health Union, the workshop

asks whether the 2006 framework remains normatively sufficient, whether it should be revised, and which legal, ethical, and policy concepts ought to shape its future development.

Expected Content

The workshop will combine legal analysis, normative reflection, and policy discussion. In terms of structure, this workshop will open with a brief account of the origins, function, and limitations of the 2006 document within the evolution of European Union health law. This introductory contribution will also examine how contemporary developments challenge existing formulations of key principles such as universality, access to good quality care, equity, and solidarity. Based on a recent paper (Frischhut *et al.*, 2026), this workshop will particularly (but not only) cover current challenges around the key themes of digitalisation, critical medicines, and workforce shortages.

The main discussion will be organized around three thematic axes. First, substance: should the existing values and principles be retained, clarified, or reformulated, and should new concepts such as One Health, sustainability, inclusion, resilience, or leave no one behind be incorporated? Second, scope: should the framework move beyond a patient-centred perspective to address the healthcare workforce, vulnerable populations, and procedural dimensions such as participation, transparency, and accountability? Third, legal and institutional form: should the document remain soft law, acquire stronger normative status, or be embedded more explicitly in European Union primary and secondary law, including the right to a high level of health protection? The workshop will also consider how a revised text could align with broader international frameworks, including those of the Council of Europe and the World Health Organization, while preserving a degree of timelessness.

Audience Involvement

Based on the Lancet paper and the findings of a workshop in the European Parliament (EP) in April 2026, participants are encouraged to actively contribute to further develop the findings achieved so far. In a similar way as in the EP workshop, the findings will be documented and summarised, naming the contributions of the individual participants, and publishing them on the website of this project.

Reference

M. Frischhut, B. Prainsack, T. Hervey, A. de Ruijter, T. Sokol, N. Guldemond, J. Cayon-De las Cuevas, A. den Exter, N. Fahy and G.M. Oscar Fares, '20 Years of EU health values (2006–2026): four proposals for the future', *The Lancet Regional Health: Europe* 61 (2026) 101589, doi: 10.1016/j.lanepe.2026.101589.

W11: Trends in Social Health Insurance Law

Andre den Exter
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Aim

This workshop will present and discuss current tendencies in social health insurance law (SHI). This workshop is part of a comparative book project on social health insurance systems from different continents.

It aims to examine SHI laws, identify common legal dilemmas, challenges, and risks, and discuss potential solutions. Given the commonalities, the outcomes may also be relevant to other SHI systems. Although SHI systems in high-income countries may face different difficulties than those in middle – and low-income countries, they share the same underlying principles and, thus, similar legal issues, although not simultaneously. These principles are particularly relevant to understanding recent challenges and dilemmas in SHI, such as the sustainability of healthcare systems and the need for healthcare rationing/ priority-setting, reimbursement of excessive pricing of innovative treatment options, waiting lists/times and delays in healthcare access, scarcity of medicines, and cross-border healthcare.

Expected Content

Achieving consensus about the principles underpinning the legal framework of social health insurance (SHI), as well as searching for common legal challenges and potential solutions. Therefore, presenters will be instructed to explain tendencies and developments in:

(1) Healthcare access (particularly vulnerable groups; waiting times; and shortages of medicines)
(2) Barriers in cross-border health care initiatives
(3) The role of health insurers in enhancing the quality of care provided and consumer choice of provider and/or insurer
(4) SHI sustainability measures and its impact on healthcare access (cost-sharing measures, the relevance of Health Technology Assessment (HTA), delisting healthcare services and goods, health care rationing/ priority-setting measures)

(5) Legal remedies of the insured to enforce health insurance entitlements, thus the justiciability of health insurance rights

The outcomes will be incorporated in the SHI book project's final chapter (Tendencies and developments in SHI)

Audience Involvement

A limited number of presenters will be invited to explain key outcomes of their SHI-related research. Each presenter (4 in total) will summarise developments and tendencies in SHI systems. The audience is encouraged to participate in the discussion (30 min). Audience participation may help amend or confirm preliminary results. The book project's editor will chair this session.

No maximum number of participants. Participants will be informed about the outcomes afterwards.

W12: Vulnerability, Access to Healthcare and Necessary Legal Mechanisms to Mitigate Discriminatory Effects

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Matteo Ciampa
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Magdalena Flatscher-Thöni
UMIT TIROL: Private University for Health Sciences and Health Technology, Hall in Tirol, Austria

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Caroline Voithofer
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Aim

Ensuring equitable access to healthcare remains a central challenge in increasingly unequal societies. Legal frameworks play a crucial yet ambivalent role: while they aim to guarantee access, they may also reproduce structural barriers for vulnerable groups. This interactive workshop addresses one central question: how do legal regimes mediate the tension between private autonomy and

solidarity in shaping access to healthcare? Adopting a comparative and interdisciplinary perspective, the workshop explores how intersectional factors, such as socio-economic status, gender, disability, and migration, affect access to care.

Barriers accessing healthcare arise, for example, at the administrative level, where complex procedures may hinder access to appropriate and adequate healthcare and may require support-mechanisms. At the same time, civil law provisions may also prove insufficient to protect vulnerable persons. Various legal systems, such as the Austrian one, base their contract law on the principle of "private autonomy" in contractual relations, obscuring substantial barriers to accessing healthcare. This effect may be mitigated by solidarity-based social security systems, such as the Austrian and German health insurance-system, which seek to compensate for this by pooling resources and securing equal access to healthcare for all. Yet even these systems may reach its limits in cases of systemic failure, resource scarcity, automated data analysis and insufficient service provision or awareness for barriers.

Against this backdrop, the workshop explores the topic of access to healthcare for vulnerable groups, by using a comparative-law-approach to discuss barriers to access and necessary legal countermeasures.

Expected Content

Attention is devoted to questions of individual "private autonomy", the scope of health insurance benefits, effects in data-driven healthcare systems and the legal support available or necessary to "vulnerable persons" in decision-making and in the exercise of their interests and autonomy. Hence, the workshop is structured around four key case studies that illustrate how legal frameworks mediate the tension between private autonomy and solidarity in access to healthcare.

First, special focus is placed on reproductive medicine, including its legal, social, and economic implications and its impact on reproductive autonomy in light of prevailing family norms and structural inequalities. In this context, the workshop asks which reproductive healthcare services should be regarded as part of a solidarity-based healthcare system and how non-discriminatory access can be ensured. It also addresses legal exclusions, social barriers, and ethical issues affecting LGBTQIA* persons in accessing reproductive healthcare.

Another key aspect will be assisted suicide as a medical service. Regarding vulnerable persons in particular, end-of-life decision-making gives rise to

significant legal and ethical tensions, including the need to protect against rash decisions on the one hand and the risk of excessive formal and financial barriers to the constitutionally protected right to self-determined dying on the other.

The workshop further discusses the European law dimension of healthcare access. In addition to the general framework governing cross-border healthcare for EU citizens, particular attention is paid to the position of third-country citizens and to the question of whether and to what extent European law can contribute to ensuring adequate or equal access to healthcare, focussing on vulnerable groups.

Finally, the workshop will address the digital dimension of equitable and fair access, focusing on data protection issues within data-driven healthcare systems in the context of a European Health Data Space. Vulnerable groups often face difficulties in effectively exercising their rights due to language barriers and limited access to information. The question of whether data- and AI-driven healthcare systems may intensify or mitigate discriminatory effects for vulnerable groups will be addressed. Based on a case study necessary legal measures required to mitigate potential barriers are discussed.

Audience Involvement

The workshop aims to spark a participation-driven discussion based on brief input from the organisers.

W13: The Future of Reproduction: IVG, Artificial Wombs and the Limits of Law

Lotta Eriksson
The Swedish National Council on Medical Ethics, Stockholm, Sweden

Lena Wahlberg
Associate Professor, Law Faculty at Lund University, Lund, Sweden

Kavot Zillén
Associate Professor in public law and a Senior Lecturer at Stockholm University's Department of Law, Stockholm, Sweden

Nicola Williams
Wellcome Lecturer in the Ethics of Human Reproduction at Lancaster University's School of Global Affairs, Lancaster, UK

Niklas Juth
Professor of Medical Ethics at Uppsala University, Sweden, chair of the research council of Uppsala region and an expert member of Swedish National Council on Medical Ethics, Uppsala, Sweden

Andrew Darby
Research Associate in Speculative Design on The Future of Human Reproduction Project, Lancaster, UK

Carolina Östgren
Research Officer at the Swedish National Council on Medical Ethics, Uppsala, Sweden

Aim

To examine the ethical and legal foundations that European reproductive law will need to develop in order to respond to in vitro gametogenesis (IVG) and artificial womb technology – not merely how existing rules should be applied or amended, but which values should guide the choices that law will be required to make.

Expected Content

In vitro gametogenesis (IVG) – deriving eggs and sperm from somatic cells – and artificial womb technology are moving from scientific possibility toward clinical reality. Both challenge foundational assumptions in European reproductive law, but in distinct ways.

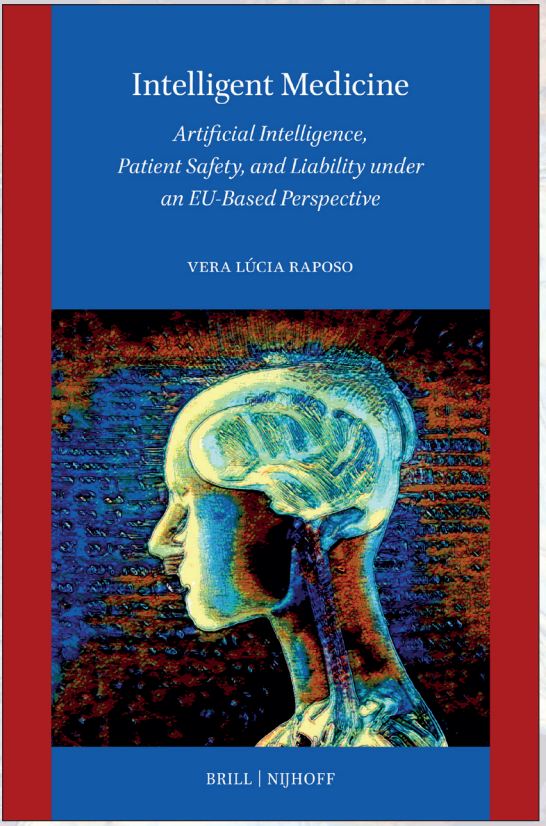
AVG disrupts established legal categories across several domains. On consent: what constitutes valid consent to the creation of gametes from a person's cells, and how do existing donation frameworks apply? On moral and legal status: should IVD gametes and embryos created from them attract the same protections as conventionally produced gametes and embryos? On parenthood: who counts as a genetic parent, whether multiplex reproduction involving three or more genetic contributors should be permitted, and whether current legal parenthood frameworks require reform. On child welfare: at what point is the technology safe enough for human reproductive use, and what evidence threshold should apply? And on selective reproduction: by enabling embryo selection at unprecedented scale, IVG intensifies existing debates about which grounds for selection are ethically acceptable, and what the cumulative effect of large-scale selection means for society.

Artificial wombs raise a related but separate set of questions. If gestation can occur entirely outside the human body, what becomes of the legal frameworks built around pregnancy, bodily autonomy, and the relationship between a woman and a foetus? Does ex utero development affect the legal status or interests of the foetus? How does the technology interact with existing abortion law? And how should regulation address technologies that may simultaneously expand reproductive options for some while generating new pressures or inequalities for others?

Legal parenthood, consent frameworks, and licensing regimes can set boundaries – but not determine which reproductive futures are worth enabling. That requires normative argument about human dignity, the meaning of parenthood and pregnancy, and the values reproductive medicine should serve.

Audience Involvement

Participants will engage through plenary discussion following the panel presentations. As a complement, a speculative design team associated with Lancaster University will present work that makes possible reproductive futures tangible and discussable – offering participants a method for reasoning about technologies that do not yet exist but are rapidly approaching.



Intelligent Medicine

Artificial Intelligence, Patient Safety, and Liability under an EU-Based Perspective

Vera Lúcia Raposo

May 2026
E-ISBN: 978-90-04-54398-0
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How safe is medicine when decisions are made by artificial intelligence? What happens when a misdiagnosis comes from an algorithm rather than a doctor? *Intelligent Medicine* explores these urgent questions. The book shows how AI transforms patient safety, redefines the medical standard of care and shifts legal responsibility when things go wrong.

It provides a clear EU-based perspective while drawing on law, ethics, medicine, and technology. Taking a practical approach, theory meets real-life dilemmas, and the combination offers concrete guidance for professionals, policymakers, and scholars facing the challenges of AI in healthcare.

NIJHOFF
De Gruyter Brill

Uppsala, 9-11 September

Tenth European Conference on Health Law

Additional Abstracts

EUROPEAN ASSOCIATION of HEALTH LAW

Oral presentations

O99: Ensuring Patient Rights in Healthcare: Lessons from Lithuanian Practice for European Health Law

Andra Lapė[1]
[1] *Mykolas Romeris University, Law School, Lithuania*

Abstract text: The protection of patient rights represents a central component of contemporary European health law, reflecting fundamental values such as human dignity, patient autonomy, and accountability in healthcare systems. Effective legal mechanisms for safeguarding patient rights are therefore essential.

This presentation examines how patient rights are ensured in practice through legal dispute resolution mechanisms. While European health law frameworks emphasise the protection of patient rights, the effectiveness of national mechanisms addressing violations varies significantly.

The research focuses on the Lithuanian healthcare system as a case study illustrating the interaction of legal instruments aimed at protecting patient rights. The analysis is based on doctrinal legal research, examining legislation, regulatory developments, and complaint and dispute resolution mechanisms in the Lithuanian healthcare system.

In Lithuania, different institutional mechanisms exist for addressing healthcare disputes. One mechanism concerns compensation for damage caused to patients during healthcare provision, while another focuses on the protection of violated patient rights. These mechanisms are implemented through pre-litigation procedures designed to evaluate complaints, assess violations, and determine appropriate remedies.

Recent developments in Lithuanian law further illustrate the evolving nature of patient rights protection. From September 2025, a new regulatory framework introduces additional procedures for the protection of violated patient rights, potentially strengthening access to remedies. Alongside these mechanisms, alternative dispute resolution methods such as mediation may play an important role in addressing conflicts between patients and healthcare providers by facilitating dialogue and restoring trust.

The research suggests that while the coexistence of several mechanisms may broaden access to remedies, it may also create fragmentation and procedural complexity. The findings indicate that strengthening alternative dispute resolution, particularly mediation, could improve the effectiveness of complaint handling and promote more constructive, trust-based solutions.

The research argues that a more structured integration of mediation within healthcare dispute resolution systems could contribute to more transparent, accountable, and patient-centred healthcare governance. The Lithuanian experience offers valuable insights into how legal frameworks may evolve to better protect patient rights while promoting trust, communication, and patient safety in healthcare.

O100: Protecting Esports Players as Digital Athletes: Health Law Gaps and Human Rights-Based Legal Protections

Vilius Lapis[1]
[1] *Mykolas Romeris University, Law School, Lithuania*

Abstract text: Electronic sports (esports), defined as competitive video gaming, has transformed into a global phenomenon, generating billions in revenue and gaining recognition within the broader sports ecosystem. Unlike traditional sports, which benefit from well-established legal frameworks and safeguarding protocols, esports lacks comparable structures to protect its players. This disparity is particularly concerning given the industry's rapid growth and the unique health challenges faced by its players, many of whom are minors.

The challenges faced by esports players – including repetitive strain injuries, poor ergonomics, anxiety, burnout, and exposure to cyberbullying – reveal significant gaps in existing health and safety frameworks. From a European health law perspective, these gaps raise concerns regarding the adequacy of current regulatory approaches in ensuring the right to the highest attainable standard of health in digital environments.

Young players are particularly vulnerable due to their developmental stage and limited legal protections. Many minors enter binding contracts lacking adequate health safeguards, exposing them to potential exploitation. This highlights the need for stronger alignment with European standards on health protection and the rights of minors.

This study adopts a doctrinal legal research approach, analysing relevant legal frameworks, human rights standards, and emerging regulatory responses applicable to esports.

The findings suggest that the current regulatory landscape remains fragmented and insufficiently adapted to esports-specific health risks. There is no coherent European-level approach, and existing regulation is dispersed across different legal fields, resulting in gaps in protection and limited legal certainty.

This paper proposes a human-rights-centred approach to addressing health concerns in esports. Key recommendations include integrating mandatory health safeguards into player contracts, ensuring access to medical and psychological support, and strengthening oversight mechanisms. Greater use of structured dispute resolution and dialogue-based approaches could further enhance trust and protection in esports environments. At the European level, improved coordination and the development of common principles or soft law guidance could support more consistent protection of esports players. National measures aligned with human rights standards can further strengthen baseline protections.

By addressing the vulnerabilities of young esports players and grounding interventions in human rights and health law, the industry can create a safer, more ethical environment. Protecting the health of its players is not only a moral and legal obligation but also a strategic necessity for the long-term sustainability and integrity of esports.

O101: The European Health Data Space in an Evolving Legal Landscape

Elisabeth Herzog[1]
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Abstract text: Since publication of the proposal for a Regulation on the European Health Data Space and continuously after the EHDS Regulation's entry into force on 26 March 2025, many articles and other contributions have focused on the EHDS Regulation's relationship to the GDPR. At the same time, despite the relevance of Intellectual Property rights (IP rights), trade secrets and, potentially, competition law and the new data and AI regulations – specifically the Data Governance Act (DGA), Data Act (DA) and AI Act – many questions regarding these other areas of law remain unanswered.

Essentially, building on the author's PhD research analysing the relevant laws and literature concerning the role of IP rights, trade secrets, competition law, the DGA, DA and AI Act concerning data access and data sharing in general and health data specifically, this presentation will mainly address the EHDS Regulation's relationship with these other laws. In light of the time it will require to do so thoroughly, the presentation will refrain from another in-depth discussion of the relationship between EHDS Regulation and GDPR.

The presentation will shine a light on why the provision in Art. 52 EHDS Regulation for cases where the electronic health data to which access is requested are protected by IP rights or as trade secrets is insufficient. It might at the same time pose a risk to Health Data Holders' IP rights and trade secrets, while also giving them a reason to block data access. Furthermore, it will be addressed how the introduction of the Health Data Access Bodies, from a competition law standpoint, are necessary, while other issues in this field remain unsolved by the Regulation. While the DGA and DA seem not play a major role, since "training, testing and evaluation of algorithms, including (…) AI systems" is specifically mentioned among the permitted purposes for health data processing in Art. 53 para. 1 lit. e (ii) EHDS Regulation, a closer look into the AI Act will be necessary to determine whether the AI Act's rules are sufficient for the trust necessary in order for the EHDS Regulation to come to its full potential. Indeed, these two regulations might leave gaps that will need to be filled by other laws, mainly the GDPR and the Medical Device Regulation.

O102: The Transparency Paradox in AI-Based Healthcare

Marie Kohoutová[1]
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Abstract text: The increasing deployment of artificial intelligence (AI) in European healthcare systems challenges traditional understandings of transparency and informed consent. While both the Medical Devices Regulation (MDR) and the EU AI Act impose transparency and human oversight obligations, the psychological and therapeutic consequences of disclosure remain insufficiently examined. This study, situated within the author's doctoral research on AI transparency in healthcare and law, addresses the emerging tension between legal transparency requirements and therapeutic efficacy.

The study applies doctrinal legal analysis of European health law instruments, including the Oviedo Convention, the MDR, the GDPR, and the EU AI Act, combined with normative bioethical evaluation. It further integrates interdisciplinary findings from placebo and nocebo research to assess how transparency practices may influence patient trust and treatment outcomes.

The study identifies a "transparency paradox" in AI-based medicine. On the one hand, insufficient disclosure regarding data origin, algorithmic functioning, or system limitations may undermine patient autonomy and erode trust. On the other hand, excessive technical disclosure could generate anxiety, reduce decisional quality, and diminish placebo-related therapeutic benefits. Drawing on the doctrine of therapeutic privilege as recognised in European bioethics and case law, the study demonstrates that limited, contextualised non-disclosure can be legally and ethically justified in exceptional circumstances. The analysis further distinguishes between epistemic trust (grounded in understanding) and institutional trust (grounded in regulatory validation), arguing that transparency affects these dimensions differently.

The study advances the concept of proportional transparency as a novel regulatory and ethical framework. Under this model, disclosure duties are calibrated to the role of the actor (developer, regulator, clinician, patient) and to the risk category of the AI system under the EU AI Act. Proportional transparency preserves patient autonomy while safeguarding therapeutic effectiveness and systemic trust. The findings contribute to European health law by reconciling transparency obligations with core bioethical principles, including autonomy, non-maleficence, and the protection of human dignity in AI-mediated healthcare.

O103: Tech-Driven Care: Navigating the Legal and Ethical Challenges

Bjoern Schmitz-Luhn[1]
[1] *Bonn University, Center for Life Ethics*

Abstract text:

Aim
This presentation explores the legal, ethical, and regulatory challenges surrounding the use of new technologies in the management of chronic diseases, such as cardiovascular conditions, diabetes, and neurodegenerative disorders. It will examine how innovations like wearable sensors, mobile health applications, and AI-driven tools can transform patient care, while addressing the complexities of technology integration in healthcare, and the protection of autonomy.

Expected Content
Chronic diseases impose significant challenges on both patients and healthcare systems globally. Emerging technologies have the potential to improve disease management by enabling real-time monitoring, personalized treatments, and efficient care delivery. Wearable sensors, mobile applications, and AI platforms can provide continuous monitoring of vital signs, predict health risks, and guide treatment adjustments based on real-time data. These technologies offer the promise of enhancing patient quality of life and alleviating the burden on healthcare providers and caregivers.

However, these advancements also raise critical legal and ethical issues. The presentation will examine the regulatory landscape for these technologies, highlighting the inconsistencies and gaps in current laws. Different countries have varying healthcare policies and data protection regulations, creating challenges for the global implementation of these technologies. Furthermore, issues of access and equity must be considered, as not all populations have equal access to these innovations due to factors like socioeconomic status, healthcare infrastructure, and insurance coverage.

Ethically, the use of technology in chronic disease management raises concerns about informed consent, data privacy, and patient autonomy. Questions about who is liable when technology fails or misjudges a patient's condition will also be discussed. Moreover, the transparency of AI-driven decisions and the protection of personal health data are critical factors that must be addressed to ensure that ethical standards are met.

The presentation will propose solutions and recommendations to address these challenges, focusing on fostering the responsible use of emerging technologies within necessary legal frameworks, balancing innovation with regulation and safeguarding the interests of patients and healthcare providers alike.

O104: Law as a determinant of risk-sharing agreements for drug coverage in Brazil

Daniel Wang[1]
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Abstract text: Risk-sharing agreements (RSAs) are contracts in which the costs of funding a medical treatment are divided between the health system and the pharmaceutical industry based on future and uncertain events. They have been adopted in many countries, particularly in Europe, to manage the financial and clinical uncertainties associated with funding high-cost treatments that enter the market with immature evidence. However, RSAs are fraught with scientific, managerial and economic complexities. There are also legal complexities that remain understudied. This article aims to fill this gap by analyzing the three attempts to reach an RSA in Brazil — for the drugs Spinraza, Zolgensma and Elevidys. It argues that, in Brazil, the law is a driver for RSA negotiations but also changes the structure of incentives for reaching an agreement and limits the possible formats. The case of RSAs in Brazil highlights two trade-offs that the legal framework may create for health systems: first, between legal mechanisms that circumvent regular HTA to expedite the funding of new technologies and the system´s capacity to control spending and negotiate prices; and second, between, on the one hand, legal certainty and accountability and, on the other, administrative flexibility and innovation. The case of Brazil, a mid-income country in the global south, offers valuable insights for comparison with the experience of European countries, where such agreements were pioneered and widely used.

Poster presentations

P13: Children's Right to Financially Accessible Health Care: A Holistic Human Rights-Based Approach

Maarten Wille[1]
[1] *Leiden University, Child and Health Law, The Netherlands*

Abstract text: Innovative pharmacotherapies, such as stem cell-based gene therapy for children, experience difficulty receiving financial coverage due to their high costs, barring access for children dependent upon these therapies. This is part of the larger and growing socio-economic challenge of keeping health care costs affordable. It involves the juxtaposition of interests between the child's interest in financially accessible healthcare and the public's interest in sustainable public finances. But how can we evaluate if the state makes equitable and rights-based reimbursement choices? Currently, there is no legal framework rooted in human and children's rights to answer the question of whether a particular healthcare service should be financially accessible.

Therefore, this presentation will answer the question of to what extent states must ensure financial accessibility of health care for children from the perspective of the right to health enshrined in Article 24 of the Convention on the Rights of the Child (CRC). Using the holistic human rights-based approach, a structured, rights-based framework is developed to guide reimbursement decisions for paediatric therapies.

It is concluded that states should strike a fair balance between the child's interest in financially accessible healthcare and the general interest of public finance sustainability. In this balance, four key criteria should be considered: whether a healthcare service (i) is life-saving, (ii) supports the child's development, including the improvement of self-reliance or active social participation, (iii) enhances dignity, and (iv) if withheld, would amount to inhuman or degrading treatment. An obligation supported by these characteristics can only be contravened if the implementation is beyond the maximum extent of available resources.

This evidently implies that decisions on financial coverage simply based on price are not compatible with human and children's rights. However, this framework does not only inform national reimbursement choices, but it also addresses emerging challenges in the European context, particularly the equitable allocation and reimbursement of health care across diverse legal systems. This presentation further contributes to ongoing debates on alternative mechanisms to ensure financial accessibility, such as enhanced collaboration between pharmaceutical companies, academia, and governments, and the strategic use of intellectual property law.

P14: Gender Equality in Healthcare Financing

Jennifer Fuschlberger[1]
[1] *University of Salzburg, Department of Public Law, Austria*

Abstract text: Medical care is made for men. Preclinical studies on pharmaceuticals are largely conducted on male animals, and clinical trials are predominantly conducted on men, which are still considered the standard for representing the human body in medicine. Therefore, too many women remain underdiagnosed or receive inadequate treatment. And this despite the fact that there are fundamental differences between the female and male body.

Both Austrian and European law stipulate obligations that require equal treatment of women and men. At the Austrian level, Article 7 Federal Constitutional Law (B-VG) stipulates that all citizens are "equal before the law" and that regional authorities are committed to a "de facto equality" of women and men. In the area of federal budgetary management, Articles 13(3) and 51(8) B-VG oblige regional authorities to consider the objective of "de facto equality". The emphasis on "de facto" equality shows that a de facto gender-specific process of advancement – e.g. through the allocation of financial resources or through funding regulations – must be actively shaped by the federal government.

At European level, there are also obligations to treat "women and men equally in all areas", enshrined in primary legislation under Article 2 TEU, Article 20 CFR and Article 23 CFR. Article 8 TFEU stipulates that the Union shall "aim to eliminate inequalities and promote equality" in all its activities – meaning, that the EU institutions are required to initiate a process of gradual convergence toward a regulatory ideal. In my dissertation, I examine

- what is meant by these statutory provisions concerning equal treatment and equality obligations regarding the biological sex,
- whether member states have an obligation to make the distribution of public resources in the health sector dependent on these,
- if Austria is currently meeting these obligations and
- what legal instruments can be used to enable these obligations to be met.

This concerns the distribution of public resources in the context of healthcare financing to local authorities, universities, hospitals, social security institutions, and economic operators. At the conference, I would like to present my findings, particularly regarding the key instruments for ensuring a positive impact on gender equality that have been identified so far:

- Budgetary Law: Stricter legal obligations for analysis, evaluation, and revision of individual budget items, including effective sanction mechanisms.
- Distribution of public resources to economic operators via state aid or public procurement procedures: Establishment of obligations for recipients of public resources regarding gender-equitable use of financial resources.

P15: At the Frontiers of Human Dignity: Legal and Ethical Challenges in the Display of Human Remains in European Museums

Maria Aluas[1]

[1] *Iuliu Hatieganu University of Medicine and Pharmacy, Cluj-Napoca, Romania*

Abstract text: As Europe reexamines the boundaries of health law and human rights, issues surrounding the collection, retention, and display of human remains in museums demand renewed legal attention. Many such collections, founded in times when consent and dignity were disregarded, raise profound questions about ownership, privacy, and the stewardship responsibilities of modern institutions.This presentation explores the legal frameworks governing human remains in European medical and cultural museums, with a focus on human dignity, integrity, and the right to post-mortem privacy. It analyzes whether body parts can be legally possessed or commercialized, and how existing laws address the offences and harms caused by the display or sale of human remains. A central consideration is whether museums have legal or ethical obligations to repatriate or recontextualize items acquired under historically illicit circumstances. By situating these issues within an evolving European health law context, one shaped by human rights principles, bioethics, and cultural heritage law, this presentation highlights how respect for the deceased can inform more coherent and ethically sustainable legal practices across European institutions.

Other contributions

Design Fiction, Public Engagement and the Future of Human Reproduction

Developments in partial ex utero gestation technologies which support pre-viable infants through artificial womb and placenta systems have increased the likelihood of full-term gestation of a human embryo outside of the womb (complete ectogenesis). Given the timescales associated with legislative reform, the prospect of partial ex utero gestation technologies justifies speculative inquiry into the socio-legal implications of far-future scenarios involving complete ectogenesis as a sensemaking exercise to inform debate and responsible anticipatory governance. However, despite recognising the need for richer dialogue to inform robust and defensible policy, policy makers face significant challenges in facilitating informed public dialogue on advancing reproductive technologies. We propose that speculative design is a valuable and accessible tool which can enable engagement with the messiness of technologically mediated biomedical futures and prompt deep values-based conversations.

A multidisciplinary academic group (n=12), drawn from Design, Law, Linguistics, Literature, Philosophy, and Psychology, employed a Speculative Design methodology to produce fictional artefacts exploring lived social experiences of complete ectogenesis. The design fiction approach was selected for its capacity to generate insight through acts of making and through the critical debate they subsequently provoke. The resulting artefacts were discussed within the group, evaluated in a closed exercise with an expert audience, and subsequently exhibited publicly. Seventeen speculative artefacts were produced spanning reproductive healthcare, policy, identity, and social infrastructure, ranging from institutional documents and campaigns to consumer products and educational materials.

Through this work, our team discovered new, creative and potentially more inclusive ways of motivating critical reflection on current social trends and possible uses of complete ectogenesis in the future. Engagement with these concrete and tangible objects motivated deep and meaningful discussions regarding the use of novel biotechnologies by encouraging the suspension of disbelief and the acceptance of speculative scenarios as plausible enough to engage with seriously. By sharing our artefacts and facilitating their effective use, we seek to open up constructive conversations between the public and policy-makers regarding possible biotechnological futures

Connected to the exhibition

Andrew Darby
Dr Andrew Darby is a Research Associate in Speculative Design on The Future of Human Reproduction project. He is interested in the ways in which alternative design practices like Speculative Design can be used to understand and debate the paths by which disruptive technologies may develop. His PhD thesis explored participatory approaches to design fiction and offered a theoretical framework and practical guidance to support design facilitators in their work with participant groups. As well as developing design fiction research in the UK, Andy has worked on several international

research projects in health and speculative design contexts in Canada, Malaysia and Ghana.

Connected to this abstract

Nicola Williams
Dr Nicola Williams is Wellcome Lecturer in the Ethics of Human Reproduction at Lancaster University's School of Global Affairs. A philosopher and bioethicist, her research focuses on reproductive ethics, transplantation ethics, personal identity, and intergenerational justice. She joined Lancaster University in 2014 and completed her PhD in Bioethics and Medical Jurisprudence at The University of Manchester in 2015, where she examined the philosophical issues surrounding pre-implantation and prenatal screening and selection.

Between 2020 and 2022, she held a Leverhulme Early Career Fellowship investigating the ethical and policy implications of novel forms of organ and tissue transplantation, including hand, face, and uterus transplantation. Since 2022, she has been a lecturer on the Wellcome-funded research programme "The Future of Human Reproduction."

Her work contributes to contemporary debates on emerging reproductive technologies, reproductive justice, and the ethical challenges posed by advances in medicine and biotechnology. Alongside her research, she teaches moral and political philosophy and is currently co-ordinator of the Ethics and Law Special Interest Group for the European Society for Human Reproduction and Embryology.

Zindzi Cresswell
Zindzi Cresswell is Partnerships and Communications Manager on the Wellcome-funded Future of Human Reproduction (FoHR) project at Lancaster University. She leads engagement and awareness-raising efforts to support the team's work on the complex cultural, ethical, legal, and social issues raised by advances in biotechnology, helping the team expand their impact, influence policy, and demonstrate best practice in the field.

Alongside her role at Lancaster, Zindzi is a business development consultant specialising in strategic foresight and scenario planning - through her consultancy she has worked with universities, NHS Foundation Trusts, government bodies, and cultural organisations across the UK, Europe, Australia, and the US.

Tenth European Conference on Health Law

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