



World Association for Medical Law



AHLEC
ANTWERP HEALTH LAW
AND ETHICS CHAIR

30th Annual World Congress for Medical Law

Book of Abstracts



University of Antwerp



Antwerp, Belgium



5–7 August 2026



World Association for Medical Law

30th Annual World Congress for Medical Law

Scientific Programme

 Antwerp, Belgium
5-7 August 2026



University
of Antwerp

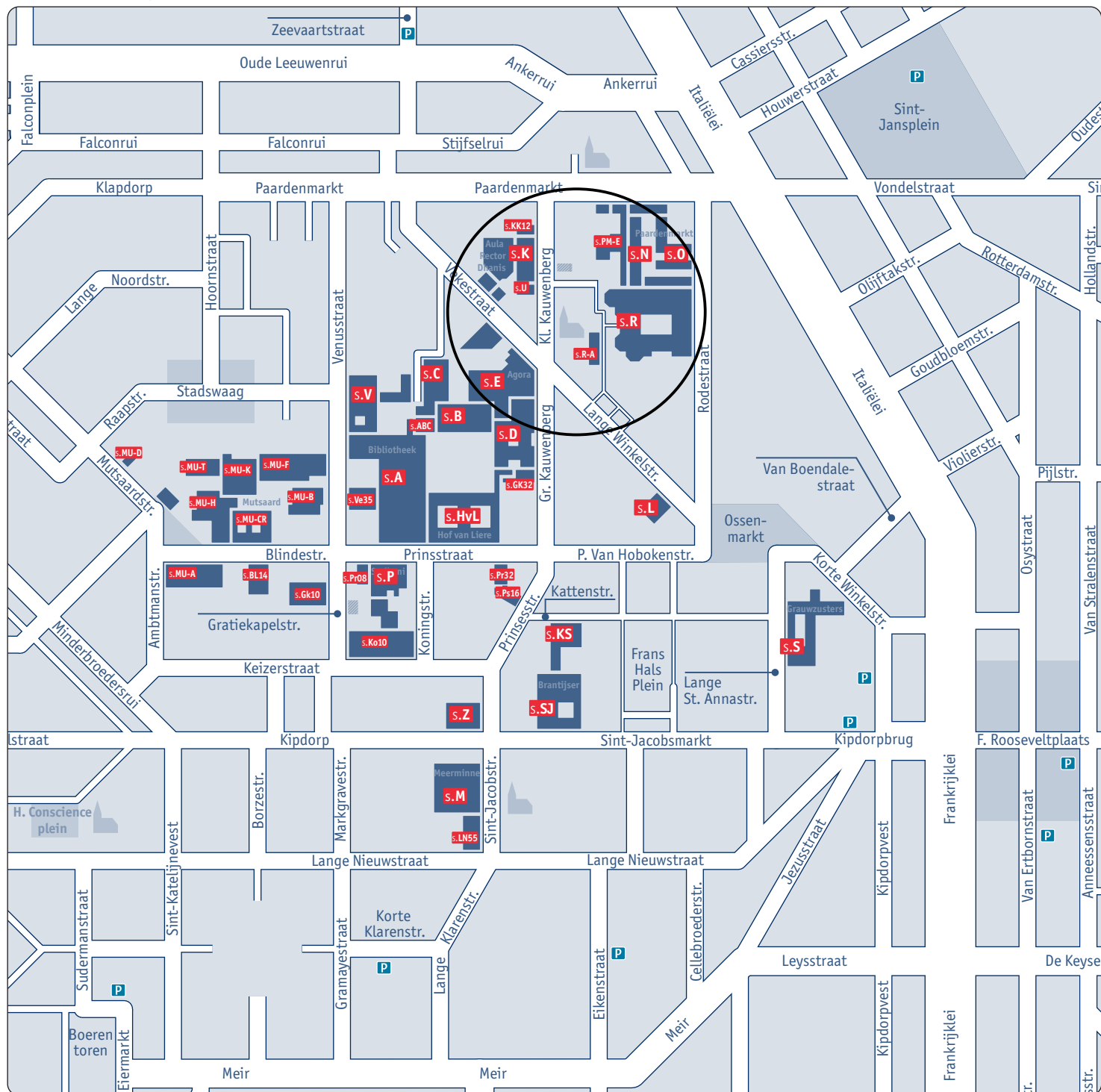
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Stadscampus



- s.A - **Library**, Prinsstraat 13
- s.B - Prinsstraat 13
- s.BL14 - **Open University / Centrum West** - Blindestraat 14
- s.C - Prinsstraat 13
- s.D - Grote Kauwenberg 18
- s.E - **Agora/Sports centre** - Grote Kauwenberg 2
- s.Gk10 - **International Relations Office** - Gratiekapelstraat 10
- s.GK32 - **Ruusbroec association** - Grote Kauwenberg 32-34
- s.HvL - **Hof van Liere** - Prinsstraat 13
- s.HvL - **University Club** - Prinsstraat 13b
- s.K** - **Aula Rector Dhanis - Kleine Kauwenberg 14**
- s.KK12 - **Linguapolis** - Kleine Kauwenberg 12
- s.Ko10 - **komida / Labotheek** - Koningstraat 8
- s.KS - **Het Brantijser** - Kattenstraat 10
- s.L - Lange Winkelstraat 40-42
- s.M - **De Meerminne** - Sint-Jacobstraat 2

- s.MU - **Mutsaard** - Mutsaardstraat 29
- s.MU-A - **Mutsaard** - Ambtmanstraat 1
- s.N - **De Paardenmarkt** - Paardenmarkt 94
- s.O - **De Paardenmarkt** - Paardenmarkt 94
- s.P - **Scribani** - Prinsstraat 10
- s.Pr08 - **Linguapolis** - Prinsstraat 8
- s.Pr32 - **Zomaar een dak** - Prinsstraat 32
- s.PM - Paardenmarkt 92
- s.Ps16 - **Universitas - Rubi - Student Council** - Prinsesstraat 16
- s.R** - **Rodestraat 14**
- s.R-A - **Annexe** - Lange Winkelstraat 9
- s.S - **Grauwzusters** - Lange Sint-Annastraat 7
- s.SJ - **Het Brantijser** - Sint-Jacobsmarkt 13
- s.V - Venusstraat 23
- s.Ve35 - **Moral consultant / Prevention Service** - Venusstraat 35
- s.Z - **Peter Benoit** - Kipdorp 61



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SCIENTIFIC PROGRAMME

TUESDAY 4 AUGUST		Pre-Congress Programme
08:30 – 12:00	WAML Board of Governors – Lessius Room (Building E)	
12:00 – 16:00	Registration – Patio K.001 (Aula) (Building K)	
12:00 – 15:15	End-of-life Session: National Reports (Chair: K. Van Assche) – Room R.008 (Building R)	
13:00 – 15:15	Young Scholars Session (Chair: A-M Duguet / S. Lievens) – Room R.007 (Building R)	
14:30 – 15:15	Book Project: Elgar Encyclopedia for Medical Law and Health Law (Chris Berry, Edward Elgar Publisher) – Lessius Room (Building E)	
15:30 – 18:00	Free Guided City Tour (Departure from Building K, Registration Hub)	

WEDNESDAY 5 AUGUST		Congress Day 1
08:30 – 17:00	Registration – Patio K.001 (Aula) (Building K)	
09:00 – 17:00	Book Stands Edward Elgar and Larcier-Intersentia – Patio K.001 (Aula) (Building K)	
09:00 – 11:00	Opening Plenary – Room K.001 (Aula) (Building K) Thierry Vansweevelt, President WAML – Opening Address Panel Discussion: Past and Future of Medical Law Keynote: Dr Siobhán O'Sullivan – 50 Years of Medical Law: Evolution and Future Challenges Panel Members: Albert Lee (Asia); Neil Kirby (Africa); Stefania Negri (Europe); Bill Hinnant (USA); Giancarlo Jiménez (Latin America) Moderator: Thierry Vansweevelt	
11:00 – 11:30	Coffee Break (Building K, Registration Hub)	
11:30 – 12:30	Parallel Sessions 7 sessions, 60 minutes	

SESSION WED-S01 · Track 1 · 11:30 – 12:30 · 3 Presentations · Room R.201 (Building R)	
Access to Healthcare I: Moderator Ian Freckelton	
WED-S01-P01	Freckelton, Ian — Thalassaemia and Sickle Cell Disease Treatment: Legal and Ethical Issues
WED-S01-P02	Aparici, Ofelia — Equidad: reto pendiente en Enfermedades Raras en el Sistema Nacional de Salud (SNS)
WED-S01-P03	Dejene Zeleke, Kassahun — Selective Universalism and the Inverse Care Law: How Health Systems Neglect Podoconiosis in Ethiopia

SESSION WED-S02 · Track 2 · 11:30 – 12:30 · 3 Presentations · Room R.007 (Building R)	
Criminal Law I: Moderator Nasser Muh	
WED-S02-P01	Patru, Larisa — When Medical Error Becomes a Crime: Physicians' Criminal Liability in Recent Romanian Jurisprudence
WED-S02-P02	Asril, Riki Tsan — Causal Relationship Model of Negligence Liability in Medical Criminal Law
WED-S02-P03	Amelink, Quirine — Regulation and Criminal Law Enforcement in Healthcare: An Uneasy Alliance or Partners in Crime?

SESSION WED-S03 · Track 3 · 11:30 – 12:30 · 3 Presentations · Room R.011 (Building R)	
Forensic and Legal Medicine I: Moderator Vugar Mammadov	
WED-S03-P01	Huseynova, Gulshan — Forensic and Medico-Legal Assessment of Neurotoxic Heavy Metals Accumulation in the Human Brain and Its Relevance in Legal Proceedings and Healthcare Regulations
WED-S03-P02	Al-Fehaid, Suha — What Kind of Swab Yields the Best Forensic Evidence Results?
WED-S03-P03	Someshwar, Saloni — Combined Application of Demirjian and Cameriere Methods for Dental Age Estimation in an Indian Population: A Cross-Sectional Study Using Digital Image Analysis

SESSION WED-S04 · Track 4 · 11:30 – 12:30 · 3 Presentations · Room R.004 (Building R)	
Health Data I: Moderator Berna Arda	
WED-S04-P01	Arda, Berna — Reconceptualizing Medical Confidentiality under Digital Health Governance: A Deontological and Legal Analysis of Turkey's Data Protection Reform

WED-S04-P02 | Eze, Nnenna — From Regulation to Innovation: Data Protection and Health Governance in Africa and Europe

WED-S04-P03 | Guo, Lulu — Legal Challenges and Countermeasures in the Protection of Personal Health Information in Digital Health Management: A Consent-Centered Approach

SESSION WED-S05 · Track 5 · 11:30 – 12:30 · 3 Presentations · Room R.008 (Building R)

Health-System Governance I: Moderator Radmyla Hrevtsova

WED-S05-P01 | Hrevtsova, Radmyla — Good Governance for Resilience and Post-Traumatic Growth: Legal Responses to Mental Health Challenges in Times of Global Upheaval

WED-S05-P02 | Vanduffel, Niesje — Operational Necessity v. Legal Limits: Delegating Critical Care to Non- or Lower-Trained Medical Military Personnel in Defence Contexts

WED-S05-P03 | Kuo, Tzu-Haw — Determinants of Clinical Discretion and SOP Adherence Among Emergency Physicians: A Nationwide Survey in Taiwan

SESSION WED-S06 · Track 6 · 11:30 – 12:30 · 3 Presentations · Room R.230 (Building R)

Hospital Law I: Moderator Filip Dewallens

WED-S06-P01 | Stevens, Chelsea — The Legal Status of the Medical Director and Good Hospital Governance

WED-S06-P02 | James, Ranjit — A National Survey of Clinical Privileging Practices in Indian Hospitals and Patient Safety Implications

WED-S06-P03 | Deprez, Cato — Internal Hospital Procedures and Administrative Supervision in Belgium: Legal Challenges for Ensuring Quality of Care

SESSION WED-S07 · Track 7 · 11:30 – 12:30 · 3 Presentations · Room R.014 (Building R)

Medical Devices: Moderator Stefaan Callens

WED-S07-P01 | Miaskowska-Daszkievicz, Katarzyna — Regulating Rarity: Legal Challenges in Access to Orphan Medical Devices

WED-S07-P02 | Vijverman, An — Classification of Medical Device Software under the (Revised) MDR

WED-S07-P03 | Amaral, Rui — Navigating the New Frontier: Macau SAR's Medical Device Regulation and the Emergence of the Greater Bay Area Harmonization Pathway

12:30 – 13:30 | **Lunch (Building K, Registration Hub)**

13:30 – 15:00 | Parallel Sessions
7 sessions, 90 minutes

SESSION WED-S08 · Track 1 · 13:30 – 15:00 · 5 Presentations · Room R.014 (Building R)

AI in Healthcare I: Moderator Victor Schollaert

WED-S08-P01 | Goffin, Tom — Navigating the Bonus Medicus Digitalis: The Physician's Legal Duties of Literacy, Autonomy, and Transparency in AI-Integrated Practice

WED-S08-P02 | Ferretti, Francesca — Rethinking Liability in AI-Powered Healthcare: Between Human Oversight and Risk Allocation

WED-S08-P03 | Mammadov, Murad — Legal Regulation of Artificial Intelligence in Healthcare: Challenges and Opportunities of an Interdisciplinary Approach

WED-S08-P04 | Zheng, Xueqian — AI + Clinical Practice in China: Current Landscape and Legal Challenges

WED-S08-P05 | Bertens, Roland — Implementing AI in Medical Guidelines: What Challenges Do Lawyers and Doctors Face?

SESSION WED-S09 · Track 2 · 13:30 – 15:00 · 5 Presentations · Room R.004 (Building R)

Deathcare: Moderator Kristof Van Assche

WED-S09-P01 | Dielis, Hanne — From Consent to Permissible Uses in Body Donation to Science: A Comparative Study

WED-S09-P02 | Marsh, Tanya — The future of death care in the US

WED-S09-P03 | Naenen, Eline — Promoting a Unified Concept of Death: Is It Possible to Arrive at a Unified Concept of Death in the Context of Organ Transplantation?

WED-S09-P04 | Kirbaş, Zeynep Sare — A Bioethical Framework for the Digital Afterlife

WED-S09-P05 | Israa, Fajri — The Right of a Corpse to a Visum et Revertum to Reveal the Truth in Law Enforcement

SESSION WED-S10 · Track 3 · 13:30 – 15:00 · 5 Presentations · Room R.008 (Building R)

Disability: Moderator Vugar Mammadov

WED-S10-P01 | Mammadov, Vugar — Legal Integration of Health Law and Disability Law in Azerbaijan: Ensuring Equal Access to Healthcare for Persons with Disabilities

WED-S10-P02 | Eseni, Joyce — The Human Rights to Healthcare: Evaluating Legal Frameworks and Barriers for Persons with Disabilities in Nigeria

WED-S10-P03 | Blomme, Naomi — Para-Sport Classification in a Disability Rights-Era: What is the Impact on Health Law and Health Professionals?

WED-S10-P04 | Mammadova, Sabina — Assistive Technology and Legal Innovation in Azerbaijan: Ensuring Accessibility and Rights Protection for Persons with Disabilities

WED-S10-P05 | Marcus, Esther-Lee — Ethical and Legal Issues Associated with the Use of Technological Devices and Artificial Intelligence Tools for the Management of Wandering in People with Dementia

SESSION WED-S11 · Track 4 · 13:30 – 15:00 · 4 Presentations · Room R.201 (Building R)

End of Life I: Moderator Ofelia De Lorenzo Aparici

WED-S11-P01 | Doležal, Adam — The Human Rights Framework of Assisted Dying and the Protection of Personality Rights in Europe

WED-S11-P02 | Papadopoulou, Nataly — Timeframes in Assisted Dying Regulation and Implementation: Access, Innovation and Interdisciplinarity

WED-S11-P03 | Pans, Esther — 25 Years of Euthanasia Practice in the Netherlands: Alignment with Legislative Intent?

WED-S11-P04 | Delbeke, Evelien — (Foregoing) Life-sustaining Treatment in Patients with a Disorder of Consciousness

SESSION WED-S12 · Track 5 · 13:30 – 15:00 · 5 Presentations · Room R.230 (Building R)

Medically Assisted Reproduction: Moderator Judit Sandor

WED-S12-P01 | Medina-Arellano, Maria — Uterus Transplantation Through a Feminist Bioethics and Biolaw Lens: Rethinking Autonomy and Motherhood

WED-S12-P02 | Smrž, Ivo — Access to Medically Assisted Reproduction in the Case Law of the European Court of Human Rights

WED-S12-P03 | Souza, Henrique — Technological Innovations in Reproductive Medicine: Hopes and Risks

WED-S12-P04 | Michielsen, Lies — Towards a Legal Framework on Surrogacy in Belgium? Key Legislative Choices and Safeguards

WED-S12-P05 | Posadkova, Maria — The Right to Have a Child Using Assisted Reproductive and Genetic Technologies in Russia and Abroad

SESSION WED-S13 · Track 6 · 13:30 – 15:00 · 5 Presentations · Room R.007 (Building R)

Pharmaceutical Law: Moderator An Vijverman

WED-S13-P01 | Hofstede, Suzan — Patentability of AI-Generated Drugs: Legal Challenges and Policy Recommendations

WED-S13-P02 | Davies, Jonathan — How does the Pharmaceutical Industry Influence Public Health Law: The Case of Finasteride and PFS

WED-S13-P03 | Lipatnikova, Valentina — Off-label Use: A Vital Necessity or a Vicious Cycle?

WED-S13-P04 | den Exter, André — Fighting High-Priced Prescription Drugs in the EU and the U.S.

WED-S13-P05 | Hodovská, Simona — Access to Highly Innovative Medicinal Products: A Comparative Study of Single-Payer, Multi-Payer, and Market-Based Health Systems

SESSION WED-S14 · Track 7 · 13:30 – 15:00 · 5 Presentations · Room R.011 (Building R)

Public Health Law I: Moderator Toma Birmontiene

WED-S14-P01 | Adeoye, Damilare — Governing the Global Migration of Healthcare Workers: A Comparative Legal Analysis of Recruitment Practices in Nigeria and Ireland

WED-S14-P02 | Nasution, M Sutan Abdul Aziz F — Principle of Gotong-Royong in Fulfilling Access Rights to Clean Water or Victims of Flash Floods in Sumatera Island, Indonesia

WED-S14-P03 | Qiao, Juan — Reconceptualizing State Obligations in Public Health Emergencies: Risk Prevention and the Protection of the Right to Health

WED-S14-P04 | Ghimire, Kanksha Mahadevia — Judicial Notice and COVID-19: A Static Lens on a Dynamic Crisis – Legal Finality in the Face of Scientific Change

WED-S14-P05 | Osei, Eric — Improving Health-Related Quality of Life and Medication Adherence among Young People Living with HIV and AIDS through Social Media Peer Support: A Before-and-After Quasi-Experimental Study in a Peri-Urban District in Ghana

15:00 – 15:30 | **Coffee Break (Building K, Registration Hub)**

15:30 – 17:15 | Parallel Sessions
7 sessions, 105 minutes

SESSION WED-S15 · Track 1 · 15:30 – 17:15 · 5 Presentations · Room R.014 (Building R)

AI in Healthcare II: Moderator Dimitri Verhoeven

WED-S15-P01 | Ploem, Corrette — Introducing Chatbots in Screening: Legal Issues

WED-S15-P02 | Snyder, Jack — What is the Impact of Artificial Intelligence on International Telemedicine & Telehealth (ITT) Law: An Update

WED-S15-P03 | Nordberg, Ana — Integration of Commercial LLMs in Clinical Practice: Between Innovation, Efficiency and Fundamental Values

WED-S15-P04 | Lu, Yi — Algorithmic Due Process in Public Health Governance: A Comparative Legal Analysis of Algorithm-Driven Health Interventions in the EU and China

WED-S15-P05 | Holčápek, Tomáš — New Technologies in Health Care: Challenges for Civil Procedure and Law of Evidence

SESSION WED-S16 · Track 2 · 15:30 – 17:15 · 4 Presentations · Room R.230 (Building R)

Beginning of Life I: Moderator Hongjie Man

WED-S16-P01 | Dalla Costa, Sara — Equitable Access and Ethical Governance in Cross-Border Reproductive Care: A Comparative European Legal Analysis

WED-S16-P02 | Franco, Luiza — Artificial Intelligence and Maternal-Fetal Health Promotion through Fundamental Rights' Lenses

WED-S16-P03 | Babayev, Hikmat — Legal Protection of the Human Fetus: International Regulation and Perspectives on National Legislation

WED-S16-P04 | Moraes, Monique — Informed Consent Documentation in Obstetrics

SESSION WED-S17 · Track 3 · 15:30 – 17:15 · 4 Presentations · Room R.011 (Building R)

Criminal Law II: Moderator Mustafa Aslam

WED-S17-P01 | Sayar Kanyış, Tansu — Commission by Omission in Health Criminal Law

WED-S17-P02 | Delefortrie, David — The Decriminalization of the Light Unintentional Medical Error in Belgian Criminal Law

WED-S17-P03 | Gabaraevi, Ioseb — Criminal Law Perspectives on Healthcare Fraud

WED-S17-P04 | Dörenberg, Vivianne — Afstemming tussen Strafrecht en Tuchtrect in de Nederlandse Gezondheidszorg

SESSION WED-S18 · Track 4 · 15:30 – 17:15 · 4 Presentations · Room R.201 (Building R)

End of Life II: Moderator Christophe Lemmens

WED-S18-P01 | Liu, Yu — A Strategy Discussion on Safeguarding the Dignity of Life Through Advance Medical Directives

WED-S18-P02 | Lemmens, Christophe — Advance Care Planning and Advance Directives in Belgium after the Reform of the Law on Patients' Rights from a Human Rights Perspective

WED-S18-P03 | Hotz, Sandra — How to Handle Advance Directives and Assisted Dying: In General and from a Swiss Perspective

WED-S18-P04 | Lemmens, Trudo — Canada's Euthanasia (MAiD) Regime: Remarkably Safe, or Remarkably Dangerous?

SESSION WED-S19 · Track 5 · 15:30 – 17:15 · 4 Presentations · Room R.004 (Building R)

Health Data II: Moderator Tim Opgenhaffen

WED-S19-P01 | Vebrina, Redha — Patients' Personal Data Protection in Electronic Medical Records: A Comparative Legal Study among ASEAN Countries

WED-S19-P02 Broeckx, Nils — Health Records and the Power of Software Vendors: The Case of the Curious Physiotherapist
WED-S19-P03 Gagliardi, Barbara — PRISMA: AI-Driven Secondary Use of Health Data for Healthcare Network Governance and Patient Stratification
WED-S19-P04 Claeys, Peter — The Impact of GDPR on AI-Driven Processing of Health Data in Insurance

SESSION WED-S20 · Track 6 · 15:30 – 17:15 · 4 Presentations · Room R.007 (Building R)
Minors I: Moderator Luis Ravanal

WED-S20-P01 Boratyńska, Maria — On the Implications of the Concept of Parental Autonomy in the Context of Futile Therapy for Children
WED-S20-P02 Vanstapel, Philip — The Antwerp Mohels: Dina de Malkhuta Dina?
WED-S20-P03 Chiou, Tzu-Yu — The Common Good Constitutionalism Perspective on Pediatric Primary Care Law: A Comparative Study of Taiwan's Designated Physician System for Young Children and the United States Legal Framework
WED-S20-P04 Goemaere, Marie & Lierman, Steven — Mapping the Legal Position of Minors in Healthcare Across Europe

SESSION WED-S21 · Track 7 · 15:30 – 17:15 · 5 Presentations · Room R.008 (Building R)
Neurotechnologies: Moderator Timo Istace

WED-S21-P01 Sharkova, Mariya — The Hacked Mind: Comparative Liability Frameworks for Malfunctioning Brain Devices
WED-S21-P02 Garland, Hannah — “Artificial” Cognition: Legal Considerations for Artificial Intelligence in Cognitive Assistive Technology
WED-S21-P03 Deibel, Talya — Patients' Right to Be ‘Oneself’ in Law and Ethics of Neuromodulation
WED-S21-P04 Istace, Timo — Challenges and Opportunities of Advanced Neurotechnologies in the Treatment of Disorders of Consciousness: A Disability Law Perspective
WED-S21-P05 Hatanaka, Ryoko — Neurorights, Freedom of Thought, and Civil Law Autonomy in Japan: Comparative Analysis of Constitutional and Private Law Protection in the Age of Neurotechnology

Wednesday Evening

19:00	Free Welcome Reception (Building K, Registration Hub)
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THURSDAY 6 AUGUST
Congress Day 2

09:00 – 10:30	Plenary Session: Inauguration of Antwerp Cusa Chair for Health Law and Religious Diversity – Room K.001 (Aula) (Building K) Naoual El Yattouti & Yvan Deckers Nathalie Dens (Vice-Rector), Thierry Vansweevelt, Kristof Van Assche Panel Discussion: Naoual El Yattouti; Marie-Claire Foblets; Gamal Serour; Amina Yakhlaf
10:30 – 11:00	Coffee Break: Poster Sessions (Building K, Registration Hub)

Poster Session I – Thursday Morning Coffee Break

Poster Session I – 13 Posters · Building K, Registration Hub	
POSTER-AM-01 Azwar, Tengku Keizerina Devi — Entrusted Services (JASTIP) through Social Media and the Prescription Drugs in Indonesia	
POSTER-AM-02 Bacoviq, Diana — Legal Guide for Healthcare Workers as an Interdisciplinary Approach to the Prevention of Medico-Legal Disputes	
POSTER-AM-03 Balaa, Fady — Cholecystectomy Related Complaints: A 20-year Review of the Canadian Medicolegal Experience	
POSTER-AM-04 Çetin, Neşe — Cognitive Bias, Empathy, and AI Decision-Making: A Medico-Legal Assessment of Human and Algorithmic Responsibility in Clinical and Legal Contexts	
POSTER-AM-05 Chen, Huan-Wen — Courts as a Guardian of Human Rights? Dilemmas in the Judicial Review of Involuntary Hospitalization Cases	
POSTER-AM-06 Damanik, Ade Irawan — Non-Discriminatory Treatment of Patients in Health Services by Justice-Based Hospitals	

POSTER-AM-07 Deković, Sanjin — Controversies of the Beginning and End of Life in the Light of the Right to Abortion and Euthanasia. Do we Have a Right to Choose?
POSTER-AM-08 Hidayat, Dian — Corporate Legal Liability for Medical Negligence in Hospitals
POSTER-AM-09 Giddings, Gordon — Trends in Professional Conduct Complaints and Review Decisions within a Canadian Medical Regulator
POSTER-AM-10 Koçar, Elif — Legislation, Education, and Practice Triangle in Advance Care Directives with a Culturally Responsive Approach
POSTER-AM-11 Lin, Ijou — Criminal Liability and the Path of Causal Determination in AI-Integrated Healthcare: Addressing the "Black-Box Problem" and the Accountability Gap
POSTER-AM-12 Lin, Shin-Rou — Reframing Vaccine Injury Compensation: Risk Governance and State Responsibility in Taiwan
POSTER-AM-13 Tamás, Orsolya — Radiologists' Perspectives on Legal, Ethical, and Practical Challenges of AI in Diagnostic Imaging

11:00 – 12:30	Parallel Sessions 7 sessions, 90 minutes
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SESSION THU-S01 · Track 1 · 11:00 – 12:30 · 5 Presentations · Room R.014 (Building R)
AI in Healthcare III: Moderator Vera Lúcia Raposo
THU-S01-P01 Hartlev, Mette — How Do Patients' Perception and Expectations of Use of AI in the Clinic Align with the Legal Framework?
THU-S01-P02 Duguet, Anne-Marie — Artificial Intelligence in Healthcare: How Would the Creation of Human Digital Twins Benefit Human Health?
THU-S01-P03 Siroka, Lucie — Predictive Medicine and the Limits of Anonymization: The Legal Status of Patient Digital Twins
THU-S01-P04 Raposo, Vera Lúcia — From the Human Touch to the AI Touch: The Question of Medical Empathy in Doctor-Patient Relationship
THU-S01-P05 Yilmaz, Emine — The New Frontiers of Informed Consent in the Use of Artificial Intelligence in Healthcare

SESSION THU-S02 · Track 2 · 11:00 – 12:30 · 5 Presentations · Room R.201 (Building R)
End of Life III: Moderator Evelien Delbeke
THU-S02-P01 O'Sullivan, Siobhán — Legal Robustness and Deliberation in Ireland's Assisted Dying Parliamentary Committee
THU-S02-P02 Krugers Dagneaux, Willemijn — Decisional Capacity Judgment for Medical Assistance in Dying on Psychiatric Grounds in Young People
THU-S02-P03 Marijnissen, Radboud — When Patients Can't Decide: Medical Assisted Dying in Dementia
THU-S02-P04 Wicks, Liz — A Right to Die? Concepts, Problems, Opportunities
THU-S02-P05 Arruego, Gonzalo — The Spanish Organic Law on Euthanasia in Context

SESSION THU-S03 · Track 3 · 11:00 – 12:30 · 5 Presentations · Room R.011 (Building R)
Health-System Governance II: Moderator Merja Turunen
THU-S03-P01 Nykänen, Eeva — The Social and Healthcare Reform in Finland: Promoting Equality?
THU-S03-P02 Park, HyeonJeong & Kim, Na-Kyoung — From Declarative Principles to Enforceable Health Governance: Structural Limits of Korea's Framework Act on Health and Medical Services in a Changing Healthcare Environment
THU-S03-P03 Birmontiene, Toma — The Role of Constitutional Doctrine in Changing Health Law
THU-S03-P04 Takahashi, Shigeki — The National Health Insurance System in Japan - 65 Years of Operation and Its Limitations
THU-S03-P05 Assis, Renato — The Particularities of Medical Law in Brazil: Dual Judicialization, Judicial Governance, and Professional Liability

SESSION THU-S04 · Track 4 · 11:00 – 12:30 · Panel Discussion · Room R.007 (Building R)
Medical Errors and Liability: Panel Discussion: Moderator Albert Lee
THU-S04-P01 Lee, Albert; Nasser, Muh; Amirthalingam, Kumaralingam; Hinnant, Bill; Jiménez Bazán, Giancarlo; Quick, Oliver & Yang, Manman — Medical Errors: Civil or Criminal Liability

SESSION THU-S05 · Track 5 · 11:00 – 12:30 · 5 Presentations · Room R.230 (Building R)**Medical Liability I: Moderator Sven Lievens****THU-S05-P01** | Doležal, Tomáš — Compensation for Non-Pecuniary Harm Resulting from Interference with Patients' Personality Rights in Cases of Medical Malpractice**THU-S05-P02** | Lipartia, Nino — Rethinking Medical Negligence in the AI Era: The Loss of Chance Doctrine as a Response to Algorithmic Decision-Making**THU-S05-P03** | Lievens, Sven — Quantifying the Lost Chance of Survival**THU-S05-P04** | Borysiak, Witold — The Scope and Limits of Deviation from Medical Standards in a Comparative Perspective**THU-S05-P05** | Aprilia, Imelda — Legal Protection for Healthcare Professionals through Liability Insurance: A Comparative Study of Indonesia and ASEAN Countries**SESSION THU-S06 · Track 6 · 11:00 – 12:30 · 4 Presentations · Room R.004 (Building R)****Mental Healthcare I: Moderator Corrette Ploem****THU-S06-P01** | Lippens-de Cerf, Marie-Noëlle — Mechanical Restraints in Belgian Healthcare Facilities: Balancing Patients' Fundamental Rights and Clinical Challenges.**THU-S06-P02** | Opgenhaffen, Tim — Who Authorises and Implements Seclusion and Restraint in Care? A Critical Analysis of Professional Responsibilities under Human Rights Law**THU-S06-P03** | Kirchgaesser, Karolin — Expanding Access or Reconfiguring Coercion? Balancing Autonomy and Security in Psychiatry and German Guardianship Law**THU-S06-P04** | Christie, Nel — The Sentence is Not Sickness: A Case for Health-Centered Detention in Europe**SESSION THU-S07 · Track 7 · 11:00 – 12:30 · 5 Presentations · Room R.008 (Building R)****Status of Embryos and Embryo Models: Moderator María de Jesús Medina Arellano****THU-S07-P01** | Dias, Daniela — Embryo Selection with Artificial Intelligence: Preventive Potential or Risk of Digital Eugenics?**THU-S07-P02** | Guesso Scarmagnan Pavelski, Bruna — The Legal Status of the Human Embryo between Assisted Reproduction, Biotechnology and Genetic Editing**THU-S07-P03** | Reyes Villarreal, Mariangela & Vidal Gutiérrez, Oscar — Fear of Missing Out on Regulatory Framework on Human Stem Cell-Based Embryo Models**THU-S07-P04** | Spaander, Merel — Embryo or No Embryo? The Emergence of Stem Cell-Derived Embryo Models from a Legal Perspective**THU-S07-P05** | Šolc, Martin — Beyond Things and Animals: Criteria for the Legal Status of Organoids and Xenobots**12:30 – 13:30** | **Lunch (Building K, Registration Hub)****13:30 – 15:00** | Parallel Sessions
7 sessions, 90 minutes**SESSION THU-S08 · Track 1 · 13:30 – 15:00 · 5 Presentations · Room R.008 (Building R)****Access to Healthcare II: Moderator Anne-Marie Duguet****THU-S08-P01** | Eglem, Marie — Prioritization in Healthcare: A Legal Perspective**THU-S08-P02** | Najhawan, Tanya — Prioritization of Patients' Access to ECMO During the COVID-19 Pandemic – Ethical, Legal and Clinical Aspects**THU-S08-P03** | Mutanen, Anu — Access to Health and the Right to Prioritization in Finland's Reformed Healthcare System**THU-S08-P04** | Mujovic, Hajrija — Understanding the Right to Continuous Healthcare in Medical Law of Serbia**THU-S08-P05** | Guerrero-Diaz, Naty — Gender Disparities in Pain Management: Eve's Curse**SESSION THU-S09 · Track 2 · 13:30 – 15:00 · Panel Discussion · Room R.007 (Building R)****Criminal Law III: Panel Discussion: Moderator Nasser Muh****THU-S09-P01** | Ruffiaddarojat, Bayqunie & Muh, Nasser — Legal Analysis of Regulatory Weaknesses in Enforcing Medical Crime Law in Indonesia**THU-S09-P02** | Tarigan, Asnaria — Criminal Intent (Mens Rea) in Medical Crimes: A Normative Juridical Analysis

THU-S09-P03 | Gayo, Sabela — A Comparative Study of General Criminal Offenses and Medical Crimes: A Normative Juridical Analysis and Interdisciplinarity in Indonesia

THU-S09-P04 | Fauzan, Muhamad — Culpable Nature in Medical Criminal Offenses

THU-S09-P05 | Jahidin, Syamsul — Concursus Realis or Multiple Criminal Acts in Medical Crime Law

THU-S09-P06 | Tack, Sylvie — Criminal Liability of Doctors for Medical Errors: Different Approaches within Europe

SESSION THU-S10 · Track 3 · 13:30 – 15:00 · 5 Presentations · Room R.230 (Building R)

Medical Liability II: Moderator Ian Freckelton

THU-S10-P01 | Šustek, Petr — Recent Malpractice Cases in Telemedicine: In Search of the Standard of Care

THU-S10-P02 | Cascao, Rui — Towards a Quantum Leap for Medical Liability in Europe

THU-S10-P03 | Campos, Maiana — Civil Liability for Dental Malpractice: Analysis of Decisions from the Court of Justice of Bahia/Brazil in the Last Decade

THU-S10-P04 | Irawan, Rendra — Physician Negligence in Hospitals: An Indonesian Medical Tort Law Perspective

THU-S10-P05 | Irawati, Renita — Reconstructing the Boundaries of Civil Liability: Judicial Expansion between Medical Risk and Professional Negligence in Indonesian Jurisprudence

SESSION THU-S11 · Track 4 · 13:30 – 15:00 · 4 Presentations · Room R.004 (Building R)

Mental Healthcare II: Moderator Shigeki Takahashi

THU-S11-P01 | Ulmanen, Maija-Sofia — Reconstructing Patient Consent in Mental Health Care: A Comparative Analysis of Finland, Germany and Scotland

THU-S11-P02 | Amanamba, Akudo — Balancing Individual and Collective Rights: Patient Autonomy versus the Best Interest of Mental Health Patients

THU-S11-P03 | Claes, Sarah — Between Care and Confidentiality: Family Involvement and Professional Confidentiality in Flemish Mental Healthcare

THU-S11-P04 | Braun, Julia — Bridging the Gap: Rethinking Proxy Decision-Making in Cognitive Decline

SESSION THU-S12 · Track 5 · 13:30 – 15:00 · 5 Presentations · Room R.201 (Building R)

Patient Rights and Medical Decision-Making: Moderator Eduardo Dantas

THU-S12-P01 | El Jundi, Sami — Reflective Time and Second Opinions in Decision-Making for Elective and Non-Therapeutic Procedures

THU-S12-P02 | Łotoczuk, Marta — Making Room for Family Involvement in Medical Decision-Making Within European Patient-Rights Law

THU-S12-P03 | Legemaate, Johan — Future-Proof Patient Rights

THU-S12-P04 | Palkova, Karina — Systemic and Systematic Implementation of Patients' Rights in Medical Treatment Institutions in the Republic of Latvia

THU-S12-P05 | Chahoud, Yasmin — (In)Validity of Therapeutic Consent Provided by a Legal Surrogate Decision-Maker

SESSION THU-S13 · Track 6 · 13:30 – 15:00 · 5 Presentations · Room R.011 (Building R)

Public Health Law II: Moderator Jonathan Davies

THU-S13-P01 | Phrueksanan, Withoo — Commercial Host Liability in Comparative Perspective: Implications for Thailand's Emerging Alcohol Control Framework

THU-S13-P02 | Ofili, Innocent — Decriminalizing Attempted Suicide in Nigeria: Appraising the Intersection of Criminal Law and Public Health Law

THU-S13-P03 | An, Seohyun — The Commercial Use of Medical Authority in Digital Advertising: A Call for a Functional Redesign of Self-Regulation

THU-S13-P04 | Johnston, James — When Standard of Care Becomes Systemic Harm: Cesarean Overuse and an Emerging Public Health Crisis

THU-S13-P05 | Nikkinen, Janne — Reform of the Gambling System and Public Health: Case of Government Proposal 16/2025 vp in Finland

SESSION THU-S14 · Track 7 · 13:30 – 15:00 · Panel Discussion · Room R.014 (Building R)

Responsible AI: Panel Discussion: Moderator Corrette Ploem

THU-S14-P01 | Doleman, Daniël P.; Jessen, Roosmarie; Ploem, Corrette; Bak, Marieke A.R. & Stock, Eva — Responsible Artificial Intelligence Usage

15:00 – 15:30	Coffee Break: Poster Sessions (Building K, Registration Hub)
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Poster Session II – Thursday Afternoon Coffee Break

Poster Session II – 13 Posters · Building K, Registration Hub	
POSTER-PM-01	Koufalitakis, Michail — Human Rights in the Delivery Room: Navigating Birth Plans, Autonomy, Consent, and the Limits of Medical Law
POSTER-PM-02	Lishchuk, Iryna — Trustworthy AI in Medical Research: What it Means and What is Technically Feasible? Experiences of the ELMUMY Project
POSTER-PM-03	Liu, Yu — Draw on the Application of the Medical Large Language Model for Hierarchical Management in Autonomous Driving
POSTER-PM-04	Lumban Gaol, Wilda Alvernia — Violation of Service Standards in the Perspective of Medical Civil Law
POSTER-PM-05	Matas, David — Preventing and Remedying Complicity in Organ Transplant Abuse Abroad
POSTER-PM-06	Sitorus, Sessy Arie — Unlawfulness (Wederrechtelijkheid) in Medical Crime Law
POSTER-PM-07	Nirmalasari, Lucia — Surrogate Informed Consent in Indonesian Medical Civil Law
POSTER-PM-08	Puspita, Ayu — Restorative Justice in Medical Tort Law
POSTER-PM-09	Salmanova, Sevinj — Early-Onset Myopia in Children: Bridging Clinical Evidence with Legal and Technological Frameworks for Equitable Eye Care
POSTER-PM-10	Sogut, Huseyin Erkut — The Role of the Physician in Forensic Medical Cases at the Intersection of Medicine and Law: A Perspective from Türkiye
POSTER-PM-11	Tan, Tong Khee — From Criminal Principles to Clinical Regulation: An Evaluation of Singapore's Harm-Culpability Matrix in Medical Disciplinary Sanctioning
POSTER-PM-12	Vreven, Noa — Layered Legal Protection: A Multidimensional and Interdisciplinary Approach to Protecting Reproductive Autonomy in Europe
POSTER-PM-13	Yuzbayova, Aytaj — Forensic Assessment of Heavy Metals in Cosmetics: Health, Safety, and Legal Regulatory Perspectives

15:30 – 17:15	Parallel Sessions 7 sessions, 105 minutes
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SESSION THU-S15 · Track 1 · 15:30 – 17:15 · 4 Presentations · Room R.014 (Building R)	
AI in Healthcare IV: Moderator Petra Holmberg	
THU-S15-P01	Litins'ka, Yana & Holmberg, Petra — Exempting Epidemics? National Security and Research at the Edges of the EU AI Act
THU-S15-P02	Lee, Won Bok — Translating Medical AI Fairness into Legal Duties: A Dual-Track Framework for Discrimination and Health Equity
THU-S15-P03	Altavilla, Annagrazia — Digital Life and Future Generations: Ethical Dilemmas and Participatory Pathways
THU-S15-P04	Ekmekci, Perihan — An Examination of University Students' and Academics' Use of Artificial Intelligence Tools in Research from a Self-Assessment Perspective

SESSION THU-S16 · Track 2 · 15:30 – 17:15 · 4 Presentations · Room R.011 (Building R)	
Beginning of Life II: Moderator Judit Sandor	
THU-S16-P01	Sándor, Judit — Suspended Lives: Laws on Cryopreservation and the Missing Health Law Component
THU-S16-P02	Lorenz, Maria — The Human Rights Implications of Divergent Storage Time Limits for Social Egg Freezing in Austria, Denmark, and the United Kingdom
THU-S16-P03	Kostadinova, Velichka — Defining the Standard of Care for Genetic Testing in IVF: Legal and Ethical Challenges in Assisted Reproduction
THU-S16-P04	Nagamizu, Yuko — Is It Possible to Accommodate “Fetal-Maternal Complex” Model to the Current Legal Framework? Intersection of Law and Ethics in the Context of Fetal Surgery Research

SESSION THU-S17 · Track 3 · 15:30 – 17:15 · 5 Presentations · Room R.201 (Building R)	
End of Life IV: Moderator Marta Łotoczuk	
THU-S17-P01	Kadile, Laura — Where Death and Life Meet: Ensuring Dignity and Respect in Palliative Care for Vulnerable Patients: The Latvian Example in Comparative Perspective

THU-S17-P02 Rahmania, Fany — Passive Euthanasia from the Perspective of Human Rights in Indonesia
THU-S17-P03 Karimova, Sevda — Euthanasia-Related Challenges in Criminal Legislation: The Case of Azerbaijan
THU-S17-P04 Manabe-Honda, Mari — Regulations Concerning Medical Care and Care in the Final Stage of Life: The Legal Situation in Japan
THU-S17-P05 Kovacs, Gabor — From Theoretical Right to Clinical Reality: The Ethical Necessity and Perceived Inaccessibility of Palliative Sedation

SESSION THU-S18 · Track 4 · 15:30 – 17:15 · 5 Presentations · Room R.007 (Building R)
Health Data III: Moderator Nils Broeckx
THU-S18-P01 Lalova-Spinks, Teodora — What Patients Value in Data Reuse for Health Research: Preparing Belgium for the European Health Data Space
THU-S18-P02 Yao, Xuxin — Balancing Scientific and Commercial Interests: The European Health Data Space Response to Commercial Scientific Research
THU-S18-P03 Huys, Louise — Access to the Electronic Health Record for AI Development: The Tension between Privacy and Innovation and the Role of the New EHDS Regulation
THU-S18-P04 Zheng, Min — Neural Data as a New Category of Sensitive Data? A Comparative Study on the Legal Characterization of Neural Data under Chinese Law and the GDPR
THU-S18-P05 Nogel, Monika — Governing Trust in Disruptive Genomics: Validity, Data Reuse, and Responsibility Allocation

SESSION THU-S19 · Track 5 · 15:30 – 17:15 · 5 Presentations · Room R.008 (Building R)
Health-System Governance III: Moderator Chelsea Stevens
THU-S19-P01 Briké, Sander — Patients before Profit? What the Halmer Judgment Means for Investment in Healthcare
THU-S19-P02 Balthazar, Tom — There is No Business Like Healthcare Business
THU-S19-P03 Meza Vásquez, Rosa Teresa — Reserva de Especialidad y Proporcionalidad Regulatoria en Medicina Estética en el Perú: Reflexiones sobre la Reciente Sentencia del Tribunal Constitucional
THU-S19-P04 Nanu, Andrei — When Law Outpaces Practice: Recent Romanian Legislative Changes Challenging Medical Competence and Clinical Safety
THU-S19-P05 Taurus, Indrawati — Legal Gaps and Injustice in Compensation Standards for Apheresis Donors within Blood Services as a Public Health Service in Indonesia

SESSION THU-S20 · Track 6 · 15:30 – 17:15 · 4 Presentations · Room R.230 (Building R)
Hospital Law II: Moderator Filip Dewallens
THU-S20-P01 Gonalons, Robin — The Criminal Liability of Healthcare Facility Managers (France)
THU-S20-P02 Van Delm, Kaat — The Inverse Proportional Allocation of Physicians' and Other Clinicians' Competences — A Comparison of Various European Jurisdictions
THU-S20-P03 Dewallens, Filip — Hospital Planning and Co-Governance: Effects on Access, Choice and Affordability in the Belgian Health System
THU-S20-P04 Kadić-Deković, Selma — Legal Fight for Legalization of the Status of the Doctors as Officials in Bosnia and Herzegovina, in Order to Protect Against Unwanted Attacks and Behavior by the Patient

SESSION THU-S21 · Track 7 · 15:30 – 17:15 · 5 Presentations · Room R.004 (Building R)
Intersex and Transgender Care: Moderator Maxime Castermans
THU-S21-P01 Joly, Yann — Intersex Care as an Emerging Frontier in Medical Law: Comparative and Global Perspectives
THU-S21-P02 Hinnant, C. William Jr. — Transgender Healthcare Challenges in the Post Hobby Lobby United States
THU-S21-P03 Castermans, Maxime — Operationalising Human Rights for Intersex Children in Europe: A Comparative Legal Analysis
THU-S21-P04 Zagra, Teresa Maria Stella — Ad-Sistere: A Comparative Inquiry into Parental Authority and Minors' Access to Gender-Affirming Treatment
THU-S21-P05 Nardello, Rosaria — Co-Occurring Psychiatric Disorders and Gender Dysphoria in Children and Adolescents: Clinical, Therapeutic, and Medico-legal Considerations

Optional Social Programme – Thursday Evening	
Time	Activity
18:30	Chocolate Museum Visit (Meet at the Venue: Chocolate Nation, Koningin Astridplein 7, Opposite Central Station)
20:00	Wine Bar Tour (Departure from Building K, Registration Hub)
20:00	Beer Pub Crawl (Departure from Building K, Registration Hub)
20:00	Royal Museum of Fine Arts Antwerp (KMSKA) (Meet at Venue (Leopold de Waelplaats 1) at 20:00 or Depart at 19.30 from Building K, Registration Hub, 30 Minute Walk)
22:00	Karaoke Evening (Departure from Building K, Registration Hub)

FRIDAY 7 AUGUST	Congress Day 3
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09:00 – 10:30	Parallel Sessions 7 sessions, 90 minutes
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SESSION FRI-S01 · Track 1 · 09:00 – 10:30 · 4 Presentations · Room R.014 (Building R)	
AI and Liability I: Moderator Dimitri Verhoeven	
FRI-S01-P01	Barbosa, Carla — Liability for Harm Caused by AI-Based Medical Devices: The SafeCaring Case
FRI-S01-P02	Verhoeven, Dimitri — The New Product Liability Directive 2024 and its Impact on the Medical Sector
FRI-S01-P03	Lin, Diane IJou — Protecting Patients and Physicians When Healthcare AI Causes Harm: A Corporate Governance Approach to Structured Accountability
FRI-S01-P04	Wu, Jeng-You — The Probabilistic Physician and the Autopilot Paradox: Rethinking Malpractice under EU and Taiwanese AI Governance

SESSION FRI-S02 · Track 2 · 09:00 – 10:30 · 5 Presentations · Room R.201 (Building R)	
Genetics I: Moderator Jolien Smets	
FRI-S02-P01	Huang, Jessica — Emerging Trend in the Private Marketing of Regenerative Medicine Innovations Across Canada, the UK, and South Korea
FRI-S02-P02	Sato, Yuichiro — Implementation of the Act on Promoting Genomic Medicine and Afterwards in Japan
FRI-S02-P03	Schmitz-Luhn, Bjoern — The Cost of Knowing: Predictive Health, Equality and the Future of Solidarity
FRI-S02-P04	Yin, Jun — How Chinese Laws Inform Supervision of International Scientific Research Cooperation on Human Genetic Resources?
FRI-S02-P05	Wuhib, Mehila Zebeñigus & Johnston, James C. — Is Genetics the Beginning of the End of the Worldwide Cerebral Palsy Litigation Crisis

SESSION FRI-S03 · Track 3 · 09:00 – 10:30 · 5 Presentations · Room R.230 (Building R)	
Medical Liability III: Moderator Giancarlo Jimenez Bazan	
FRI-S03-P01	Babayeva, Elnara — Boundaries of Legal Liability in Medical Practice: Negligence, Risk and Criteria for “Public Official” Status
FRI-S03-P02	Jiménez Bazán, Giancarlo — Consentimiento Informado y Medicina Defensiva en el Perú: entre la Autonomía del Paciente y la Protección Jurídica del Médico
FRI-S03-P03	Yıldız, Merve — Assessment of Defensive Medicine in the Context of Recourse Lawsuits against Public Service Physicians: A Legal Review Following Law N° 7406
FRI-S03-P04	Joisten, Céline & Fontaine, Lucas — Responsabilités en Matière de Maladies Rares: Standard de Prudence des Acteurs de Soins, Organisation Hospitalière et Politiques Publiques
FRI-S03-P05	Heylen, René — Methodological Critique of Singular Causal Judgments in Preventable Adverse Events

SESSION FRI-S04 · Track 4 · 09:00 – 10:30 · 5 Presentations · Room R.007 (Building R)	
Medical Research Governance: Moderator Margot Panneel	
FRI-S04-P01	Van Scharen, Audrey — Innovation Versus Protection? Comparative Governance of Research Ethics Committees in Global Clinical Research
FRI-S04-P02	Panneel, Margot — Governing Ethical Review in Medical Research: Scope Limitations and Compliance with the Declaration of Helsinki

FRI-S04-P03 Ivanc, Blaž — Challenges of Legal Regulation of Ethics Committees in Slovenia
FRI-S04-P04 Chapelle, Julie — The Legal Framework Surrounding Clinical Research Involving Pregnant Women: Towards Responsible Inclusion
FRI-S04-P05 Dorinet, Samantha & Dubruel, Noémie — Vers un Déplacement du Pouvoir Normatif dans le Domaine des Innovations en Santé: Quels Rôles pour les Équipes de Recherches ?

SESSION FRI-S05 · Track 5 · 09:00 – 10:30 · 5 Presentations · Room R.008 (Building R)
Professional Regulation, Disciplinary Law, and Medical Standards: Moderator Berna Arda
FRI-S05-P01 Dronkers, Wouter — Disciplinary Complaints against Resident-Physicians and their Supervisors: An Analysis of Cases in the Netherlands 2009 – 2024
FRI-S05-P02 Aslam, Mustafa — License Revocation of Physician for Professional Misconduct by the Pakistan Medical and Dental Council (PMDC/ PMC)
FRI-S05-P03 Kiuchi, Karla — Legal Certainty in Ethical Proceedings Against Physicians: Lessons from Portugal to Reduce Discretion in Brazil
FRI-S05-P04 Turunen, Merja — Can Organizational Guidelines Ensure Fundamental and Human Rights in Health Care in Lack of Legislation? Analysis of the Former Finnish Hospital Districts' Guidelines on Restrictive Measures in Somatic Care
FRI-S05-P05 Simons, Rogier — Guidelines for Medical Practice: A Reconsideration of Their Legal Significance

SESSION FRI-S06 · Track 6 · 09:00 – 10:30 · 5 Presentations · Room R.011 (Building R)
Transplantation: Moderator Kristof Van Assche
FRI-S06-P01 Sermikli, Zahide — Ethical Dilemmas Surrounding Anencephalic Newborns and Organ Donation: Reflections on Legal, Ethical Issues and Policy Recommendations
FRI-S06-P02 Bewel, Daniel — Bridging the Organ Deficit in Ghana: A Socio-Legal Analysis and Framework for a Culturally Compatible Presumed Consent Legal Regime
FRI-S06-P03 Mammadova, Leyli — Organ Transplantation and Donation: A Comparative Medico-Legal Analysis of Consent Models, Legal Regulation, and Bioethical Challenges in Azerbaijan and Selected Jurisdictions
FRI-S06-P04 e Silva, Érika — Ethical Boundaries and Regulatory Gaps in Heterologous Hair Transplantation: A Bioethical Analysis
FRI-S06-P05 Van Assche, Kristof — Ethical Implementation of Organ Donation Following Medical Assistance in Dying: Recommendations of the Ethics Committee of The Transplantation Society

SESSION FRI-S07 · Track 7 · 09:00 – 10:30 · 5 Presentations · Room R.004 (Building R)
Access to Healthcare III: Moderator Neil Kirby
FRI-S07-P01 Frederiks, Brenda — Inzet van digitale zorg bij ouderen: wat is volgens ouderen nodig voor goede zorg?
FRI-S07-P02 Javdani Sanatagar Moghaddam, Zahra — Inequitable Access to Healthcare in Nursing Homes in Belgium
FRI-S07-P03 Ioan, Beatrice — When More Means Less. Harmful Consequences of Defensive Medical Practice on Patients
FRI-S07-P04 Nguyen, Bao Anh — The Right to Medical Treatment of Vulnerable Groups in Vietnam: A Comparative Analysis
FRI-S07-P05 Hanganu, Bianca — Medical Professional Liability and Defensive Medicine: Implications for Equitable Access to Health Services

10:30 – 11:00	Coffee Break (Building K, Registration Hub)
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11:00 – 12:30	Parallel Sessions 6 sessions, 90 minutes
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SESSION FRI-S08 · Track 1 · 11:00 – 12:30 · 5 Presentations · Room R.004 (Building R)
Access to Healthcare IV: Moderator Stefaan Callens
FRI-S08-P01 Callens, Stefaan — Impact of Recent ECJ Cases on the Reimbursement of Cross-Border Telemedicine Services
FRI-S08-P02 Binyet, Manfreddy — Énergie Solaire Et Résilience Hospitalière En Zone De Conflit : Une Stratégie Pour Renforcer L'équité En Santé Dans L'est De La République Démocratique du Congo, Cas De L'hôpital General De Référence de Nyangezi
FRI-S08-P03 Jahangirova, Aygul — Human Dignity and Equitable Access to Healthcare: The Case of Azerbaijan

FRI-S08-P04 | Ebrahim, Abul Fadl — Health as a Trust (Amānah): A Maqāṣid-Based Framework for Equitable Access, Ethical Innovation, and Interdisciplinary Health Law

FRI-S08-P05 | Nuruzade, Gulnara — State-Supported Rehabilitation of War Veterans: A Medico-Legal and Clinical Assessment of Technology-Based Rehabilitation and Legal Guarantees in Azerbaijan

SESSION FRI-S09 · Track 2 · 11:00 – 12:30 · 4 Presentations · Room R.014 (Building R)

AI and Liability II: Moderator Victor Schollaert

FRI-S09-P01 | Schollaert, Victor — Medische AI & het vernieuwde Belgische & Europese aansprakelijkheidsrecht

FRI-S09-P02 | Hajibayli, Anara — The Algorithmic Patient: Redefining Medical Liability and the Duty of Care in the Era of Artificial Intelligence

FRI-S09-P03 | van Staalduinen, Jan — The Liability Sink is Leaking: Limits to Clinician Responsibility for AI in English and Dutch Law

FRI-S09-P04 | Dantas, Eduardo — Informed Consent 5.0 and the Epistemic Transformation of Civil Liability in Algorithm-Driven Healthcare

SESSION FRI-S10 · Track 3 · 11:00 – 12:30 · 5 Presentations · Room R.008 (Building R)

Forensic and Legal Medicine II: Moderator Manal Bamousa

FRI-S10-P01 | Bamousa, Manal — Does an Effective Child Forensic Interview Result in a Better Expert Testimony?

FRI-S10-P02 | Cahyani, Putri — Visum et Repertum as Evidence in Medical Criminal Offenses

FRI-S10-P03 | Nol, James — Neuroimaging, Traumatic Encephalopathy and the Limits of Legal Medicine Inference by Expert Witnesses

FRI-S10-P04 | Wijaya, Patricia — Scientific Criminal Investigation in Medical Criminal Offences

FRI-S10-P05 | Hatami, Fitria Esti; Nasser, Muh; Ramdhani, Mochamad Fajar & Zanahar, Donny Ferizon — Analysis of Medical Secret Disclosure as an Unlawful Act

SESSION FRI-S11 · Track 4 · 11:00 – 12:30 · 5 Presentations · Room R.201 (Building R)

Genetics II: Moderator Yann Joly

FRI-S11-P01 | Smets, Jolien — Preventive GGE through the Lens of the ECHR

FRI-S11-P02 | Feeney, Oliver — Genobility Revisited: Re-evaluating Mehlman's Existential Threat of Heritable Genomic Enhancement to Liberal Democracy

FRI-S11-P03 | Cassiers, Aurélie — Biotechnologies and Perfect Children: Is There a Right to Choose Their Genetic Characteristics?

FRI-S11-P04 | Dimitrova, Mariya — The Evolution of Bodily Integrity: Genomic Intervention and Artificial Intelligence in Human Rights Law

FRI-S11-P05 | Almqvist, Jessica — Renewing the Foundations of HHGE Regulations in the European Union

SESSION FRI-S12 · Track 5 · 11:00 – 12:30 · 4 Presentations · Room R.230 (Building R)

Medical Liability IV: Moderator Nino Lipartia

FRI-S12-P01 | Leflar, Robert — Medical Injury Compensation and Dispute Resolution Systems in Japan, Taiwan, and Russia

FRI-S12-P02 | Amsiejute, Ausrine — The No-Fault Compensation System in Lithuania: Analysis of Mandatory Pre-Litigation Data on Patient Harm

FRI-S12-P03 | Watson, Ngaire — The Use of Apologies Given at Mediation in Medical Negligence Matters: A View Through a Psychological Lens of a Plaintiff in Australia

FRI-S12-P04 | Wagatsuma, Manabu — How Does the Obstetric Compensation System for Cerebral Palsy Affect Compensation in Japan

SESSION FRI-S13 · Track 6 · 11:00 – 12:30 · 5 Presentations · Room R.007 (Building R)

Minors II: Moderator Sanjin Dekovic

FRI-S13-P01 | Aly, Batool — Evaluating the Legal and Ethical Duties of Transparency and Consent Currently Mandated under Irish law for Healthcare Providers and Institutions with the Lens of the CHI (Children Health Ireland) Scandal to Highlight the Pitfalls of the System

FRI-S13-P02 | Wendel, Lotta — When Protection Causes Harm: Structural Injustice and Children's Rights in Anti-FGM Interventions

FRI-S13-P03 Bruynseels, Lieselotte — Discreet Childbirth in Belgium? Towards a Legal Balance Between Access to Healthcare and the Right to Ancestry Information
FRI-S13-P04 Kropiwnicki, Michał — Repenser l'Accès des Mineurs aux Soins de Santé Mentale : Lacunes Normatives et Nécessité d'un Modèle Fondé sur la Maturité
FRI-S13-P05 Ślaski, Krzysztof — La Nouvelle Procédure de la Modification de la Mention du Sexe dans les Actes de l'État Civil en Pologne à la Lumière des Solutions Adoptées par d'Autres Pays

12:30 – 13:30	Lunch (Building K, Registration Hub)
16:00 – 17:30	Closing Ceremony, Special Session: Establishing the Field of Global Health Law: Remembering Professor Brigit Toebes†, and General Assembly (Antwerp Zoo (Next to Central Station): Darwin Hall) Moderator: Thierry Vansweevelt Panel: Benjamin Mason Meier; Lisa Forman; Gorik Ooms; Rosella De Falco; Rachel Hamonds; Stefania Negri
17:30 – 18:30	Aperitif
18:30 – 19:30	Guided Tour Antwerp Zoo
19:30 – 22:00	Gala & Awards Dinner (Antwerp Zoo: Marble Hall) Young Scientist Award, Davies Award, and AHLEC Award Ceremony
22:00 – ??	WAML Party (Antwerp Zoo: Marble Hall)

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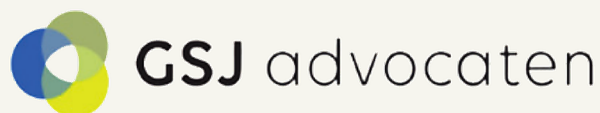
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30th Annual World Congress for Medical Law

BOOK OF ABSTRACTS

SESSION WED-S01 · TRACK 1 · 11:30 – 12:30

Access to Healthcare I · Room R.201

Moderator: Ian Freckelton

WED-S01-P01

Session: Access to Healthcare I · Room: R.201

Thalassaemia and Sickle Cell Disease Treatment: Legal and Ethical Issues

Professor Ian T Freckelton AO KCBA (Hons) LLB PhD LLD Dip Th M

University of Melbourne, Melbourne, Victoria, Australia

Background

Thalassaemia and sickle cell disease are disorders that impose heavy burdens on those who inherit them and upon the community. This has had a variety of consequences manifested in diverse areas of law for those with the conditions arising from patients' vulnerability. Immigration law, child protection law, social security entitlements, discrimination law, family law and criminal law (in particular, in terms of both fitness for interview and sentencing) have generated difficult issues that have been litigated in relation to persons with thalassaemia and sickle cell disease. Over recent decades, evolving conventional treatments, principally in the form of blood transfusions, have enabled persons with the conditions to survive longer, but together with the need for treatment for iron overload arising from transfusions requiring chelation therapy, the conditions profoundly affect the quality of life for most patients. In addition, these treatments are expensive and such as to make it very difficult for patients to maintain consistent employment and to lead lives with any semblance of normality. Positively, ante-natal screening has reduced the numbers of cases in some (generally higher income) countries. However, in many countries it is not available.

Breakthroughs in curative treatment through gene editing (only available since 2022/23 in the United States and Europe) hold substantial promise for dramatically reducing the numbers of those inheriting thalassaemia and sickle cell disease. However, gene editing is not feasible for all patients, internationally there is as yet very limited access to it, and for now it is exceptionally expensive, costing in excess of US\$2 million per patient.

Research Question

The efficacy of the emerging treatments, and their expense, raise challenging ethical and health rights questions for patients, governments and insurers. Given the burden of both diseases, as well as the many legal issues that have arisen for persons with the conditions, there is an urgent need for progress toward international access to the new therapies (including by innovative new modes of provision of the therapies) at costs that can be afforded and which enable the manufacturers of the therapies to recoup their R & D costs. Recalibration is needed of the cost-benefit equation for the one-off gene editing therapies until their expense reduces and they become universally available.

Concluding Remarks

Treatments for thalassaemia and sickle cell disease are in the process of revolution with a cure finally available. However, and unacceptably, at present the cure is only accessible to a very few in high income countries. This dilemma raises issues that must be resolved to improve access on a non-discriminatory basis to breakthrough treatments. Profiteering by pharmaceutical companies in relation to "advanced therapies" cannot be allowed to be the determinant of availability. However, the cost-benefit matrix for a one-off curative treatment, as against lifetime pharmacotherapy, may require greater tolerance for high costs which are likely to save large sums of community expense in the long term. This is especially so for the new thalassaemia and sickle cell treatments.

WED-S01-P02

Session: Access to Healthcare I · Room: R.201

Equidad: reto pendiente en Enfermedades Raras en el Sistema Nacional de Salud (SNS)

Ms Ofelia De Lorenzo Aparici

De Lorenzo Abogados, Madrid, Spain

Asociación Española de Derecho Sanitario, Madrid, Spain

Antecedentes

En el ámbito sanitario, la equidad se erige como uno de los principios estructurales del Sistema Nacional de Salud español, en conexión con el mandato de igualdad efectiva y de no discriminación propio del Estado social y democrático de Derecho. A diferencia de la igualdad, concebida como exigencia de uniformidad en el trato jurídico, la equidad integra las diferencias geográficas, sociales y económicas, partiendo de que los sujetos no se sitúan en idénticas condiciones de partida ni disponen de las mismas oportunidades, lo que justifica la adopción de medidas diferenciadas orientadas a compensar dichas desventajas.

En el ámbito de las enfermedades raras, la baja prevalencia, la complejidad clínica y la limitada disponibilidad de recursos especializados agravan las brechas de acceso al diagnóstico, a la atención y a los tratamientos, haciendo que el código postal, el nivel socioeconómico o la comunidad autónoma de residencia puedan determinar el itinerario asistencial de los pacientes.

Pregunta de investigación

¿Cómo impactan los condicionantes demográficos, organizativos, financieros y normativos del Sistema Nacional de Salud en la equidad del acceso al diagnóstico, la atención sanitaria y los tratamientos de las personas con enfermedades raras en España, y qué líneas de mejora pueden proponerse desde una perspectiva jurídico-sanitaria?

Método

Se realiza un análisis jurídico de la normativa estatal y autonómica relevante, entre las que se incluye la Estrategia Nacional en Enfermedades Raras y sus desarrollos, complementado con la revisión de informes oficiales y datos recientes sobre cribado neonatal, distribución de Centros, Servicios y Unidades de Referencia y acceso a medicamentos huérfanos. A partir de este marco se identifican los principales focos de inequidad y se formulan propuestas normativas y organizativas orientadas a reforzar la cohesión y la equidad en el Sistema Nacional de Salud.

Resultado

El estudio evidencia inequidades significativas en tres ámbitos clave: (i) diagnóstico, (ii) atención sanitaria y (iii) acceso a tratamientos. En diagnóstico, la heterogeneidad de los programas autonómicos de cribado neonatal y la implantación desigual de técnicas genómicas genera diferencias territoriales relevantes. En la atención, la concentración geográfica de los centros de referencia, la dispar coordinación entre niveles asistenciales y la insuficiente formación en enfermedades raras dificultan una atención continuada y especializada. En los tratamientos, se constatan retrasos en la financiación de medicamentos huérfanos, así como reevaluaciones autonómicas y hospitalarias que introducen variabilidad en la disponibilidad efectiva de estos fármacos.

Conclusión

La equidad en enfermedades raras sigue siendo una meta pendiente que exige actuar sobre los determinantes estructurales del sistema, más allá del esfuerzo individual de pacientes y familias. Resulta prioritario reforzar el Registro Estatal de Enfermedades Raras, actualizar la Estrategia Nacional, homogeneizar el cribado y el acceso a tecnologías diagnósticas avanzadas, ampliar y equilibrar la red de centros de referencia, mejorar la formación profesional e implementar vías aceleradas y coherentes de financiación de medicamentos huérfanos. Estas medidas requieren respaldo presupuestario específico y reformas legislativas que reconozcan derechos y obligaciones claros, consolidando la equidad como eje vertebrador del abordaje de las enfermedades raras en España.

WED-S01-P03**Session:** Access to Healthcare I · **Room:** R.201**Selective Universalism and the Inverse Care Law: How Health Systems Neglect Podoconiosis in Ethiopia**PhD Candidate Kassahun Dejene Zeleke

Lingnan University, Hong Kong, Hong Kong

Wolkite University, Wolkite, Ethiopia

Background

Neglected tropical diseases are often framed within universal health coverage, equity, and “leave no one behind” agendas, yet highly stigmatized chronic conditions remain unevenly incorporated into routine health systems. Despite global commitments, the burden remains concentrated in Sub-Saharan Africa, reflecting not only epidemiology but also unequal distribution of social rights and state capacity. Podoconiosis, caused by prolonged exposure to irritant volcanic soils among barefoot rural populations, disproportionately affects smallholder farmers in Ethiopia’s highland regions where access to WASH and basic health services are limited offers a revealing critical case for social policy analysis.

Research Question

How do national health policy priorities and primary healthcare governance in Ethiopia shape the marginalization or integration of podoconiosis care, and how these policy arrangements reproduce persistent inequalities in access to care, analyzed through the lens of the Inverse Care Law.

Methodology

Drawing on Julian Tudor Hart’s Inverse Care Law, this study examines how national health policies and primary healthcare governance in Ethiopia shape access to care for podoconiosis, using a critical social policy approach combining policy analysis and qualitative evidence examine how governance and finance arrangements translate equity commitments into everyday service delivery. Thematic analysis was employed to examine how governance arrangements, financing structures, and institutional employment principles translate equity commitments into everyday service delivery.

Results

Despite formal recognition in national strategies, Podoconiosis delivery remains poorly integrated into routine health information systems, financing, and accountability frameworks, resulting in political invisibility, long-standing underinvestment, and reliance on intermittent NGO support, which in turn leads to fragmented and discretionary care. At the frontline, affected people face long travel distances, high self-care costs, stigma, and unpredictable service availability, creating an inverse relationship between need and provision.

Conclusions

The combined forces of political invisibility, selective integration, and dependence on external funders have led to a negative service-need relationship, reflected in limited shared resources, weak continuity of care, and insufficient mental health and social support at the PHC level. The inverse care arises not from policy absence but from selective integration within formally universal systems, where equity-oriented rhetoric coexists with governance structures privileging campaign-based over chronic care. Podoconiosis thus serves as a “tracer condition” to illustrate how symbolic policy inclusion can coexist with systematic institutional neglect, reproducing inequality through everyday administrative and fiscal practices. Addressing the inverse care law thus requires moving beyond rhetorical universalism toward governance arrangements that secure sustained, rights-based access for marginalized populations in practice.

SESSION WED-S02 · TRACK 2 · 11:30 – 12:30**Criminal Law I · Room R.007**

Moderator: Nasser Muh

WED-S02-P01**Session:** Criminal Law I · **Room:** R.007**When Medical Error Becomes a Crime: Physicians’ Criminal Liability in Recent Romanian Jurisprudence**Lecturer Larisa Pătru PhD, Lecturer Ciprian Laurențiu Pătru

PhD, Lecturer Elena Cristina Andrei PhD

University of Medicine and Pharmacy of Craiova, Craiova, Romania

Background

The interaction between health law and criminal law becomes particularly complex when adverse medical outcomes lead to criminal investigations against physicians. In the Romanian legal system, physicians may incur criminal liability whenever their professional conduct fulfils the legal elements of a criminal offence, unless the circumstances of the case justify or excuse the conduct and thereby exclude its criminal character. Against this general framework, medical malpractice has traditionally been addressed through civil or disciplinary mechanisms. However, recent Romanian judicial practice shows an increasing tendency to assess certain medical acts through criminal law instruments, particularly in cases involving serious bodily injury or death.

Research Question

This paper seeks to identify the types of medical acts that most frequently engage physicians’ criminal liability in Romania and to clarify the legal criteria used by courts to distinguish criminally relevant medical conduct from non-criminal medical negligence.

Methodology

The study is based on a qualitative analysis of Romanian criminal case law concerning physicians from the last five years, focusing primarily on offences such as negligent manslaughter and negligent bodily injury committed in the exercise of medical duties. Judicial reasoning is examined in correlation with medico-legal expert assessments, professional standards of care, and statutory obligations governing medical practice. Reference is also made to relevant European human rights principles regarding the procedural obligations of states in cases of medical-related deaths.

Results

The analysis identifies several recurring categories of medical conduct leading to criminal liability: delayed or incorrect diagnosis, particularly in emergency situations; failure to comply with established clinical protocols; inadequate monitoring and follow-up care; omission of essential diagnostic investigations or specialist referrals; and breaches of professional duties directly affecting patient safety. Romanian courts consistently emphasize the existence of a clearly identifiable professional rule that has been violated, the foreseeability of the harmful outcome, and the establishment of a direct causal link between the medical act or omission and the injury or death.

Conclusions

The findings indicate a gradual consolidation, within Romanian jurisprudence, of a distinct sphere of criminal liability for medical professionals, separating ordinary medical malpractice from conduct deemed criminally negligent. Clarifying this boundary contributes to legal predictability and highlights the importance of preventive compliance measures, including adherence to clinical guidelines, comprehensive medical documentation and effective institutional risk management.

WED-S02-P02**Session:** Criminal Law I · **Room:** R.007**Causal Relationship Model of Negligence Liability in Medical Criminal Law**MD Riki Tsan Asril, Dr M Nasser SpDV

Institute of Health Law, Military School of Law, Jakarta, Indonesia

In Indonesia, the doctrine of causality in criminal law, which explains the causal relationship between a doctor’s negligence and the consequences arising in medical crimes, has not been clearly

regulated. Similarly, the normative construction of a doctor's criminal liability in negligence-based medical crimes has not been regulated in positive law, despite the numerous cases that occur in practice. As a result, many doctors experience unfair and unbalanced legal proceedings. This study will explain why the doctrine of causality is the basis for a doctor's criminal liability in negligence-based crimes. It is hoped that it will answer the question of what is the appropriate construction of the doctrine of causality to determine a doctor's criminal liability in negligence-based medical crimes? The study was conducted in a normative juridical manner, paying close attention to legal facts that occur in the field, such as competency violations and standard violations, or the presence of a medical risk in medical crime cases. Medical negligence cannot be equated with negligence in general crimes, as it typically involves different criminal characteristics. The conclusion of this study is that a thorough examination of the causal relationship in a medical crime case is necessary, as this will determine the severity of a medical crime. Keywords: medical criminal law, causality doctrine, medical negligence, criminal liability of doctors, causal relationship

WED-S02-P03

Session: Criminal Law I · **Room:** R.007

Regulation and Criminal Law Enforcement in Healthcare: An Uneasy Alliance or Partners in Crime?

Mr. Quirine J.M.A. Amelink LLM^{1,2}, Dr. Jan-Willem Weenink PhD¹, Prof. Dr. Ian P. Leistikow PhD^{1,2}

¹ Erasmus School of Health Policy & Management, Rotterdam, Netherlands

² Health & Youth Care Inspectorate, Utrecht, Netherlands

Background

In the healthcare sector, criminal law enforcement and the regulator are frequently confronted with cases that touch on both domains, such as sexual abuse in a hospital, the illegal trade in medicines, and healthcare administration fraud. Effective coordination and collaboration between the regulator and criminal law enforcement can contribute to responses after incidents in healthcare that do justice to those involved, whether this is criminal prosecution or a regulatory intervention. Research on this specific type of collaboration is currently lacking in literature. At the same time, previous literature does suggest that there are opportunities for mutual disciplinary enrichment when it comes to regulatory and criminological insights.

Research Question

How does the collaboration between the regulator and criminal law enforcement in the healthcare sector work out in practice and what are the challenges and opportunities for an integrated approach of incidents in healthcare and interdisciplinary enrichment?

Methodology

On-site nonparticipant observations were conducted of eighteen meetings about ongoing investigations between the regulatory body (Inspectie Gezondheidszorg en Jeugd) and the public prosecutor's office (Openbaar Ministerie) in The Netherlands. In addition, four focus group interviews were conducted with inspectors from the regulatory body and officials working under the direction of the public prosecutor's office.

Results

Two underlying factors are distinguished that create challenges in the collaboration between the regulator and criminal law enforcement: legal issues and ideological differences. Legal difficulties and ambiguities complicate the collaboration between the inspectorate and criminal law enforcement in The Netherlands. Legislation regarding medical information hinders the regulator from providing useful information to criminal law enforcement, which makes an integrated approach of incidents challenging. The divergent ideologies and values between regulation and criminal law enforcement also seem to hinder an integrated approach to incidents in healthcare. The regulator and criminal law enforcement have a common drive to improve patient safety, but their beliefs about how to best achieve this conflict.

Conclusions

Consideration should be given at the policy and legislative level to how the regulator and criminal law enforcement should work together in the healthcare sector and which (legal) arrangements are needed to achieve successful cooperation. Furthermore, by explicitly articulating and valuing each other's ideological differences, the regulator and criminal law enforcement could create an opportunity for mutual

disciplinary enrichment and a successful integrated approach to incidents in healthcare. This could mitigate the inherent biases of both actors and thus provide otherwise unseen opportunities to prevent similar future incidents.

SESSION WED-S03 · TRACK 3 · 11:30 – 12:30

Forensic and Legal Medicine I · Room R.011

Moderator: Vugar Mammadov

WED-S03-P01

Session: Forensic and Legal Medicine I · **Room:** R.011

Forensic and Medico-Legal Assessment of Neurotoxic Heavy Metals Accumulation in the Human Brain and Its Relevance in Legal Proceedings and Healthcare Regulations

MD Gulshan Alisker Huseynova PhD Student¹, MD Alkawthar A. Al-Hchaimi Student²

¹ Azerbaijan Medical University, Baku, Azerbaijan

² Neurosurgery Teaching Hospital, Baghdad, Iraq

Background

Brain tissue analysis can reveal exposure history to neurotoxic heavy metals even after death and therefore plays a significant role in forensic medical examinations. In the framework of health legislation and medical law, the identification and interpretation of toxic metal accumulation are important not only for medical diagnosis but also for legal proceedings, including determination of causality, assessment of medical liability, and evaluation of environmental and occupational exposure. Neurotoxic metals are known to contribute to the development and progression of neurological diseases such as Parkinson's disease and Alzheimer's disease. The topographic distribution of heavy metals in specific brain regions may serve as objective forensic evidence in the court and may be used in medico-legal expert reports in accordance with medical legislation and forensic standards.

Research Question

How can forensic analysis of the topographic distribution of heavy metals in the human brain contribute to medico-legal assessment, legal proceedings, and the application of health and medical legislation?

Methodology

A structured literature review was conducted using the MEDLINE (PubMed) database. The search included studies related to neurotoxic heavy metals and their distribution in human brain tissue. Twenty-one relevant studies were selected for full-text analysis, including cross-sectional and case-control post-mortem studies using elemental analysis techniques. The research focused on regional distribution patterns of heavy metals and their forensic and medico-legal significance, particularly in relation to expert evidence, legal documentation, and regulatory standards in forensic medical practice.

Results

The review demonstrates that heavy metals accumulate in specific brain regions associated with neurodegenerative diseases. Distinct spatial patterns of metal deposition were identified, including co-localization with Lewy bodies in Parkinson's disease and amyloid plaques in Alzheimer's disease. From a medico-legal perspective, these findings may be used as objective scientific evidence in legal proceedings, particularly in cases involving suspected toxic exposure, environmental hazards, occupational disease, or questions of causality. The findings also highlight the importance of standardized forensic methods to ensure reliability and admissibility of expert conclusions in court.

Conclusions

Forensic analysis of heavy metal distribution in the human brain has significant medico-legal importance. It contributes to evidence-based expert evaluation in legal proceedings, supports the assessment of causality, and assists in the application of health legislation and medical law in cases involving toxic exposure and neurological disease. Strengthening the integration of forensic medicine and medical law improves the quality of expert evidence, supports judicial decision-making, and contributes to public health protection and regulatory compliance.

WED-S03-P02**Session:** Forensic and Legal Medicine I · **Room:** R.011**What Kind of Swab Yields the Best Forensic Evidence Results?**Dr. Suha Mohammed Al-Fehaid Forensic consultant, Saudi board in forensic and legal medicine, Korean fellowship in Pathology

Forensic Medicine Centre, Dammam, Saudi Arabia

Background

Choosing the best kind of swab is critical in cases of sexual assault examination. To try to overcome the scarcity of positive DNA results coming from body swabs. Vaginal swabs for example yield positive DNA results in only around 35% of cases (if the swabs were taken in the first 24 hours) and that percentage will drop drastically in every passing hour. Making it crucial to choose the most suitable swab materials to ensure the best yield for these critical cases.

Swab materials vary according to: A) tip: 1) cotton swabs 2) flocked nylon 3) foam 4) polyester or rayon. B) tip shape: round, tapered, reduced surface tip, flicked, cylindrical tip. C) Casing system: 1) rigid tube 2) paper pouch 3) with added desiccant. D) shaft or stick rigidity/flexibility: wooden, polystyrene, polypropylene, acetal.

All these variables will affect the rate of DNA detection making it a very crucial choice.

Research Question

Which swab material (tip material, tip shape, casing system, shaft flexibility) would yield the best DNA results in laboratory tests?

Methodology

After reviewing several studies in Science direct, PubMed, and other search engines.

Results

When comparing all tips to cotton tips as the baseline then the Flocked Nylon is the best and yielding 1.5x – 6x and even 7x more results the regular cotton tips which is around 40-50%, but rayon is slightly worse than flocked Nylon, and foam produces almost similar results to the cotton swabs. In accordance to shape then the results did vary according to the site and age of the swabbed person. Paper pouches are better but not preferable for long storage periods. Flexible polypropylene shaft is better in most ways, but it will be discussed further in the lecture.

Conclusions

A flocked cylindrical tip Nylon with flexible shaft and a paper pouch with added desiccant is statistically the best model for most purposes

Take-Home Message

There are many choices and variables, but the choice of swabs should be tailored to the forensic center's practices, site of swabbing, cost effectiveness, storage, drying practices, pediatric/adult, antemortem/postmortem, so choose according to your needs.

WED-S03-P03**Session:** Forensic and Legal Medicine I · **Room:** R.011**Combined Application of Demirjian and Cameriere Methods for Dental Age Estimation in an Indian Population: A Cross-Sectional Study Using Digital Image Analysis**Dr. Saloni Someshwar BDS, MSc, Dr. Ademir Franco DDS, MSc, PhD

Faculdade São Leopoldo Mandic, São Paulo, Brazil

Background

Age estimation using dental development is a cornerstone of forensic odontology, paediatric dentistry, and legal medicine. The Demirjian method evaluates the developmental stages of seven mandibular teeth, while the Cameriere et al., 2008 based on quantitative measurement of open apices, particularly of the third molar are among the most widely used approaches. With increasing digitization of radiographs, open-source tools such as GIMP provide a cost-effective platform for image analysis. However limited evidence exists on the combined application of qualitative (Demirjian) and quantitative (Cameriere) in large datasets in the Indian population.

Research Questions

What is the correlation between Demirjian stages and Cameriere indices in 739 OPG's? Does combining both methods improve age estimation accuracy?

Methodology

A cross-sectional study was conducted on 739 digital OPGs from North West Indian population. Demirjian staging was performed on mandibular left teeth (31–37). Cameriere analysis was applied to tooth 38; when absent, tooth 48 was used. Cases lacking both third molars, were excluded for Cameriere analysis. Measurements included tooth height(h) and widths of open apices (A₁: Mesial, A₂: Distal) and Cameriere Index was calculated as (A₁+A₂)/h. In single rooted teeth, only one apex width was recorded. All measurements were obtained in pixels using GIMP at a standardized zoom level of 120%. Reproducibility was assessed through repeated measurements.

Results

The Demirjian method showed high applicability in early and mixed dentition stages, while the Cameriere method was more useful in late adolescence. GIMP-based measurements demonstrated good intra-observer reproducibility. A positive correlation was observed between Demirjian stages and Cameriere indices. The combined use of both methods improved overall age estimation accuracy compared to individual methods.

Preliminary Concluding Remarks

The combined application of Demirjian and Cameriere methods using GIMP is a reliable and cost-effective approach for dental age estimation in the Indian population. Demirjian is more suitable for younger individuals, whereas Cameriere enhances precision in older age groups. Standardization of measurement protocols and operator training are essential for minimizing variability. Further statistical validation is ongoing to observe the combined effect for both the methods.

SESSION WED-S04 · TRACK 4 · 11:30 – 12:30**Health Data I · Room R.004**

Moderator: Berna Arda

WED-S04-P01**Session:** Health Data I · **Room:** R.004**Reconceptualizing Medical Confidentiality under Digital Health Governance: A Deontological and Legal Analysis of Turkey's Data Protection Reform**Professor Berna Arda

Ankara University, Ankara, Turkey

Background

The digital transformation of healthcare has substantially reshaped the normative and regulatory foundations of medical confidentiality. In Türkiye, the constitutional recognition of personal data protection in 2012, followed by the enactment of the Personal Data Protection Law (Law No. 6698) in 2016, established a comprehensive framework governing privacy and data security, particularly in relation to sensitive health data. These reforms intersect with the physician's traditional duty of confidentiality, as articulated in the 1998 Regulation on Patient Rights, thereby redefining the relationship between professional ethics and statutory regulation in clinical practice.

Research Question

How has Türkiye's data protection reform influenced the deontological duty of medical confidentiality in clinical settings, and what normative challenges arise from the interaction between individual privacy rights, data security obligations, and the institutional expansion of digital and open health data systems?

Methodology

This study conducts a normative legal analysis informed by deontological theory. It examines constitutional provisions, statutory reforms, and secondary regulations governing the processing of health data. The analysis differentiates privacy as a fundamental individual right from data security as a structural and institutional responsibility. It further assesses how these dimensions operate within digital health infrastructures, including electronic health records, clinical documentation practices, and secondary data use frameworks.

Results

The findings indicate that data protection reform has shifted confidentiality from a predominantly physician-centered ethical duty toward a more structured model of shared legal responsibility. Accountability increasingly extends to healthcare institutions, digital systems, and regulatory authorities. While the legal framework strengthens formal safeguards for sensitive health data, it also introduces interpretive complexity in clinical practice, particularly concerning secondary data processing, data sharing mechanisms, and open health data initiatives. As a result, confidentiality is progressively mediated through regulatory compliance structures alongside professional ethical judgment.

Conclusions

Türkiye's regulatory evolution illustrates how expanding technological governance recalibrates classical deontological obligations within contemporary health law. Ensuring the protection of medical confidentiality in digital environments requires alignment between ethical principles and regulatory design. The Turkish case offers a structured example of how health law can balance innovation, access, and the safeguarding of fundamental rights.

WED-S04-P02

Session: Health Data I · **Room:** R.004

From Regulation to Innovation: Data Protection and Health Governance in Africa and Europe

Nnenna J. Eze¹, Ebere Amaor¹, Etorobasi Akpabio², Dr. Jude C. Omeke³

¹ JENNA LP, Abuja, Nigeria

² Norebase, Abuja, Nigeria

³ NHS, Liverpool, United Kingdom

Background

The swift digitalization of healthcare, encompassing electronic health records, artificial intelligence, and transnational data exchange, is revolutionizing health systems worldwide. Regulatory frameworks in Africa and Europe, like the EU's General Data Protection Regulation (GDPR) and developing African data protection laws, seek to secure personal health data while fostering innovation. Nonetheless, variations in legislative frameworks, enforcement capabilities, and technical preparedness present significant governance problems, especially in guaranteeing fair access and ethical utilization of health data.

Research Question

What are the ways technology-driven legal innovation can improve data protection and governance in healthcare systems throughout Africa and Europe, while ensuring a balance between innovation, equity, and patient rights?

Methodology

This research engages a comparative doctrinal and policy examination of data protection systems in selected European and African jurisdictions. It analyzes statutory instruments, regulatory frameworks, and institutional practices, augmented by case studies on digital health projects and transnational data flows. The analysis incorporates interdisciplinary viewpoints from health law, information technology law, and governance theory.

Results

Initial findings suggest that although Europe exhibits considerable regulatory harmony under GDPR, issues remain concerning the secondary utilization of health data and accountability in artificial intelligence. African jurisdictions exhibit heightened legislative activity influenced by international standards; nonetheless, they encounter fragmentation, inadequate enforcement, and infrastructure limitations. Innovative initiatives, like regulatory sandboxes, regional data governance frameworks, and privacy-by-design technologies, are emerging as effective instruments to address disparities in both regions.

Conclusions

Technology and legal innovation can significantly improve health data governance when tailored to certain contextual conditions. An integrated paradigm that combines strong legal protections, technical innovations and adaptable regulatory frameworks is crucial for cultivating trust, safeguarding patient rights, and guaranteeing equitable access to digital health developments. Improved collaboration between Africa and Europe provides a means to establish

interoperable, morally sound, and innovation-friendly data protection frameworks in global health law.

WED-S04-P03

Session: Health Data I · **Room:** R.004

Legal Challenges and Countermeasures in the Protection of Personal Health Information in Digital Health Management: A Consent-Centered Approach

Assistant Professor Lulu Guo Dr.

East China University of Political Science and Law, Shanghai, China

Background

The rapid integration of digital technologies—ranging from wearable sensors to AI-driven health apps—has revolutionized health management, aligning with national strategies like "Healthy China 2030." This transformation has turned personal health information (PHI) into a vital asset for chronic disease prevention and personalized wellness. However, the pervasive nature of digital surveillance creates unprecedented risks for data privacy. While China's Personal Information Protection Law (PIPL) designates PHI as "sensitive data" requiring "separate consent," the current implementation often falls into a trap of "formalistic compliance." This rigidity fails to address the unique dynamics of health management, where the balance between individual privacy and the social value of health data remains precarious.

Research Question

This study seeks to address a fundamental legal tension: How can we reconstruct the consent mechanism in digital health management to move beyond symbolic gestures? Specifically, it explores how to safeguard individuals' "control" interests while coordinating the multifaceted relationships between data subjects, profit-driven commercial processors, and the state's public health obligations.

Methodology

Adopting an interdisciplinary approach, this research synthesizes legal theory, bioethics, and policy analysis. It traces the evolution of the "Fair Information Practice Principles" (FIPPs) and applies Kantian deontology and Millian utilitarianism to define "control" as the core interest of PHI. Furthermore, it utilizes stakeholder analysis and the "intervention ladder" model to evaluate the rights and duties within the "individual-processor-state" triad, ensuring the proposed framework is both legally sound and practically viable.

Results

The research identifies three systemic dilemmas: the mismatch between diverse PHI types and mechanistic consent rules, the ambiguity of consent's purpose, and the complexity of stakeholder interests. To resolve these, the study proposes a tripartite framework: 1) A Tiered Consent Mechanism that applies separate consent for highly sensitive physiological data, general consent for behavioral data, and an "opt-out" model for publicly disclosed information. 2) A Process-Oriented Disclosure Framework comprising systematic pre-processing disclosure, personalized "machine-plus-human" explanations during processing, and mandatory risk-based breach notifications post-processing. 3) A Proportional State Intervention Model where the state utilizes "soft" regulatory tools to incentivize participation and foster information literacy without overriding individual autonomy.

Conclusions

Consent should be viewed as a dynamic instrument of "informational self-determination" rather than a one-time procedural hurdle. By shifting from a uniform "separate consent" rule to a context-aware, tiered mechanism, we can ensure that digital empowerment enhances public health without compromising personal dignity. The state must act as a facilitator of trust, balancing the commercial viability of the health industry with the fundamental rights of the individual.

SESSION WED-S05 · TRACK 5 · 11:30 – 12:30**Health-System Governance I · Room R.008**

Moderator: Radmyla Hrevtsova

WED-S05-P01**Session:** Health-System Governance I · **Room:** R.008**Good Governance for Resilience and Post-Traumatic Growth: Legal Responses to Mental Health Challenges in Times of Global Upheaval**Professor of Public Health Law, Attorney-at-Law Radmyla Yu. Hrevtsova JD, PhD (Law), MSc (Psychology)

Kyiv Medical University, Private Higher Educational Establishment, Kyiv, Ukraine

Background

In the era of polycrisis (in the sense used by A. Tooze), the mental health of individuals and societies has become a social imperative that must be ensured, *inter alia*, by means of law. This elevates the role of the interdisciplinary approach that integrates both the developments of various branches of law (health law, international, constitutional, administrative, military law, human rights law, etc.) and the interaction between jurisprudence, public administration, psychology, clinical medicine, and public health. The research suggests the innovative paradigm that views good governance not only as a politico-legal category but also as a key determinant for the resilience and, moreover, for the post-traumatic growth of the individuals and the society experiencing the trauma of war or other psychotraumatic events.

Research Question

The study aims at clarifying the impact of good governance on the resilience and post-traumatic growth of society under conditions of existential psychotraumatic events.

Methodology

A comprehensive approach has been applied, integrating theoretical-legal analysis with the interpretation of empirical data. The research develops and legally rethinks the findings of an empirical database established by the author within her interdisciplinary Master's thesis in Psychology, dedicated to the impact of good governance on the post-traumatic growth of Ukrainian society in the context of the Russo-Ukrainian war and the recovery of Ukraine. The database of the study consists of the results of a survey of 109 respondents (physicians, lawyers, and veterans) and 5 in-depth interviews using the diagnostic toolkit developed by the author.

Results

Empirical data confirmed the role of the state's recognition of human dignity as a critical factor for restoring a sense of self-worth. A direct correlation was established between legal certainty and a decrease in the level of background anxiety, which proves the function of the rule of law as a "secure base" (as per J. Bowlby). At the same time, the modest level of respondents' confidence in the effectiveness of judicial protection indicates barriers to the perception of law as such a "secure base," which may inhibit post-traumatic growth.

The transparency of state institutions was identified as a necessary condition for confidence in the future. Furthermore, digital interaction with the state has a significant "psychotherapeutic potential," provided that such interaction is service-oriented.

An important result was the identification of a widespread demand for "institutional courage" (as per J. Freyd): the ability of the administrative system to acknowledge and rectify errors, which is a prerequisite for increasing public trust.

The experience of Ukrainian society proves that an integral component of the institutional and legal framework for post-traumatic growth is good governance based on the rule of law as a fundamental principle for the viability and development of a modern democratic state.

Concluding Remarks

The post-traumatic growth of a society is not only a psychological phenomenon but also a legal outcome achieved through the synergy of health law and other branches of law, public administration, and public health. Effective psycho-legal support for post-traumatic growth requires not only national strategic decisions but also effective international cooperation.

WED-S05-P02**Session:** Health-System Governance I · **Room:** R.008**Operational Necessity v. Legal Limits: Delegating Critical Care to Non- or Lower-Trained Medical Military Personnel in Defence Contexts**Niesje Vanduffel

Royal Military Academy, Brussels, Belgium. University of Antwerp, Antwerp, Belgium

Background

The operational reality of modern warfare significantly limits the possibility to evacuate wounded soldiers to medical facilities, requiring life-saving interventions to be performed on the battlefield. It is, however, operationally impossible to guarantee the continuous presence of a qualified physician or nurse. As a result, non- or lower-trained medical military personnel are often required to carry out critical interventions that, under Belgian medical law, are legally reserved to physicians and nurses. This tension between operational necessity and the existing legal frameworks leaves military personnel performing such acts in a legal limbo. Yet legal certainty is crucial for the effective functioning of Belgian Defence's Medical Service, especially in a context where readiness and rapid response are essential.

Research Questions

Consequently, this research attempts to answer the following research questions: (1) Which rules apply to the delegation of medical acts to non- or lower-trained (medical) personnel during military operations? (2) What (legal) risks are associated with the performance of medical acts by such personnel during military operations? (3) Which reforms could mitigate these risks and enhance legal certainty?

Methodology

Methodologically, the study combines a structural legal analysis of Belgian medical law and relevant provisions of international humanitarian law with a comparative approach that examines the delegation model applicable in England and the Netherlands to identify alternative regulatory approaches in allied NATO states. Six essential life-saving procedures serve as case studies: (1) placement of an intravenous catheter, (2) placement of an intra-osseous catheter, (3) intravenous administration of medication, (4) intra-osseous administration of medication, (5) cricothyrotomy, and (6) needle decompression for tension pneumothorax. Drawing on existing military medical protocols and observations of military exercises, the research evaluates whether, and under which conditions, these procedures could be delegated in both operational and educational Defence contexts. As for scope, the research is limited to the legal frameworks governing Belgian Defence; while interoperability between allied Medical Services is acknowledged as important, it falls outside the present analysis. Likewise, medical acts performed by civilian personnel in Defence-related contexts are excluded.

Preliminary Concluding Remarks

In conclusion, the research aims to address a pressing legal issue that directly affects the operational readiness of Belgian Defence's Medical Service. By clarifying the legal boundaries and identifying where reform is needed, it hopes to contribute to stronger legal preparedness - an essential condition for enabling effective medical support in future operations.

WED-S05-P03**Session:** Health-System Governance I · **Room:** R.008**Determinants of Clinical Discretion and SOP Adherence Among Emergency Physicians: A Nationwide Survey in Taiwan**PhD Candidate Tzu-Haw Kuo

NYCU, Taipei, Taiwan

Background

The legal framework often presumes that physicians will strictly adhere to clinical practice guidelines; however, empirical reality suggests a significant dichotomy. Observations of emergency physicians reveal that medical decision-making is not merely the mechanical execution of Standard Operating Procedures (SOPs). Instead, it involves a complex negotiation between protection against legal risks and the perceived costs of medical interventions, including procedural risks and time constraints. Consequently, identifying the factors that influence clinical

decisions and determining how legal liability should be assessed in this context are critical issues.

Research Question

Which determinants shape the clinical decisions made by emergency department physicians? Specifically, to what extent do clinical practice guidelines and legal accountability constrain or define their clinical discretion?

Methodology

This study employs an empirical cross-sectional survey design, with data collected during the 2026 Taiwan National Annual Meeting of Emergency Medicine. Partial Least Squares Path Modeling (PLS-PM) was used to analyze decision-making models among emergency physicians nationwide, while PLS-Multi-Group Analysis (PLS-MGA) was utilized to examine disparities in decision-making pathways between physicians practicing in medical centers and non-medical centers.

Results

The research analyzes the impact of four constructs on these pathways: Motivations for Defensive Medicine (MDM), Clinical Self-Confidence (CSC), Perceived Costs and Risks (PCR), focusing on central venous catheter (CVC) complications and time sensitivity, and Perceived Procedural Rigidity (PPR). Preliminary findings indicate that MDM is the primary driver behind physicians' preference for SOPs, whereas PCR serves as a critical push factor for exercising clinical discretion. Notably, in medical centers or environments with extreme resource constraints, physicians' sensitivity to PCR is expected to moderate their willingness to comply with SOPs significantly.

Conclusions

This study elucidates the risk trade-offs faced by emergency physicians in clinical practice. The findings suggest that future clinical pathways should incorporate concepts of risk stratification and staged medication administration to achieve a balance between legal protection and clinical emergency efficiency.

SESSION WED-S06 · TRACK 6 · 11:30 – 12:30

Hospital Law I · Room R.230

Moderator: Filip Dewallens

WED-S06-P01

Session: Hospital Law I · Room: R.230

The Legal Status of the Medical Director and Good Hospital Governance

Chelsea Stevens

University of Antwerp, Antwerp, Belgium

Background

The growing pressure to address quality and safety problems has increased interest in appointing physicians as hospital leaders. The participation of a medical specialist can offer several advantages, such as input of specific medical expertise, managerial flexibility and efficiency. An example of a physician leader is the medical director, who is often entrusted with the competence to monitor and improve the quality of care. Even though the function of medical director varies in different countries according to the prevailing laws, regulation and practices, there is a general trend that the medical director's role has shifted in the last several decades. The role of medical director evolved from a strictly medical role to an expanded set of roles that include managerial duties. Nevertheless, e.g. in Belgium, the legal framework surrounding the medical director has seen minimal alteration. This is problematic because the medical director cannot properly fulfil his duties without proper embedding in the (legal) governance structure.

Research Question

The question arises as to how the legal framework can be adapted to seamlessly incorporate the medical director into the hospital's governance structure while aligning with the principles of good hospital governance. Adherence to these principles holds the potential to significantly enhance the quality of care.

Methodology

To answer this research question I will conduct a comparative analysis of the legal status of medical directors/physicians hospital leaders across various countries (e.g. Belgium, France and The Netherlands). These legal frameworks will subsequently be assessed in light of the

principles of good hospital governance. Good hospital governance refers to the structures, processes, and principles through which a hospital is directed, controlled, and held accountable. This research examines how responsibilities and decision-making authority are distributed among hospital actors (e.g. the board, management and hospital physicians) and evaluates whether the legal status of the medical director within the governance structure aligns with the criteria of responsibility, accountability, integrity, and competence.

Results and Conclusions

This research will offer insights into potential improvements to the legal status of the medical director in hospitals, as well as broader enhancements to legal hospital governance structures.

WED-S06-P02

Session: Hospital Law I · Room: R.230

A National Survey of Clinical Privileging Practices in Indian Hospitals and Patient Safety Implications

Dr Ranjit Immanuel James MD, DNB¹, Dr Lallu Joseph PhD^{1,2}, Dr Dhanya Michael PhD³, Dr Latif Rajesh Johnson MD¹, Ms Seema Rao LLB, LLM¹, Dr Vijay Agarwal MD²

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Background

Since the inclusion of healthcare services under the Consumer Protection Act in 1995, India has experienced a substantial rise in litigation against doctors and hospitals. This rising tide of legal actions is intricately linked to the training, competence, and overall accountability of medical professionals. This trend underscores growing concerns about the quality of care rendered. Despite its critical importance for patient safety, India lacks statutory guidelines for healthcare privileging, which involves authorizing practitioners to perform specific medical procedures. This regulatory vacuum not only increases patient vulnerability but also leaves healthcare providers without definitive direction amidst rising concerns about physician accountability. Consequently, the conflicting verdicts by consumer dispute redressal commissions in various cases, when adjudicating allegations of negligence, are a serious concern.

Methodology

To understand the issue at the grassroots level, we conducted a cross-sectional, survey-based study aimed at providing a comprehensive overview of current privileging practices in Indian hospitals and identifying gaps, inconsistencies, and their impact on patient safety. Thus, in a first-of-its-kind attempt, we conducted a pan-India survey, with the help of the Consortium of Accredited Healthcare Organizations (CAHO).

Results

We have received 275 responses from hospitals across all regions of the country. Our findings indicate that more than 10% of these hospitals do not have a clinical privileging system in place. The most common method for granting clinical privileges is through a privileging committee, followed by approval from the department head. Furthermore, over sixty percent of hospitals have a mechanism for revoking privileges, and one-third have an existing temporary privileging system.

Conclusions

This study emphasizes the necessity of a uniform healthcare privileging system in India to ensure patient safety and physician accountability.

WED-S06-P03

Session: Hospital Law I · Room: R.230

Internal Hospital Procedures and Administrative Supervision in Belgium: Legal Challenges for Ensuring Quality of Care

PhD researcher Cato Deprez Master of Laws

KU Leuven, Leuven, Belgium

Background

Healthcare quality is a multidimensional concept encompassing safety, effectiveness and patient-centeredness. In hospitals, safeguarding quality requires coordination between organizational and medical-technical actors operating within a complex, multidisciplinary

environment. Hospitals function in a dense web of internal procedures and external administrative obligations (e.g. recognition requirements, administrative supervision and enforcement) intended to structure and ensure quality management. However, these instruments do not always align with internal governance structures, creating ambiguities regarding accountability and procedural applicability. In addition, insufficient external oversight undermines the effective safeguarding of the public interest. This study examines these tensions by analyzing how internal and external processes operate when confronted with concrete quality-of-care challenges.

Research Question

To what extent are internal procedures and external obligations to structure and ensure quality aligned with the distinct responsibilities of organizational and medical-technical hospital actors, and how do internal hospital procedures interact with external monitoring mechanisms in situations of quality-of-care failures?

Methodology

This study conducts a legal analysis using two hypothetical cases triggering internal hospital procedures. The first concerns an adverse event resulting from a combination of human errors and organizational shortcomings. The second focuses on a structurally underperforming healthcare provider within a multidisciplinary team. For each case, the applicable internal procedures are assessed in terms of clarity, effectiveness and role division. Furthermore, their interaction with external administrative mechanisms is evaluated.

Results

Three main challenges emerge. First, boundaries between organizational and medical-technical responsibilities remain insufficiently defined, particularly where legal requirements are not adequately translated into internal structures. This leads to legal uncertainty, unclear task division and the risk of procedural gaps. Second, the legal framework primarily targets physicians, insufficiently integrating other healthcare professionals. This results in uncertainty and inequality within multidisciplinary teams. Third, the link between internal procedures and external supervision is limited. Even in a system of conditioned self-regulation, where legislators set minimal standards and hospitals further develop internal quality frameworks, adequate guarantees are required to ensure these frameworks are both properly developed and correctly applied. External monitoring is necessary to verify compliance and maintain minimal consistency across hospitals. The current lack of thorough supervision risks leading to fragmented quality management and insufficient protection of the public interest.

Conclusions

Internal hospital procedures often lack clarity, coherence and appropriate role differentiation, undermining effective quality management. Additionally, limited alignment with external monitoring mechanisms contributes to inconsistencies between hospitals, indicating a need for stronger coordination to safeguard the public interest.

SESSION WED-S07 · TRACK 7 · 11:30 – 12:30

Medical Devices · Room R.014

Moderator: Stefaan Callens

WED-S07-P01

Session: Medical Devices · **Room:** R.014

Regulating Rarity: Legal Challenges in Access to Orphan Medical Devices

Assistant Professor Katarzyna Miaskowska-Daszkiewicz PhD
The John Paul II Catholic University of Lublin, Lublin, Poland

Background

Patients suffering from rare diseases often face significant barriers in accessing appropriate medical technologies, including orphan medical devices. While the European Union has developed a relatively comprehensive framework for orphan medicinal products, regulatory mechanisms addressing orphan medical devices remain fragmented and less developed. This creates structural inequalities in access to innovative and life-saving technologies, raising concerns under the right to health and principles of equity in healthcare systems.

Research Question

This study asks whether existing legal instruments at the EU and national levels are sufficient to ensure adequate availability and accessibility of orphan medical devices, and what regulatory gaps hinder effective patient access.

Methodology

The research is based on doctrinal legal analysis and comparative methodology. It examines EU regulatory frameworks, including the Medical Device Regulation (MDR), alongside selected national approaches to market access. The study also draws on policy documents and soft law instruments to assess emerging regulatory trends.

Results

The analysis demonstrates that, unlike orphan medicinal products, orphan medical devices lack a dedicated and coherent legal framework. Existing instruments—such as general medical device regulations, public procurement rules, and reimbursement schemes—are insufficiently tailored to the specific challenges of small patient populations and limited market incentives. As a result, manufacturers face regulatory and economic disincentives, leading to reduced availability of such devices. The study identifies key gaps, including the absence of targeted incentives, limited regulatory flexibility, and inconsistencies across Member States.

Conclusions

Improving access to orphan medical devices requires the development of more targeted legal instruments at both EU and national levels. This includes the introduction of specific regulatory pathways, financial incentives, and greater integration of health policy and innovation frameworks. Without such reforms, patients with rare diseases will continue to experience unequal access to essential medical technologies, undermining both the effectiveness and fairness of healthcare systems.

WED-S07-P02

Session: Medical Devices · **Room:** R.014

Classification of Medical Device Software under the (Revised) MDR

Lawyer-partner An Vijverman

Dewallens & Partners, Leuven, Belgium

Background

When AI medical software qualifies as a medical device based on its intended use, determining the correct MDR risk class (I, IIa, IIb, III) is essential. Only Class I devices are exempt from involving a notified body before market placement. Classification Rule 11 of Annex VIII MDR determines the risk class for software. The Proposal for a Regulation amending the MDR of 16 December 2025 (MDR 2.0) includes a revision of Rule 11.

Research Question

What does Rule 11 mean for AI medical device software? In which class is an AI medical device software application typically placed? What are the challenges and pitfalls of the current system, and how does the European Commission aim to address them through the revised Rule 11?

Methodology

Using concrete examples of medical AI applications, their classification under the current Rule 11 is assessed and the challenges of the existing system identified. The same examples are then used to examine the potential impact of the proposed new Rule 11.

Results

Rule 11 leads to broad up-classification of AI medical device software. Software providing information for diagnostic or therapeutic decision-making is Class IIa unless inaccurate outputs may cause serious deterioration (IIb) or death or irreversible harm (III). Examples include an AI dermatology classifier flagging suspicious lesions, AI stroke-triage tool prioritizing urgent imaging, or an insulin dose-support AI system, which may fall under Class IIa or IIb depending on the clinical risk associated with incorrect recommendations. Software monitoring physiological processes is generally Class IIa unless it involves vital parameters causing immediate danger, leading to IIb. Examples include an AI arrhythmia-detection algorithm or a respiratory-monitoring AI model. All other software remains Class I,

such as a home blood-pressure diary or a cardio app offering general workout recommendations.

Under MDR 2.0, Rule 11 will better reflect inherent risk. Class I becomes the starting point, and software is up-classified only when criteria distinguishing critical, serious and non-serious situations are met. Non-urgent support may remain Class I, while diagnostic tools in non-critical contexts may fall under IIa. Only software used in critical, time-sensitive situations, such as detecting life-threatening arrhythmias or early sepsis, moves to IIb or higher. The revised rule also considers the software's clinical role and level of human oversight.

Conclusions

The current Rule 11 consistently up-classifies AI medical device software, often placing it in Class IIa or higher regardless of actual clinical risk. The proposed revision seeks to reverse this by making Class I the default and applying higher classes only when clear clinical-risk thresholds are met, creating a more proportionate, realistic and innovation-friendly framework.

WED-S07-P03

Session: Medical Devices · **Room:** R.014

Navigating the New Frontier: Macau SAR's Medical Device Regulation and the Emergence of the Greater Bay Area Harmonization Pathway

Legal Adviser Rui Pedro Amaral Master of Law

Macau Biomedical Law Association, Macau, China, Macao

Background

The Guangdong-Hong Kong-Macao Greater Bay Area (GBA), a megaregion of 86 million people, is evolving into a global health innovation hub. A central pillar of this evolution is the transition of the Macau Special Administrative Region (SAR) from a passive import-based system to a formal, modern regulatory framework. With the enactment of Law No. 12/2025, Macau establishes a robust legal regime aligned with international standards and regional strategies.

Research Question

How does Macau's new medical device legal framework (Law No. 12/2025) function as the essential legal catalyst for the "Hong Kong and Macao Medicine and Equipment Connect" mechanism, and what specific liability and data protection challenges does this integration pose for legal practitioners?

Objectives

To analyze the structure and processes of Macau's new legal order; to examine the technical cooperation between the Pharmaceutical Administration Bureau (ISAF) and Mainland China's NMPA; and to dissect Macau's strategic role as a regulatory gateway to the Mainland market via the GBA harmonization pathway.

Methodology

The presentation analyzes Law No. 12/2025 (effective July 1, 2026), focusing on the risk-based classification (Class I-III) and the dichotomy between "listing" (notification) and "registration" (technical review). It explores the operationalization of the GBA Connect Program, which allows devices approved in Macau to be used in designated Mainland institutions, evaluating 2025 data showing 17,000 patients benefited across 77 devices.

Conclusions

The new regulation is a landmark development because it ends decades of regulatory informality, transforming Macau from an isolated market into a strategic "legal laboratory." It is a foundational pillar for GBA integration because it provides international manufacturers with a familiar, Lusophone-influenced legal entry point to test innovations within the GBA ecosystem before full Mainland expansion.

Take-Home Message

For legal counsel, Law No. 12/2025 shifts the focus from simple importation to complex cross-border compliance. Practitioners must immediately update post-market liability clauses and informed consent protocols, as devices approved by Macau's ISAF are now clinical precursors for use in Mainland hospitals. Compliance with this law is the mandatory "key" to unlocking the GBA's fast-track commercialization route.

SESSION WED-S08 · TRACK 1 · 13:30 – 15:00

AI in Healthcare I · Room R.014

Moderator: Victor Schollaert

WED-S08-P01

Session: AI in Healthcare I · **Room:** R.014

Navigating the Bonus Medicus Digitalis: The Physician's Legal Duties of Literacy, Autonomy, and Transparency in AI-Integrated Practice

Professor Dr. Tom Goffin

University of Ghent, Ghent, Belgium

Background

As Artificial Intelligence (AI) transitions from experimental applications to ubiquitous clinical decision-support, the traditional parameters of medical negligence and professional conduct are undergoing a fundamental transformation. Under the evolving European legal framework—most notably the AI Act, the Medical Device Regulation, and the GDPR—the physician's role is shifting from a mere user to a critical "human-in-the-loop." However, it is not sufficiently clear what this human-in-the-loop means in terms of legal obligations for the physician.

Research Question

This presentation addresses a critical gap in health law: what are the specific legal obligations of the individual physician when integrating high-risk AI systems into his daily practice?

Methodology

The analysis focuses on three core normative pillars:

First, it examines the emerging duty of AI literacy. The professional standard now encompasses a "digital competence" requirement. A physician cannot legally deploy a tool he does not understand; thus, a failure to grasp the basic logic, limitations, and potential biases of a clinical algorithm may constitute a breach of the standard of care or even obliges a physician not to use the AI tool.

Second, the presentation dissects the preservation of professional autonomy. With the rise of "automation bias," there is a significant legal risk that physicians will defer blindly to algorithmic outputs. What is the legal mandate for meaningful human oversight, asserting that professional autonomy is not merely a right but a legal responsibility to act as a "gatekeeper," validating AI recommendations against clinical intuition and patient-specific variables.

Third, it is important to focus on the duty of transparency towards the patient to ensure valid informed consent. As AI begins to dictate diagnostic and therapeutic pathways, the scope of disclosure must expand. Patients have a right to know when AI significantly influences their care. This section evaluates the extent to which and the way in which a physician must explain "black-box" processes to ensure that consent remains truly informed, balancing the complexity of the technology with the patient's right to self-determination.

Results

This presentation argues that while AI may augment clinical capabilities, it does not dilute legal responsibility.

Conclusions

By clarifying the three duties of literacy, professional autonomy and transparency, a roadmap is provided for physicians to navigate the digital shift without compromising the legal integrity of the patient-physician relationship.

WED-S08-P02

Session: AI in Healthcare I · **Room:** R.014

Rethinking Liability in AI-Powered Healthcare: Between Human Oversight and Risk Allocation

PhD Francesca Ferretti PhD in Private Law

University of Siena, Siena, Italy

Background

Technological evolution in healthcare requires rethinking the traditional relationship between medicine, law, and technology. The growing use of high-tech medical devices is not uniform but articulated across a plurality of models: 'executive' robotics, non-embedded artificial intelligence (decision-support systems), and 'embedded artificial intelligence' integrated into robotic systems.

This differentiation affects the reconstruction of liability, as each technology reshapes the relationship between physician, patient, and instrument. However, it is necessary to ensure that the use of technology remains subject to human oversight and does not result in a responsibility gap, while preserving the centrality of the patient.

Research Question

This paper examines how liability should be allocated in cases of patient harm resulting from advanced healthcare technologies. It addresses:

- whether and to what extent AI affects traditional criteria for attributing liability;
- how to prevent technological autonomy from leading to a dilution of human responsibility;
- which legal tools ensure that harm does not remain with the patient but is attributed to 'human responsibility,' even in the presence of opaque or unpredictable systems.

Methodology

The analysis adopts a case-based approach, grounded in the distinction between the various technologies employed: robotics, non-embedded AI, and embedded AI. The reconstruction considers general models of civil liability, as applied in the medical context, with attention to the interplay between contractual and tort liability and the different evidentiary regimes they entail.

The investigation focuses on attributing liability to healthcare providers (physicians and institutions), emphasising the role of professional diligence and organisational duties.

Results

The analysis shows that the criteria for attributing liability are not uniform but vary depending on the technology employed. In cases involving non-embedded AI, which operates as a decision-support tool, the fault-based paradigm remains central: the physician retains control over the decision-making process and is liable for negligence, imprudence, or lack of expertise in using the tool.

Conversely, in systems involving embedded AI – characterized by capacity for direct intervention in the physical world – human control is attenuated, and the fault-based criterion is insufficient. In such cases, risk-based liability emerges more prominently, particularly on the part of the healthcare institution, as the entity that introduces and organizes the use of the technology.

This results in a composite model in which fault-based liability coexists with forms of enterprise-based risk liability. The unpredictability or opacity of AI systems does not exempt from liability; rather, it reinforces the need to allocate risk to those who benefit from the technology.

The possibility of recourse actions against the manufacturer of a defective device remains, without undermining the need to ensure effective patient protection.

Concluding Remarks

The use of advanced technologies in healthcare does not entail abandoning traditional liability models, but requires their evolution toward a pluralistic and integrated framework.

The centrality of the patient demands avoiding any responsibility gap: liability must remain anchored to human actors through a combination of fault-based and risk-based criteria. Therefore, civil liability performs a rebalancing function, ensuring that innovation does not reduce protection, but strengthens patient safety and the right to health.

WED-S08-P03

Session: AI in Healthcare I · **Room:** R.014

Legal Regulation of Artificial Intelligence in Healthcare: Challenges and Opportunities of an Interdisciplinary Approach

Vafa Mammadova¹, Murad Mammadov²

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Background

Expanding boundaries in health law refers to a change in approach from traditional doctor-centric clinical relationships to wider issues of access, technological innovation, and interdisciplinary governance. The legal complexities arising after the introduction of artificial intelligence in healthcare present legal issues that the modern legal regulations of medical practice lack the ability to address, as the health law continues to experience significant transformation, consequently expanding the scope of healthcare.

Research Question

The abstract evaluates whether the expansion of health law reveals the weakness of the current legal frameworks, and whether the existing laws are incapable of responding to modern technological and systemic challenges arising from the use of AI, and requires more innovative and interdisciplinary regulations.

Methodology

By focusing on the involvement of artificial intelligence in medical practice, the evaluation applies the integration of technological development, access to healthcare, and interdisciplinary regulation. It reviews the potential of legal frameworks addressing the risks and complications created by the technology, with an emphasis on the ability of existing frameworks to handle the AI-assisted health system.

Results

The development of technology in medical practice has emerged as one of the central factors in the expansion of health law, such as the increasing use of artificial intelligence in medical courses of action — diagnostics, treatment planning and healthcare delivery. Such innovations produce considerable opportunities to maximize efficiency and promote broader access to healthcare services. However, the existing legal frameworks are not prepared to handle complexities potentially arising from the use of innovations including AI in healthcare. Thus, the current health law requires effective engagement with various disciplines, through the implementation of modern medical competence, technological capabilities, and ethical considerations to adopt a broader framework of the traditional regulations.

Conclusions

Therefore, the dependence on the current legal frameworks lacking the capacity to merge the elements of expertise, technology, and ethics reveals the necessity for better interdisciplinary legal regulations, to ensure that the health law is ready to incorporate such innovations, including AI, into healthcare systems.

WED-S08-P04

Session: AI in Healthcare I · **Room:** R.014

AI + Clinical Practice in China: Current Landscape and Legal Challenges

Professor Xueqian Zheng PhD Candidate¹, Professor Liqiang Deng Bachelor²

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Background

In China, "AI + clinical practice" has become a national strategy. While AI widely improves diagnostic efficiency and resource allocation, it also raises questions about liability allocation, clinical risk, and legal responsibility.

Methodology

We reviewed Chinese statutes, policies, and case data to map AI's permitted roles, application scenarios, and emerging risks, then proposed regulatory fixes.

Results

AI may only "assist" diagnosis and treatment; hospitals and licensed physicians remain legally responsible. Approved uses cover image interpretation, report drafting, prescription decision support, pharmacy review, disease prediction, surgical planning, and AI-run hospitals. Yet regional data bias, limited rare-disease recognition, lack of humanistic communication, and potential misdiagnosis persist. As AI edges toward autonomous practice, legal boundaries are still undefined.

Conclusions

Innovation must be balanced with regulation. China should adopt scenario-specific protocols, tighten full-process licensing, enforce corporate self-discipline, stiffen penalties, invite public oversight, and accelerate enactment of an AI Law that clarifies liability and steers "AI + clinical practice" toward safe, standardized growth.

WED-S08-P05**Session:** AI in Healthcare I · **Room:** R.014**Implementing AI in Medical Guidelines: What Challenges Do Lawyers and Doctors Face?**Roland M. Bertens PhD, LL.M.

Van Benthem & Keulen Advocaten en Notarissen BV, Utrecht, Netherlands

Background

Professional medical associations struggle with the translation of rapidly emerging European AI law into practicable clinical guidelines. The EU Artificial Intelligence Act (AI Act), the General Data Protection Regulation (GDPR) and Dutch patients' law (notably the Wet op de geneeskundige behandelingsovereenkomst — WGBO — and related quality rules) create overlapping legal duties for healthcare professionals but leave substantial interpretive and operational questions for associations issuing conduct rules and protocols.

Research Question

What are the experiences with Dutch professional associations operationalizing EU AI requirements within practical, legally compliant guidelines for clinical practice that align with Dutch patients' law and privacy obligations so far? And how can legal professionals best operationalize complex (European and national) legislation for medical experts?

Methodology

Doctrinal analysis of the AI Act (proposal), GDPR, WGBO and relevant Dutch healthcare statutes and case law; comparative review of existing EU and national guidance documents, technical standards and professional protocols; and synthesis of practitioner experience involving implementation problems (knowledge deficits about AI, uncertainty about liability, data-processing roles, and consent).

Results

Key findings thus far: (1) there is conceptual uncertainty among associations about the scope and technical characteristics of "AI" and "high-risk" systems; (2) there is a lack of concrete mapping between AI Act obligations (e.g. conformity assessment, logging, human oversight, transparency) and clinicians' legal duties under WGBO and professional rules; (3) there are gaps in GDPR operationalization—particularly on lawful basis for processing, DPIAs, data minimization, controller/processor allocation and data subject rights in AI contexts; and (4) there is insufficient guidance on procurement, contractual protections and incident reporting. Practical solutions include guideline templates: practicable definitions and clear risk-classification; mandatory training (also on 'AI literacy'); model procurement and data-processing clauses; and procedures for informed patient communication and clinical oversight.

Conclusions

AI is a new technology, but the norms by which it is governed are mostly not. Professional associations should therefore issue operational guidelines that translate AI Act and GDPR duties into concrete rights and norms which tie into norms with which medical professionals are already familiar. Clear mapping of legal obligations to practitioner actions, combined with mandatory training and real-world examples will reduce legal uncertainty and promote responsible adoption of AI in Dutch healthcare (and abroad).

SESSION WED-S09 · TRACK 2 · 13:30 – 15:00**Deathcare · Room R.004**

Moderator: Kristof Van Assche

WED-S09-P01**Session:** Deathcare · **Room:** R.004**From Consent to Permissible Uses in Body Donation to Science: A Comparative Study**PhD researcher Hanne Dielis LL.M.

University of Antwerp, Antwerp, Belgium

Background

Body donation to science plays an essential role in medical education and research, while directly affecting post-mortem bodily integrity and therefore warranting careful normative scrutiny. However, regulatory frameworks remain limited in Belgium and the Netherlands, compared with France and Ireland (not yet in force), which have introduced

comprehensive health-law frameworks governing body donation. In those countries, greater attention is paid to consent requirements, including capacity and information, and to the delineation of permissible uses of donated bodies to ensure the dignified treatment of the donor.

Research Question

Against this background, the question arises whether countries in which limited regulatory attention is paid to consent and permissible use afford sufficient protection to donors. Closely connected is the question how oversight is organised to ensure that use remains within the scope of the initial consent and how permissible use is defined in law and practice so as to ensure ethical acceptability.

Methodology

To address these questions, a comparative legal analysis was conducted of regulatory frameworks in Belgium, the Netherlands, France, and Ireland, supplemented by relevant bioethical guidance in the anatomical sector and in comparable contexts involving the donation of human bodily material.

Results

Across all examined jurisdictions, strong emphasis is placed on the donor's explicit and genuinely expressed wishes. Nonetheless, significant differences exist regarding formal consent requirements and capacity thresholds, particularly in relation to minors and legally incapacitated adults, sometimes leading to categorical exclusions without individualised assessment. All jurisdictions predominantly rely on broad consent, under which donors consent to broadly defined educational and research uses. In comparable domains, such models are considered ethically acceptable only when accompanied by institutional safeguards, including ethical oversight and governance structures. While these safeguards are clearly embedded in the statutory frameworks adopted in France and Ireland, they remain largely absent in Belgium and the Netherlands, raising concerns as to whether donor autonomy and dignity are sufficiently protected. Moreover, permissible uses are often not clearly delineated in law in all examined countries, leaving considerable interpretative discretion to receiving institutions. Consequently, concepts such as "research" and "education" may be interpreted broadly, potentially extending beyond traditional medical purposes to applications such as decomposition studies or car safety testing.

Conclusions

The findings support the need for clearer regulatory guidance on consent and permissible use in body donation. Key recommendations include statutory minimum information requirements with specific attention to sensitive or uncommon uses, the introduction of oversight mechanisms to monitor compliance with consent and ethical standards, and complementary safeguards such as layered consent options.

WED-S09-P02**Session:** Deathcare · **Room:** R.004**The future of death care in the US**Professor of Law Tanya D Marsh JD

Wake Forest University, Winston-Salem, North Carolina, USA

Background

For over a century, the American funeral industry has been defined by an occupational licensing regime premised on the assumption that the deceased will be embalmed and buried in a casket and vault. This legal framework, which requires extensive embalming education, lengthy apprenticeships, and costly facility requirements, has created significant barriers to entry in the funeral profession and limited competition and innovation. However, American consumer preferences have undergone a dramatic transformation in recent years. The cremation rate has risen from single digits in 1980 to over 60% in 2024. Simultaneously, there is growing interest in environmentally friendly methods of disposition, including green burial (no embalming, casket or vault), natural organic reduction (human composting), and alkaline hydrolysis (water cremation), methods that are not yet universally legal in the United States.

Research Question

Will the legal system and the structure of the funeral industry in the United States accommodate changing consumer preferences?

Methodology

This presentation draws upon a body of interdisciplinary scholarship, including analysis of state occupational licensing regimes, and original

empirical data from the 2024, 2025, and 2026 Wake Forest Law Surveys on Consumer Preferences in Death Care—the first academic surveys of a representative sample of the U.S. adult population designed to assess preferences for six methods of disposition.

Results

Survey data reveal a fundamental misalignment between consumer preferences and the existing legal and market structures. In both the 2024 and 2025 surveys, less than 40% of respondents reported that they would even “consider” embalming. Over half of respondents expressed willingness to consider green burial, and nearly one in four ranked natural organic reduction among their top two choices. The 2025 survey revealed a “Cremation Paradox”—a significant gap between the high national cremation rate and consumers’ actual first-choice preferences—suggesting the market may be constraining rather than serving consumer demand. Significant legal barriers persist: water cremation is legal in only 27 states, natural organic reduction in only 14, and efforts to establish green burial grounds have faced resistance from legislatures and local zoning boards.

Conclusions

The American funeral industry’s legal and regulatory framework is increasingly misaligned with consumer demand. Meaningful reform—including two-track licensing that decouples funeral directing from embalming, legalization of emerging methods of disposition, and removal of unnecessary barriers to green burial—is essential to ensure that the law serves consumer choice rather than industry incumbents.

WED-S09-P03

Session: Deathcare · **Room:** R.004

Promoting a Unified Concept of Death: Is It Possible to Arrive at a Unified Concept of Death in the Context of Organ Transplantation?

Eline Naenen

University of Antwerp, Antwerp, Belgium

Background

The ongoing medical, legal, and ethical debate about the concept of death. Traditionally, death is determined by the irreversible cessation of circulatory functions. However, advancements in life-sustaining technologies have shifted the focus toward brain-based criteria for declaring death, particularly in cases involving organ donation. Transplant professionals and international transplant guidelines increasingly emphasise the importance of adopting a unified concept of death to build public trust, streamline organ donation practices, and eliminate inconsistencies in death determination. This oral presentation will discuss these developments and ongoing discussions surrounding a unified concept of death.

Research Question

Is it possible to arrive at a unified concept of death in the context of organ transplantation?

Methodology

The methodology consists of a literature desk study and a short comparative law study. The first part of my desk study focuses on: • Existing definitions of death in the context of organ transplantation and their conceptual, medical, and ethical foundations; • The Belgian regulatory framework in the context of organ transplantation and its coherence with international standards; • Recent developments, debates, feasibility and implications for medical practice, ethics, and legislation of a uniform concept of death.

The second part focuses on supranational regulatory frameworks, with particular attention to similarities and differences between jurisdictions. The researched jurisdictions are Belgium, the Netherlands, France, Germany, India, Japan, the USA, China and some Islamic countries.

Results

- Death determination is based on four main criteria: cardiorespiratory death, whole brain death, brainstem death, and higher brain death;
- Belgian law provides limited guidelines and refers to the ‘latest scientific developments’, meaning medical practice remains decisive. International instruments leave the definition of death to national systems, although they emphasise the right to life and physical integrity. The concept of death and the surrounding policies differ per country;
- Cultural and religious differences hinder broad acceptance of brain death. Philosophical questions about the nature of death and medical uncertainties surrounding diagnostic tests amplify the complexity.

Public intuition about breathing and warmth influences confidence in organ donation.

Conclusions

A unified concept of death is desirable and necessary to ensure consistency, transparency and ethical integrity in death determination and organ donation. However, it requires resolving conceptual ambiguities, aligning clinical procedures with biological and/or philosophical definitions, and addressing societal, religious and cultural concerns about death determination. Therefore, it requires an interdisciplinary approach consisting of interdisciplinary dialogue, education of the public and professionals, and international comparative medical research.

WED-S09-P04

Session: Deathcare · **Room:** R.004

A Bioethical Framework for the Digital Afterlife

Zeynep Sare Kırbas Medicine, Efe Yiğit Çınar Medicine, Melih Altıntakan Medicine, Prof. Dr. Perihan Elif Ekmekci Medicine
TOBB University of Economics and Technology, Ankara, Turkey

Background

As social media usage climbs, so does the number of accounts belonging to the deceased, creating a vast “virtual graveyard.” The data and profiles left behind constitute a digital legacy. This novel concept demands a strong ethical framework to be translated into a legal one. After all, management of digital legacies lies in the unique intersection of inheritance and personality law. Artificial intelligence (AI) integration complicates this further. Meta’s recent patents allow platforms to simulate a deceased individual’s persona, enabling accounts to interact with the living as if the user were still alive. Issues of consent, privacy, and vulnerability have become so pivotal that legal frameworks alone no longer suffice. This shift necessitates a bioethical perspective, which offers a more nuanced lens for navigating these complexities.

Research Question

How can bioethical principles provide a framework for the legal and ethical management of ‘digital legacies,’ specifically concerning AI-driven interactions (such as Meta’s patent) that simulate deceased individuals?

Methodology

We employ a two-step approach: first, a scoping review of the current legal and ethical literature regarding digital legacy; second, an analysis of these findings through the lens of bioethical principles, accounting for the perspectives of both the deceased and their bereaved loved ones.

Results

Privacy concerns extend beyond the deceased to those they interacted with online. Because digital communication is reciprocal, accessing a decedent’s data inherently risks exposing the private information of surviving parties.

Autonomy becomes complicated when agentic AI models or LLMs use a decedent’s data to simulate their persona. While a person can consent to data access, they cannot foresee or control how an AI might misalign or behave, causing issues ranging from family distress to defamation. The question is, can one truly consent to unpredictable posthumous interactions?

Non-maleficence might be the most pertinent principle when considering this specific algorithm, which is patented to a for-profit company that might exploit people who are already in a vulnerable position due to their grief to market certain products or services using their loved one’s likeness.

Conversely, if implemented ethically, these innovations can provide a therapeutic outlet for grief, offering comfort and helping survivors maintain a sense of connection.

Conclusions

Addressing these complexities requires a transdisciplinary framework that merges bioethics with tech innovation. When data governance impacts both individual privacy and the collective social psyche, policy must integrate legal rights with the core principles of clinical ethics.

WED-S09-P05**Session:** Deathcare · **Room:** R.004**The Right of a Corpse to a Visum et Revertum to Reveal the Truth in Law Enforcement**Dr Fajri F Israq S2

Graha Hermine Hospital, Batam, Indonesia

Visum et Repertum (VeR) is a certificate of explanation made by experts in the field of forensic medical science, based on the investigator's request, to find facts about the cause of death of a person. However, in the implementation of the VeR, there are rights of the corpse related to the family's right to refuse or accept the dissection of the corpse for the post-mortem, as well as the right to know the results of the post-mortem, which are regulated in Articles 133 and 134 of the Criminal Procedure Code. However, investigators also have the authority to continue to perform a post-mortem if there is a greater judicial interest, the right to know the results of the post-mortem and the right to demand justice. Uncovering the legal truth through a post-mortem has challenges if the family refuses to perform a VeR for religious, cultural, or emotional reasons, which can hinder the law enforcement process. With this gap, this research aims to identify and analyze the right of the corpse to VeR to uphold truth in law. This research uses normative legal research methods, using secondary data collected through literature research. This study found that in several cases in Indonesia, there are still many cases where families refuse to conduct a VeR on victims, which ultimately hampers the investigation process, or the truth is not revealed. Law enforcers have carried out their duties, but are overwhelmed in requesting family consent for a post-mortem or forensic post-mortem, ultimately leaving these cases unsolved. As a result, the perpetrators do not get a deterrent effect and continue to commit acts of taking people's lives. Based on these findings, it is concluded that no conception or theory provides human rights as a corpse to its body to be used in revealing the legal truth. The Minnesota Protocol on the Investigation of Potentially Unlawful Death (2016) has established the importance of investigating suspicious deaths, so that the cause of death/truth can be revealed, this is part of the body's right to undergo a Visum et Repertum

SESSION WED-S10 · TRACK 3 · 13:30 – 15:00**Disability · Room R.008**

Moderator: Vugar Mammadov

WED-S10-P01**Session:** Disability · **Room:** R.008**Legal Integration of Health Law and Disability Law in Azerbaijan: Ensuring Equal Access to Healthcare for Persons with Disabilities**Professor Vugar Qurban Mammadov MD; JD; PhD; Professor Azerbaijan Medical University / Ministry of Labor & Social Protection of Population of Azerbaijan, Baku, Azerbaijan**Background**

The integration of health law and disability law represents a crucial dimension of contemporary legal and healthcare frameworks. While disability was historically approached as a medical issue, modern international standards—such as the UN Convention on the Rights of Persons with Disabilities (CRPD)—emphasize its social, legal, and human rights dimensions. In Azerbaijan, legislative reforms over the last decade, including the Law on the Rights of Persons with Disabilities and amendments to healthcare legislation, have sought to harmonize healthcare provision with anti-discrimination protections, reflecting the growing recognition of disability rights as a central component of public health governance.

Research Question

How do health law and disability law intersect in Azerbaijan, and to what extent do legal mechanisms ensure equitable access to healthcare services and protection of patient rights for persons with disabilities?

Methodology

This study employs doctrinal legal research combined with comparative analysis. National legislation, regulatory acts, and official policy documents in Azerbaijan were examined, alongside international legal instruments including CRPD and WHO guidelines. Key areas of analysis included patient rights, informed consent, accessibility standards, rehabilitation services, and anti-discrimination mechanisms.

Results

The research identifies several intersections between health law and disability law in Azerbaijan: legal provisions ensure access to rehabilitation programs, medical treatment, and assistive devices while simultaneously regulating informed consent and patient autonomy. However, gaps remain in enforcement mechanisms, particularly regarding accessibility standards and systemic monitoring of healthcare institutions. Comparative analysis demonstrates that integrating disability principles within health law significantly enhances protection of human rights and improves outcomes for persons with disabilities.

Conclusions

The integration of health law and disability law is essential for promoting inclusive healthcare systems in Azerbaijan. Effective harmonization of legal frameworks ensures equal access, safeguards patient rights, and aligns national practice with international human rights obligations. Policymakers should continue refining regulatory mechanisms to strengthen compliance, enforcement, and systemic monitoring.

WED-S10-P02**Session:** Disability · **Room:** R.008**The Human Rights to Healthcare: Evaluating Legal Frameworks and Barriers for Persons with Disabilities in Nigeria**Joyce Nnenna Eseni LLM¹, Professor Eseni Azu Udu PhD, PhD²¹Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Ebonyi, Nigeria. ²Alex Ekwueme Federal University, Ndufu-Alike, Ikwo, Ebonyi, Nigeria**Background**

The United Nations Convention on the Rights of Persons with Disabilities and its Optional Protocol aim to ensure that all persons with disabilities enjoy full and equal human rights, with their inherent dignity respected, promoted, and protected. Despite these global commitments and the existence of national legislation, the realisation of the human right to healthcare for persons with disabilities in Nigeria remains limited. Disabilities, including sensory impairments (vision, hearing, and speech), physical disabilities, and mental or intellectual disabilities interact with social, structural, and environmental barriers that hinder effective participation in healthcare on an equal basis with others. Although, the Discrimination Against Persons with Disabilities (Prohibition) Act of 2018 established the National Commission for Persons with Disabilities to access healthcare and socioeconomic protections, advance rights and wellbeing, discriminatory attitudes and inaccessible healthcare environments continue to undermine equal access.

Research Questions

This study explores two research questions: (1) How adequately do existing legal frameworks in Nigeria protect the healthcare rights of persons with disabilities? and (2) What structural, social, and institutional barriers impede their practical realisation of these rights?

Methodology

A mixed method approach is adopted, combining doctrinal analysis with sociolegal review. The doctrinal component examines constitutional provisions, disability legislation, health policies, and relevant international and regional human rights instruments. The sociolegal component synthesises evidence from surveys, reports, scholarly literature, and systemic patterns of exclusion within the healthcare sector.

Results

The analysis reveals significant gaps in legal protection, persistent discrimination, and weak implementation mechanisms that contribute to sustained inequalities in healthcare access for persons with disabilities. Key barriers include the absence of healthcare interpreters for visually, hearing, and speech impaired patients, which comprises the legal principles of informed consent, effective communication, and patient autonomy. Inadequate structural accessibility such as ramps and other mobility supportive features, despite statutory requirements further restrict physical access, particularly for wheelchair users. Implementation of disability regulations consistently vary across jurisdictions and healthcare institutions. These findings reflect broader patterns in low- and middle-income countries, where limited disability-

inclusive policies, insufficient funding, and inadequate provider training exacerbate inequities.

Conclusions

Achieving equitable, rights-based healthcare for persons with disabilities in Nigeria requires more than addressing individual barriers. It demands confronting their combined and mutually reinforcing effects. Strengthened accountability mechanisms, comprehensive disability-inclusive healthcare policies, and targeted training for healthcare professionals are essential. More nuanced, intersectionally informed interventions are needed to promote meaningful access and advance the objectives of international disability rights instruments.

WED-S10-P03

Session: Disability · **Room:** R.008

Para-Sport Classification in a Disability Rights-Era: What is the Impact on Health Law and Health Professionals?

Naomi Blomme Master

Vrije Universiteit Brussel, Brussels, Belgium. Hogeschool VIVES, Bruges, Belgium

Background

Article 30 of the UN Convention on the Rights of Persons with Disabilities (CRPD) guarantees the right of persons with disabilities to participate, on an equal basis with others, in sporting activities. Among the obligations arising for States Parties is the duty to ensure that persons with disabilities have opportunities to organise, develop, and participate in disability-specific sporting activities. Para-sport classification is an essential component of such activities: it determines who is eligible to compete in particular sport classes and is therefore central to the realisation of the rights protected under Article 30 CRPD. Although classification is formally situated within sports law, it relies heavily on medical assessments, diagnostic categories, and functional evaluations conducted by health professionals. This creates a structural tension between, on the one hand, the CRPD's human-rights model of disability, which stands in direct opposition to the medicalised approach and its reliance on disability-based gatekeeping.

Research Question

What are the implications for health law and the health-law profession arising from the interaction between the current para-sport classification system and the CRPD's human-rights framework?

Methodology

This study combines doctrinal legal analysis with qualitative insights drawn from the author's ongoing doctoral research. The qualitative component, conducted using NVivo, has already been completed. It involved a systematic coding and analysis of the CRPD Committee's Concluding Observations relating to Article 30 and other relevant provisions, with particular attention to how the Committee interprets States Parties' obligations concerning participation in sport. Building on these findings, the next stage of the research involves a doctrinal examination of international sport classification regulations to assess how current classification practices interact with the CRPD's human-rights framework and to identify the resulting implications for health law and the health profession.

Preliminary Results

The current classification system reveals a strong reliance on disability-based criteria that conflict with the CRPD's shift toward a social and human-rights-based understanding of disability. Health professionals are placed in a quasi-regulatory role, making determinations with significant consequences for athletes' rights. Yet classification procedures often lack the procedural protections normally required when health professionals make legally significant assessments, raising concerns about transparency, accountability, and the potential for discriminatory outcomes. Moreover, the medical framing embedded in classification reinforces outdated assumptions about disability, limiting the transformative potential of Article 30 CRPD.

Preliminary Conclusions

The system of para-sport classification clearly sits at the intersection of sports law, disability-rights law, and health law. As long as classification remains grounded in medical categories, it risks undermining the CRPD's human-rights model and placing health professionals in ethically and legally ambiguous positions. Health-law scholarship and regulation must engage more directly with classification practices to ensure that participation in sport is governed by rights-compliant, transparent, and accountable procedures. Redesigning classification

through a CRPD-aligned lens is essential to safeguarding equal access to sport for persons with disabilities, while also maintaining an equal field of play. Achieving an appropriate balance between equality and equity remains a central challenge.

WED-S10-P04

Session: Disability · **Room:** R.008

Assistive Technology and Legal Innovation in Azerbaijan: Ensuring Accessibility and Rights Protection for Persons with Disabilities

Dr. Sabina Adil Mammadova Medical Doctor¹, Professor Vugar Qurban Mammadov MD; JD; PhD; Professor^{2,3}, Turana Aliyeva⁴

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Background

Assistive technologies are rapidly developing and play an important role in improving the quality of life and transforming opportunities for persons with disabilities globally. These technologies include mobility devices, communication tools, digital accessibility tools, and AI-based assistance systems. However, technological development also creates new legal challenges related to accessibility, affordability, intellectual property, data protection, and digital rights.

In Azerbaijan, recent initiatives promote access to assistive technologies, yet regulatory frameworks remain underdeveloped, particularly regarding quality of the products, their accessibility, affordability, digital rights, intellectual property, and ethical standards. Legal innovation is therefore crucial to ensure that technological advances translate into tangible social inclusion and rights protection.

Research Question

How can Azerbaijani legal frameworks adapt to technological innovations to ensure equitable access to assistive technologies and uphold the rights of persons with disabilities?

Methodology

The study employs doctrinal legal research and policy analysis, examining Azerbaijani legislation, regulations, and official programs on assistive technologies, disability rights, and innovation policy. International standards, including CRPD and WHO guidelines on assistive devices, are used as comparative benchmarks.

Results

The study shows that legal innovation plays a key role in ensuring access to assistive technologies through public funding programs, accessibility standards, anti-discrimination laws, and digital rights protection. The research also demonstrates that without proper legal regulation, assistive technologies may remain inaccessible to many people due to high costs and lack of legal guarantees.

Analysis indicates that legislative measures in Azerbaijan partially address access to assistive technologies through public funding and disability programs, yet gaps exist in intellectual property regulation, digital accessibility standards, and enforcement. Legal innovation—through adaptive regulatory mechanisms, standard-setting, and public-private partnerships—can significantly enhance accessibility, affordability, and social inclusion.

Conclusions

Assistive technology and legal innovation must develop together. Legal systems should create flexible and inclusive regulatory frameworks that promote innovation while ensuring accessibility, affordability, and protection of the rights and dignity of persons with disabilities.

Integrating legal innovation with assistive technology policy is essential for advancing disability rights in Azerbaijan. A proactive, adaptive legal framework ensures that technological progress translates into meaningful social inclusion, protection of digital rights, and empowerment of persons with disabilities.

WED-S10-P05**Session:** Disability · **Room:** R.008**Ethical and Legal Issues Associated with the Use of Technological Devices and Artificial Intelligence Tools for the Management of Wandering in People with Dementia**Prof. Esther-Lee Marcus M.D.^{1,2}, Dr. Ali Mustafa Gibril M.D.^{1,2}, Dr. Yehezkel G. Caine M.D.^{1,2}¹Herzog Medical Center, Jerusalem, Israel. ²Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel**Background**

Wandering is defined as "a syndrome of dementia-related locomotion behavior having a frequent, repetitive, temporally-disordered, and/or spatially-disordered nature manifested in lapping, random, and/or pacing patterns, some of which are associated with eloping, eloping attempts, or getting lost unless accompanied." The estimate is that up to 60% of people with dementia would "wander" into the community at some stage during their illness. Wandering can kill! It can increase caregiver burden and anxiety, and can put a caregiver's home at legal risk. Recently, in Israel, a 78-year-old theater scholar, director, and dramaturge with dementia, went missing. She was last seen near the hospital where she had accompanied her husband. She was found only after a week of intensive searching in critical condition and died a week later.

Research Question

What insights does recent literature offer to our understanding of the ethical and legal aspects of the use of technological devices, including artificial intelligence (AI), in the management of wandering?

Methodology

PubMed and Google Scholar searches of relevant terms.

Results

There are four technologies applicable to wandering with different ethical risks: (1) door alarms: low to moderate risk level, primarily movement restriction and reduction in autonomy; (2) wearable and portable Global Positioning System (GPS) with a moderate ethical risk level, where the key concern is privacy and patient/caregiver consent. (3) geofencing applications: These use a real-time location system that provides continuous tracking through an interactive map interface, enhanced by customizable geofencing utilities. Caregivers can draw boundaries directly on the map that provide crucial early warning of potential wandering incidents. Those applications entail moderate-to-high ethical risks and raise an additional ethical concern: the need for continuous surveillance. (4) AI predictive wandering systems carry a high ethical risk due to behavioral profiling of people with dementia. There are no specific laws and regulations regarding the use of tracking devices for people with dementia. In the European Union, the General Data Protection Regulation (GDPR) treats location data as part of the personal data that requires protection. In Israel, according to the Law of Protection of Privacy, personal data includes location data.

Conclusions

The use of technological devices and AI tools to manage wandering in people with dementia may increase "safe walking", be life-saving, and reduce the anxiety of caregivers. However, issues of data privacy and security, autonomy, patient/family consent, justice, and equity must be considered. AI tracking devices should not replace human caring and compassion.

SESSION WED-S11 · TRACK 4 · 13:30 – 15:00**End of Life I · Room R.201**

Moderator: Ofelia De Lorenzo Aparici

WED-S11-P01**Session:** End of Life I · **Room:** R.201**The Human Rights Framework of Assisted Dying and the Protection of Personality Rights in Europe**JUDr. PhD LLM Adam Doležal

Institute of State and Law of the Czech Academy of Science, Prague, Czech Republic

Background

Assisted dying remains one of the most controversial issues in contemporary bioethics and constitutional law. Over the past two

decades, European legal discourse has shifted from a predominantly criminal-law perspective to a human rights-based framework, focusing on the protection of personality rights, autonomy, and human dignity. The case-law of the European Court of Human Rights (ECtHR), particularly from *Pretty v. the United Kingdom* to *Karsai v. Hungary*, has played a central role in shaping this development. At the same time, several national constitutional courts have adopted increasingly autonomy-oriented interpretations of fundamental rights in end-of-life decision-making.

Research Question

Does a trend toward a more liberal human rights interpretation of assisted dying exist in Europe? How do the approaches of the ECtHR and selected constitutional courts differ in their understanding of the right to life, private life, self-determination, and human dignity? Can a subjective right to assisted dying be derived from the protection of personality rights within the European human rights framework?

Methodology

The study is based on a doctrinal and comparative analysis of the ECtHR's case-law concerning assisted dying, with particular attention to Articles 2 and 8 of the European Convention on Human Rights. It further examines landmark decisions of constitutional courts in selected European states, including Germany, Austria, Italy, Spain, Portugal, the Czech Republic, and Hungary. The legal analysis is complemented by a reflection on relevant bioethical theories concerning the sanctity of life, autonomy, and human dignity.

Results

The ECtHR maintains a cautious approach, rejecting the existence of a Convention-based right to die while accepting that regulated decriminalisation of assisted dying is not per se incompatible with the right to life, provided sufficient safeguards exist. In contrast, some constitutional courts—most notably in Germany and Austria—have derived from human dignity and personal autonomy a subjective right to a self-determined death, including access to assistance. Other courts adopt a more restrained stance, emphasising legislative discretion and the protection of vulnerable individuals.

Conclusions

Although no clear European consensus on a right to assisted dying currently exists, a discernible shift toward stronger protection of self-determination and personality rights can be observed in several national jurisdictions. The emerging tension between the ECtHR's margin-of-appreciation doctrine and constitutional developments at national level may shape the future evolution of the European human rights framework governing end-of-life decisions.

WED-S11-P02**Session:** End of Life I · **Room:** R.201**Timeframes in Assisted Dying Regulation and Implementation: Access, Innovation and Interdisciplinarity**Dr Nataly Papadopoulou PhD

Leicester Law School, Leicester, United Kingdom

Background

Currently, several countries in Europe and the US, as well as Canada, Australia, New Zealand, Ecuador, Colombia, and Cuba permit a form of assisted death. One of the key criteria of access is the criterion describing the condition of the individual. Generally speaking, some countries choose to focus on suffering, and describe it in different terms often using the term 'intolerable'. This suffering may or may not include also mental suffering (besides obviously a physical one). On the other side, some countries choose to focus on patients whose conditions are terminal or close to terminal, and some of these countries require also a prognostic requirement. This is the focus of this presentation, especially as this has been seen in the new proposal before the UK Parliament, to apply in England and Wales only. It should be noted that several jurisdictions choose a criterion that falls somewhere in between these two broad categories, or may have different requirements for different kind of patients (for instance, requiring terminality for minors).

Research Question

What are the access limitations for choosing a timeframe to death for patients, clinicians, and society? Why do countries choose to adopt the timeframe, prognostic requirement in their legal frameworks? What are some potential implementation challenges?

Methodology

The question will be examined in particular from the perspective of legislation in England and Wales, drawing from the US, Scotland, Australia, and New Zealand, to assess recent developments on the matter of the 'timeframe to death' requirement (innovations adopted in some of these countries). The presentation will refer to recent data from countries with existing frameworks, and investigate how these legislations was first introduced to assess the 'why' include a timeframe question. The presentation also includes reference to clinical studies to show limitations of prognosticating from a clinical perspective (interdisciplinarity).

Results

The choice of including a timeframe to death seems to be a combination of clinical, cultural, and political factors, but even so has significant challenges.

Conclusions

Although ultimately, this combination of clinical, cultural and political factors justify, in some instances, the choice of a timeframe to death as a restriction for access to assisted dying, this approach does not prioritise patient needs and could reasonably be adjusted within the parameters of each country.

WED-S11-P03

Session: End of Life I · **Room:** R.201

25 Years of Euthanasia Practice in the Netherlands: Alignment with Legislative Intent?

Dr. Esther Pans PhD

Expertisecentrum Euthanasie, Den Haag, Netherlands. Vrije Universiteit, Amsterdam, Netherlands. Gezondheidsraad, Den Haag, Netherlands

Background

The Dutch Euthanasia Act (2002) codified an existing medical practice under strict due care criteria, aiming to find a good balance between the principles of compassion, patient's autonomy and the protection of human life. The legislator sought to create a controlled and transparent framework in which euthanasia would remain exceptional, subject to careful medical judgment and ex post review by the Regional Euthanasia Review Committees. The system was designed not only to permit euthanasia under defined conditions, but also to monitor and contain its application.

Research Question

To what extent has the practice of euthanasia in the Netherlands, over the past 25 years, developed in accordance with the intentions of the legislator?

Methodology

This presentation entails a longitudinal analysis of the annual reports of the Regional Euthanasia Review Committees. These reports provide comprehensive data on euthanasia cases, including patient age, medical conditions, and the application of statutory due care criteria. By examining trends across a twenty-five-year period, the study assesses both the stability of the legal framework in practice and potential shifts in its application.

Results

The findings suggest that, in its core features, Dutch euthanasia practice has developed largely in line with the legislative design. The due care criteria continue to structure decision-making, and the system of review has functioned as an effective mechanism of oversight and normalization. At the same time, the data reveal a gradual expansion in the use of euthanasia, including changes in the types of conditions involved and the contexts in which it is applied. These developments indicate an increasing willingness to make use of the legal possibilities inherent in the framework.

Conclusions

Over 25 years, Dutch euthanasia practice has remained broadly faithful to the intentions of the legislator, combining regulation, transparency, and professional control. However, the steady exploration and use of the law's outer limits suggest a dynamic in which expansion occurs within a formally stable legal structure. This raises the question whether the current equilibrium reflects the original intent of the law or an incremental shift in its practical meaning.

In my presentation I aim to offer a descriptive account of the Dutch framework governing euthanasia and physician-assisted suicide. It outlines the structure and operation of the Termination of Life on Request and Assisted Suicide (Review Procedures) Act, explains the due-care criteria, the reporting obligation and ex post review by regional committees, and summarizes available practice figures. Specific attention is given to recurring issues—advance directives and dementia, psychiatric suffering, and minors.

WED-S11-P04

Session: End of Life I · **Room:** R.201

(Foregoing) Life-sustaining Treatment in Patients with a Disorder of Consciousness

Prof. dr. Delbeke Evelien PhD

University of Antwerp, Antwerp, Belgium. Mediure, Antwerp - Middelkerke, Belgium

Background

Disorders of consciousness (DoC) are commonly classified into three categories. Coma is characterised by the absence of both wakefulness and awareness. Patients with unresponsive wakefulness syndrome (UWS) may display wakefulness without behavioural signs of awareness and perform only reflexive, non-volitional movements. By contrast, patients in a minimally conscious state (MCS) exhibit fluctuating but reproducible or sustained indicators of residual awareness. With ANH, patients with DoC may survive for many years without regaining a level of awareness sufficient for conscious experience. The ethical and legal debate on whether or not to continue ANH is certainly not new; the landmark *Matter of Karen Ann Quinlan* (1976) decision is often cited as its starting point. Advances in diagnostic technologies have highlighted persistent risks of misdiagnosis and -prognosis. Even when state-of-the-art diagnostic methods are applied, diagnosis and prognosis remain probabilistic. Nevertheless, treatment decisions must be made, and clinical practice demonstrates that such decisions may give rise to tensions between family and treating team.

Research Question

Which decision-making framework should guide determinations about (non-)treatment for patients with DoC in a context of probabilistic diagnosis and prognosis?

Methodology

The medical literature is reviewed to ensure that the proposed framework is aligned with current scientific knowledge. Ethical scholarship and legal doctrine, complemented by case law from multiple jurisdictions, are analysed to identify relevant criteria.

Preliminary Results

Medical assessments must follow the most current medically accepted professional standards. Treatment decisions should, in principle, be grounded in the patient's actual or presumed wishes. A recent judgment of the European Court of Human Rights indicates, however, that this principle applies only to wishes aimed at foregoing treatment: on 4 February 2026, the Court held that non-compliance with an advance directive requesting the prolongation of life, even artificially, does not violate Article 2 ECHR. The most complex cases arise when neither actual nor presumed wishes can be established and disagreement persists between the representative and the clinical team. In such situations, decision making defaults to the so-called 'objective' best-interests standard, although in practice this standard is unavoidably value-laden and sensitive to divergent conceptions of acceptable quality of life. Comparative legal analysis will further explore how courts allocate ultimate decision-making authority in these disputes.

Conclusions

Given the persistent uncertainty on the diagnosis and prognosis of DoC, a structured and conceptually robust decision-making framework is required to support clinically sound, ethically defensible and legally coherent treatment decisions.

SESSION WED-S12 · TRACK 5 · 13:30 – 15:00

Medically Assisted Reproduction · Room R.230

Moderator: Judit Sandor

WED-S12-P01

Session: Medically Assisted Reproduction · **Room:** R.230

Uterus Transplantation Through a Feminist Bioethics and Biolaw Lens: Rethinking Autonomy and Motherhood

Professor Maria de Jesus Medina-Arellano PhD¹, Postdoctoral Researcher Elisa Constanza Calleja-Sordo PhD²

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Background

Uterus transplantation (UTx) has emerged as a groundbreaking biomedical innovation, offering individuals with uterine factor infertility the possibility of gestation. While often framed as a triumph of reproductive medicine and individual autonomy, UTx develops within broader cultural norms that equate womanhood with motherhood and privilege gestation as the defining feature of “authentic” maternal identity. Feminist bioethics and legal scholars raises concerns that such technologies may reinforce the ideology of intensive motherhood and contribute to the medicalization of women’s bodies.

Research Question

This analysis asks whether UTx can truly be considered an autonomous reproductive choice, or whether it operates within—and potentially reinforces—social structures that symbolically coerce women into conforming to gendered expectations of motherhood.

Methodology

Using a feminist bioethics and intersectional human rights framework, the study critically examines UTx beyond its technical and clinical dimensions. It analyzes the concept of informed consent, particularly in cases involving living donors within family relationships, where emotional bonds and gender norms may shape decisions presented as voluntary. The chapter also draws on key legal precedents, including *Atala Riffo v. Chile* before the Inter-American Court of Human Rights and Mexico’s *Amparo 1596/2010*, to illustrate how judicial discourse perpetuates stereotypes of the “good” and “bad” mother. These cases provide a comparative legal lens to understand how gender bias influences reproductive governance.

Results

The analysis demonstrates that UTx is embedded in a cultural framework that privileges gestation and sustains symbolic forms of coercion. It shows how family-based donation contexts complicate the authenticity of informed consent and how legal narratives reinforce the idea that motherhood is a moral duty. Together, biomedical practice and judicial reasoning may reproduce structural gender inequalities and undermine reproductive justice.

Conclusions

UTx should not be evaluated solely as a matter of technological progress or individual choice. A feminist bioethics approach reveals the need to challenge the assumption that motherhood—particularly gestational motherhood—is women’s destiny. Protecting reproductive autonomy requires dismantling the social pressures and gendered expectations that shape “choices” in the first place.

WED-S12-P02

Session: Medically Assisted Reproduction · **Room:** R.230

Access to Medically Assisted Reproduction in the Case Law of the European Court of Human Rights

JUDr. Ivo Smrž PhD

Ústav státu a práva AV ČR, v. v. i., Prague, Czech Republic

Background

Medically assisted reproduction represents an area in which rapid technological developments intersect with sensitive ethical and legal questions. The European Court of Human Rights (ECtHR, Court) has repeatedly held that the decision to conceive a child and to make use of medically assisted reproduction is protected by Article 8 of the European Convention on Human Rights (the Convention) as part of the right to respect for private and family life. At the same time, in this field the Court grants member States a wide margin of appreciation,

particularly because of the lack of a European consensus and the sensitive nature of the issues involved.

Research Question

What are the limits of access to medically assisted reproduction under Article 8 of the Convention in the light of the ECtHR’s case law?

Methodology

The presentation is based on an analysis of the ECtHR’s key cases concerning medically assisted reproduction. Particular attention is paid to the application of Article 8 of the Convention, the Court’s dynamic and evolutive interpretation, the distinction between positive and negative obligations, the proportionality test and the doctrine of the margin of appreciation.

Results

The Court’s case law recognises that Article 8 encompasses the right to respect for the decision to become a genetic parent and to make use of medically assisted reproduction for that purpose, including certain related procedures, such as pre-implantation genetic diagnosis. These rights, however, are not absolute. The Court consistently grants States a wide margin of appreciation, as assisted reproduction raise sensitive moral questions against a background of fast-moving scientific developments, and because no clear common ground exists among the member States. A decisive role is played by the proportionality of the measures and the fair balance between competing interests. The ECtHR’s approach remains largely case-specific, which makes it difficult to derive general legal principles from individual judgments.

Conclusions

The ECtHR’s case law confirms that access to medically assisted reproduction forms part of reproductive autonomy protected under Article 8 of the Convention. Nevertheless, its particular scope remains largely dependent on national regulations. Assisted reproduction thus constitutes an area in which the protection of individual rights is systematically confronted with a wide margin of appreciation granted to States. The protection of rights is rather based on case-by-case proportionality than on a transparent and structured methodological framework.

WED-S12-P03

Session: Medically Assisted Reproduction · **Room:** R.230

Technological Innovations in Reproductive Medicine: Hopes and Risks

Henrique Freire de Oliveira Souza

Hfreire Advogados Associados, Rio de Janeiro, Rio de Janeiro, Brazil

Research Question

Technological advances in healthcare, exemplified by the development of artificial wombs (ectogenesis), is it leading to a potential rupture in the social and biological structures of humanity? For the purposes of legal analysis of these impacts, the following hypothetical scenario will be considered and examined: the contracting of a multidisciplinary medical service for the creation of an embryo (with selected characteristics), its complete gestation in an artificial womb with delivery of the newborn at a designated location, and subsequent monitoring through sensors (“Service”).

Methodology

Analysis of the research question based on theoretical and legislative research grounded in current Brazilian law and UNESCO’s international declarations.

Conclusions

This article analyzes the legal, ethical, and socio-environmental reflections arising from technological innovations in reproductive medicine, with a specific focus on the development of the artificial womb. The study is based on the hypothesis of a near future in which extrauterine gestation, the selection of genetic characteristics, and monitoring by sensors could be the subject of medical service contracts. From the perspective of the Brazilian legal system (including the Federal Constitution, the Consumer Protection Code, and norms from the Federal Council of Medicine) and UNESCO’s international declarations, the research examines the legal limits of this practice. It is observed that the adoption of the artificial womb shifts the focus of medical care and legal protection to the unborn child at a time prior to nidation itself, configuring the unborn as the main patient and an equated consumer (consumidor por equiparação). Although the right to

procreation is a fundamental human right, the work warns against the risks of eugenics, widening the social gap, the commodification of the person, and the reduction of human biodiversity. Therefore, it concludes that the application of the Precautionary Principle is imperative to ensure that biotechnological evolution does not compromise human dignity or the rights of future generations to a balanced environment. The role of law is not to restrain scientific progress, but to ensure that technology serves the preservation of life rather than the mere satisfaction of consumer desires. Human intelligence must be directed toward safeguarding humanity itself and the natural environment that sustains it.

WED-S12-P04

Session: Medically Assisted Reproduction · **Room:** R.230

Towards a Legal Framework on Surrogacy in Belgium? Key Legislative Choices and Safeguards

Lies M. I. Michielsens Master of Laws

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Background

Surrogacy increasingly offers a solution to involuntary childlessness. In Belgium, however, there is currently no specific statutory framework governing surrogacy arrangements. Despite sustained societal and political debate and the submission of several legislative proposals over the years, no regulation has been enacted. This regulatory vacuum gives rise to significant legal uncertainty for all parties involved, namely the intended parents, the surrogate, and the child. Unresolved issues concern the validity and enforceability of surrogacy agreements, the establishment of legal parentage, and questions of private international law in cross-border surrogacy cases. Although states retain, in principle, a wide margin of appreciation under international law to regulate or prohibit surrogacy, the matter has attracted increasing attention at the international level, notably in the jurisprudence of the European Court of Human Rights and in ongoing work within the Hague Conference on Private International Law.

Research Question

This thesis examines how a Belgian statutory framework on surrogacy should be structured in order to provide legal certainty while ensuring adequate protection of the rights and interests of the intended parents, the surrogate, and, in particular, the child.

Methodology

The research is conducted using the classical doctrinal legal method. It consists of a systematic analysis of existing legislation, legislative initiatives, case law, and academic literature. First, the current legal treatment of surrogacy is examined at both the international and domestic levels. Particular attention is paid to the European Convention on Human Rights, European Union law, and the Parentage and Surrogacy Project of the Hague Conference on Private International Law. The Belgian legal practice is then analysed in order to identify the specific areas in which the absence of statutory regulation generates legal uncertainty. Finally, a comparative analysis with the United Kingdom, which introduced surrogacy legislation in 1985, is undertaken to draw lessons from both its regulatory model and the critiques it has generated.

Results

The analysis demonstrates that the absence of a statutory framework in Belgium leads to unequal access to surrogacy and to considerable uncertainty regarding contractual obligations, the establishment of legal parentage, and the recognition of foreign surrogacy arrangements. In response, this thesis advocates the introduction of a comprehensive statutory regime permitting both high-technology and low-technology surrogacy, including compensated arrangements, within a clearly defined and justified scope of application. The proposed framework provides for a new form of original parentage in order to secure the legal status of the intended parents from birth, while safeguarding the surrogate's right to bodily integrity and ensuring the child's right to access information concerning their origins.

Conclusions

A balanced and coherent statutory framework on surrogacy in Belgium is both necessary and attainable. By combining legal certainty with safeguards for the surrogate and the child, and by providing a broad but principled scope of access, such legislation would address the current deficiencies of the unregulated system and enhance the protection of all parties involved.

WED-S12-P05

Session: Medically Assisted Reproduction · **Room:** R.230

The Right to Have a Child Using Assisted Reproductive and Genetic Technologies in Russia and Abroad

Associate Professor, Maria Posadkova Candidate of Legal Sciences (PhD in Law)

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Background

Contemporary advances in Assisted Reproductive and Genetic Technologies (ARGT) offer new possibilities for individuals facing infertility and hereditary genetic conditions. However, no international consensus exists on their regulation; states independently determine the legal model and the scope of the right to procreation using ARGT. While ARGT are increasingly integrated into society, certain applications provoke skepticism. Practices such as using preimplantation genetic diagnosis to create “savior siblings” for stem cell donation, sex-selection for non-medical reasons, and biosecurity risks associated with genetic data and biological materials are widely considered ethically and legally problematic. Furthermore, the jurisprudence of international and national constitutional courts in this area remains inconsistent, occasionally conflicting with domestic legislation.

Research Question

Constitutional legal scholarship has yet to develop a unified understanding of human rights aimed at ensuring reproductive and genetic well-being. This research aims to formulate a scholarly conception of the right to procreation using ARGT, analyze the various regulatory models and identify the approaches its protection.

Methodology

The research employs a systematic, practice-oriented methodology. Key methods include comparative-legal analysis and comprehensive analysis of legislative frameworks and constitutional court rulings. The study further relies on classifying information into distinct approaches and modeling the new right by analogy with other established complex rights to predict protective mechanisms and potential risks.

Results

1. Regulatory Models based on accessibility, four main models for regulating reproductive genetics are identified:
 - individual choice: access to ARGT is based on individual choice, not restricted to specific medical diagnoses (e.g., Australia, Israel, Canada, Colombia, New Zealand, Mexico, USA);
 - regulation and control: it is treated as therapy for infertility and for preventing severe hereditary or infectious diseases (e.g., Belarus, UK, Greece, India, Iran, Kazakhstan, Kyrgyzstan, Portugal, Russia, USA (Louisiana), Ukraine);
 - strict restriction or prohibition: ARGT is permitted only in extreme cases, with surrogacy often fully banned and preimplantation genetic diagnosis requiring special state approval (e.g., Germany, Denmark, Spain, Italy, China, Norway, Singapore, Switzerland, Japan);
 - legal vacuum: ARGT lacks legislative regulation but is sometimes practiced (e.g., Nigeria, Malaysia, Kenya).
2. In comparative constitutional law, three approaches to codifying the right to ARGT emerge: 1) enshrined in national constitutions (Slovenia, Portugal, Switzerland); 2) articulated in constitutional court rulings (Italy, India, Portugal, Israel); 3) defined at the statutory or regulatory level (Russia, USA, Germany). While constitutional enshrinement is preferable, it is not essential for constitutional recognition due to the rapid evolution of technology.
3. Constitutional courts employ three main approaches to protecting this right:
 - restrained interpretation: courts defer to legislative discretion, finding no constitutional violation;
 - progressive interpretation: courts use constitution-conforming interpretation to align constitutional provisions with contemporary realities or strike down non-compliant norms;
 - formation of a “new” right: courts derive a distinct subjective right from the interpretation of traditional fundamental rights.

Conclusions

The right to procreation using ARGT is fundamentally constitutional in nature. This is evidenced by its grounding in traditional constitutional rights, which necessitate its protection at the constitutional level.

SESSION WED-S13 · TRACK 6 · 13:30 – 15:00**Pharmaceutical Law · Room R.007**

Moderator: An Vijverman

WED-S13-P01**Session:** Pharmaceutical Law · **Room:** R.007**Patentability of AI-Generated Drugs: Legal Challenges and Policy Recommendations**Suzan R. Hofstede¹, Lawyer/Physician Emine Neval Yılmaz MD, PhD, LL.M., PhD²¹Bilkent University Faculty of Law, Ankara, Turkey. ²Ankara Bar Association, Ankara, Turkey**Background**

The pharmaceutical industry is undergoing a digital transformation, moving toward an artificial intelligence (AI)-based approach to optimize R&D costs and timelines. While traditional drug development takes 10 to 15 years, AI can compress pre-clinical discovery into record time. However, this shift creates an ontological conflict with patent law, which requires an "inventor" to be a natural person. If AI-generated drugs are denied protection, companies may resort to "trade secrets," hindering scientific disclosure and public health.

Research Question

How does the current "human-centric" patent framework handle inventions produced autonomously by AI without direct human intervention? Furthermore, what are the potential risks to public health and innovation if these inventions remain outside the scope of patent protection?

Methodology

This study provides a comparative legal analysis of international patent frameworks, including the European Patent Convention (EPC), the US Patent Act, and the Turkish Industrial Property Code (SMK). It examines global judicial precedents, specifically the DABUS cases across the EPO, USPTO, UK, and Australian courts, to determine the evolving status of AI inventorship.

Results

Analysis reveals a consistent global rejection of AI as an inventor due to its lack of legal personhood and "mental conception". The research identifies that AI's processing power disrupts the "Person Having Ordinary Skill in the Art" standard by significantly raising the bar for the "inventive step" criterion, potentially making many discoveries "obvious" in an AI-equipped environment. Additionally, the study finds that the "trade secret" trend would prevent the timely entry of low-cost generic drugs, jeopardizing global access to medicine.

Conclusions

The current patent system is ill-suited for the high-speed output of autonomous AI. To prevent a shift toward secrecy and to ensure industrial sustainability, a sui generis (unique) protection model is necessary. This model should offer shorter protection terms (3–10 years) and prioritize the protection of investment over the "creative spark". Legal frameworks must evolve to encompass AI-generated inventions to balance the incentives for innovation with the fundamental right to public health.

WED-S13-P02**Session:** Pharmaceutical Law · **Room:** R.007**How does the Pharmaceutical Industry Influence Public Health Law: The Case of Finasteride and PFS**Advocate Jonathan Davies LL.M.

Society for Medicine and Law in Israel, Tel Aviv, Israel

Background

Finasteride 1 mg, an elective cosmetic drug prescribed to millions globally for male hair loss, is increasingly recognized as a primary cause of severe, persistent neuropsychiatric adverse effects, including cognitive decline, irreversible sexual dysfunction, anxiety, and suicidal thoughts. This condition is medically documented as Post-Finasteride Syndrome (PFS). For two decades, the original manufacturer, Merck, denied causation, relying on flawed pharmacovigilance to maintain FDA approval. In 2021, Merck quietly transferred the profitable drug to Organon, raising critical questions about shifting corporate responsibility without public disclosure. Recently, regulators like the EMA and the UK's MHRA have mandated explicit warnings, finally

acknowledging the biological link between finasteride and suicidal ideation.

Research Objective: I have filed a personal injury claim and a class action v. several pharmaceutical companies that for two decades failed to conduct proper epidemiological trials despite mass of adverse reports. The claim examines how the deliberate concealment of finasteride's risks constitutes a preventable public health crisis, akin to the opioid epidemic. Furthermore, it explores how complex civil litigation—specifically claims of intentional data suppression and prioritizing cosmetic profits over safety—can proactively compel systemic regulatory reform and heavily influence impending class-action lawsuits.

Methodology

The Presentation employs an historical literature review to identify gaps between emerging medical evidence—such as a 2020 JAMA meta-analysis of the WHO database—and delayed regulatory interventions. It utilizes a comparative analysis of international mandates, internal corporate documents dating back to 2009, and global investigative journalism (including CBC Canadian Broadcast TV and BBC) exposing warning-free access to the drug. This evidence is analyzed alongside an ongoing landmark personal-injury lawsuit in Israel to evaluate the efficacy of tort litigation in uncovering suppressed clinical data.

Results

The class action reveals that the pharmaceutical industry's calculated suppression of safety data and reliance on "soft" labeling delayed crucial clinical warnings by over a decade, effectively conducting an unsupervised experiment on the public. Core legal arguments highlight severe medical negligence, including physicians ignoring major contraindications like a family history of suicide while failing to obtain informed consent. However, aggressive legal discovery is successfully penetrating corporate denial. Crucially, the Israeli litigation's core informed-consent argument has now been internationally validated: France's ANSM mandated that starting April 2026, finasteride cannot be dispensed unless both physician and patient sign a dedicated consent form explicitly acknowledging enduring neuropsychiatric risks.

Take-Home Message

The finasteride crisis illustrates a vital intersection between pharmaceutical liability and public health. When governmental bodies fail to proactively safeguard populations, personal injury and class-action lawsuits serve as powerful mechanisms. They force corporate transparency, mandate strict informed-consent protocols, and reshape overarching public health law to prioritize patient safety over industry profit, ensuring life-altering side effects are no longer suppressed.

WED-S13-P03**Session:** Pharmaceutical Law · **Room:** R.007**Off-label Use: A Vital Necessity or a Vicious Cycle?**Valentina Lipatnikova

Moscow Clinical Science and Research Center 52, Moscow, Russian Federation

Background

Off-label therapy is often necessary for severe diseases lacking approved clinical indications or established treatment lines, typically in patients with complex, chronic, and life-threatening conditions. The prescription of off-label drugs is a recognized international clinical practice, especially in fields such as oncology, pediatrics and psychiatry. It serves as a vital tool, bridging the gap between a drug's official registration and the patients' real-world needs.

Off-label medication is the only viable treatment option for many patients with rare diseases or for whom standard therapy is ineffective. The official approval process for new drug indications takes years, whereas new efficacy data for other conditions emerge much more rapidly. Consequently, prescribing decisions are often based on publications in reputable international journals, recommendations from expert consensus, and registry data – all available before official prescribing information is updated.

However, off-label therapy is associated with a complex set of serious medical, ethical, and legal risks, common to healthcare systems worldwide.

Methodology

The study employs a doctrinal research methodology and a comparative review of the legal regulations and legislative frameworks governing off-label drug prescription in Russia and other international jurisdictions. An analysis of case studies highlights common legal challenges associated with off-label therapy. The study also examines

the systemic issue of insufficient funding and clinical research aimed at reducing off-label prescriptions.

Results

The research reveals a fundamental conflict between patient care imperatives and formal regulatory compliance, wherein the prescribing physician bears full responsibility. A key finding is that an insufficient number of clinical research acts as a catalyst for increased off-label use, creating a vicious cycle: the lack of convincing scientific evidence on safety and efficacy hinders the development of official indications, which in turn limits investment in the necessary research. This situation creates legal uncertainty and impedes patient access to the latest therapeutic approaches.

Conclusions

The use of off-label drugs requires a balanced, evidence-based approach, clear legal frameworks, protection of patient rights, and solutions to funding issues. The ideal model is one in which off-label use serves as a bridge to obtaining new official indications, rather than a permanent and risky standard of care. Only a comprehensive approach can maintain the flexibility needed in clinical practice for complex cases, while simultaneously ensuring patient safety and legal protection for healthcare providers.

WED-S13-P04

Session: Pharmaceutical Law · **Room:** R.007

Fighting High-Priced Prescription Drugs in the EU and the U.S.

André den Exter LL.M., PhD

Erasmus University Rotterdam, Rotterdam, Netherlands

Background

Excessive pricing of prescription drugs is a well-known phenomenon in both Europe and the U.S. Safeguarding equal access to these medicines as a fundamental human right requires specific legal measures to address their availability and affordability. For several reasons, existing price control measures have so far remained problematic and appear less effective. Is there an alternative?

Research Question

How can competition law, in particular the abuse of dominant position, contribute to pharmaceutical price control?

Methodology

This study explores both the regulatory framework and case law on abuse of a dominant position in pharmaceutical pricing in both Europe and the US.

Results

Balancing economic interests and public health considerations, occasionally, the European Court of Justice has accommodated public interest/public health concerns in competition enforcement. Since *United Brands*, the fairness test has been applied and accepted in several excessive drug pricing cases by both national and European competition authorities. In addition to existing policies and legal instruments, antitrust law, specifically the abuse-of-dominant-position approach as applied in the *Aspen* case, provides a promising tool for effective action against market distortions by pharmaceutical companies and for enforcing reasonable prices for expensive medicines.

Contrary to Europe, U.S. legal doctrine barely recognizes the antitrust 'sanctuary function'. Instead, it has developed a legislative tool - the Inflation Reduction Act - to 'negotiate' maximum fair prices. CMS will make an offer for a select number of drugs that manufacturers cannot refuse, other than by paying a monetary penalty. This approach allows CMS to effectively influence drug pricing once it takes effect (2026). To enhance its negotiation position, introducing a European-like HTA gatekeeping mechanism is recommended.

Conclusions

In Europe, the abuse-of-dominant-position doctrine can be an effective tool for enforcing reasonable prices for expensive medicines.

WED-S13-P05

Session: Pharmaceutical Law · **Room:** R.007

Access to Highly Innovative Medicinal Products: A Comparative Study of Single-Payer, Multi-Payer, and Market-Based Health Systems

PhD student Simona Hodovská Mgr. Bc.^{1,2}, Head of Department of Public Health Michal Koščik Mgr. Bc., PhD et PhD¹, Associate Professor Hsuanlei Shao³

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Background

Highly innovative medicinal products (HIMPs), including advanced therapy medicinal products and gene therapies, present a structural challenge to health financing systems worldwide. Their extraordinary upfront cost and evidentiary uncertainty at regulatory approval have exposed the normative and fiscal limits of existing reimbursement frameworks, placing health systems under pressure to stimulate innovation, guarantee equitable access, and protect the long-term solvency of public insurance funds.

Research Question

How do a single-payer social insurance system, a heterogeneous multi-payer union, and a market-based system regulate market access, price governance, and reimbursement for HIMPs, and what do these differences reveal about the operational meaning of the right to health? Comparative scholarship examining Taiwan, the EU, and the USA in tandem remains limited despite their collective relevance to global HIMP governance. Their apparent structural incomparability makes this comparison analytically valuable with central question being whether attributes improving access in one jurisdiction can be transposed to another, or whether structural and constitutional differences render transfer unfeasible.

Methodology

This article employs comparative legal and policy analysis across Taiwan, selected EU states, and the United States, reflecting structural variation in health system design and jurisdictional expertise. Primary legislation, institutional reports, and peer-reviewed literature are examined across legislative evolution, market access and accelerated approval pathways, price control and entry mechanisms, and dispute resolution. Empirical analysis draws on quantitative data on drug pricing, reimbursement lag, and related access metrics.

Results

All three jurisdictions have adopted adaptive licensing frameworks, yet regulatory convergence does not translate into comparable patient access. Solidarity-based single-payer models with outcome-based managed entry agreements (e.g. Taiwan) deliver relatively swift reimbursement despite fiscal constraints. Social insurance systems (e.g. the EU) exhibit significant intra-jurisdictional variation, with reimbursement lag and coverage breadth diverging between member states. The United States, despite partial reform through Medicare price negotiation under the Inflation Reduction Act of 2022, remains fragmented, with patients sometimes reliant on litigation for access. Pricing and reimbursement lag data confirm that approval speed and access equity are structurally decoupled across all three systems.

Conclusions

This article contributes to comparative health law scholarship by analyzing HIMP governance across Taiwan, the EU, and the United States. The analysis identifies a structural disconnect between regulatory approval and meaningful patient access across all three jurisdictions and suggests that evidence-based reforms informed by cross-jurisdictional learning could substantially narrow this gap. The article identifies transferable governance attributes while critically assessing the structural and normative limits of such transposition.

SESSION WED-S14 · TRACK 7 · 13:30 – 15:00**Public Health Law I · Room R.011**

Moderator: Toma Birmontiene

WED-S14-P01**Session:** Public Health Law I · **Room:** R.011**Governing the Global Migration of Healthcare Workers: A Comparative Legal Analysis of Recruitment Practices in Nigeria and Ireland**Lawyer Damilare Adetayo Adeoye LL.M

Medical Law Hub, Dublin, Ireland. Institute of Medical and Health Law, Abuja, Nigeria. Dublin City University, Dublin, Ireland

Background

The accelerating global shortage of healthcare professionals has intensified the international migration of healthcare workers, transforming recruitment practices into a central issue in health law and global health governance. While high-income countries increasingly depend on foreign-trained professionals to sustain healthcare delivery, many low- and middle-income countries face persistent workforce depletion. Nigeria exemplifies this trend through sustained outward migration, whereas Ireland continues to rely on international recruitment to address domestic shortages. This evolving dynamic exposes a fundamental tension between the mobility rights of healthcare professionals and the capacity of states to maintain resilient and equitable healthcare systems.

Research Question

How can legal and regulatory frameworks reconcile healthcare worker mobility with the obligation of states to ensure sustainable healthcare systems and equitable access to care?

Methodology

This paper employs a comparative legal analysis of Nigeria and Ireland, examining national regulatory approaches alongside international ethical recruitment standards developed by the World Health Organization. It assesses how existing frameworks respond to the challenges posed by cross-border healthcare workforce migration.

Findings

The analysis identifies a structural regulatory imbalance between source and destination countries. While destination countries derive significant benefits from international recruitment, source countries continue to experience critical workforce losses. Existing international frameworks provide normative guidance but remain largely voluntary and insufficiently enforceable to address these disparities.

Conclusions

The paper argues that current governance approaches are inadequate to address the systemic inequalities underpinning healthcare worker migration. It proposes a shift toward more coordinated regulatory models, including bilateral agreements and shared investment in workforce development. Reframing international recruitment as a matter of legal responsibility, rather than policy discretion, is essential to achieving a more equitable global health system.

WED-S14-P02**Session:** Public Health Law I · **Room:** R.011**Principle of Gotong-Royong in Fulfilling Access Rights to Clean Water or Victims of Flash Floods in Sumatera Island, Indonesia**M Sutan Abdul Aziz F Nasution S.H, M.H, MH.Kes

Yayasan Rumah Harapan 23, Medan, Sumatera Utara, Indonesia

Background

The occurrence of flash floods in three provinces on Sumatera Island, Indonesia, in November 2025, resulted in significant damage to various infrastructures. One of the vital sectors affected was the provision of clean water services. This situation led to thousands of individuals experiencing difficulties in obtaining clean water to meet their daily living needs. This is, of course, a concerning circumstance given that access to clean water is a fundamental human right.

Research Question

This raises questions about the efforts made to fulfill access rights to clean water in the flood-affected areas and how the principle of gotong-royong, as a living law for Indonesian society, can address these issues.

Methodology

The methodology employed in this research is an empirical legal study, which involves conducting research through literature reviews, interviews and direct observations at one of the sites of the flash flood disaster, specifically in Aceh Tamiang Regency, Aceh Province, Indonesia. This study aims to determine the efforts that have been made to fulfill access to clean water as one of the basic human rights.

Results

The findings of this research indicate that the principle of gotong-royong remains a highly esteemed principle as a living law within Indonesian society. This is evident from the significant role of the community, who voluntarily participate in assisting the victims of flash floods, including by providing supplies of clean water, without any obligation or coercion from the government.

Conclusions

In conclusion, the research reveals that the right to access clean water, as a fundamental human right, has been met through the active involvement of the Indonesian community, who continue to uphold the principle of gotong-royong as a living law.

WED-S14-P03**Session:** Public Health Law I · **Room:** R.011**Reconceptualizing State Obligations in Public Health Emergencies: Risk Prevention and the Protection of the Right to Health**Special researcher Juan Qiao PhD

Sichuan University, Chengdu, China

Background

Constitutional states are increasingly confronted with threats that are not merely “dangers” with calculable probabilities, but “risks” characterized by scientific uncertainty and potentially catastrophic consequences. This transformation challenges traditional models of state responsibility, which have largely been reactive rather than preventive. The question arises: how can constitutional law accommodate a proactive state duty to protect life and health under conditions of uncertainty, without sacrificing the rule of law and fundamental rights?

Research Questions

1. How can the constitutional duty of risk prevention be articulated to guide state action in future health crises?
2. What legal safeguards are necessary to ensure that emergency measures remain proportionate and rights-protective?
3. How does this duty extend beyond infectious disease control to encompass emerging health threats such as antimicrobial resistance and climate-related health risks?

Methodology

This paper adopts a comparative constitutional law approach, analyzing legal frameworks from jurisdictions including Germany, France, China, and the United States. It draws on a range of public health challenges—from the COVID-19 pandemic to antimicrobial resistance and climate-induced health crises—as illustrative cases to examine how the state's duty to prevent harm can be operationalized across diverse contexts.

Conclusions

The paper argues that the state's obligation to protect the right to health is not limited to responding to known dangers, but extends to preventing foreseeable risks—whether from infectious diseases, environmental degradation, or technological innovation. This expanded conception of state obligation provides a constitutional foundation for safeguarding a wide range of health-related rights, including the right to a healthy environment and the right to be protected from future harm. A constitutional framework that institutionalizes risk prevention as a justiciable state duty, subject to procedural safeguards and proportionality review, is essential for resilient and rights-respecting health governance in an era of emerging biological and environmental threats.

WED-S14-P04**Session:** Public Health Law I · **Room:** R.011**Judicial Notice and COVID-19: A Static Lens on a Dynamic Crisis – Legal Finality in the Face of Scientific Change**Kanksha Mahadevia Ghimire SJD¹, Professeur adjoint Patrick Garon-Sayegh SJD², Professor Trudo Lemmens DCL¹¹University of Toronto Faculty of Law, Toronto, Ontario, Canada. ²Faculté de droit, Université de Montréal, Montréal, Québec, Canada

The COVID-19 pandemic amplified longstanding tensions between the evolving nature of scientific knowledge and courts' need for stable, readily available and taken-for-granted knowledge. This paper investigates how Canadian family courts used the doctrine of judicial notice to resolve disputes over COVID-19 vaccination and how, in the process, provisional scientific claims were transformed into "settled" truths.

The paper analyzes a selection of illustrative decisions from 2020 to 2023 and exposes the underlying doctrinal structure and practical outcomes of judicial notice in science-intensive disputes. It shows how, in some situations, judicial notice risks settling provisional scientific understandings as "facts." Indeed in the case of COVID-19, courts anchored factual findings in regulatory approvals or government policies at times when public health guidelines, knowledge of viral transmission, and data on vaccine efficacy were rapidly changing. In so doing, courts may have inadvertently sidelined legitimate scientific concerns and amplified procedural disadvantages faced by self-represented litigants.

The paper concludes by advocating for a more dynamic, temporally sensitive approach to judicial notice in science-laden adjudication. It ultimately calls for an approach to judicial notice grounded in epistemic humility: an intellectual posture that acknowledges the provisional nature of scientific knowledge and resists allowing procedural efficiency to harden still-evolving scientific claims into fixed legal truths.

WED-S14-P05**Session:** Public Health Law I · **Room:** R.011**Improving Health-Related Quality of Life and Medication Adherence among Young People Living with HIV and AIDS through Social Media Peer Support: A Before-and-After Quasi-Experimental Study in a Peri-Urban District in Ghana**Dr Eric Osei PhD, Mr. Emmanuel Mensah MPhil

University of Health and Allied Sciences, Ho, Ghana

Background

Young people living with HIV (YPLHIV) face persistent challenges of poor health-related quality of life (HRQoL) and suboptimal medication adherence, particularly in sub-Saharan Africa. Peer support through social media has emerged as a promising intervention to address psychosocial barriers and improve treatment outcomes.

Research Question

Can social media-based peer support intervention improve HRQoL and medication adherence among YPLHIV?

Methodology

We conducted a before-and-after quasi-experimental study in four phases: (1) acceptability interviews, (2) baseline assessment, (3) peer-support intervention delivered via Chatterbox and WhatsApp, and (4) post-intervention assessment. Participants were 124 YPLHIV aged 15–35 years. HRQoL was measured with WHOQOL-BREF and adherence with the 10-item MARS. Paired t-tests compared pre- vs post-intervention means for WHOQOL-BREF domain and total scores and for the MARS total score; McNemar's test assessed change in binary adherence status (adherent vs non-adherent); Pearson correlations examined baseline associations between WHOQOL-BREF domains and MARS scores; and multivariable logistic regression identified predictors of high post-intervention QoL (above-median) and post-intervention adherence (adherent vs non-adherent). Qualitative data from Phase 1 were analyzed using thematic analysis.

Results

acceptability interviews indicated strong willingness to participate contingent on privacy and confidentiality. At baseline, the mean HRQoL was lower in the physical (2.6 ± 0.4) and psychological (2.6 ± 0.6) domains and higher in the social (2.9 ± 0.4) and environmental (3.2 ± 0.5) domains. Overall, the mean HRQoL was (3.1 ± 0.3). After the intervention, the overall HRQoL increased by 1.79 points ($p < 0.001$)

with significant gains across all domains. The prevalence and medication adherence rose from 23.4% at pre-intervention to 90.3% at post-intervention ($p < 0.001$). Psychological well-being showed the strongest positive association with adherence ($r = 0.6$, $p < 0.001$), and regression analyses identified medication adherence as a key predictor of improved quality of life ($r = 0.8$, $p < 0.001$).

Conclusions

Social media-based peer support is acceptable, and effective in enhancing HRQoL and medication adherence among YPLHIV in resource-limited settings. The findings support the integration of structured digital peer support into HIV care programmes to complement facility-based services.

SESSION WED-S15 · TRACK 1 · 15:30 – 17:15**AI in Healthcare II · Room R.014**

Moderator: Dimitri Verhoeven

WED-S15-P01**Session:** AI in Healthcare II · **Room:** R.014**Introducing Chatbots in Screening: Legal Issues**Prof. mr. Corrette Ploem PhD

Amsterdam UMC, Amsterdam, Netherlands. Law School, University of Amsterdam, Amsterdam, Netherlands

Background

An important tool for keeping our screening programs affordable and feasible is the use of (AI-based) chatbots, that provide individuals with information, enable them to ask questions, request their consent for screening, and instruct them on how to get tested. These new "digital screening clinics" can offer citizens maximum access to information and advice without taking up a disproportionate amount of time from the healthcare professionals involved. Such clinics are currently still mostly in the research phase, but it will not be long before chatbots interacting with individuals about the ins and outs of screenings tests are introduced on a larger scale in screening and beyond. Examples include screening of families (or individuals from families) at increased risk of sudden cardiac arrest or breast cancer, or prenatal screening of pregnant women. As with all technological innovations, it is important to examine whether replacing a human healthcare provider with a (AI-based) chatbot raises new questions about its legal context.

Methodology

This study highlights the most important legal issues regarding the implementation of chatbots in screening. What are the implications of the current legal framework for a responsible introduction of this AI-based technology by professionals and institutions? First, an example in genetic screening (the 'digital DNA clinic') will be discussed to illustrate what a chatbot supported clinic could look like. Then in light of the legal framework the most salient legal issues will be addressed, paying particular attention to the significance of relevant international principles and European legislation, such as the Medical Devices Regulation and the Artificial Intelligence Act. Finally, recommendations for both the screening practice and regulators are proposed.

Results

When introducing chatbots in screening practices responsibly, health care professionals and institutions unavoidably need to deal with legal issues related to the applicable legal framework. These include the start of the treatment relationship (and the corresponding responsibilities), the protection of patient rights (in particular informed consent and the protection of medical data), and the duty of the professional to provide good care and act in accordance with professional standards. One of the main requirements following the legal framework is that a chatbot may not function completely autonomous.

Conclusions

Key to the responsible introduction of (AI-based) chatbots in screening (and broader in health care), is to identify and assess the main legal issues. From the perspective of the professional and the institution, this means taking into account certain requirements, from the perspective of the legislator or self-regulators clarifying and further elaborating current legal standards.

WED-S15-P02**Session:** AI in Healthcare II · **Room:** R.014**What is the Impact of Artificial Intelligence on International Telemedicine & Telehealth (ITT) Law: An Update**Dr. Jack Snyder MD, JD, PhD, DABLM, FACLM

Allucent, Washington, DC, USA

Background

In 2026, the intersection of AI and international telemedicine and telehealth is dominated by the need to reconcile rapid technological adoption with strict, evolving legal frameworks regarding data privacy, liability, and reimbursement. Key issues include navigating fragmented international data regulations, AI-driven diagnostic bias, and the urgent push for permanent, cross-border, and interstate telehealth policies.

Research Question

What is the Impact of Artificial Intelligence on International Telemedicine & Telehealth (ITT) Law?

Methodology

Assembly, organization, and synthesis of information from legislation, regulations, court decisions, guidance documents, blogs, journal articles, and artificial intelligence tools

Results

Presentation will focus on emerging and evolving issues at the interface of artificial intelligence and ITT law. As AI integration increases, telemedicine and telehealth providers face intensified cyber risks (e.g., ransomware) and must navigate complex, varied international and domestic data protection laws (examples will be provided). Legal frameworks are struggling to address liability when AI decision support systems contribute to diagnostic or treatment errors, particularly in remote settings (examples to be provided). The expiration of pandemic-era flexibilities means providers face severe constraints on practicing across state or national borders, demanding new, permanent regulatory solutions (examples to be provided). Deployment of AI, including in mental health chatbots, requires strict guidelines on transparency (examples to be provided), combating bias, and ensuring patient data is used ethically. Inconsistent insurance coverage for AI-driven remote monitoring and, in the U.S., volatile Medicare rules regarding virtual care create financial risk and operational uncertainty (examples to be provided). Regulatory authorities worldwide are under pressure to foster innovation while setting "guardrails" for high-risk AI, with increased enforcement on telehealth billing, documentation, and patient access.

Conclusions

These legal and ethical challenges are driving a shift toward requiring "human-in-the-loop" systems, requiring AI to be explainable and validated, and demanding that international legal standards adapt to digital-first healthcare delivery (examples to be provided).

WED-S15-P03**Session:** AI in Healthcare II · **Room:** R.014**Integration of Commercial LLMs in Clinical Practice: Between Innovation, Efficiency and Fundamental Values**Associate Professor Ana Nordberg PhD¹, Dr. Petra Holmberg PhD¹, Sarah de Heer Master of Laws²¹Lund University, Faculty of Law, Lund, Sweden. ²Lund University, Faculty of Law, Lund, Sweden**Background**

Large Language Models (LLMs) such as ChatGPT Health, Perplexity Health, and Docus are rapidly entering health-related environments, often faster than legal frameworks can respond. Patients have already been using LLMs as the default 'first contact' for health information, and via AI-powered connected objects. As hospitals, e-health platforms, and insurers experiment with LLM integration, the gap between technological capability and legal oversight is widening at an alarming pace. Raising concerns about the ability of EU Law and medical technology regulation frameworks to respond to the challenge. Central to the analysis is the phenomenon of "function creep," whereby general-purpose AI systems gradually assume medical functions without formal recognition or oversight.

Research Question

What legal tools in EU Law can be used to balance health technological innovation and the promise of efficiency gains with safeguarding the values and interests of patients? Specifically, are these mechanisms and protections sufficient when LLMs, despite disclaimers and lack of certification, are used in clinical and e-health environments?

Methodology

This study conducts a doctrinal legal analysis supported by a conceptual mapping of regulatory tensions. It examines the interaction between EU frameworks for medical devices, consumer protection, contractual liability, data protection, and public procurement.

Preliminary Results

So far, the analysis reveals several urgent legal questions requiring further clarification and/or legal intervention. Currently, LLMs can evade certification as medical devices. Their persuasive fluency, combined with well-documented limitations such as hallucinations and a lack of explainability, creates a new category of risk not fully addressed. Left unchecked, integration into clinical practice risks amplifying known issues of automation bias, patient datafication, and the loss of health privacy and respect for fundamental rights and patients' legitimate interests. Legal interpretative uncertainty leads to unclear allocation of compliance responsibilities, risking fuelling a growing sphere of unregulated "shadow e-healthcare" where LLMs are deployed with minimal oversight. Marketing claims risk misleading patients, while secondary use of LLM inferences could lead to overarching health profiling. Disclaimers are commonplace solutions, dislodging the burden of risk and liability to the patient/user. Public procurement is seen as an additional regulatory layer, but follows a market regulation logic and not necessarily quality assurance.

Preliminary Conclusions

In the absence of clear regulatory solutions, the burden of safety and quality assurance is left to developers, who in turn contractually transfer responsibility to patients and healthcare practitioners. These systems risk becoming an unregulated area of quasi-medical practice, undermining patient safety, distorting accountability, and fragmenting healthcare standards.

WED-S15-P04**Session:** AI in Healthcare II · **Room:** R.014**Algorithmic Due Process in Public Health Governance: A Comparative Legal Analysis of Algorithm-Driven Health Interventions in the EU and China**Dr. Yi Lu J.S.D.

Peking University, Shenzhen, China. Max Planck Institute for Comparative Public Law and International Law, Heidelberg, Germany. Boğaziçi University, Istanbul, Turkey

Background

Public health governance increasingly relies on algorithmic tools with quasi-regulatory market effects. In the EU, nutrition scoring systems such as Nutri-Score deploy algorithmic formulas to classify food products, shaping consumer behavior and industry market access for non-communicable disease (NCD) prevention. When these algorithms are revised, the consequences for manufacturers and public health are significant, yet revision procedures lack conventional administrative law safeguards. For instance, the 2024 Nutri-Score update—which reclassified thousands of products, including upgrading olive oil from C to B—triggered fierce opposition from Italy and prompted major companies to remove labels. Yet, no administrative remedy existed for challenging scoring changes.

The EU AI Act (high-risk phase effective August 2026) establishes transparency obligations for AI in healthcare, but its applicability to deterministic public health formulas remains uncertain. In China, the 2022 Provisions on Algorithmic Recommendations introduced algorithm filing and ethical review, while food safety governance increasingly incorporates digital tools. However, China's food delivery platforms, such as Meituan, currently rely on merchant self-reporting for nutritional labeling without a unified algorithmic scoring system, raising questions about whether the existing filing regime could accommodate future public health algorithms. This convergence of algorithmic governance and public health regulation raises fundamental questions for health law.

Research Questions

This paper addresses three interrelated legal questions through a comparative analysis of EU and Chinese regulatory frameworks. First,

what procedural safeguards currently govern the revision of algorithms used in public health interventions, and do existing administrative law mechanisms provide adequate opportunities for stakeholder participation and judicial review? Second, to what extent do emerging algorithmic transparency regimes—including the EU AI Act, the General Data Protection Regulation (GDPR), and China's algorithm governance regulations—apply to deterministic public health algorithms that fall below the threshold of machine learning? Third, what remedial frameworks are available to parties adversely affected by algorithmic changes in health governance, and how might health law develop appropriate accountability mechanisms for algorithm-driven public health tools?

(Preliminary) Concluding remarks

Preliminary analysis reveals structural gaps in both jurisdictions. In the EU, while the AI Act imposes rigorous obligations on high-risk AI systems in clinical contexts, deterministic public health tools occupy a regulatory grey zone—subject to neither AI Act transparency requirements nor established administrative procedure protections. In China, the algorithm filing regime provides a distinct supervisory model through ex ante registration and ethical review. Yet, its extension to health-related algorithmic tools beyond internet recommendation systems remains underdeveloped. As public health governance becomes increasingly algorithm-dependent, health law must develop procedural safeguards commensurate with the regulatory impact of these tools. This paper proposes the concept of “algorithmic due process for public health”—a framework requiring that algorithm-driven health interventions satisfy standards of procedural fairness, scientific transparency, and effective remedial access, drawing on complementary insights from both EU and Chinese regulatory traditions.

WED-S15-P05

Session: AI in Healthcare II · **Room:** R.014

New Technologies in Health Care: Challenges for Civil Procedure and Law of Evidence

Tomáš Holčápek PhD

Charles University, Law Faculty, Prague, Czech Republic

New biotechnologies, telemedicine and other forms of remote health care, and utilisation of AI compel the regulatory environment to adapt. Novel medical practice can lead to reconsideration of the law of civil procedure and evidence, particularly in medical malpractice or reimbursement disputes. An illustrative example is a clinical examination performed by a physician over a video link, during which a software system utilising AI assists the physician in evaluation of the patient's symptoms. From the legal perspective, issues of liability for professional conduct and product liability may arise, and different legal rules, including also rules of evidence, may operate in their respect. A duty to disclose evidence or various presumptions may come into play. Should any duty to disclose evidence or presumption be applied not just to product liability, but also liability for professional conduct? Should the obligation only cover disclosure of evidence, or also a duty to retain it, or even a duty to create it for the potential benefit of the harmed party?

We will use a doctrinal and normative method to analyse the current legal approach and discuss the arguments in favour and against modifications of rules of civil procedure and evidence. For this purpose, we will take into consideration the rules related to product liability as they follow from the EU Product Liability Directive, and also the proposed EU AI Liability Directive.

The result of the analysis should help to determine whether the now-existing approach is still appropriate, or whether and how it should be amended either by EU law or national law. Such modification could involve broadening of the evidentiary duties of the health care provider and/or establishment of new presumptions in favour of the other party. A preliminary conclusion points towards the position that procedural law will probably need to change in some respects to help maintain the essential fairness in the relationship between patients and health care providers. However, for the time being it may be reasonable to limit its innovation to a broader duty to allow access to evidence, but not the obligation to create it for the hypothetical benefit of the other party.

SESSION WED-S16 · TRACK 2 · 15:30 – 17:15

Beginning of Life I · Room R.230

Moderator: Hongjie Man

WED-S16-P01

Session: Beginning of Life I · **Room:** R.230

Equitable Access and Ethical Governance in Cross-Border Reproductive Care: A Comparative European Legal Analysis

Dr. Sara Dalla Costa

Deusto University, Bilbao, Spain. Instituto Bernabeu, Venezia, Italy

Background

Assisted reproductive technologies (ART) have expanded the boundaries of health law, reshaping concepts of family, parenthood, and reproductive autonomy. Yet, despite scientific innovation and increasing reproductive mobility, access to ART in Europe remains highly unequal. Divergent national regulations on gamete donation, embryo preservation, and surrogacy generate a patchwork of legal and ethical standards. These disparities raise critical questions about equitable access to care and the governance of reproductive materials across borders.

Methodology

This research undertakes a comparative legal analysis of ART and embryo governance frameworks in five European jurisdictions—Spain, France, Italy, Germany, and Austria—chosen for their contrasting regulatory models. The study examines legislative texts, bioethics committee reports, and recent jurisprudence of both national courts and the European Court of Human Rights (ECHR). A secondary focus explores the interaction between domestic laws and EU cross-border healthcare provisions, identifying systemic inconsistencies and their implications for patients and clinics.

Results

The findings reveal persistent legal asymmetries that limit equitable access to ART. While Spain and France have adopted inclusive models grounded in reproductive rights and public health principles, Italy and Austria maintain restrictive approaches rooted in embryo protection and moral reservations. Germany's embryo protection law, for instance, constrains embryo handling and research, indirectly affecting clinical innovation. These disparities incentivize cross-border reproductive travel, often resulting in legal uncertainty for patients and professionals, especially concerning embryo transfer, destruction, and consent validity. The absence of interoperable legal frameworks exacerbates ethical dilemmas and undermines trust in cross-border care.

Conclusions

The study highlights the urgent need for a coordinated European approach to ART regulation that reconciles ethical pluralism with the principle of equitable access to healthcare. Establishing minimum legal standards for embryo governance and transparent cross-border procedures would enhance both patient safety and ethical accountability. The intersection of health law, bioethics, and EU regulation offers fertile ground for innovation—where interdisciplinarity becomes essential to ensure justice, coherence, and respect for reproductive autonomy in an increasingly mobile and technology-driven Europe.

WED-S16-P02**Session:** Beginning of Life I · **Room:** R.230**Artificial Intelligence and Maternal-Fetal Health Promotion through Fundamental Rights' Lenses**

Researcher Luiza T. C. Franco PhD Candidate in Law at the Faculty of Law at the University of Coimbra^{1,2,3}, Researcher Daniela M. Dias PhD Candidate in Law at the Faculty of Law at the University of Coimbra^{1,2,4}

¹Faculty of Law at the University of Coimbra, Coimbra, Portugal. ²University of Coimbra Institute for Legal Research (UCILeR), Coimbra, Portugal. ³PhD Scholarship Holder funded by Foundation for Science and Technology, -, Portugal. ⁴Center for Biomedical Law, Coimbra, Portugal

Background

The United Nations estimates that one woman loses her life every two minutes due to complications related to pregnancy or childbirth, revealing the persistence of maternal mortality as a severe public health issue.

Research Question

How can Artificial Intelligence (AI) promote the health of pregnant women and the fetus in light of the right to health?

Methodology

The methodology consists of a conceptual legal approach with a qualitative analysis of the literature. Initially, the study analyses the primary applications of AI, a system capable of autonomous analysis and decision-making, with maternal-fetal health. Emphasis is placed on learning systems capable of effectively predicting obstetric complications, such as pre-eclampsia, as well as tools for monitoring and forecasting public health risks regarding pregnancy, maternal and neonatal mortality, and postpartum depression. Subsequently, the study examines the contribution of these technologies to health promotion from a preventive perspective, alongside the ethical issues guiding the use of AI in this domain.

Results

Despite medical advancements, pregnancy, even when not classified as high-risk, is susceptible to various complications. Nowadays, these can be anticipated and prevented through the use of AI-powered technology, revealing its significant potential to improve the health of both the woman and the fetus during gestation and the postpartum period.

While the use of AI has the potential to strengthen and expand the protection of rights, particularly the right to health, it simultaneously presents complex legal challenges due to the algorithmic transparency and potential biases arising from non-representative databases. Consequently, the importance of protecting human rights is revealed, highlighting human dignity, maximizing beneficial effects, and minimizing harm in the application of technologies. This includes respect for individual autonomy in decision-making, informed consent, confidentiality and data protection, equality, justice, and non-discrimination, as provided in UNESCO 2006 Universal Declaration on Bioethics and Human Rights.

Conclusions

It is concluded that AI, when based on models of equity, transparency, and safeguard of fundamental rights, can constitute an important instrument for promoting maternal-fetal health, aligned with SDG 3, to ensure quality global health and eradicate or reduce deaths and diseases.

WED-S16-P03**Session:** Beginning of Life I · **Room:** R.230**Legal Protection of the Human Fetus: International Regulation and Perspectives on National Legislation**

Law Faculty Lecturer, Attorney Hikmat Babayev PhD candidate Baku State University, Baku, Azerbaijan. Azerbaijani Bar Association, Baku, Azerbaijan

Background

The legal and ethical status of abortion and the protection of the human fetus have remained among the most controversial issues throughout history. From the ancient Code of Hammurabi and the Hippocratic Oath to modern religious doctrines in Catholicism and Islam, the sanctity of life has been interpreted through varying lenses. While some traditions

view the fetus as a sacred life from conception, others provide nuanced permissions based on the mother's health or the stage of fetal development. In the contemporary era, these historical and theological perspectives have evolved into complex legal frameworks that attempt to balance fetal protection with reproductive autonomy.

Research Question

This study investigates the legal status of the fetus and the regulation of abortion across different jurisdictions. It seeks to answer how international human rights instruments and national legislations (specifically in the UK, Germany, Turkey, USA, and Azerbaijan) define the rights of the unborn and under what conditions the artificial termination of pregnancy is legally permitted.

Methodology

The research employs a comparative legal analysis, examining international documents such as the Universal Declaration of Human Rights (UDHR), the Convention on the Rights of the Child (CRC), and the Oviedo Convention. Furthermore, it analyzes specific national statutes, including the UK's Abortion Act 1967, the German Criminal Code (StGB), the Turkish Penal Code, and US Supreme Court precedents like *Roe v. Wade* and *Planned Parenthood v. Casey*. The study also incorporates biological and medical definitions regarding the transition from embryo to fetus.

Results

The findings reveal a significant divergence in legal approaches. European nations vary between granting the fetus specific rights from conception and prioritizing maternal autonomy. For instance, the UK allows abortion up to 24 weeks under broad health criteria, while Germany maintains a general prohibition with specific medical and social exceptions. In the United States, the legal landscape is increasingly fragmented at the state level. In Azerbaijan, the "Law on Protection of Public Health" grants women the right to decide on motherhood, allowing abortion up to 12 weeks by choice and up to 22 weeks for social indications, while criminalizing illegal procedures outside medical facilities.

Conclusions

The study concludes that there is no universal consensus on the legal personhood of the fetus. While international law emphasizes maternal health and reproductive rights, national legislations often reflect a compromise between biological milestones (such as organogenesis) and societal values. The research suggests that as bioethics continues to evolve alongside medical technology, legal frameworks must become more sophisticated to address the delicate balance between the "right to life" and "individual autonomy," ensuring that medical and legal definitions of the fetus are harmonized with human rights standards.

WED-S16-P04**Session:** Beginning of Life I · **Room:** R.230**Informed Consent Documentation in Obstetrics**

Lawyer Monique Magalhães Moraes LL.B., Postgraduate Degree

Rua Miguel de Frias,, Niteroi, Rio de Janeiro, Brazil

Background

Informed consent has become a central legal and ethical requirement in contemporary medical practice, particularly in gynecology and obstetrics. These specialties involve procedures that directly affect bodily integrity, reproductive autonomy, and fundamental patient rights. In medical litigation, disputes increasingly arise not from technical medical error but from the absence or inadequacy of documented informed consent. The documentation of information provided to patients therefore plays a critical role in determining the legal legitimacy of medical interventions.

Research Questions

How does the absence or insufficient documentation of informed consent affect the legal assessment of medical liability in gynecology and obstetrics in Brazil and Portugal?

(Preliminary) Concluding Remarks

This study adopts a comparative legal-dogmatic approach based on the analysis of constitutional principles, civil liability frameworks, ethical medical regulations, and judicial decisions in Brazil and Portugal. The analysis demonstrates that both legal systems recognize informed consent as a fundamental expression of patient autonomy and a

prerequisite for the lawful performance of medical interventions. However, when documentation is absent or insufficient, the legal evaluation often shifts from the technical correctness of the medical act to the evidentiary assessment of whether adequate information was provided to the patient.

The comparative analysis reveals structural differences between the two jurisdictions. In Portugal, informed consent is primarily examined within the framework of personality rights and the general theory of civil liability. In Brazil, the legal analysis may also be influenced by consumer protection principles, which tend to strengthen the patient's evidentiary position and increase expectations regarding the documentation of medical information.

In both legal systems, the absence of individualized documentation of the consent process significantly weakens the physician's ability to demonstrate compliance with the duty to inform and may increase exposure to legal disputes in obstetric and gynecological practice.

SESSION WED-S17 · TRACK 3 · 15:30 – 17:15

Criminal Law II · Room R.011

Moderator: Mustafa Aslam

WED-S17-P01

Session: Criminal Law II · **Room:** R.011

Commission by Omission in Health Criminal Law

Research Assistant PhD Tansu Sayar Kanyis PhD

Izmir University of Economics, Izmir, Turkey

Abstract

Background

The offense of commission by omission occurs when an individual with a guarantor status fails to act, leading to a harmful consequence of death or injury. Healthcare professionals hold a guarantor status due to the nature of their profession and the legal authority granted to them for medical interventions. This distinction is legally critical because, in certain jurisdictions like Turkey, negligence in an omission may not be penalized, whereas negligent commission results in criminal liability.

Research Questions

A significant challenge in legal practice arises in borderline cases, where omissive and commissive behaviors overlap, complicating the distinction between intentional omission and negligent commission. For example, in a case where a nurse administers an insufficient dose of medication, did the death result from the nurse's omission (the withheld amount) or from a commission (administering an incorrect dose), and how do such classifications directly determine whether a healthcare professional bears criminal liability?

Methodology

This study employs a qualitative and categorical analysis of judicial precedents retrieved from the Lexpera database using the search terms "negligent homicide" and "omissive conduct." After an initial screening of more than 50 rulings, a selection of relevant cases was analyzed by applying the argument that the correct interpretation technique should prioritize typicality, followed by an evaluation of culpability (intent vs. negligence). These selected rulings were then categorized into three distinct groups: the first representing correct legal application, and the remaining two focusing on problematic judicial trends in borderline cases.

Results

The examination of Turkish Court of Cassation precedents reveals that the Court frequently struggles to establish consistent criteria in borderline cases. There are instances in which the Court renders a conviction for intentional commission by omission when a link cannot be established between the commissional negligent act and the fatal outcome. Conversely, in instances where the conduct was essentially omissive but performed through negligence, the Court has ruled it as negligent homicide by way of commission.

Conclusion/Take-Home Message:

We argue that the correct interpretation technique should prioritize typicality, followed by an evaluation of culpability. Establishing a mandatory sequence of typicality before culpability is not just a theoretical preference but a requirement for the rule of law in medical malpractice cases, as it is essential to ensure legal certainty and the right to a fair trial for healthcare professionals. The findings of this research on borderline cases provide the necessary theoretical and jurisprudential foundation for a broader analysis of criminal liability within complex, organized healthcare environments, which often lead to high-profile legal cases.

WED-S17-P02

Session: Criminal Law II · **Room:** R.011

The Decriminalization of the Light Unintentional Medical Error in Belgian Criminal Law

Lawyer David Delefortrie Master of Law

Bonus Medicus Law, Ghent, Belgium

Background

For decades, Belgian criminal law applied the principle of *culpa levissima in abstracto* to unintentional offenses, including medical errors. This doctrine equated the lightest form of negligence with criminal fault, based on the standard of the *bonus medicus*. As a result, even minimal medical negligence could trigger criminal liability for physicians. This approach was justified by the long-standing unity of civil and criminal fault, whereby the same negligence standard applied in both domains.

Research Question

How does the introduction of the requirement of a "serious lack of care or caution" in the new Belgian Criminal Code affect the criminal liability of physicians for unintentional medical errors, and what are the legal and societal implications of this shift?

Methodology

This article conducts a doctrinal legal analysis of the new Belgian Criminal Code, published on 8 April 2024 and entering into force on 8 April 2026. It examines the legislative texts, parliamentary preparatory works, and relevant case law to assess the scope and interpretation of the newly introduced concept of "serious fault" in relation to unintentional bodily harm and unintentional homicide. Particular attention is paid to its impact on medical liability.

Results

The new Criminal Code abandons the traditional unity of civil and criminal fault by requiring a serious fault—defined as an "egregious lack of care or caution"—for criminal liability in cases of unintentional harm. Consequently, light unintentional medical errors will no longer be criminally punishable. The interpretation of "serious fault" remains largely open and will be shaped by future case law, although the legislator provides indicative criteria such as recklessness, repetition of errors, foreseeability of harm, and the professional expertise of the offender. This reform will also have retroactive effect as the more lenient criminal law, potentially rendering many ongoing prosecutions without object.

Conclusions

The decriminalization of light unintentional medical errors represents a fundamental shift in Belgian criminal law and significantly limits the criminal exposure of physicians. While this reform aligns with the subsidiary nature of criminal law and reduces unjustified stigmatization, the vague definition of "serious fault" raises concerns regarding legal certainty. Overall, the reform encourages a clearer separation between civil compensation mechanisms and criminal sanctioning, reserving criminal law for truly exceptional cases of grave medical negligence.

WED-S17-P03

Session: Criminal Law II · **Room:** R.011

Criminal Law Perspectives on Healthcare Fraud

Professor Ioseb Gabaraevi Doctor of Law

LEPL David Aghmashenebeli National Defence Academy of Georgia, Gori, Shida Kartli, Georgia

Background

Healthcare systems worldwide are increasingly vulnerable to fraud due to their complexity, high financial flows, and the involvement of multiple stakeholders, including providers, insurers, patients, and intermediaries. Healthcare fraud encompasses a wide range of unlawful activities such as billing for services not rendered, upcoding, kickbacks, identity theft, and manipulation of insurance systems. These practices not only lead to significant economic losses but also undermine trust in healthcare institutions, distort resource allocation, and may compromise patient safety. From a legal perspective, healthcare fraud raises critical challenges for criminal law, including issues of detection, prosecution, jurisdiction, and the adequacy of existing penalties. Despite growing attention, regulatory and enforcement approaches vary widely across jurisdictions, reflecting differences in legal traditions, institutional capacity, and policy priorities.

Research Question

This study examines how criminal law frameworks address healthcare fraud across different jurisdictions and evaluates the effectiveness of legal mechanisms in detecting, prosecuting, and deterring fraudulent activities in healthcare systems. It further investigates the key challenges faced by enforcement authorities and the extent to which current criminal law provisions are sufficient to respond to evolving forms of healthcare fraud.

Methodology

The research adopts a qualitative comparative legal analysis based on secondary sources, including statutes, case law, academic literature, policy reports, and international guidelines. Selected jurisdictions representing different legal systems are analyzed to identify variations in definitions of healthcare fraud, investigative procedures, evidentiary standards, and sanctions. A thematic approach is used to synthesize recurring legal principles, enforcement strategies, and institutional practices, with particular attention to the role of specialized anti-fraud units, inter-agency cooperation, and international collaboration.

Results

The findings reveal significant divergence in how healthcare fraud is conceptualized and prosecuted under criminal law. Some jurisdictions employ comprehensive statutory frameworks with specialized enforcement bodies, while others rely on general fraud provisions with limited healthcare-specific adaptation. Effective systems tend to incorporate proactive auditing mechanisms, whistleblower protections, and integrated data-sharing platforms. However, common challenges include underreporting, difficulties in gathering admissible evidence, cross-border fraud schemes, and resource constraints in enforcement agencies. Additionally, disparities in legal definitions and procedural rules hinder international cooperation and harmonization of anti-fraud efforts.

Conclusions

Healthcare fraud presents a persistent and evolving threat that requires robust and adaptive criminal law responses. Strengthening legal frameworks, enhancing investigative capacities, and fostering international cooperation are essential to improving detection and deterrence. Policymakers should consider harmonizing definitions, expanding institutional specialization, and promoting transparency and accountability within healthcare systems. A coordinated legal approach that integrates prevention, enforcement, and cross-border collaboration is crucial to effectively combat healthcare fraud and safeguard the integrity of global health systems.

WED-S17-P04

Session: Criminal Law II · **Room:** R.011

Afstemming tussen Strafrecht en Tuchtrecht in de Nederlandse Gezondheidszorg

Assistant professor Vivianne Dörenberg LLM PhD¹, Senior researcher Nicolette Woestenburg LLM², Professor Corrette Ploem LLM PhD¹

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Background

De rol van het strafrecht in de gezondheidszorg in Nederland is van oudsher beperkt. Toch lijkt die rol toe te nemen. Daarbij komt het voor dat het strafrecht naast of in opvolging van het tuchtrecht wordt ingezet. Deze samenloop roept vragen op over de effectiviteit en proportionaliteit van het inzetten van het strafrecht.

Research Question

Hoe functioneert het strafrecht in de gezondheidszorg in relatie tot de regeling van het tuchtrecht in de Wet BIG in Nederland?

Methodology

In 2025 heeft de derde evaluatie van de Wet op de beroepen in de individuele gezondheidszorg (Wet BIG) plaatsgevonden. De evaluatie richtte zich in hoofdzaak op de regeling van het tuchtrecht. Daarnaast is aandacht besteed aan enkele andere onderwerpen van de Wet BIG, die raken aan de doelstellingen of het functioneren van het tuchtrecht, waaronder het strafrecht. Voor de evaluatie is een combinatie van juridische en empirische onderzoeksmethoden gebruikt, bestaande uit onder meer tekstanalyse van parlementaire documenten, literatuuronderzoek, semi-gestructureerde interviews en expertmeetings.

Results

Binnen de systematiek van de Wet BIG vervult het strafrecht ten opzichte van het tuchtrecht een aanvullende rol. Dit betekent dat het strafrecht alleen in beeld komt als strafvervolgung vanwege ernstige tekortkomingen in de kwaliteit van zorg of andere bijzondere omstandigheden noodzakelijk is. De evaluatie biedt geen aanknopingspunten voor een andere visie op de rol van het strafrecht. Cruciaal voor een dergelijke afstemming tussen het strafrecht en het tuchtrecht is wel een goede samenwerking tussen het Openbaar Ministerie (OM) en de Inspectie Gezondheidszorg en Jeugd (IGJ). Die samenwerking blijkt (nog altijd) niet in alle gevallen goed te verlopen. Dit hangt onder meer samen met een moeizame gegevensuitwisseling tussen beide instanties die deels te wijten is aan onduidelijkheid (of in ieder geval discussie) over de exacte betekenis en reikwijdte van de regels voor die gegevensuitwisseling.

Conclusions

De Nederlandse regering moet duidelijkheid verschaffen over de juiste interpretatie van de regels voor het uitwisselen van gegevens tussen het OM en de IGJ zodat dit knelpunt niet langer aan constructieve samenwerking tussen beide instanties in de weg staat. Dit zal bijdragen aan een betere afstemming tussen het strafrecht en het tuchtrecht in de gezondheidszorg.

SESSION WED-S18 · TRACK 4 · 15:30 – 17:15

End of Life II · Room R.201

Moderator: Christophe Lemmens

WED-S18-P01

Session: End of Life II · **Room:** R.201

A Strategy Discussion on Safeguarding the Dignity of Life Through Advance Medical Directives

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Background

With the accelerating aging of society, many elderly people without immediate family encounter practical challenges in medical decision making. To ensure that patients' own wills serve as the basis for medical decision-making, this paper proposes specific strategies to safeguard life dignity through advance medical directives (AMDs).

Research Question

AMDs refer to oral or written decisions made by mentally competent patients with full civil capacity, specifying medical interventions that the patient is willing to accept or refuse at the terminal stage of illness when death is imminent. Specific medical interventions include, but are not limited to: Whether to continue medical treatment that may cause significant suffering and adverse effects when there is no prospect of cure; Whether to use life-sustaining medical equipment, such as ECMO, in critical conditions when such measures can't reverse the course of disease; Whether to employ resuscitation interventions during end-of-life emergencies, including CPR, electrical defibrillation, endotracheal intubation, or tracheotomy.

Methodology

Through literature review, expert interviews, case analysis and comparative study, this study explores the applicability and legislative barriers of AMDs, focusing on practical challenges faced by elderly individuals without accompanying relatives, analyzing ethical and legal boundaries in implementation from both ethical and practical dimensions, combined with domestic and international experiences. An AMD is deemed as effective when a medical decision must be made, and the patient is unable to think clearly or express their own opinions, while a trustworthy and valid AMD exists. Dilemma arises in this context: What if a patient's immediate relatives appear at that time and put forward opinions contradicting the patient's AMD as legal guardians? We contend that priority should be given to respecting the patient's own expressed decision, with proper communication and persuasion to immediate relatives.

Conclusions

The implementation of AMDs faces two major challenges. First, in jurisdictions without legal euthanasia, any AMD that actively seeks death must be excluded. However, the boundary between active and passive measures remains ambiguous. For example, withholding artificial nutrition delivered via nasogastric tubes or intravenous infusion is often regarded as a passive measure. But a considerable proportion of doctors consider this an unacceptable practice. Second, determining who should act as the executor of AMDs presents another difficulty. A designated social organization should assume responsibility for the registration, preservation, notarization, and execution of AMDs. This role could be undertaken by nonprofit public social organizations, and the feasibility of involving insurance companies implementing AMDs as a service project could also be explored.

WED-S18-P02

Session: End of Life II · **Room:** R.201

Advance Care Planning and Advance Directives in Belgium after the Reform of the Law on Patients' Rights from a Human Rights Perspective

Dr. Christophe Lemmens PhD

University of Antwerp, Antwerp, Antwerp, Belgium. Dewallens & partners, Leuven, Flemish Brabant, Belgium

Background

The Belgian Law on Patients' Rights dates from 2002 and was thoroughly reformed in 2024. Since then, more attention has been paid to advance care planning and advance directives. Definitions of these concepts have been included and different types of advance directives have been regulated, namely the positive advance directive, the negative advance directive and the appointment of a representative. The legal value of these advance directives is also laid down in the law. Finally, the law contains a cascade arrangement for determining the patient's representative, who will exercise the patient's rights as soon as and for as long as the patient is incompetent.

Research Question

The question arises as to whether the reform of the Belgian Law on Patients' Rights has effectively created important innovations or opportunities for advance care planning, and whether the Belgian regulations are in accordance with the European Convention on Human Rights.

Methodology

The Belgian Law on Patients' Rights is analysed, in particular with regard to the provisions relating to advance care planning, advance directives and the representation system for incapacitated patients. First, the initial regulation of these issues in the 2002 Law on Patients' Rights is examined. Next, the changes implemented in 2024 are analysed. Finally, the case law of the European Court of Human Rights is analysed and the Belgian regulations are assessed upon their conformity.

Results

The analysis shows that, in reforming the Law on Patients' Rights, the legislator did indeed pay more attention to advance care planning and advance directives. In 2002, attention to these issues was rather limited. This is a good thing in itself, but on closer inspection, the additions to the law do not appear to be particularly innovative. They often concern additions that were not previously included in the text of the law, but were evident from parliamentary documents and/or legal doctrine. Moreover, a number of implementing royal decrees are still lacking, so that the legislator's intention has not yet been fully realised. It follows from the case law of the European Court of Human Rights that member states have a wide margin of appreciation in the absence of consensus on these issues in Europe, so that the Belgian Law on Patients' Rights is in line with the European Convention on Human Rights.

Conclusions

The Belgian Law on Patients' Rights was reformed in 2024, but it cannot really be called innovative. This law is in accordance with the European Convention on Human Rights, although the King does need to work on the various implementing decrees that have still not been adopted.

WED-S18-P03

Session: End of Life II · **Room:** R.201

How to Handle Advance Directives and Assisted Dying: In General and from a Swiss Perspective

Professor Sandra Hotz

University of Neuchâtel, Neuchâtel, Neuchâtel, Switzerland

Background

The presentation integrates a broad comparative perspective on cases involving dementia and end-of-life decisions to facilitate a more comprehensive understanding of the potential conditions under which the scope of assisted dying in Switzerland might be expanded.

This contribution examines the legal framework in Switzerland governing assisted suicide, analysing the contradictions between criminal and civil law, particularly with regard to the promotion of individual autonomy and advance directives, as reflected in the 2013 civil law revision.

Research Questions

This includes firstly the question of why the legal condition of legal capacity for assisted suicide shall not be substituted by a form of advance directive, when normally this is exactly the scope of an advance directive to regulate medical decisions, when one has no more legal capacity. This, in turn, leads to the question, what other necessary conditions and regulations would a person need to be sufficiently protected. One specific question in the Swiss context is the legal framework for the private organisations that are de facto in charge of assistance and accompanying, and how to preserve their knowledge and roles while still maintaining a certain degree of control. Another question concerns the equality of access to safe tools/medication to assist in dying.

On a more meta level, it often remains a political question of autonomy vs the ongoing medicalisation of end-of-life decisions, in Switzerland. This demands a more profound and critical analysis of autonomy and the so-called medicalisation itself. Especially as the borders between palliative care and assisted dying are fluid and the person concerned is normally in a relational setting, accompanied by family members, friends and private accompanying teams, who are, in fact, very interdisciplinary.

Concluding Remarks

Discussing these questions, one legal solution could be to put assisted dying in a more relational and social context and therefore develop a form of advance directive regarding assisted suicide / dying in a relational, interdisciplinary setting, including a foreseeable time limit.

WED-S18-P04

Session: End of Life II · **Room:** R.201

Canada's Euthanasia (MAiD) Regime: Remarkably Safe, or Remarkably Dangerous?

Professor Trudo Lemmens Lic Jur, LL.M (bioethics), DCL

Jackman Faculty of Law, University of Toronto, Toronto, Ontario, Canada

Background

Advocacy organizations and scholars supporting Canada's Euthanasia and Assisted Dying regime, known as Medical Assistance in Dying [MAiD], argue that Canada's MAiD practice is exemplary safe. They claim it is regulated in more detail than any standard form of medical practice. For them, the country's internationally unprecedented expansion of euthanasia, with rates that have bypassed in less than one decade the rates of Belgium and the Netherlands, simply reflects consumer demand. Others, including legal and bioethics scholars, about all of Canada's disability advocacy organizations, and the UN Committee on the Rights of Persons with Disabilities, have argued that Canada's MAiD law and practice undermine the right to life and equal protection of persons with disabilities and put numerous Canadians at risk of premature death.

Research Questions

What is the context in which decisions about access to MAiD are made in Canada? What does existing scholarly literature in health law and bioethics reveal about claims of 'consumer demand' to explain high numbers of MAiD? What is the evidence about the reasons why Canadians request MAiD? What is the evidence about the rigour of MAiD assessments and provisions?

Methodology

The presentation will discuss scholarly literature related to health law and bioethics to indicate why the claim of 'consumer demand' reflects a remarkably detached view of how medical decisions are made. It will further discuss evidence from reports of Ontario's Chief Coroner's MAID Death Review Committee, Health Canada, and ongoing litigation. This evidence reveals the reasons why people opt for MAID, and shows how some Canadians received MAID following remarkably sloppy and minimalistic capacity and consent assessment practices, and based on at times remarkably flexible interpretations of safeguards and eligibility criteria. It will also explore how institutional responses to identified problems reveal a remarkable lack of willingness among professional regulatory colleges, health authorities, and other decision makers, to question a practice that appears particularly driven by a small number of committed providers, who appear to drive the practice in a direction many other medical practitioners are not comfortable with. Some of the evidence discussed in the presentation has been mentioned in recent observations of the United Nations Committee on the Rights of Persons with Disabilities. I will highlight why the Committee is right in urging Canada to withdraw key components of its MAID law (with respect to persons not approaching their natural death) and not to introduce MAID for sole reasons of mental illness and on the basis of advance requests.

Concluding Remarks

the presentation will set out why Canada's MAiD regime is a warning sign for countries contemplating some form of legalizing euthanasia or assisted suicide.

SESSION WED-S19 · TRACK 5 · 15:30 – 17:15

Health Data II · Room R.004

Moderator: Tim Opgenhaffen

WED-S19-P01

Session: Health Data II · Room: R.004

Patients' Personal Data Protection in Electronic Medical Records: A Comparative Legal Study among ASEAN Countries

Dr Redha Vebrina Master of Law, Dr. Imelda Ika Aprilia Master of Law

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Background

The rapid digitalization of healthcare services has driven the widespread implementation of Electronic Medical Records (EMRs) across ASEAN countries. The adoption of EMRs is expected to improve efficiency, accessibility, and the quality of healthcare services. Nevertheless, the implementation of EMRs also gives rise to significant legal issues, particularly with regard to the protection of patients' personal data, including aspects of privacy, data security, and accountability. Therefore, this study aims to conduct a comparative analysis of the legal frameworks governing the protection of patients' personal data in Electronic Medical Records in several selected ASEAN member states.

Research Questions

1. How is the normative legal framework governing patient consent constructed in relation to the protection of personal data within Electronic Medical Records in Indonesia, Singapore, Malaysia, and Thailand?
2. How are legal sanctions for violations of patients' personal data protection in Electronic Medical Records normatively regulated, and to what extent do these sanctions reflect the principles of legal certainty, proportionality, and effectiveness within the respective legal systems?

Methodology

This study constitutes normative legal research employing a statutory approach and a comparative legal approach. The research materials consist of primary and secondary legal sources, which are analyzed qualitatively through the examination of legal norms governing the protection of patients' personal data in Electronic Medical Records in Indonesia, Singapore, Malaysia, and Thailand.

Results

The findings indicate that Indonesia's legal framework for protecting patients' personal data in Electronic Medical Records remains less developed than those of Singapore, Malaysia, and Thailand, particularly in terms of regulatory coherence, enforcement

mechanisms, and supervisory authority. While these jurisdictions demonstrate more mature and structured data protection regimes, Indonesia continues to encounter regulatory and institutional challenges, highlighting the need for further normative and institutional reform.

WED-S19-P02

Session: Health Data II · Room: R.004

Health Records and the Power of Software Vendors: The Case of the Curious Physiotherapist

Prof. Dr. Nils Broeckx PhD

University of Antwerp, Antwerp, Belgium

Background

A physiotherapist accessed the hospital records of an ex-patient and unlawfully viewed her test results. A complaint was filed with the Belgian Data Protection Authority, arguing that the hospital did not take sufficient measures to safeguard the confidentiality of the health records. The hospital contended that its software vendor did not allow for appropriate user access settings, noting that it had requested modifications from its vendor, and that switching vendors would be prohibitively expensive. The Belgian Authority quickly dismissed this argument, but the case nonetheless merits further discussion.

Research Question

To what extent should the 'software limitations defense' be accepted in a healthcare context?

Methodology

The Belgian case serves as a starting point for a normative analysis, based on a review of existing legislation, case law, and doctrine within the European Union (EU).

Results

European case law indicates that granular access settings (e.g. based on data type and care path type) are an 'appropriate' safeguard for an electronic health record (EHR). Under EU data protection law, the HCP has a significant responsibility to implement those settings (art. 25 and 32 GDPR) and to work only with vendors capable of implementing them (art. 28 GDPR). In theory, a HCP could invoke a 'software limitations defense' if the vendor fails to do so. The GDPR indeed allows technological and economical limitations to be factored into the assessment of what constitutes 'appropriate' measures. However, this defense has not yet been accepted in jurisprudence, which emphasizes the sensitive nature of health data. Either way, the 'software limitations defense' would not absolve the software vendor. Under EU data protection law, a vendor can be held directly responsible for failing to implement appropriate security measures (art. 28 and 32 GDPR). It can be argued that any technological and cost considerations for the HCP and the vendor should be assessed independently.

Conclusions

Underlying the discussion of the software limitations defense is the recognition that patient privacy has a cost. The real question is who should bear it. Current enforcement actions focus primarily on HCP's. This focus is arguably too narrow, as they do not always have the technological or economical 'power' to change software. There are strong arguments for placing greater responsibility on software vendors, either by punishing non-compliant vendors (via GDPR fines and liability) or by rewarding compliant vendors (e.g. through state subsidies).

WED-S19-P03

Session: Health Data II · Room: R.004

PRISMA: AI-Driven Secondary Use of Health Data for Healthcare Network Governance and Patient Stratification

Prof. Barbara Gagliardi PhD

University of Turin, Torino, Italy

Background

National health systems generate large volumes of administrative and clinical data, including hospital discharges, outpatient services, pharmaceutical prescriptions, and emergency department records. In Italy, however, these data are still used predominantly for accounting and reporting purposes, while their potential for healthcare planning, territorial equity, and chronic care management remains underexploited. This gap is becoming more critical in a context marked by population ageing, multimorbidity, and growing territorial inequalities

in access to care. At the same time, the emerging European Health Data Space framework is pushing regional health systems to develop lawful and operational models for the secondary use of health data.

Research Question

How can secondary use of routine health data be organized in a legally compliant, technically robust, and territorially meaningful way to support AI-based patient stratification and regional healthcare planning?

Methodology

The paper presents the preliminary findings of the PRISMA project, an interdisciplinary initiative that adopts a combined legal, epidemiological, and data science approach. The project involves academic institutions, regional health authorities, and a public ICT infrastructure provider. It applies record linkage techniques across heterogeneous healthcare datasets, develops machine learning models for predictive patient stratification, and integrates spatial analysis to assess territorial inequalities in access to care. In parallel, the project elaborates a legal and organizational framework for the secondary use of health data, addressing data protection, interoperability, and governance requirements.

Results

The project is expected to deliver: (1) a prototype AI-based platform for identifying vulnerable patient groups and supporting evidence-based allocation of healthcare resources; (2) a transferable governance model for lawful secondary use of health data; (3) operational guidance for regional health authorities on integrating data analytics into healthcare planning; and (4) an open, scalable, and interoperable model suitable for replication in other Italian regions. Particular attention is given to chronic care pathways, unmet demand, healthcare mobility, and inequalities between urban, rural, and mountain areas.

Conclusions

PRISMA shows how health data governance can move from a purely administrative function to a strategic tool for public decision-making. Its main contribution lies in integrating legal compliance, AI-based analytics, and territorial health planning into a single replicable framework for more equitable and effective healthcare governance.

WED-S19-P04

Session: Health Data II · **Room:** R.004

The Impact of GDPR on AI-Driven Processing of Health Data in Insurance

Peter Claeys Master

University of Antwerp, Antwerp, Belgium

Background

The increasing use of artificial intelligence (AI) in the insurance sector is significantly transforming risk assessment and underwriting practices. Insurers are in the position to perform AI-driven data analytics to process large volumes of personal and sensitive data, including health data, in order to individualize insurance products and pricing. While these technologies add to efficiency, they also raise substantial concerns regarding data protection, discrimination, and the erosion of traditional solidarity mechanisms in insurance. The General Data Protection Regulation (GDPR) provides a legal framework for the protection of personal data, but its adequacy in addressing AI-driven processing of health data in insurance must be questioned.

Research Question

To what extent does the GDPR effectively protect policy holders against the risks associated with AI-driven processing of health data in insurance, and where are the (structural) limitations of the current legal framework?

Methodology

The study adopts a doctrinal legal method, analyzing relevant provisions of the GDPR, with particular attention to the lawfulness of processing, the prohibition of automated individual decision-making (including profiling), and core data protection principles such as data minimization and purpose limitation. A comparative perspective is employed, focusing primarily on Belgian and Dutch data protection law. In addition, qualitative interviews with insurers and academic experts were conducted to gain (practical) insight.

Results

The analysis shows that the GDPR provides strong individual-level safeguards for policy holders, particularly through strict requirements

for lawful processing and enhanced protection of health data. However, in the context of AI-driven insurance practices, these safeguards are often difficult to operationalize. Reliance on explicit consent proves problematic due to structural power imbalances between insurers and policy holders, while the scope of the prohibition on automated decision-making remains limited in practice. Moreover, GDPR compliance does not prevent broader market developments towards increasingly individualized risk assessment, which may disadvantage persons with higher health risks.

Conclusions

This research concludes that although the GDPR offers important protections against unlawful and unfair processing of health data, it is insufficient to address the broader structural effects of AI-driven insurance practices, particularly the gradual erosion of risk solidarity. Addressing these challenges requires targeted national legislative interventions to complement data protection law and to balance innovation, efficiency, and social protection within the insurance sector.

SESSION WED-S20 · TRACK 6 · 15:30 – 17:15

Minors I · Room R.007

Moderator: Luis Ravanal

WED-S20-P01

Session: Minors I · **Room:** R.007

On the Implications of the Concept of Parental Autonomy in the Context of Futile Therapy for Children

University Professor Maria Boratyńska dr hab.

University of Warsaw, Warsaw, Poland. Medical University of Warsaw, Warsaw, Poland

Background

The concept of parental autonomy assumes public authorities should not interfere with parents' freedom to make decisions regarding their child's health as parents are the best guardians of their child's welfare. The criteria for intervention in cases of inadequate care vary from country to country, ranging from the initial assumption of the duty to act in the best interests of the child (as in the Convention on the Rights of the Child), through non-interference unless there is a risk of significant harm, to the approach of treating the child as the de facto property of the parents. When further treatment appears futile, it is permissible to argue that since nothing can help the patient, continuing care will not harm them, and to maintain the child's fading life for as long as possible or allow the parents to do so on their own, to seek experimental or so-called alternative methods.

Research Question

At this point arises the question how deep the protection of the child coincides with the personal interests of the parents – the value of enjoying an undisturbed family life?

Methodology

The method applied to the question is dogmatic analysis of the literature and practical analysis of case studies. The cases will be parted into stages and matched with the theoretical background.

Results

Parents argue that they should be allowed to decide at their own pace and according to their own convictions, because they perceive keeping the child alive as an intrinsic good that is threatened with violation. The concept of parental autonomy is essentially about unrestricted decision-making on life support and the search for untested treatments. The ethics of abdicating responsibility in the face of parental demands seems to relieve doctors of the moral burden of decision-making. However, it exposes the child to charlatans, quacks, unauthorised experimenters and may cause unnecessary suffering instead of dying in peace and dignity – as stipulated by Polish law. The parent's sense of injustice in light of respecting the child's right to a dignified death cannot be protected, because removing this injustice would be tantamount to violating the child's legal rights.

Conclusions

The problem boils down to whether a child in a terminal condition should be artificially kept alive to satisfy the emotional needs of their parents when no significant harm is being done to them. However, how can we define significant harm in someone who is no longer even aware of their own existence? The question is therefore whose values are at stake here and whether the spiritual comfort of the parents takes precedence

because a child in such a condition no longer lives for themselves but for parents.

WED-S20-P02

Session: Minors I · **Room:** R.007

The Antwerp Mohels: Dina de Malkhuta Dina?

Mr. Philip D Vanstapel Master of Laws
Dewallens & Partners, Leuven, Belgium

Background

In February 2026 a diplomatic scandal rocked Belgian media after tweets by the US ambassador Bill White concerning the “antisemitic” judicial investigation of three *Mohels* (Jewish ritual circumcisers) in Antwerp. The allegations concerned the performance of medical acts without the assistance of a licensed medical practitioner and charges of assault and battery to children due to the practice of *metzitzah b'peh* (oral suction of blood by the *Mohel*).

Research Question

The research question is threefold:

- 1) How do Belgian and Jewish Law enable or hinder the practice of oral suction during circumcision?
- 2) Which philosophical assumptions underlie the extreme positions in the debate on oral suction during circumcision?
- 3) What are the takeaways for Belgian law on this issue?

Methodology

I analyze the applicable rules in Belgium and the Jewish world regarding a) *metzitzah b'peh*; and b) the Belgian concept of religious freedom *versus* the Jewish concept of *dina de malkhuta dina* (i.e. the doctrine that Jews must, within reasonable limits, abide by the Law of the land).

I then conduct a literature study of the philosophical doctrines concerning the role of the child as a legal subject in modern societies and in traditional Judaism and the role of the State as the protector and enforcer of bodily rights, health and safety and personal freedoms.

Results

An analysis of Belgian and Jewish Law shows that informed consent laws, and the assistance of a medical practitioner, as well as a robust system of civil and criminal liability offer safeguards for a continued practice of *metzitzah b'peh* in Belgium.

Two paradoxes are noted on the philosophical level: an increasing societal and legal promotion of individual agency and bodily autonomy somehow stops where a) so-called backwards religious practices are concerned and b) risk aversion and health and safety protection take precedence in public policy.

Conclusions

Although it may seem evident that ambassador White was too harsh in his judgment of the Belgian authorities, there are strong arguments for the continued practice of *metzitzah b'peh*, as the current Belgian legal framework foresees sufficient levers (both in health law and criminal law) to deal with excesses.

However, criminal investigations and national legislation should not be applied as a form of lawfare against the Jewish community and lawmakers and pundits wishing to ban certain religious practices should be careful to examine their own presumptions.

WED-S20-P03

Session: Minors I · **Room:** R.007

The Common Good Constitutionalism Perspective on Pediatric Primary Care Law: A Comparative Study of Taiwan's Designated Physician System for Young Children and the United States Legal Framework

Assistant Professor Tzu-Yu Chiou
Hsuan Chuang University, Hsinchu, Taiwan

Early childhood healthcare governance raises fundamental questions about the state's affirmative obligation toward its most vulnerable members. Taiwan's Ministry of Health and Welfare piloted the Designated Physician for Young Children program in 2020 and extended it nationwide in 2023, assigning each enrolled child a personal physician responsible for well-child visits, immunizations, developmental surveillance, and referrals at no cost to families. Despite its nationwide reach, the program operates solely as an administrative scheme without statutory basis, rendering it susceptible to unilateral revision or abolition. The 2023 Kai-Kai case — in which a fourteen-

month-old boy was fatally abused in foster care despite qualifying for the program — further exposed critical institutional gaps across health, social welfare, and cross-agency reporting networks, intensifying demand for systemic legislative reform.

This article asks whether Taiwan's current administrative framework for early childhood healthcare satisfies the state's constitutional obligations toward young children, and what legal reforms are required to fulfill those obligations, examined through comparative analysis with the United States federal pediatric care framework.

This article employs Common Good Constitutionalism (CGC), as formulated by Harvard Law School Professor Adrian Vermeule, as its normative analytical framework. CGC conceives of law as a reasoned ordering toward the common good, asserting that the state bears an affirmative duty to actively secure the conditions of human flourishing rather than merely refrain from interference. Against this framework, the article conducts a comparative legal analysis of Taiwan's administrative program alongside the United States federal pediatric care regime, encompassing the Affordable Care Act, Early and Periodic Screening Diagnosis and Treatment (EPSDT) provisions, and Medicaid pediatric funding structures.

The analysis reveals three structural deficiencies in Taiwan's current framework. First, the absence of a statutory basis violates the principle of statutory reservation, as matters implicating the fundamental rights to life and health cannot be adequately secured by executive programs alone. Second, Taiwan's 2014 CRC Implementation Act confers domestic legal force on Article 24's guarantee of the highest attainable standard of child health — a standard that an administrative program imposing no binding obligations on providers or local governments cannot satisfy, rendering the gap between treaty commitment and legislative action a constitutional failure. Third, the United States experience demonstrates that reliance on administrative discretion and decentralized implementation produces deep geographic inequalities in pediatric coverage and the systematic exclusion of lower-income children — a cautionary trajectory Taiwan risks replicating.

CGC demands legally enforceable assurance, not administrative aspiration, for children in the first three years of life. Taiwan's Legislative Yuan should enact dedicated legislation providing a statutory basis for the Designated Physician program, mandating enrollment of children from vulnerable families, imposing binding physician reporting obligations, establishing cross-agency data integration, and guaranteeing sustained public funding — transforming early childhood healthcare from an administrative benefit into a legally cognizable right, and fulfilling the affirmative constitutional duty that Common Good Constitutionalism requires.

WED-S20-P04

Session: Minors I · **Room:** R.007

Mapping the Legal Position of Minors in Healthcare Across Europe

Marie Goemaere¹, Professor Steven Lierman², Professor Ingrid Boone²

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Background

Medical decision-making involving minors constitutes a legally and ethically complex field at the intersection of health law, children's rights, and family law, where the child's autonomy, parental responsibility, and professional medical duties must be carefully balanced. 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 substantially in how they regulate the legal position of minors in healthcare, each reflecting a distinct balance between autonomy and protection. At present, no up-to-date and comprehensive overview exists of how European countries regulate consent, confidentiality, and parental involvement in healthcare for minors.

Research Question

This presentation addresses the following research question: how is the legal position of minors in medical decision-making regulated across European jurisdictions, and what similarities, differences, and broader regulatory patterns emerge from a comparative analysis?

Methodology

It is based on an extensive comparative legal study covering 20 European countries, conducted through a questionnaire completed by national legal experts. The questionnaire addressed various aspects of minors' healthcare decision-making, including the rules governing

consent to medical treatment, the assessment of decision-making capacity, and confidentiality. It further examined how the legal position of minors is regulated in specific legal frameworks applicable to particular types of medical decisions, such as sexual and reproductive healthcare, mental health treatment, end-of-life decisions, and cosmetic procedures. The collected data were analysed using a systematic comparative mapping approach.

Results

The findings reveal a highly fragmented European regulatory landscape. Although all jurisdictions recognise that minors should be involved in healthcare decision-making, they operationalise this involvement through markedly different legal models. Some legal systems rely primarily on the age of majority, while others adopt more flexible frameworks based on individual assessments of decision-making capacity, or combine age limits with presumptions of decision-making capacity.

Conclusions

By offering a structured comparative overview, this presentation demonstrates how shared children's rights principles translate into divergent legal solutions across Europe. The findings highlight key points of convergence and divergence and provide a foundation for further discussion on best practices, legal coherence, and the evolving role of minors in healthcare decision-making.

SESSION WED-S21 · TRACK 7 · 15:30 – 17:15

Neurotechnologies · Room R.008

Moderator: Timo Istance

WED-S21-P01

Session: Neurotechnologies · **Room:** R.008

The Hacked Mind: Comparative Liability Frameworks for Malfunctioning Brain Devices

Dr. Mariya Georgieva Sharkova PhD

University of National and World Economy, Sofia, Bulgaria

Background

Invasive Brain-Computer Interfaces (BCIs), pioneered by various companies, are rapidly transitioning from experimental trials to clinical reality for patients with severe neurological impairments. Those novel technologies promise new therapeutic outcomes and serve as a strong bridge between cognitive function and physical action in neurologically impaired patients. However, the boundaries of independent human control are getting blurred. As BCIs directly interface with neural pathways, they introduce new and unsettled legal dilemmas when a device stands between a thought and a physical outcome.

Research Question

In case an invasive BCI mistranslates a neural signal—or is compromised by malicious third-party hacking—resulting in a physical action that causes harm to a third party, what would be the legal responsibility and who is responsible for the damages? Who is liable: the patient (whose brain initiated the basic thought), the prescribing clinician, or the software developer?

Methodology

As there is no case law as of today, this legal vacuum could be addressed by a comparative study of three distinct regulatory and jurisdictional paradigms:

Results

The analysis shows that existing regulatory frameworks are not prepared to address the challenges posed by emerging neurotechnology. In the U.S., federal FDA preemption often insulates developers, potentially deserting possible victims of "hacked minds" without adequate legal redress. The EU offers stringent *ex-ante* compliance standards yet struggles to cleanly map statutory strict liability onto disrupted neural activity. Meanwhile, Chile's constitutional protections provide a strong normative baseline for cognitive liberty but currently lack the specific, actionable tort mechanisms required to adjudicate complex, multi-party BCI failures in civil courts.

Conclusions

Trying to forcibly impose traditional liability doctrines on the unique cases involving complex new technologies will neither protect patients nor the public. International legal systems urgently require a novel, tiered liability model specifically tailored to neurotechnology. This model

must fairly distribute risk among developers and medical providers, ensuring equitable redress for victims without impeding medical innovation or compromising the patient's right to cognitive liberty.

WED-S21-P02

Session: Neurotechnologies · **Room:** R.008

“Artificial” Cognition: Legal Considerations for Artificial Intelligence in Cognitive Assistive Technology

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Background

Artificial Intelligence (AI) has significant potential to transform the development and utilisation of assistive technology for persons with disabilities. An emerging topic in the field of medical and disability law is the regulation of such assistive technologies when they are used in the context of human cognition. Whereas the regulation of cognition focused AI systems and neurotechnology is of importance to all people, it is of particular importance to persons with disabilities, who have long faced discrimination and maltreatment based in part upon perceived lack of cognitive ability.

The United Nations Convention on the Rights of Persons with Disabilities (CRPD) offers broad protection of legal capacity, highlighting the importance for persons with disabilities to be supported in making decisions that reflect their personal wills and preferences. The EU AI Act directly recognises the risk of utilising AI systems that impair autonomy, decision-making, and free choice, and prohibits such systems when they cause or are reasonably likely to cause significant harm. However, the EU AI Act specifies that this prohibition does not apply to medical treatment, including psychological treatment, when used legally and with the consent of the individual or a legal representative.

Research Question

Acknowledging the rapid technological advancements that are presently occurring, the historic and ongoing discrimination persons with disabilities face, and the relative infancy of existing regulations, there is a vital and urgent need to explore the cohesion of existing legal frameworks and identify high-risk gaps. This presentation analyses the question of how the relevant components of the CRPD and the EU AI Act are, or are not, congruent with one another. It examines specific areas of high-risk, including the potential involuntary use of AI systems in medical or legal settings.

Methodology

Research for this presentation was conducted through an analysis of current doctrine and evaluation of existing literature.

Results & Conclusions

The outcome of this inquiry highlights the potential for persons with disabilities to both benefit and face harm through the use of cognition focused AI systems. Thus, comprehensive and forward-facing protections for persons with disabilities necessitate the rigorous application of existing disability legislation and the development of domestic AI regulations to work in concert with the EU AI Act.

WED-S21-P03

Session: Neurotechnologies · **Room:** R.008

Patients' Right to Be 'Oneself' in Law and Ethics of Neuromodulation

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Background

Neuromodulation technologies (e.g. deep brain stimulation (DBS), transcranial direct current stimulation (tDCS), and transcranial magnetic stimulation (TMS)) carry significant therapeutic promise for psychiatric and neurological conditions such as depression, schizophrenia, and epilepsy. As these technologies transition from experimental interventions to established clinical practice, they advance the right to health and broader public health goals. Yet their expansion raises questions about whether existing frameworks in medical law, human rights, and criminal justice are well equipped to respond.

Research Question

This paper focuses on one particular legal-theoretical question that lies at the heart of these emerging challenges: is the patient who is the subject of continuous neurotechnological intervention the same person who originally consented to it? Specifically, the paper asks whether traditional understandings of personhood and related concepts such as personal identity and psychological continuity are adequate to recognize and remedy the novel challenges these technologies may produce.

Methodology

Drawing on biomedical and neuroethics, legal philosophy, and medical law, the paper first examines the theoretical underpinnings of natural personhood, in particular its Kantian, Cartesian, and Lockean inheritance, in which the mind is understood as the locus of autonomy, control, narrative identity, and self vis-à-vis the body. It then interrogates to what extent neuromodulation can change the 'mind' when it directly affects how information is processed and transmitted within the central nervous system. To structure this inquiry, the paper draws on Schechtman's conceptualization of narrative and numerical identity, focusing on cases in which narrative identity might shift during neuromodulation. It further distinguishes between application areas: whereas changes in personhood may be an intended goal in mental health applications, such changes typically appear as side effects in somatic health contexts.

Results

The paper demonstrates that neuromodulation simultaneously restores agency and autonomy while potentially changing what it means to have mental integrity and psychological continuity, thereby creating a tension in the protection of the human as the traditional legal subject. It identifies psychological continuity and narrative identity as legally recognizable interests, expressed in the right to be oneself, protected through personality rights, fundamental rights frameworks, and an expanded conception of bodily integrity.

Concluding Remarks

The paper reframes the challenges posed by neuromodulation not merely as clinical or data-protection issues, but as interdisciplinary challenges essential for ensuring that research and regulation of neurotechnology responsibly realize its therapeutic promise within a broader judicial and ethical framework.

WED-S21-P04

Session: Neurotechnologies · **Room:** R.008

Challenges and Opportunities of Advanced Neurotechnologies in the Treatment of Disorders of Consciousness: A Disability Law Perspective

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Background

Diagnosing, prognosticating, and treating patients with disorders of consciousness (DoC) remains profoundly challenging due to their limited ability to communicate and the absence of reliable behavioural markers of awareness or cognitive function. Recent advances in neuroimaging, neurostimulation, and brain-computer interfaces (BCIs) have begun to transform this landscape. These neurotechnologies (NTs) show significant potential for detecting covert consciousness, supporting recovery, and even enabling rudimentary communication with patients previously considered entirely unconscious. Beyond their clinical implications, these developments challenge long-standing assumptions about patients' capacities and create new possibilities for recognising and supporting them as autonomous individuals.

Research Questions

As NTs move closer to integration into clinical practice, they raise urgent ethical and legal questions concerning their responsible use. In this presentation, I outline key challenges from a fundamental rights and disability rights perspective. At a general level, I examine how the emergence of technologies capable of uncovering or restoring consciousness interacts with core principles of disability law, including autonomy, inclusion, and accessibility. More specifically, I address questions such as: To what extent do the right to autonomy (Article 3 Convention on the Rights of Persons with Disabilities) and the right to access assistive technologies (Article 26 CRPD) obligate clinicians to employ advanced BCI-based assessments to evaluate and operationalise a patient's potential to participate in their care trajectory? What are the implications for the right to supported decision-making

(Article 12 CRPD)? And under what circumstances might the use of sophisticated neurostimulation therapies become required under the duty to provide appropriate healthcare services to persons with disabilities (Article 25 CRPD)? By mapping these challenges, the presentation offers an overview of the opportunities and complexities associated with integrating NTs into the care of DoC patients, particularly regarding the exercise of their disability rights.

Methodology

The research presented is doctrinal in nature. It brings together insights from: i. medical and biotechnological literature; ii. primary and secondary legal sources relating to international disability law; and iii. neuroethical and bioethical scholarship.

Take-Away Message

The presentation highlights the opportunities and challenges NTs introduce for enabling DoC patients to exercise their fundamental disability rights, explicitly accounting for the technological and neuro-ethical complexities of this rapidly evolving field.

WED-S21-P05

Session: Neurotechnologies · **Room:** R.008

Neurorights, Freedom of Thought, and Civil Law Autonomy in Japan: Comparative Analysis of Constitutional and Private Law Protection in the Age of Neurotechnology

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Background

Rapid advances in neurotechnology—including brain-computer interfaces (BCIs), deep brain stimulation (DBS), and neural data analytics—challenge traditional legal distinctions between the internal mental sphere and externally observable conduct. While Chile has constitutionalized "neurorights" and the European Union addresses cognitive risks through data protection and AI regulation, Japan has not adopted neuro-specific fundamental rights. Instead, potential protection must be derived from existing doctrines, particularly freedom of thought under Article 19 of the Japanese Constitution and private law principles governing autonomy and consent. The Japanese legal framework therefore presents an important test case: whether established constitutional and civil law concepts can respond to emerging neurotechnological risks without creating new rights.

Research Question

This paper addresses three central questions: Can Article 19 (freedom of thought and conscience) be interpreted to include neural data and technologically mediated access to mental processes? How do Japanese civil law doctrines—especially capacity, legal capacity, and informed consent—respond to neuro-interventions that may influence cognition or volition? Does Japan require explicit neurorights legislation, or can doctrinal reinterpretation within existing law provide sufficient protection?

Methodology

The study employs doctrinal legal analysis of Japanese constitutional and civil law, drawing upon academic literature, legislative materials, and case law concerning freedom of thought, autonomy, and medical consent. It further adopts a comparative law approach, examining Chile's rights-innovation model and the European Union's regulatory-integration model. The analysis focuses on structural differences in how legal systems conceptualize mental integrity and respond to neurotechnological developments.

Results

The analysis reveals that Japanese law contains a dual normative structure capable of addressing neurorights concerns. Article 19 has long been interpreted as safeguarding the inviolability of the inner mental sphere. A principled reinterpretation supports extending this protection to neural data where such data reveal or reconstruct mental content. Simultaneously, Japanese civil law protects self-determination through doctrines of capacity and informed consent. Neuro-interventions that alter cognition or influence volition may undermine the validity of juridical acts and medical consent, thereby activating existing private law safeguards.

Comparatively, Chile represents a constitutionalization model, creating explicit mental integrity rights, while the EU integrates cognitive protection through regulatory frameworks. Japan offers a third pathway: strengthening pre-existing constitutional freedoms and civil law autonomy rather than proliferating new rights categories.

Conclusions / Take-Home Message

Japan does not require constitutional amendment to address neurorights challenges. Instead, three doctrinal developments are necessary: (1) recognition that neural data fall within the protective scope of freedom of thought; (2) heightened consent standards for cognitively transformative neuro-interventions; and (3) integration of mental integrity into civil law capacity doctrine and medical liability standards.

The Japanese model demonstrates that neurorights need not be framed solely as new fundamental rights. Effective protection of mental integrity can emerge through coordinated development of constitutional interpretation and private law autonomy, offering a coherent and institutionally stable contribution to the global neurorights debate.

POSTER-AM-01

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Entrusted Services (JASTIP) through Social Media and the Prescription Drugs in Indonesia

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In an era of increasingly integrated social media and lifestyles, the phenomenon of Entrusted Services (JASTIP) has transformed from a simple interpersonal service into a massive cross-border distribution channel. Initially dominated by fashion and cosmetic products, this practice has now expanded into a far more sensitive area: the distribution of prescription drugs. This article examines how jastip has become a new loophole in Indonesia's drug monitoring system, as well as its impact on society and the accompanying regulatory challenges. In Indonesia, the distribution of prescription drugs is strictly regulated by Law Number 17 of 2023 concerning Health and various derivative regulations from the Food and Drug Monitoring Agency (BPOM). Every drug in circulation must have an official distribution permit and can only be obtained with a doctor's prescription. However, jastip operates outside this framework: drugs are purchased from pharmacies in other countries, brought in privately, and delivered to the customer without BPOM verification, a doctor's prescription, or any guarantee of safety. This phenomenon has at least two significant impacts. First, from a public health perspective, self-medication practices pose a high risk, as customers consume prescription drugs without a valid medical diagnosis and without guarantees of product authenticity. Second, from a legal and oversight perspective, jastip creates a "blind spot" in the drug distribution chain. Its sporadic, individual-based nature, and its use of passenger arrival routes make it difficult for authorities such as the BPOM (Food and Drug Monitoring Agency) and Customs to effectively monitor and enforce them.

Using a normative-descriptive approach to health regulations and a case study of JASTIP practices on social media, this paper argues that JASTIP for prescription drugs is not simply an administrative violation but a real threat to the national pharmaceutical resilience system. This practice not only undermines the state's authority to protect its citizens from illegal drug trafficking but also opens the door to the potential for wider abuse of prescription drugs. This article recommends strengthening synergy between regulatory agencies, increasing public digital literacy about the dangers of drugs without distribution permits, and re-evaluating domestic drug pricing and availability policies to discourage people from seeking risky alternatives through jastip.

POSTER-AM-02

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Legal Guide for Healthcare Workers as an Interdisciplinary Approach to the Prevention of Medico-Legal Disputes

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Background

In Kosovo, medical professionals are increasingly confronted with legal and ethical challenges related to the exercise of their duties. The growing awareness of patients, the development of legislation, and increased public attention to medico-legal issues emphasize the legal responsibility of healthcare workers. Based on my professional experience as former Head of the Legal Unit at the General Hospital in Peja, and currently in my capacity as an attorney, it is evident that many legal disputes are linked to insufficient legal knowledge among medical staff and the lack of structured mechanisms for legal education within healthcare institutions. This situation demonstrates the need for a more organized and interdisciplinary approach to addressing this issue.

Research Question

Can a structured legal guide serve as an effective tool for increasing the legal awareness of healthcare workers and preventing violations and medico-legal disputes?

Methodology

The study has an exploratory character and is based on interviews and questionnaires conducted with 100 healthcare professionals (40 doctor and 60 nurses), with the aim of assessing their level of legal knowledge and identifying the need for structured legal education. It also relies on the analysis of medico-legal cases derived from my professional experience. The findings served as the foundation for the development of the document "Legal Guide," which aims to clearly summarize the duties, responsibilities, and rights of healthcare workers in the exercise of their profession, in accordance with national legislation and international principles.

Results

The findings from the questionnaire indicate that healthcare workers' legal knowledge regarding their duties and responsibilities is limited and requires improvement through structured education. Nearly all interviewed medical staff agree that there is a clear need for the development of a legal guide as a practical tool to enhance legal awareness and prevent medico-legal violations, thereby evidencing broad institutional acceptance of the importance of such a document.

Conclusions

The integration of legal education into healthcare practice is essential for reducing professional risks, preventing medico-legal disputes, and improving the quality of services. The legal guide represents an interdisciplinary approach that enhances institutional cooperation between the legal and medical fields, contributing to the creation of a safer and more professional healthcare environment.

POSTER-AM-03

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Cholecystectomy Related Complaints: A 20-year Review of the Canadian Medicolegal Experience

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INTRODUCTION

Cholelithiasis is a common problem amongst adults, with 1-3% becoming symptomatic. Laparoscopic cholecystectomy remains the standard of care for symptomatic patients, and is one of the most commonly performed procedures by general surgeons in Canada. Significant post cholecystectomy complications are rare, but can have devastating consequences on patients, surgeons, and the healthcare system. This is especially true for common bile duct injuries (BDI). This study aims to provide a 20-year review and examine trends in Canadian medicolegal data related to post-cholecystectomy complaints.

Methodology

This is a 20-year retrospective review of the Canadian Medical Protective Association (CMPA) repository of cases involving cholecystectomy related complaints between 2003-2022. Cases included all those in which the physician contacted the CMPA for assistance, and included civil legal actions, medical regulatory (College) complaints, and hospital level complaints. Data analysis was limited to descriptive statistics using SAS software.

Results

A total of 488 complaints were closed during the study time period, with 175 cases involving BDI. There was a trend of decreasing complaints during the study period. The majority of patients were female (66%), and generally healthy (ASA I/II-73.6%). The top 5 complications leading to complaint initiation were BDI (35.9%), leak (15.2%), bowel injury (12.7%), sepsis (10.9%), and hemorrhage (10.2%). A total of 555 members were involved, with 484 operating surgeons named in complaints. Most surgeons were ³ 11 years in practice (70%). The mean time from incident to case closure was 63.2±42.3 months. BDI were more likely to result in a favourable medicolegal outcome for the patient (77%) compared to other complications.

Conclusions

This study demonstrates that in the Canadian medicolegal landscape, the majority of post cholecystectomy complaints involved generally healthy female patients. Unsurprisingly, BDI was the most common complication resulting in a complaint and was more likely to result in a successful claim. Surgeons later in practice were more likely to be named in a complaint in comparison to those who are early in their careers. There are significant delays from event incident to resolution, which places a burden on the impacted patient, surgeon, and the medicolegal system.

POSTER-AM-04

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Cognitive Bias, Empathy, and AI Decision-Making: A Medico-Legal Assessment of Human and Algorithmic Responsibility in Clinical and Legal Contexts

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Background

The increasing integration of artificial intelligence (AI) into decision-making processes in healthcare and legal systems raises important medico-legal questions regarding responsibility, bias, and accountability. Both human decision-makers and AI systems are influenced by cognitive factors such as bias, empathy, and risk perception. While human decisions are shaped by neurocognitive processes, AI systems rely on data-driven learning algorithms that may replicate or amplify existing biases. From a medico-legal perspective, understanding how bias and decision-making patterns operate in both humans and AI systems is essential for ensuring fair outcomes, protecting patient rights, and establishing appropriate standards of responsibility within health legislation and legal practice.

Research Question

How do cognitive bias and empathy influence decision-making in human professionals and AI systems, and what are the medico-legal implications for responsibility and accountability in clinical and legal contexts?

Methodology

This study applies a mixed-methods approach combining empirical and computational analysis. A total of 285 lawyers participated in a structured survey consisting of 39 descriptive and open-ended questions assessing risk perception, empathy, and decision-making behavior. In parallel, AI models, including large language models and machine learning classification tools, were analyzed using WEKA algorithms to identify patterns in responses and clustering behavior. The study compares human cognitive responses with algorithmic outputs to assess similarities, differences, and implications for decision-making processes.

Results

The analysis demonstrates that human decision-making is significantly influenced by cognitive bias and empathy, particularly in relation to perceived risk and in-group/out-group dynamics. Lawyers showed increased empathetic responses in high-risk scenarios involving perceived proximity, while more detached responses were observed in out-group contexts. AI systems initially produced emotionally responsive outputs but demonstrated reduced variability and emotional expression with repeated queries. Machine learning clustering revealed distinct behavioral patterns between human and algorithmic responses. From a medico-legal perspective, both human and AI decision-making processes may introduce bias, potentially affecting fairness, transparency, and reliability in clinical and legal decision-making.

Conclusions

Both human and AI decision-making systems are susceptible to bias, but differ in the nature, consistency, and transparency of those biases. AI should be regulated as a decision-support tool requiring human oversight, with legal frameworks ensuring accountability, transparency, and bias mitigation. Understanding cognitive and algorithmic bias is essential for developing medico-legal standards that protect patient rights, ensure fairness in decision-making, and support responsible integration of AI into healthcare and legal systems.

POSTER-AM-05

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Courts as a Guardian of Human Rights? Dilemmas in the Judicial Review of Involuntary Hospitalization Cases

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Background

Involuntary hospitalization severely impacts patient rights and has thus drawn sharp criticism from the CRPD and numerous human rights groups. In light of the growing international emphasis on the rights of persons with disabilities, existing literature has proposed potential mechanisms to reconcile the competing demands of human rights protection, public safety, and therapeutic needs. However, empirical research remains scarce regarding how courts safeguard patient rights, prevent abuses of power by administrative agencies or hospitals, and the specific experiences of involuntarily hospitalized patients in navigating the judicial system.

Research Question

What role does the court play in adjudicating applications for relief regarding involuntary hospitalization? Can the court promote the rights and interests of patients subject to involuntary hospitalization?

Methodology

This empirical study collected 631 court rulings issued from 2009 to 2024 to analyze the basis and rationale behind the courts' decision-making in Taiwan. Additionally, interviews were conducted with two judges experienced in adjudicating applications for relief from involuntary hospitalization, and the quantitative and qualitative data were cross-analyzed.

Results

This study yields four major findings: (1) The access to justice for patients subject to involuntary hospitalization is significantly restricted; (2) Patients often misperceive the court hearings as criminal proceedings rather than as a mechanism for safeguarding their rights. (3) It is difficult for judges to establish a trusting relationship with patients due to a lack of mental health literacy and the constraints of formal legal procedures. (4) Lacking specialized knowledge of mental illness, judges are compelled to rely heavily on the clinical judgment of psychiatrists.

Conclusions

This study argues that involuntary hospitalization has a profound impact on patients' human rights. As guardians of human rights, courts must play a proactive role in both procedural and substantive aspects to fulfill the spirit of the CRPD to the greatest extent possible. From a Therapeutic Jurisprudence (TJ) perspective, this study examines the court's role in adjudicating applications for relief from involuntary hospitalization. It proposes normative goals for improvement and attempts to bridge the gap between TJ theory and the challenges of its practical implementation in civil law jurisdictions.

POSTER-AM-06

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Non-Discriminatory Treatment of Patients in Health Services by Justice-Based Hospitals

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Background

Healthcare is a fundamental human right mandated by the 1945 Indonesian Constitution and Law No. 17 of 2023 on Health, requiring non-discriminatory provision. However, discriminatory practices persist in Indonesian hospitals, particularly based on socio-economic status, such as Social Security Administrator Health insurance classes, leading to disparities in service quality between wealthy/general patients and poor/ Social Security Administrator (BPJS) patients. This creates inequities in access, comfort, and medication, violating principles of justice and human rights protection.

Research Questions

1. What is the philosophical basis for the principle of non-discrimination against patients in Indonesian health services? 2. How is non-discriminatory treatment implemented in health services by Indonesian hospitals based on justice? 3. What efforts can minimize such discriminatory treatment in the future?

Methodology

This study employs normative legal research with legislative and conceptual approaches. Data sources include primary (laws and regulations), secondary (legal literature), and tertiary (dictionaries and encyclopedias) materials. Qualitative analysis is conducted using justice theory (John Rawls), legal system theory (Lawrence M. Friedman), and public service theory. A comparative analysis with Malaysia's healthcare system is included to highlight best practices.

Results

Philosophically, non-discrimination is rooted in social justice and human rights. However, norm conflicts exist: regulations prohibit discrimination, yet technical policies establish facility classes differentiating comfort and drug access. In practice, BPJS patients face stigmatization, longer waits, and inferior services due to economic disparities. A comparison with Malaysia shows that professional management, fiscal policies (such as tax exemptions on medicines), standard treatment rooms (maximum of two patients per room), Early Cancer Detection (Pap Smear Tests for Cervical Cancer), Pre-marital Cancer Tests (Thalassemia, Hemophilia, Leukemia Tests), and doctors who are fully committed to one hospital can significantly reduce cancer patient care costs and service gaps. The implementation of the principle of fairness in health services in Indonesia has not been optimal due to differences in treatment based on economic ability.

Conclusions

It is necessary to strengthen regulations through a truly inclusive Standard Inpatient Class (KRIS) program, apply good governance principles, and increase the professionalism of health workers so that every patient receives the same rights regardless of their socioeconomic status. Early Detection and Cancer Testing (Pre-Marital Early Detection and Testing) prevents an increase in cancer treatment costs. This effort is expected to minimize discrimination, increase patient satisfaction, and reduce the tendency for people to seek treatment abroad.

POSTER-AM-07

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Controversies of the Beginning and End of Life in the Light of the Right to Abortion and Euthanasia. Do we Have a Right to Choose?

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Introduction

Abortion and right to abortion, as well as euthanasia represent the two biggest ethical, medical, legal and even philosophical dilemmas in Medical Law. For both, there are decades - long conflicts and opinions for or against, and it is not enough only for the patients decision, but also for adequate legal regulations, which are often not in accordance with what the patients would like.

Aim

of study: Analyze all the aspects that would go in favor of the right to choose an abortion in accordance with the law of the country in which the women lives, with processing and dilemma of whether the fetus in addition to the right to be born, has the right to be unborn. And when it comes to the end of life, whether euthanasia could be the free will of each individual and right to decide on euthanasia, and in accordance with that, attempts at legal regulations for this procedure.

Discussion

The right to abortion always causes many controversies between those who put the mother first and those who lead a prolife policy, believing that fetus has right to be born. in this paper we open the topic of whether a fetus has the right not to be born, especially if it is a fetus that has physical abnormality. All religious communities are against abortion and euthanasia. However, their argument about sanctity of human life can be questioned because an embryo in early pregnancy cannot have feeling, thoughts, or awareness of the future. When it comes to euthanasia, we do not believe that it is abandoned and allowed, solely for sake of staying alive, he agreed to its extension at cost of being tied to bed and devices in some medical institution. In the context of the right to decide on the choice of euthanasia, the latest case of "Noeila" from Spain opens up the question of personal autonomy in deciding on

ones own death, for which the court in Starsbourg had to make the final decision.

Conclusions

We are of the opinion that a women has the right to her own decision to perform an abortion in cases of unwanted pregnancy, as well as a high termination, and even feticide in second and even feticide in the third trimester of pregnancy in the case of diagnosing severe anomalies of the fetus within the legal framework of the country in which she lives. Euthanasia as a decision to end life for people who are mentally healthy, but terminally ill, should exist. As a possibility, right and autonomy for the individual to decide without the interference of family and the community for the end of life with the help of euthanasia, provided that it is legally allowed in the country where he lives. Because if we dont decide to come into this world, we should have autonomy to decide to leave it in a dignified way if we think it is acceptable to us. Nevertheless, dilemmas of the beginning and the end of life will continue.

POSTER-AM-08

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Corporate Legal Liability for Medical Negligence in Hospitals

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Background

Healthcare services in hospitals often present dilemmas regarding the legal responsibilities that must be fulfilled in medical disputes resulting from medical negligence in hospitals. The practice of legal liability for negligence committed by hospitals as corporations is not yet fully clear in Indonesia, often giving rise to legal debate. One of the main issues that arises is how legal liability is defined from a corporate civil law perspective, particularly in the hospital context. The importance of analyzing corporate legal liability for medical negligence against hospitals from a civil law perspective is increasingly relevant, given the increasing number of cases holding hospitals liable.

Research Question

What are the legal indicators and boundaries of 'Vicarious Liability' and 'Direct Corporate Liability' in determining a hospital's accountability for negligence committed by medical practitioners under Indonesian Civil Law?

Methodology

This paper is written based on a normative juridical research method that uses law as a normative basis with analytical prescriptive research.

Results

Hospitals hold a significant position in legal liability for medical negligence, both in terms of supervision of doctors and in meeting required health service standards. Hospitals can be held liable for negligence by doctors, either directly or through the principle of vicarious liability. This liability requires a legally binding doctor-hospital agreement, which does not apply to matters beyond the control of hospital management. Regardless of the type of relationship pattern between doctors and hospitals, doctors are a profession that has independence and autonomy in carrying out their profession and applying their knowledge.

Conclusion/Take-Home Message: This provides patients with assurance that the hospital and doctor are obligated to provide safe services in accordance with required professional standards.

POSTER-AM-09

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Trends in Professional Conduct Complaints and Review Decisions within a Canadian Medical Regulator

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Background

Some medical regulatory authorities in Canada are experiencing sustained increases in professional conduct complaints, placing

growing demands on statutory decision-makers operating within administrative law frameworks. Complaints directors and review bodies exercise broad delegated discretion at the front end of the disciplinary process, where principles of procedural fairness, proportionality, and reasonableness must be balanced against institutional capacity and public protection mandates. Recent increases in complaint volume appear to be driven less by changes in physician conduct than by structural developments affecting administrative decision-making, including enhanced regulatory transparency, increased public awareness of oversight mechanisms, and the introduction of digital complaint submission tools. In Alberta, the launch of an online complaints portal has reduced procedural and practical barriers to filing complaints, contributing to increased complaint volumes and reshaping the intake function within the regulatory process. This presentation examines how these trends manifest in complaint outcomes and review decisions within the Professional Conduct and Hearings Director's Office of the College of Physicians and Surgeons of Alberta.

Methodology

A retrospective descriptive analysis of Professional Conduct complaints received and resolved in 2024 was conducted, alongside a review of CRC requests and outcomes administered through the Hearings Director's Office. Complaint volumes, disposition pathways, investigation rates, referrals to hearing, and CRC decision outcomes were analyzed using operational data from the 2024 reporting year.

Results

In 2024, 1,543 new complaint files were created. This represents a 77.9% increase from 2023, when 867 complaints were received, and a 112.8% increase from 2022, when 725 complaints were recorded. Despite this sharp rise in volume, complaint disposition patterns remained stable. Approximately 49% of complaints were dismissed at an early stage, 25% were triaged for expert opinion, 16% proceeded to formal investigation, and 10% were resolved through early consensual resolution. Only 1-2% of complaints were referred for disciplinary hearing or legal proceedings.

Requests to review dismissed complaints increased in parallel. In 2024, 97 complainant-initiated CRC review requests were submitted. CRC decisions upheld the Complaints Director's dismissal decision in the majority of cases, issuing 123 decisions confirming reasonableness. Sixteen matters were returned for further investigation, and no matters were referred directly to hearing. Hearing activity remained limited, with 22 hearing tribunals convened, all resulting in findings of unprofessional conduct on at least one allegation.

Conclusions

The experience in 2024 reflects a pattern of rising complaint volumes, while outcomes remain relatively stable and only a small proportion of matters proceed to formal discipline. Increased complaint numbers appear driven more by accessibility, awareness, and cultural shifts toward accountability than by changes in physician conduct. Robust triage, expert screening, and independent review processes are essential to sustaining regulatory proportionality and credibility as complaint volumes continue to grow within modern medical regulatory systems.

POSTER-AM-10

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Legislation, Education, and Practice Triangle in Advance Care Directives with a Culturally Responsive Approach

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Background

Advance directives (AD) are living wills given by patients, which help healthcare workers to practice according to their will. They make patients active participants in their care and reduce unnecessary distress for both their families and healthcare workers. Promoting the use of ADs helps to achieve a gentle and more respectful palliative care experience for all parties involved.

Research Question

To ensure a culturally sensitive advance directive framework, this article analyzes the necessary legislative support, educational outreach, and practical steps required for its integration.

Results

Efforts to increase AD completion tend to think of this process linearly. Where sound laws will set the ground for better education, and this will translate to increased AD usage.

However, this linear approach fails when we examine the AD completion rates in countries with similar legislation. Germany and Spain, for example, have similarly binding AD laws but vastly different comparison rates, favoring Germany. This is true even when Spain had a 7-year head start on AD laws. The completion rates become more problematic in countries where, unlike Spain and Germany, the alignment between international and national AD laws isn't that robust. The misalignment in legislation creates a grey area where physicians have to walk the line between honoring their patients' wishes and complying with the regulations carefully. Although academic studies show that healthcare workers who are educated on this topic are more comfortable with assisting patients with ADs, completion rates are still low owing to the lack of regulations in some areas.

AD laws and curricula risk being idle systems in the healthcare conversations if they are not implemented through a culturally sensitive lens. We should be aware of the general culture we are practicing and educating in, but we should also keep in mind that cultures are not a monolith and contain multitudes of individual and different group perspectives. Especially Western dominant conversations regarding AD put patient autonomy in the forefront of care planning, and this creates the illusion that cultures subverting from this "norm" give less value to autonomy. This ignores the idea that communal decision-making is not a restriction of patients' autonomy but an extension of that. Educational models hold a vital position in this step through not just the inclusion of healthcare professionals and patients, but society at large, which shapes the culture dynamically.

Conclusions

This study argues that the road to better AD practice is paved by a triangular approach where legislation, education, and practice operate in a fine-balanced system where they both affect and are affected by each other, and cultural ethical norms are bridging the gaps between them. This triangular approach may lead to better AD practice, which lies in creating responsive, tailored educational modules that are organically adoptable to professionals operating under different legislative and cultural contexts.

POSTER-AM-11

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Criminal Liability and the Path of Causal Determination in AI-Integrated Healthcare: Addressing the "Black-Box Problem" and the Accountability Gap

Bachelor of Laws Sing-An Pan Bachelor Degree, Assistant Professor IJou Lin PhD

Chung Yuan Christian University, School of Law, Taoyuan City, Taiwan

Background

The rapid integration of Artificial Intelligence (AI) into healthcare has fundamentally transformed traditional medical decision-making and physician-patient relationships. AI systems are no longer limited to auxiliary roles but increasingly participate in clinical diagnosis and treatment planning, particularly in areas such as Clinical Decision Support (CDS) and Software as a Medical Device (SaMD). While these developments enhance efficiency and precision, often supported by Real-World Data (RWD), they also challenge existing legal frameworks, particularly in the field of criminal liability. Traditional doctrines based on physician negligence are insufficient to address the opacity of AI decision-making (the "black-box problem"), the multiplicity of actors involved (the "Problem of Many Hands"), and the complexity of causation in AI-assisted medical incidents. Consequently, significant uncertainty arises in determining responsibility when medical harm occurs, giving rise to a potential accountability gap.

Research Questions

This study seeks to address several critical inquiries:

1. Whether AI-assisted medical activities should be legally classified as "medical practice" and the potential for AI systems to be analogized to juridical persons in liability attribution.
2. The impact of AI on the determination of criminal negligence, specifically regarding the physician's duty of care and the standard of foreseeability when AI recommendations deviate from established medical standards.
3. The establishment of causation where multiple factors—such as algorithmic design, training data bias, and physician reliance—jointly contribute to harm.

In addressing these questions, the study examines four major risks: the black-box effect, shifts in power structures that undermine patient autonomy, risks to informational privacy, and the emergence of algorithmic bias and discrimination.

Methodology

Adopting a combined approach of literature analysis and comparative legal research, this study reviews Taiwan (R.O.C.)'s current precedents on medical negligence, informed consent, and the theory of proximate causation. It further benchmarks international frameworks, specifically the European Union's Artificial Intelligence Act (AI Act) risk-classification system and U.S. FDA regulatory standards for AI-based medical devices.

Concluding Remarks

The findings indicate that the introduction of AI significantly destabilizes the traditional framework for determining criminal liability. The "black-box" nature of AI limits transparency, making it difficult to trace decision-making processes and establish causal links between actions and outcomes. Moreover, the coexistence of multiple causal factors leads to fragmented responsibility, creating a potential "accountability gap" or an unfair concentration of accountability on practitioners. To respond to these challenges, this study proposes a "multi-layered accountability framework" that allocates responsibilities among AI developers, healthcare providers, and regulators. It also advocates for enhanced AI explainability requirements and the introduction of supplementary mechanisms, such as no-fault compensation schemes, to balance technological innovation with the protection of patient rights and the realization of criminal justice.

POSTER-AM-12

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Reframing Vaccine Injury Compensation: Risk Governance and State Responsibility in Taiwan

Professor Shin-Rou Lin PhD

Chang Gung University, Taoyuan, Taiwan

Background

Taiwan's Vaccine Injury Compensation Program (VICP), established in 1988, was initially grounded in product liability. Over time, with the expansion of vaccine coverage and compensable injuries, it has progressively evolved into a state-centered risk allocation mechanism with features of a social welfare-oriented compensation scheme.

Research Question

This study investigates whether the current reliance on the "special sacrifice" doctrine provides an adequate constitutional foundation for vaccine injury compensation in Taiwan, and how vaccine-related risks—including the increasingly lenient eligibility criteria for compensation—should be normatively allocated.

Methodology

The analysis draws on a doctrinal examination of compensation practices—particularly those following mass COVID-19 vaccination—combined with judicial decision analysis of HPV vaccine litigation. It further engages constitutional principles, including the doctrine of special sacrifice, state duty to protect fundamental rights, and theories of risk allocation and social solidarity.

Results

The findings indicate that Taiwan's VICP has effectively developed into a no-fault compensation scheme in which uncertainty of causation is largely borne by the state. In practice, compensation requirements have been progressively relaxed, allowing claims to succeed even in the absence of conclusive scientific evidence. Judicial application of the special sacrifice doctrine has reinforced this trend by adopting a causation standard that favors compensation unless causation can be definitively excluded. This approach extends beyond the doctrinal limits of special sacrifice and insufficiently accounts for the non-mandatory nature of vaccination.

Conclusions

This article argues that vaccine injury compensation should be reconceptualized within a framework of state risk responsibility. While grounded in fundamental rights protection and social solidarity, such a framework should aim to secure a minimum threshold of livelihood and human dignity. The relaxation of compensation criteria may be justified as a tool of risk distribution, but it should be normatively bounded to avoid transforming the system into one of unconditional compensation.

POSTER-AM-13

Session: Poster Session I · **Room:** Patio K.001 (Aula)

Radiologists' Perspectives on Legal, Ethical, and Practical Challenges of AI in Diagnostic Imaging

Prof. Dr. Gábor Kovács Medical doctor (MD), lawyer (LLB), specialist in forensic medicine, PhD in Law (criminal sciences), Dr. Orsolya Ágota Tamás Law
Széchenyi István University's Doctoral School of Law and Political Sciences, Győr, Hungary

Background

Human-machine collaboration (cognitive infocommunication) has advanced significantly in recent years. Artificial intelligence (AI) systems are increasingly integrated into medical practice, particularly in radiology.

Research Question

This study investigates physicians' perspectives on the use of AI in radiological diagnostics, focusing on legal liability, regulation and authorization, system transparency, licensing, bias and discrimination, and the boundaries of clinical application.

Methodology

A representative social science study was launched on January 1, 2026, using a structured questionnaire survey among radiologists in Hungary.

Results

A total of 84% of respondents reported using AI-based diagnostic systems. However, 96% believe these systems are not suitable for independent diagnosis. All respondents (100%) identified bias as a significant concern and recommended independent auditing as a solution. Most respondents (84%) did not inform patients about the use of AI, and 64% did not consider such disclosure necessary. Half of the respondents (50%) attributed responsibility for diagnostic errors to physicians, while 48% believed that AI may reduce the risk of malpractice litigation. Furthermore, 67% stated that licensing-related ownership should belong to the institution, and 72% emphasized the need for continuous system updates. A majority (76%) expect AI systems to remain in a supportive role in radiology over the next five years.

Conclusions

The processing of incoming responses and a representativeness-focused analysis is still fully ongoing; however, preliminary results already indicate that the majority of radiology professionals use AI systems in diagnostics. At present, these systems are not considered suitable for performing diagnostic work independently. To avoid bias caused by AI systems, independent auditing is recommended. Most respondents omit informing patients about the use of AI systems, and half of them believe that physicians should be held responsible in the event of diagnostic errors. According to two-thirds of the doctors, licensing-related ownership rights should belong to the institution, and three-quarters believe that these systems will require continuous updates. Despite this, three-quarters of respondents also think that AI systems will play only a supplementary role in radiology over the next five years.

THURSDAY 6 AUGUST

SESSION THU-S01 · TRACK 1 · 11:00 – 12:30

AI in Healthcare III · Room R.014

Moderator: Vera Lúcia Raposo

THU-S01-P01

Session: AI in Healthcare III · **Room:** R.014

How Do Patients' Perception and Expectations of Use of AI in the Clinic Align with the Legal Framework?

Professor Mette Hartlev PhD, LL.D

Faculty of Law, University of Copenhagen, Copenhagen, Denmark

Background

Patients are already and will increasingly be exposed to the use of AI in connection with diagnostics, treatment, and care. However, there is only limited empirical knowledge of the perceptions and expectations of patients regarding the use of AI in clinical care.

Research Question

In the context of an ongoing international and interdisciplinary research project (WISDOM) concerned with the development and application of AI in the treatment of patients with multiple sclerosis (MS), one of the research questions and aims is to explore, how patients perceive, and which expectations they have, to the use of AI in their encounters with the health care services, with a view to ensure that the AI models developed in the project are aligned with patients interests and expectations. Another aim is to analyse, whether the existing legal framework can meet these interests and expectations.

Methodology

This has first been investigated through a comprehensive literature review regarding patient's perceptions and expectations of use of AI. Secondly, in collaboration with a partnering patient organisation, there is ongoing consultations with a community advisory board of MS-patients concerning their preferences regarding development of specific AI-tools to be used in connection with their treatment and care. The paper will present the preliminary results of the literature review regarding patient's perceptions and expectations of use of AI in the clinic together with the insights gained from continuous consultation with the group of MS-patients concerning their preferences regarding development of specific AI-tools in the project and an analysis of the legal framework.

(Preliminary) Concluding Remarks

Based on these insights it seems that a crucial point for patients is that there should be a "human in the loop" and that their health care provider should make the final decision regarding diagnostic and treatment. Another important message is to ensure the inclusion of patients in the entire life cycle of AI-models from the idea development to the application in the clinic (shared decision making), and subsequent evaluation. The paper will also critically discuss how patients' perceptions and expectations align with the overall legal framework, including patients' rights regulation, the GDPR, the EU AI-Act, the EU Medical Device Regulation, and the EHDS, and provide recommendations for how to adjust the legal framework to better meet patients' preferences and expectations. For this part preliminary results suggests that while there is some legal recognition regarding ensuring human oversight, user involvement and shared decision is poorly recognized in the legal framework.

THU-S01-P02

Session: AI in Healthcare III · **Room:** R.014

Artificial Intelligence in Healthcare: How Would the Creation of Human Digital Twins Benefit Human Health?

Dr., Emeritus Senior Lecturer Anne-Marie Duguet MD PhD^{1,2}, Noemie Dubruel PhD Candidate^{1,2}, Emmanuelle Rial-Sebbag PhD^{1,2}

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Background

The digital twin of a system is a reality, having proven its effectiveness in weather forecasting and in the aviation industry.

The prospect of creating digital twins of the human body has emerged as a tremendous development opportunity for the future of healthcare, justifying multidisciplinary research, fundraising, and media hype that goes hand in hand with the promises of artificial intelligence.

Human organs can be partially modeled based on clearly identified characteristics. The combination of digital twins with real-world simulations makes it possible to understand uncertainty and make predictions based on the analysis of large amounts of data, which is only possible thanks to digital tools and artificial intelligence.

Research Questions

1) What prospects does the human digital twin open up for healthcare? The human digital twin is "a dynamic virtual representation of human physiology or pathology, which uses mathematical models and algorithms to calculate the evolution of its physical counterpart."

A virtual human digital twin (VHT) could be created at different levels of human anatomy (cells, tissues, organs). The modeling of an organ will then be customized to be associated with a patient and interact as their physiology or pathology evolves. The potential of this technology will enable the development of targeted prevention, the provision of appropriate clinical pathways, and the planning of surgical procedures and their follow-up.

2) What research has been conducted, and what are the results?

To date, scientific literature shows that after numerous experiments, we are beginning to design and validate a few human digital twin applications. Analysis of its prospects is fueling extensive scientific, technical, ethical, and legal debate.

The European Union has facilitated collaborative research by strengthening computing capabilities with the MareNostrum5 supercomputer, which came into service in 2023. Seventy-five organizations in Europe have published a declaration of intent on the development of the VHT ecosystem in healthcare systems. The first experiments are promising, funded, supported, and implemented by prestigious research organizations.

In France, companies that have developed digital twins for industry have turned their attention to healthcare. This is the case for Dassault Systèmes, a partner in the MediTwin project, whose consortium, led by INRIA, brings together hospitals and start-ups and focuses on three areas: oncology, neurology, and cardiology. In another field, SymbiotX combines computational biology at the cellular level with fluid mechanics to create virtual patients for treatment simulation.

Conclusions

Human digital twins are not yet a reality, as there are still many technical obstacles despite more than 20 years of experimentation and research. However, the first drafts in biology and for the creation of a twin of heart are very promising for assistance in preventive surgery for heart rhythm disorders and the creation of virtual patients for pharmaceutical research.

THU-S01-P03

Session: AI in Healthcare III · **Room:** R.014

Predictive Medicine and the Limits of Anonymization: The Legal Status of Patient Digital Twins

Lucie Siroka

Department of Medical Law, Faculty of Law, Charles University, Prague, Czech Republic

Background

"Digital twins"—virtual replicas of patients based on multi-omic data, lifestyle tracking, and real-time sensors—are revolutionizing predictive medicine. However, their high level of personalization challenges traditional data protection frameworks, as true anonymization is practically impossible without compromising the model's clinical utility.

Research Question

How does the high degree of individualization and predictive capability of patient digital twins affect the legal status of such data under current privacy regulations, and can these models ever be considered "anonymized" in a legal sense?

Methodology

The study employs a normative legal analysis. It compares the technical requirements for digital twin functionality against the legal threshold for anonymization, which requires the permanent impossibility of re-identification.

Results

Digital twins function as "living" identifiers. Because they utilize high-dimensional data unique to the individual, the risk of re-identification is extremely high. Consequently, they rarely meet the legal standard for anonymization. Current regulations fail to address the nuances of these "pseudo-anonymous" models, creating a legal gap that complicates informed consent and secondary data usage.

Conclusions

Digital twins have outpaced static definitions of anonymization. To protect patient rights, legal frameworks must shift away from the fiction of "anonymity" and toward models centered on dynamic consent, purpose limitation, and rigorous stewardship and accountability for these virtual representations.

THU-S01-P04

Session: AI in Healthcare III · **Room:** R.014

From the Human Touch to the AI Touch: The Question of Medical Empathy in Doctor-Patient Relationship

Prof. Vera Lúcia Raposo PhD-Habilitation

NOVA School of Law, Lisbon, Portugal

Background

The doctor–patient relationship has never been static, continually reshaped by technological, social, and ethical change. The integration of AI into healthcare marks a new turning point, altering both the practice and perception of medical care.

Methodology

This presentation undertakes a normative and analytical exploration of how AI reconfigures the doctor–patient relationship. It draws on ethical and legal reasoning to examine two parallel dynamics: (1) the dilution of the direct human bond between doctor and patient through the delegation of clinical tasks to machines; and (2) the emergence of new relational models between patients and AI systems, particularly those capable of affective or adaptive interaction.

Results

The analysis reveals a dual tension. On one side, the increasing reliance on AI systems risks deepening the dehumanisation of medicine, undermining trust and empathy as the cornerstones of care. On the other hand, advances in affective computing and human–machine interaction introduce the possibility of a simulated form of empathy: AI systems capable of recognising biometric cues, modulating language and tone, and mirroring attentiveness. These developments challenge established notions of care, responsibility, and trust in the clinical setting.

Conclusions

AI's encroachment into the affective and relational dimensions of medicine compels a fundamental rethinking of what it means to care. The key questions are both ethical and legal: can machines be entrusted with roles grounded in human empathy, and should the law recognise any form of 'caring capacity' in entities that do not experience mortality or suffering? The answer must preserve human dignity without denying technological innovation. The future of healthcare will depend on finding an equilibrium between empathy, trust, and technology, ensuring that the digital transformation of medicine enhances, rather than replaces, its human core.

THU-S01-P05

Session: AI in Healthcare III · **Room:** R.014

The New Frontiers of Informed Consent in the Use of Artificial Intelligence in Healthcare

Lawyer/Physician Emine Neval Yilmaz MD, PhD, LL.M, PhD

Ankara Bar Association, Ankara, Ankara, Turkey

Background

The integration of Artificial Intelligence (AI) and Clinical Decision Support Systems (CDSS) into medical practice is transforming the traditional physician-patient relationship from a dyadic structure into a tripartite mechanism involving the physician, patient, and AI. This transition from digitalization to "algorithmic medicine" challenges the traditional legal frameworks of informed consent. The "black box" nature of deep learning algorithms creates "epistemic opacity," where the logical rationale behind a diagnosis may be inexplicable even to the physician, raising fundamental questions about patient autonomy and the validity of consent.

Research Question

How does the "black box" nature of AI affect the scope of the physician's duty to inform, and to what extent can patient consent be considered "informed" when the decision-making logic of the AI tool remains opaque?

Methodology

This study employs a doctrinal legal analysis of Turkish Health Law (including the Constitution, Oviedo Convention, and Patient Rights Regulation) and Data Protection Law (KVKK and GDPR), supported by a comparative analysis of US case law. Specifically, analogies are drawn from cases such as *Perna v. Pirozzi* (ghost surgery), *Johnson v. Kokemoor* (lack of experience), and *Moore v. Regents* (conflict of interest) to conceptualize AI as a "shadow decision-maker." The study further examines the distinction between "technical transparency" (access to code) and "legal explainability" (understanding the logic) within the context of algorithmic bias and automation bias.

Results

The analysis reveals that the traditional standard of disclosing only medical risks is insufficient for AI-driven medicine, which introduces "algorithmic risks" including data bias and lack of transparency. The study argues that patients have a "right to explanation" rather than mere technical transparency. Furthermore, physicians face behavioral risks such as "automation bias" and "defensive medicine," where they may blindly follow AI recommendations to avoid liability, effectively reducing their role to a procedural "rubber stamp."

Conclusions

To address these challenges, this study proposes a risk-based "Tiered Disclosure Model" (Ask, Tell, or Neither) tailored to the autonomy level of the AI tool. It is concluded that "AI literacy" must be established as a fundamental duty of care for physicians. To preserve patient autonomy, the "human-in-the-loop" principle must be legally guaranteed, ensuring that AI remains a consultant rather than a substitute for the physician's professional judgment.

SESSION THU-S02 · TRACK 2 · 11:00 – 12:30

End of Life III · Room R.201

Moderator: Evelien Delbeke

THU-S02-P01

Session: End of Life III · **Room:** R.201

Legal Robustness and Deliberation in Ireland's Assisted Dying Parliamentary Committee

Dr Siobhán M O'Sullivan PhD

Royal College of Surgeons Ireland, Dublin, Ireland

Background

A cross-party parliamentary Committee was established in 2023 to consider legislative and policy changes regarding a statutory right to assisted dying in Ireland. Over nine months, the Committee received 63 written submissions, held 24 public meetings, and engaged with 106 witnesses across medicine, law, ethics, disability, and lived experience. It ultimately recommended legislation permitting assisted dying in restricted circumstances for terminally ill adults, supported by rigorous safeguards and independent national oversight, across 38 recommendations.

Research Question

To what extent do the deliberative process and recommendations of the Committee provide a legally robust framework for assisted dying legislation in Ireland. This paper employs doctrinal legal analysis and procedural legitimacy assessment, critically examining the Committee's deliberative process and recommendations.

Results

Several aspects of the Committee's terms of reference (ToRs) shaped the deliberative process and outcomes. The ToRs required consideration of safeguards, unintended consequences, and constitutional, ethical and legal issues, as well as regard to a 2021 report which found prior legislation lacked sufficient safeguards. This produced a balanced but risk-focused debate, foregrounding concerns about coercion, vulnerability and implementation. The predominance of medical witnesses likely contributed to a clinical governance model, emphasising safeguards, clinical oversight and medicalised eligibility criteria.

Several procedural shortcomings are identified. The absence of a public call for submissions represents a significant gap and departure from best practice. Witnesses were selected by Committee members or the Secretariat without transparent criteria or explanation of how balance was ensured. There was also no systematic engagement with evidence quality or distinction between empirical and normative claims. Nonetheless, the inclusion of a full voting record in Appendix 4 enhances transparency by showing where consensus existed.

The recommendations themselves contain a number of gaps that weaken the report's capacity to serve as a legal framework. No coherent governing principle is articulated: autonomy, human dignity, and alleviating suffering are mentioned but appear to have limited influence on eligibility criteria, which are firmly grounded in terminal prognosis. Procedural gaps include an unspecified interval between two formal requests, unclear mechanisms for suspension and reinstatement of eligibility following loss of capacity, absence of an appeal process, and no cost analysis, representing a significant operational omission.

Conclusions

The report does not constitute a legislative blueprint, it does, however, provide a structured policy framework that could inform and guide the development of future assisted dying legislation in Ireland.

THU-S02-P02

Session: End of Life III · **Room:** R.201

Decisional Capacity Judgment for Medical Assistance in Dying on Psychiatric Grounds in Young People

Arne van den Bosch BSc¹, Willemijn L.T. Krugers Dagneaux LLM², Denise J.C. Hanssen PhD¹, Richard C. Oude Voshaar MD, PhD¹, Radboud M. Marijnissen MD, PhD¹

¹Department of Psychiatry (CC11), University Medical Center Groningen, Groningen, Netherlands. ²Faculty of Law, University of Groningen, Groningen, Netherlands

Background

Medical Assistance in Dying (MAID) is regulated in the Netherlands by the Termination of Life on Request and Assisted Suicide Act. It states that MAID is not punishable if the physician acts in accordance with the due care criteria. Physicians are legally required to establish that a MAID request is voluntary and well-considered, implying decisional capacity. The requirement of decisional capacity is particularly challenging when the patient has a psychiatric disorder. How decisional capacity is assessed in psychiatric MAID cases, particularly among young people, remains unclear.

Research Question

Which factors, and how, influence the judgment of decisional capacity regarding a request for Medical Assistance in Dying (MAID) on psychiatric grounds in people under 30 years?

Methodology

A qualitative study -using the grounded theory approach- of all publicly available anonymized case reports (N=18) of individuals <30 years who received MAID on psychiatric grounds in the Netherlands. Reports were summaries of MAID cases published by the Dutch Regional Euthanasia Review Committees between 2012 and 2025. Two researchers independently coded the reports and developed themes through iterative comparison and team discussion.

Results

All 18 case reports mentioned assessment of decisional capacity, though the level of detail varied widely. Six direct criteria influenced physicians' capacity judgment: consciousness, understanding, thinking, expressing a choice, substantiating a choice, and consistency of the MAID request. In addition, supporting and compromising factors shaped whether these criteria were deemed fulfilled. Supporting factors included high intelligence, the progress of the MAID request, and actions taken regarding MAID; compromising factors included low intelligence, young age, current mental state, physical sickness, and influence of others. An independent expert was consulted in all but one case. Explicit reference to formal frameworks (e.g., Appelbaum and Grisso criteria) was rare. Physicians differed in the factors they considered relevant to decisional capacity. Some reports showed indications of selective or stylized reporting.

Conclusions

In psychiatric MAID cases involving young people, physicians differ in the factors they used to assess decisional capacity. These assessments extend beyond formal clinical frameworks, incorporating contextual and subjective factors. These findings highlight the variability and complexity of capacity judgments in psychiatric MAID in young people, suggesting a need for clearer guidance, enhanced physician training, and ethical discussion about the acceptable degree of subjectivity in capacity assessments.

THU-S02-P03

Session: End of Life III · **Room:** R.201

When Patients Can't Decide: Medical Assisted Dying in Dementia

Dr Radboud Marijnissen MD PhD, Arne van den Bosch BSC, Dr Denise Hanssen PhD, Prof. Dr. Richard Oude Voshaar MD PhD

University Medical Center Groningen, Groningen, Netherlands

Background

Physician-assisted dying (PAD) in persons with dementia is one of the most contentious topics in medical law, ethics, and clinical practice. Patients face progressive cognitive decline, loss of social awareness, and the fear of institutionalization. While PAD offers a self-determined end-of-life option, dementia complicates traditional concepts of autonomy, voluntariness, and decisional competence. In the Netherlands—the first country to legalize euthanasia (2002) and among the few allowing PAD based on dementia—cases are increasing sharply, raising debate over whether the law can meaningfully safeguard autonomy when capacity diminishes. Critics argue that performing PAD in cognitively impaired individuals challenges fundamental ethical and legal norms, creating tensions between patient rights, professional discretion, and societal values.

Research Question

Which factors influence how physicians assess decisional competence in PAD requests from persons with dementia, and what broader lessons can inform legal, clinical, and ethical debates internationally?

Methodology

Sixty publicly available dementia-related euthanasia case summaries (Dutch Regional Euthanasia Review Committees, 2012–2021) were analyzed using grounded theory. Two researchers independently coded all references to decisional competence, iteratively developing a framework capturing cognitive, relational, and contextual determinants. Cases included both decisionally competent patients and those relying on advance directives.

Results

Competence assessment was multidimensional and often implicit. Six supporting factors shaped judgments: communication ability, psychiatric comorbidity, personality, presence of an advance directive, consistency of the request, and the patient–physician relationship. Contextual factors—including the number of physicians involved and investigative procedures—further influenced evaluations. Appelbaum and Grisso's cognitive criteria were indirectly referenced, with variable thresholds, highlighting considerable interpretative flexibility and subjective discretion.

Conclusions

Decisional competence in dementia PAD emerges as a complex, context-sensitive judgment rather than a fixed legal criterion. This

multidimensionality intensifies ethical and legal controversy, underscoring the delicate balance between respecting autonomy, ensuring protection, and maintaining professional integrity. Dutch experience demonstrates both the possibilities and the pitfalls of implementing PAD in cognitively impaired populations. As countries worldwide consider assisted dying legislation, these insights provoke critical reflection on how laws, guidelines, and clinical practice can ethically reconcile patient choice with societal responsibility.

THU-S02-P04

Session: End of Life III · **Room:** R.201

A Right to Die? Concepts, Problems, Opportunities

Professor Liz Wicks

University of Leicester, Leicester, United Kingdom

Background

The 'right to die' is a contentious and ambiguous term within the health law literature which potentially covers end-of-life choices such as suicide, assisted suicide/assisted dying, euthanasia/mercy killing, and refusal/withdrawal of life-sustaining treatment. Whether there is, or should be, a legal 'right' in respect of these choices are questions that underlie a lot of contemporary legal, ethical and political discourse.

Research Question

Is there a 'right to die'? And, if so, what exactly does that mean?

Methodology

Human rights analysis.

Results

Human rights law does not explicitly recognise a right to die, although there is legal protection for a variety of related rights including a right to life, a right to be free from degrading treatment, a right to autonomy, a right to health and a right to equal treatment. All of these rights, and the interplay between them, are relevant to the legal regulation of end-of-life choices. Indeed, in recent years, choices about dying have often been reconceptualised using human rights law language. It is now well established that the law on end-of-life is heavily influenced by human rights law and human rights conceptualisation within many jurisdictions. Any suggestion of an explicit 'right to die', however, is often rejected, for both fundamental and pragmatic reasons.

Conclusions

This talk will focus on the meaning of a 'right to die' within current legal discourse. It will highlight the ambiguous nature of such a concept, revealing its potential weaknesses as a legal 'right', but also argue for its value as a legal concept that brings together a disparate range of legal rules under a coherent unity. This is particularly important in the context of the law's current isolation of different end-of-life issues, such as suicide and assisted dying, which can make coherent legal reasoning difficult and may result in unfairness and inequality.

THU-S02-P05

Session: End of Life III · **Room:** R.201

The Spanish Organic Law on Euthanasia in Context

Professor Gonzalo Arruego

University of Zaragoza, Zaragoza, Spain. Euthanasia Commission of the Autonomous Community of Aragón, Zaragoza, Spain. EOL Network, Zaragoza, Spain

Background

In March 2021, Spain legalised medically assisted death via the Organic Law, March 24, on Euthanasia (LORE). The law was immediately appealed to the Spanish Constitutional Court, which upheld it in Rulings 19 and 94/2023, making only some (very) minor considerations/changes. To some extent, the decision of the Spanish Constitutional Court was anticipated by the ECtHR Case of *Mortier v. Belgium* (2023).

Research Questions

In this context, this paper will address the following two questions:
-Was the legalisation of medically assisted death a response to social demand and to normative need?
-Is the LORE regulation of medically assisted death constitutional and compliant with international fundamental/human rights standards?

Methodology

In order to answer the aforementioned questions, the paper is divided into two sections.

The first section will explore the social and legal contexts that led to the legalisation of medically assisted death in Spain. To this end, the section will examine the available data on the Spanish public opinion on assisted death since the 1980's ["Barometers" and Studies by the Spanish Centre for Sociological Research (CIS)], the evolution of the Spanish legal framework on end-of-life decisions under the Spanish Constitution (1986-2021) and the currently available data on the medically assisted death system's performance provided by the annual reports of the Spanish Ministry of Health using the figures provided by the Autonomous Communities and Cities via the Euthanasia Information System (SIE).

The second section will analyse the LORE's regulation of medically assisted death (particularly the substantive and procedural safeguards adopted) in its constitutional context, based not only on the doctrines of the Spanish Constitutional Court and the European Court of Human Rights, but also on the jurisprudence of other Constitutional/Supreme Courts that have upheld the constitutionality of (medically) assisted death (Colombia, Canada, Italy, Germany, Austria, Portugal and Ecuador).

Results

The paper will show that:

(a) from a social and legal perspective, the legalisation of medically assisted death was unavoidable: it was a response to sustained social demand and necessary to ensure consistency within the Spanish legal framework for end-of-life decisions. Accordingly, more than four years later the data show that the system progressively consolidates with minimal conflict.

(b) although it is perfectible, the LORE's regulation of medically assisted death is irreproachable from a constitutional point of view and, actually, it is arguably one of the most constitutionally appropriate regulations of assisted death.

Conclusions

The legalisation of medically assisted death in Spain was inevitable from a social and normative point of view and the LORE's system of medically assisted death is constitutionally impeccable.

SESSION THU-S03 · TRACK 3 · 11:00 – 12:30

Health-System Governance II · Room R.011

Moderator: Merja Turunen

THU-S03-P01

Session: Health-System Governance II · **Room:** R.011

The Social and Healthcare Reform in Finland: Promoting Equality?

Professor Eeva Nykänen

University of Eastern Finland, Joensuu, Finland. Finnish Institute for Health and Welfare, Helsinki, Finland

Background

At the beginning of 2023 in Finland was implemented a reform of the social and healthcare service system. In this reform the responsibility for organizing social and health care services was transferred from more than 300 municipalities and joint municipal authorities to the city of Helsinki and 21 wellbeing service counties that constitute a new level of public administration. The primary purpose of the reform was to promote equality and to narrow the differences in welfare and health between different population groups and inhabitants of different regions, as well as to curb cost growth of social and health care.

Wellbeing service counties are self-governing entities. However, their autonomy is considered weak as they do not have a right to collect taxes, their funding comes from the state, and they are subject to strong state steering. Promotion of equality and protection of fundamental rights is seen to require strong state involvement.

Research Questions

This presentation begins by analyzing the key legal parameters of the reform. Thereafter it assesses the effects of the reform during the first years of its implementation. The main research question is whether the promise of promoting equality, that was one of the primary aims of the reform, is redeemed.

Methodology

The presentation is based on legal dogmatic analysis of the reform legislation. Attention is paid to those elements of this legislation that aim to promote equality. The real-life effects of the reform are described using empirical data contained in the evaluation reports on the functioning of the wellbeing service counties published by the Finnish Institute for Health and Welfare annually.

Conclusions

The social and health care reform was a major administrative and operational reform, the implementation of which is still ongoing. The reform legislation contains mechanisms that are suitable for promoting the realization of equality. However, implementation problems and especially the scarcity of resources have a detrimental effect on the progress of equality.

THU-S03-P02

Session: Health-System Governance II · **Room:** R.011

From Declarative Principles to Enforceable Health Governance: Structural Limits of Korea's Framework Act on Health and Medical Services in a Changing Healthcare Environment

HyeonJeong Park MPH^{1,2}, Prof.Dr. So Yoon Kim MD, PhD³, Prof.Dr. Na-Kyoung Kim Dr.jur.⁴

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Background

Health systems worldwide are being reshaped by climate-related health risks, demographic change, public health emergencies, digital health technologies, and persistent workforce imbalances. In Korea, renewed debate over the Framework Act on Health and Medical Services has been driven not only by these broader transformations, but also by recent legislative and policy efforts to use the Act as a legal basis for workforce estimation and policy deliberation in response to continuing shortages in regional, essential, and public care. Although the Act formally occupies a central position in the national health law system, its capacity to operate as more than a declarative statute remains uncertain.

Research Question

This study asks whether Korea's Framework Act on Health and Medical Services can function as an enforceable governance framework for contemporary health policy challenges, and if not, what structural limitations in its legal design hinder effective coordination, accountability, and implementation.

Methodology

This study employs doctrinal and policy analysis of the Act using a three-part analytical framework: (a) the expansion of the Act's statutory scope in response to emerging health policy agendas, (b) the allocation of authority and mechanisms of inter-institutional coordination, and (c) the extent to which the Act provides effective structures for accountability and implementation. The analysis is based on the Act's statutory structure, recent amendments, and related policy developments.

Results

The analysis shows that the Act has expanded to absorb new policy agendas, including climate-related health risks, healthcare workforce planning, public access to healthcare service evaluation, national health crisis response, and the governance implications of digital health technologies. Yet this policy expansion has not been matched by a corresponding strengthening of legal mechanisms. While the Act broadens state responsibilities and policy objectives, it weakly specifies who must coordinate, through what legal instruments, and with what consequences when coordination fails. As a result, governance remains fragmented across sector-specific statutes and institutions, and key functions such as policy integration, accountability, and implementation remain structurally underdeveloped. Workforce planning controversies illustrate this broader pattern, showing that even where the Act provides a formal platform for policy deliberation, it does not by itself resolve conflicts over institutional authority, legitimacy, or execution.

Conclusions

The Korean case illustrates a broader challenge in contemporary health law: framework legislation may expand its policy reach without developing the institutional and legal architecture necessary for effective governance. In complex twenty-first-century health systems, framework statutes cannot remain merely aspirational or symbolic. They must include clearer allocations of responsibility, binding coordination mechanisms, and implementation tools capable of making health rights effective in practice.

THU-S03-P03

Session: Health-System Governance II · **Room:** R.011

The Role of Constitutional Doctrine in Changing Health Law

Professor Toma Birmontiene

Mykolas Romeris University, Vilnius, Lithuania

Background

Health law in Lithuania is closely intertwined with constitutional law. In reviewing the constitutionality of legislation regulating the health sector, the Constitutional Court has developed an official constitutional doctrine of health law that is binding on the legislature. In particular, the Court has clarified the constitutional obligations that arise when the legislature chooses *inter alia* a health system financing model based on compulsory health insurance as well as on other sources of funding. It has emphasized that health insurance funds may be used only to reimburse services provided by health care institutions that have concluded contracts with an authorized public authority under conditions established by law and grounded in fair competition among providers.

Research Question

a 2025 the Government initiated amendments to the Law on the Health System and the Law on Health Insurance, which are currently under parliamentary consideration. The proposed amendments give preferential treatment to so-called public health care institutions in the reimbursement of services from the compulsory health insurance budget. According to the constitutional doctrine and legislation, public healthcare providers have priority only when it comes to acquiring funds directly from the state budget. The central research question is whether these amendments comply with the constitutional doctrine formulated by the Constitutional Court.

Methodology

The study adopts a qualitative doctrinal research design complemented by institutional analysis. It systematically examines Constitutional Court jurisprudence and the proposed legislative amendments to assess the constitutional limits of legislative discretion in reforming the health system. The systemic method is used to evaluate the coherence between constitutional doctrine and statutory regulation. Through descriptive reconstruction and analytical generalization, the research identifies potential deviations from established constitutional standards.

Results

The analysis shows that the proposed amendments, without providing appropriate additional funding, seek to restructure the reimbursement framework in a way that privileges public providers, restricts the participation of other health care institutions in the compulsory health insurance scheme, and indirectly limits patients' freedom of choice. Proposed regulation appears to depart from the Constitutional Court's jurisprudence requiring fair competition and equal conditions for contracting.

Conclusions

Despite repeated Constitutional Court rulings declaring health-related legislation unconstitutional, legislative initiatives continue to test constitutional boundaries. The findings suggest growing tension between political priorities and constitutional imperatives in health care legislation, raising broader questions whether such a trend will lead to growing tension — or even open confrontation — between constitutional law and health law.

THU-S03-P04**Session:** Health-System Governance II · **Room:** R.011**The National Health Insurance System in Japan - 65 Years of Operation and Its Limitations**Dr Shigeki Takahashi MD, PhD Attorney at Law

Hamani-Takahashi Law Office, Tokyo, Japan

Background

Under Japan's National Health Insurance Act, enacted in 1961, all citizens must be enrolled in public health insurance. Once insured, individuals can freely seek treatment at medical institutions of their choice, subject to a co-payment of 10–30%, with no restrictions on frequency or number of visits. Furthermore, the high-cost medical care benefit system exempts individuals from further co-payments once their medical expenses exceed a certain threshold. While this system has enabled Japan to become a leading longevity nation, it has also brought several challenges.

Questions and Results

One is drug loss. under this system, funding constraints necessitate setting low official prices for recently developed high-cost pharmaceuticals. Consequently, some overseas pharmaceutical companies often refrain from selling in Japan, deeming it unprofitable. The government supports domestic drug development start-ups through a system granting conditional approval for insurance coverage for seven years based on limited case reports alone. Approval is revoked if results are not demonstrated within this period. To date, eight products have received this limited approval, yet none have demonstrated efficacy. This has resulted in wasted public funds and increased burdens on patients.

Another issue is doctors' remuneration. The government, seeking to minimise increases in healthcare costs, has raised medical fees only marginally, meaning doctors' salaries barely changed thirty years ago. Meanwhile, new tests and treatments have proliferated, dramatically increasing doctors' workloads. Those working in acute care hospitals face high workloads for low pay. Some disillusioned doctors have begun working in cosmetic dermatology and surgery. Furthermore, some doctors offer dubious treatments such as cancer immunotherapy and regenerative therapy at high cost, as these lack scientific basis and are therefore not covered by health insurance.

Conclusions

Japan's current system is expected to undergo a transformation, with a reassessment of burdens and benefits leading to a new framework. Firstly, the co-payment rate for the elderly, currently set at 10% of medical expenses as a rule, should be raised to 30% – equivalent to that of the working population – with income-based relief measures established. Secondly, the insurance coverage for over the counter (OTC) medicines should be completely abolished, and some prescription medicines should be reclassified as OTC. Thirdly, for high-cost pharmaceuticals, drug prices should be set at levels comparable to those in Europe and America, with a system expanded to reduce prices based on the financial performance of pharmaceutical companies. Fourthly, the functional division of labour among medical institutions, from acute to chronic care, should be strengthened. Fifthly, strengthening the family doctor system. Sixthly, introducing remuneration incentives for healthcare professionals based on treatment outcomes. Additionally, it is considered essential to persistently call upon the Japan Medical Association, which wields formidable power as a political pressure group, to cooperate in establishing a sustainable system; to enhance the health literacy of the public; and to strengthen audits of medical institutions providing private medical services.

THU-S03-P05**Session:** Health-System Governance II · **Room:** R.011**The Particularities of Medical Law in Brazil: Dual Judicialization, Judicial Governance, and Professional Liability**Dr. Renato Assis

ANADEM, Brasília, DF, Brazil

Background

Medical Law in Brazil has developed within a distinctive constitutional framework in which health is recognized as a fundamental right and a duty of the State. This constitutional design produced a universal public healthcare system alongside a robust private health insurance sector. Over time, this institutional arrangement intensified the judicialization of health, which now extends beyond disputes over access to services

and treatments. It increasingly encompasses the civil, criminal, ethical, and reputational accountability of healthcare professionals. Brazilian Medical Law is therefore marked by a phenomenon of dual judicialization: the judicialization of healthcare systems and the judicialization of medical practice itself.

Methodology

This paper adopts a qualitative methodology grounded in doctrinal legal analysis, institutional review, and jurisprudential examination. It analyzes leading judicial decisions, regulatory frameworks, and governance mechanisms shaping health-related litigation in Brazil. The study integrates constitutional law, administrative law, tort law, criminal law, disciplinary law, and bioethics, with particular attention to how judicial institutions structure decision-making standards and manage systemic health disputes.

Results

The analysis shows that Brazilian courts—particularly at the constitutional level—have assumed a structuring role in healthcare governance by setting criteria for treatment coverage, allocating responsibilities within a federal system, and rationalizing large-scale litigation. Simultaneously, healthcare professionals face expanding legal exposure driven by technological innovation, increased public visibility, digital communication, and evolving patient expectations. Civil liability claims, criminal investigations, disciplinary proceedings, and reputational harm increasingly overlap, generating a complex and often unpredictable risk environment for medical practice.

Conclusions

The Brazilian experience reveals an institutionalized and complex model of Medical Law in which courts do not merely adjudicate individual disputes but actively influence the architecture of healthcare systems and standards of professional responsibility. This model offers comparative insights into both the benefits and risks of extensive judicial involvement in healthcare governance. It underscores the need for legal frameworks capable of balancing equitable access to health services, legal certainty, and the protection of medical practice against excessive, fragmented, and overlapping liability exposure.

SESSION THU-S04 · TRACK 4 · 11:00 – 12:30**Medical Errors and Liability: Panel Discussion · Room R.007**

Moderator: Albert Lee

THU-S04-P01**Medical Errors: Civil or Criminal Liability**

Professor Albert Lee MD DMed LLM MPH GDLP FRCP FACLM FCI Arb^{1,2,3}, Professor Muh Nasser⁴, Professor Kumaralingam Amirthalingam LLB PhD⁵, Dr Bill Hinnant MD JD⁶, Professor Giancarlo Jiménez Bazán⁷, Professor Andre Pereira PhD⁸, Professor Oliver Quick LLB PhD⁹, Dr Manman Yang PhD¹⁰

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Background

Medical malpractice is usually brought under the tort of negligence but what if the act of defendant doctor is gross negligent causing grievous bodily harm or death?

Research Questions

How would medical negligence be classified as civil, criminal or disciplinary matter?

Findings

The English case *R v Adomako* [1994] 3 WLR 288 HL is one landmark case. The Court of Final Appeal in Hong Kong unanimously dismissed the appeal of a doctor on the question of the requirement to prove the culpability of the defendant's state of mind subjectively aware of the obvious and serious risk of death, [2019] HKCFA 37, and only application of the objective standard of reasonableness, as in *Adomako*, was needed. India applies a gross negligence standard while Singapore applies a civil negligence standard. In criminal prosecution

for clinical negligence, Singapore courts have adopted an intermediate test for professional misconduct cases, "serious negligence", a concept lying between civil negligence and gross negligence. There have been rare instances of deliberate harm in UK resulting criminalisation. This has been considered a disproportionate response that scapegoats individuals and prevents a culture of openness around safety. Tracing the evolution of the law and practice of gross negligence manslaughter and considering a number of regulatory based criminal offences as a more appropriate response to safety breaches in healthcare should be analysed. Medical errors in US are virtually always handled civilly, and a matter of state law rather than federal. Medical professionals argue that prosecuting unintentional human errors discourages reporting and destroys "just-culture," ultimately undermining patient safety and system improvements. The threshold of gross negligence versus simple negligence is a mixed question of law and fact. Only after that answer identifies gross negligence, recklessness, or intentional conduct would criminal prosecution be considered. There is a gap between the theoretical framework of Medical Law and its practical application within the Peruvian criminal justice system, particularly in cases of alleged medical malpractice. Justice operators adopt criteria deviating from established doctrinal standards, e.g., assessment of harm based exclusively on private medical reports submitted by the complainant, without obtaining objective evaluations from the Peruvian Institute of Legal Medicine and Forensic Sciences in the legal classification of bodily injury offenses. The prosecutor requires the defense to justify the "reasonableness" of calling the physician to testify but the very purpose of the investigation is to determine the existence of the alleged harm. In medical disputes in China, the division between criminal and civil liability rests on the degree of negligence and the severity of the harm. Violations of basic clinical standards resulting in severe consequences are more likely to be prosecuted criminally. Medical negligence, i.e., misdiagnosis, typically imposes civil liability on medical institution. The boundary essentially lies in the distinction between serious negligence and ordinary negligence, and whether the harm meets the criminal law threshold of "death or serious harm to health."

Concluding Remarks

This panel discussion aims to illuminate further to delineate civil and criminal liabilities for serious medical errors with research findings from different jurisdictions.

SESSION THU-S05 · TRACK 5 · 11:00 – 12:30

Medical Liability I · Room R.230

Moderator: Sven Lievens

THU-S05-P01

Session: Medical Liability I · Room: R.230

Compensation for Non-Pecuniary Harm Resulting from Interference with Patients' Personality Rights in Cases of Medical Malpractice

Tomáš Doležal doc. JUDr. PhD LLM

Institute of State and Law of the Academy of Sciences of the Czech Republic, Prague, Czech Republic

Background

The presentation addresses the issue of compensation for non-pecuniary harm resulting from interference with patients' personality rights in cases of medical malpractice, in particular substandard medical treatment. In most cases, such treatment leads to harm to the patient's health, which constitutes a well-recognised basis for compensation across legal systems. However, certain cases are more complex: although a physician has provided medical treatment not meeting the required standard of care, no harm to health occurs, or it cannot be convincingly established that the harm is causally linked to the defective treatment (causal uncertainty). This presentation focuses on these difficult cases and seeks to determine which legally protected interests (personality rights) may be affected and whether the resulting harm is compensable.

Czech tort law, similarly to German and Austrian law, does not recognise the doctrine of loss of chance, despite extensive judicial debate. This creates a gap in cases where a physician provides treatment not meeting the required standard of care but the patient cannot prove that this caused the adverse outcome.

In response, the Czech Supreme Court (notably decisions 31 Cdo 2376/2021 and 25 Cdo 3332/2020) has suggested that such conduct may give rise to non-pecuniary harm in the form of psychological distress or uncertainty interfering with personality rights, such as privacy or personal integrity, even without proven harm to health.

Research Question

The case law of the Supreme Court thus opens the possibility of recognising an independent claim for non-pecuniary harm based on an interference with personality rights (such as privacy or personal integrity), even where harm to health cannot be proven. This approach is supported by references to patient autonomy and analogies to cases involving insufficient information and lack of informed consent.

The key question, however, is whether this construction is convincing and dogmatically sound. In particular, can medical malpractice in the form of substandard medical treatment be understood as an interference with personality rights, such as privacy, integrity, or autonomy, and is it appropriate to draw parallels with cases of defective informed consent?

Conclusions

The analysis shows that the approach of the Czech Supreme Court, while formally rejecting the doctrine of loss of chance, implicitly creates a functional equivalent by allowing compensation for harm connected with the deprivation of a possibility of recovery. This construction is, however, problematic.

Unlike cases of defective informed consent, where the core issue is the deprivation of the patient's ability to decide about a medical intervention, substandard medical treatment constitutes a breach of an objective professional duty aimed at protecting health. The patient cannot consent to treatment below the required standard and therefore cannot be deprived of a relevant decision-making opportunity.

Comparative analysis confirms that the protection of autonomy is primarily linked to informed consent, not to medical malpractice. Extending this reasoning to substandard treatment risks blurring the distinction between different forms of unlawfulness (*Behandlungsfehler* vs. *Aufklärungsfehler*) and effectively introducing loss of chance liability through the back door.

THU-S05-P02

Session: Medical Liability I · Room: R.230

Rethinking Medical Negligence in the AI Era: The Loss of Chance Doctrine as a Response to Algorithmic Decision-Making

Dr Nino Lipartia PhD

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Georgian lawyers for Independent profession, Tbilisi, Georgia

Background

The integration of artificial intelligence (AI) into healthcare—from diagnostic imaging and predictive analytics to robotic-assisted surgery—offers transformative potential for patient care, enabling faster, more precise, and personalized interventions. AI algorithms can detect subtle patterns in medical data, optimize treatment plans, and even anticipate clinical deterioration before symptoms manifest. Yet, this technological progress challenges classical legal frameworks for medical negligence. Traditional doctrines rely on direct causation, clearly defined outcomes, and a linear relationship between physician conduct and patient harm. In contrast, AI-driven clinical decisions are probabilistic, opaque, and partially autonomous. Consequently, establishing fault and liability becomes highly complex, particularly when patient harm manifests as a reduction in the likelihood of a favorable outcome rather than a clear adverse event. The loss of chance doctrine recognizes compensable harm resulting from a statistically significant decrease in a patient's probability of recovery and provides a potential legal mechanism for addressing these novel challenges.

Research Questions

This paper investigates how existing negligence frameworks can accommodate AI-related harm and evaluates the applicability of the loss of chance doctrine. Key questions include: (1) How do traditional causation standards fail to capture probabilistic harm arising from AI-assisted clinical decisions? (2) How has the loss of chance doctrine been applied in France, the United States, Germany, and England in cases involving diagnostic errors, delayed treatment, or algorithmic misjudgments? (3) How can responsibility be fairly allocated among physicians, hospitals, and AI developers? (4) What insights can be drawn from the EU Artificial Intelligence Act regarding proactive regulation, and how can civil liability frameworks complement preventive measures?

In addressing these questions, the study introduces three potential legal models for AI-assisted medicine:

Shared Responsibility Model: Physicians retain the ultimate decision-making duty, AI developers assume product liability for known system

defects, and hospitals bear vicarious liability for staff actions, the selection and maintenance of AI systems.

Algorithmic Negligence Standard: A novel standard accounting for AI-specific factors, such as declared algorithmic accuracy, conformity with CE marking under the Medical Devices Regulation, and whether physicians were adequately trained to use the system.

Proportional Liability Approach: Loss of chance compensation is distributed proportionally according to the contribution of each actor.

Preliminary Concluding Remarks

Initial analysis suggests that combining the loss of chance doctrine with tailored responsibility models provides a promising framework for reconciling patient protection and technological innovation. Jurisdictions like France and select U.S. states show that compensating probabilistic harm is feasible, lowering the evidentiary threshold compared to strict causation approaches. German and English systems, relying on classical causation principles, provide limited remedies for AI-related errors. Implementing shared responsibility, algorithmic negligence, or proportional liability models could ensure equitable allocation of responsibility among physicians, hospitals, and AI developers while supporting continued innovation. Ultimately, rethinking medical negligence in the AI era through these lenses harmonizes patient safety, ethical obligations, and the emergent role of AI in clinical practice, creating a legal environment capable of accommodating both technological complexity and the probabilistic nature of algorithmic decision-making.

THU-S05-P03

Session: Medical Liability I · **Room:** R.230

Quantifying the Lost Chance of Survival

PhD Student Sven Lievens Master of Law
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Background

The loss of chance doctrine has proven useful in medical liability cases across several jurisdictions. Patients who have lost chances to recover or to survive can sue their healthcare providers to claim damages, covering not the damage consisting of the death itself but solely the chance to recover or to survive.

Questions arise, however, as to how to prove the extent of the lost chance. Which indicators can be used to quantify or calculate the lost chance? Some scholars argue that such calculations are inherently speculative, often advocating a refusal of the theory or suggesting that only amounts of damages *ex aequo et bono* could be awarded.

Research Question

What are obstacles in calculating and quantifying the lost chance and how should they be tackled?

Methodology

Classic legal research (Legal texts, case law and jurisprudence)
External legal comparative research (using the United States, Belgium and the Netherlands)

Results

Traditional tort law requires that, where damage is established, it should be duly compensated. Similarly, when claimants can prove the existence of a lost chance of survival or recovery, they should be adequately compensated.

Several obstacles arise when quantifying these lost chances, such as the knowledge paradox of the judge, use of *junk science* by parties, the deduction problem and the fear of imprecise calculations.

We suggest using an objective approach, based on a myriad of studies, statistical evidence or data, but to clearly complement these objective and validated data with subjective features of the patient who have lost chances of survival or recovery. Such an adaptation complies with the demand of a precise compensation, not over- or undercompensating the injured party.

Only in cases where no statistical data, that can be transposed to the subjective features of the patient, is available, recourse should be made to compensation *ex aequo et bono*.

Conclusions

Damages for a lost chance of recovery or survival should only be compensated *ex aequo et bono* as a measure of last resort. As a primary step, reference should be sought to reliable statistical data, commonly relied upon by medical experts. This more objective approach should be complemented by a individualized assessment to the specific characteristics of the patient concerned.

THU-S05-P04

Session: Medical Liability I · **Room:** R.230

The Scope and Limits of Deviation from Medical Standards in a Comparative Perspective

Dr (Doctor of Law) Witold Borysiak PhD in Law

University of Warsaw, Faculty of Law and Administration,
Warszawa (Warsaw), Poland

Background

According to the criterion of legal significance, one may distinguish 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 that created them rather than from law. The medical professionals' conduct in accordance with them should usually give rise to at least a factual presumption that due care has been exercised. Conduct contrary to those standards usually gives rise to a factual or even legal presumption that due care has not been exercised and triggers contractual, tort, criminal or disciplinary liability.

Research Question

Are there situations in which medical professionals can or should deviate from either ex-lege binding medical standards or ex-auctoritate binding medical standards?

Methodology

The aim of the paper is to present in a comparative perspective (based on Austrian, Belgian, English, French, German, Polish and Swiss law) the situations in which a medical professional can deviate from medical standards and the consequences of deviating from them. This is one of the main topics of the research project titled 'The role of codes of medical ethics and professional standards in biomedicine and their relevance to private law liability', conducted at the University of Warsaw.

Results

The most important factor determining the deviation from medical standards is the fact that they do not meet the requirement of up-to-dateness, which means that they are not in conformity with the current state of medical knowledge determined in compliance with evidence-based medicine (EBM). Moreover, a deviation should also be the case when those standards are not appropriate for specific circumstances of a given case (i.e. the condition of a given patient). In such circumstances, the burden of proof lies with the medical professional. In those situations, the withdrawal from a method of treatment, even if it has been successfully tried and tested in medicine and is established in the standards, is not per se defective; however, it should be carried out with the patient's knowledge and will (if possible).

Conclusions

Even if ex-lege binding medical standards have a binding effect similar to the provisions of law, medical professionals should have the right to deviate from the standards, and the deviation should not create their liability. Similar rules should apply to the ex-auctoritate binding medical standards. Medical professionals are not legally bound by them and, similarly, could find them inappropriate for a particular situation.

THU-S05-P05

Session: Medical Liability I · **Room:** R.230

Legal Protection for Healthcare Professionals through Liability Insurance: A Comparative Study of Indonesia and ASEAN Countries

Doctor Imelda Ika Aprilia Master, Doctor Redha Vebrina

Indonesian Health Law Society, Pontianak, Kalimantan Barat, Indonesia

Background

The increasing complexity of healthcare services, coupled with heightened legal awareness among patients, has led to a growing number of legal claims against healthcare professionals. This development necessitates legal protection mechanisms that not only safeguard patients' rights but also provide legal certainty and financial protection for healthcare professionals. Professional liability insurance constitutes a crucial instrument within modern health law systems. However, in Indonesia, the regulation of liability insurance for healthcare professionals has not yet been comprehensively integrated into the legal framework for professional protection, in contrast to practices adopted in several ASEAN countries.

Research Question

1. How is liability insurance regulated as a legal protection instrument for healthcare professionals within the Indonesian legal system?
2. How does the regulation of liability insurance for healthcare professionals in Indonesia compare with that of ASEAN countries?

Methodology

This research employs a normative legal research method using statutory and comparative law approaches. Legal materials consist of health-related legislation, legal doctrines, and regulatory practices concerning professional liability insurance for healthcare professionals in several ASEAN jurisdictions.

Results

The findings indicate that in Indonesia, liability insurance for healthcare professionals is not established as a normative legal obligation attached to professional licensing and largely depends on individual initiative or institutional policies of healthcare facilities. In contrast, several ASEAN countries have incorporated liability insurance as a professional standard and an integral component of healthcare governance, either through mandatory individual coverage or institutional liability schemes. These regulatory differences significantly affect the level of legal protection afforded to healthcare professionals and the effectiveness of patient compensation mechanisms.

Conclusions

This study concludes that strengthening the regulatory framework governing liability insurance for healthcare professionals in Indonesia is an urgent necessity to achieve a balanced protection of healthcare professionals, the fulfillment of patients' rights, and the sustainability of the national healthcare system. Lessons learned from ASEAN countries may serve as a valuable reference for developing a more comprehensive and equitable policy framework.

SESSION THU-S06 · TRACK 6 · 11:00 – 12:30

Mental Healthcare I · Room R.004

Moderator: Corrette Ploem

THU-S06-P01

Session: Mental Healthcare I · **Room:** R.004

Mechanical Restraints in Belgian Healthcare Facilities: Balancing Patients' Fundamental Rights and Clinical Challenges.

Marie-Noëlle Lippens-de Cerf Masters of Laws, LLM
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Background

Belgian medical law is often considered one of the most progressive legal frameworks in terms of patients' individual rights. Patients' fundamental rights are largely protected in Belgium, notably by the Law of 22 August 2002 on Patients' Rights, whose 2024 amendment further strengthened patients' role and autonomy within the healthcare relationship. However, the issue of restraints in healthcare facilities remains an area where patients' rights can be overlooked, due to patients' vulnerability and isolation, and because such measures are often used behind closed doors.

While restraints are often associated with psychiatric facilities, they are used across various healthcare contexts, including general hospitals and elderly care facilities. Restraints can be chemical, mechanical, or manual. This study focuses on mechanical restraints, defined by the European Committee for the Prevention of Torture as the action of "*applying instruments of restraint, such as straps, to immobilise a patient*".

Research Question and Methodology

This study analyses the international and Belgian legal, regulatory, and case law frameworks, as well as guidelines regarding mechanical restraints in healthcare institutions, to investigate how patients' rights can be protected while taking clinical realities into account.

Results

It will show that mechanical restraints constitute serious violations of human rights, including the right to liberty, to free and informed consent, to human dignity, the prohibition of inhuman and degrading treatment, and the right to private and family life, protected by both the ECHR and the Belgian Constitution. Moreover, although accurate data on restraints remain limited, evidence indicates that while the main goal of

mechanical restraints is to ensure patients' safety, they can also, paradoxically, cause severe or even fatal physical and psychological harm.

In addition, practical constraints such as staff shortages and time pressure make it difficult for healthcare professionals to restrict the use of mechanical restraints to strictly necessary situations. This analysis shows that although certain hospitals have tried to implement their own guidelines on mechanical restraints, there is a lack of legislation governing mechanical restraints that contributes to a severe lack of clarity regarding how restraints should be applied to prevent dangerous situations and breaches that could lead to medical negligence.

Conclusions

In conclusion, this study adopts both a legal and practical perspective to address the issue constructively, and explores potential solutions to balance patients' fundamental rights with clinical challenges, such as clear hospital protocols, adapted equipment, staff training, interdisciplinary decision-making, enhanced monitoring, and record-keeping.

THU-S06-P02

Session: Mental Healthcare I · **Room:** R.004

Who Authorises and Implements Seclusion and Restraint in Care? A Critical Analysis of Professional Responsibilities under Human Rights Law

Prof. dr. Tim Opgenhaffen^{1,2}, Sam Baert¹, dr. Kathleen De Cuyper¹

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Background

Although intended as measures of last resort, seclusion and restraint remain prevalent across many care settings. To reduce their use and safeguard quality, safety, and compliance with human rights standards, a guideline was developed in Flanders (Belgium). The guideline covers a range of residential contexts — including mental health care, youth care, disability care, and elderly care — and applies to both acute emergencies and non-emergency responses to challenging behaviour. Because the guideline was developed on the basis of human rights standards, scientific evidence, and practical insights, tensions emerged between these sources. One of these tensions is central to this presentation: the question of who holds responsibility for decision-making and the implementation of seclusion and restraint.

Research Question

This contribution addresses two central questions: (1) Which obligations and constraints arise from the Council of Europe's human rights framework for medical and non-medical professionals regarding decision-making and the implementation of seclusion and restraint in residential care? (2) How do these obligations relate to scientific evidence and practical realities, and what challenges do they pose for guideline development?

Methodology

To answer the first question, recommendations were derived from the country reports of the European Committee for the Prevention of Torture and from the case law of the European Court of Human Rights. To address the second question, and based on an adapted version of the GRADE methodology, these recommendations were considered alongside those based on scientific evidence and translated into a guideline, the feasibility of which was subsequently assessed in practice.

Results

The analysis demonstrates that human rights standards do not always align with available scientific evidence or with practical realities. In particular, the human rights framework places strong emphasis on the role of physicians, assigning them an extensive role in both decision-making and implementation. This applies even in non-medicalised care settings where medical staff are not routinely present, and sometimes in situations where neither the underlying cause nor the required training is medical in nature. This emphasis partly conflicts with insights from the literature and with existing practices, which allow greater involvement of other professional groups.

Key Takeaways

At the substantive level, the analysis reveals a notable tension between human rights standards, scientific evidence, and practice. Beyond this substantive observation, the contribution also addresses the

methodological challenges inherent in developing guidelines that integrate both human rights standards and scientific evidence, and proposes strategies to navigate these tensions.

THU-S06-P03

Session: Mental Healthcare I · **Room:** R.004

Expanding Access or Reconfiguring Coercion? Balancing Autonomy and Security in Psychiatry and German Guardianship Law

Karolin Kirchgaesser

Max Planck Institute for Comparative and International Private Law, Hamburg, Germany

Background

Psychiatry and German guardianship law are two disciplines with a long history of responding to behaviour classified as “deviant”. Employed measures range from care and support to coercion and confinement. Both fields have undergone major normative and structural transformations, particularly regarding legitimacy and limits of coercive interventions. Within disciplinary boundaries, these developments are already analysed. What remains understudied is their interdependence, on both a substantial as well as a conceptual level.

Research Question

The paper looks for a common driving force behind these reforms. It asks whether, ultimately, it is the balance of autonomy and security determining institutional responses to deviant behaviour (while societal norms define deviance) and if this axis of analysis proves fruitful for both disciplines. ‘Security’, in this context encompasses legal certainty, scientific safety as well as protection from threats to self or others. Factors potentially shaping this balancing process (e.g., scientific expertise, public discourse, lobbying) are examined for their influence on the weight attributed to autonomy and security and how these attributions influence the other field. Influence can be conceptual, e.g., coercion as *ultima ratio*, or substantial, e.g., judicial acceptance of electroconvulsive interventions.

Methodology

The research approach follows three steps: First, it reconstructs the history of psychiatric interventions (e.g., medication, coercive physical interventions) and of the measures provided by guardianship law (e.g., incapacitation, support). Second, it identifies key turning points through a comparative, diachronic analysis across both fields. Third, it examines these turning points using elements of discourse analysis to verify if arguments and institutional dynamics can be placed along the autonomy–security axis.

Results

Findings reveal a structured but asymmetrical interdependence between psychiatry and guardianship law. The law selectively incorporates medical knowledge while maintaining normative autonomy; clinicians oftentimes perceive legal regulations as interference with clinical judgement. Legislation accommodates public discourse more readily than primarily science-driven medical conceptions. Shifts in the autonomy–security balance do not uniformly reduce coercion but transform its modalities: from overt forms (e.g., confinement) to more subtle or contested practices (e.g., covert medication, electroconvulsive therapy, substitute consent for outpatient coercive treatment). Notably, calls for access to coercion and substitute decision making are advanced in the context of re-establishing autonomy.

Conclusions

The autonomy–security axis is a useful framework for the interdisciplinary analysis of institutional responses to deviant behaviour. The paper demonstrates that neither psychiatry nor law simply reduce coercion in favour of autonomy, but rather reframe and redistribute it through reciprocal utilisation.

THU-S06-P04

Session: Mental Healthcare I · **Room:** R.004

The Sentence is Not Sickness: A Case for Health-Centered Detention in Europe

Nel Christie

Dewallens & partners, Leuven, Belgium

Background

Across Europe, prisons have become repositories for unmet mental health needs. Approximately one in three people in detention live with a mental health condition, and suicide remains a leading cause of death in custody. Although the principle of equivalence of care requires that healthcare in detention meet community standards, persistent governance failures prevent implementation. The jurisprudence of the European Court of Human Rights under Article 3 of the European Convention on Human Rights has clarified that inadequate medical care may constitute inhuman or degrading treatment. Yet deficiencies remain widespread.

Research Question

How do governance structures within European penal systems contribute to failures in mental health care delivery, and to what extent do these failures undermine States’ human rights obligations?

Methodology

This study combines comparative legal analysis with empirical findings from the RESIZE project (2025–2029), examining detention governance frameworks in 15 European states. It draws on national surveys conducted with experts in the field of criminal justice to identify recurring patterns affecting mental health provision.

Results

The findings demonstrate that governance structures directly produce and perpetuate inadequate mental health care in detention. Where prison health services are placed under ministries of justice rather than ministries of health, custodial priorities systematically outweigh clinical judgment. This institutional design creates conflicts of interest, limits medical independence, and weakens accountability mechanisms, resulting in delayed treatment, inconsistent screening, and restricted access to specialist care.

Fragmented responsibilities between justice and health authorities further impede coordination, producing gaps in suicide prevention, psychiatric referral, and post-release continuity of care. Chronic understaffing and insufficient psychiatric expertise are not merely resource shortages but consequences of health systems structurally disconnected from national public health frameworks.

Together, these governance arrangements undermine implementation of the principle of equivalence and expose states to violations of Article 3 of the European Convention on Human Rights.

Conclusions

The mental health crisis in European prisons is fundamentally a governance failure. When prison health systems remain subordinated to custodial hierarchies and isolated from public health structures, the right to mental health becomes structurally unattainable. Ensuring compliance with human rights law requires institutional reform that secures medical independence, integrates prison health into national health systems, and strengthens accountability. The sentence is deprivation of liberty, not deprivation of care.

SESSION THU-S07 · TRACK 7 · 11:00 – 12:30**Status of Embryos and Embryo Models · Room R.008**

Moderator: María de Jesús Medina Arellano

THU-S07-P01**Session:** Status of Embryos and Embryo Models · **Room:** R.008**Embryo Selection with Artificial Intelligence: Preventive Potential or Risk of Digital Eugenics?**Researcher Daniela Marques Dias Master's in Civil Law^{1,2,3}, Researcher Luiza Tosta Cardoso Franco Master's degree in Civil Law^{1,2,4}¹University of Coimbra Institute for Legal Research (UCILeR), Coimbra, Portugal. ²Faculty of Law at the University of Coimbra, Coimbra, Portugal. ³Biomedical Law Centre, Coimbra, Portugal. ⁴PhD Scholarship Holder funded by Foundation for Science and Technology - Portugal, Coimbra, Portugal**Background**

The increasing use of Artificial Intelligence (AI) in embryo selection within the context of in vitro fertilization (IVF) represents one of the most promising, yet simultaneously most controversial, applications of this technology in reproductive medicine. Embryo assessment relies on a process designed to predict the embryo's potential for implantation and healthy development. The introduction of AI systems, particularly those oriented toward preventive medicine, enables the generation of time-lapse images of embryonic development, the processing and interpretation of complex datasets, and the standardization and automation of assessment procedures. These systems produce more objective and detailed evaluations, achieving levels of precision and consistency that may surpass those of human embryologists.

Research Question

How might the use of artificial intelligence lead to eugenic practices?

Methodology

The methodology is based on a qualitative analysis of the literature and the current regulatory and technological framework. The first step is to identify the purpose of using AI to enhance the accuracy of embryo assessment, whether to evaluate embryo quality or to predict implantation success. Subsequently, the analysis focuses on the main risks associated with this use, including a lack of transparency and algorithmic bias, which may give rise to harmful eugenic practices. Finally, the study contrasts the potential benefits of AI in this domain with the emerging phenomenon of "digital eugenics."

Results

The application of AI in this domain inevitably raises significant ethical concerns, primarily stemming from issues of transparency and bias. System opacity (the "black box effect"), that is, the failure to disclose which factors are considered in the assessment, may result in the use of inadequate or population-specific data, leading to flawed evaluations of embryos. Moreover, AI systems based on machine learning operate through continuous learning, and if bias is introduced at any stage of this process, it may be perpetuated in subsequent assessments. Consequently, an algorithm may erroneously correlate a disadvantageous characteristic with successful embryo implantation, thereby endangering the health and well-being of the future child. In addition, the use of AI may facilitate non-therapeutic selection by mistakenly identifying certain traits (unrelated to disease) as superior, thereby approaching scenarios associated with "digital eugenics".

Conclusions

The integration of AI into embryo selection holds undeniable potential to transform reproductive medicine, making it more efficient, precise and preventive. However, technical risks may lead to serious consequences, including "digital eugenics", by inadvertently promoting the selection of certain characteristics. For this reason, the development and implementation of such systems must be accompanied by safeguards designed to prevent these outcomes, particularly those established in the AI Act, most notably the principles of transparency (Article 13) and human oversight (Article 14).

THU-S07-P02**Session:** Status of Embryos and Embryo Models · **Room:** R.008**The Legal Status of the Human Embryo between Assisted Reproduction, Biotechnology and Genetic Editing**Legal Researcher and Lawyer Bruna Guesso Scarmagnan Pavelski PhD in Law

Universidad Pública de Navarra (UPNA), Pamplona, Navarra, Spain

Background

The expansion of assisted human reproduction (AHR), biotechnology and gene editing places the embryo at the centre of ethical and legal implications. The blurring of normative categories results in fragmented responses, generally lacking coherence, sometimes rooted in property law, sometimes in personalist frameworks, without reasonable grounds for consistently regulating new forms of intervention on reproductive and embryonic material.

Research Question

In what terms should the human embryo be legally situated in the face of contemporary AHR practices and genetic editing techniques, without classifying it unrestrictedly as available material, nor equating it, in an unreflective manner, with a person? Method: The study adopts a legal-bioethical approach, involving a dogmatic and bibliographic analysis, centred on civil-constitutional categories, bioethical references and international regulatory frameworks related to AHR and genetic modification biotechnologies. The analysis presents vulnerability as a hermeneutic vector for shaping rights and duties of guardianship and responsibility. Result: The research identifies the inadequacy of dichotomous perspectives in determining the legal status of the human embryo. It proposes recognising a legal status specific to the embryo, distinct from both mere material availability and subjectivity, grounded in biological premises, its susceptibility to biomedical interventions, and the concept of its own status and standing. This framework gives rise to normative implications, such as the duty of therapeutic justification for interventions involving embryos, ethical convergence, and the establishment of precise guidelines for research, disposition, and clinical use.

Conclusions

The current landscape highlights the need for a legal framework for the human embryo within the practices of reproductive health care and biotechnology. This vulnerability, grounded in scientific data, provides parameters for calibrating protection and exceptions, without adhering to either an extreme protective stance or the total availability of the latent entity, but with the rationale and normative substance for an integrated and coherent legal framework within medical law.

THU-S07-P03**Session:** Status of Embryos and Embryo Models · **Room:** R.008**Fear of Missing Out on Regulatory Framework on Human Stem Cell-Based Embryo Models**Dr. Mariangela Reyes Villarreal^{1,2}, Dr. Oscar Vidal Gutiérrez¹¹Universidad Autónoma de Nuevo León, Monterrey, Nuevo León, Mexico. ²Universidad de Murcia, Murcia, Murcia, Spain**Background**

Human stem cell-based embryo models (SCBEMs), also called synthetic embryos or embryo-like structures, are derived from stem cells rather than fertilized eggs and do not qualify as "human embryos" under current laws in many countries, creating regulatory uncertainty.

Research Question

Is the current regulatory framework for SCBEMs suitable for research and development?

Methodology

Analysis of SCBEMs regulatory framework, including both international and regional/country-specific approaches.

Results

1. International Consensus and "Soft Law."

The International Society for Stem Cell Research (ISSCR) 2021 guidelines are the primary international standard. They categorize

synthetic human embryos as "stem cell-based embryo models" and advise that specialized committees oversee their research. There is an international consensus that they must not be transferred into the uterus of a human or an animal. While research on natural embryos is limited to 14 days, some argue that this limit should not apply to SCBEMs because they lack a clear "day zero" (fertilization), making strict application difficult.

2. Regional and National Approaches

United Kingdom

The Human Fertilisation and Embryology Authority (HFEA) considers SCBEMs not to be "embryos" under the Human Fertilisation and Embryology Act 1990, meaning they are not strictly bound by its 14-day limit. The New Code of Practice (2024) has been introduced by researchers to guide work with these models, emphasizing oversight committees and prohibiting implantation.

Canada

The Assisted Human Reproduction Act (2004) defines an embryo as a human organism created by "fertilization or creation", thereby subjecting SCBEMs to the 14-day limit and prohibiting their use for purposes other than research.

United States

There is no specific federal law governing SCBEMs. Dickey-Wicker Amendment prohibits federal funding for research involving the creation or destruction of human embryos. Most U.S. scientists follow voluntary, institutional guidelines and ethical standards. The FDA is prohibited from reviewing research involving the intentional creation or modification of human embryos with heritable genetic modifications.

France

The Bioethics Act 2021 requires researchers to declare projects using SCBEMs to the Agence de la biomédecine, with potential criminal sanctions for noncompliance.

Conclusions

The current regulatory framework for SCBEMs is inadequate and outdated. Although some jurisdictions have begun implementing guidelines, most remain in a legal "gray area" that fails to address the rapid advances in creating embryo-like structures from stem cells. Therefore, interdisciplinary work must be undertaken to develop specialized, "middle-ground" regulations that enable beneficial research on SCBEMs in early development while preventing the creation of fully formed, viable human beings in a laboratory.

THU-S07-P04

Session: Status of Embryos and Embryo Models · **Room:** R.008

Embryo or No Embryo? The Emergence of Stem Cell-Derived Embryo Models from a Legal Perspective

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Background

Stem cell-derived embryo models (SCEMs) are self-organizing 'models' generated from pluripotent or embryonic stem cells that mimic the developmental processes of a human embryo. Unlike human embryos, the generation of these models does not require fertilization or gametes. SCEMs are increasingly considered a potential alternative to research with human embryos, which is often restricted or prohibited due to the ethical concerns surrounding early human life. On the other hand, such restrictions limit important medical-scientific research on early human development, particularly the peri-implantation period. Therefore, research with SCEMs might be promising to offer new insights.

In order to pursue these possibilities, it is important to establish the legal status of these SCEMs: are they embryos or not? In most jurisdictions, the scope of protective legal frameworks regarding human embryo research is dependent on how an embryo is (legally) defined. If SCEMs are compliant with the legal definition and are -therefore- considered embryos, they would be subject to the same restrictions as human embryos. However, on a national level, definitions vary significantly with some jurisdictions linking the embryo to fertilization and others to the 'potential to develop into a human being'. Moreover, an 'embryo' is not explicitly defined on an international level, nor on European level.

Research Question

What is the current legal landscape regarding the scope of embryo regulation and how does it apply to research with SCEMs?

Methodology

This article provides an overview of existing legal definitions of the embryo across different jurisdictions and examines the potential challenges they pose for the regulation of SCEMs. The study employs a literature review of international, European, and national legal frameworks.

Results

The divergence between national jurisdictions regarding (human) embryo research leads to uncertainty about the regulation of research with different types of SCEMs. At the same time, emerging legislative initiatives on a national level as well as (updates of) international guidelines demonstrate attempts to address these regulatory gaps.

Conclusions

SCEMs are a promising alternative for research with human embryos. Yet, it is important to clarify how SCEMs relate to human embryos from a legal perspective as well as the (im)possibilities with regard to research. This way, jurisdictions can become more future-proof in light of rapidly evolving developments in the field of reproductive science.

THU-S07-P05

Session: Status of Embryos and Embryo Models · **Room:** R.008

Beyond Things and Animals: Criteria for the Legal Status of Organoids and Xenobots

Dr. Martin Šolc

Department of Medical Law, Charles University Faculty of Law, Prague, Czech Republic

Background

Modern biotechnology and synthetic biology are creating previously non-existent biological entities, including organoids (in vitro organ or tissue models) and xenobots (new living constructs engineered to perform simple tasks). Legal regulation of such research and related activities requires defining the legal status of these novel beings. There are several options: the law can treat them merely as things, or it can recognise their special nature by considering their closeness to human tissues or animals, or by establishing an entirely new sui generis status. Each of these options would have ramifications in applicable regulations, research oversight, and other legal aspects.

Research Question

In light of this dilemma, a broader and fundamental question arises: what criteria should we use to determine the legal approach to new entities? How much weight should be given to their genetic similarity to existing beings, their functional capabilities, or the practical consequences of each legislative option?

Methodology

We will use a doctrinal and normative method to analyse existing legal categories (thing, animal, human biological material, and sui generis regimes), compare the candidate criteria (genetic-based, capacity-based, consequence-based, etc.), and evaluate their regulatory implications in biomedical research and healthcare contexts.

Results and Conclusions

The fascinating issue of organoids and xenobots might serve us as a case study for understanding one of the deepest questions of law: how legal systems should draw boundaries between persons, things, animals, and potentially new categories of entities.

SESSION THU-S08 · TRACK 1 · 13:30 – 15:00**Access to Healthcare II · Room R.008**

Moderator: Anne-Marie Duguet

THU-S08-P01**Session:** Access to Healthcare II · **Room:** R.008**Prioritization in Healthcare: A Legal Perspective**dra. Marie Eglen

Instituut voor Sociaal Recht (KU Leuven), Leuven, Belgium

Background

Due to multiple societal changes, including the aging population, the increasing healthcare costs and recurring economic and financial crises, the demand for healthcare is increasingly outweighing the available resources. A growing imbalance that often compels states to adopt prioritization mechanisms to determine the order in which individuals gain access to the required healthcare.

The establishment of these prioritization mechanisms has traditionally been regarded as a purely political matter, falling outside the scope of judicial review. Consequently, these mechanisms have largely been excluded from the legal sphere, and legal scholarship on prioritization 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, challenge, and even overturn established prioritization mechanisms, when infringing fundamental rights.

Research Question

Therefore, the question arises which legal boundaries, derived from the (case law of the) EC(t)HR, must be respected when designing and implementing prioritization mechanisms.

Methodology

Since the research question seeks to identify the boundaries applicable to the design and implementation of prioritization mechanisms, the specific context in which these boundaries arise, namely access to healthcare, is secondary. Therefore, the analysis will not be confined to cases that explicitly address healthcare prioritization. Instead, it will adopt a broader perspective, encompassing different yet related areas, including case law concerning prioritization in social assistance, social security and the determination of eligibility criteria.

Results

Adopting this methodological approach, the contribution will identify and examine three legal boundaries, derived from the (case law of the) EC(t)HR, that must be respected when designing and implementing prioritization mechanisms in the access to healthcare. First, prioritization must not result in a discrimination. Second, it cannot infringe individuals' legitimate expectation regarding access to healthcare. Third, the use of prioritization must not obstruct the access to an appropriate level of care and dignity.

Conclusions

Prioritization mechanisms governing access to healthcare have traditionally been considered as a matter lying beyond the scope of judicial review. A traditional view that, however, has been significantly challenged by a recent and noticeable evolution within the courts. Regarding this evolution, it is high time to identify and examine the legal boundaries that govern and shape these prioritization mechanisms, including those explored in this contribution.

THU-S08-P02**Session:** Access to Healthcare II · **Room:** R.008**Prioritization of Patients' Access to ECMO During the COVID-19 Pandemic – Ethical, Legal and Clinical Aspects**

Assoc. Prof Jerzy Bednarski MD, PhD¹, Doctor Jeng-You Robert Wu MD, MBA^{2,3}, Assistant Professor I Jou Lin PhD⁴, Doctor Tanya K Najhawan MD⁵, Atty. Magdalena Sroka LL.M.⁶

¹Department of Human Anatomy, Medical University of Lublin, Lublin, Poland. ²Department of Radiation Oncology, Wan Fang Hospital, Taipei Medical University, Taipei, Taiwan. ³Graduate Institute of Biomedical Informatics, College of Medical Science and Technology, Taipei, Taiwan. ⁴Chung Yuan Christian University, School of Law, Taoyuan, Taiwan. ⁵Thorndale Medical Clinic, Dublin, Ireland. ⁶Cracow Bar Association, Cracow, Poland

Background

The COVID-19 pandemic exposed dramatic challenges related to the limited availability of advanced medical technologies, including extracorporeal membrane oxygenation (ECMO). Deficits in equipment, personnel, and organizational resources necessitated prioritization, rationing, and allocation of healthcare services, placing physicians in the midst of fundamental ethical and legal dilemmas.

Methodology and Results

An analysis of the Polish legal framework (including the Code of Medical Ethics and the Act on the Professions of Physician and Dentist) indicates that many treatment-related decisions may be legally permissible, provided that the obligation to ensure humane care is maintained. Similar standards are reflected in international clinical guidelines: Italian (SIAARTI), Spanish (SEMICYUC), British (NICE), as well as the recommendations of the Extracorporeal Life Support Organization (ELSO) regarding the use of ECMO in patients with severe ARDS in the course of COVID-19. A common denominator across these documents is the primacy of medical criteria—namely, the patient's clinical need and prognosis—while rejecting simplistic discriminatory criteria such as chronological age or social status.

Conclusions

The authors emphasize the necessity of developing triage algorithms based on transparent, collegial, and ethically justified principles to support physicians in decision-making under conditions of resource scarcity. They also highlight the importance of establishing triage committees, which may reduce the moral burden placed on individual physicians and enhance public trust. A key lesson from the pandemic experience is the need for parallel development of medical infrastructure, systemic coordination, and the establishment of clear ethical and legal frameworks for prioritization, in order to minimize the risk of arbitrary and potentially discriminatory decisions in future public health crises.

THU-S08-P03**Session:** Access to Healthcare II · **Room:** R.008**Access to Health and the Right to Prioritization in Finland's Reformed Healthcare System**Associate Professor of Public Law Anu Mutanen LL.D.

Tampere University, Tampere, Finland

Background

Access to healthcare is a core component of the right to health, yet it is increasingly challenged by fiscal constraints and structural reforms. In many welfare states, pressures to contain public expenditure have intensified debates on the legal and ethical acceptability of prioritizing healthcare services. Finland provides a particularly illustrative case. In 2023, responsibility for organizing public healthcare was transferred from municipalities to newly established, self-governing wellbeing services counties. This reform has reshaped governance, accountability, and resource allocation within the healthcare system, raising renewed questions about how access to care and prioritization practices align with constitutional and human rights as well as medical, and ethical standards.

Research Question

How can access to healthcare as an element of the right to health be reconciled with legally and ethically acceptable prioritization of healthcare services in a publicly funded system, particularly in the context of Finland's post-2023 healthcare governance reform?

Methodology

The presentation employs doctrinal legal analysis combined with an interdisciplinary approach. It examines constitutional norms, human rights obligations, and statutory regulation relevant to healthcare access and prioritization in Finland. This legal analysis is contextualized through insights from medicine and ethics, focusing on medical need, effectiveness, and fairness as guiding principles for prioritization.

Results

The analysis shows that Finnish constitutional law and international human rights standards recognize access to healthcare as a legally significant, though not unlimited, aspect of the right to health. Prioritization of healthcare procedures can be compatible with this right when it is grounded in transparent criteria such as medical need, effectiveness, and proportionality, rather than solely in cost containment. The shift to wellbeing services counties has increased the importance of system-level prioritization, while simultaneously highlighting tensions between individual rights, population-level health outcomes, and financial sustainability.

Conclusions

The Finnish experience demonstrates that the right to health does not preclude prioritization, but it sets substantive and procedural limits on how prioritization may be carried out. Prioritizing healthcare services is challenging, as law, medicine, and ethics intersect in defining acceptable boundaries for allocating scarce healthcare resources. The study contributes to international debates by showing how structural health system reforms can recalibrate, but not displace, the legal and ethical commitments underpinning access to health.

THU-S08-P04

Session: Access to Healthcare II · **Room:** R.008

Understanding the Right to Continuous Healthcare in Medical Law of Serbia

Dr. Hajrija M. Mujovic PhD

Association of Lawyers for Medical and Health Law of Serbia, Belgrade, Serbia, Serbia

Background

Serbian health legislation contains provisions that foresee the patient's right to continuous healthcare. The principle of continuity of healthcare is proclaimed, which is achieved through the overall organization of the healthcare system and ensures functional connectivity and coherence of healthcare from the primary through secondary to tertiary levels, providing uninterrupted healthcare to citizens at all stages of life (Article 24 of the Healthcare Act, Official Gazette of the Republic of Serbia, No. 25/2019, 92/2023 - authentic interpretation and 29/2025 - decision of the Constitutional Court). Patients are guaranteed equal rights to quality and continuous healthcare in accordance with their health condition, generally accepted professional standards, and ethical principles, in the best interest of the patient and with respect for their personal views (Article 3 of the Patients' Rights Act, Official Gazette of the Republic of Serbia, No. 45/2013 and 25/2019 - other law). It follows that the concept of continuity is conceptually linked to the quality-of-service delivery and applicable medical standards. More precisely, continuity of care is an essential element of quality, and every healthcare provider should be attentive to this.

Methodology

The analytical and methodological approach to issues concerning the realization of this right finds its models in comparative law theory and practice.

Research Questions and Results

It can be discussed which patients experience less or more pronounced continuity of care depending on their health status. The criteria may include the nature of the disease, such as whether it is chronic or rare. The reason may also lie in the characteristics of the patient, such as age or years of life. An example from practice provided in this context is the transition of a patient from pediatric to adult healthcare. How to enable this transition while ensuring continuity of treatment with minimal negative consequences for the patient? There are also examples of realizing this right when patients receive care from several physicians working together to ensure high-quality care or when patients have significant and lasting health needs.

Concluding Remarks

In Serbian law, from a medical law perspective, still there is not enough knowledge about all these categories and situations. The conclusion is that the exercise of the right to continuous healthcare is insufficiently implemented in practice. Efforts should be made towards better interpretation, education, and creating better conditions for healthcare organization and in every other aspect.

THU-S08-P05

Session: Access to Healthcare II · **Room:** R.008

Gender Disparities in Pain Management: Eve's Curse

Ms Naty Guerrero-Díaz LLB¹, Professor Mike O'Connor MD FRANZCOG MHL²

¹SLater & Gordon, Melbourne, Victoria, Australia. ²Womens & Childrens Helath, Sydney, NSW, Australia

Background

The recent investigation of an Australian gynaecologist accused of hundreds of counts of unnecessary surgery for endometriosis has highlighted the plight of women who have endured years of pelvic pain and the desperation which drives them to seek relief at any cost.

In November 2025 a Victorian Governmental report entitled Bridging the Gender Pain Gap was released. Of the 13,000 submissions by women, 95 percent sought medical help but seventy one percent experienced dismissal of their symptoms for reasons of gender identity, race, disability and bodily weight issues. The recommendations included developing and promulgating standards for management of women's pain and expanding women's health care facilities to include 20 additional Sexual and Reproductive Health Hubs in the public sector at a cost of \$153 million.

Research Question

What legal initiatives are possible to assist the gender disparity in pain management in Australia?

Methodology

Australian & UK case law will be reviewed to identify cases of delayed diagnosis of chronic pain as an indication of endometriosis.

Results

Australian law restricts damages for non-economic loss—pain, suffering, and loss of amenity—through state-based Civil Liability Acts, typically requiring a minimum threshold of impairment (e.g., >10% or 15% in NSW) and capping maximum payouts (e.g., ~\$350,000–\$691,000+ in NSW depending on the case) to address only the most extreme cases.

The State of Victoria introduced a State-based *Charter of Human Rights and Responsibilities Act* 2006, which inter alia includes rights such as equality before the law, freedom of expression, privacy, and protection from cruel or inhuman treatment. The Victorian Charter does not explicitly guarantee a "right to freedom from pain," but it offers related protections under Section 10, which prohibits cruel, inhuman, or degrading treatment.

Conclusions

Gender disparity in pain management is only likely to improve if health professionals have a paradigm shift in their attitude to pain in female patients. This would be supported by a national Australian Bill of Human Rights which enshrines the right to pain relief as a basic human right.

SESSION THU-S09 · TRACK 2 · 13:30 – 15:00

Criminal Law III: Panel Discussion · Room R.007

Moderator: Nasser Muh

THU-S09-P01

Session: Criminal Law III: Panel Discussion · **Room:** R.007

Legal Analysis of Regulatory Weaknesses in Enforcing Medical Crime Law in Indonesia

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In medical criminal law, a mistake is a reprehensible state of mind where a person should have avoided a consequence, but did not do so or failed to prevent it. According to the general Theory of Legal

Responsibility, every alleged crime must first be tested based on the basic principle of "geen straf zonder schuld," which states that there is no crime without fault. This principle asserts that a doctor can only be held criminally responsible if there is a reprehensible error, whether the motive is intentional (*dolus*) or due to negligence (*culpa*). Essentially, medical practice directly relates to human life, which in many cases cannot be predicted with certainty because it is closely related to factors inherent in the patient's constitutional condition, which is highly variable and individual, making it diverse. That is why medical procedures always carry risks, both small and large, so that not all consequences that harm patients can be immediately viewed as solely the fault of the doctor. This study was conducted using a normative juridical method with the aim of testing whether the elements of medical crimes in hospitals can be sufficiently enforced if one of these three conditions is met, namely: a clear violation of written medical standards, the doctor does not have the competence and third, there is a causal relationship between the medical procedure performed and the consequences that harm the patient such as serious injury, disability, or death. According to John Blum (2002), in principle, a doctor can only be held legally accountable for his work if proven to work in violation of one of the three conditions above. According to him, this means that the doctor has explicitly neglected the legal obligations that must be fulfilled to his patient. Unfortunately, such an affirmation is not clearly regulated in all existing laws and regulations in Indonesia, including Law No. 17 of 2023 concerning Health, thus placing a heavy burden on doctors in Indonesia who are accused of medical crimes. This study proves that there are weaknesses in law enforcement for medical crimes in Indonesia.

THU-S09-P02

Session: Criminal Law III: Panel Discussion · **Room:** R.007

Criminal Intent (Mens Rea) in Medical Crimes: A Normative Juridical Analysis

MD Asnaria - Tarigan, MD, Doctor of Law Nasser - Muh - Institute, JAKARTA, DKI, Indonesia

Background

Medical crimes are defined as acts involving physicians, dentists, or other healthcare professionals as perpetrators of a criminal offense. These alleged acts may manifest through intent, negligence, or professional malpractice. In alignment with general criminal doctrine, investigators must determine the presence of *mens rea* (criminal intent) or a premeditated plan. However, proving intent in a medical context remains inherently complex, as medical interventions are fundamentally predicated on patient recovery, safety, and the mitigation of clinical risks.

Research Question

Does criminal intent exist within medical crimes, and how can it be legally established?

Methodology

This study employs a normative juridical analysis to examine the conceptual and legal parameters of criminal intent within medical practice.

Results

The analysis demonstrates that indications of intent depend not only on formal evidence of the act (*actus reus*) but also on the specific clinical context, patient safety protocols, and adherence to the standard of care. For instance, a physician providing emergency care in accordance with Standard Operating Procedures without omission cannot be held criminally liable for suboptimal outcomes, provided there is no evidence of willful intent or gross negligence. To establish criminal intent in medical crimes, investigators must provide robust evidence concerning four critical criteria: violations of the standard of care, breaches of professional competence, a demonstrable causal relationship, and the exclusion of inherent medical risks or contributory negligence.

Conclusions

If these elements remain unproven, the presence of intent—and thus the existence of a medical crime—is effectively negated. Establishing a precise conceptual understanding of intent is vital to balancing the protection of patient rights with the safeguarding of professional medical practice conducted with accountability.

THU-S09-P03

Session: Criminal Law III: Panel Discussion · **Room:** R.007

A Comparative Study of General Criminal Offenses and Medical Crimes: A Normative Juridical Analysis and Interdisciplinarity in Indonesia

MD Imelda Rachmawati¹, MD Doctor of Law Nasser Muh¹, Prof Sabela Gayo PhD²

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Medical interventions are fundamentally aimed at patient recovery, risk mitigation, and the prevention of disability. However, such actions occasionally result in adverse outcomes, triggering potential criminal liability. In Indonesia, the general principles of criminal law regarding offenses and intent serve as the *lex generalis* when addressing medical crimes. As a developing field, the application of Medical Crime Law by law enforcement—including police, prosecutors, and judges—requires specific interpretation given the unique characteristics of medical practice, which differ significantly from general criminal cases. Ambiguities often arise in identifying, interpreting, and qualifying the *actus reus* of healthcare professionals compared to the conception of *actus reus* in general criminal law.

This issue is critically urgent as it carries broad implications. For the medical profession, the lack of clear boundaries regarding "criminal acts" in a medical context can foster a climate of fear and disproportionate criminalization. This, in turn, may encourage the practice of defensive medicine, where practitioners prioritize legally safe interventions over clinical necessity, often resulting in higher healthcare costs. Utilizing a normative juridical approach, this paper elucidates the comparison between general criminal offenses and medical crimes. This study contributes to the advancement of Medical Crime Law, aiming to foster legal certainty and justice for physicians and healthcare

THU-S09-P04

Session: Criminal Law III: Panel Discussion · **Room:** R.007

Culpable Nature in Medical Criminal Offenses

Medical Doctor Muhamad Fauzan, Professor Muhammad Nasser

Institute of Health Law, Military Law School, Jakarta, Indonesia

The concept of culpable nature (unlawfulness and despicable nature - culpable/blameworthy element) in criminal offenses, as articulated by J.E. Jonkers, a renowned Dutch criminal law expert, is highly relevant. In the context of medical criminal offenses, M. Nasser provides a significant contribution by outlining two main categories of culpable nature: Special Culpable Nature, which arises from violations of written professional service standards, such as those established by medical professional organizations (peer groups) or institutional medical service standards. The second is General Culpable Nature, which stems from violations of public propriety measured by common standards. Within the framework of medical crime law, a substantial aspect to investigate is whether a violation of written standards, which have carefully considered patient safety, can be deemed a culpable act. For instance, if an obstetrician and gynecologist performs a Cesarean section with an unusual oblique incision that subsequently injures the baby's head, this can clearly be categorized as a culpable nature in medical practice. Such an act must be investigated and considered a culpable act that can serve as an entry point into one of the categories of medical crime law. Meanwhile, if a medical procedure receives public condemnation for violating common standards of propriety, the court judge must also consider this in their ruling. This paper is prepared using a normative juridical approach to enrich expert views on Medical Crime Law.

THU-S09-P05

Session: Criminal Law III: Panel Discussion · **Room:** R.007

Concursus Realis or Multiple Criminal Acts in Medical Crime Law

Lawyer Syamsul Jahidin Law degree¹, Doctor Iswandi MARS Doctor Degree², Alfian Maulani Bachelor Degree³, Professor Muhammad Nasser Doctor of law⁴

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Concursus realis, or multiple criminal acts, refers to a legal situation where a perpetrator is charged with committing more than one distinct criminal offense, also known as *meerdaadse samenloop*. Some legal scholars argue that *concursus realis* cannot be applied to medical crimes, primarily because each act must first be proven independently, and any element of intent (*dolus*) would shift the classification from a medical crime to a general criminal offense. This study investigates the manifestation of *concursus realis* specifically within the medical crime context. Findings suggest that multiple offenses can occur through a combination of negligence (*culpa*) and omission. For example, a child failing to receive a mandatory vaccination due to a surveillance failure, followed by the administration of contraindicated steroids causing complications, represents two distinct acts: medical omission in vaccination and medical negligence in treatment management. If such instances result in death or permanent disability, medical criminal proceedings become an available legal avenue. Utilizing a normative juridical research approach, this paper discusses the level of caution required of healthcare professionals to avoid unforeseen criminal pitfalls. From the perspective of the "sense of justice," while these concepts are common in general criminal law, they present unique challenges and complexities within the specialized field of medical crime law.

THU-S09-P06

Session: Criminal Law III: Panel Discussion · **Room:** R.007

Criminal Liability of Doctors for Medical Errors: Different Approaches within Europe

Prof. Dr. Sylvie Tack PhD

Ghent University, Ghent, Belgium. Antwerp University, Antwerp, Belgium. Sanalex Law firm, Knokke, Belgium

Background

In recent decades, the number of proceedings against doctors has increased worldwide. Medical errors include, for example, inadequate preoperative preparation for a procedure or careless execution of the treatment. These are usually civil proceedings between the patient and the doctor (or his liability insurance) in which the question of compensation is central. However, doctors are sometimes criminally prosecuted for medical errors, with the investigation being conducted by the public prosecutor. The investigation then focuses on whether the doctor has committed a criminal offence.

Within Europe, criminal law is not uniformly and there are significant national differences. This raises the question of whether the criteria for due care required to convict a doctor are equally strict everywhere.

Research Question

Do the criteria for due care required to convict a doctor differ across Europe and, if so, what are these differences?

Methodology

The study is conducted on the basis of comparative legal research.

Results

There are significant differences between criminal law in various European countries. In Belgium, "classic" medical errors are generally classified as "unintentional assault and battery". Since the new Criminal Code came into force in April 2026, the concept of "intent" has been relaxed and only "serious" errors are now considered. As a result, most medical liability cases are likely to result in acquittal.

This change brings Belgian legislation into line with criminal law in other countries, such as the Netherlands and Germany, where only "seriously culpable" shortcomings can lead to a criminal conviction.

Other countries, such as Spain and France, have stricter rules. In those countries, a criminal conviction is already possible for "minor errors" or "ordinary negligence". In yet other countries, such as Croatia, Slovenia and Serbia, there is a separate offence for medical errors. In the United Kingdom, on the other hand, medical errors are only punishable in cases of "gross" negligence with fatal consequences.

Conclusions

The conditions for convicting a doctor for medical errors vary between European countries. As a result, the same medical error may lead to a criminal conviction in one country but not in another. An overly strict interpretation of the duty of care criterion can lead to highly defensive medicine, which is not conducive to good patient care. It is desirable to harmonise the duty of care criterion within Europe so that only "serious" negligence can lead to criminal sanctions.

SESSION THU-S10 · TRACK 3 · 13:30 – 15:00

Medical Liability II · Room R.230

Moderator: Ian Freckelton

THU-S10-P01

Session: Medical Liability II · **Room:** R.230

Recent Malpractice Cases in Telemedicine: In Search of the Standard of Care

Assoc. Prof. Petr Šustek PhD

Department of Medical Law, Charles University Faculty of Law, Prague, Czech Republic

Background

Telemedicine is increasingly becoming part of routine clinical practice. While it offers important benefits in terms of access to care, convenience, and at times even patient safety and quality, it also creates new risks. The standard of care, breach of which commonly grounds civil liability in healthcare, remains under-defined in the context of remote care. Uncertainty persists as to when telemedicine is appropriate, how remote services should be delivered safely and effectively, and whether requirements developed for in-person care should be modified for telemedicine.

Research Questions

This presentation addresses two research questions. The first question asks whether emerging case law sufficiently responds to the above-outlined issues, particularly to the problem of defining and possible modifying the standard of care in telemedicine. The second research question asks which direction courts tend to take in resolving these issues, especially whether their approach is better characterised as conservative or activist.

Methodology

Methodologically, the presentation combines doctrinal legal analysis with a problem-oriented qualitative examination of emerging malpractice case law in telemedicine. On a selected set of real-world disputes, mainly from the Czech legal context, it performs a structured analysis of judicial reasoning aimed at three objectives: first, to assess how far courts engage with the need to specify or modify the standard of care for remote services; secondly, to position judicial approaches on a conservative–activist spectrum; and thirdly, to inductively identify preliminary judicially supported criteria for evaluating telemedical practice. The Czech legal framework is used as a case study of a Continental European legal system currently moving towards explicit regulation of telemedicine.

Results

Preliminary results suggest that courts tend to adopt a rather conservative approach, mostly applying existing general standards of care to telemedicine without substantial modification. At the same time, the analysed cases suggest several emerging criteria relevant to the assessment of remote care, including careful consideration of whether telemedicine was indicated and adequate provision of information to the patient, and appropriate justification where remote care substitutes for in-person care.

Take-Home Message

Case law can provide an important starting point for shaping the telemedicine standard of care, but it is unlikely to remove legal uncertainty on its own. More specific professional standards and guidelines will probably be needed to address legal uncertainty and prevent overly strict reliance on rules developed for in-person care.

THU-S10-P02

Session: Medical Liability II · **Room:** R.230

Towards a Quantum Leap for Medical Liability in Europe

Prof. Dr. Rui MPP Cascao PhD

Universidade Lusófona, Porto, Portugal. CEAD (Law), Lisbon, Portugal

Background

Quantum computing (QC) harnesses properties of quantum physics – such as superposition and entanglement – to solve problems intractable for classical computers and artificial intelligence (AI) systems. In healthcare, early proof-of-concept applications are emerging: quantum-enhanced MRI (e.g., the European Union's Q-MRI Pilot Infrastructure) promises earlier detection of neurodegenerative

diseases; quantum machine learning (QML) models analyse medical images (CT, X-ray) for cancer and pneumonia with reported accuracies of 95-99%; and hybrid quantum-classical algorithms optimise radiotherapy planning and predict patient-specific drug responses. Unlike classical computing, QC operates probabilistically – a fundamental shift from the deterministic models of causation on which current liability rules rest in most European jurisdictions. Although still in the experimental phase, quantum technology is expected to become generalised in medical devices in the foreseeable future (10-15 years).

Research Question

Are Europe's medical liability frameworks, at EU level (Product Liability Directive, or the shelved AI Liability Directive proposal) and in Member States' domestic laws, fit for the quantum age? Or do their rigid, all-or-nothing approaches to causation and burden of proof risk creating a compensation gap for patients harmed by quantum-enabled medical devices?

Methodology

Against the backdrop of the 'Quantum Europe Strategy', the forthcoming EU Quantum Act proposal, and the recent overhaul of AI, technology regulation, and product liability, this contribution critically examines existing liability frameworks concerning healthcare QC applications, identifying legal shortcomings through a comparative assessment of burden of proof rules, causation standards, and damage calculation in selected legal systems (Portugal, Germany, France, Sweden, Finland, Netherlands).

Results

Most current liability systems are deterministic and formalistic: they rely on binary "but-for" causation, rigid allocation of the burden of proof and high standards of evidence, and lack mechanisms for proportional compensation. In quantum-driven healthcare, where outputs are intrinsically probabilistic and harm may be a statistical increase in risk rather than a manifest injury, these rules create insurmountable evidentiary hurdles. Without reform, patients will face systematic under-compensation, and innovators could face unpredictable liability exposure, bringing a chilling effect to innovation in quantum healthcare applications.

Conclusions

To bridge the gap, this contribution proposes three alternative compensation frameworks: (1) strict liability for quantum device manufacturers, (2) a no-fault compensation scheme for unavoidable injury related to quantum devices (modelled on Scandinavian Patient Insurance Schemes), and (3) fault-based liability with proportional damages for uncertain causation and a scalable burden of proof that adapts to the probabilistic nature of quantum causation.

THU-S10-P03

Session: Medical Liability II · **Room:** R.230

Civil Liability for Dental Malpractice: Analysis of Decisions from the Court of Justice of Bahia/Brazil in the Last Decade

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Background

The increasing judicialization of healthcare has also significantly impacted dentistry, leading to a growing number of lawsuits involving alleged dental malpractice. In Brazil, civil liability claims against dentists often depend on complex technical evaluations, particularly judicial expert reports, which assist judges in determining whether professional conduct met the applicable standard of care.

Research Question

This study aimed to investigate civil jurisprudence concerning dental malpractice cases judged by the Court of Justice of Bahia over the last decade (2016-2025). The central research hypothesis proposed that judicial dental expert evidence presents a direct associative relationship with the judge's decision-making process in civil liability cases.

Methodology

To test this hypothesis, the study examined if judicial decisions addressed the judicial expert reports. Specifically, the research sought to identify: (1) the number of decisions that based their conclusions on the contractual nature of the dentist's obligation, distinguishing between obligations of means and obligations of result; (2) the number of decisions that relied on either subjective or objective civil liability as the

legal foundation for the decision; and (3) the number of decisions that grounded their conclusions on the outcome of judicial dental expert reports. This research adopted an observational, analytical, cross-sectional, and quantitative design. Data were collected from publicly available decisions published on the official website of the Court of Justice of Bahia. The search was conducted between 2025 and 2026 using the keyword "dentist," limited to second-instance appellate decisions. The selected cases were analyzed to identify the legal reasoning adopted by the courts and the relationship between expert evidence and judicial outcomes.

Results

The analysis of the decisions revealed a complete convergence between the conclusions of the judicial expert reports and the final outcomes of dental civil liability cases. In all analyzed decisions, the judges' determinations were consistent with the technical findings presented in the expert reports. This result highlights the central role of forensic dental expertise in the resolution of litigation involving dental care. The findings demonstrate that the determination of professional fault and the recognition of technical error remain strongly dependent on specialized evaluation produced within the scope of judicial expert examination.

Conclusions

These results suggest that expert evidence continues to play a decisive role in guiding judicial reasoning in dental malpractice disputes. Consequently, strengthening forensic dental expertise and ensuring high methodological quality in expert reports are essential for improving legal certainty and fairness in the adjudication of dental civil liability cases.

THU-S10-P04

Session: Medical Liability II · **Room:** R.230

Physician Negligence in Hospitals: An Indonesian Medical Tort Law Perspective

MD Rendra Irawan, MD Muhammad Nasser
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Background

Hospitals occupy a precarious position regarding legal liability for medical negligence committed by affiliated physicians. Article 193 of Health Law No. 17 of 2023 mandates that hospital management bears responsibility for negligence committed by healthcare resources within the institution. This implies that hospitals can be held liable either directly or through the principle of *vicarious liability*. However, this provision remains controversial, as it is perceived as unrealistic and potentially in conflict with other prevailing Indonesian statutes. Typically, civil relationships are governed by legally binding cooperation agreements between physicians and hospitals. While these agreements incorporate the essence of Article 193, liability should theoretically not extend to clinical aspects beyond the hospital management's control, a stance reinforced by Article 1367, paragraph (4) of the Indonesian Civil Code (KUH Perdata).

The core of this controversy lies in the hospital's obligation to guarantee safe services and adherence to mandatory professional standards.

Research Question

This research examines the complexities of legal liability from a corporate civil law perspective, specifically concerning negligence within hospital settings.

Results

Given the increasing number of disputes targeting hospitals as defendants, an analysis of corporate liability is becoming critically relevant.

Methodology

This study employs a normative juridical method, utilizing law as a basis for norms through prescriptive-analytical research.

Conclusions

The findings highlight the need for legal harmonization to resolve ongoing juridical debates and improve the future landscape of medical tort law in Indonesia.

THU-S10-P05**Session:** Medical Liability II · **Room:** R.230**Reconstructing the Boundaries of Civil Liability: Judicial Expansion between Medical Risk and Professional Negligence in Indonesian Jurisprudence**MD Renita Irawati¹, MD, D. Law Muh Nasser², Mena Melyssa Saragih Simarmata³, Ahmad Jaeni³¹Institute of Health Law, Military School of Law, Jakarta, DKI Jakarta, Indonesia. ²Institute of Health Law, Military School of Law, Jakarta, DKI Jakarta, Indonesia. ³**Background**

Civil liability litigation in healthcare services has evolved into a primary instrument for patient rights recovery in Indonesia. However, the judiciary still grapples with fundamental doctrinal issues stemming from the ambiguity between unavoidable medical risks, inherent to clinical practice, and professional negligence, which is legally

Research Question

This article aims to analyse how Indonesian courts have progressively expanded the interpretation of civil liability through shifts in evidentiary standards and the broadening of joint and several liability for health institutions.

Methodology

This analysis employs a jurisprudential approach (case law analysis) and doctrinal legal analysis of strategic court decisions from District Courts, High Courts, to the Supreme Court, focusing on the interpretation of fault elements based on Article 1365 of the Indonesian Civil Code and the expansion of corporate liability under Article 1367 of the Indonesian Civil Code. The research was conducted using a normative juridical approach, based on statutory regulations and expert papers.

Results

The findings reveal a significant shift from a formalistic approach at the *judex facti* level—where the existence of informed consent and adherence to standard operating procedures were deemed sufficient to classify an event as a medical risk—towards a substance and outcome-based assessment at the Supreme Court level. This reflects a tendency to apply the *res ipsa loquitur* principle, using the fact of injury itself as a basis for inferring fault. Furthermore, a tendency to shift the burden of proof to healthcare providers was observed, particularly in cases of permanent disability or death, as well as an expansion of hospitals' joint and several liability even for medical professionals with independent partner status.

Conclusions

Although this judicial expansion reflects a patient protection orientation and corrects information asymmetry between doctors and patients, the lack of a clear doctrinal distinction between medical error, civil negligence, and unavoidable risks potentially encourages defensive medicine practices and hinders medical innovation. Therefore, an interdisciplinary harmonization between clinical standards and legal standards is urgently needed to maintain a balance among access to justice, sustainability of healthcare services, and advancement of medical technology.

SESSION THU-S11 · TRACK 4 · 13:30 – 15:00**Mental Healthcare II · Room R.004**

Moderator: Shigeki Takahashi

THU-S11-P01**Session:** Mental Healthcare II · **Room:** R.004**Reconstructing Patient Consent in Mental Health Care: A Comparative Analysis of Finland, Germany and Scotland**Doctoral Researcher Maija-Sofia Kristina Ulmanen MA, M. Soc. Sc.

University of Vaasa, Vaasa, Finland, Finland

This abstract draws on two of my ongoing peer-reviewed articles titled as *"Patient Consent in Mental Health Care – A Comparative Review"* and a companion analysis examining whether Finnish mental-health legislation meets the equality requirements of the CRPD, titled as *"Is Finnish Mental Health Regulation Equal and Non-Discriminatory Under the CRPD?"*

Background

Patient consent in psychiatric care raises complex legal and ethical questions because the boundary between autonomy and coercive intervention is unusually thin. Across Europe, legal systems struggle to reconcile patient self-determination with public health concerns, safety assessments, and clinical authority. Although consent is a cornerstone of modern health law, its meaning, depth and operational force vary considerably between jurisdictions. This study examines how Finland, Germany and Scotland legally construct consent in mental health care, and how structural choices determine whether patients remain rights-bearing subjects or become objects of institutional authority.

Research Question

The main focus of the study is to discover, how do Finland, Germany and Scotland regulate patient consent in psychiatric treatment, and what do these differences reveal about the normative thresholds at which autonomy can be limited, supported, or overridden?

Methodology

The study uses a comparative legal methodology integrating statutory analysis, case law, oversight-body reports and human-rights standards (ECHR and CRPD). To analyse normative differences, the article develops (1) a **concentric "inner-outer circle model"** illustrating the structural shift from self-determination to substituted decision-making, and (2) a **five-dimensional framework of consent**—general, specific, ongoing, supported, and refusal/withdrawal—reflecting consent as a dynamic process rather than a single act.

Results

The main results clearly demonstrate how the three legal systems adopt distinct perspectives on patient consent, reflecting different societal understandings of autonomy and the role of the state. They also reveal the specific mechanisms each system uses to define, support, or limit patient consent in psychiatric care. Finland follows an administrative model where consent can be overridden through medical discretion when Mental Health Act criteria are met, and judicial review occurs typically afterwards—creating questions of eroding autonomy and accumulating vulnerability. In Germany, consent is constitutionally protected: any override requires prior court authorization, and the patient's will remains the guiding principle in both coercive treatment and guardianship. Scotland follows a participatory model: coercive measures require external review, and can be authorized only when the statutory test of significantly impaired decision-making ability is met. Human-rights frameworks increasingly push all systems toward supported rather than substituted decision-making.

Conclusions

The main conclusion is that consent in psychiatric care is not a single moment of agreement but a multilayered, evolving process that reflects the underlying institutional values attached to autonomy, dignity and the legitimate scope of clinical authority. Independent gatekeeping—by courts, tribunals and oversight bodies—is essential to protect individual autonomy. Aligning mental-health legislation with CRPD standards requires strengthening supported decision-making, improving documentation and reason-giving duties, and ensuring that refusals of treatment carry meaningful legal effect.

THU-S11-P02**Session:** Mental Healthcare II · **Room:** R.004**Balancing Individual and Collective Rights: Patient Autonomy versus the Best Interest of Mental Health Patients**Dr. Barr. Akudo Nnenne Amanamba Law

Gregory University, Uturu, Abia, Nigeria. Amanamba & Amanamba Associates, Ezeugo Law Firm, Umuahia, Abia, Nigeria

Background

The tension between individual rights and collective interests has become a central issue in modern healthcare law, particularly in the treatment of mental health patients. Patient autonomy, which recognises individuals' right to make informed decisions about their medical treatment, is widely regarded as a fundamental principle of medical ethics and human rights. However, in the context of mental health care, the exercise of autonomy may conflict with the need to protect the patient or the wider public from harm. Mental illnesses may impair a patient's decision-making capacity, thereby raising questions

about whether healthcare professionals should respect the patient's wishes or intervene in what they consider the patient's best interests. The challenge, therefore, lies in balancing the individual rights of mental health patients with the collective interest of society in ensuring safety and effective healthcare. Ethical principles such as autonomy, beneficence, and non-maleficence also play a crucial role in guiding healthcare decision-making in these situations.

Research Questions

This study examines the legal and ethical tension between individual autonomy and collective welfare in mental health care. It addresses the following questions: To what extent does Nigerian law protect the autonomy of mental health patients? Under what circumstances may healthcare professionals limit patient autonomy in order to protect the patient or society? How can legal and ethical principles be balanced to ensure both respect for patient rights and protection of public interest?

Methodology

The study adopts a doctrinal legal research method involving the analysis of relevant statutes, judicial decisions, and scholarly literature on medical law and bioethics. Particular attention was given to the provisions of the National Health Act 2014 and the Mental Health Act 2021. The study also examines judicial authorities such as *Medical and Dental Practitioners Disciplinary Tribunal v Okonkwo*, which affirm the principle of patient autonomy.

Results

The study finds that while Nigerian law recognises patient autonomy as a fundamental right, mental health legislation allows limited restrictions on autonomy where patients lack decision-making capacity or pose a risk to themselves or others. In such cases, the best interest principle and considerations of public safety justify medical intervention.

Conclusions

The study concluded that an effective balance between individual autonomy and collective welfare is essential in mental health care. While strengthening legal safeguards, promoting ethical medical practice, and ensuring proper oversight of involuntary treatment are necessary to protect both the rights of mental health patients and society's interests.

Take-Home Message

Patient autonomy is important but not absolute. When a mental health patient cannot make an informed decision or poses a risk, the law allows limited interventions to protect both the patient and others. The key idea is achieving a careful balance between individual rights and safety, with healthcare professionals acting ethically and within legal safeguards.

THU-S11-P03

Session: Mental Healthcare II · **Room:** R.004

Between Care and Confidentiality: Family Involvement and Professional Confidentiality in Flemish Mental Healthcare

Sarah Claes

KU Leuven, Leuven, Belgium

Background

Family members are playing an increasingly prominent role in the provision of long-term mental healthcare. This development reflects broader shifts towards person-centred, recovery-oriented, community-based, and integrated care. Consequently, responsibility for providing long-term mental healthcare increasingly lies with family members rather than exclusively with professional care providers in psychiatric settings.

Although this shift is internationally supported, including by the World Health Organization (WHO), legal and non-legal analyses of the position of family members in mental healthcare in Flanders remain limited. Moreover, family members do not fulfil one uniform role but assume diverse roles involving specific tasks, responsibilities, and expectations that have not yet been systematically mapped. Professional confidentiality is frequently identified in the literature as a legal barrier to their effective involvement in mental healthcare.

Research Question

This study examines the extent to which the current Flemish legal framework on professional confidentiality facilitates the implementation of the different roles of family members in mental healthcare and identifies where legal barriers arise in relation to their tasks and responsibilities.

Methodology

The study proceeds in two stages. First, a typology of the roles that family members may assume in mental healthcare is developed through a systematic review of national and international literature, defining and conceptualising the content of these roles. Second, the legal framework on professional confidentiality is analysed and applied to each role to assess the extent to which it enables or hinders its effective performance.

Results

The findings show that professional confidentiality is not an absolute barrier to family involvement in many cases. However, the legal framework does not always align seamlessly with the sometimes broad roles family members are expected to assume, creating tensions or uncertainties in specific situations. In practice, professional confidentiality is also often perceived as a greater obstacle than it is from a strictly legal perspective. Provided that the applicable legal conditions are met, the existing framework allows family members to be involved in care to a considerable extent.

Conclusions

The Flemish framework on professional confidentiality offers both opportunities and limitations for family involvement in mental healthcare. A clearer understanding and articulation of this framework, linked to the different roles of family members, may enhance legal certainty and support more effective collaboration between professional care providers and family members. This is essential to support the current shift towards greater family involvement in care in a legally sound and practically feasible manner.

THU-S11-P04

Session: Mental Healthcare II · **Room:** R.004

Bridging the Gap: Rethinking Proxy Decision-Making in Cognitive Decline

Julia Braun Atty.-at-Law (Germany), Bjoern Schmitz-Luhn J.D., PhD, Atty.-at-Law (Germany)

Bonn University, Bonn, Germany

Background

Informed consent is a cornerstone of medical law. However, for individuals experiencing cognitive decline—whether due to forms of dementia or other neurodegenerative conditions—the ability to provide valid consent becomes increasingly compromised. Cognitive decline can be gradual and fluctuating, leading to challenges in determining a patient's capacity to understand and engage in medical decisions. The question of how to respect patients' autonomy while facilitating proxy decision-making as cognitive abilities decline remains a pressing issue in health law, particularly regarding advance directives and fluctuating capacity.

Research Question

This study explores how legal frameworks address proxy decision-making in patients experiencing cognitive decline, regardless of the underlying condition. It asks: How do legal systems manage the evolving capacity of patients to consent to medical treatment? How can these systems allow for a gradual transition from self-determination to proxy involvement, while still respecting patients' preferences as their cognitive abilities change?

Methodology

A comparative legal analysis was conducted across several jurisdictions to examine how legal systems regulate decision-making for patients with progressive cognitive impairments. The analysis focused on the assessment of capacity, the role of proxy decision-makers, and how advance directives are incorporated into decision-making frameworks. Special attention was given to how these systems account for fluctuating or partially diminished capacity and whether they allow for gradual shifts in decision-making authority.

Results

The study highlights that most legal frameworks adopt a binary view of capacity, often categorizing it as either present or absent. As a result, when incapacity is determined, decision-making authority is transferred entirely to a proxy, without mechanisms for a gradual or flexible transition. Moreover, legal systems often fail to provide clear guidelines for collaborative decision-making, where both patients and proxies can contribute to decisions based on the patient's fluctuating ability to consent. There is limited consideration for patients' evolving preferences, as expressed through advance directives, over time.

Conclusions

The current “all-or-nothing” approach to proxy decision-making can create significant challenges for patient autonomy. This research presents a more nuanced model, where proxy involvement increases gradually as cognitive capacity declines, and collaborative decision-making mechanisms are introduced, and discusses its advantages and limitations.

SESSION THU-S12 · TRACK 5 · 13:30 – 15:00

Patient Rights and Medical Decision-Making · Room R.201

Moderator: Eduardo Dantas

THU-S12-P01

Session: Patient Rights and Medical Decision-Making ·

Room: R.201

Reflective Time and Second Opinions in Decision-Making for Elective and Non-Therapeutic Procedures

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Background

Contemporary neuropsychology and neuroethics show that human decisions are shaped by somatic markers, emotional anchoring to desired outcomes, and transferential bonds with authority figures, rather than by abstract rational deliberation alone. In elective and especially non-therapeutic medical procedures, these mechanisms are actively recruited by cultural norms, social media, and persuasive clinical communication, which may compress reflection and narrow patients' effective decisional freedom.

Research Question

How can the concepts of decisional degrees of freedom, emotional anchoring to outcomes, and transferential bonding with professionals justify a normative requirement for extended reflection time and independent second opinions in elective and particularly non-therapeutic procedures?

Methodology

This work adopts an interdisciplinary, exploratory and critical approach combining neuroscience (somatic marker hypothesis and value circuits), cognitive psychology (heuristics and coherence-based decision models), psychoanalytic notions of desire and transference, cultural anthropology, marketing and neuromarketing studies, and bioethical and legal analysis of informed consent. Two paradigmatic hypothetical scenarios were articulated as baseline for reflection: a life-saving high-risk surgery confirmed by a second opinion, and high-risk aesthetic surgeries sought by a young woman influenced by social media and a single, highly idealized professional.

Results

Across these literatures and scenarios, the analysis shows that emotional anchoring to specific outcomes (cure, beauty, social acceptance) and to particular professionals operates as a pre-reflexive filter that limits the range of options the patient can genuinely consider. When combined with time pressure, persuasive framing, and asymmetric information, these anchors reduce the degrees of decisional freedom even when formal informed consent requirements are met. Conversely, structured pauses for reflection, exposure to alternative narratives and risk framings, and consultation with an independent second professional reopen the field of possibilities, weaken rigid affective anchors, and increase the likelihood that consent expresses the patient's own elaborated values rather than unexamined desires or external pressures.

Conclusions

Neuropsychological and psychoanalytic evidence suggests that autonomy in elective and especially non-therapeutic procedures is best understood as a variable degree of freedom, not as an all-or-nothing property. Because emotional anchoring and transferential dynamics can silently capture decision-making, ethical and legal practices should explicitly build in time for reflection and strongly favor second opinions as structural counterweights to these mechanisms. Such safeguards do

not eliminate influence but maximize the patient's practical freedom to say “yes” or “no” from a position that is more reflective, less affectively captive, and better aligned with their long-term identity and well-being.

THU-S12-P02

Session: Patient Rights and Medical Decision-Making ·

Room: R.201

Making Room for Family Involvement in Medical Decision-Making Within European Patient-Rights Law

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Background

European patient-rights law commonly frames legitimate medical intervention through the paradigm of individual autonomy, operationalised as free and informed consent given by the competent patient. In everyday clinical practice, however, decision-making is frequently relational. Patients often want family members or other trusted persons present to help them process complex information, recall details, translate or contextualise explanations, manage emotional distress, and articulate values and preferences. The tension between a predominantly individualist legal architecture and relational clinical realities becomes especially salient in culturally and linguistically diverse settings, where norms about information disclosure, collective deliberation, and family roles may differ from dominant Western-European expectations. Unstructured family involvement can also create risks, including confidentiality breaches, gatekeeping of information, and undue influence.

Research Question

How can European patient-rights law accommodate meaningful family involvement in medical decision-making while preserving the non-transferable core of competent patients' autonomy and the safeguards required for valid consent?

Methodology

A principled framework is developed through doctrinal and normative analysis. The approach (1) differentiates forms of family involvement across decision-making models (informational support, deliberative support, interpretive or cultural mediation, and substitute decision-making); (2) clarifies the legal and ethical requirements for valid consent, with particular attention to adequate information, comprehension, voluntariness, and the patient's continuing control over participation and disclosure; and (3) identifies clinical “risk points” at which family dynamics may compromise autonomy, including pressure, coercion, selective translation, and exclusion of the patient from discussions.

Results

The analysis shows that European patient-rights frameworks allow more flexibility than is often assumed, provided that the patient remains the decision-maker and can limit or revoke family participation at any time. Lawful accommodation is best achieved through procedural tools that “make room” for family without transferring authority: explicit elicitation and documentation of who the patient wants involved; topic- and moment-specific consent for information sharing; structured family meetings with clear role delineation and ground rules; routine opportunities for private clinician-patient communication; access to professional interpreters and cultural mediators; and mechanisms such as advance care planning, ethics consultation, and escalation pathways when undue influence is suspected.

Conclusions

Family involvement is not a legal substitute for a competent patient's consent, but it can be legitimately integrated as a patient-led procedural accommodation that supports understanding and value-concordant choices. When clinicians actively structure participation and apply safeguards for voluntariness, comprehension, confidentiality, and equality, family involvement can strengthen communication and trust while preserving the legal integrity of informed consent.

THU-S12-P03**Session:** Patient Rights and Medical Decision-Making ·**Room:** R.201**Future-Proof Patient Rights**Prof. Johan Legemaate PhD

University of Amsterdam, Amsterdam, Noord-Holland, Netherlands

Background

About 30 years ago, several European countries enacted legislation on patients' rights. Since then, healthcare has changed significantly. It looks very different from 30 years ago, in terms of size, organization/financing, coherence, division of responsibilities, and the impact of technology. Furthermore, various relevant developments in society are influencing the content and vision of healthcare, such as the significant increase in digitalization. These developments have consequences for patient rights. New regulations regarding patient rights have been established in recent years, but many current laws are still rooted in thinking from several decades ago.

Research Question

Are the current regulations regarding patient rights sufficiently future proof? And if not, how can these regulations best be adapted?

Preliminary Conclusions

An analysis of European developments in the field of patients' rights reveals a mixed picture. Many regulations are still based on traditional perspectives within healthcare law and healthcare. There are few examples of regulations that incorporate modern developments (including digitalization and the changing position of the patient). The extent to which relevant international treaties have been incorporated into national legislation is also still disappointing. Developments in recent decades provide ample reason to specify or supplement patient rights. It is becoming increasingly important to find ways to properly inform citizens and patients about the increasingly complex regulations concerning patients' rights. Without proper information, the legal position of patients is under pressure. This also raises the question of the best means to regulate and disseminate patients' rights: should this always be done through law, or are there other options?

THU-S12-P04**Session:** Patient Rights and Medical Decision-Making ·**Room:** R.201**Systemic and Systematic Implementation of Patients' Rights in Medical Treatment Institutions in the Republic of Latvia**Assoc. Prof. Karina Palkova PhD^{1,2}, Assist. Prof. Laura Šāberte PhD¹¹Rīga Stradiņš University, The Faculty of Social Sciences, Riga, Latvia. ²The Ombudsman of the Republic of Latvia, Riga, Latvia**Background**

In the Republic of Latvia, the protection and implementation of patients' rights have traditionally been regulated by the Law on the Rights of Patients, which obliges medical treatment institutions to respect patients' rights in healthcare delivery. However, implementation has often depended on individual institutional practices rather than a unified approach. To strengthen effective observance of patients' rights, significant amendments to the Law on the Rights of Patients entered into force on 1st July 2025.

According to amendments Section 3, paragraph 7 of the Law on the Rights of Patients provides that medical treatment institutions are obliged to promote respect for patients' rights in a systemic and systematic manner and to ensure the protection and implementation of patients' rights in every healthcare situation. Inpatient medical treatment institutions and multiprofile outpatient medical treatment institutions are required to develop a patients' rights implementation plan and to ensure its execution.

Research Question

The aim of this research is to analyse the new legal obligation to ensure the systemic and systematic implementation of patients' rights in medical treatment institutions in the Republic of Latvia, to assess its significance for healthcare practice, and to identify key challenges and opportunities related to the development and implementation of patients' rights implementation plans within inpatient and multiprofile outpatient healthcare institutions.

Methodology

General scientific research methods are used in this study. The content of the legislation, legal literature and scientific articles are analysed. The grammatical (philological), the historical, the systemic, and the teleological method of interpretation has been used in the research. Patients' rights are an integral component of human rights, in accordance with Section 89 of the Constitution of the Republic of Latvia, which guarantees fundamental human rights in compliance with the Constitution, laws, and binding international treaties. Emphasis in this study is placed on the integration of patient rights as a continuous and institutionalised aspect of the governance of healthcare facilities.

Results

Systemic and systematic implementation of patients' rights in Latvian medical institutions enhances patient security, confidence, and healthcare quality. Patients' rights implementation plan integrates rights into institutional operations: documentation, personnel training, organizational processes, and patient involvement in decision-making. Functioning as practical operational algorithm, patients' rights implementation plan ensures personnel understand and apply patients' rights, comply with national law and international obligations, demonstrate, monitor, and reinforce rights, resolve disputes, and adapt to institution type.

Conclusions

The experience of the Republic of Latvia demonstrates that systematically embedding patients' rights within the governance of healthcare facilities is not only an effective means of promoting patient rights but also a practical way of operationalizing human rights in the healthcare context.

THU-S12-P05**Session:** Patient Rights and Medical Decision-Making ·**Room:** R.201**(In)Validity of Therapeutic Consent Provided by a Legal Surrogate Decision-Maker**Lawyer Yasmin C Chahoud Master's student in Medical Law,Lawyer Tuane V Tonon Master's degree in Medical Law

University of Santo Amaro (UNISA), São Paulo, São Paulo, Brazil

Background

The increasing diversity of family configurations and affective bonds challenges the assumption that a legally recognized surrogate decision-maker is able to faithfully represent the patient's values and convictions. In contexts of decisional incapacity, therapeutic decisions are typically delegated to legally recognized surrogates who, in practice, may fail to ensure moral alignment between substituted judgments and the patient's values. This mismatch reveals a tension that transcends the strictly legal sphere and extends into the moral and ethical domain. Patient autonomy is intrinsically associated with morality, understood as the relationship between actions and self-determination, allowing for the possibility of a universal law grounded in the agent's maxims. In cases of loss of decision-making capacity, the legitimacy of clinical decision-making requires adherence to the agent's maxims, such that the substitution of this will with external values compromises the moral structure grounding action and may undermine the dignity of the individual whom one intends to protect.

Research Question

Can therapeutic consent provided by a legal surrogate decision-maker who does not share the patient's moral convictions be considered a legitimate exercise of substituted autonomy?

Methodology

This study adopts a qualitative and interdisciplinary approach, combining legal analysis with bioethical theory. It is based on a critical doctrinal and theoretical review, with emphasis on principlism and the concept of "moral strangers," articulated with the Kantian notion of autonomy as its interpretive foundation. Within this framework, the interrelation between *legal capacity*, moral vulnerability, and medical decision-making is examined through the principles of autonomy, beneficence, non-maleficence, and justice, particularly in connection with fundamental rights.

Results

The analysis suggests that surrogate decision-making by an individual who does not share the patient's moral framework may constitute not merely a limitation but a violation of autonomy. By relying on their own values, the surrogate ceases to reflect the patient's presumed preferences and instead imposes an external moral standpoint, thereby disrupting the unity between self-governance and normativity that defines autonomy. Under such conditions, substituted autonomy, when dissociated from the represented individual's moral universe, becomes ethically compromised and potentially invalid.

Conclusions

These findings point to the need to reconsider the normative criteria governing surrogate decision-making. In particular, affective and relational closeness along with moral alignment, should be treated as relevant factors in determining representational legitimacy, raising the possibility that individuals with shared moral commitments ("moral friends") may, in certain cases, provide more legitimate representation than formally designated surrogates.

SESSION THU-S13 · TRACK 6 · 13:30 – 15:00

Public Health Law II · Room R.011

Moderator: Jonathan Davies

THU-S13-P01

Session: Public Health Law II · **Room:** R.011

Commercial Host Liability in Comparative Perspective: Implications for Thailand's Emerging Alcohol Control Framework

Withoo Phrueksanan M.D., LL.M. (Global Health Law)¹, Rinyapath Na Songkhla LL.D.², Nednapa Prommouk Phrueksanan LL.B., LL.M, M.P.A.³

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Background

Alcohol-related morbidity and mortality remain a major medico-legal and public health concern worldwide. Commercial host or dram shop liability—civil liability imposed on alcohol vendors for harm caused by intoxicated patrons—has developed unevenly across jurisdictions. Thailand's evolving alcohol control framework invites consideration of whether and how vendor liability could function within Thai tort law.

Objective

To conduct a comparative legal analysis of commercial host liability across selected jurisdictions and assess its doctrinal feasibility and public health implications for Thailand.

Methodology

Comparative doctrinal analysis of statutory provisions, leading case law, and regulatory frameworks in the United States, Canada, the United Kingdom, Australia, Japan, and selected European civil law systems. Findings were analyzed against Thailand's Civil and Commercial Code (CCC) and the new alcohol control legislation to evaluate compatibility, causation standards, and medico-legal consequences.

Results

Commercial host liability ranges from explicit statutory regimes (United States) to negligence-based judicial development (Canada, Australia) and restrictive or indirect approaches (United Kingdom, civil law Europe). Evidence suggests deterrent effects on over-service and alcohol-related injuries where liability is clearly codified. Thailand's tort framework could doctrinally support negligence-based vendor liability; however, statutory clarification is necessary regarding foreseeability, causation, apportionment, and evidentiary standards.

Conclusions

A carefully structured vendor liability provision could strengthen Thailand's preventive health strategy if aligned with proportionality, insurance mechanisms, and evidentiary clarity. Legislative precision is essential to avoid medico-legal uncertainty.

THU-S13-P02

Session: Public Health Law II · **Room:** R.011

Decriminalizing Attempted Suicide in Nigeria: Appraising the Intersection of Criminal Law and Public Health Law

Innocent Nkwandu Ofili LL.M

University of Abuja, Abuja, Federal Capital Territory, Nigeria

Background

The criminalization of attempted suicide in Nigeria has long been a contentious issue at the intersection of law, policy, and public health. Under Section 327 of the Nigerian Criminal Code, attempting suicide is treated as a criminal offence punishable by imprisonment. This strict legal stance reflects colonial legacies and moralistic interpretations of self-harm, but it has increasingly been criticized as outdated, unjust, and counterproductive. The punitive approach fails to address the underlying mental health challenges that often precipitate suicidal behaviour, instead compounding stigma and discouraging individuals from seeking help. Recent policy debates and advocacy efforts have therefore focused on decriminalization as a necessary reform to align Nigeria's legal framework with contemporary human rights standards and global best practices.

Research Questions

What is the policy rationale and legal implications of decriminalizing attempted suicide in Nigeria? How does it fit within broader discourses on mental health, human dignity, and the role of the state in regulating personal autonomy? How does criminalization perpetuate silence and shame, undermine suicide prevention strategies, and burden the justice system with cases better suited for medical and psychosocial intervention? To what extent do comparative perspectives from jurisdictions such as Ghana, India, and Kenya—where decriminalization has been enacted—illustrate the positive impact of shifting from punitive to supportive responses, including improved access to mental health services and reduced stigma?

Methodology

Using the doctrinal and analytical research approaches, the work explored the policy momentum within Nigeria, including legislative proposals, advocacy by civil society organisations, and recommendations from international bodies such as the World Health Organization.

Results

The finding is that successful decriminalization will require not only legislative amendment but also robust public education, investment in mental health infrastructure, and the development of non-punitive support systems. The work further revealed that decriminalization is a critical step toward recognizing attempted suicide as a public health concern rather than a criminal act, thereby fostering compassion, reducing preventable deaths, and promoting Nigeria's compliance with international human rights obligations.

Conclusions

The paper concludes that decriminalizing attempted suicide in Nigeria is both a legal and moral imperative. By reframing suicide attempts as signals of distress rather than crimes, Nigeria can move toward a more humane, effective, and rights-based response to one of the most pressing mental health challenges of our time. The work, therefore, recommended a holistic policy approach that integrates law reform with mental health advocacy, community support, and institutional capacity building.

THU-S13-P03

Session: Public Health Law II · **Room:** R.011

The Commercial Use of Medical Authority in Digital Advertising: A Call for a Functional Redesign of Self-Regulation

Dr Seohyun An PhD

Ewha Womans University, Seoul, Korea, Republic of

Background

In South Korea, the Act on Labeling and Advertising of Foods prohibits physicians and other designated experts from endorsing or otherwise promoting health supplements in advertising, but it permits advertisements that show a medical professional as having directly participated in the product's research or development. The purpose of this exception is to allow for factual disclosure. In digital advertising, however, the application of this exception becomes difficult to justify

when a medical professional's image, title, and developmental role appear alongside efficacy claims, promotional language, and direct purchase links. In such settings, disclosure does not necessarily operate as neutral information but instead as commercial use of medical authority. The problem is likely to deepen as advances in medical technology and the growth of the health supplement market make medical professionals' authority an increasingly powerful commercial asset in digital advertising. Furthermore, following the Constitutional Court of Korea's 2018 decision invalidating the state-administered pre-screening of supplement advertisements, the transition from direct governmental pre-screening to an industry-based self-regulatory review system only compounded this problem.

Research Question

This paper poses two questions. First, how should the legal definition of permissible disclosure and prohibited endorsement be clarified in contexts where digital advertising uses a medical professional's image, title, or research and development role in ways that may extend past the scope of mere factual disclosure? Second, how should self-regulatory review be restructured to address this commercial use of professional authority without infringing constitutional protection for freedom of expression?

Methodology

This paper combines doctrinal analysis with an advertising-communication perspective. It first clarifies the legal distinction in Korean law regarding health supplement advertising between prohibited endorsement and permitted disclosure of a medical professional's participation in research or development. It then examines how digital advertisements that combine a medical professional's image, title, and developmental role with efficacy claims, branding, and purchase cues may transform such disclosure into a persuasive endorsement. On this basis, it proposes a normative framework for restructuring self-regulatory review consistent with constitutional protections of expression.

Results

This study finds that digital advertisements blur the boundary between disclosure and endorsement when a medical professional's image, title, and developmental role are used not simply to convey their participation, but to build product credibility or encourage purchase. Rather than changing the legal definitions of permissible disclosure and prohibited endorsement, a reform of the regulatory framework should be conducted. Therefore, this study suggests three reforms: a shift from text-based review to contextual and visual review; mandatory disclosure of relevant economic relationships between advertisers and medical professionals; and platform-level safeguards against AI-generated physician imagery in the promotion of supplements.

Conclusions

In digital health supplement advertising, disclosure of a physician's participation often functions as endorsement. This study offers three actionable steps that can improve the way in which information is communicated, protecting consumers' right to information. Moreover, further scholarly debate on how a self-regulatory regime can be structured to protect consumers while holding supplement advertisers, participating medical professionals, self-regulatory review bodies, and advertising platforms responsible is needed.

THU-S13-P04

Session: Public Health Law II · **Room:** R.011

When Standard of Care Becomes Systemic Harm: Cesarean Overuse and an Emerging Public Health Crisis

James C. Johnston MD, JD^{1,2,3}, Thomas P. Sartwelle BBA, LLB⁴, Professor Berna Arda MD, Med Spec, PhD⁵

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Background

Cesarean section (CS) is a life-saving intervention when clinically indicated, yet its global overuse now constitutes a significant and preventable public health burden. Since 1990, CS rates have more than tripled, exceeding 21% worldwide and surpassing 40-60% across large regions of South America, the Middle East, and Southern Europe. Brazil's private sector rates exceed 80%; Turkey approaches 60%; and rates above 40% are commonplace across much of the middle- and

high-income world. These rates far exceed the 10-15% population level associated with optimal maternal and neonatal mortality.

Research Question

The predominant but unregulated driver of this trend is a near universal application of continuous electronic fetal monitoring (EFM) during labor. Decades of randomized controlled trials have consistently demonstrated that continuous EFM failed to improve neonatal outcomes, but significantly increased cesarean delivery rates by approximately 60%. Yet, EFM remains standard obstetrical practice in many settings, institutionalizing a pattern of intervention with known risks of harm in the absence of demonstrable benefit.

Results

The EFM-driven CS consequences extend well beyond the perinatal period. A growing body of evidence links cesarean delivery to a significantly increased risk of autoimmune and immune-related disorders in children. The disruption of neonatal microbial colonization from bypassing vaginal delivery alters microbiome development with downstream effects on immune regulation attributable to reduced colonization by *Bifidobacterium* and *Bacteroides*, impacting short-chain fatty acid production and regulatory T-cell induction. These dysbiotic patterns are associated with increased risk of type 1 Diabetes Mellitus, inflammatory bowel disease, celiac disease, juvenile idiopathic arthritis, and atopic disease. Emerging evidence suggests broader impacts on infection responses, malignancy risks, and neurodevelopment. With approximately 32 million cesarean deliveries performed annually, and projections that by 2030 one in three children worldwide will be delivered by CS, this represents a large-scale, highly preventable driver of chronic childhood disease burden. The routine, unregulated use of continuous EFM constitutes the predominant upstream factor in this iatrogenic cascade, and meaningful reform of intrapartum monitoring practice is critical in reducing unnecessary CS and mitigating the long-term public health consequences impacting millions of children.

Conclusions

Reevaluation of intrapartum monitoring practices is not merely a matter of clinical preference, but a global public health imperative. Reducing unnecessary EFM use represents the most actionable strategy to curtail cesarean overuse and mitigate its long-term consequences for population health.

THU-S13-P05

Session: Public Health Law II · **Room:** R.011

Reform of the Gambling System and Public Health: Case of Government Proposal 16/2025 vp in Finland

University Researcher Janne Nikkinen LL.M.
University of Helsinki, Helsinki, Finland

Background

Gambling is a serious public health concern (WHO, 2024). Approximately 450 million people globally experience gambling harm, of which 80 million have gambling disorder (Lancet, 2024). Gambling harms include crime, decrements to health, over-indebtedness, relationship issues and suicidality (Langham et al., 2016). Although the industry extracts wealth from the poor and underprivileged, it frames its products as harmless and stresses the economic (tax) benefits of gambling (Lancet, 2024). For this reason, governments assigned with a task to protect the public health often align with the industry, and act against the interests of some of the most vulnerable people (Orford, 2011). The situation is further exacerbated by the fact that global gambling industry is a powerful lobby, capable of influencing public policy, legislation and government decisions (Cassidy, 2020).

Research Question

The renewal of Finnish gambling legislation has ended the (online) gambling monopoly in Finland in 2026. Publicly stated aims for this major overhaul of the system were two-fold: first, to enhance the competition in the market and to prevent and, second, to reduce gambling-related harm. This presentation examines whether the government proposal 16/2025 vp prioritizes economic objectives, such as government tax revenue and support for national economy via cost-dependents, instead of harm prevention and protection of public health.

Methodology

The perspective taken in here aligns methodologically with problem-centered jurisprudence. In the methodological literature regarding legislative studies, it has been viewed possible to limit the analysis to one government bill only. The analysis has been accomplished by using

WPR (What is the problem represented to be?) -framework developed by Carol Bacchi in assistance.

Results

Government proposal 16/2025 vp advances more economic objectives of the government than harm prevention. It shields the national gambling monopoly (Veikkaus) from competition in land-based gambling and advances economic objectives, by shaping the gambling legislation in such a manner that advertising monies are funneled through national media. The recommendations of public health experts, including advertising ban, were sidestepped during the legislative process.

Conclusions

There is a lack of critical legal studies with focus on gambling, especially how the industry influences legislative processes. Gambling industry avoids corrective policymaking due to significant political influence, which hinders public health efforts. Lawyers and specialized law firms play a central role in this lobbying. Tobacco-related diseases proliferated partly because of tobacco company lawyers. There is a need for critical legal studies with focus on gambling and public health law.

SESSION THU-S14 · TRACK 7 · 13:30 – 15:00 Responsible AI: Panel Discussion · Room R.014 Moderator: Corrette Ploem

THU-S14-P01

Responsible Artificial Intelligence Usage (from a European perspective)

LLM Daniël P. Doeleman LLM1, Roosmarie Jessen LLM1, PhD Marieke A.R. Bak PhD, MA, MSc1, Professor Corrette Ploem PhD1, MSc Eva Stock MSc2

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Background

The development of artificial intelligence is steadily progressing and can be applied in various contexts. Nevertheless, the transition from development to implementation remains a difficult one to achieve.[1] There are several underlying reasons for this. One of them is that the legal framework governing the responsible use of AI has not yet been fully defined. In the European medical context, the General Data Protection Regulation and the Medical Devices Regulation have influenced AI development. Recently, the Artificial Intelligence Act has been added to this framework. An important document that still leaves room for interpretation. The European Commission has requested the development of harmonized standards that translate legal requirements into common technical language.[2] The European Health Data Space will also play a role. In addition to key European laws, national frameworks should not be overlooked. What constitutes responsible healthcare is primarily regulated at the national level. And although national frameworks provide important guiding principles, there are certainly still questions about what responsible AI use would look like in practice. This panel discussion aims to engage in a dialogue about where we currently stand regarding responsible AI use, and where we want to go. Some relevant themes include the explainability of AI and human oversight.

Research Question

What should responsible AI use look like and how do abstract legal requirements bear on the development and implementation of AI for medical purposes?

Methodology

We are assembling a multidisciplinary panel consisting of an ethicist, two lawyers, a philosopher, and an AI-specialist. Each of us will briefly present our own area of expertise or case study on the subject, after which we will engage in a discussion based on questions from the audience.

POSTER-PM-01

Session: Poster Session II · **Room:** Patio K.001 (Aula)

Human Rights in the Delivery Room: Navigating Birth Plans, Autonomy, Consent, and the Limits of Medical Law

Michail Koufalitakis

Open University of Cyprus, Nicosia, Cyprus

Background

Birth plans have been widely discussed in recent European clinical and midwifery literature as tools that emphasize and support autonomy, informed choice, and patient consent among birthing women from a clinical perspective. In contrast, research on birth plans through legal scholarship remains limited, and the topic is largely unexplored. Birth plans are generally treated as quasi-legal documents with no formal legal status. Childbirth should not be understood solely as a medical event, but as a deeply personal experience, marked by physical and emotional dimensions for the woman giving birth and a vicarious yet meaningful emotional experience for the man; dimensions that raise critical questions of autonomy, consent and legal protection. At the same time, obstetricians, and to a lesser extent midwives, tend to adopt defensive practices aimed at minimizing perceived risks of harm and liability.

Research Question

This gap raises a central legal question: do birth plans operate merely as non-binding clinical records, or do they expose limitations in medical law's protection of decisional autonomy during labour? From a legal perspective, this creates a critical tension: should priority be given to the agreed birth plan as a quasi-legal expression of patient consent, or to the subsequent clinical decisions of healthcare professionals who choose a different course of action?

Methodology

This poster presentation examines the issue from a legal and human rights lens, focusing on potential violations in the delivery room, even where a birth plan has been discussed with a midwife or obstetrician and formally documented in advance. The literature review examines how this subject has been addressed within European legal scholarship, while also drawing on selected examples of countries with more developed legal and professional guidelines governing the status of birth plans, based on a doctrinal and comparative analysis informed by human rights law.

Results

Birth plans are at times overridden in practice, raising questions as to whether such interventions may constitute interferences with private life and personal autonomy under Article 8 of the European Convention of Human Rights and free informed consent under Article 5 of the Oviedo Convention.

Conclusions

Birth plans reflect a woman's autonomy, consent, and dignity during childbirth. While they are discussed and agreed upon with healthcare professionals, the practice highlighting gaps and raising questions about how effectively medical and human rights law protects these rights in the delivery room.

POSTER-PM-02

Session: Poster Session II · **Room:** Patio K.001 (Aula)

Trustworthy AI in Medical Research: What it Means and What is Technically Feasible? Experiences of the ELMUMY Project

Dr. Iryna Lishchuk

Institut für Rechtsinformatik, Leibniz Universität Hannover, Hannover, Lower Saxony, Germany. Medizinische Hochschule Hannover, Hannover, Lower Saxony, Germany

Background

Trustworthy AI stands for artificial intelligence (AI) systems that implement "traceability", "reproducibility" and "explainability" by-design. Use of AI in support of clinical decision-making intervenes into a patient-physician relationship where trustworthiness is critical: "if we can't reproduce it, we can't trust it". Moreover, AI intrudes into informed consent process. It mandates the way how AI makes its decisions should be humanly comprehensible.

Research Question

The research question centres around the meaning of trustworthy AI in legal terms and how the parameters of “trustworthiness”, in particular “explainability” can be implemented by-design.

Methodology

The methodology combines normative approach, conceptual analysis and legal pragmatism.

Starting with the parameters of “trustworthy AI” first. “Traceability” means that “every” model decision must be traceable to its training data, parameters and version. “Reproducibility” means that AI output shall be replicable by other teams. “Explainability” means understanding as much as possible how and why AI models make predictions. “Explainability” often associates with “explicability” - a concept that refers to the reduction of opacity of AI systems. However, higher accuracy often comes at a cost of more training data and increased opacity, respectively. This presents a challenge for medical AI applications, where “explainability” is a must, which may not be satisfied at the expense of accuracy. From data protection (patient) perspective, in case of automated decision-making, there is no explicit right to explanation as such. However, there is a right to obtain human intervention (Art. 22(3) GDPR) and “meaningful information about the logic involved” (Art. 13(2)(f) GDPR). On the technical side, “transparency” is binding on high-risk AI systems (Art.13 AI Act), including AI applications used for medical purpose (Art. 6(1) i.c.w. Annex 1 No.11 AI Act). Transparency refers to the AI configured in a way enabling “deployers to interpret a system’s output and use it appropriately”. “Explanatory opacity”, a type of conceptual opacity, deems to answer the regulatory requirements best. It denotes “lack of causal explanation between input and output” and focuses on how algorithms operate at the scale of application.

Results

Resolving “explanatory opacity” and understanding how and why AI models make predictions comes out as the most appropriate way to reach compliant trustworthy AI in technical terms. OSS MLOps, logging feature importance and comparing model outputs is of help.

Conclusions

The development of trustworthy medical AI stands at the intersection of several domains and multiple regulatory frames what requires interdisciplinary approach for the AI trustworthiness to be fulfilled.

POSTER-PM-03

Session: Poster Session II · **Room:** Patio K.001 (Aula)

Draw on the Application of the Medical Large Language Model for Hierarchical Management in Autonomous Driving

YuePeng Li¹, HuaDan Huang^{1,2}, Professor YanLin Cao¹, Professor Yu Liu³, Shawnholm Lau⁴, Fei Jia¹, ZiJun Li¹

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Background

Medical artificial intelligence has achieved rapid development and has been widely applied in various clinical scenarios, but its seamless integration with routine clinical care has been severely hindered by long-term regulatory challenges. At present, the governance framework of medical artificial intelligence is insufficient to address the core issues of the dynamic evolution of AI systems, the ambiguity of human-machine responsibility attribution, and the context-dependent characteristics of algorithm output. With the accelerated deployment of increasingly autonomous artificial intelligence tools in the healthcare sector, the lack of a coherent and hierarchical regulatory framework has become a prominent bottleneck. Therefore, there is an urgent need to develop tailor-made practical regulatory methods for medical artificial intelligence.

Research Question

How can a regulatory framework be constructed to adapt to the uniqueness of medical artificial intelligence and address the existing governance dilemmas? How to balance the innovation of adaptive medical artificial intelligence systems with the necessity of patient safety and clinical accountability? Furthermore, how can insights from safety-critical areas outside of healthcare be transformed into an

operational regulatory structure for medical artificial intelligence to facilitate communication and coordination among regulatory agencies, clinicians, and developers?

Results

This study proposes a novel, context-sensitive, and risk-oriented hierarchical regulatory framework for medical artificial intelligence by adopting the hierarchical logic of the mature SAE J3016 framework in the field of autonomous driving. The proposed framework aligns the technical capabilities of medical artificial intelligence with clearly defined operational boundaries, clarifies the division of human-machine responsibilities, and incorporates a safety redundancy mechanism tailored to the clinical environment. Research and classification are conducted on the conditions under which medical large model systems can operate and how to respond when conditions are exceeded or the system is uncertain - that is, the Fallback mechanism. Build a corresponding framework for autonomous driving and medical artificial intelligence in terms of tasks, scenarios and responsibility mechanisms. It is far from a prescriptive solution but serves as an operational reference, directly addressing the practical obstacles to the adoption of medical artificial intelligence, such as clinicians' hesitation about highly autonomous artificial intelligence systems due to unclear responsibilities.

Conclusions

By bridging the dimensions of transformation, clinical practice and policy, this framework provides a unified conceptual and practical perspective for stakeholders in the governance of medical artificial intelligence, and can inform the ongoing global discussions on the effective and sustainable governance of medical artificial intelligence, ultimately supporting its safe and innovative integration into routine medical practice.

POSTER-PM-04

Session: Poster Session II · **Room:** Patio K.001 (Aula)

Violation of Service Standards in the Perspective of Medical Civil Law

MD Wilda Alvernia Lumban Gaol¹, MD, Dr Law Muh Nasser², Ruffiatdarojat Bayqunie³

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Background

Violations of service standards or professional standards within a series of medical services can be considered medical negligence, especially if conducted with a disregard for caution, unless it can be proven that there was an element of intent.

Research Question

Is performing a medical procedure, or not performing one, categorized as an act that violates the rights of others, for which compensation can be demanded by the party harmed by such medical action?

Methodology

This normative juridical research will discuss the legal consequences arising from standard violations in medical services that result in patient harm, along with the foundations of Medical Civil Law that can be used to prosecute medical professionals or healthcare workers who are negligent in carrying out their legal duties. It will also elaborate on various concepts of negligence and the juridical elements resulting from violations of service standards from the perspective of medical civil law.

Results

A violation of service standards occurs if a doctor does not act in accordance with Standard Operating Procedures (SOPs) or the demands of current medical science, thereby harming the patient and fulfilling the elements of negligence. In civil law, this can take the form of a breach of contract (wanprestasi) or an unlawful act (Perbuatan Melawan Hukum), measured by whether the action violates the patient's legal rights and/or contradicts the legal obligations of the doctor or hospital.

Conclusions

Violations of service standards in medical civil law should not solely focus on the final outcome (death/disability), but rather on proving the element of negligence in the process and must consider the violation of professional obligations (standard of care). Generally, medical civil

liability aims to provide redress (compensation) for patient losses through lawsuits in any form, whether breach of contract or unlawful act (tort law).

POSTER-PM-05

Session: Poster Session II · **Room:** Patio K.001 (Aula)

Preventing and Remediating Complicity in Organ Transplant Abuse Abroad

David Matas B.A., M.A., B.C.L.

International Coalition to End Transplant Abuse in China, Winnipeg, Manitoba, Canada

Background

Prisoners of conscience have been killed for their organs on an industrial scale throughout China since the early 2000s. Organ recipients have been transplantation tourists and wealthy and well-connected Chinese. Victims have been practitioners of the spiritually based set of exercises Falun Gong, Uyghurs, Tibetans and House Christians. This abuse has been confirmed by one investigation after another, with certainty, beyond reasonable doubt.

Legally, when the abuse began, there were no laws in place or proposed either inside or outside of China directed against the abuse. Laws in foreign countries specifically directed against organ transplant abuse, when the abuse in China began, were territorial in scope.

In the intervening years, there has been a Council of Europe Convention against Trafficking in Human Organs with an extraterritorial component that has fifteen state parties. There are also several jurisdictions not party to the Convention with legislation either enacted or proposed directed against complicity in the abuse outside of the jurisdiction.

In China, several laws have been enacted which on their face prohibit continuation of the abuse. Yet, there is no rule of law in China and investigations show that the abuse continues.

Research Question

How can legal jurisdictions prevent and remedy organ transplant abuse outside their jurisdictions?

Methodology

The presentation would summarize the evidence of organ transplant abuse in China and the conclusion of investigators. The presentation would then canvass and assess the existing laws and legal proposals aimed at preventing and remediating extraterritorial organ transplant abuse.

The presentation would examine laws or proposed laws which provide for

- 1) prohibitions against complicity in organ transplant abuse abroad,
- 2) an immigration ban,
- 3) a private or general insurance ban,
- 4) sanctions,
- 5) government exclusion of suppliers involved in forced organ harvesting,
- 6) passport issuance control,
- 7) country reporting on organ transplant abuse,
- 8) patient, health professional, institution or customs reporting on transplants abroad,
- 9) aggregate public reporting on transplantation abroad,
- 10) examination of institutional medical records,
- 11) prohibitions against brokering, advertising, financial transactions or trafficking related to organ transplantation, and
- 12) professional licensing consequences.

Results

Some laws have been more effective than others. Generally, the problem of organ transplant abuse in China and foreign complicity in that abuse persists.

Conclusions

The efforts to date, though far from comprehensive, point the way to what needs to be done to prevent and remedy foreign complicity in organ transplant abuse in China.

POSTER-PM-06

Session: Poster Session II · **Room:** Patio K.001 (Aula)

Unlawfulness (*Wederrechtelijkheid*) in Medical Crime Law

MD, Doctor of law Sessy Arie Sitorus¹, MD, Doctor of law Nasser - Muh²

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In Indonesia, a significant number of legal complaints and lawsuits directed at hospitals or physicians are not substantiated by factual evidence of negligence or omission, but are instead driven by emotional distress or ignorance of medical procedures. To prevent unwarranted litigation, it is essential to establish a screening mechanism based on the concept of unlawfulness (*wederrechtelijkheid*). This study explores how to measure substantive unlawfulness (*materiële wederrechtelijkheid*) within medical crime cases. Theoretically, an act is deemed unlawful not only if it violates written statutes but also if it contravenes unwritten legal principles, propriety, and the public sense of justice. This doctrine transcends formal legality by focusing on the material nature (essence) of the act.

In medical crimes, an act that meets the formal statutory elements (*formele wederrechtelijkheid*) may have its unlawfulness nullified if it aligns with unwritten law or the sense of justice—for example, a surgeon performing an emergency procedure on a patient in the Emergency Care Unit without prior informed consent due to the criticality of the situation. Conversely, healthcare professionals may be held liable even if their actions are not explicitly prohibited by written law, provided the act violates unwritten standards, such as an Emergency Department failing to provide rabies vaccines in an endemic area, leading to avoidable patient death. This paper utilizes a normative juridical research method to delineate the nature of unlawfulness. A profound understanding of this concept by law enforcement agencies is crucial to effectively filter public complaints regarding medical crimes.

POSTER-PM-07

Session: Poster Session II · **Room:** Patio K.001 (Aula)

Surrogate Informed Consent in Indonesian Medical Civil Law

Dr Lucia Nirmalasari general surgeon¹, Muhammad Nasser dermatovenereologist, Doctor of Law²

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Healthcare services in Indonesia are based on the principle of legal obligations that require informed consent for medical procedures. Every medical procedure must always require the consent of the patient or their closest family member, preceded by the provision of complete and comprehensive information. However, when, in special circumstances, the patient is unable to provide consent to a medical procedure, a substitute or guardian (surrogate informed consent) is required. This situation raises legal issues because Indonesian regulations do not yet specifically regulate the mechanisms, family hierarchy, or legal responsibilities for granting surrogate informed consent. This study aims to analyze the role and legal responsibilities of surrogate informed consent from a civil health law perspective and to formulate normative solutions to address this legal gap. The research method used is normative juridical, with a legislative approach, legal doctrine, and comparative studies of practices in several other countries. The results of the study indicate that surrogate informed consent has a dual function: as legal legitimacy for doctors and as an instrument for protecting patient rights. Regulatory weaknesses create the potential for disputes and unlawful acts, primarily due to the lack of clarity regarding the legitimate subject of the surrogate informed consent. Hospitals may also be liable for the actions of their medical personnel, and guardians or substitutes also have legal responsibility, albeit to a limited extent. In conclusion, surrogate informed consent requires more detailed regulation, including family hierarchy, formal procedures, and limits on legal liability. Suggestions include the need to harmonize legal regulations with the Civil Code regarding strengthening the law, as well as the competence of judges and the establishment of ethics committees in hospitals to oversee the implementation of surrogate informed consent, especially for certain medical procedures that carry risks.

POSTER-PM-08**Session:** Poster Session II · **Room:** Patio K.001 (Aula)**Restorative Justice in Medical Tort Law**Ayu Puspita¹, Rebekka Daulay², MD, Doctor of Law Nasser Muh¹, Lili Andriani³, Selis Frisa³¹Institute of Health Law, Military Law School, Jakarta, Indonesia. ²Jakarta Health Office, Jakarta, Indonesia. ³Jakarta, Indonesia**Background**

The civil dispute resolution system in Indonesia is still dominated by an adversarial litigation approach that emphasizes legal certainty but often overlooks the relational and emotional dimensions underlying conflicts. Civil case resolution through mediation has long been implemented in Indonesia, specifically since the Supreme Court issued Regulation No. 1 of 2003, which was most recently revised by Regulation No. 1 of 2016 concerning Mediation Procedures in Courts. Restorative Justice, besides aiming to achieve justice and punish the guilty, also seeks to restore harmony, repair damaged relationships, and provide more meaningful and sustainable win-win solutions compared to conventional court decisions. In medical disputes, this becomes crucial as this approach shifts the paradigm from legal confrontation to the restoration of substantive justice that prioritizes deliberation and rehabilitation. In this context, doctors and hospitals do not become targets of public hatred or victims of the civil legal process.

Research Question

The researcher aims to prove that the values of restorative justice are not only aligned with Indonesia's living law traditions, such as deliberation (*musyawarah*) and customary law (*adat*), but also have a normative basis for resolving medical disputes within the framework of civil procedural law.

Methodology

This normative juridical research examines the opportunities for integrating restorative justice principles into civil procedural law as an alternative approach oriented towards dialogue, responsibility, and reconciliation.

Results

The results indicate that a restorative approach has the potential to reduce the burden on courts, accelerate dispute resolution, and produce more sustainable agreements that should satisfy both parties. Restorative justice offers a viable and culturally complementary alternative for resolving medical disputes within the Indonesian civil law framework.

Conclusions

Explicit regulatory formulation is needed to integrate restorative justice principles into the medical dispute resolution mechanism, either through revising existing regulations or developing technical guidelines for mediators.

POSTER-PM-09**Session:** Poster Session II · **Room:** Patio K.001 (Aula)**Early-Onset Myopia in Children: Bridging Clinical Evidence with Legal and Technological Frameworks for Equitable Eye Care**Ophthalmologist Sevinj Salmanova PhD¹, General practitioner (GP) Sevinj Ismayilova²¹National Center of Ophthalmology named by academician Zarifa Alieva, Baku, Azerbaijan. ²ANDOP (Academy of Nutrition, Dietetics and Obesity Prevention), Baku, Azerbaijan**Background**

Early-onset myopia (before 3 years of age) is a high-risk condition associated with rapid progression, axial elongation, and increased likelihood of pathological myopia later in life. Despite its clinical significance, early detection remains inconsistent due to structural barriers, including limited access to pediatric ophthalmology services, low health literacy, and unequal availability of diagnostic technologies, particularly in low- and middle-income settings.

Research Question

How can clinical evidence on early-onset myopia be integrated with digital health solutions and legal frameworks to improve equitable access to early diagnosis and care in young children?

Methodology

This study applies a multidisciplinary approach combining: (1) clinical analysis of early-onset myopia and its pathophysiological mechanisms, including autonomic nervous system (ANS) involvement and early ocular growth patterns; (2) evaluation of emerging technologies such as artificial intelligence–assisted screening and tele-ophthalmology; and (3) legal analysis of healthcare access, pediatric screening policies, and health data governance frameworks.

Results

Early-onset myopia is frequently underdiagnosed due to the absence of standardized screening protocols for children under 3 years of age. Clinical findings suggest that early neurophysiological and metabolic factors, including ANS dysregulation, may contribute to abnormal ocular development. Digital health technologies demonstrate significant potential to expand early detection, particularly in underserved or remote populations. However, key legal gaps persist, including lack of regulatory standards for pediatric vision screening, unclear liability in AI-assisted diagnostics, and challenges in managing sensitive pediatric health data.

Conclusions

Addressing early-onset myopia requires an integrated framework that combines clinical science, digital innovation, and health law. Implementing standardized early screening programs, supported by telemedicine and AI tools, can improve access and outcomes. At the same time, robust legal frameworks are necessary to ensure data protection, define professional responsibility, and promote equitable healthcare delivery. Early intervention in visual health should be recognized as a critical component of children's right to health.

POSTER-PM-10**Session:** Poster Session II · **Room:** Patio K.001 (Aula)**The Role of the Physician in Forensic Medical Cases at the Intersection of Medicine and Law: A Perspective from Türkiye**Huseyin Erkut Sogut M.D., PhD Candidate¹, Asst. Prof. Abdullah Yildiz M.D., PhD²¹Ankara University, Graduate School of Health Sciences, Faculty of Medicine, Department of Medical History and Ethics, Ankara, Turkey. ²Ankara University, Faculty of Medicine, Department of Medical History and Ethics, Ankara, Turkey**Background**

Forensic medical cases are the intersection of medicine and law and therefore hold a special position from both medical and legal perspectives. One of the main professional groups directly involved with these cases is physicians. In Türkiye, when forensic medical cases arise, physicians are assigned various professional and legal responsibilities independent of their areas of expertise. These responsibilities include providing medical care, the obligation to report suspected or proven forensic cases, forensic medical expertise, and preparing forensic medical reports that can be evaluated within the scope of expertise. With limited specialty-specific exceptions, these responsibilities apply broadly to all physicians, from forensic medicine specialists to newly graduated general practitioners. However, their professional and emotional experiences in such high-responsibility situations remain insufficiently studied in Türkiye.

Research Question

The main research question of our study is what kind of experiences physicians in Türkiye have when they encounter forensic cases and how these experiences and legal responsibilities affect them professionally and emotionally.

Methodology

This study combines a review of relevant legislation on physicians' legal responsibilities in Türkiye with a preliminary analysis of semi-structured interviews conducted with physicians who have forensic medical case experiences

Results

Preliminary findings indicate that physicians' specialties, the institutions where they work, and the cities where they practice influence their experiences with forensic medical cases. Forensic medical cases have different implications for the physician-patient relationship depending on case type. It is understood that physicians are more intensely affected by these cases when the likelihood of personal or legal

authorities' involvement increases. Forensic cases have significant emotional and professional effects on physicians, primarily a heightened sense of responsibility due to legal obligations. Physicians report that medico-legal training during their medical education is insufficient for handling forensic cases, and they struggle most when they're newly graduated.

Conclusions

The unique characteristics of each case make forensic cases an important area of medico-legal experience for physicians. Understanding these experiences will enable physicians to assess these cases more accurately within the framework of medical, legal, and ethical principles.

This study derives from an ongoing doctoral thesis supported by the TÜBİTAK 2211-A (The Scientific and Technological Research Council of Türkiye) National PhD Scholarship Program. This abstract was translated from Turkish and linguistically refined with the assistance of AI-supported tools (GPT-5.2 and DeepL-26.1) to enhance clarity and fluency. All outputs were reviewed and revised by the authors, who take full responsibility for the final text and interpretations.

POSTER-PM-11

Session: Poster Session II · **Room:** Patio K.001 (Aula)

From Criminal Principles to Clinical Regulation: An Evaluation of Singapore's Harm-Culpability Matrix in Medical Disciplinary Sanctioning

A/Professor Tong Khee Tan FRCA, LL.M., MMedEd

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Background

The Singapore Medical Council (SMC) Disciplinary Tribunals have implemented a 3x3 harm–culpability matrix, adapted from criminal sentencing principles, to standardize sanctions for medical misconduct. This framework categorizes harm—slight, moderate, or severe—against culpability levels to determine indicative outcomes ranging from fines and censures to multi-year suspensions or striking off.

While the matrix is credited with enhancing transparency and predictability, concerns persist regarding the "criminalization" of professional regulation and whether such rigid structures can adequately account for the idiosyncratic nuances of clinical practice.

Methodology

This qualitative study evaluates matrix application patterns through an analysis of recent SMC tribunal decisions. The methodology synthesizes medicolegal ethics literature regarding proportionality, deterrence, and remediation. Real-world case critiques identify specific instances where mathematical rigidity within the matrix produced controversial or disproportionate outcomes, specifically examining the friction between standardized legal frameworks and medical judgment.

Results

The matrix effectively quantifies patient impact and isolates the mental element of misconduct, facilitating graduated, predictable sanctions. It further differentiates intentional recklessness from honest clinical errors.

However, its efficacy is often undermined by subjective severity thresholds on the harm axis and a systemic failure to account for institutional pressures. Specifically, the current framework frequently overlooks organizational factors—such as excessive workloads, inadequate protocols, or resource limitations—which fundamentally mitigate individual culpability.

Furthermore, "outcome bias" remains a significant risk, where the gravity of patient harm may trigger over-punishment for lapses characterized by only moderate culpability. This highlights a persistent tension between rigid standardization and the necessity for nuanced professional judgment.

Conclusions

While the harm–culpability matrix significantly advances the transparency of medicolegal sanctioning in Singapore, refinements may be needed to avoid unfairly penalizing practitioners for inherent clinical risks.

Proposed improvements include calibrated harm assessments, empirical banding derived from historical data, and a renewed emphasis on rehabilitative outcomes.

Balancing public protection with professional viability, Singapore's framework offers a sophisticated, albeit evolving, model for global medical regulation.

POSTER-PM-12

Session: Poster Session II · **Room:** Patio K.001 (Aula)

Layered Legal Protection: A Multidimensional and Interdisciplinary Approach to Protecting Reproductive Autonomy in Europe

Noa Vreven

University of Antwerp, Antwerp, Belgium

This poster presents the progress of an ongoing PhD project, which examines the protection of reproductive autonomy within European legal frameworks. While the concept of reproductive autonomy is increasingly invoked in academic and political debates, its legal meaning remains conceptually underdeveloped, and its scope of protection remains fragmented across European jurisdictions. The project analyses how a broad, multidimensional understanding of reproductive autonomy can inform its legal protection in decisions relating to contraception, abortion and medically assisted reproduction (MAR).

To this end, the research project develops a theoretical framework of reproductive autonomy that goes beyond a narrow framing of autonomy as an individual freedom from interference and instead conceptualises autonomy as shaped by additional social/relational, institutional, and societal dimensions. This framework functions as an analytical tool for evaluating how legal systems create enabling or constraining conditions for the exercise of meaningful reproductive choice.

The poster outlines the three stages of the project. Firstly, it outlines the completed multidisciplinary literature review, which systematises legal, philosophical, bioethical, feminist, and sociological accounts of (reproductive) autonomy into a multidimensional framework. Secondly, it presents preliminary findings from an ongoing comparative analysis of European abortion laws and policies in France, the Netherlands and England/Wales. This analysis uses the established theoretical framework and combines doctrinal and feminist research methods. Despite the liberal reputations of the selected jurisdictions, there are important differences in how they embed reproductive decision-making in their legal frameworks. In the Netherlands and England/Wales, abortion remains a criminal law exception, whereas in France, it is considered a constitutional and public health matter. These differences in legal design impact access to abortion care, the distribution of decision-making authority and the broader institutional and societal conditions in which reproductive autonomy is exercised. Thirdly, this poster introduces the forthcoming analysis of the case law of the European Court of Human Rights. This part focuses on how the Court addresses reproductive rights claims within the framework of the European Convention on Human Rights and explores how it could more meaningfully address the different dimensions of autonomy.

This poster invites discussion on how reproductive decision-making is shaped at the intersection of multiple legal fields and academic disciplines and takes place within interacting dimensions of autonomy. The proposed multidimensional framework aims to understand what this complexity requires from European legal systems to ensure more context-sensitive legal protection of reproductive autonomy, both at the national and supranational levels.

POSTER-PM-13

Session: Poster Session II · **Room:** Patio K.001 (Aula)

Forensic Assessment of Heavy Metals in Cosmetics: Health, Safety, and Legal Regulatory Perspectives

Student Aytaj Yuzbayova Student, Assistant Professor Gulshan Huseynova Assistant Professor

Azerbaijan Medical University, Baku, Azerbaijan

Background

Cosmetic products are used daily and represent a continuous source of low-dose exposure to potentially toxic contaminants. Among these contaminants, heavy metals such as arsenic (As), lead (Pb), mercury (Hg), cadmium (Cd), chromium (Cr), and nickel (Ni) have been detected in cosmetic products worldwide. Chronic exposure to heavy metals is associated with neurotoxicity, nephrotoxicity, endocrine disruption, contact dermatitis, reproductive toxicity, and carcinogenicity.

Although regulatory frameworks establish maximum permissible limits (MPLs) for individual products, increasing evidence suggests that cumulative exposure from multiple cosmetic products may pose long-term public health risks beyond regulatory compliance thresholds.

Research Question

Do cosmetic products available in the Azerbaijani local market comply with internationally accepted heavy metal safety standards, and does

current regulatory compliance sufficiently mitigate potential long-term health risks associated with cumulative exposure?

Methodology

A forensic toxicological analysis was conducted on 16 February 2026. Six categories of cosmetic products (foundation, moisturizing cream, face powder, blusher, lipstick, and lip gloss) were purchased from the Azerbaijani local market.

From each product, a 10 g representative sample was collected and analyzed. The concentrations of arsenic (As), mercury (Hg), and lead (Pb) were determined using standardized laboratory procedures in accordance with AZS GOST 31460:2012.

Measured concentrations were compared with internationally accepted permissible limits:

- As ≤ 5 mg/kg
- Hg ≤ 1 mg/kg
- Pb ≤ 5 mg/kg

All analyses were performed under controlled laboratory conditions to ensure analytical reliability.

Results

Arsenic concentrations ranged from 0.0 to 3.25 mg/kg.

Lead concentrations ranged from 0.0 to 2.25 mg/kg.

Mercury was below the limit of detection in all samples.

All tested products complied with established regulatory limits. However, arsenic levels reached up to 65% of the maximum permissible limit. Detectable lead concentrations were found in lip products, which present a potential risk of incidental oral ingestion. Comparative international data indicate that in some regions, Pb levels have reached 6–10 mg/kg or higher. Additionally, chromium levels in certain international samples have exceeded 1 mg/kg dramatically, reaching up to 2554 mg/kg in some lipstick products. Elevated cadmium and nickel levels reported in international studies have been associated with increased lifetime cancer risk (LCR).

In contrast, the analyzed Azerbaijani market samples demonstrated relatively lower contamination levels while remaining within regulatory standards.

Conclusions

Cosmetic products available in the Azerbaijani local market comply with current international heavy metal safety standards. However, the detection of arsenic at 65% of the MPL and the presence of lead in lip products raise concerns regarding cumulative exposure and bioaccumulation.

Regulatory compliance based solely on individual product limits may not fully address long-term health risks associated with chronic multi-product exposure. To enhance consumer protection, a more comprehensive regulatory framework incorporating cumulative risk assessment and harmonization with broader international cosmetic safety standards is recommended. Continuous monitoring and risk-based regulatory refinement are essential to safeguard public health.

SESSION THU-S15 · TRACK 1 · 15:30 – 17:15

AI in Healthcare IV · Room R.014

Moderator: Petra Holmberg

THU-S15-P01

Session: AI in Healthcare IV · Room: R.014

Exempting Epidemics? National Security and Research at the Edges of the EU AI Act

Dr Petra Holmberg PhD, Associate Professor Yana Litins'ka LL.D.

Faculty of Law, Lund University, Lund, Sweden

Background

AI-driven disease surveillance is increasingly relevant to public health governance, yet its status under the EU Artificial Intelligence Act (AIA) remains uncertain. This uncertainty is especially acute where disease surveillance intersects with national security and with scientific research conducted by universities or public research actors.

Research Question

The presentation questions whether AI systems used for disease surveillance may fall outside the AIA material scope through the national security and research exemptions, and how these exemptions should be interpreted when such systems or their outputs are later used in public decision-making.

Methodology

In our research, we use doctrinal legal analysis. We examine Articles 2(3), 2(6), and 2(8) AIA in light of the structure and purposes of the AIA, relevant Treaty provisions, EU legislation on cross-border health threats, and CJEU case law on national security and the EU competences.

Results

We argue that both exemptions should be interpreted narrowly. First, disease surveillance may sometimes relate to national security, but it rarely serves national security exclusively. It also overlaps with public health and public security, which weakens attempts to remove such systems from the AIA on the basis of Article 2(3). Second, the research exemption should not extend to situations in which AI systems, or their outputs, are operationalised beyond scientific research and used to support administrative or public-health decisions. A broad reading would create a loophole allowing public authorities to avoid AIA safeguards by relying on academic partners.

Conclusions

The presentation will show that the national security and research exemptions cannot be treated as easy escape routes from AIA oversight in the context of disease surveillance. A narrow, functional interpretation is needed to preserve the AIA's risk-based logic.

THU-S15-P02

Session: AI in Healthcare IV · Room: R.014

Translating Medical AI Fairness into Legal Duties: A Dual-Track Framework for Discrimination and Health Equity

Prof. Won Bok Lee SJD

Ewha Law School, Seoul, Korea, Republic of

Background

"Fairness" in medical AI is often framed through technical metrics, while legal accountability is framed through anti-discrimination doctrines and patient-safety obligations. In some health systems, however, empirically documented, actionable discrimination patterns in clinical care may be limited or context-dependent, and many inequities manifest through non-protected vulnerabilities (e.g., socioeconomic or language barriers). This weakens a one-size-fits-all metric approach and complicates direct importation of classic anti-discrimination models.

Research Question

How can medical AI fairness be operationalized as enforceable legal duties when (i) discrimination signals are uncertain or heterogeneous, and (ii) commonly used fairness metrics do not map cleanly onto legal concepts such as disparate treatment/impact and justification?

Methodology

The paper develops a doctrinal-and-design framework that separates (A) discrimination-based fairness claims tied to legally protected characteristics from (B) equity-based fairness claims tied to clinically salient but non-protected vulnerabilities. It then proposes a "translation matrix" that links protected legal interests (equal access, non-discrimination, patient safety) to auditable technical practices (subgroup performance evaluation, calibration checks, error-cost asymmetry review), combined with documentation and ongoing monitoring requirements across the lifecycle (development, deployment, post-market surveillance).

Results

The paper proposes a dual-track fairness governance model. Track A (Discrimination): triggers enhanced duties when outcome disparities plausibly track protected characteristics and cannot be justified by clinically necessary factors, requiring transparent metric selection, subgroup validation thresholds, and remediation triggers. Track B (Equity): addresses health-relevant vulnerabilities through procedural safeguards—impact assessment, deployment constraints, and monitoring—without presuming categorical entitlements or a single dispositive metric. Across both tracks, the key deliverable is a compliance-ready set of procedural duties (document, test, monitor, explain, remediate).

Preliminary Concluding Remarks

Recasting medical AI fairness from abstract principles or single-metric compliance into auditable procedural duties improves legal

enforceability while supporting innovation and equitable access in clinical AI.

THU-S15-P03

Session: AI in Healthcare IV · **Room:** R.014

Digital Life and Future Generations: Ethical Dilemmas and Participatory Pathways

Dr. Annagrazia Altavilla PhD/HDR¹, Jennifer Elbaz²

¹Espace Ethique PACA-Corse, Marseille, France.

²Commission Nationale de l'Informatique et des Libertés (CNIL), Paris, France

Background

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, Study sept.2025). In the meantime, 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 fundamental 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.

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. A need to involve children into discussions and decisions is also highlighted.

Research question and methodology

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 (10-25y) have been set up with a participatory methodology based on children's 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 National Bioethics Forum ("États généraux de la bioéthique"), an initiative led by the National 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.

Results

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.

Conclusions

The first findings emphasize the critical role of proper education and the need for transparency in setting up algorithms and handling personal data.

THU-S15-P04

Session: AI in Healthcare IV · **Room:** R.014

An Examination of University Students' and Academics' Use of Artificial Intelligence Tools in Research from a Self-Assessment Perspective

Professor Perihan Elif Ekmekci M.D. PhD Professor¹, Ms. Zeynep Sare Kirbaş², Ms. Beri Berfin Karaman²

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Background

Artificial intelligence (AI) tools are transforming the research ecosystem through the speed they provide in processes such as literature review, data analysis, and hypothesis generation. However, the absence of human-specific abilities such as creativity, critical thinking, discovering interdisciplinarity connections, and making ethical judgments creates risks for the quality and reliability of research and diminishes trust in science. The potential violation of fundamental ethical principles—such as transparency, informed consent, and data privacy—during AI use has prompted both national and international authorities to publish guidelines. Currently, researchers experience uncertainty about at which stage the use of AI may be considered an “ethical violation.”

Research Question

Is it possible to develop a mechanism that will allow researchers to self-assess how they use AI tools in their research processes? How can self-assessment tools be developed to ensure that researchers use artificial intelligence not solely out of an external obligation to comply with norms, but through an internalized sense of ethical responsibility? Can we guide researchers in evaluating the ethical compliance of their work before applying to an ethics committee, conducting their research, or submitting for publication, and in using AI tools as “active agents” with a sense of ethical responsibility? How can we enhance the ethical self-awareness of researchers when they are using AI tools in their academic work?

Methodology

Within the scope of the study, an ethical self-assessment questionnaire is created by matching analyses of the academic functions of existing and emerging AI models with current AI usage guidelines.

Preliminary Results

A mixed-method study design was adopted. The research collected quantitative data via online surveys and qualitative data via focus group studies with researchers from various disciplines to identify the AI usage habits and perceptions about ethical risks, problems, and potential solution approaches. The quantitative data analysis employed descriptive statistics, correlations, and t tests; thematic analysis of qualitative data is carried out via MaxQDA. Preliminary results present deep ethical concerns about the disruptive nature of AI integration in scientific research in terms of the integrity, robustness, and reliability of scientific research.

Concluding Remarks

A self-assessment questionnaire was developed as a result of this study to enhance transparency in the academic ecosystem, help prevent potential ethical violations in the early stages of research, and foster research integrity by placing ethics as a matter of contemplation rather than compliance.

SESSION THU-S16 · TRACK 2 · 15:30 – 17:15**Beginning of Life II · Room R.011**

Moderator: Judit Sandor

THU-S16-P01**Session:** Beginning of Life II · **Room:** R.011**Suspended Lives: Laws on Cryopreservation and the Missing Health Law Component**Full professor Judit Sándor PhD

Central European University, Vienna, Vienna, Austria. Center for Ethics and Law in Biomedicine, Budapest, Budapest, Hungary

Background

Reproductive medicine and cryopreservation technologies have advanced steadily since the 1980s. The legal norms that have been developed to regulate these procedures and their use, however, are strikingly different not only globally but also within Europe. While the first human birth after sperm cryopreservation dates back to 1954, egg donation and egg cryopreservation have been still regarded problematic. This inconsistency urges that the law on gender equality is addressed here. Furthermore, one specific element of the cryopreservation is distancing the donation (in time) of the sample and its use. Lemke connects cryopreservation with the “politics of suspension” by which he means that the use of gametes or DNA are delayed for the uncertain future. This phenomenon is rarely addressed in medical law.

Research Question

How do delay and suspension shape the legal framework of various cryopreservation practices in biomedicine?

Methodology

In this study process tracing and legal analysis are combined with the multidisciplinary approach. The presentation will analyze various court cases, legal norms and examine what alternative solutions could be developed at the intersections of reproductive rights, health law, and anti-discrimination law, in the fields of reproductive medicine and cryopreservation.

Results

Cryopreservation is applied not only in reproductive medicine, but it has become indispensable in DNA research and biobanks, as well. Based on several legal cases and legal norms we found that it is necessary to develop more consistent legal solutions by extending the legal analysis to law on biomedical research, assisted reproduction, and to anti-discrimination law, as well.

Conclusions

Cryopreservation delays parental decisions, and the extended time framework of assisted reproductive procedures demands considerable consent and information protocols. Cryopreservation used in other fields of research also demands innovative legal solutions that consider the prolonged availability of DNA samples and other tissues for research purposes.

THU-S16-P02**Session:** Beginning of Life II · **Room:** R.011**The Human Rights Implications of Divergent Storage Time Limits for Social Egg Freezing in Austria, Denmark, and the United Kingdom**Maria C Lorenz

Centre for Ethics and Law in the Life Sciences, Leibniz University Hannover, Hannover, Germany

Background

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 oocyte cryopreservation (OC) determine the outer boundaries within which women may plan genetic parenthood.

Research Question

When do storage periods for social OC constitute unjustified interferences with the right to private and family life under Art. 8 ECHR? When does differential treatment of social OC relative to medically indicated freezing, embryo or sperm storage amount to discrimination under Art. 14 ECHR? And which regulatory models represent best practice for future European legislation?

Methodology

This work employs a comparative analysis of three jurisdictions representing distinct regulatory approaches: Austria (a statutory ban on social OC, declared unconstitutional by the 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 Art. 8 and 14 ECHR is integrated with feminist bioethics as theoretical framework to contextualise human rights norms within the gendered realities of reproductive labour.

Results

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

Conclusions

Outright bans and short fixed storage caps for social OC are difficult to sustain under the ECHR and reproduce 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. Storage periods are 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.

THU-S16-P03**Session:** Beginning of Life II · **Room:** R.011**Defining the Standard of Care for Genetic Testing in IVF: Legal and Ethical Challenges in Assisted Reproduction**Attorney At Law Velichka Kostadinova Master

Abrashev and Partners, Sofia, Bulgaria

Background

Many intended parents rely on third-party gamete donors (sperm and egg) in assisted reproductive technology (ART). In these situations, genetic screening for mutations is critical. While expanded carrier screening panels have improved, they are not exhaustive and are not mandatory for many countries. Therefore, a significant risk remains that an undetected genetic mutation in a donor may be transmitted to an embryo, resulting in the birth of a child with a severe, life-altering, or fatal genetic illness.

Research question

This paper examines the complex legal and ethical challenges in defining the standard of care for the genetic screening of gamete donors. It evaluates the legal responsibilities and potential liabilities of fertility clinics, sperm/egg banks, and clinicians when a preventable genetic disease is transmitted from a donor to a resulting child.

Methodology

This study examines the legal requirements of donor screening protocols through a comparative review of international case law, statutory frameworks, and professional society guidelines. The most important questions are related to the quality of genetic testing panels, reliance on self-reported donor medical histories, the legal duty to warn recipients if a donor is later found to carry a severe mutation, and the standard for informing the intended parents about the risks.

Results

The analysis reveals a fragmented legal framework in which the standard of care for donor screening is often unclear. The findings indicate that many jurisdictions lack mandated, uniform screening panels, leaving clinics and cryobanks to self-regulate. When serious genetic illnesses are missed, litigation frequently concentrates on the informed consent—specifically, whether intended parents were adequately warned about the residual risks and limitations of current carrier screening. Furthermore, post-donation tracking and the duty to notify other families that use the same donor remain legally ambiguous.

Conclusions

The serious consequences of transmitting severe genetic illnesses through donor gametes require a strong legal framework to guarantee safety and reliable IVF procedures with donor gametes. This paper advocates for internationally recognized guidelines that establish a mandatory, frequently updated baseline for expanded carrier screening of donors. Clarifying the standard of care, strictly defining the duty to warn, and ensuring robust informed consent are imperative to protect intended parents, mitigate the liability of fertility institutions, and safeguard the health of donor-conceived children.

THU-S16-P04

Session: Beginning of Life II · **Room:** R.011

Is It Possible to Accommodate “Fetal-Maternal Complex” Model to the Current Legal Framework? Intersection of Law and Ethics in the Context of Fetal Surgery Research

Professor Yuko Sato Nagamizu LLM¹, Professor Yuichiro Sato LLM²

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Background and Research Question

Physical intervention of pregnant woman is necessary for the development of fetal surgery. In Japan, the fetus is not a legal person as a rule, and the research subject is considered to be the pregnant woman alone. However, the direct subject of the research is the fetus, and it seems strange to consider the pregnant woman as a research subject who doesn't need any treatment of her own. Also, it is difficult to adapt a “fetus as a patient/subject” model, which has contributed to the development of fetal surgery, from a legal perspective because the fetus is not a person as mentioned above. So, a bioethical research proposes to adapt a “fetal-maternal complex” model. This model considers the fetus and the pregnant woman to be an inseparable complex with each having their own unique interests yet also sharing mutual interests for a better and safer childbirth. This presentation examines whether we can accommodate this model to the current legal framework and gives suggestions to research ethics.

Methodology

The methodology is based on a literature review

Results

Even though the fetus is not a party to a contract, the doctors' duty of care extends to the fetus considering the purpose of the fetal surgery research contract. However, when conflicts of interest (COI) occur between the pregnant woman and the fetus, the doctors need to prioritize one over the other. In the medical research context, it is possible to predict COI beforehand. So, from the perspective of contract law, it is advisable to write those COI situations in the protocol and the informed consent document to protect their interests and inform the woman beforehand.

The pregnant woman owes a duty to the fetus under tort law, but considering their inseparability, there should be a limit to it. Also, after examining the law on abortion, we suggest that there should be time limits to the liability. With our legal interpretation, we can protect both the fetus and the pregnant woman by putting a proper restriction to the risks especially imposed on the woman.

Take Home Message

It is difficult to adapt this model directly to the current law, but the ideal of it can be included in the contract law scheme. By doing this, the predictable risks are all clear and understood by the pregnant woman beforehand and the possibility of tort liability would be minimized.

SESSION THU-S17 · TRACK 3 · 15:30 – 17:15

End of Life IV · Room R.201

Moderator: Marta Łotoczuk

THU-S17-P01

Session: End of Life IV · **Room:** R.201

Where Death and Life Meet: Ensuring Dignity and Respect in Palliative Care for Vulnerable Patients: The Latvian Example in Comparative Perspective

Assist. Prof. Laura Kadile

Riga Graduate School of Law, Riga, Latvia

Background

The right to give consent in healthcare is a pivotal to a patient's ability to exercise their private autonomy. The right to consent to, refuse, or withdraw consent for medical treatment, as well as the healthcare practitioner's assessment of the patient's decision-making capacity, are based on a relationship of mutual trust. This requires an individual approach, grounded in the patient's rights, particularly at the end of life. Vulnerable patient groups, particularly palliative care patients, are subject to treatment and care where death is inevitable. Therefore, the fact of impending death also affects the patient's decision-making capacity. In Latvia, the right to receive palliative care at home for social component requires the patient's written consent. Failure to obtain this consent in time can result in the denial of patient rights.

Research Question

This research examines whether the requirement for written consent to receive palliative care at home adequately protects vulnerable and seriously ill patients in Latvia, in comparison with legal regulation in foreign countries?

Methodology

The study employs a literature review methodology to collect and analyse the data from research in legal sciences. Comparative legal research will be carried out to collect, compare and analyse the legal framework in Latvia and foreign countries, policy documents and case law, focusing on different forms of informed consent in palliative care and legal mechanisms in place.

Results

The analysis reveals that patients can express their will in multiple forms across different legal systems. However, Latvia's strict requirement for written consent for the social component restricts patient autonomy and fails to ensure dignity for vulnerable patients at the end of their lives. It further reveals that it is necessary to develop a system that allows patients to change their wishes, including the option to refuse treatment or express their wishes in advance.

Conclusions

This paper stresses that death is a part of life, therefore ensuring proper care while respecting the patient's wishes, is crucial in order to provide the control over their lives and the needed patient-centered care. These findings indicate the need to reform the legal regulation in Latvia by introducing more flexible forms of informed consent. Additionally, the concepts of legal capacity and decision-making capacity must be distinguished. Alternative mechanisms are required to ensure and support the patient decision-making at the end of life.

THU-S17-P02

Session: End of Life IV · **Room:** R.201

Passive Euthanasia from the Perspective of Human Rights in Indonesia

MD Fanty Rahmania Surgeon¹, MD, Doctor of Law Nasser Muh²

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Background

Regulation of euthanasia in Indonesia expressly addresses active euthanasia under Article 461 of Law No. 1 of 2023 (the Penal Code). Passive euthanasia, however, remains uncoded and thus a subject of unresolved debate. In an era of rapid development in health law, a legal framework for passive euthanasia that aligns with progressive legal thought and human rights is both timely and necessary.

Methodology

This study employs a normative juridical method and conducts a comparative analysis of jurisdictions that permit euthanasia under strict requirements and procedures, notably the Netherlands and Belgium.

Results

Findings indicate that, to realize progressive legal principles and uphold human rights, Indonesia should promptly regulate passive euthanasia—for example, by amending or supplementing Article 461 of the National Penal Code with a clause on passive euthanasia, or by revising subordinate regulations such as Minister of Health Regulation No. 37 of 2014 and Minister of Health Regulation No. 290 of 2008. Such reforms would provide a lawful avenue for passive euthanasia in defined circumstances and under stringent procedural safeguards.

Conclusions

The study concludes that immediate regulation is essential if Indonesia, as a sovereign state, is to demonstrate genuine respect for human rights. This paper presents a normative juridical study with a descriptive-analytical specification grounded in a human rights-based approach.

THU-S17-P03

Session: End of Life IV · **Room:** R.201

Euthanasia-Related Challenges in Criminal Legislation: The Case of Azerbaijan

Sevda Karimova¹, Ulviyya Isayeva²

¹Baku State University, Baku, Azerbaijan. ²Tovuz District Executive Power, Baku, Azerbaijan

Background

Euthanasia remains one of the most controversial issues at the intersection of criminal law, medical law, and bioethics. In the Republic of Azerbaijan, euthanasia is strictly prohibited under current criminal legislation, reflecting prevailing legal and moral norms.

Research Question

This study aims to analyze the existing legal framework governing euthanasia in Azerbaijan, to examine relevant international practices, and to assess the need for potential legal reforms in light of expert opinion and societal values.

Methodology

The research employs a doctrinal legal analysis of Azerbaijani criminal legislation alongside a comparative review of advanced international regulatory approaches. In addition, empirical data were collected through a survey targeting medical professionals, legal scholars, philosophers/bioethicists, and public figures.

Results

The findings indicate a growing divergence between the absolute legal prohibition of euthanasia and evolving perspectives within professional and academic communities. The survey results demonstrate nuanced attitudes that support a more differentiated legal approach under strictly regulated conditions.

Conclusions

Taking into account the national, moral, religious-philosophical, ethical, and legal values of Azerbaijani society, the study argues for a reconsideration of the current absolute prohibition of euthanasia. It proposes a gradual and carefully controlled reform process aimed at balancing the inviolability of life with the protection of human dignity, as well as reconciling individual medical autonomy with broader societal considerations. Key recommendations include the clarification of legal definitions, the promotion of public awareness, the establishment of transparent and multi-layered oversight mechanisms, and the development of a comprehensive and multi-perspective state policy.

THU-S17-P04

Session: End of Life IV · **Room:** R.201

Regulations Concerning Medical Care and Care in the Final Stage of Life: The Legal Situation in Japan

Professor Mari Manabe-Honda LLM

Shibaura Institute of Technology, Saitama-city, Saitama, Japan

Background

From 2011 to 2012, the non-partisan 'Parliamentary League for Considering Legislation on Death with Dignity' has published a draft bill for 'death with dignity' in Japan; however, as of February 2026, no law has been enacted. In a 2015 guideline revision, the Ministry of Health, Labour and Welfare (MHLW) replaced the term 'end-of-life (EOL) care' with 'medical care in the final stages of life'. Later in 2018, the MHLW added 'care' and emphasised the importance of advance care planning (ACP).

Research Question

This study poses the question: 'Why has legislation concerning EOL care been slow to materialise in Japan?' It analyses how medical care and care in the final stages of life are regulated in Japan.

Methodology

We examine four key areas: (1) terminology definitions (ambiguity); (2) the Penal Code and its application (case law); (3) concerns regarding eugenic ideology; and (4) diverse guidelines. We now consider how these areas function, focusing on recent developments.

Results

(1) The polysemous nature of the term 'dignity' has been brought up, and that legislation should not employ ambiguous terminology. (2) Judgements are made by courts in individual-specific instances despite arguments that the conditions for negating the illegality of murder or assisted suicide should be clearly defined by law. (3) Regarding the bill of 'death with dignity' and individual cases, there is concern that the focus on disease or disability could lead to a 'slippery slope'. Some argue that if 'death with dignity' is to be legalised, legislation must first be enacted to protect patient rights. (4) In clinical settings, emphasis is placed on dialogue and multidisciplinary collaboration based on guidelines and recommendations. In recent years, the Japanese Society of Intensive Care Medicine and other organisations have revised their guidelines, while the Japan Geriatrics Society has updated its position statements. For adolescent and young adult (AYA) cancer patients, close collaboration between paediatric and adult medical departments is required.

Conclusions

In Japan, the focus is not on hastening death but on 'living authentically' through the final stages of life. Supporting an individual's unique life journey is paramount. Even if legislation is enacted, it would be meaningless unless grounded in mutual consideration between the individual and those around them. For information on 'EOL planning' and funeral customs in Japan, please refer to several films.

THU-S17-P05

Session: End of Life IV · **Room:** R.201

From Theoretical Right to Clinical Reality: The Ethical Necessity and Perceived Inaccessibility of Palliative Sedation

Dr Gabor Stánicz MD¹, Dr Csaba Gyula Hermann MD, PhD², Prof. Gabor Kovacs PhD MD. JD.²

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Background

Patients with life-limiting illnesses may experience severe physical, psychological, or existential suffering at the end of life. Even optimal palliative care may fail in some cases. Palliative sedation (PS) aims to relieve refractory suffering through the monitored use of medication to reduce consciousness. As an ultimate intervention without alternative, PS may represent not only a clinical option but an ethical obligation. Hungarian law guarantees the right to pain and symptom relief; however, the lack of a specific procedural framework for PS creates legal and clinical uncertainty. Despite its importance, PS remains poorly understood, highlighting the need to assess awareness and attitudes.

Research Question

This study examines theoretical knowledge, ethical attitudes, and perceived accessibility of PS among future legal and healthcare professionals.

Methodology

A cross-sectional survey was conducted using a voluntary, anonymous online questionnaire among law and health science students. Given the novelty of PS in Hungary, participants received a standardized description of the concept. A validated health literacy tool was included to assess the ability to process complex medical information. The survey measured factual knowledge, perceived access to PS, and ethical perspectives on decision-making.

Results

The preliminary sample included 65 respondents (N=65): 28 law students (43.1%) and 37 health science students (56.9%). Awareness of PS was limited: only 35.4% had prior knowledge, with higher familiarity among health students (46%) than law students (21%). Respondents expressed skepticism regarding clinical availability, rating it low on a 5-point scale (law: 2.0; health: 2.7). Most participants (70.8%) correctly identified that PS does not necessarily shorten life expectancy, with similar results across disciplines (67% legal vs. 72% health). Ethically, 78.5% agreed that patients have the right to request PS, with stronger support among law students (89%) than health students (70%). Both groups agreed that healthcare professionals have a duty to consider PS when other treatments fail (mean: 4.2–4.4/5). Regarding decision-making, respondents were divided between prioritizing patient autonomy (46% legal; 43% health) and shared decision-making (46% and 48%, respectively), indicating a shift away from medical paternalism.

Conclusions

The findings reveal a clear gap between ethical acceptance and perceived clinical reality. While PS is widely regarded as justified and aligned with patient rights, awareness and perceived accessibility remain low. Given its role as an intervention of last resort, this gap highlights the need for improved education and a standardized ethico-legal framework in Hungary to ensure that the right to relief from refractory suffering is effectively realized.

SESSION THU-S18 · TRACK 4 · 15:30 – 17:15

Health Data III · Room R.007

Moderator: Nils Broeckx

THU-S18-P01

Session: Health Data III · Room: R.007

What Patients Value in Data Reuse for Health Research: Preparing Belgium for the European Health Data Space

Dr Teodora Lalova-Spinks PhD^{1,2}, Dr Ine van Zeeland PhD^{3,4}, Silke Léonard⁵, Dr Florence Horicks⁶, Dr Brent Taels^{1,2}, Patricia Cervera de la Cruz¹, Lyzette Bax⁴, Bernard Carton⁴, Willy Dirckx⁴, Prof. Mahsa Shabani PhD⁷

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Background

The reuse of health data is critical for advancing health research, yet it raises complex ethical, legal, and societal challenges. In the European Union, the recently adopted European Health Data Space (EHDS) regulation aims to harmonize access to and reuse of health data for research and innovation, while safeguarding individual rights.

Research questions

Questions remain about what patients value in data reuse and how these values can be embedded in governance frameworks. Belgium, with its strong research tradition and central role in EU policymaking, offers an important testbed for these questions.

Methodology

We conducted a qualitative study combining semi-structured interviews with 39 professionals (policy and governance representatives, researchers, physicians, industry, law and ethics experts, and

supporting actors) and three focus groups with ten oncology patients and patient representatives. The interviews explored professional perspectives on data reuse and informed the design of the focus groups. Data were analyzed using the framework method, integrating inductive and deductive coding. Patient-researchers were involved throughout the study design, data collection, and interpretation.

Results

Participants unanimously recognized the value of health data reuse at both individual (improved healthcare) and collective (advancing scientific research) levels. Patients emphasized the importance of transparency, feedback on research results, and opportunities for meaningful involvement in governance. While patients were generally willing to share their data, they highlighted conditions such as trust in the system, strong data protection, and safeguards against misuse. Both professionals and patients considered the EHDS a positive step for facilitating research but expressed concerns about its practical implementation. All participants recognized the value of both individual and collective control over health data, though challenges of representation and resource constraints were noted when it came to patient involvement.

Conclusions

This study provides the first in-depth investigation in Belgium of what patients and professionals value in relation to health data reuse, particularly in the context of the EHDS. Findings underscore that the legitimacy of the EHDS will depend on embedding patient values into its implementation through transparency, participatory governance, and legal and technical safeguards. The results provide actionable insights for policymakers, researchers, and practitioners to build a value-oriented and socially legitimate health data ecosystem at national and EU levels.

THU-S18-P02

Session: Health Data III · Room: R.007

Balancing Scientific and Commercial Interests: The European Health Data Space Response to Commercial Scientific Research

Dr Xuxin / Yao, Prof. Hongjie Man, Ms. Zheyuan Sun
East China University of Political Science and Law, Shanghai, China

Background

Commercial interests have increasingly engaged in scientific research, particularly as the European Health Data Space (EHDS) allows access to electronic health records for such studies.

Methodology

Normative legal research was conducted to examine EU member states' effective medical research legislation and landmark cases.

Results

Eleven EU Member States' legislations do not reference commercial medical research. Regarding the others, some adopt stricter rules for commercial research. Others prioritize incentives for non-commercial research. Related legislation primarily regulates research based on funding sources, diverging from the multi-actor and multi-interest nature of health data research. Both the GDPR and ethical guidelines generally exempt anonymized data from oversight, creating a governance gap. Low marginal costs and the black-box nature of data-driven approaches further intensify funding biases, potentially undermining public trust. Member States also differ in data subjects' right to opt out of scientific research. Such regulatory fragmentation undermines EHDS implementation and creates opportunities for regulatory arbitrage.

Conclusions

Commercial scientific research should be understood as a type of research conducted by profit-driven actors through ongoing business operations. Special measures should be applied to commercial scientific research within the EHDS, including mandatory consideration reflecting data market pricing, tiered data dividends, compulsory health data access body ethical review, conflicts of interest declaration, and opt-out rights for data subjects. Rules for providing data access are tailored to the stage of research and require a balancing test between research interests and trade secrets. Raw data should be made accessible. Processed data should be made available when classified as essential. Research results should always be provided. A centralized EU platform is recommended to reduce administrative burdens.

THU-S18-P03**Session:** Health Data III · **Room:** R.007**Access to the Electronic Health Record for AI Development: The Tension between Privacy and Innovation and the Role of the New EHDS Regulation**Lawyer Louise Anna Huys Masters of Law

Dewallens & partners, Leuven, Belgium

Background

The increasing volume of health data and the digitalization of society are making technology in healthcare increasingly important. AI systems can analyze medical data to identify patterns, improve diagnoses, and optimize treatments. Access to electronic health records (EHRs) is essential for the development of such systems, while ensuring the privacy of patients. The COVID-19 pandemic demonstrated that access to and sharing of EHR data is not a given, which hinders innovation and research. To address this tension, the European Commission introduced the European Health Data Space (EHDS) Regulation, the final text of which was adopted on January 21, 2025.

Research Question

To what extent does the EHDS Regulation succeed in striking a balance between safeguarding privacy and facilitating medical innovation, specifically for the development of AI systems?

Methodology

A literature review was conducted to analyze the access conditions for health data for AI development, with particular attention to the GDPR, the AI Regulation, and the additional provisions of the EHDS. Subsequently, an assessment was made of the extent to which the EHDS can bridge the tension between privacy and innovation.

Results

Complying with the access requirements of the GDPR and the AI Regulation encounters the tension between privacy and innovation. The EHDS aims to bridge this tension but continues to place a strong emphasis on privacy protection. For instance, data may, in principle, only be downloaded from secure processing environments in an anonymized form, whereas in practice such data are not always truly anonymous, and the distinction from pseudonymized data is often limited.

In addition, the EHDS introduces an opt-out system for secondary use: data may, in principle, be used unless the individual objects. Although the regulation provides an exception to this opt-out right for reasons of public interest or scientific research, Member States have broad discretion to decide whether to actually apply this exception. As a result, access to data is not always guaranteed, even when all conditions are met.

Thus, the EHDS provides both opportunities for innovation and privacy safeguards, but the balance remains fragile, and the tension persists.

Conclusions

With targeted adjustments, the EHDS can provide an effective framework in which AI systems can be developed in a privacy-friendly and innovative manner.

THU-S18-P04**Session:** Health Data III · **Room:** R.007**Neural Data as a New Category of Sensitive Data? A Comparative Study on the Legal Characterization of Neural Data under Chinese Law and the GDPR**PhD candidate Min Zheng

East China University of Political Science and Law, Shanghai, China

Background

The rapid advancement of brain-computer interface (BCI) technology has made the legal protection of neural data a global concern. Neural data not only reflects physiological states but also reveals thoughts, emotions, and intentions, posing fundamental challenges to human dignity. However, its legal characterization under existing frameworks remains highly uncertain.

Research Question

Should neural data be recognized as a new category of "sensitive data"? How do China's Personal Information Protection Law (PIPL) and the EU's General Data Protection Regulation (GDPR) address this

characterization challenge? What are the similarities, differences, and implications of these two approaches?

Methodology

This paper adopts a comparative legal analysis method, examining the applicability of GDPR Article 9 on "special categories of personal data" and PIPL Article 28 on "sensitive personal information" to neural data. It draws on legal interpretation theories, guidelines from the European Data Protection Board, and relevant CJEU case law.

Results

The study reveals that both models face equally significant—though different—difficulties. The EU model's challenge lies in GDPR Article 9's closed-list approach: none of the three existing categories—health data, biometric data, and genetic data—fully capture the unique characteristics of neural data. The China model's challenge lies in PIPL Article 28's "general clause plus enumeration" technique: while interpretive space exists, no authoritative interpretation has confirmed whether neural data qualifies as "sensitive personal information," leaving judicial practice in a vacuum. Interpreting neural data as "privacy" under the Civil Code offers supplementary protection, but privacy's negative, defensive nature cannot fully address the dynamic process of data processing.

Conclusions

For China, the EU experience highlights the indispensable role of judicial precedent in clarifying the boundaries of legal concepts. Chinese courts should be encouraged to gradually develop adjudicative rules on neural data characterization through individual cases, thereby transforming the openness of PIPL Article 28 into operational standards. Additionally, China could learn from the GDPR's "data protection impact assessment" mechanism by introducing mandatory data protection risk assessment requirements into BCI clinical trial regulations.

In the long term, the transnational nature of neurotechnology renders isolated national legislation inadequate. Building upon UNESCO's Recommendations on the Ethics of Neurotechnology, efforts should be directed toward forging international soft law consensus on neural data protection.

The protection of neural data ultimately concerns the balance between technological innovation and human dignity. This equilibrium admits no permanent solution, yet through sustained transnational dialogue and institutional mutual learning, we may progressively approach more optimal resolutions in this dynamically evolving field.

THU-S18-P05**Session:** Health Data III · **Room:** R.007**Governing Trust in Disruptive Genomics: Validity, Data Reuse, and Responsibility Allocation**Dr. Monika Nogel dr. jur. dr. habil. PhD

Széchenyi István University, Győr, Hungary

Background

Trust is a precondition for the uptake, legitimacy, and social sustainability of health-related genetic testing. At the same time, disruptive genomics may widen a trust gap when technological promises outpace clinical validity, governance safeguards, and clarity regarding responsibility. This challenge is particularly visible in the evolving EU landscape, where clinical genetics, data infrastructures, and hybrid public-private service models increasingly intersect. Expanding test menus, polygenic risk scores, algorithmic interpretation, and large-scale data reuse create new opportunities, but also redistribute uncertainty, blur institutional boundaries, and complicate accountability.

Research Questions

This paper examines how trust is built and undermined in disruptive genomics, with a focus on three interrelated dimensions.

First, it asks how clinical validity can function as a trust anchor in an environment of rapidly expanding genomic applications. The paper analyses how uncertainty is shifted from laboratories to clinicians and patients, and what conditions are necessary for justified trust. These include transparent communication of limitations (such as ancestry bias and dataset representativeness), quality assurance across the entire testing pathway, and clear evidentiary thresholds for clinical actionability.

Second, it investigates how secondary use of genomic and phenotypic data affects trust, especially in contexts marked by purpose drift. Biobanks, learning health systems, and commercial platforms depend on data reuse, yet such practices may generate consent fatigue and

opacity concerning downstream access and uses. The paper maps the key ethical pressure points — including privacy, solidarity, and justice — and examines how purpose limitation, access controls, auditability, and accountability mechanisms shape whether secondary use is experienced as socially beneficial or as extractive.

Third, it asks how responsibilities are being redistributed in disruptive genomics, and whether current governance frameworks adequately reflect actual capacities and control. As empowerment narratives intensify, risk management may be offloaded to individuals (for example through self-triage, family notification, and data-sharing decisions), while intermediaries such as laboratories, vendors, and app developers remain comparatively less visible and only diffusely accountable. In response, the paper develops a responsibility-sensitive framework for allocating duties according to capacity, control over data flows, and epistemic advantage.

Methodology

Methodologically, the paper combines legal analysis and bioethical argumentation and draws on controversies related to direct-to-consumer genetic testing and cross-sector data access in order to identify recurring governance failures and trust-relevant institutional design choices.

Preliminary Concluding remarks

The paper argues that closing the trust gap in disruptive genomics requires verifiable safeguards and institutional arrangements that earn trust rather than rhetoric that merely demands it. It proposes actionable recommendations in three areas: (1) minimum benchmarks for validity and communication, (2) governance models that make secondary use intelligible, contestable, and equitable, and (3) explicit responsibility assignment across clinical, laboratory, and platform ecosystems. The analysis suggests that trustworthiness in genomics depends not only on scientific innovation, but also on transparent governance, fair distribution of burdens, and accountable socio-technical infrastructures.

SESSION THU-S19 · TRACK 5 · 15:30 – 17:15

Health-System Governance III · Room R.008

Moderator: Chelsea Stevens

THU-S19-P01

Session: Health-System Governance III · **Room:** R.008

Patients before Profit? What the Halmer Judgment Means for Investment in Healthcare

Mr. Sander Briké LL.M.

Dewallens & partners, Leuven, Belgium. Antwerp University, Antwerp Health Law and Ethics Chair, Antwerp, Belgium

Background

The growing involvement of external, purely financial investors in healthcare organisations has raised fundamental legal concerns across the European Union. In many Member States, national rules restrict or prohibit capital participation in companies of liberal professions, including those owned by physicians. These restrictions are increasingly being challenged under EU internal market law as obstacles to the freedom of establishment and the free movement of capital.

The judgment of the Court of Justice of the European Union of 19 December 2024 in *Halmer* (C-295/23), although delivered in the context of the legal profession, is highly relevant to the medical sector, as it provides guidance on the permissibility of such restrictions.

Research Question

This presentation addresses: (1) To what extent EU law allows Member States to restrict investments by purely financial investors in physician-owned companies, and how *Halmer* justifies such restrictions in the medical sector; (2) What *Halmer* reveals about the Court's different treatment of liberal professions and ordinary undertakings.

Methodology

The presentation provides a doctrinal analysis of the *Halmer* judgment, focusing on the Court's approach to the freedom of establishment, the free movement of capital and investment restrictions under the Services Directive. It examines how the Court evaluates restrictions on shareholding structures in physician-owned companies in light of justification, necessity and proportionality.

Results

In *Halmer*, the Court accepts that purely financial investors may exert influence on companies owned by liberal professionals, potentially compromising professional independence. It emphasises that profit-driven investors may influence organisational choices, strategic priorities or investment decisions, and that even the threat of disinvestment may affect professional decision-making.

The Court further recognises that, given the specific nature of liberal professions, Member States may consider statutory or contractual safeguards insufficient. Preventive restrictions on shareholding by purely financial investors are therefore suitable and proportionate to protect professional independence and the interests of service recipients.

This reasoning reflects long-standing concerns in the medical sector regarding investor influence on clinical autonomy and the quality of healthcare delivery.

Conclusions

Halmer confirms that EU internal market law takes account of the specific nature of the medical profession. Where purely financial investment threatens professional independence, Member States may legitimately limit market openness to safeguard core professional values. The judgment thus shows that the Court does not depart from an approach in which liberal professions are treated identically to other undertakings, and that a differentiated treatment may be justified under EU law.

THU-S19-P02

Session: Health-System Governance III · **Room:** R.008

There is No Business Like Healthcare Business

Prof Tom Balthazar Professor

UGent, Gent, Belgium

Background

Health care is expensive and the health care professionals may expect a correct remuneration for their expertise and their efforts. On the other hand, the right to health care can only be exercised when there is an affordable access to health care and if the "out of the pocket payments" by the patients are limited. The affordable access can be stimulated or guaranteed by investing in the social security and the universal health coverage. It can also be guaranteed by limiting the price of the health services, and more especially the fees of the physicians. These limitations are often not accepted or contested by physicians, especially by doctors working in private practices or with no contractual relation with the health insurers. The limitation of prices is considered as an infringement on the freedom to conduct a business.

Research Question

What is the relation between the right to health care and the freedom to conduct a business? Can the right to affordable health care motivate restrictions on the freedom to conduct a business and to determine the price for the services provided by health care professionals, especially for doctors working in private practices or private hospitals?

Methodology

We will describe the regulation within four European countries and give a general empiric overview based on the reports of the European observatory on health systems and policies.

Legally we will examine if the freedom to conduct a business has other restrictions in price-setting for independent health care providers than for the providers of other businesses and liberal professions? What can motivate such restrictions and what are the conditions and the legal boundaries of such restrictions?

Concluding Remarks

The right to affordable health care can be the legal basis for restrictions on free price setting, but not for all types of health care and under strict conditions.

THU-S19-P03**Session:** Health-System Governance III · **Room:** R.008**Reserva de Especialidad y Proporcionalidad Regulatoria en Medicina Estética en el Perú: Reflexiones sobre la Reciente Sentencia del Tribunal Constitucional**Professor Rosa Teresa Meza Vásquez Master in Medical Law and Bioethics^{1,2}, Professor Giancarlo Jiménez Bazán Master in Medical Law and Bioethics^{1,2}¹Meza & Jiménez Abogados, Lima, Lima, Peru. ²Peruvian Affiliate of the Latin American Association for Medical Law-Asolademe Peru, Lima, Lima, Peru**Antecedentes**

La reciente Sentencia del Tribunal Constitucional en el Exp. 00017-2024-PI/TC (en adelante, La Sentencia), declaró inconstitucional el extremo del artículo 4.2 de la Ley N° 31014, incorporado por la Ley N° 32118 (en adelante, La Ley), que habilitaba al médico cirujano con maestría en Medicina Estética a realizar procedimientos no invasivos y mínimamente invasivos no quirúrgicos. Aunque la controversia se inserta en la regulación del uso de sustancias modelantes, el fallo proyecta efectos más amplios sobre la delimitación del ejercicio profesional especializado en medicina estética en el Perú, en conexión con el artículo 24 del Código de Ética y Deontología del Colegio Médico del Perú que sanciona el acto médico fuera del ámbito de la especialidad médica que se ostenta.

Pregunta de Investigación

¿La Sentencia ofrece una respuesta constitucionalmente proporcional al problema de seguridad del paciente, o consolida una reserva de especialidad excesivamente rígida al invalidar toda habilitación distinta al Residentado Médico y al Registro de Especialidad?

Método

Se realizó una investigación jurídica dogmática y crítica, mediante análisis sistemático de La Sentencia, de La Ley, de la Ley General de Salud, las normas del Colegio Médico del Perú sobre todo la referida al Registro de Especialidad y el artículo 24 del Código de Ética y Deontología. El estudio examinó la estructura argumentativa de La Sentencia, su noción de calidad asistencial y su impacto sobre la delimitación del acto médico especializado.

Resultado

El análisis muestra que La Sentencia identifica correctamente el riesgo de equiparación entre maestría y especialidad; sin embargo, adopta una solución de invalidez total sin diferenciar suficientemente entre procedimientos de distinta complejidad y riesgo. Asimismo, La Sentencia no valora alternativas regulatorias intermedias, tales como habilitaciones limitadas por competencias acreditadas, delimitación anatómica estricta, supervisión o certificación práctica específica. De ese modo, La Ley termina interpretada bajo un modelo de reserva fuerte de especialidad que excede el control de sustancias modelantes y penetra el núcleo duro del ejercicio profesional en medicina estética.

Conclusión

La Sentencia fortalece la protección de la salud del paciente, pero lo hace mediante una respuesta maximalista particularmente restrictiva. El verdadero desafío regulatorio peruano no es optar entre equivalencia plena o exclusión absoluta, sino construir un sistema proporcional que distinga riesgos, procedimientos y competencias verificables.

THU-S19-P04**Session:** Health-System Governance III · **Room:** R.008**When Law Outpaces Practice: Recent Romanian Legislative Changes Challenging Medical Competence and Clinical Safety**Associate Professor Andrei C. Nanu MD, LLB, PhD

University of Medicine and Pharmacy "Carol Davila", Bucharest, Romania

Background

Recent legislative developments in Romanian healthcare law, including amendments to Law no. 95/2006 and related regulatory acts, have aimed to address structural challenges such as access to care, workforce shortages, and system efficiency. However, the practical implications of these interventions have not always been sufficiently

assessed, leading to unintended consequences for medical professionals and raising concerns regarding clinical safety.

Research Question

To what extent do recent Romanian legislative changes (2024–2025) affect medical competence, professional boundaries, and clinical decision-making, and do they generate interpretative uncertainty with potential implications for patient care and legal responsibility?

Methodology

This study consists of a qualitative legal analysis of legislative and regulatory changes adopted between 2024 and 2025, examined in relation to existing provisions, including those in force since 2006. The analysis focuses on identifying inconsistencies, overlaps, and practical implications for physicians' scope of competence and clinical practice.

Results

The analysis highlights a series of recent legal changes that place physicians in complex and, at times, contradictory positions. In certain cases, doctors are required to provide care beyond their formally recognized competence—for example, treating adult patients in paediatric hospital settings—without corresponding adjustments in training or institutional safeguards.

In parallel, other regulatory initiatives expand medical prerogatives across specialties—for example, by allowing physicians from all specialties to establish medical rehabilitation plans, justified as a means of avoiding the restriction of such competence to a single specialty, namely physical and rehabilitation medicine. Rather than enhancing clarity, these approaches contribute to the blurring of professional boundaries.

Additionally, recent legislative changes introduce case-specific rules regarding the possibility for physicians to act beyond their formal competence. A 2024 provision allows physicians treating adults to provide care to minor patients in emergency situations where a pediatrician is not available in due time. However, this overlaps with a broader rule in force since 2006, which permits any physician to exceed their competence in emergencies when no adequately specialized doctor is available to save the patient's life. The coexistence of these norms, combined with the emphasis placed on the newer provision, may create the misleading impression that such extensions are limited to narrower scenarios, thereby generating confusion in interpretation and application.

Conclusions

Taken together, these developments generate interpretative uncertainty, complicate clinical decision-making, and increase the risk of both legal exposure and inconsistent patient care. They reflect a growing disconnect between legislative intent and clinical reality. A more coherent and evidence-informed legislative approach, grounded in interdisciplinary dialogue between legal experts, policymakers, and medical professionals, is necessary to ensure that legal norms remain clear, applicable, and aligned with the realities of medical practice.

THU-S19-P05**Session:** Health-System Governance III · **Room:** R.008**Legal Gaps and Injustice in Compensation Standards for Apheresis Donors within Blood Services as a Public Health Service in Indonesia**Indrawati Taurus, MD. Doctor of Law Nasser Muh

Institute of Health Law, Military School of Law, Jakarta, Indonesia

Background

Blood services, as a cornerstone of public healthcare, must operate under the principles of the rule of law, requiring administrative policies to be regulatory-based, non-discriminatory, and accountable, while strictly adhering to the prohibition of blood commercialization. Simultaneously, the state is mandated to ensure the availability of safe, high-quality, and accessible blood components. Increasing domestic plasma supply is critical to reducing dependency on imported products like albumin. However, a legal injustice emerges from inconsistent compensation regulations. Health Law No. 17 of 2023 and Government Regulation No. 28 of 2024 explicitly permit compensation for plasma donors in the form of "transportation and/or health maintenance costs." In contrast, platelet donors using the same apheresis method lack similar regulatory support, despite enduring equivalent time burdens and clinical requirements.

Research Question

(1) how apheresis donor compensation is structured within Indonesian health regulations; and (2) why the differentiation in compensation between plasma and platelet donors constitutes legal injustice. Method: Utilizing a normative juridical research method with statutory and conceptual approaches.

Results

This study identifies a rechtvacuum (legal vacuum) and normative inconsistencies regarding apheresis compensation standards, leaving field practices dependent on inconsistent institutional discretion. Analyzed through the theories of distributive justice, equality before the law, legal certainty, and bioethical principles, such differentiation fails the test of proportionality and undermines legal certainty.

Conclusions

The study recommends harmonizing and standardizing compensation based on reasonable cost recovery (transportation and time) for all apheresis donors, with strict boundaries to prevent commercialization while supporting national plasma self-sufficiency.

SESSION THU-S20 · TRACK 6 · 15:30 – 17:15

Hospital Law II · Room R.230

Moderator: Filip Dewallens

THU-S20-P01

Session: Hospital Law II · **Room:** R.230

The Criminal Liability of Healthcare Facility Managers (France)

Robin Gonalons Master's degree

Université Paris-Cité, Paris, France

Background

While extensive research exists on the criminal liability of healthcare professionals - particularly physicians - studies focusing specifically on the liability of healthcare facility managers remain scarce. However, the potential for these individuals to be held personally liable is not merely theoretical.

Research Questions

Questions regarding the legal framework and frequency of their personal liability may weigh as heavily on managers as they do on healthcare professionals in their daily practice. This study examines the conditions and procedures under which healthcare facility managers can be held personally accountable for offences before criminal courts in France, as well as the frequency of such cases.

Methodology

Analysis of case law from 1948 to 2025, based on judgments collected by the author, most of which have never been studied before. The number of judgments amounts to around 200. In this study, healthcare facility managers are defined as individuals holding administrative management positions (e.g., general director, chief financial officer, head of human resources, head of clinical research etc.) role in hospitals or nursing homes, both public and private. Those professionals may or may not have a medical background.

Results

The analysis of case law reveals that legal proceedings and judgments involving healthcare facility managers are not uncommon. These cases address a broad spectrum of offences, although the frequency of convictions varies significantly depending on the nature of the offence. In most instances, managers are convicted of breaches of integrity or general workplace misconduct. Conversely, they are less frequently held personally accountable for harm suffered by patients or medical accidents.

Conclusions

When addressing criminal liability in the healthcare sector, the personal liability of managers in administrative positions should also be considered, rather than focusing solely on healthcare professionals. Healthcare facility managers may be held personally liable for harm suffered by patients, typically alongside physicians. However, their liability is most often not linked directly to patient care.

THU-S20-P02

Session: Hospital Law II · **Room:** R.230

The Inverse Proportional Allocation of Physicians' and Other Clinicians' Competences — A Comparison of Various European Jurisdictions

Dr. Kaat Van Delm LLM¹, Prof.Dr. Ulrich Becker LLM¹, Jana Bub LLM², Dr. Edoardo D'Alfonso Masarié¹, Dr. Irene Domenici¹, Dr. Christian Günther¹, Prof.Dr. Steven Lierman³, Dr. Rodolphe Royal¹

¹Max Planck Institute for Social Law and Social Policy, Munich, Germany. ²Hochschule Fulda - University of applied sciences, Fulda, Germany. ³KU Leuven, Leuven, Belgium

Background

Historically, physicians have been awarded a broad monopoly for the provision of healthcare. However, as the COVID-crisis demonstrated, by loosening vaccination administration restrictions, this monopoly is not set in stone. Indeed, longer standing demographic, economic and technological trends have led to a progressive empowerment of associated clinical professionals, with divergent approaches developing in different jurisdictions. A key question thus arises regarding the law's role in the redistribution of competences and responsibilities between them and physicians.

Research Question

"Can one identify convergences in the balancing of the physician's monopoly in the exercise of the provision of healthcare and other clinicians' competences, and the implications thereof on liability, when comparing the legal systems in place in various European jurisdictions?"

Methodology

This presentation starts from the hypothesis that the presumed allocation of competences between the physicians and other clinicians regarding the provision of healthcare is not linear. The diverging tendencies at various national levels may provide inspiration for the management of the division of competences considering the contemporary healthcare challenges identified throughout the research (presumably financial, demographic etc). The research focusses both on primary legal sources and establishes the broader context through a consideration of the policy and scientific literature.

Results

Comparing the laws of Belgium, Germany, the Netherlands, Switzerland, Italy, the UK and France, there seems to be a gradation in the division of competences, ranging from the substitution of the right to provide healthcare, to the delegation thereof, all the way until the mere toleration of certain infringements (translated into exceptions to criminal liability). This presentation compares the systems in place in the selected countries, in a first phase focusing on the factual background and the reason for the shift in approach towards the monopoly of the physician. In a second phase the presentation provides insights on the implications on liability and on the cost of the treatment.

Conclusions

The division of competences between physicians and other healthcare providers is not set in stone. The democratisation thereof might have been sped up by the COVID crisis though can definitely not solely be brought back to this event. Although this tendency entails risks considering the quality and safety of the provision of healthcare, it can also provide opportunities considering efficiency. The end result is a complicated balancing exercise and as this comparison will demonstrate, countries may benefit from looking into each other's achievements and challenges.

THU-S20-P03

Session: Hospital Law II · **Room:** R.230

Hospital Planning and Co-Governance: Effects on Access, Choice and Affordability in the Belgian Health System

Professor Filip Dewallens PhD

University of Antwerp, Antwerp, Belgium. KU Leuven, Leuven, Belgium. Dewallens & partners, Brussels, Belgium

Background

Healthcare in the EU is organised nationally, though shaped by common European legal principles. This paper examines how the Belgian hospital system is structured and regulated. Belgium relies on

national planning rules, recognition standards, mandatory hospital networks and physician participation in governance. These instruments aim to secure access and control costs within a compulsory health insurance framework. At the same time, they influence patient choice, service availability and financial burden. International and EU norms provide context, but the focus remains on the functioning of the Belgian model.

Research Question

How do hospital planning, mandatory networking and physician co-governance affect patient access, free choice and affordability in the Belgian health system?

Methodology

The study is based on legal analysis of Belgian hospital and social security legislation, supported by policy reports and comparative European health data. It links regulatory structures to their effects on waiting times, geographic access and patient payments.

Results

The Belgian system operates through two main mechanisms. First, supply control. Planning rules limit the number and distribution of hospitals, services and certain medical equipment. Hospitals must participate in regional networks that allocate care tasks among them. Some services are offered locally; others are concentrated in selected centres. This can improve coordination and efficiency, but it may also reduce the range of options available to patients and increase travel distances.

Second, financial and governance rules. Hospitals are financed through public budgets, health insurance and patient contributions. Most physicians are self-employed and paid per service, and they participate in hospital governance through medical councils. This co-governance model influences investment decisions, cost allocation and fee policy. Financial pressure may lead to higher supplements or changes in physicians' adherence to public tariff agreements, affecting out-of-pocket spending.

Belgium maintains broad coverage and generally short waiting times. However, strict planning and financial incentives may narrow effective patient choice and create differences in financial burden.

Conclusions

The Belgian model shows how planning and co-governance can support access and cost control. Static quantitative programming can shift toward needs-based planning combined with clear quality standards. Construction and equipment bans can be replaced by licensing or reimbursement conditions linked to measurable criteria. Wider use of convention-based financing and pathology-based flat fees can improve transparency and align incentives. Clear rules on the share of physicians' fees retained by hospitals, combined with a stronger link between governance roles and access objectives, can reduce unintended financial effects. These adjustments would preserve accessibility and affordability while improving flexibility and coherence.

THU-S20-P04

Session: Hospital Law II · **Room:** R.230

Legal Fight for Legalization of the Status of the Doctors as Officials in Bosnia and Herzegovina, in Order to Protect Against Unwanted Attacks and Behavior by the Patient

Prim. dr. Selma Kadić - Deković¹, Prim mr sci dr Sanjin Deković², Prim. dr. sci Nataša Trifunović¹, Dr Zumreta Bihorac - Kučuk¹

¹Public Institution of Community Health Care, Sarajevo, Canton Sarajevo, Bosnia and Herzegovina. ²Clinical Center of University in Sarajevo, Gynecology and Obstetric Clinic, Sarajevo, Canton Sarajevo, Bosnia and Herzegovina

Background

Doctors and medical personnel in Bosnia and Herzegovina(B&H) formally and legally do not have the status of an official according to the Criminal code in both of its B&H entities. That means, an attack on them is not automatically subject to heavier sanctions than attack on police officers or judges. Nevertheless, trade unions and chambers are trying to influence the implementation of legal changes, in order to provide them with similar legal protection, due to increasingly frequent attacks in the workplaces.

Research Question and Methodology

The goal of research: Through arguments and examples from practice, prove the necessity of introducing a stricter criminal policy, through

legislation, in order to reduce the number of attacks on doctors and verbal insults to the minimum is possible. And when they do happen, the patient who committed the attack faces very serious legal consequences.

Results

In B&H verbal attacks by patients on doctors and medical staff happen every day, and often remain unrecorded, potentially represent a prelude to physical attacks, such as occurred in recent past in the smaller B&H place where the doctor was beaten. Almost all medical workers are exposed to violence, but primarily those in Emergency services and primary health care. This is also contributed to by the fact that the decreasing number of doctors and medical staff is forced to treat a larger number of patients because young doctors are increasingly leaving B&H. Due to the fact that they are not treated as officials, doctors and medical staff have the status of health workers who perform activities of general interest. Attacks on them represent frequent risks on their work, and are processed according to the severity of physical injuries. Therefore the association of doctors in B&H, are asking for urgent changes to the law so that an attack on them while performing their duties will be treated as an attack on an official. Health institutions are obliged to ensure safety and take measures to reduce risk factors especially in primary health care, where we believe that introduction of panic testers would be one of the solutions to the impossibility of every ambulance having physical security. While the solution to this issue is still awaited-only in the entity of Federation of B&H for two years since initiative was submitted.

Conclusions

It will be necessary to make innovations in the criminal and misdemeanor legislation in both entities in Bosnia&Herzegovina, as well as in the countries of the ex-Yugoslav area that do not have this law. In this way, an attempt would be made to prevent more and more frequent attacks, verbal and physical, on healthcare workers. To protect their integrity and the life, they dedicated to the noble calling of treating people. Considering the social conditions and reality we live in, it will be needed to be done soon as possible. One of the obstacles continues to be the absence of the Ministry of Health at the state level of B&H, but exclusively at entity level, so there could be differences in legal solutions.

SESSION THU-S21 · TRACK 7 · 15:30 – 17:15

Intersex and Transgender Care · Room R.004

Moderator: Maxime Castermans

THU-S21-P01

Session: Intersex and Transgender Care · **Room:** R.004

Intersex Care as an Emerging Frontier in Medical Law: Comparative and Global Perspectives

PhD(c) Meng Wang L.L.M¹, Professor Yann Joly DCL (PhD)²

¹University of Macau, Macau, China. ²McGill University, Montreal, Quebec, Canada

Background

Human rights violations affecting intersex persons—including infringements on bodily integrity, autonomy, and self-determination—have long received limited attention from legislatures and governments. Only in 2015 did Malta adopt the first comprehensive legal prohibition on medically unnecessary genital surgeries, grounding its approach in rights to gender identity, gender expression, and bodily autonomy. While a growing number of jurisdictions have begun to introduce legal protections for intersex individuals, such measures remain uneven and limited globally. In parallel, medical and policy guidelines designed to improve the social and legal status of intersex adolescents and adults remain sparse and are rarely informed by qualitative evidence or by the perspectives of intersex communities themselves.

Research Question

What legal and normative protections currently exist for intersex individuals worldwide, and what challenges remain for achieving inclusive and equitable treatment under emerging medical and legal frameworks?

Methodology

This study provides a global overview of existing legal and normative protections for intersex persons, followed by a comparative analysis of two countries with distinct cultural and legal traditions. The comparative legal approach (Canada, China, international human rights) is used to

identify converging trends, regulatory gaps, and context-specific challenges in the development of rights-respecting legal and medical frameworks.

Results

The analysis reveals that although legal protections for intersex persons are gradually expanding, they remain fragmented and unevenly implemented. Few comprehensive statutory frameworks exist, and international guidance remains limited. Existing medical and policy guidelines often lack grounding in qualitative research and insufficiently incorporate the lived experiences and perspectives of intersex communities. Comparative findings highlight persistent tensions between medical practice, cultural norms, and evolving human rights standards.

Conclusions

Ensuring meaningful protection for intersex persons requires more robust and coordinated action from lawmakers, regulators, and medical professional bodies. Comparative insights underscore the need for more inclusive, evidence-based, and community-informed legal and clinical frameworks capable of safeguarding bodily integrity and promoting equal treatment under the law across diverse jurisdictions.

THU-S21-P02

Session: Intersex and Transgender Care · **Room:** R.004

Transgender Healthcare Challenges in the Post Hobby Lobby United States

Professor C. William Hinnant, Jr. MD JD FCLM

Medicolegal Consultants, LLC, Anderson, SC, USA

Background

In the United States, transgender people face a complex legal landscape with significant variations between states, some states offering protections for transgender individuals, others actively restricting their rights in areas like healthcare, participation in sports, and access to public accommodations. The latter significantly infringe on these individual's quality of life. This paper concerns federal law.

Research Question

What are the healthcare access barriers facing the transsexual community, why do they exist and what are the best solutions to eliminating those barriers?

Methodology

A literature and online review of healthcare access challenges facing transsexuals was conducted as well as interviews of transsexuals and the parents of transsexual youth to determine the primary access challenges facing this unique group who, in many cases are misunderstood particularly by religious, fiscal and social conservatives. The specific access barriers were identified with attention then turned to potential solutions and workarounds which could eliminate them. This was done within the backdrop of the U.S. Supreme Court Case, *Burwell v. Hobby Lobby*, 573 U.S. 682 (2014) and certain political factions active in the U.S.

Results

Practically, how transgender individuals are treated most generally correlates to whether the state is "red" or "blue" politically but clearly equitable access to necessary healthcare is a fundamental human right with legal precedent and the Affordable Care Act ("ACA") mandating that any exemption not impact any third-party's rights, particularly as to those ten essential healthcare benefits mandated within the meaning of the ACA. Yet, the U.S. Supreme Court in *Hobby Lobby* holds that the Religious Freedom Restoration Act allows for a non-profit closely held company to deny even less controversial contraception coverage much less more divisive gender affirmation to employees based on its owner's religious objection(s) and the "substantial burden" imposed upon them and the U.S. Constitution's Free Exercise clause. A reasonable question arises as to in doing so, does the Court essentially "establish" religious beliefs that *inter alia* are extremely conservative and out of touch with modern-day more moderate beliefs. Single payer government sponsored healthcare would likely eliminate these challenges.

This presentation will examine multiple scenarios wherein transgender individuals have attempted to exercise fundamental health care and related rights only to be thwarted by emerging case law, local ordinances or state or federal statutes. The opposing rationales for or against those rights will be examined and discussed practically and from a legal and policy standpoint.

Conclusions

The transsexual community faces challenges to healthcare delivery during and after transitioning and not always related to gender, in some cases arguably infringing on their Constitutional rights and violative of the Establishment Clause. These include indirectly mandating that they pay for healthcare that might otherwise be indemnified and in other cases being completely denied such care with no recourse, nor any legal work-around. Clearly, more equitable examination and an approach excluding individual religious belief as a consideration in the payment for and delivery of necessary healthcare services is needed.

THU-S21-P03

Session: Intersex and Transgender Care · **Room:** R.004

Operationalising Human Rights for Intersex Children in Europe: A Comparative Legal Analysis

Maxime Castermans

University of Antwerp, Antwerp, Belgium

Background

Intersex, or differences of sex development (dsd), refers to individuals born with variations in their sex characteristics, resulting in bodies that do not fit normative definitions of male or female. For decades, intersex children were subjected to so-called sex-'normalising' medical treatments and surgeries aimed at conforming their bodies with binary sex norms, even when they were most often not medically necessary. Because these interventions are typically performed shortly after birth or in early childhood, decision-making rested entirely with parents as legal representatives.

Although these interventions continue to occur, they have increasingly been criticised by human rights bodies within the United Nations, the Council of Europe, and the European Union. Invoking principles such as the child's physical integrity, personal autonomy, participation, and consent, they call on states to halt non-essential interventions and postpone them until the child can participate in the decision.

Since 2015, six European states – Malta, Portugal, Iceland, Germany, Greece and Spain – have adopted legislation responding to these calls. However, little is known about how these laws concretely operationalise intersex children's human rights. How are the aforementioned principles interpreted? What similarities and divergences emerge across the legal texts? And do they result in effective protection?

Research Question

How are the human rights of intersex children operationalised in recent European legal frameworks regulating early sex-'normalising' medical interventions?

Methodology

To answer the research question, I conducted a comparative legal analysis. For reasons of feasibility, the presentation focuses on the legislation adopted in Malta (2015), Iceland (2020) and Germany (2021).

Results

Although all countries have adopted legislation banning early, non-consensual sex-'normalising' medical interventions, significant divergences emerge. These divergences concern the targeted interventions and children, the criteria underpinning prohibitions (age thresholds, an *in concreto*-assessment of the child's capacity or will, or a combination of both), the exceptions allowed, the procedural safeguards provided – such as those relating to information, participation and assessment – and the sanctions for non-compliance. These divergences are inherent to the relative nature of human rights principles such as physical integrity, personal autonomy, participation, and consent, each of which requires contextual interpretation.

Concluding Remarks

Legislation can be an important tool to safeguard the human rights of intersex children. However, the interpretation and application of legislation, particularly its open-ended standards, ultimately remain in the hands of medical professionals. For that reason, an even more important strategy might be to focus on medical protocols and promote awareness-raising within the healthcare sector.

THU-S21-P04**Session:** Intersex and Transgender Care · **Room:** R.004**Ad-Sistere: A Comparative Inquiry into Parental Authority and Minors' Access to Gender-Affirming Treatment**PhD Candidate Teresa Maria Stella Zagra Master's Degree in Law (Italy)

Università Cattolica del Sacro Cuore, Milano, Italy

Background

Access to gender-affirming treatment for minors raises a difficult question for contemporary health law: who should decide when the patient has not yet reached full legal capacity to consent to medical treatment and the decision bears directly on personal identity during psycho-physical development? Comparative law offers no uniform answer: England has moved towards a more restrictive model; U.S. law remains fragmented; Italy leaves broader space to parental participation and case-by-case clinical assessment.

Research Question

This paper asks whether parents may legitimately exercise representative authority over a minor's access to gender-affirming treatment, or whether, if such access is to be permitted at all, it should depend on a rigorous inquiry into the minor's maturity, authenticity and freedom together with a reconsideration of the parental role.

Methodology

The paper combines a doctrinal analysis of the private-law categories of representation and assistance, focusing on their implications for clinical decision-making and for the autonomy of sufficiently mature minors, with a comparative inquiry into Italian, English, and U.S. law in order to identify more refined solutions consistent with the principles of children's rights and health law.

Results

The paper suggests that existing legal approaches address the relationship between minor autonomy and parental involvement in different ways, without resolving the underlying tension. Ordinary models of parental representation may be insufficient in this field, given the identity-shaping and often difficult-to-reverse character of these treatments and the minor's psycho-physical development. If access is legally permitted, the law should require a demanding inquiry into whether the minor's decision is free, adequately informed, sufficiently mature, and unaffected by pressures compromising its authenticity. Within this process, parents should be understood not as determining the content of the choice, but as accompanying the minor in the discernment of self and identity. Their role may be captured by the notion of *ad-sistere*: a legally relevant form of assistance. In this sense, *ad-sistere* describes both the relational mode of the evaluative process and, where that process establishes a conscious and authentic choice, the meaning of the parental act of authorization, understood less as representation than as formal acknowledgment of a decision attributable to the minor.

Conclusions

In gender-affirming care for minors, law should move beyond the opposition between parental representation and self-determination. If access is permitted, it should be framed within a relational model in which the role of parents is to *ad-sistere*, rather than determine the content of the minor's choice.

THU-S21-P05**Session:** Intersex and Transgender Care · **Room:** R.004**Co-Occurring Psychiatric Disorders and Gender Dysphoria in Children and Adolescents: Clinical, Therapeutic, and Medico-legal Considerations**Prof. Rosaria Nardello Associate Professor¹, Dr Ylenia Carbonaro¹, Dr Adele Maria Frisina², Alessandra Giliberti¹, Dr Stefania Giustiniano²¹University of Palermo, Palermo, Palermo, Italy. ²University of Palermo, Palermo, Italy**Background**

In recent years, there has been a significant increase in the number of children and adolescents presenting with gender dysphoria (GD). GD rarely occurs as an isolated condition and is frequently associated with neuropsychiatric comorbidities such as Autism Spectrum Disorder,

borderline personality disorder, attention-deficit/hyperactivity disorder (ADHD), and mood disorders.

Many of these patients seek gender-affirming treatments, including puberty blockers and cross-sex hormones, which entail both potential benefits and risks. Brain development during childhood and adolescence is strongly influenced by sex hormones. In particular, puberty is characterized by profound neurobiological reorganization, including changes in gray and white matter that affect cognition, emotional regulation, and social functioning. The administration of puberty blockers may interfere with these processes.

Research Question

What factors can guide clinicians in evaluating whether to support a patient's request for gender transition, particularly in the presence of psychiatric comorbidities?

Methodology

We conducted a retrospective analysis of cases followed at the Child and Adolescent Neuropsychiatry Unit of our Department. The study included 34 patients presenting with symptoms related to gender dysphoria. Patients were stratified into those with isolated GD and those with associated psychiatric comorbidities.

Results

Among the 34 patients analyzed, only 40% proceeded with the gender transition process. The remaining 60% discontinued the pathway following neuropsychiatric evaluation, which suggested that gender dysphoria represented a manifestation of broader psychological distress. Notably, two patients required hospitalization due to suicide attempts.

Conclusions

This study highlights the complexity of managing gender dysphoria in children and adolescents, particularly in the presence of psychiatric comorbidities. Clinical decision-making requires a cautious, multidisciplinary approach that carefully distinguishes between persistent, well-established gender dysphoria and forms that may be secondary to or intertwined with broader psychopathological conditions.

The findings underscore the importance of comprehensive neuropsychiatric assessment prior to initiating medical interventions, especially those with potentially irreversible effects. Furthermore, they raise important ethical and medico-legal considerations regarding informed consent, the patient's developmental stage, and the long-term impact of treatment decisions.

Future research is essential to better delineate diagnostic criteria, prognostic factors, and optimal therapeutic pathways. Longitudinal studies, in particular, are needed to clarify outcomes and to support evidence-based guidelines that balance patient autonomy with clinical responsibility. Ultimately, a personalized, developmentally informed, and ethically grounded approach remains crucial in the care of this vulnerable population.

FRIDAY 7 AUGUST

SESSION FRI-S01 · TRACK 1 · 09:00 – 10:30

AI and Liability I · Room R.014

Moderator: Dimitri Verhoeven

FRI-S01-P01

Session: AI and Liability I · Room: R.014

Liability for Harm Caused by AI-Based Medical Devices: The SafeCaring Case

Carla Barbosa

University of Coimbra Institute for Legal Research (UCILeR), Coimbra, Portugal. Biomedical Law Center - Coimbra Law Faculty, Coimbra, Portugal

Background

Artificial intelligence is increasingly integrated into healthcare through systems that qualify as AI-based medical devices, transforming clinical decision-making, care delivery, and administrative processes. While these technologies promise improvements in efficiency, personalization, and patient safety, they also raise fundamental legal questions when harm occurs. In such cases, the core issue becomes the attribution of civil liability and the identification of the applicable legal regime. The SafeCaring project, funded by the European Regional Development Fund, offers a concrete case through which to analyse these challenges within the legal framework of the EU. As an AI-driven system designed to support healthcare professionals, SafeCaring raises the question of who may be held responsible when damage is caused or aggravated by the use of an AI-based medical device, and how EU product liability, medical liability, and AI-specific regulation interact in such scenarios.

Methodology

This communication is based on a qualitative case analysis of the SafeCaring project, combining a functional description of the system with a legal-dogmatic and ethical analysis of responsibility. The system is examined as an AI-based medical device embedded in everyday care practices, with particular attention to how automated alerts and documentation reshape professional workflows. The analysis focuses on the redistribution of decision-making authority between healthcare professionals and digital systems, and on how this redistribution affects traditional models of civil liability under EU and national law.

Results

SafeCaring is designed to assist healthcare professionals caring for dependent patients by generating alerts for timely clinical interventions and by automating the recording of care activities, with the aim of preventing adverse events such as falls while reducing administrative burden. When harm occurs, however, liability attribution becomes complex. From the perspective of EU product liability law, the producer may be held liable if the system is defective, whether due to design flaws, inadequate training data, software malfunction, insufficient instructions for use, or failure to ensure appropriate updates. The opacity and adaptive behaviour of AI systems complicate the assessment of defectiveness and causation, challenges that current EU liability reforms seek to address.

At the same time, national regimes of medical liability continue to apply. Healthcare professionals retain duties of care, vigilance, and professional judgment, even when relying on AI-supported decision-making. Harm may therefore still be attributed to professionals who rely uncritically on system outputs or fail to intervene appropriately. Healthcare institutions may also incur liability where damage is linked to organizational choices, such as system deployment, staff training, or inadequate oversight. The AI Act adds a further regulatory layer by classifying many healthcare AI systems as high-risk and imposing obligations related to risk management, human oversight, transparency, and data governance. Although primarily preventive, these obligations are likely to influence civil liability assessments indirectly.

Conclusions

The SafeCaring case demonstrates that AI-based medical devices do not eliminate responsibility but reconfigure it across producers, professionals, and healthcare institutions. EU product liability law, national medical liability regimes, and the AI Act together form a multi-layered framework governing harm caused by AI in healthcare.

FRI-S01-P02

Session: AI and Liability I · Room: R.014

The New Product Liability Directive 2024 and its Impact on the Medical Sector

Prof. Dr. Dimitri Verhoeven PhD

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Background

Product liability has been a hot topic in the European Union for several decades. In particular, a specific Product Liability Directive was introduced in 1985. Under this Directive, the manufacturer is liable “for damage caused by a defect in his product.” In the light of new technologies, among other things, the Product Liability Directive was modernized in 2024.

Research Question

In what manner does the 2024 Product Liability Directive introduce changes that are relevant to the medical sector, and how will these changes effectively impact medical products, such as medicines, medical devices, etc.?

Methodology

This presentation will provide an overview of the most important changes to be made in the 2024 Product Liability Directive, with reference to their impact on medical products.

Results

The 2024 Product Liability Directive explicitly classifies software and digital services as a product. As a result, control mechanisms for medical products – e.g. surgical robots – can also give rise to product liability. AI-applications used in the medical sector – for example, to analyze medical imaging – also fall under the specific product liability legislation.

The expansion of the concept “product” raises another crucial question for the medical sector: can information itself – for example a written advice or a prescription from a physician – be considered a product? Given the *Krone Verlag*-judgement of the European Court of Justice, that question must be answered negatively.

Furthermore, the 2024 Product Liability Directive explicitly states that in the case of a product specifically intended to prevent damage, any failure of the product to fulfill that purpose shall be taken into account for the safety assessment of that product. One could therefore argue that various medical products – such as pacemakers but also certain medicines – should automatically be considered defective as soon as the product fails to achieve its intended purpose.

Finally, the new Directive extends the long-stop limitation period from 10 to possibly 25 years in cases involving latent harm, a change with substantial relevance for some medical products. Examples include the well-known scandals involving breast implants that caused damage only many years after implantation, or the distressing cases in which the harmful effects of certain medicines only became apparent years after use.

Conclusions

The 2024 revision of the Product Liability Directive marks a significant shift in the liability landscape, also for healthcare actors. This legislation, which was already victim-friendly when it was introduced in 1985, will now be even more favorable to victims.

In particular, when a medical product is involved, this product will be deemed defective much more quickly, and even automatically if the product is intended to prevent damage and fails to do so. In addition, many more (parts of) medical products – including their underlying software – will be covered by the directive. Finally, it is important to note that the limitation period in cases of latent damage will be significantly extended, and it is precisely medical products that often cause such latent damage.

FRI-S01-P03**Session:** AI and Liability I · **Room:** R.014**Protecting Patients and Physicians When Healthcare AI Causes Harm: A Corporate Governance Approach to Structured Accountability**

Assistant Professor Diane IJou Lin PhD¹, Case Manager Nai-Yi Yang MS², Associate Professor Jerzy Wlodzimierz Bednarski MD, PhD³, Doctor Tanya K Najhawan MD⁴, Doctor Jeng-You Wu MD, MBA^{5,6}

¹Chung Yuan Christian University, School of Law, Taoyuan City, Taiwan. ²Department of Radiation Oncology, Taipei Medical University Hospital, Taipei City, Taiwan. ³Medical University of Lublin, Department of Human Anatomy, Lublin, Poland. ⁴Thorndale Medical Clinic, Dublin, Ireland. ⁵Department of Radiation Oncology, Wan Fang Hospital, Taipei City, Taiwan. ⁶Graduate Institute of Biomedical Informatics, College of Medical Science and Technology, Taipei City, Taiwan

Background

Artificial intelligence is increasingly integrated into clinical decision-making. When AI-assisted decisions result in patient harm, existing legal frameworks create a paradox: physicians face disproportionate civil and criminal exposure despite limited control over algorithmic processes, while patients struggle to identify accountable parties within a complex chain of developers, data trainers, and healthcare institutions. The EU's 2017 "electronic personhood" proposal was abandoned after widespread criticism, and divergent approaches—the EU's developer-first liability model versus the US's user-first model—each leave significant gaps. Neither adequately addresses the full spectrum of responsibility nor balances the interests of patients seeking redress and physicians facing litigation.

Research Question

Can the civil law doctrine of constructive legal personhood, drawing on corporate governance principles, allocate both civil and criminal responsibility across the healthcare AI ecosystem while safeguarding patient compensation rights and protecting physicians from disproportionate liability?

Methodology

This study employs comparative legal analysis across three jurisdictions—the EU, the United States, and Taiwan—examining their respective approaches to healthcare AI liability. It applies an analogical methodology, mapping corporate governance role-based accountability structures onto the healthcare AI value chain, analyzing both civil and criminal dimensions.

Results

The constructive legal entity model conceptualizes the healthcare AI ecosystem as an organizational body analogous to a corporation, where each stakeholder assumes a governance role with corresponding obligations. AI developers correspond to directors bearing design oversight responsibility; downstream customizers function as officers with deployment duties; data scientists serve as professionals accountable for training data quality; regulatory bodies parallel auditors with verification obligations; hospitals assume institutional liability for selection and supervision; and physicians occupy operational roles with defined duties of care. In the criminal dimension, this mirrors how corporate law allocates prosecution based on decision-making authority rather than operational proximity—comparable to securities fraud where directors, officers, and auditors each face exposure proportionate to their control.

Conclusions

This framework benefits multiple stakeholders. Patients gain expanded compensation channels, enabling claims against any responsible participant across the AI value chain rather than solely against the treating physician. Physicians receive structured protection from disproportionate civil and criminal exposure when exercising reasonable professional judgment with validated AI tools. Healthcare institutions benefit from clearer risk allocation when procuring and deploying AI systems. AI developers and manufacturers gain predictable liability boundaries that encourage innovation without evading accountability. Collectively, this model creates a balanced responsibility architecture that promotes beneficial AI adoption while maintaining robust patient safeguards—accountability without scapegoats.

FRI-S01-P04**Session:** AI and Liability I · **Room:** R.014**The Probabilistic Physician and the Autopilot Paradox: Rethinking Malpractice under EU and Taiwanese AI Governance**

Doctor Jeng-You Robert Wu MD, MBA^{1,2}, Associate Professor Jerzy Wlodzimierz Bednarski MD, PhD³, Doctor Tanya K Najhawan MD⁴, Professor Min-Huei Hsu PhD^{5,6}, Professor Chia-Yu Emily Su PhD^{7,8,9}, Assistant Professor IJou Lin PhD¹⁰

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Background

Medical negligence law traditionally relies on qualitative standards such as "reasonable care" and judicial discretion, reflecting a narrative model of adjudication centered on individualized fault. By contrast, clinical artificial intelligence operates through quantifiable probabilistic metrics—sensitivity, specificity, and error margins—where a defined proportion of false outcomes is structurally embedded. This epistemic divergence creates a conceptual tension: statistical error (inherent risk), factual wrongness (adverse outcome), and malpractice (normative breach) are frequently conflated. The European Union, through the EU AI Act and medical device regulations, increasingly governs AI as an ex ante risk-classified system, whereas Taiwan continues to rely primarily on ex post fault-based adjudication under general malpractice doctrine.

Research Question

How should liability be allocated when AI-assisted clinical decisions produce statistically foreseeable errors? Does reliance on high-level AI create a distinct category of liability when physicians use technology beyond their unaided competence ("skill creep")? And can legal standards distinguish inherent probabilistic error from actionable negligence without collapsing into outcome-based reasoning?

Methodology

This paper develops two conceptual integration models. The "Scalpel Model" treats AI as augmentation within the physician's established competence. The "Autopilot Model" captures skill extension beyond baseline expertise. These models are analyzed comparatively under EU risk governance architecture and Taiwanese fault-based adjudication, incorporating theories of automation bias and systemic risk allocation.

Results

The analysis identifies a regulatory–liability divergence. Under the Scalpel Model, adverse outcomes within validated algorithmic uncertainty margins constitute residual systemic risk rather than malpractice. Under the Autopilot Model, liability may arise not from the erroneous output itself but from the physician's decision to rely on AI without adequate supervisory capacity. EU regulatory design partially accommodates systemic risk through ex ante compliance structures, while Taiwanese adjudication remains centered on individualized fault evaluation, potentially leading to inconsistent treatment of statistically inherent error.

Conclusions

AI-assisted medicine exposes the limits of narrative, outcome-driven adjudication. A coherent framework should differentiate between (1) statistically embedded algorithmic risk and (2) professional overreliance or competence abdication. Aligning malpractice doctrine with probabilistic risk governance—while preserving accountability for

misuse—offers a path beyond the false equivalence of error and negligence.

SESSION FRI-S02 · TRACK 2 · 09:00 – 10:30

Genetics I · Room R.201

Moderator: Jolien Smets

FRI-S02-P01

Session: Genetics I · Room: R.201

Emerging Trend in the Private Marketing of Regenerative Medicine Innovations Across Canada, the UK, and South Korea

Professor Yann Joly DCL (PhD)¹, Ms. Anjie Ni¹, Ms. Rose-Marie Seguin¹, Me. Jung-Hyun Lee², Jessica Huang¹

¹McGill University, Montreal, Quebec, Canada. ²Yonsei University, Seoul, Korea, Republic of

Background

Oversight of unproven stem-cell interventions (SCIs) has tightened in many high science- and technology-capacity jurisdictions. However, closely related regenerative medicine-based interventions, particularly platelet-rich plasma (PRP) therapies, continue to be marketed directly to consumers under comparatively loose regulatory scrutiny. This raises questions about whether recent declines in non-compliant stem cell businesses reflect genuine progress toward responsible innovation or merely the adaptation of commercial practices to circumvent existing legal frameworks.

Research Question

Does the apparent decline in non-compliant stem cell clinics signal improved regulatory effectiveness, or a strategic shift toward alternative regenerative medicine interventions operating in regulatory grey zones?

Methodology

We conducted a comparative analysis of the regenerative medicine marketplace across three jurisdictions with active regulatory engagement and advanced biotechnology sectors—Canada, the United Kingdom, and South Korea. These countries represent distinct regulatory models and provide a basis for identifying converging trends in the marketing and provision of unproven regenerative interventions.

Results

Our findings reveal a significant shift from the marketing of unproven stem cell interventions toward platelet-rich plasma (PRP) therapies—another largely unproven regenerative intervention frequently promoted using unsubstantiated scientific claims. Across all three jurisdictions, we identified a substantial and expanding PRP marketplace, suggesting that current oversight mechanisms have not kept pace with the diversification and evolution of the regenerative medicine sector.

Conclusions

The migration from stem cell-based offerings to PRP illustrates the adaptive capacity of the direct-to-consumer regenerative medicine marketplace in response to regulatory pressure. Existing oversight frameworks remain insufficiently anticipatory and risk becoming obsolete as new interventions emerge. We propose the development of more adaptive and forward-looking governance models for PRP and analogous regenerative interventions to better protect patients, preserve public trust, and support responsible innovation in regenerative medicine.

FRI-S02-P02

Session: Genetics I · Room: R.201

Implementation of the Act on Promoting Genomic Medicine and Afterwards in Japan

Professor Yuichiro Sato LLM¹, Professor Yuko Nagamizu LLM²

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Background

In Japan, the Act on Promoting Genomic Medicine was enacted in July 2023, and the fundamental program was implemented recently (December 2025). But “genomic medicine” is usually referred to as advanced medical care usually provided in university hospitals and national centres. But the act provides that genomic medicine should be

provided to the people broadly. What kind of genomic medicine can be provided so broadly?

Research Question

Clinical geneticists in university hospitals proposed the act. So it is natural to presuppose that “genomic medicine” is referred to as advanced medical care such as whole-genome sequencing for rare diseases and cancer screening programmes. But considering the prospective progress in genetic analysis and genomic medicine, genetic information might be used in daily medical care, such as for diabetes and hypertension. In those cases, family doctors will use patients’ genetic information. But family doctors in clinics are relatively old (over half of them are 60 y/o or older), so their ability to use genetic information and have proper consultations with clinical geneticists should be considered.

Methodology

I distinguish genomic medicine in three parts: (1) cancer treatment, (2) rare disease, and (3) other common diseases. I examine the fundamental programme with the interest of the use of genetic information of patients by family doctors. I also examine the measures of the Japanese Medical Association.

Results

(1) In cancer treatment, the main treatment is surgery and chemotherapy, which are mainly provided in university hospitals and cancer centres, so there are few problems in using genetic information. (2) In the treatment of rare diseases, diagnoses are mainly done by specialists. But patients would be referred to family doctors, and they provide usual treatment and medication. So sharing genetic information between the specialists and family doctors will be of great importance. (3) Treatment of common diseases has a lot of difficulties which should be discussed further. The recent amendments of the Medical Care Act and actual political measures that stress the differentiation and specialisation of advanced medical care in hospitals and daily care in clinics make the problems more difficult and important.

Conclusions / Take-Home Message

As discussed above, there are rooms to be discussed and solved, especially in cases of family doctors. This could be solved in the medical education for prospective doctors. But in the near future, not only patients but the general public have their own genetic information as personal health records. How do we handle our genetic information? Should the direct-to-consumer type genetic analysis service be allowed, prohibited or be controlled?

FRI-S02-P03

Session: Genetics I · Room: R.201

The Cost of Knowing: Predictive Health, Equality and the Future of Solidarity

Bjoern Schmitz-Luhn J.D., PhD, Atty.-at-Law (Germany)

Bonn University, Bonn, Germany

Background

Health prediction is on the rise. Immense technological advances and new medical insights have made the identification of an increased risk for a variety of diseases long before symptoms manifest easily accessible, cheaper and less invasive. While these innovations can improve prevention and early intervention, they also raise significant challenges for solidarity-based statutory health care systems which are grounded in principles of collective risk-sharing, equal access, and non-discrimination. The increase in predictive possibilities therefore requires careful consideration of their ethical, legal, and social implications.

Research Question

How do predictive advancements in disease risk assessment affect solidarity-based health care systems, particularly regarding non-discrimination, equality, and individual liberty? What are the ethical, legal, and social consequences of knowing one’s increased risk, and how can health care systems adapt to protect both individual rights and collective welfare?

Methodology

This interdisciplinary study integrates legal, ethical, and social perspectives to examine the implications of predictive health technologies. It analyzes legal principles governing solidarity, non-discrimination, and equality in statutory health care systems. The study also incorporates empirical data from surveys and interviews conducted

in Switzerland, Spain, and Germany, focusing on public attitudes towards predictive testing, the right not to know, risk literacy, and data protection. This cross-national analysis helps explore societal views and legal contexts surrounding the prediction of various diseases, including AD, cancer, and heart disease.

Results

The findings highlight a dual impact of predictive testing. On one hand, early prediction enables better life planning, preventive actions, and preparedness for future treatments. On the other hand, it risks undermining solidarity by potentially fragmenting collective risk-sharing, as individuals at higher risk may face stigmatization or exclusion in employment and insurance. Contrary to genetic testing, prediction based on other biomarkers or digital data are legally largely ungoverned. Furthermore, access to predictive tools must be equitable to prevent exacerbating health disparities. However, if accessible to all, predictive testing could strengthen solidarity by allowing everyone an equal opportunity to benefit from early interventions.

Conclusions

Predictive health testing presents both risks and opportunities for solidarity-based health care systems. While it may challenge traditional risk-pooling models, it can also empower individuals and support prevention. To balance these outcomes, health care systems must develop regulatory frameworks that protect against discrimination while encouraging innovation that ensures equitable access to early detection and treatment options, thus preserving solidarity in health care.

FRI-S02-P04

Session: Genetics I · **Room:** R.201

How Chinese Laws Inform Supervision of International Scientific Research Cooperation on Human Genetic Resources?

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Background

China has emerged as a key player in international Human Genetic Resources research, bolstered by substantial investments in research and development and a growing policy framework to govern genetic resource management. China's legal landscape, shaped by numerous laws and regulations, reflects an increasing focus on biosecurity, intellectual property, and ethical governance. These legal supervision frameworks allow China to play a leading role in international research collaborations while managing the complex tension between openness and sovereignty. However, the legal supervision of International Scientific Research Cooperation on Human Genetic Resources, particularly in cross-border contexts, remains underexplored in the existing literature, particularly from a Chinese perspective.

Research Questions

This study aims to provide a narrative review of the characteristics, shortcomings, and potential avenues for improvement of the latest legal and regulatory framework governing international scientific research cooperation involving China's Human Genetic Resources (HGR), through a systematic examination thereof.

Methodology

A normative analysis was conducted on 28 currently effective legal documents issued or entered into by Chinese authorities concerning the regulatory oversight of international scientific research cooperation on HGR. These documents include laws, administrative regulations, departmental rules, and other department documents from authorities. Furthermore, a comprehensive literature search was performed across CNKI, Wanfang, VIP, PubMed, and Web of Science for the period from 1990 to 2025. Following the PRISMA framework, 801 papers were screened, resulting in 24 articles closely relevant to the theme, which were then analyzed to identify current research focuses and gaps in perspective.

Results

Based on the analysis of legal instruments and academic literature, the Chinese regulatory framework is characterized by a rigorous and complex system of administrative licensing, multi-departmental synergistic supervision, and the prioritization of national sovereignty and security. However, several critical issues persist, including the

oversimplification of Ethics Investigations procedures, a redundancy of supervisory bodies for procedural oversight, convoluted review processes, and ambiguous criteria for "substantial involvement" by foreign entities.

Conclusions

This narrative review proposes appropriate strategies to optimize the current legal regulatory oversight of international scientific research cooperation on HGR in China, with the aim of ensuring that the domestic legal regulatory framework better aligns with international rules and global standards.

FRI-S02-P05

Session: Genetics I · **Room:** R.201

Is Genetics the Beginning of the End of the Worldwide Cerebral Palsy Litigation Crisis

Thomas P. Sartwelle BBA, LLB¹, James C. Johnston MD, JD^{2,3,4}, Dr. Mehila Zebenigus Wuhib⁵

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Background

Worldwide Cerebral Palsy [CP] litigation, wherein trial lawyers pocket huge sums from verdicts and settlements by falsely accusing birth caregivers of causing CP, began about ten years after electronic fetal monitoring [EFM], also known as cardiotocograph [CTG], became standard of care [SOC] for all labors in the early 1970s. The foundations for trial lawyer accusations were then and now EFM inventors' false claims and physicians' belief in the birth myth that CP is primarily caused by asphyxia during labor.

Research Question and Results

EFM inventors, with little knowledge of fetal compensatory responses to labor and no clinical trials, made unverified claims related to EFM's ability to predict impending birth asphyxia and claimed that quick delivery, primarily by caesarean section [C-section], would save thousands of babies from CP. Obstetricians accepted the inventors' unproven claims and made EFM the SOC for all labors, a SOC that continues today. In doing so, most physicians and many of their professional organizations have ignored CP-EFM research proving that caregivers rarely cause CP, that EFM and C-sections do not predict or prevent asphyxia or CP, that EFM has a 99% false positive rate, and has caused more harm than good to mothers and babies by millions of unnecessary C-sections with the concomitant risks to mothers and babies. As a result, caregivers and their professional organizations are preserving CP litigation which is consuming worldwide health care budgets at an alarming rate and subjecting their colleagues to fault-finding lawsuits and trials with devastating verdicts.

Today, caregivers are being offered a possible off ramp for some CP lawsuits. It has been well known for decades that only 2%-10% of CP is possibly related to birth and that the real causes are complex factors associated with antenatal, perinatal, and post-natal antecedents. Advances in genomic medicine are reshaping the understanding of CP etiology. Recent studies, particularly in Australia and the United States, have identified a substantial contribution of genetic variants to CP, with diagnostic yields from exome sequencing reported as high as 38%. These findings challenge longstanding assumptions regarding causation and have significant implications for clinical practice and birth injury litigation.

Conclusions

In this context, incorporation of genomic testing into the evaluation of every CP case represents a critical step toward more accurate etiological classification. A shift from presumptive intrapartum causation to evidence-based, multifactorial models will reduce misattribution, inform preventive strategies, and mitigate unnecessary intervention and resultant litigation. EFM must be reassessed to align obstetric practice with scientific evidence.

SESSION FRI-S03 · TRACK 3 · 09:00 – 10:30**Medical Liability III · Room R.230**

Moderator: Giancarlo Jimenez Bazan

FRI-S03-P01**Session:** Medical Liability III · **Room:** R.230**Boundaries of Legal Liability in Medical Practice: Negligence, Risk and Criteria for “Public Official” Status**Biologist Elnara Babayeva¹, Attorney, Lecturer Hikmat Babayev Candidate of PhD^{2,3}¹MediClub Hospital, Baku, Azerbaijan. ²Azerbaijani Bar Association, Baku, Azerbaijan. ³Baku State University, Baku, Azerbaijan**Background**

"In modern medical law, the legal evaluation of a physician's professional conduct remains one of the most intricate challenges. This complexity stems from the inherent uncertainties of medical intervention and the expansive interpretation of the term 'public official.' While the national legislation establishes a fundamental framework for maintaining legality in this field, the 'fine line' between a medical error and criminal negligence continues to be a subject of intense debate."

Research Question

When determining a physician's liability, three distinct concepts must be strictly differentiated: Medical Error, Negligence and Justifiable Risk in Medicine

Medical Negligence (Malpractice): A subjective deviation by the physician from established medical protocols and job descriptions. However, pursuant to Article 4.2 of the Constitutional Law of the Republic of Azerbaijan "On Normative Legal Acts," internal instructions cannot serve as the direct material basis for criminal liability; such violations must be evaluated only in conjunction with the relevant articles of the Criminal Code.

Justifiable Risk in Medicine: A risky step taken by a physician when no alternative exists to save a patient's life. If the risk is scientifically grounded and there is patient consent, it should be viewed as a circumstance that excludes criminal liability.

Methodology

Is a Physician a "Public Official"? National and International Perspectives Under Azerbaijani legislation, a physician can only be a subject of Article 308 of the Criminal Code if they perform organizational-managerial or administrative-economic functions. A physician engaged purely in clinical treatment does not act in the capacity of a "public official."

Results

International Practice: European Court of Human Rights (ECHR): According to the court's approach (e.g., Lopes de Sousa Fernandes v. Portugal), the state's primary obligation in the field of medical liability is not to subject physicians to criminal prosecution for every error, but to establish effective legal and administrative systems.

German and French Legal Systems: Errors committed by physicians during professional practice are not classified as "abuse of power", but rather as "inflicting bodily harm through negligence" or "failure to properly perform professional duties." In these jurisdictions, if a physician lacks an administrative management role, they are under no circumstances prosecuted under the status of a "public official" or "civil servant."

Conclusions

Criminalizing professional medical activity through the artificial expansion of administrative status contradicts international legal standards and undermines the principle of proportionality in law.

FRI-S03-P02**Session:** Medical Liability III · **Room:** R.230**Consentimiento Informado y Medicina Defensiva en el Perú: entre la Autonomía del Paciente y la Protección Jurídica del Médico**Professor Giancarlo Jiménez Bazán Master in Medical Law and Bioethics^{1,2}, Professor Rosa Teresa Meza Vásquez Master in Medical Law and Bioethics^{1,2}¹Meza & Jiménez Abogados, Lima, Lima, Peru. ²Peruvian Affiliate of the Latin American Association for Medical Law - Asolademe Peru, Lima, Lima, Peru**Antecedentes**

El progresivo proceso de judicialización de la práctica médica en el Perú ha generado un incremento en la percepción de riesgo legal por parte de los profesionales de la salud, propiciando la adopción de conductas asociadas a la denominada medicina defensiva. En este contexto, el Consentimiento Informado, tradicionalmente concebido como expresión del Principio de Autonomía del paciente, adquiere nuevas dimensiones funcionales.

Pregunta de investigación

Así, la presente investigación se plantea la siguiente interrogante: ¿El Consentimiento Informado en el contexto peruano opera como garantía de autonomía del paciente o como herramienta de protección jurídica del médico en un entorno de medicina defensiva?

Método

El estudio se desarrolla bajo un enfoque dogmático-jurídico con análisis crítico, incorporando una perspectiva interdisciplinaria que articula el derecho, la medicina y la bioética. Se examina el marco normativo vigente, especialmente la Ley General de Salud (Ley N.º 26842), así como la doctrina relevante sobre responsabilidad médica y medicina defensiva, complementado con referencias a la casuística y criterios jurisprudenciales en el ámbito peruano. Este abordaje permite identificar las transformaciones en la función del Consentimiento Informado dentro de la práctica clínica contemporánea.

Resultados

Los resultados evidencian que el Consentimiento Informado cumple una doble función en el escenario actual. Por un lado, se mantiene como una herramienta esencial para garantizar el ejercicio del Principio de Autonomía del paciente, permitiéndole adoptar decisiones libres, conscientes e informadas respecto de su salud. Por otro lado, se configura como un mecanismo de protección jurídica para el médico, en tanto, ante un eventual escenario de controversia de responsabilidad profesional en el que se cuestione su acto médico, el Consentimiento Informado se constituye en un elemento probatorio relevante que permite acreditar que se brindó al paciente información oportuna, suficiente y comprensible para la toma de decisiones. Estas funciones no resultan excluyentes, sino que coexisten y se potencian en un contexto marcado por la creciente litigiosidad en el ámbito sanitario.

Conclusión

En conclusión, el Consentimiento Informado experimenta una reconfiguración funcional en el Perú, integrándose en las dinámicas de la medicina defensiva sin perder completamente su fundamento bioético. No obstante, su uso predominantemente instrumental con fines de protección legal puede generar riesgos de desnaturalización. En tal sentido, se propone la necesidad de una reinterpretación equilibrada del Consentimiento Informado que armonice la autonomía del paciente, la seguridad jurídica del médico y la calidad de la atención sanitaria, a fin de preservar su legitimidad tanto ética como jurídica.

FRI-S03-P03**Session:** Medical Liability III · **Room:** R.230**Assessment of Defensive Medicine in the Context of Recourse Lawsuits against Public Service Physicians: A Legal Review Following Law N° 7406**Dr. Merve Yıldız^{1,2}, Prof. Dr. Serkan Çınarlı³¹Department of Public Health, Faculty of Medicine, Ege University, İzmir, Turkey. ²Bakırçay University Graduate School of Education, Department of Health Law, İzmir, Turkey.³Department of Administrative Law, Faculty of Law, Bakırçay University, İzmir, Turkey**Background**

Law No. 7406 on the Amendment of the Turkish Penal Code and Certain Laws added an additional Article 18 to the Basic Law on Health Services No. 3359 and introduced important amendments regarding the permission to investigate and recourse for healthcare professionals. A Professional Liability Board was established and the Board was authorized to authorize investigations and recourse. In this context, the Professional Liability Board will decide on whether the compensation paid by the administration will be recourse and the amount of recourse for physicians and other healthcare professionals working in public health institutions and organizations and state universities.

The increase in medical malpractice lawsuits in the world and in our country causes the issue to be widely discussed among physicians and causes physicians to feel under legal pressure. The administrative, criminal sanctions and compensation pressure that may arise due to medical malpractice cause physicians to hesitate in their professional practices in order to protect themselves, and this situation is called 'defensive medicine'.

Research Question

Does the fear of medical malpractice and the pressure to pay damages lead physicians to practice defensive medicine?

Methodology

Within the scope of the study, the recourse mechanism will be evaluated and its relationship with physicians' defensive medicine practices will be interpreted in the light of the literature. The study is based on a literature review and legal analysis.

Results

Studies have indicated that fear of malpractice is among the leading causes of defensive medicine practices. In addition, fear of complaints, fear of lawsuits, violence in healthcare, the healthcare system and healthcare policies, performance systems, the influence of the media, physicians' workload, lack of professional experience, communication errors, financial incentives, the desire for fame and perfection, and communication among physicians can be cited as causes of defensive medicine practices.

Conclusions

Law No. 7406, which entered into force on May 27, 2022, introduced significant regulations regarding the authorization to initiate investigations and the right of recourse for physicians, dentists, and other healthcare professionals. It is believed that the Professional Liability Board's authority to decide on indemnification and determine the amount of indemnification, as well as the requirement that the crime of intentional abuse of office be established for indemnification, will provide legal assurance to healthcare professionals. The decisions of the High Courts will serve as a guide in this matter, and the implementation of these regulations will be better understood.

FRI-S03-P04**Session:** Medical Liability III · **Room:** R.230**Responsabilités en Matière de Maladies Rares: Standard de Prudence des Acteurs de Soins, Organisation Hospitalière et Politiques Publiques**Céline Joisten^{1,2}, Lucas Fontaine^{1,3}¹Université de Liège, Liège, Belgium. ²Cour de cassation, Bruxelles, Belgium. ³CASE avocats, Bruxelles, Belgium**Contexte**

La notion de « maladie rare » est définie par l'Union européenne comme « une maladie qui ne touche pas plus de 5 personnes sur 10000 sur son territoire ». Ces maladies sont caractérisées par la rareté des connaissances et de l'expertise à leurs propos et le nombre restreint de

patients touchés, ce qui engendre un nombre élevé d'erreurs de diagnostic et de dommages. Le traitement de ces maladies suscite dès lors des questions en matière de responsabilité publique et civile.

Question de Recherche

Dans ce contexte, nous appréhendons la responsabilité en matière de maladie rare selon ces deux aspects: comment la rareté reconfigure-t-elle simultanément le standard de prudence du praticien et de l'hôpital et les obligations d'organisation du système de santé?

D'une part, la responsabilité individuelle du médecin et de l'hôpital suppose d'apprécier la règle générale de prudence à l'aune de l'état des connaissances scientifiques, lesquelles sont moins avancées dans ce domaine. Ce standard de conduite spécifique a également une incidence sur certaines obligations du praticien professionnel, notamment l'obligation d'information, la conservation des données dans le dossier médical et la protection des données personnelles.

D'autre part, ce standard de conduite suppose un environnement permettant d'atteindre ce seuil, ce qui nécessite une concentration d'expertise, une pluridisciplinarité et une coopération des filières de soins. La question se pose alors de l'existence et de l'étendue d'une obligation de l'État en matière d'organisation des soins visant les maladies rares.

Méthodologie

Au départ de plusieurs cas pratiques d'actualité, nous proposons d'envisager la responsabilité de ces acteurs au départ d'une grille d'analyse en deux niveaux: (I) responsabilité du médecin et de l'institution hospitalière et (II) responsabilité publique au regard de l'organisation de programmes de soins, de la centralisation des lieux de soins et de leur accessibilité.

Résultats

L'incertitude scientifique rend délicate l'appréciation de la faute d'un médecin et de l'institution hospitalière, ce qui ne permet pas une indemnisation adéquate des victimes. La responsabilité doit plutôt être envisagée au niveau de l'État dans l'organisation des soins de santé, par la mise en place d'un environnement où le niveau d'expertise permettrait, d'une part, de relever le standard de prudence des acteurs du système, d'autre part, d'éviter la réalisation de nouveaux dommages.

Conclusions

L'enjeu des politiques publiques en matière de maladies rares est de rehausser le standard général de prudence de manière à mieux prévenir et réparer les dommages causés par ces maladies.

FRI-S03-P05**Session:** Medical Liability III · **Room:** R.230**Methodological Critique of Singular Causal Judgments in Preventable Adverse Events**Prof. Dr. René Heylen

A&E, Genk, Belgium

Background

Estimates suggest that 34% to 83% of in-hospital adverse events are preventable, with a median of approximately 51%. These figures strongly influence patient safety policies. However, they are largely based on retrospective chart reviews and subjective reviewer judgments, raising concerns about methodological validity.

Research Question

To what extent are current estimates of preventable adverse events methodologically reliable, and do they provide a valid basis for improving quality of care?

Methodology

A critical methodological analysis of widely cited studies on preventable adverse events was conducted. Key elements assessed included definitions of preventability, causal inference, levels of certainty, reviewer methodology, and the presence of adversarial evaluation. Concepts from legal science, particularly standards of causation, were used as a comparative framework.

Results

Five main shortcomings were identified: (1) use of unrealistic standards for preventability; (2) insufficient establishment of causal relationships, with limited application of causal reasoning methods; (3) poorly defined certainty levels (e.g., "possible" vs. "probable"); (4) reliance on

subjective, non-reproducible reviewer judgments; (5) absence of adversarial review involving the physicians concerned. These limitations result in highly variable and likely inflated estimates. Frequently cited figures appear to reflect an idealized rather than realistic assessment of avoidability.

Conclusions

Current estimates of preventable adverse events are based on methodologically fragile foundations and tend to overestimate real-world avoidability. While they may support a culture of safety, they are not suitable for accurately guiding quality improvement. A more robust framework is needed, incorporating clear causal reasoning, well-defined certainty thresholds, and evaluation by experienced experts within the same field, preferably in an adversarial review setting.

SESSION FRI-S04 · TRACK 4 · 09:00 – 10:30

Medical Research Governance · Room R.007

Moderator: Margot Panneel

FRI-S04-P01

Session: Medical Research Governance · **Room:** R.007

Innovation Versus Protection? Comparative Governance of Research Ethics Committees in Global Clinical Research

Audrey Van Scharen Master

Vrije Universiteit Brussel, Brussel, Belgium. UZ Brussel, Brussel, Belgium

Background

Across the world, health law increasingly seeks to accelerate biomedical innovation while maintaining strong safeguards for research participants. The rapid expansion of advanced therapies, digital health technologies, and data-driven medical research has prompted regulatory reforms designed to streamline clinical trials and strengthen international competitiveness in the life sciences sector. At the same time, research ethics committees remain central to protecting participants' rights, dignity, and safety. This evolving landscape raises fundamental questions for health law: how can legal frameworks facilitate innovation without weakening the ethical oversight that underpins public trust in clinical research?

Research Question

How can health law systems reconcile policies promoting faster biomedical innovation with the need to preserve robust and consistent ethical oversight of clinical research?

Methodology

This study draws on doctoral research examining the functioning of the Belgian research ethics review system within the evolving European regulatory framework. The analysis combines legal doctrinal research with empirical data, including a content analysis of nearly 8,500 Requests for Information issued by Belgian Medical Research Ethics Committees between 2017 and 2024, surveys among the fifteen committees authorised to review studies under the Clinical Trial Regulation (CTR) and Medical Device Regulation (MDR), stakeholder workshops with regulators and sponsors, and comparative interviews with ethics oversight systems in Ireland, Denmark, Latvia, and Spain. The research further situates these findings within a broader comparative analysis of clinical research governance in the United States, Australia, and China.

Results

The findings demonstrate that ethics committees continue to prioritise core participant protections, particularly the clarity and completeness of informed consent documents and transparency regarding the processing and reuse of personal data. Committees also regularly scrutinise methodological aspects of clinical studies, including study design and statistical justification. At the same time, the analysis reveals variations in how ethical and legal requirements are interpreted across committees, particularly concerning consent procedures and secondary data use. Comparative analysis shows that similar governance tensions arise internationally. While the United States relies on Institutional Review Boards operating under the Common Rule, Australia emphasises nationally accredited Human Research Ethics Committees, and China has strengthened ethics oversight within broader reforms aimed at accelerating biomedical innovation.

Conclusions

The global expansion of biomedical innovation places increasing pressure on research oversight systems. Comparative experience suggests that improving coordination, guidance, and governance of ethics committees is essential to ensure that regulatory acceleration does not erode ethical safeguards or public trust in clinical research.

FRI-S04-P02

Session: Medical Research Governance · **Room:** R.007

Governing Ethical Review in Medical Research: Scope Limitations and Compliance with the Declaration of Helsinki

PhD candidate Margot Panneel Master of Laws

University of Antwerp, Antwerp, Antwerp, Belgium

Background

Across Europe, the regulatory landscape for medical research involving human participants has become increasingly complex due to the emergence of supranational instruments (e.g. the EU Clinical Trials Regulation, Medical Devices Regulation, and In Vitro Medical Devices Regulation) on top of national legal frameworks. This has led to fragmentation in ethical oversight, especially for medical research falling outside strictly defined categories such as clinical trials.

Fundamental ethical standards, particularly those laid down in the Declaration of Helsinki, require that all medical research involving human participants be subject to independent ethical review by a research ethics committee in advance. This raises questions about how such oversight can be ensured when national legal frameworks cover a limited scope. At the same time, certain types of oversight bodies may be better suited to assess specific categories of medical research. For example, data protection authorities may provide more appropriate review for observational research primarily involving personal data, raising the question of whether ethics committees should remain the central review body for all forms of medical research.

Belgium provides a timely case study. The 2004 Law on Experiments on the Human Person (WME), originally implementing the 2001 EU Clinical Trials Directive, is currently being reformed. The proposed amendments aim to refocus the Law solely on interventional research that affects participants' physical and/or psychological integrity, which may result in certain forms of observational or retrospective medical research being excluded from its scope.

Research Question

What are the implications of restricting mandatory ethics committee review to interventional research affecting participants' physical and/or psychological integrity, and what alternative oversight mechanisms are necessary to ensure compliance with the Declaration of Helsinki?

Methodology

This study employs a mixed-methods approach, combining empirical and comparative legal analysis. Firstly, an exploratory survey will be conducted among all ethics committees in Belgium to assess interpretations of the proposed scope definition, anticipated changes in responsibilities, and implications for review practices.

Secondly, a comparative analysis with the regulatory system in the Netherlands will be carried out to situate the Belgian reform within a broader European trend and to identify transferable lessons.

Results

The study will provide insights into how the implications of restricting ethics committee review to interventional medical research is interpreted and operationalised in practice, and how this affects the governance of observational medical studies. It will identify potential gaps in ethical oversight, including inconsistencies in review practices, uncertainty regarding responsibility allocation, and risks related to insufficient independent evaluation.

In addition, the study will assess the extent to which alternative oversight mechanisms are available, and whether they are perceived as adequate to ensure continued compliance with core ethical principles, including the requirement of prior independent review. Given the absence of a comprehensive supranational legal framework governing other forms of medical research involving human participants in Europe, these findings will also provide insight into challenges that may arise across different national legal systems.

Conclusions

By examining the implications of narrowing the scope of mandatory ethics committee review, this study highlights the risk that observational

medical research may fall into regulatory grey zones if no appropriate alternative oversight mechanisms are established.

Grounded in the principles of the Declaration of Helsinki, the findings underscore that limiting formal review obligations does not eliminate the ethical requirement for independent evaluation prior to the involvement of human participants or their data.

In the absence of a harmonised supranational legal framework at the European level, this study also highlights the potential for divergent national approaches, raising broader questions about consistency, legal certainty and the protection of research participants across jurisdictions.

FRI-S04-P03

Session: Medical Research Governance · **Room:** R.007

Challenges of Legal Regulation of Ethics Committees in Slovenia

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Background

The article explores the legal framework governing various Ethics Committees in the Slovenian healthcare system. Effective oversight by ethics committees represents one of the main requirements or assumptions for the professional and legal functioning of the healthcare system in the areas of research, clinical practice, and education.

Research Question

The central research question of the study is whether a sufficient and comprehensive legal basis has been established in the Republic of Slovenia for the operation of various ethics committees in the field of healthcare.

Methodology

The discussion first brings forward an analysis of legal basis for operation of Ethics Committees. It begins by evaluating whether they operate on a sound legal foundation. While Ethics Committees function across different levels of the healthcare system, the National Medical Ethics Committee of the Republic of Slovenia plays a central role. The paper further investigates the extent to which they have been successfully established and developed within secondary and tertiary hospitals, drawing on an analysis of hospital annual reports.

Results

Hospital Ethics Committees are increasingly tasked with responsibilities related to ensuring patient safety and the quality of care. A key finding of the analysis is that Article 60 of the Health Care Act lacks sufficient detail to support the effective functioning of these bodies. Specifically, it fails to address critical procedural and structural elements such as the formation process, eligibility criteria, terms of office, reporting obligations, and transparency mechanisms.

Conclusions

First, a comprehensive reform of the legal provisions governing ethics committees should take place. Second, it must be upgraded with an implementation project to strengthen the competencies and operational capacities of ethics committees in healthcare.

FRI-S04-P04

Session: Medical Research Governance · **Room:** R.007

The Legal Framework Surrounding Clinical Research Involving Pregnant Women: Towards Responsible Inclusion

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Background

Pregnant women remain structurally underrepresented in clinical research, despite the fact that between 64% and 90% of them use medication during pregnancy. This exclusion has resulted in a significant lack of evidence-based knowledge regarding the safety and efficacy of medicinal products in this population. Consequently, treatment decisions are often made under conditions of uncertainty, frequently involving off-label prescribing. Historically rooted fears, particularly following the DES and thalidomide tragedies, have reinforced a protective approach, leading to strict regulatory

frameworks at international, European, Belgian, and U.S. levels. While intended to safeguard both the pregnant woman and the fetus, these frameworks have instead contributed to systematic exclusion, raising concerns regarding pregnant women's rights to health, to benefit from scientific progress, and to bodily autonomy.

Research Question

To what extent does the existing legal framework governing clinical research involving pregnant women balance protection and inclusion, and does it provide sufficient room for their ethically and legally responsible participation in clinical studies?

Methodology

This article conducts a doctrinal and comparative legal analysis of the regulatory framework governing clinical research involving pregnant women. It examines international ethical instruments such as the CIOMS Guidelines and the Oviedo Convention and its Additional Protocol on Biomedical Research, alongside European legislation, including the EU Clinical Trials Regulation and the EU Medical Devices Regulation. The Belgian implementation and advisory opinions (notably from the Belgian Bioethics Advisory Committee and the Belgian Association of Research Ethics Committees) are analysed, followed by a comparison with the U.S. federal regulatory framework. The analysis is structured around key legal conditions: risk-benefit assessment, minimal risk thresholds, subsidiarity, informed consent, procedural safeguards, follow-up obligations, and vulnerability classification.

Results

The analysis reveals a predominantly protection-oriented framework that allows research involving pregnant women only under strict conditions. Research without direct individual benefit is generally prohibited unless cumulative criteria are met, including minimal risk, subsidiarity, and societal relevance. The CIOMS Guidelines (2016) offer the most progressive approach, rejecting automatic vulnerability categorisation and actively promoting responsible inclusion based on contextual risk assessment. European and Belgian frameworks permit participation but maintain high regulatory thresholds, while U.S. law uniquely requires paternal consent in certain cases where only foetal benefit is anticipated. Across jurisdictions, informed consent, prior preclinical research, and independent ethical review constitute central safeguards.

Conclusions

The current legal framework does not impose an absolute prohibition of clinical research involving pregnant women, but it does create a demanding regulatory structure that discourages inclusion unless interpreted progressively. The central question should no longer be whether pregnant women may be included, but how they can be included ethically and lawfully under proportionate safeguards. This requires strengthening preclinical research, promoting postmarketing data collection and pregnancy registries, ensuring robust informed consent procedures, and addressing structural barriers such as liability concerns and funding gaps are essential. Responsible inclusion, rather than systematic exclusion, is essential to achieving equitable, evidence-based healthcare for pregnant women and their children.

FRI-S04-P05

Session: Medical Research Governance · **Room:** R.007

Vers un Déplacement du Pouvoir Normatif dans le Domaine des Innovations en Santé: Quels Rôles pour les Équipes de Recherches?

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Contexte

Les innovations en santé se déploient aujourd'hui dans un environnement normatif dense, évolutif et polycentrique, marqué par la coexistence de normes juridiques, d'exigences éthiques et de standards techniques. Dans ce contexte, les équipes de recherche sont confrontées à un ensemble hétérogène de normes, contraignantes ou non, applicables à leurs activités. Cet ensemble comprend notamment des normes volontaires (principes éthiques, lignes directrices, etc.) ainsi que des normes dites endogènes, c'est-à-dire élaborées à travers des pratiques d'autoréglementation (chartes, protocoles, etc.). Il en résulte une évolution du rôle normatif des équipes de recherche, qui ne

se limitent plus à l'application des normes, mais participent désormais à leur interprétation, à leur articulation et, dans certains cas, à leur production. Ces dynamiques se manifestent particulièrement dans un contexte d'émergence de technologies, outils et méthodes innovantes ne disposant pas encore d'un encadrement clair et unifié.

Question de Recherche

Nous souhaitons alors nous demander en quoi l'évolution du rôle normatif des équipes de recherche transforme les modes contemporains de régulation des innovations en santé.

Conclusion Préliminaire

Cette analyse s'appuie sur un projet européen pour l'encadrement des jumeaux numériques (VHT initiative), sur une initiative française concernant les données artificielles (Association SILICA) ainsi que sur un projet québécois développant des systèmes de neuromodulations (RE-MOVE). À travers ces exemples, la réflexion menée suggère que l'évolution du rôle normatif des équipes de recherche s'inscrit dans une transformation plus large des modes de régulations des innovations en santé, marquée par un déplacement du pouvoir normatif en dehors des cadres étatiques traditionnels.

Cette évolution participe à l'émergence d'une forme renouvelée de création de la norme, issue des pratiques scientifiques elles-mêmes. Si cette forme de création normative peut, au premier abord, donner l'impression d'une densification du cadre normatif, elle contribue également à garantir une meilleure effectivité des exigences encadrant les innovations en santé. Elle permet en outre de répondre aux attentes et besoins des chercheurs, tout en garantissant une intégration plus précoce, dès la phase de conception, de considérations éthiques et juridiques dans les processus de recherche, orientant ainsi le développement des innovations vers des formes plus responsables. Enfin, ces évolutions invitent à interroger le devenir de ces normes endogènes. Celles-ci pourraient ne pas être seulement pensées comme un outil ponctuel d'accompagnement des chercheurs, mais également contribuer à l'émergence d'un socle de production normatif de type « bottom-up ».

SESSION FRI-S05 · TRACK 5 · 09:00 – 10:30

Professional Regulation, Disciplinary Law, and Medical Standards · Room R.008

Moderator: Berna Arda

FRI-S05-P01

Session: Professional Regulation, Disciplinary Law, and Medical Standards · **Room:** R.008

Disciplinary Complaints against Resident-Physicians and their Supervisors: An Analysis of Cases in the Netherlands 2009 – 2024

Wouter Dronkers MD LLM MA¹, Quirine Amelink LLM², Willemijn Krugers Dagneaux LLM³, Jan van Rees MD PhD¹, Dennis Buis MD PhD LLM⁴, Marike Broekman MD PhD LLM⁵, Markus Klimek MD PhD¹, Clemens Dirven MD PhD¹, Ian Leistikow MD PhD², Jochem Spoor MD PhD LLM¹

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Background

Resident-physicians (residents) occupy a distinctive dual role within healthcare systems: they are trainees while simultaneously providing frontline clinical care. This dual role creates ethical and legal challenges, as it requires balancing the delivery of the highest possible quality of care, typically associated with experienced physicians, with the necessity of training less experienced physicians to safeguard the quality of future care. Alleged lack of quality of care may result in patients' complaints including those filed under Disciplinary law.

Research Question

What are the characteristics, motives, and outcomes of disciplinary complaints against residents and supervising physicians in the Netherlands?

Methodology

A retrospective analyses of consecutive Dutch disciplinary cases involving residents and supervising medical specialists between 2009

and 2024. A search for relevant cases was performed through www.tuchtrecht.overheid.nl. Both first-instance cases and cases on appeal were included. Each case could contain one or more individual complaints. Themes of complaints and specific categories within a theme, and outcomes at case level (ruling) were analysed.

Results

In the Netherlands, between 2009-2024, 178 first instance disciplinary cases were handled that were filed against a resident (n=116; 364 individual complaints) or supervisor (n=62; 107 individual complaints). Resident cases mostly involved residents from General Surgery (n=19), OB&GYN (n=15), and Psychiatry (n=12). Themes of individual complaints against residents were mostly related to direct patient care/medical management (61%), followed by communication (16%), a lack of professionalism (15%), and lack of (required/requested) supervision (9%). Categories of complaints were mostly related to 'diagnostic & treatment' (44%), various forms of unprofessional behaviour (13%), and 'physician-patient communication' including informed consent issues (12%). Most cases were ruled unfounded (74%), compared to 25% founded, and 1% of inadmissible cases. Measures imposed at first instance included a warning (16%), reprimand (3%), conditional suspension (1%), and a revocation of the medical licence in two cases (2%). In five (4%) cases, no measure was imposed. In one case, no measure was imposed. Most resident cases in appeal did not result in a change of the ruling. Supervisor related complaints were mostly related to insufficient supervision. Most of these cases were unfounded (68%), compared to 32% founded cases resulting in 11 warnings, 7 reprimands, one revocation.

Conclusions

Disciplinary proceedings involving residents and their supervisors are uncommon, and most complaints are ruled to be unfounded. While a surgical learning curve is inherent and unavoidable, the legal outcomes do not suggest that the care delivered falls below accepted standards.

FRI-S05-P02

Session: Professional Regulation, Disciplinary Law, and Medical Standards · **Room:** R.008

License Revocation of Physician for Professional Misconduct by the Pakistan Medical and Dental Council (PMDC/ PMC)

Dr. Mustafa Aslam MBBS, DMJ, MBETH, CPB, FCPS©, Dr Marriam Gul Thahim MBBS, DMRT, MBETH CPB
Aga Khan University, Karachi, Sindh, Pakistan

Background

Professional accountability in medicine is a cornerstone of patient safety and public trust. In Pakistan, Pakistan Medical and Dental Council (PMDC) — reconstituted as the Pakistan Medical Commission (PMC) under the PMC Act 2020 — serves as the principal regulatory body empowered to register, oversee, and where necessary, revoke the licenses of medical and dental practitioners found guilty of professional misconduct, negligence & malpractice. Despite this mandate, the mechanisms for license revocation remain poorly understood, inconsistently applied, and infrequently studied, raising concerns about the effectiveness of professional regulation in protecting patients.

Research Question

What are the legal and procedural frameworks governing license revocation for professional misconduct under the PMDC/PMC, and how effectively are these mechanisms implemented in practice?

Methodology

This narrative review examined relevant legislative instruments including the PMDC Ordinance 1962, PMC Act 2020, and associated disciplinary regulations. Peer-reviewed articles, institutional reports, and grey literature were retrieved from PubMed, Google Scholar, and official PMC/PMDC documentation. Comparative reference was made to regulatory frameworks in the United Kingdom (GMC) and India (NMC) to contextualize Pakistan's approach within a broader international framework.

Results

The review identifies significant structural and procedural shortcomings in Pakistan's medical disciplinary system. Definitions of professional misconduct lack specificity, creating inconsistency in adjudication. Disciplinary proceedings are often protracted, opaque, and susceptible to political and institutional pressures. Data on the number of license

revocations are not systematically published, undermining public accountability. Furthermore, the transition from PMDC to PMC, while intended to modernize regulation, has introduced transitional ambiguities that have temporarily weakened enforcement capacity. Comparative analysis reveals that Pakistan lags behind peer jurisdictions in transparency, timeliness, and victim support mechanisms within disciplinary processes.

Conclusions

Effective license revocation is not merely a punitive tool but a critical instrument of patient protection and professional integrity. Pakistan's regulatory framework requires urgent reform to ensure clearly defined misconduct categories, transparent and timely disciplinary proceedings, and publicly accessible outcomes. A multidisciplinary dialogue among legislators, medical professionals, patient advocates, and legal experts is essential to build a regulatory environment that commands both professional and public confidence.

FRI-S05-P03

Session: Professional Regulation, Disciplinary Law, and Medical Standards · **Room:** R.008

Legal Certainty in Ethical Proceedings Against Physicians: Lessons from Portugal to Reduce Discretion in Brazil

Karla Kiuchi

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Background

Administrative ethical proceedings before Medical Councils in Brazil have increased markedly, and the Brazilian system suffers from legal uncertainty due to broad discretion in sanctioning. The Portuguese model provides a normative grading of infractions and explicit dosimetry criteria that may enhance predictability and fairness.

Research Question

Can procedural and normative elements of the Portuguese disciplinary framework serve as a model to reduce discretionary disparities and increase legal certainty in Brazilian professional-ethics proceedings?

Methodology

Doctrinal, comparative legal analysis of primary sources (Brazil: Law No. 3.268/57; the Code of Process of Ethical-Professional Proceedings; and relevant CFM resolutions; Portugal: Decree-Law 282/77 and Law No. 9/2024), regulatory instruments (Regulation 631/2016), specialized doctrine, and higher-court jurisprudence. The study maps process stages (investigation, instruction, defense, judgment) and compares sanctioning regimes and dosimetric criteria.

Results

Both systems share deontological foundations but differ significantly in procedural design and sanctioning guidance. Portugal secures defense guarantees from the initial stage, classifies infractions (minor, serious, very serious), enumerates aggravating and mitigating factors, and permits pecuniary accessory sanctions—features that improve predictability and allow case-filtering before formal accusation. In Brazil, the more inquisitorial nature of the preliminary investigation, nonbinding deadlines, and absence of normative gradation produce asymmetric outcomes across Regional Councils and foster perceptions of arbitrariness.

Conclusions

Implementing three practical reforms inspired by the Portuguese model—(i) normative graduation of infractions; (ii) explicit dosimetry criteria (e.g., intent/culpability, severity of outcome, disciplinary history); and (iii) national sanctioning guidelines issued by the Federal Medical Council—can reduce discretionary divergence while preserving council autonomy. These measures would enhance legal certainty for physicians, protect reputations, and strengthen institutional legitimacy without undermining patient protection.

FRI-S05-P04

Session: Professional Regulation, Disciplinary Law, and Medical Standards · **Room:** R.008

Can Organizational Guidelines Ensure Fundamental and Human Rights in Health Care in Lack of Legislation?

Analysis of the Former Finnish Hospital Districts' Guidelines on Restrictive Measures in Somatic Care

Visiting lecturer Merja Turunen LL.D., M.D., M.Sc. (Admin.)

University of Lapland, Rovaniemi, Finland

Background

The current national legislation on involuntary care and restrictive measures in Finland does not cover all somatic care situations in which restrictive measures are used to ensure the life and health of a patient or the life and health of other people. In lack of legislation the Finnish Parliamentary Ombudsman, as the overseer of legality, has considered important that health care organizations give internal guidelines to steer and control the use of restrictive measures in somatic care. The concept of restrictive measures is used here in conformity with the Finnish concept 'rajoittaminen', meaning physical, chemical and mechanical restraints and seclusion or isolation, and it is interchangeable with the concept of coercive measures that is common in international usage.

Research Question

How can health care organizations control the unlegislated situation and steer the use of restrictive measures in somatic care by their internal guidelines?

Methodology

Organizational guidelines are a non-binding source of law, but in lack of legislation they play an important role in steering the everyday practice of health care professionals. In one part of my legal research dissertation published in 2025, I used for research material the former Finnish Hospital Districts' guidelines on restrictive measures in somatic care as a sample of health care organizations' guidelines. The Hospital Districts' guidelines were collected from 18 out of 21 Hospital Districts in Finland in late 2022 to early 2023 and 29 out of 62 guidelines received were included in research material. The guidelines were anonymized, and analysed for several characteristics on restrictive measures. The guidelines were also analyzed for reference to the principles of fundamental and human rights restrictions, other applicable national legislation, the Parliamentary Ombudsman's decisions, and other features.

Results

There was fluctuation in quality, content and procedures between the guidelines. The research data indicate that different health care units employ restrictive measures based on different grounds, different preconditions for restrictions, and different restrictive measures. Lack of legal remedy is one observation, but legal remedy cannot be created by organisational guidelines.

Conclusions

The Finnish hospital districts' guidelines on restrictive measures in somatic care cannot guarantee equal implementation and protection of patients' fundamental and human rights in hospitals across the country.

FRI-S05-P05

Session: Professional Regulation, Disciplinary Law, and Medical Standards · **Room:** R.008

Guidelines for Medical Practice: A Reconsideration of Their Legal Significance

Dr. mr. R.C. Rogier C. Simons PhD | LL.M

Amsterdam University Medical Center, Amsterdam, Netherlands. Van Benthem & Keulen Advocaten, Utrecht, Netherlands

Background

Clinical guidelines and other quality documents (e.g., standards, protocols, position statements and handbooks) are of great importance for medical practice. They support clinical decision-making, enhance transparency, and reduce unwarranted practice variation. In many settings, guidelines form the practical foundation of medical conduct. However, guidelines are not legally binding norms. This creates legal complexity: while deviation is in principle permissible, guidelines often play a significant role in disciplinary and civil liability proceedings. The rapid increase in the number and scope of guidelines — such as the approximately 140 standards and guidelines applicable in Dutch general practice — has further intensified uncertainty regarding their legal status, hierarchy, and normative force, particularly where different quality documents conflict.

Research Question

What is the legal status and normative significance of clinical guidelines within the Dutch healthcare system, and how do courts and disciplinary tribunals assess adherence to, or deviation from, different categories of guidelines?

Methodology

This study employs doctrinal legal research. First, it analyses the legal qualification and definition of clinical guidelines and examines their relationship to other quality documents within the framework of the professional and medical-professional standards. A distinction is made between (1) medically substantive guidelines forming part of the medical-professional standard and (2) broader normative guidelines forming part of the overarching professional standard. Second, the study systematically reviews relevant Dutch disciplinary and civil case law to assess how both categories of guidelines are interpreted and applied in liability proceedings.

Results

The analysis demonstrates that although guidelines lack formal binding force, they carry significant normative weight in legal assessments of professional conduct. Courts and disciplinary tribunals frequently treat medically substantive guidelines as authoritative expressions of the medical-professional standard, making deviation possible only if adequately justified in light of the specific circumstances of the case. Broader normative guidelines, while generally less prescriptive, increasingly inform judicial reasoning concerning due care and professional responsibility. Case law reveals a nuanced but growing reliance on guidelines as concretisations of open legal norms, particularly the standard of “good care.”

Conclusions

Clinical guidelines occupy a hybrid position between professional self-regulation and legal normativity. Although not legally binding, they substantially shape the interpretation of the professional standard in disciplinary and civil proceedings. Greater conceptual clarity regarding the legal qualification and hierarchy of different types of guidelines is essential to enhance legal certainty for healthcare professionals and to support careful, context-sensitive decision-making in clinical practice.

SESSION FRI-S06 · TRACK 6 · 09:00 – 10:30

Transplantation · Room R.011

Moderator: Kristof Van Assche

FRI-S06-P01

Session: Transplantation · **Room:** R.011

Ethical Dilemmas Surrounding Anencephalic Newborns and Organ Donation: Reflections on Legal, Ethical Issues and Policy Recommendations

Medical Student Zahide Yagmur Sermikli Medical Student, Medical Student Gul Sena Cinar Medical Student, Professor Perihan Elif Ekmekci MD, PhD, Professor Hatice Tatar Aksoy MD

TOBB ETU, Ankara, Turkey

Background

Anencephaly, a neural tube defect, defies the common understanding of life and human rights due to missing parts of the brain tissue and short life expectancy. These newborns were not qualified to be considered as organ donors; however, as a consequence of medical advancements, the lifespan of anencephalic newborns has been extended. Therefore, the dilemma about organ donation from anencephalic newborns has become a subject of ethical debate. In anencephalic cases, we cannot apply established brain death procedures because of the missing parts of the brain tissue. The increasing necessity of determining brain death on anencephalic newborns is forcing stakeholders to seek a solution.

Research Question

This study investigates the ethical question that arises from the lack of clear guidelines and the necessity for a structured decision-making framework after the question prompted by whether the death of one individual can be justified if it benefits others. How can medical and legal committees decide on the brain-dead final decision? Even if the family of the anencephalic newborn approves organ donation, the stakeholders still assume responsibility to guard the rights of the newborn to resolve the conflict.

Methodology

This study examines how anencephalic newborns fit into brain death criteria and the organ donation process while discussing some ethical concerns such as the concepts of life, personhood, and human rights through referring to real-life cases.

Results

Due to the lack of guidelines and laws in determining the death of anencephalic newborns and organ transplantation, stakeholders are confronted with ethical and legal dilemmas. We propose that particularly in anencephalic cases, there should be a guideline to follow that is developed by an interdisciplinary group of experts in their fields. This group of experts should include doctors (anesthesiologist, pediatrician, neonatologist, psychiatrist, intensive care specialist, neurologist-neurosurgeon), nurses, judges, prosecutors, lawyers, ethicists and families who suffered from the situation. Other experts may be added if deemed necessary.

Conclusions

This study aims to develop a policy framework for the governance of organ donation in anencephalic newborns. The main features of our proposal to the governance model are flexibility, adaptability, and a living document open to public debate. With this prepared framework, we aim to advance our last year's conducted research on “Ethical Dilemmas Surrounding Anencephalic Newborns and Organ Donation” and reach interested parties to start a passionate research collaboration to elucidate the long-standing ethical dilemma.

FRI-S06-P02

Session: Transplantation · **Room:** R.011

Bridging the Organ Deficit in Ghana: A Socio-Legal Analysis and Framework for a Culturally Compatible Presumed Consent Legal Regime

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Background

Ghana has been experiencing a growing incidence of end-stage organ failure and a persisting deficit of organs for transplantation. Live donation is the only source of organs for transplantation in Ghana. A recent survey in Accra, Ghana, documented that approximately 50% of 480 participants were willing to proceed with a living donation, and most donors are related to the recipients. Although a similar survey reveals that approximately 70% of Ghanaians are willing to consent to organ harvesting after death, the socio-cultural concept of family ownership of corpse, transition of the dead to the spiritual realm, belief in reincarnation and the communitarian way of living in Ghana impairs organ harvesting after death. A legislative vacuum exacerbates this precarious situation, as Ghana's existing laws are inadequate to regulate modern transplant medicine and the growing demand for organs.

Research Question

The germane question this paper seeks to address is whether a legal regime of presumed consent (opt-out) without the involvement of the deceased's family will yield the desired result of increased organ supplies from cadaveric sources.

Methodology

The paper adopts a doctrinal approach by analysing legal and socio-cultural barriers to cadaveric supply of organs in Ghana. A Comparative approach is also employed in analysing comparative legislative models, including explicit consent (opt-in) and presumed consent (opt-out) systems. The paper examines entrenched cultural beliefs about bodily integrity after death and the legal primacy of the extended family in post-mortem decisions, using secondary data, including existing research on organ supply in Ghana.

Results

Our findings reveal that adopting an opt-in or opt-out approach alone is not a solution to the organ shortage, especially in societies like Ghana, where autonomy cannot be exercised without family involvement. In our comparative analysis of countries with opt-in or opt-out systems, we found that the cultural underpinnings of societies and how they are addressed in the law play a major role. It reveals that a simple

transposition of any model into Ghana will be unworkable because of the culturally laden and family-centred approach to post-mortem decisions.

Conclusions

The paper concludes with a proposal for a culturally laden legal framework of presumed consent (opt-out) in Ghana. This model would establish donation as the default while legally mandating family involvement, thereby respecting both individual autonomy and Ghana's unique communitarian values to improve the organ supply for transplantation. Ghana must also adopt a robust legal regime to ensure regulatory oversight and sustained public education on organ donation.

FRI-S06-P03

Session: Transplantation · **Room:** R.011

Organ Transplantation and Donation: A Comparative Medico-Legal Analysis of Consent Models, Legal Regulation, and Bioethical Challenges in Azerbaijan and Selected Jurisdictions

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Background

Organ transplantation represents a life-saving medical intervention that simultaneously raises complex bioethical and legal challenges. Central issues include consent to organ donation, protection of donor and recipient rights, prevention of organ trafficking, and equitable access to transplantation services. Different jurisdictions adopt varying legal models, including opt-in (explicit consent) and opt-out (presumed consent) systems, reflecting diverse ethical, cultural, and legal traditions. In Azerbaijan, transplantation and donation are regulated within a developing legal framework that seeks to balance medical necessity, ethical safeguards, and public trust. Comparative analysis of international experience is essential to identify effective regulatory approaches and improve national legislation.

Research Question

How do different legal models of organ donation and transplantation regulate consent, donor protection, and ethical safeguards, and what lessons can be applied to strengthen the legal framework in Azerbaijan?

Methodology

This study applies comparative legal analysis of transplantation legislation across selected jurisdictions, including post-Soviet countries, members of the Commonwealth of Independent States (CIS), regional countries such as Turkey and Iran, and selected European legal systems. The analysis focuses on key regulatory dimensions: consent models (opt-in vs. opt-out), legal safeguards against organ trafficking, institutional oversight mechanisms, and protection of donor and recipient rights. International legal standards and bioethical principles are also considered in the evaluation.

Results

The analysis demonstrates significant variation in legal approaches to organ donation. European countries increasingly apply presumed consent (opt-out) models supported by strong institutional oversight and public awareness mechanisms, which are associated with higher donation rates. In contrast, many post-Soviet and regional systems, including Azerbaijan, rely on explicit consent models, often combined with limited public awareness and institutional capacity. Turkey and Iran present hybrid or distinctive regulatory approaches, including structured state oversight and, in some cases, regulated living donation systems. Across jurisdictions, effective transplantation systems are associated with transparent governance, clear legal definitions of consent, and robust safeguards against organ commercialization and trafficking.

Conclusions

Effective regulation of organ transplantation requires a balanced medico-legal framework that integrates bioethical principles, clear consent models, and strong institutional oversight. Transitioning toward more effective consent systems—combined with public awareness, transparency, and legal safeguards—may enhance donation rates while protecting human rights and preventing abuse. For Azerbaijan,

aligning national legislation with international standards and best practices may strengthen public trust, improve access to transplantation, and ensure ethical and legally sound implementation of donation systems.

FRI-S06-P04

Session: Transplantation · **Room:** R.011

Ethical Boundaries and Regulatory Gaps in Heterologous Hair Transplantation: A Bioethical Analysis

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Background

Advances in regenerative medicine have expanded therapeutic possibilities in hair restoration, including experimental approaches such as heterologous hair transplantation. Although autologous transplantation is well established, heterologous techniques, using biological material from a donor, raise complex ethical, legal, and regulatory concerns. In aesthetic medicine, where procedures are often elective and market-driven, the intersection between innovation, patient autonomy, professional responsibility, and commercial pressure becomes particularly sensitive.

Research Question

What are the main bioethical challenges associated with heterologous hair transplantation in aesthetic medicine, and how should principles such as autonomy, beneficence, non-maleficence, and justice guide clinical decision-making in this context?

Methodology

This study adopts a qualitative, normative bioethical analysis based on the principlist framework. It examines the ethical implications of heterologous hair transplantation through the lens of core bioethical principles and professional responsibility standards. The discussion integrates considerations related to informed consent, risk disclosure, scientific validation, regulatory oversight, and the commercialization of innovative therapies in aesthetic practice.

Results

The analysis indicates that heterologous hair transplantation presents significant ethical tension points. First, patient autonomy may be compromised when information about experimental status, scientific uncertainty, and long-term risks is insufficient or influenced by marketing strategies. Second, the principles of beneficence and non-maleficence demand heightened caution in elective procedures, especially when robust clinical evidence is limited. Third, justice concerns arise regarding equitable access, donor protection, and the allocation of medical resources to primarily aesthetic purposes. Additionally, regulatory gaps may expose both patients and professionals to avoidable risks.

Conclusions

Heterologous hair transplantation requires rigorous ethical scrutiny before integration into routine clinical practice. Transparent communication, robust informed consent, strict adherence to scientific evidence, and clear regulatory standards are essential to safeguard patient dignity and professional integrity. In aesthetic medicine, innovation must be ethically grounded, ensuring that technological advancement does not outpace bioethical responsibility.

FRI-S06-P05

Session: Transplantation · **Room:** R.011

Ethical Implementation of Organ Donation Following Medical Assistance in Dying: Recommendations of the Ethics Committee of The Transplantation Society

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Antwerp Health Law and Ethics Chair (AHLEC), Antwerp, Belgium

Background

Medical assistance in dying (MAiD) is legally permitted in a growing number of jurisdictions and, in six of these, may currently be followed by organ donation. Organ donation following MAiD offers patients an opportunity to address the transplant needs of others as a final act of altruism.

Research Question

The research question concerns what safeguards are necessary to protect patients, professionals, and public trust in light of the complex ethical and legal questions raised by organ donation following MAiD.

Methodology

Key ethical and legal issues and proposed safeguards were identified through analysis of published protocols from the six countries where organ donation following MAiD is performed: Australia, Belgium, Canada, the Netherlands, New Zealand, and Spain. This presentation is based on a manuscript with the same title, recently accepted by *Transplantation*, developed under the auspices of the Ethics Committee of The Transplantation Society by medical, ethical, and legal experts from these jurisdictions, with the presenter as first author.

Results

Three domains of ethical and legal concern emerged: (1) safeguarding the integrity of patients' decision-making (voluntariness, informed consent, and the timing and framing of information about donation); (2) ethical governance of donation following MAiD (adherence to the Dead Donor Rule, determination of death, and consent for pre-mortem interventions); and (3) implications for care relationships and professional practice (end-of-life impacts, recipient information and donor anonymity, and professional support, including conscientious objection).

Key recommendations include clear and consistent policies; a patient-centred, non-directive approach; rigorous assessments of eligibility and voluntariness; and strict separation between MAiD and donation/transplantation teams. Additional recommendations include structured training and psychosocial support for staff, transparent data collection and reporting, and ongoing research to address emerging ethical issues and refine protocols.

Conclusions

These recommendations provide practical guidance for the implementation of organ donation following MAiD in jurisdictions where it is practised or under consideration. They aim to support patients' end-of-life wishes while safeguarding ethical and legal standards and maintaining trust in both MAiD and organ transplantation.

SESSION FRI-S07 · TRACK 7 · 09:00 – 10:30

Access to Healthcare III · Room R.004

Moderator: Neil Kirby

FRI-S07-P01

Session: Access to Healthcare III · **Room:** R.004

Inzet van digitale zorg bij ouderen: wat is volgens ouderen nodig voor goede zorg?

mr dr Brenda Frederiks, Mr dr Vivianne Dörenberg, dr. Kasper Kruithof

Amsterdam UMC, Amsterdam, Netherlands

Achtergrond

Het aantal ouderen in Europa neemt toe. Om oplopende kosten en personeelstekorten in de ouderenzorg te mitigeren wordt steeds meer gebruik gemaakt van digitale zorg en ondersteuning. Maar wat betekent deze inzet voor de zorg aan ouderen die nog thuis wonen? Wanneer ervaren ouderen deze zorg als goede zorg?

Methoden

In deze studie voerden we eerst een analyse uit van kwalitatieve literatuur over ervaringen van thuiswonende ouderen met digitale zorg. We richtten ons op de opbrengsten en kosten, vanuit het perspectief van ouderen, in de literatuur. Vervolgens hebben we 27 ouderen in de thuissituatie geïnterviewd over hun ervaringen met digitale zorg en ondersteunde technologieën. We hebben onze bevindingen thematisch geanalyseerd met behulp van een mensenrechtelijke benadering op goede zorg.

Resultaten

Op basis van het mensenrechtenkader, ethische principes en de uitkomsten van de literatuurstudie en interviewstudie hebben we een juridisch en ethisch raamwerk opgesteld dat gebruikt kan worden door thuiszorgorganisaties bij de implementatie van zorgtechnologie voor thuiswonende ouderen.

Conclusie

Ouderen ervaren digitale zorg en ondersteuning als goede zorg als de inzet ervan aansluit bij hun behoeften mogelijkheden en waarden. Deze criteria sluiten aan bij belangrijke mensenrechten, waaronder het VN-verdrag voor mensen met een beperking.

FRI-S07-P02

Session: Access to Healthcare III · **Room:** R.004

Inequitable Access to Healthcare in Nursing Homes in Belgium

Dr. Zahra Javdani Sanatagar Moghaddam Specialist in ophthalmology^{1,2}, Prof. Dr. Robert Kuijpers Specialist in ophthalmology³, Prof. Dr. Dominique Bremond-Gignac Specialist in ophthalmology⁴, Dr. Frank Goes Specialist in ophthalmology⁵, Prof. Dr. Guido Van Hal Specialist in Epidemiology⁶

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Background

In Belgium, older adults in nursing homes frequently require specialist care that is not available on-site. Access is limited by financial, logistical, physical, and cognitive barriers. Notably, 85-91% of visual impairments are preventable or treatable, yet remain highly prevalent. Although prevention is widely recognized as cost-effective, investment in preventive healthcare has declined in Belgium and across Europe.

Research Question

To what extent do financial and organizational barriers, particularly transportation costs, contribute to inequitable access to specialist healthcare, such as ophthalmology, among nursing home residents in Belgium?

Methodology

A qualitative, descriptive approach was used, combining literature review with observations from Belgian nursing home practice. Key dimensions of the healthcare system, accessibility, equity, patient-centeredness, and efficiency, were analysed, with a focus on ophthalmological care.

Results

A substantial gap exists between the need for and use of specialist care. Approximately 65% of nursing home residents are visually impaired due to treatable conditions such as cataracts, yet only 8% consult an ophthalmologist. Structural barriers, including high out-of-pocket transportation costs, logistical burden, limited on-site services, and perceived low benefit among frail patients—discourage care utilization. At the same time, declining investment in prevention in 2025 by 0.4% in Belgium and 4.1% on average across Europe, further exacerbates these disparities. This is in violation of Article 5 of the Patient Rights Act regarding the right to quality care, effective care, professional guidelines, and the alleviation of pain.

Conclusions

Scope remains for the application of existing legislation, or the enactment of new laws, to enhance equity within the healthcare system.

FRI-S07-P03

Session: Access to Healthcare III · **Room:** R.004

When More Means Less. Harmful Consequences of Defensive Medical Practice on Patients

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¹Grigore T. Popa University of Medicine and Pharmacy, Iasi, Romania. ²Institute of Legal Medicine, Iasi, Romania

Introduction

Defensive medicine refers to a medical behavior primarily driven by fear of litigation, characterized by requesting additional investigations in the absence of solid clinical justification. In emergency medicine, this medical behaviour is common, fueled by diagnostic uncertainty and medico-legal pressure. Although seemingly aimed at increasing patient

safety, overinvestigation is associated with overdiagnosis and delays in establishing the diagnosis and initiating appropriate treatment.

Research Question

The authors aim to analyse the extent to which defensive medicine truly benefits patients or, conversely, contributes to unfavourable clinical outcomes, particularly in acute clinical conditions.

Methodology

The paper is based on the analysis of a medico-legal clinical case, integrated with literature data regarding the frequency and impact of defensive medicine in emergency departments.

Results

We present the case of a 56-year-old man who died approximately 24 hours after presenting to the ER. The patient reported a three-day history of low back pain radiating to the left lower limb, associated with left-sided motor deficit, and had multiple comorbidities, including duodenal ulcer, toxic liver cirrhosis, splenectomy, pulmonary tuberculosis, aseptic necrosis of the femoral head, high blood pressure, and chronic pancreatitis. Death occurred due to septic shock of pulmonary origin. Investigations performed in the emergency department extended over several hours; some were not justified or targeted chronic conditions without immediate life-threatening risk (e.g., MRI for disc protrusions), thereby delaying hospital admission and initiation of appropriate, potentially life-saving treatment. The literature indicates that a significant proportion of physicians acknowledge ordering investigations without clear indication, mainly for medico-legal reasons, while some report they would reduce such practices in the absence of legal pressure. Defensive medicine does not correlate with improved quality of care and is associated with increased costs and decision-making complexity. The “diagnostic cascade” effect describes the situation in which unnecessary tests generate false-positive results, leading to further investigations and sometimes unjustified interventions. In medico-surgical emergencies, where time is critical, the time spent on non-essential investigations may become a decisive factor in adverse patient outcomes.

Conclusions

Defensive medicine based on excessive investigations may have negative consequences for patients, particularly by delaying appropriate treatment. In emergency settings, where decisions must be rapid and efficient, the balance between prudence and clinical judgment is essential, and avoiding over investigation represents a key component of responsible medical practice.

FRI-S07-P04

Session: Access to Healthcare III · **Room:** R.004

The Right to Medical Treatment of Vulnerable Groups in Vietnam: A Comparative Analysis

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Background

The right to health and more specifically, the right to medical treatment among vulnerable groups, is a fundamental component of human dignity, social equality, and social justice. The right to health, in particular, the right to medical treatment rights for vulnerable groups, is a fundamental right to human dignity, social equality, and social justice. In Vietnam, this right is constitutionally recognized in the Constitution of the Socialist Republic of Vietnam and, later, on the legislative level, in laws on medical examinations and treatment, health insurance, and social protection. Although significant progress has been made in expanding health insurance coverage and formalizing legal guarantees, vulnerable groups, including the poor, ethnic minorities, children, the elderly, and persons with disabilities, still face structural and financial barriers to accessing adequate medical care. High copayments, out-of-pocket payments, services not covered by insurance, and referral procedures constitute the main obstacles to adequate healthcare access. 40% patients from the vulnerable groups cannot afford medical treatment, and numerous cases died as a consequence.

Research Question

This study checks the extent to which Vietnam's legal and policy framework that governs medical treatment of vulnerable groups aligns with international human rights standards and comparative

international practices, with particular focus on equality, non-discrimination, accessibility, affordability, and the State's obligations to respect, protect, and fulfill the right to health.

Methodology

The methodology is based on a comparative legal analysis underpinned by international human rights law. It assesses Vietnam's constitutional and statutory provisions against relevant international treaties and selected foreign legal systems. The focus is on normative, institutional, anti-discriminatory, and oversight and accountability frameworks of health governance encompassing formal legal recognition and practical enforceability.

Results

The findings indicate that Vietnam has established a relatively comprehensive legal framework that recognizes and promotes the right to medical treatment for vulnerable groups. However, there are some implementation gaps related to ensuring effective access to specialized healthcare services, financial protection mechanisms, monitoring and complaint-resolution mechanisms, and mechanisms for amelioration and accountability. Compared to international best practices, institutional guarantees remain insufficiently integrated and inconsistently enforced.

Conclusions

While Vietnam has made significant progress in formalizing the right to medical treatment within its legal system, further reforms are needed to bridge the gap between normative commitments and actual implementation. Strengthening financial protection, institutional accountability, and enforcement mechanisms is essential to ensure vulnerable groups can effectively exercise the right to health in conformity with international human rights standards.

FRI-S07-P05

Session: Access to Healthcare III · **Room:** R.004

Medical Professional Liability and Defensive Medicine: Implications for Equitable Access to Health Services

Bianca Hanganu MD, PhD^{1,2}, Cristina Petronela Popa¹, Beatrice Gabriela Ioan MD, PhD, JD, BA, MA^{1,2}

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Background

Medical professional liability is an essential mechanism for patient protection and ensuring the quality of medical care globally. However, in recent years, the phenomenon of defensive medicine has increasingly emerged, involving that the clinical decisions are influenced by the fear of litigation, not exclusively by the patient's best interest. This phenomenon, existing in various health systems, raises issues related to the efficient use of resources and equitable access to care.

Research Question

The authors of this paper aim to identify to what extent the fear of complaints influences the behavior of doctors and contributes to inequalities in patients' access to medical services.

Methodology

To this end, the authors analyzed relevant studies from the medical literature, conducted in different countries of the world, in different social and cultural contexts.

Results

The data available in the literature indicate a high prevalence of defensive medicine in specialties with a high risk of litigation, manifested by over-investigation and avoidance of complex cases or high-risk patients, with a direct impact on access to care. These practices generate important consequences for the health system, contributing to increased costs and inefficient use of resources, but also to limiting access for vulnerable patients or those requiring complex interventions, affecting equity in health through adaptive behaviors of professionals. This phenomenon is influenced by both the legal framework and social and cultural factors- a more pronounced litigation culture increases pressure on doctors, while a high level of doctor-patient trust can reduce these behaviors.

Conclusions

Although professional liability is indispensable for patient protection, its indirect effects can generate imbalances in access to medical services. Defensive medicine, through its impact on clinical decisions, can contribute to both inefficiency and the exclusion of certain categories of patients. Thus, it is necessary to identify a balance between legal accountability and the creation of a framework that supports equitable and patient-centered medical practice.

SESSION FRI-S08 · TRACK 1 · 11:00 – 12:30

Access to Healthcare IV · Room R.004

Moderator: Stefaan Callens

FRI-S08-P01

Session: Access to Healthcare IV · **Room:** R.004

Impact of Recent ECJ Cases on the Reimbursement of Cross-Border Telemedicine Services

Prof. Stefaan H. Callens professor of health law^{1,2}, Florence Saelemaekers master of laws student²

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Background

Telemedicine is developing rapidly in the EU. This technology allows the treatment and follow-up of patients living in other countries than the country where the telemedicine services are established.

Research Question

Some Member States, including Belgium, allow reimbursement of telemedicine services only if the patient had at least one physical consultation in at least one of the two calendar years prior to receiving cross-border telemedicine. The question is whether such rules constitute a justified obstacle to the free movement of services.

Methodology and Results

Two recent Court of Justice decisions deal with cross-border telemedicine services on the one hand and on as administrative requirements regarding reimbursement of cross-border care at the other hand. Case C-489/23 of 4 September 2025 relates to reimbursement of a patient residing in Romania who underwent an operation with a surgical robot in Germany. The request for reimbursement was refused because the patient had not attached to his request a copy of the 'request for hospitalisation' drawn up by a health professional providing health services under the Romanian social health insurance system. According to the Court this requirement is not in conformity with art. 7, 7 of Directive 2011/24/EU read in the light of Article 56 TFE.

In C-115/24 of 11 September 2025 the Court confirmed that telemedicine healthcare comes within the scope of Directive 2011/24, with the result that telemedicine services must be provided in accordance with the legislation of the Member State where the provider is established. The ECJ clarified also that Article 3(d) and (e) of Directive 2011/24 must be interpreted as meaning that the concept of cross-border healthcare provided in the case of telemedicine, for the purposes of that article, corresponds solely to healthcare provided, exclusively via ICT, to a patient by a healthcare provider established in a Member State other than that patient's Member State of affiliation, at a distance and therefore without that patient and that provider being simultaneously physically present in the same location.

Conclusions

According to EU law it can be argued that reimbursement of many cross-border telemedicine services should not depend of a first physical consultation in at least one of the two calendar years prior to receiving the cross-border telemedicine services.

FRI-S08-P02

Session: Access to Healthcare IV · **Room:** R.004

Énergie Solaire Et Résilience Hospitalière En Zone De Conflit: Une Stratégie Pour Renforcer L'équité En Santé

Dans L'est De La République Démocratique du Congo, Cas De L'hôpital General De Référence de Nyangezi

Dr Manfredy Annette Olivia Binyet MD, MPH(HSDC)¹, Dr Romain Mukupi MD, MPH², Dr Jacques Niyonkuru MD, MPH³, Dr Antoine Nihire Rumbaka MD, MPH², Yves Nama¹

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Contexte

L'accès équitable aux soins de santé reste un défi majeur dans les zones affectées par des conflits armés prolongés. À l'Est de la République Démocratique du Congo (RDC), les crises sécuritaires récurrentes ont entraîné une détérioration progressive du système de santé, caractérisée par une insuffisance d'infrastructures fonctionnelles, une pénurie de ressources humaines qualifiées et une instabilité énergétique chronique.

L'électricité constitue un déterminant fondamental de la qualité des soins hospitaliers. Son absence ou son irrégularité compromet directement les interventions chirurgicales d'urgence, la prise en charge obstétricale et néonatale, la conservation des produits sanguins et des vaccins ainsi que le fonctionnement des équipements biomédicaux.

Dans ce contexte, les solutions énergétiques traditionnelles, principalement basées sur les groupes électrogènes à diesel, présentent des limites importantes : coûts élevés, dépendance logistique, impact environnemental et vulnérabilité en période d'insécurité.

L'énergie solaire photovoltaïque apparaît ainsi comme une alternative durable, fiable et adaptée aux contextes fragiles. Elle s'inscrit également dans les objectifs de développement durable, notamment l'ODD 7 (énergie propre et d'un coût abordable) et le Pacte vert pour l'Europe recommandent de sources d'énergie moins polluantes.

Le projet mis en œuvre à l'Hôpital Générale de Référence (HGR) de Nyangezi vise à répondre à ces défis en installant un système photovoltaïque pour assurer une alimentation électrique continue.

Question de Recherche

Cette étude visera à déterminer l'impact de l'installation d'un système photovoltaïque sur l'accès équitable aux soins des patient·e·s à l'HGR Nyangezi dans un contexte de conflit.

Méthodologie

Une étude mixte combinant une approche quantitative quasi-expérimentale avant/après et qualitative exploratoire sera utilisée. La collecte des données quantitatives (Nombre d'interventions chirurgicales mensuelles, nombre d'accouchements, Disponibilité de l'électricité, couts mensuels d'énergie) seront rassemblées sur 12 mois: 3 mois avant l'installation de la centrale photovoltaïque (Juin 2025 - Aout 2025) et 9 mois (septembre 2025 - juin 2026) après son installation. Les données qualitatives (perception de la qualité des soins, continuité des services, conditions de travail du personnel) par les entretiens semi structurés et l'observation seront aussi captées. L'analyse statistique comparative (avant/après) des données quantitatives et l'analyse thématique des données qualitatives pour atteindre la saturation seront faites.

Résultats

L'installation de l'énergie photovoltaïque à l'HGR Nyangezi est une source d'énergie efficiente, écologique et fiable qui améliore la continuité des soins à travers la réduction des interruptions et l'offre de service 24h/24 et 7j/7, augmente l'utilisation des services, améliore la qualité des soins en garantissant la conservation des vaccins et médicaments, réduits nettement les coûts de gestion énergétique liés aux activités hospitalières et renforce l'équité en santé à travers l'accès accru aux soins pour les populations vulnérables des zones de conflit.

Conclusions

Dans un contexte d'insécurité persistante à l'Est de la RDC, l'accès à une énergie solaire fiable constitue un élément clé pour renforcer l'équité en santé et une gestion efficiente de maigre ressources générées par l'hôpital. Cette expérience représente un modèle innovant, reproductible et durable pour renforcer les systèmes de santé dans des environnements fragiles.

FRI-S08-P03**Session:** Access to Healthcare IV · **Room:** R.004**Human Dignity and Equitable Access to Healthcare: The Case of Azerbaijan**PhD Candidate Aygul A Jahangirova LLM

Baku State University, Faculty of Law, Baku, Azerbaijan

Background

Human dignity is a core pillar of international law and bioethics, recognizing every individual's intrinsic value. Its most vital manifestation is equitable access to healthcare, which is essential for preserving life. This link is codified in several international instruments:

In Azerbaijan, human dignity is a constitutional mandate. Under Article 46, the state must protect individual dignity, which is realized also through Article 41's guarantee of medical care. Therefore, providing healthcare is essential to upholding a citizen's inherent dignity.

The transition to Mandatory Health Insurance (MHI) in Azerbaijan marks a historic shift toward "Equitable Access". According to the Law on Medical Insurance, the goal is to ensure that every citizen, regardless of their social or economic status, has access to a basic package of medical services.

Azerbaijan's Law on Protection of Public Health reinforces that medical assistance must be provided without discrimination. This aligns with the international "Equitable Access" standard, ensuring that vulnerable groups (the elderly, IDPs, and low-income families) receive care that respects their personhood.

In Azerbaijan, equational access now includes informational dignity through informed consent. By ensuring regional and capital patients have the same rights to information and choice, territorial equity is achieved. This closes the status gap and legally affirms that every life holds equal value.

Research Questions and Results

While the legislative framework is robust, the practical realization of "Equitable Access" remains a work in progress. To ensure the Dignity Principle is not merely a legal abstraction but a lived reality for every citizen, Azerbaijan's healthcare strategy must prioritize the following structural advancements:

Concluding Remarks

For Azerbaijan, the synergy between human dignity and equitable access is the cornerstone of its modern social policy. By codifying the right to health and implementing universal insurance, the state moves beyond charity toward a rights-based approach. True dignity in medicine is achieved when a citizen's survival is guaranteed not by their wealth, but by their inherent rights as a human being.

FRI-S08-P04**Session:** Access to Healthcare IV · **Room:** R.004**Health as a Trust (Amānah): A Maqāṣid-Based Framework for Equitable Access, Ethical Innovation, and Interdisciplinary Health Law**Emeritus Professor Abul Fadl Mohsin Ebrahim PhD

University of KwaZulu-Natal, Durban, South Africa

Background

Global health law is undergoing rapid transformation in response to persistent inequities in healthcare access, accelerating technological innovation, and increasing regulatory complexity. Dominant frameworks often rely on secular bioethics and human rights discourse. However, religious legal traditions—particularly Islamic jurisprudence—remain underutilized in shaping contemporary health governance. Islamic law conceptualizes health as an *amanah* (trust), generating enforceable moral and communal obligations rooted in *maqasid al-shari'ah* (objectives of Islamic law), especially the protection of life (*hifz al-nafs*) and promotion of public welfare (*maslahah*).

Research Question

Can a *maqasid*-based Islamic legal framework provide a coherent normative model for addressing equitable access, regulating medical innovation, and fostering interdisciplinary health governance in contemporary legal systems?

Methodology

This study adopts a normative and comparative legal methodology. It examines classical and contemporary Islamic jurisprudence, including *fiqh al-tibb* (medical jurisprudence) and *usul al-fiqh* (legal theory), with particular emphasis on objectives-based reasoning. These principles

are analytically engaged with international health law, bioethics, and human rights doctrines. The paper applies this framework to three domains: access to essential healthcare services, governance of emerging medical technologies (including AI-assisted diagnostics and genomics), and institutional health regulation in plural legal environments.

Results

The analysis demonstrates that Islamic legal reasoning establishes equitable healthcare access as a structural obligation derived from justice (*'adl*), harm prevention (*dar' al-darar*), and collective welfare (*maslahah*). It further shows that innovation is not impeded but facilitated through dynamic mechanisms such as *ijtihad* (independent juristic reasoning) and *istislah* (public interest reasoning), enabling adaptive regulation of new technologies while preserving ethical safeguards. Moreover, the *maqasid* framework inherently bridges disciplines by integrating constitutional principles, public policy, family law, and institutional governance into a unified health law paradigm.

Conclusions

Understanding health as a trust (*amanah*) offers a robust, adaptable, and ethically grounded model for expanding the boundaries of health law. A *maqasid*-based framework contributes meaningfully to global debates on access, innovation, and interdisciplinary governance, demonstrating that Islamic legal theory can serve not merely as a cultural accommodation but as a substantive normative resource in contemporary health law reform.

FRI-S08-P05**Session:** Access to Healthcare IV · **Room:** R.004**State-Supported Rehabilitation of War Veterans: A Medico-Legal and Clinical Assessment of Technology-Based Rehabilitation and Legal Guarantees in Azerbaijan**Gulnara Tofiq Nuruzade¹, Associate Professor Shahla Tofiq Nuruzade Doctor of Science²

¹Director, Department of Physiotherapy and Rehabilitation, Medera Hospital Lecturer, Department of Physiotherapy and Rehabilitation, Azerbaijan Medical University, Baku, Baku, Azerbaijan. ²Baku Slavic University, Baku, Azerbaijan

Background

Severe injuries resulting from armed conflicts require not only emergency medical treatment but also long-term rehabilitation, psychological support, and social reintegration. In modern medical law, rehabilitation is increasingly recognized as part of the fundamental right to health and the right to social protection for persons with disabilities and war veterans. In Azerbaijan, rehabilitation of war veterans is implemented through state-supported institutional mechanisms and legal frameworks that regulate access to medical rehabilitation, assistive technologies, and psychological services. The "YASHAT" Fund, established by presidential decrees, operates as a state-supported and donation-based system providing financial assistance, rehabilitation services, and social protection for wounded veterans and families of those who died during armed conflict. This institutional model represents an example of the practical implementation of health legislation, disability law, and state obligations in the field of rehabilitation.

Research Question

How does the combined application of state-supported rehabilitation programs, assistive technologies, and psychological support improve functional and psychological recovery of war veterans within the framework of health legislation and social protection law?

Methodology

This observational study is based on the author's clinical rehabilitation practice. Over a three-month period, 301 war veterans with severe injuries were observed during rehabilitation programs. Patients presented with mobility limitations, muscle weakness, and psychological challenges associated with trauma and disability. Rehabilitation interventions included physiotherapy, postural and mobility exercises, individualized psychological support, and assistive technologies, particularly Reciprocating Gait Orthoses (RGO) devices. The study reflects real-world clinical practice within a state-supported rehabilitation system and evaluates rehabilitation outcomes in a medico-legal and social protection context.

Results

The use of Reciprocating Gait Orthoses (RGO) devices significantly improved mobility outcomes and reduced the average rehabilitation period from approximately one year to about five months in several observed cases. Some patients who initially were able to walk only short distances achieved extended ambulation within two weeks of device-assisted rehabilitation. Psychological support improved motivation, treatment adherence, and reduced stress-related symptoms. Rehabilitation outcomes varied depending on injury severity, patient physiology, and level of individualized rehabilitation support. The integration of technology-based rehabilitation and psychological support demonstrated positive functional and psychological outcomes within a structured state rehabilitation program.

Conclusions

The Azerbaijani experience demonstrates that state-supported rehabilitation programs, implemented within a clear legal and institutional framework, can significantly improve functional recovery, psychological well-being, and social reintegration of war veterans. From a medico-legal perspective, rehabilitation should be considered not only a medical intervention but also a legal guarantee and a component of the right to health, disability rights, and social protection. The integration of assistive technologies, psychological rehabilitation, and state support programs represents an effective model that may be applicable in other post-conflict countries developing veteran rehabilitation systems.

SESSION FRI-S09 · TRACK 2 · 11:00 – 12:30

AI and Liability II · Room R.014

Moderator: Victor Schollaert

FRI-S09-P01

Session: AI and Liability II · Room: R.014

Medische AI & het vernieuwde Belgische & Europese aansprakelijkheidsrecht

Guest Professor Victor Schollaert Doctor of Laws

University of Antwerp, Antwerp, Belgium. KU Leuven, Leuven, Belgium

Achtergrond

Heel wat onderzoek toonde reeds aan dat ons oud Belgisch en Europese aansprakelijkheidsrecht niet opgewassen was tegen schade die werd veroorzaakt door (medische) artificiële intelligentie (AI). Zo rezen er vragen omtrent de toepassing van het foutcriterium en het vereiste causaal verband bij foutaansprakelijkheid. Met andere woorden: wanneer handelen artsen of ziekenhuizen foutief bij het gebruik van AI? Echter, ook het toepassen van onze foutloze aansprakelijkheidsregimes leidde tot moeilijkheden. Denk hierbij aan het nationale aansprakelijkheidsregime van de gebrekkige zaak. Wanneer is een medisch AI-systeem "gebrekig"? Op Europees niveau rees de vraag of AI wel een product was dat viel onder de Europese regels omtrent productaansprakelijkheid.

Recent werd het Belgische en Europese aansprakelijkheidsrecht hervormd. Is het vernieuwde aansprakelijkheidsrecht nu wél geschikt om met (medische) AI-systemen om te gaan?

Onderzoeksvragen

In deze presentatie wordt een antwoord geboden op de vraag in welke mate het vernieuwde Belgische en Europese aansprakelijkheidsrecht geschikt is voor de grote risico's die medische AI-systemen met zich meebrengen. Is het nieuwe aansprakelijkheidsrecht op dat vlak een gemiste kans, of een stap in de goede richting? Er wordt zowel gefocust op de nationale foutaansprakelijkheid als op de nationale en Europese foutloze aansprakelijkheid.

Resultaten en Conclusies

De wetgever heeft bijzonder weinig expliciete aandacht gegeven aan nieuwe technologieën. Toch betekent dat niet dat er geen stappen vooruit gezet werden met betrekking tot de toepassing van ons aansprakelijkheidsrecht op medische AI. De bepalingen van het BW bevatten voortaan bijvoorbeeld enkele uitzonderingen op de strikte equivalentieleer die relevant kunnen zijn in een AI-context, met name wanneer de schade zo ver verwijderd is dat het kennelijk onredelijk zou zijn om deze toe te rekenen aan de potentieel aansprakelijke persoon. Denk aan een arts die patiëntengegevens invoert in een diagnostisch AI-systeem. In de daaropvolgende maanden wordt het systeem meerdere keren geüpdatet: de trainingsdata worden uitgebreid en het

algoritme wordt bijgesteld door externe softwareontwikkelaars. Geruime tijd later stelt het AI-systeem, in een andere klinische context en voor een andere patiënt, een verkeerde diagnose. In een dergelijk scenario zou het kennelijk onredelijk kunnen zijn om de arts aansprakelijk daarvoor aansprakelijk te stellen.

Op andere vlakken brengt de nieuwe wet dan weer meer onduidelijkheid. Leidt de opaciteit van AI-systemen schade door de nieuwe definitie van overmacht (art. 6.7 BW) bijvoorbeeld sneller tot de bevrijding van artsen?

Wat betreft de foutloze aansprakelijkheid voor schade door AI-systemen zijn er twee opmerkelijk vernieuwingen ingeschreven in het nationaal recht. Vooreerst is in artikel 6.16 BW (aansprakelijkheid voor gebrekkige zaken) een nieuwe gebreksdefinitie opgenomen. Verder voorziet de wetgever nu in een vermoeden van aansprakelijkheid bij eigenaars. Deze vernieuwingen zijn niet zo slachtoffervriendelijk als ze op het eerste gezicht lijken.

Belangrijker nog is de recente hervorming van de Europese productaansprakelijkheid. Door de verruiming van het begrip product tot software zal deze nieuwe richtlijn een enorme impact hebben op schade veroorzaakt door (medische) AI-systemen.

FRI-S09-P02

Session: AI and Liability II · Room: R.014

The Algorithmic Patient: Redefining Medical Liability and the Duty of Care in the Era of Artificial Intelligence

Dr Anara K Hajibayli¹, Researcher Chinara Novruzova²

¹Baku State University, Baku, Azerbaijan ²Nakhchivan State University, Nakhchivan, Azerbaijan

Background

The integration of Artificial Intelligence (AI) into healthcare is transforming traditional legal pillars, specifically medical fault, patient autonomy, and the duty of care. While AI offers unprecedented diagnostic accuracy as seen in landmark cases involving GPT-assisted neurology and IBM Watson it introduces "black box" opacity, algorithmic bias, and conflicts between machine recommendations and human judgment. This shift necessitates a rigorous re-evaluation of civil liability and professional ethics.

Research Question

How must classical medical duties (information disclosure, loyalty, and protection) be reshaped when algorithms act as clinical intermediaries, and what framework can ensure "multi-layered accountability" without stifling technological innovation?

Methodology

This study performs a comparative legal analysis of emerging regulatory frameworks, including the EU AI Act and Brazil's 2023 drafted AI Law. It categorizes medical conduct into three distinct patterns: automation bias (excessive reliance), technological dismissal (unjustified rejection), and the "diligent middle path" (critical cross-checking).

Results

The research finds that medical fault must be assessed through a modernized lex artis. Diligence in the AI era requires clinicians to understand the underlying logic of models, verify demographic applicability, and meticulously document the rationale for following or overriding algorithmic suggestions. Responsibility is no longer defined by the fallibility of the outcome, but by the rigor of human supervision and transparency.

Conclusions

AI will not replace the physician but will redefine the "active and responsible" practitioner. The future of medicine lies in a vigilant partnership where technology enhances human capability, yet the physician remains the ultimate interpreter of data and the primary guardian of patient dignity. Legal systems must prioritize the preventive function of civil liability to ensure ethics remain the guiding force of the clinical encounter.

FRI-S09-P03**Session:** AI and Liability II · **Room:** R.014**The Liability Sink is Leaking: Limits to Clinician Responsibility for AI in English and Dutch Law**Jan H van Staalduinen MSc LLM

Leiden University, Faculty of Law, Leiden, Netherlands

Background

Recent works voiced concerns that clinicians might become 'liability sinks' or 'moral crumple zones' when using medical AI. They could "take the blame for errors or accidents not entirely in their control". Others are concerned that existing liability frameworks might be underinclusive in the face of AI-mediated damage, meaning that certain AI characteristics preclude establishing liability where this would otherwise be justified, 'leaking' risk to the patient.

Research Question

The validity of these two concerns is examined for two jurisdictions through the following research question: to what extent are clinicians at risk of taking the blame for AI-related errors or accidents not entirely in their control and are the relevant legal rules justifiable in light of 'liability sink' concerns?

Methodology

First, to define what 'not entirely in their control' could mean, concepts from socio-technical systems (STS) literature are used. Then, English and Dutch law are analysed through a functional comparative analysis with a descriptive and an evaluative component. The descriptive analysis identifies and characterizes dominant elements in the liability framework that are limiting factors for liability to attach in cases of AI-induced harm. The evaluative analysis tests their justification in light of 'liability sink' concerns.

Preliminary Results

In English law, of the six elements of medical negligence (duty, breach, damage, factual causation, legal causation, remoteness), only breach of duty is a relevant limiting factor for clinician liability for medical AI. It is quite a potent limiting factor, justifying the conclusion that liability sink concerns have little to no legal basis in English law. This factor is also relatively inflexible, potentially causing AI-related risk to 'leak' towards the patient. In Dutch law, the relevant limiting factors are breach (of contract) and attribution. Both offer more flexibility than breach in English law. This is the result of explicit legislative choices anticipating societal and technological developments, structuring the balancing of patient and clinician interests. Additionally, procedural rules favour the clinician as the defendant. As such, clinicians' interests are woven into the fabric of the framework and the label of 'liability sink' or 'crumple zone' is not an accurate depiction of their position.

Conclusions

Concerns that clinicians might become 'liability sinks' are legally unfounded. Where they do face liability for factors beyond their control, this is not induced and certainly not exacerbated by new AI risks but the result of an anticipated and structured balancing of interests aimed at fairly distributing risk of medical technologies.

FRI-S09-P04**Session:** AI and Liability II · **Room:** R.014**Informed Consent 5.0 and the Epistemic Transformation of Civil Liability in Algorithm-Driven Healthcare**Dr Eduardo V S Dantas PhD

Eduardo Dantas Advocacia, Recife, PE, Brazil

Background

Informed consent has historically functioned as a legal mechanism ensuring patient autonomy and allocating responsibility in healthcare. Traditional consent models were designed for face-to-face communication between physician and patient and documented through written forms. However, contemporary medical practice increasingly relies on digital platforms, telemedicine systems, clinical decision-support algorithms, and artificial intelligence tools that mediate the flow of medical information. These technological transformations raise new legal questions regarding how consent is communicated, documented, and verified.

Research Question

How must informed consent evolve in order to remain legally valid and ethically meaningful in healthcare environments mediated by digital platforms and artificial intelligence?

Methodology

This study uses doctrinal legal analysis and comparative examination of regulatory frameworks in medical law, civil liability, and data protection. The research contrasts traditional consent models with emerging technological practices in digital healthcare, focusing on the legal implications of algorithm-mediated communication, electronic records, and platform-based medical services.

Results

The analysis identifies a structural difference between traditional informed consent and what can be described as "Informed Consent 5.0." Traditional models (paper-based forms or simple digital signatures) focus primarily on documenting patient authorization before a procedure. In contrast, digital healthcare environments introduce new elements that affect the legal validity of consent: algorithmic filtering of information, platform interfaces that structure patient choices, automated clinical recommendations, and complex data-sharing ecosystems.

These conditions generate several concrete legal challenges. First, determining responsibility when medical information is mediated by software platforms rather than communicated directly by physicians. Second, establishing reliable digital evidence demonstrating that patients actually received and understood relevant information. Third, addressing risks of "automated consent," where patients click acceptance without meaningful comprehension due to interface design or information overload.

The proposed "Informed Consent 5.0" model reframes consent as a dynamic informational process supported by digital traceability. Instead of relying solely on signed forms, the process includes layered explanations, multimedia information, comprehension verification tools, and verifiable audit trails capable of reconstructing how information was presented to the patient.

Conclusions

The transition from traditional consent models to digitally mediated healthcare requires a shift from static documentation to governance of medical information flows. In this new paradigm, the legal validity of consent depends not only on the existence of authorization but on demonstrable processes that ensure transparency, traceability, and meaningful patient understanding. Developing legal standards for this new form of consent will be essential for protecting patient autonomy and ensuring accountability in the era of AI-driven medicine.

SESSION FRI-S10 · TRACK 3 · 11:00 – 12:30**Forensic and Legal Medicine II · Room R.008**

Moderator: Manal Bamousa

FRI-S10-P01**Session:** Forensic and Legal Medicine II · **Room:** R.008**Does an Effective Child Forensic Interview Result in a Better Expert Testimony?**

Dr Manal Saeed Bamousa MD, Dr. Suha Mohammed Alfehaid
Forensic consultant, Saudi board in forensic and legal medicine, Korean fellowship in Pathology
Forensic Medicine Centre, Dammam, Eastern Province, Saudi Arabia

Background

Interviewing skills are an integral part of sexual assault examination, and that is more so true in pediatric cases given that children have cognitive, memory and suggestibility issues that further complicate the interviewing process and if not done correctly it may render the testimony invalid due to inserted memories and other issues that will be discussed in the presentation.

The presentation will describe the dynamics of abuse, how children experience said dynamics, and demonstrate scientific support for "Child Sexual Abuse Accommodation Syndrome (CSAAS)" and how it would affect children's disclosures. Adding some emphasis on the effect of linguistic development, suggestibility, sexual development, cognitive development, memory development with age and their effect on court testimonies.

The session will demonstrate causes of blocks in the interview, and methods of information extraction and how to employ the different questioning types that are defensible in court testimonies.

Research Question

How to achieve the best interviewing practices that can extract the most information, without damaging memories, eliminating the need for re-interviewing and reducing the chances of court rejection of the testimony due to miss-interview.

This panel discussion is designed as a first line tool for child abuse professionals, including law enforcement officers, social workers, prosecutors, child protection attorneys, physicians, investigators and forensic interviewers.

Methodology

A deep review of articles through several search engines like PubMed, Science direct and google scholar, and several textbooks on child forensic interviewing.

Results and Conclusion

We concluded a concise method to conduct a professional interview that may prove helpful in court testimonies, making these testimonies more admissible to court, removing unnecessary doubts that may arise in court like issues of suggestibility and inserted memories and other serious issues that may arise from weak interviewing skills.

Take-Home Message

Child interviewing is not to be taken lightly in needs a deep understanding of children's cognitive, psychological, memory and suggestibility development with a thorough understanding of information extraction and overcoming memory blocks

FRI-S10-P02

Session: Forensic and Legal Medicine II · **Room:** R.008

Visum et Repertum as Evidence in Medical Criminal Offences

Putri Aulia Cahyani, Muh - Nasser MD Doc Law, Siti Jaimunah, Titin Mastini

Institute of Health Law, Military Law School, Jakarta, DKI Jakarta, Indonesia

Background

Visum et repertum (VeR) is a vital piece of evidence in Indonesia's criminal justice system, including in the adjudication of alleged medical criminal offenses. The VeR document contains a medical description of the victim's condition, the degree of injury or damage, and initial indicators that assist law enforcement in understanding the criminal event and its consequences.

Research Question

In the context of medical offenses, a central question arises: how does VeR elucidate the relationship between a medical act and its outcome, particularly with respect to proving causation and assessing the elements of an alleged medical crime?

Methodology

This study employs a normative juridical method to examine the position of VeR within Indonesia's criminal evidentiary regime and the challenges of its application in medical criminal cases.

Results

Findings indicate that while VeR holds a strong evidentiary status in criminal cases generally, in medical criminal cases it becomes crucial for assessing whether there was a lack of due care in medical procedures that may have harmed the patient.

Conclusions

The study concludes that key challenges include inconsistent quality of examination and VeR drafting, the precision of requests for examination by law enforcement, and the inherent limitations of VeR in articulating professional standards without adequate corroboration from expert testimony.

FRI-S10-P03

Session: Forensic and Legal Medicine II · **Room:** R.008

Neuroimaging, Traumatic Encephalopathy and the Limits of Legal Medicine Inference by Expert Witnesses

Professor James Nol PhD^{1,2}, Professor Roy Beran^{1,3}

¹Western Sydney University - School of Medicine, Sydney, NSW, Australia. ²Blacktown & Mount Druitt Hospitals - Medical Imaging, Sydney, NSW, Australia. ³University of New South Wales - Faculty of Medicine, Sydney, NSW, Australia

Background

Chronic traumatic encephalopathy (CTE) has emerged as a condition of significant medico-legal interest due to its association with repetitive head trauma in sport, military service, and occupational settings. CTE remains a neuropathological diagnosis that can only be definitively established at post-mortem examination. In living individuals, clinical presentations are often described under the construct of traumatic encephalopathy syndrome (TES), a research framework intended to standardise symptom reporting rather than to confirm disease.

Research Question

This distinction, between CTE and TSE, poses substantial challenges in legal medicine contexts, where questions of causation, attribution, impairment, and prognosis must be addressed in the absence of diagnostic certainty. The paper to be presented examines these issues and questions.

Methodology

This presentation examines the legal medicine implications of contemporary neuroimaging in the assessment of suspected traumatic encephalopathy. It explores conventional imaging which frequently fails to demonstrate abnormalities, while advanced techniques, such as diffusion tensor imaging (DTI) may reveal microstructural white matter changes consistent with axonal or network-level injury.

Results

The findings of the more sophisticated imaging are non-specific and do not diagnose CTE nor demonstrate tau pathology. Their legal relevance lies in providing objective evidence of brain injury burden and structural disconnection that may inform assessments of functional impairment and longitudinal change. There is a need to clearly separate established pathology, clinical syndromes and imaging findings when forming expert opinions within the legal medicine context. These considerations highlight risks of conflating association with causation and of overstating the diagnostic significance of imaging biomarkers.

Conclusions

By framing neuroimaging as adjunctive and supportive, rather than determinative, the discussion outlines a defensible approach to expert testimony that aligns with current scientific evidence while meeting legal standards of reasoning and transparency.

FRI-S10-P04

Session: Forensic and Legal Medicine II · **Room:** R.008

Scientific Criminal Investigation in Medical Criminal Offences

MD Patricia Sylviane Yuliana wijaya Master Degree¹, MD, Doctor of Law Nasser - Muh Profesor²

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Background

In law enforcement of medical criminal cases, examining witnesses and suspects alone is not enough to uncover premeditated crimes. Therefore, a more comprehensive approach is needed. Scientific Crime Investigation (SCI) is an investigative process that utilizes science and technology in its evidentiary system, applied in forensic functions.

Research Questions

This article aims examine the role of SCI in proving medical criminal cases and to analyze how this approach strengthen the evidentiary process in medical crimes.

Methodology

This study employs a normative juridical method, analyzing legal norms, doctrines, principles, and literature related to medical criminal

law and evidentiary systems. The focus is on the application of SCI, including forensic methods such as autopsy in supporting evidence and establishing causality.

Results

SCI is crucial in the process of uncovering complex medical criminal cases. As is known, not all criminal cases, especially medical crimes, can be solved easily, especially cases related to procedural violations or even medical criminal cases mixed with general crimes such as poisoning, assault, or crimes committed in a planned and orderly manner. In such cases, evidence is often minimal or hidden, so an in-depth scientific approach is needed. Scientific data from this method provides high validity because it comes from measurable and retestable analysis. Thus, SCI makes a significant contribution in helping investigators find strong evidence and ensure justice in the criminal justice process by uncovering the true facts. In disclosing Medical Crimes, it is somewhat different from General Crimes where in Medical Crimes, investigators must be able to prove that the Doctor or health worker has done something that violates standards, violates competence and must also present the logic of the causal relationship between the effects that occur and the cause. This is not at all easy but is complicated and requires the hard work of many parties. A doctor who is suspected of committing a procedural error or error in a medical procedure, must be proven through a series of proofs that rely on evidence, which is different from general crimes, the evidence must be traced through SCI. In this study on the use of SCI in Medical Crimes, one of the most important pieces of evidence is the results of an autopsy.

Conclusions

In conclusion, it can be said that in Criminal Health Law, Scientific Crime Investigation is one of the effective ways used by investigators to prove that patient losses due to negligence and neglect by doctors or health professionals can truly present scientific evidence that is able to convince the Panel of Judges.

FRI-S10-P05

Session: Forensic and Legal Medicine II · **Room:** R.008

Analysis of Medical Secret Disclosure as an Unlawful Act

MD, Pathologist Hatami Fitria Esti¹, MD, Doctor of Law Nasser Muh², Mochamad Fajar Ramdhani³, Donny Ferizon Zanahar³
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Background

Article 10 of the Indonesian Ministry of Health Regulation Number 24 of 2022 mandates all health facilities to submit all medical data to an application claimed to be a Ministry of Health application. This paper discusses the obligation to transmit sensitive personal information, including by name, by address, by diagnostic, and by treatment, to an application with an unclear server location. This requirement potentially conflicts with the principles of explicit consent, accountability, and personal data protection as guaranteed by Law Number 27 of 2022 concerning Personal Data Protection, which is strongly protected by Article 28G of the 1945 Constitution. Furthermore, this act also potentially violates the Electronic Information and Transactions Law (UU ITE), Health Law, and the Indonesian Penal Code 2023. The obligation for health service facilities to integrate and report patient Electronic Medical Record data into this application raises legal issues concerning the boundaries of medical secret disclosure and the legitimacy of patient data disclosure, and may also infringe upon human rights.

Research Question

This research aims to analyse the disclosure of medical secrets as an unlawful act from the perspective of Health Law and State Administrative Law, particularly in the context of electronic medical record access and reporting obligations.

Methodology

The study employs a normative juridical method with a statutory and conceptual approach, is descriptive-prescriptive in nature, and is analysed qualitatively.

Results

The findings indicate that the disclosure of medical data without a clear legal basis and patient consent, or without adhering to the principles of purpose limitation and proportionality, can potentially be classified as

an unlawful act. Such violations can lead to legal consequences in civil, criminal, and professional ethics domains.

Conclusions

Harmonization of regulations and a comprehensive evaluation of health service digitalization policies are necessary to align with the principles of patient rights protection, legal certainty, and respect for human rights, especially in health data governance. If evidence of legal violations is found, this Ministerial Regulation must be revised as it contradicts higher legal regulations.

SESSION FRI-S11 · TRACK 4 · 11:00 – 12:30

Genetics II · Room R.201

Moderator: Yann Joly

FRI-S11-P01

Session: Genetics II · **Room:** R.201

Preventive GGE through the Lens of the ECHR

Jolien Smets Masters

University of Antwerp, Antwerp, Belgium

Background

Germline gene 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 on 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.

Research Question

The features outlined above raise the question whether, once safety is demonstrated, a differentiated regulatory framework compatible with European human rights law could be feasible.

Methodology and Results

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.

Drawing on ECtHR jurisprudence concerning assisted reproductive technologies, it is unlikely that an absolute right to access preventive GGE could be derived from the ECHR.

Conclusions

If a state would adopt regulations permitting preventive GGE, the ECtHR would assess whether a "fair balance" has been struck between competing interests: the prospective parents' reproductive autonomy (article 8), the protection of the future child, respect for human dignity, and broader societal interests. In conducting this assessment, the Court would make use of its doctrines on margin of appreciation and European consensus, and also consider the quality of the domestic decision-making process, the proportionality of the regulatory scheme, and relevant international instruments, notably the Oviedo Convention, the UDHGHR and the UDBHR, as interpretative guidance.

FRI-S11-P02**Session:** Genetics II · **Room:** R.201**Genobility Revisited: Re-evaluating Mehlman's Existential Threat of Heritable Genomic Enhancement to Liberal Democracy**Dr Oliver Feeney PhD

University of Tübingen, Tübingen, Germany

Background

Calls for moratoria on heritable human genome editing (HHGE) are returning centre stage (Knoepfler, 2026) due to new developments in embryonic base editing (Egli, 2026). Like previous calls in 2015 with the first embryonic CRISPR research (McCarthy 2015) and in 2019 with the He Jiankui case (Lander et al. 2019), there are specific concerns of safety and the like, as well as broader concerns over the potential social impact of enhancements and associated inequalities. Here, it is less the reality and more the mistaken beliefs of genetic enhancements creating or reinforcing social inequalities (Andorno et al. 2020). Therefore, the justification of such moratoria is partly based on such 'assertions on what people will believe'.

Research Question

I revisit Maxwell Mehlman's (2005/2003) 'genobility' thesis to illustrate how such assertions are insufficient to support for a legal prohibition on HHGE. Mehlman's argument – heritable genetic enhancements, bar draconian measures, leads to the permanent formation of a genetically enhanced elite destroying liberal society – made unwarranted presumptions on the speculative impact of a new technology while downplaying the proven impact of other inequalities. Two questions arise: a) are other relevant areas downplayed again and b) to whatever degree that HHGE enhancements materialise, how problematic would be such 'mere perceptions' arising from wrong beliefs be to constitute legitimate grounds for moratoria?

Methodology

Combining ethical theory with (political) sociology, social psychology, and the nature of genomic research, this paper examines the various calls for HHGE moratoria, their similar themes and any basis given for various assertions regarding post HHGE beliefs. A comparison is done with the main ethical issues and related responses to somatic interventions.

Results

a) While other areas are downplayed (e.g. inequalities in, and from, somatic interventions), b) HHGE enhancement research would co-exist with significant empirical uncertainty, especially regarding complex traits like intelligence. This uncertainty gives space for unverifiable beliefs, increasing the risk of 'false yet consequential beliefs' in reproductive contexts. I argue this to plausibly arise from self-fulfilling prophecies alone, shaped by parental expectations, education, and socio-economic status, and comparable in impact to whatever HHGE enhancement research might actually achieve.

Conclusions

In the current context of growing social division and polarisation, the above dynamics may increasingly risk something resembling Mehlman's 'genobility' without effective genetic enhancement technologies actually arising, while still (oddly) justifying some calls for moratoria.

FRI-S11-P03**Session:** Genetics II · **Room:** R.201**Biotechnologies and Perfect Children: Is There a Right to Choose Their Genetic Characteristics?**Dr. Aurélie Cassiers

UNamur, Namur, Belgium. UHasselt, Hasselt, Belgium

Background

The rapid development of reproductive biotechnologies has significantly expanded parental choice in human procreation. In addition to assisting conception, technologies such as preimplantation genetic testing (PGT), prenatal testing, gamete donor selection, and emerging techniques, including CRISPR-Cas9 and reproductive cloning, increasingly enable the selection of a future child's genetic characteristics. While these innovations strengthen parental reproductive autonomy, they also raise major ethical and legal concerns regarding the interests of the unborn and prospective child and the risk of new forms of eugenics.

Research Question

Should parents have the right to choose the genetic characteristics of their children, insofar science allows it?

Methodology

This research adopts a legal methodology combined with ethical analysis and empirical research. It first examines the practical possibilities offered by current and emerging reproductive technologies and then analyses the bioethics literature. Finally, after a thorough study of the international, European, and Belgian legal frameworks, it concludes with a set of legal recommendations.

Results

The analysis demonstrates that parental reproductive choice is not unlimited and is already subject to legal restrictions in several contexts. However, existing legal frameworks show some legal gaps allowing, in some cases, eugenics and unclear legal interpretation and application. The analysis of the emerging protection of future generations results in the conclusion that the protection of the interests of the future generations of children (i.e., the prospective children) is legally possible.

Conclusions

A balanced legal framework should first balance the interests of the child, the parent, and society, while giving priority to those of the (prospective) children, preserving reproductive autonomy, and preventing eugenics.

FRI-S11-P04**Session:** Genetics II · **Room:** R.201**The Evolution of Bodily Integrity: Genomic Intervention and Artificial Intelligence in Human Rights Law**Dr Mariya Petrova Dimitrova

Sofia University "St. Kliment Ohridski" Law Faculty, Sofiya, Sofiya, Bulgaria

Background

Recent advances in genome editing technologies, particularly CRISPR-Cas systems, and the incorporation of artificial intelligence (AI) into health sciences have revolutionized possibilities for human intervention at the most fundamental biological level. These developments challenge traditional legal concepts of bodily integrity, which have focused primarily on protection against unwanted physical intrusion or coercive medical treatment. Contemporary biotechnologies enable pre-implantation genetic editing, heritable genetic modification, and algorithm-driven decisions about human life trajectories, raising novel ethical and legal dilemmas about autonomy, identity, and human rights.

Research Question

How should international health law and human rights frameworks evolve to protect genomic and algorithmic integrity as core dimensions of bodily autonomy in the context of CRISPR-mediated gene editing and AI-supported biomedical decision-making?

Methodology

This study employs a comparative doctrinal and normative analysis of international instruments (e.g., UNESCO's Universal Declaration on the Human Genome and Human Rights and the Oviedo Convention), relevant human rights jurisprudence, and emerging bioethical scholarship. It also analyzes regulatory policies in diverse jurisdictions (EU, USA, China) to identify gaps and convergences in the protection of genomic integrity and AI governance in health. The framework integrates legal theory on autonomy with empirical evidence regarding the use of AI diagnostic and predictive tools in genomics.

Results

The analysis reveals that current legal regimes inadequately address the risks posed by germline editing and AI's growing role in clinical and genetic decision-making. Existing protections against non-consensual physical intrusion do not extend to algorithm-mediated biases, opaque data processing, or irreversible germline alterations affecting future persons. Regulatory divergence among states creates ethical inequities and potential "biotech tourism" for genomic modification. Furthermore, AI systems shape health choices without transparent safeguards, threatening informational and decisional autonomy tied to an individual's biological identity.

Conclusions

The concept of bodily integrity must be expanded to include genomic and algorithmic integrity in global health law. A human-rights based legal paradigm is needed that recognizes the indivisibility of physical, genetic, and informational aspects of autonomy, ensures transparent AI governance in health, and prevents discriminatory or harmful genomic interventions. Policymakers, legal scholars, and bioethicists should collaboratively pursue international standards to harmonize protections and uphold the inherent dignity of all individuals in the biotechnological era.

FRI-S11-P05

Session: Genetics II · **Room:** R.201

Renewing the Foundations of HHGE Regulations in the European Union

Professor Jessica Almqvist

Lund University, Lund, Sweden

Background

International law is often described as fragmented as it is made by specialised regimes operating semi-autonomously. An issue may fall within the mandates of several regimes with different outcomes. Heritable human genome editing (HHGE) has prompted engagement by multiple universal organizations, including UNESCO, WHO, and UN. Fragmentation notwithstanding, there has been agreement that HHGE clinical trials and applications must not be tolerated.

This stance is also manifested regionally. While not all Council of Europe members have ratified the Oviedo Convention (1997) establishing that an "intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants" (art 13), EU regulation on clinical trials (2014) overrides variation within the EU with its rule that "no gene therapy clinical trials may be carried out which result in modifications to the subject's germ line genetic identity (art 90). Other regional organizations (OAS, OAU, ASEAN) have remained silent. Such silence should not be interpreted as acceptance, though, since all states are expected to regulate HHGE domestically in line with human rights obligations and universal agreement.

However, the universal stance may be eroding. Examples include the 2024 South African amendment of its research guidelines to allow HHGE; significant investments of US-based biotech companies in HHGE, and new gene-editing rules in China which may not cover private ventures outside conventional research institutes. Meanwhile, the EU is developing a Biotech Act for a more agile, harmonised, and strategically autonomous biotech market, and plans to address the tension between innovation facilitation and precaution in the context of gene editing.

Research Question

What is a sound EU policy towards HHGE in the context of legal fragmentation?

Methodology

The study adopts a normative and value-oriented methodology grounded in European human rights law to renew the foundations of the existing EU policy of restraint towards HHGE.

Results and Conclusions

A sound policy must be grounded in basic human rights principles of human dignity and human equality, including of future generations, and clarify if clinical trials/applications are inherently incompatible with these principles or compatible with openness coupled with strict safeguards.

Take-Home Message

Market-driven interests will push the EU to flexibilise its rules once the safety concerns are eliminated. This calls for a renewal of the foundations for these rules in light of human rights.

SESSION FRI-S12 · TRACK 5 · 11:00 – 12:30

Medical Liability IV · Room R.230

Moderator: Nino Lipartia

FRI-S12-P01

Session: Medical Liability IV · **Room:** R.230

Medical Injury Compensation and Dispute Resolution Systems in Japan, Taiwan, and Russia

Visiting Professor Robert B. Leflar J.D., M.P.H.^{1,2}, Professor Futoshi Iwata PhD³, Professor Wen-Yu Chia PhD¹, Professor Maxim Kratenko PhD⁴

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Background

Deaths and injuries from mistaken medical care are widespread in every advanced nation. Different countries have responded in various ways. The differences in approach spring not only from legal and cultural variations, but also from political conflicts within each of the nations considered here. (This paper is part of a larger comparative research project addressing other Asian nations including India.)

Research Question

What are the strengths and weaknesses of medical injury compensation and dispute resolution systems in Japan, Taiwan, and Russia, and what factors explain the differences in approach?

Methodology

The research in each target country is based on reviews of health care literature, published statistics (including a 2026 report from Japan), and interviews with leading scholars, medical and legal practitioners, patients' advocacy organizations, and government officials, as well as on scholarship about alternative dispute resolution in general.

Results

The paper addresses failures in reporting of iatrogenic injuries in Japan, ongoing implementation of a new system of alternative dispute resolution (ADR) in Taiwan, and difficulties in pursuing ADR in Russia. (Research on the situation in Russia is still at a preliminary stage, due to international conflicts.) Japan and Taiwan have set up limited systems for addressing birth-related injuries on a no-fault basis. No other nation but New Zealand has initiated a comprehensive no-fault system for tortious injury.

Take-Home Message

An understanding of political and cultural factors is essential to analyzing the effectiveness of various approaches to reducing medical error, and to compensating victims adequately and efficiently. This paper offers one attempt to address these difficult issues on a comparative basis.

FRI-S12-P02

Session: Medical Liability IV · **Room:** R.230

The No-Fault Compensation System in Lithuania: Analysis of Mandatory Pre-Litigation Data on Patient Harm

Ausrine Amsiejute Master of Laws

Hospital of the Lithuanian University of Health Sciences Kauno Klinikos, Kaunas, Lithuania

Background

In 2020, special legal provisions on compensation for harm to a patient's health, known as the no-fault model, entered into force in Lithuania. This model offers simpler compensation conditions than standard civil liability because it does not require proof of fault by medical personnel. It also enables a quicker compensation process. An additional goal of this model is to enhance patient safety by focusing on objectively assessing circumstances and preventing errors rather than assigning blame. Since this model has been in place for over five years, it is now appropriate to evaluate its practical effectiveness.

Research Question

This presentation addresses the following questions: (1) How has the Lithuanian no-fault compensation system evolved in practice, as

measured by claim volume, approval rates, and compensation amounts? Which medical specialties are most involved in claims, by county, by claim volume, and by awarded amounts? (2) How does Lithuania's compensation practice compare with Finland's established pre-trial model in terms of claim frequency and approval rates? (3) Do the observed trends indicate institutional consolidation of the compensation mechanism, and to what extent do they suggest progress toward broader patient safety objectives?

Methodology

This presentation is based on a retrospective, descriptive, and analytical assessment. Statistical data on Lithuania's no-fault compensation system were gathered and analyzed from publicly available administrative sources, including annual reports from the Commission and three university hospitals. Given the relatively low number of complaints recorded in 2020–2021, the analysis focuses on 2022–2025, when the number of complaints increased significantly, providing a more reliable basis for evaluation. Additionally, a comparative analysis was performed utilizing publicly available aggregated data from the Finnish pre-trial compensation authority. The analysis relied solely on aggregated data.

Results

Over the past four years (2022–2025), during the implementation of the Lithuanian no-fault compensation system, the number of claims reviewed by the Commission increased almost double. Total awarded compensation more than tripled. While odontology consistently received the most complaints in 2023–2025, the largest compensation amounts were awarded in high-risk specialties like surgery, orthopedics, and traumatology. The percentage of satisfied complaints in Lithuania is comparable to Finland; however, the number of complaints per capita remains significantly lower.

Conclusions

Data indicates that the no-fault system has become more accessible and operationally stable. The steady growth in both the number of complaints and the awarded amounts in 2022–2023, followed by stabilization in 2023–2025, suggests a maturing and credible compensation process. Although the number of patient complaints per 10,000 inhabitants in Lithuania remains low compared to Finland, the percentage of complaints that are satisfied is quite similar. However, based on available data, there is no evidence that broader system-level goals - such as improving patient safety, enhancing risk detection, or promoting preventive healthcare measures - have yet been achieved. Ongoing monitoring and more detailed data collection are necessary to evaluate these areas.

FRI-S12-P03

Session: Medical Liability IV · **Room:** R.230

The Use of Apologies Given at Mediation in Medical Negligence Matters: A View Through a Psychological Lens of a Plaintiff in Australia

Barrister Ngaire Caroline Watson Bachelor of Science (Nursing), Post.Grad.Dip (Mental Health Nursing), M.A (Psychoanalytic Studies), LLB

NSW Bar Association, Sydney, NSW, Australia. Australian College of Nurse Practitioners (Associate), Sydney, NSW, Australia. Australian Lawyers Alliance, Sydney, NSW, Australia. Australasian College of Legal Medicine, Sydney, NSW, Australia

Background

In 2002 sweeping changes were made to tort law in the wake of the largest corporate collapse in Australia's history. Insurance giant HIH collapsed in 2001 with AU\$5.3 billion in losses due to malfeasance. HIH was a major re-insurer of Australia's largest medical defence organisation.

The causative factors of the collapse were later re-framed with a focus on the number and size of claims. The theory advanced was that societal expectations and a better educated public resulted in people wanting to make someone "pay" if something bad happened.

In New South Wales in 2002 the *Civil Liability Act* came into force. Provisions were made to legally protect any express or implied admissions of fault or liability by the health provider. This included apologies given at any time after an incident. Health providers and hospitals were widely encouraged to apologise after an adverse event as research had indicated patients were less likely to litigate or at least have lower financial expectations regards compensation.

Methodology

A clinical background is in nursing, specialising in mental health and later training as a Lacanian psychoanalyst has provided an opportunity to draw on these disciplines over the course of 18 years working as a Barrister. During this time, I have observed many apologies given by representatives of insurance companies to plaintiffs on the day their case was being mediated.

I will draw on one particular case study of a legal matter where I attended the mediation as counsel for the plaintiff. With the permission of the plaintiff, I will outline their response to the apology they received at mediation.

Results

My legal practice is 'trauma-informed' and I gathered psychological insights after speaking to the plaintiff about their experience following the mediation.

Conclusions

This single case study provided an opportunity for an in-depth exploration of a complex issue in a real-life legal setting where high levels of trauma response were present in the plaintiff. My findings suggested this may be an area for qualitative research using a hybrid of legal/psychological methods.

FRI-S12-P04

Session: Medical Liability IV · **Room:** R.230

How Does the Obstetric Compensation System for Cerebral Palsy Affect Compensation in Japan

Professor Manabu 携 Wagatsuma

Tokyo Metropolitan Law School, Tokyo, Japan

The Japan Obstetric Compensation System for Cerebral Palsy (hereafter referred to as "the System") was launched in 2009. Background of the System was as follows. First, as part of building the environment in which obstetric care can be smoothly delivered in response to growing concern about Japan's deteriorating perinatal care and national low birthrate. Second, as a Japan's first no-fault compensation system in the medical field with the background to correspond the concern of litigation to improve the shortage of obstetricians and increase the number of medical Institution which deliver baby and ensure the obstetric care provision system. The Object is as. First the Quickly compensating for the economic burden on the families and children with severe cerebral palsy developed related with delivery. Second analyzing the cause of cerebral palsy and providing information that will help prevent the recurrence of similar cases. Third prevention and early settlement of conflicts and improvement of quality in obstetric care.

All the cases accredited to be eligible for compensation, the operating organization analyzes the cause from medical point of view based on the information described in the medical records and other documents submitted from the childbirth facilities and information from parents. It does not decide whether the negligence is admitted.

The number of new medical negligence case is low in Japan. In 2024, only 661 cases. It takes time and it is difficult to win the medical litigation because it is hard to prove negligence and the cause of damage. Average duration of trial is 24.7 months compared with other civil case is 9.2 months. Almost half of litigation is settled. In some cases the Cause Analysis Report is used as a reference to decide negligence in litigation. Because the report is reliable and it takes time and cost to find the proper expert witness.

I will research some case files to examine how the report of cause is used in litigation and I am going to interview some lawyers and judges specialized in medical negligence to analyze whether to file a litigation or choose the system. My presentation will clarify the differences between the compensation system of litigation and the no fault compensation of the system to provide much better remedies for patient and their families.

SESSION FRI-S13 · TRACK 6 · 11:00 – 12:30

Minors II · Room R.007

Moderator: Sanjin Dekovic

FRI-S13-P01

Session: Minors II · **Room:** R.007

Evaluating the Legal and Ethical Duties of Transparency and Consent Currently Mandated under Irish law for Healthcare Providers and Institutions with the Lens of the

CHI (Children Health Ireland) Scandal to Highlight the Pitfalls of the System

Ms Batool Aly Msc

DCU, Dublin, Ireland

Background

Irish law provides statutory and common law duties on healthcare providers and institutions regarding transparency and consent. However, the recent events of the Children's Health Ireland controversy regarding the poor care of minor patients including unnecessary surgeries recommended to parents for their children, lack of consent and informing the patients guardians of risks and available alternatives; have highlighted the multi-level failure of hospital governance including lack of support for whistleblowers, low visibility on clinical decisions and lack of clinical safeguarding procedures.

Research Question

As a result of this scandal, there are concerns surrounding the practical operation within institutional healthcare settings. This paper attempts to evaluate the legal and ethical duties of transparency and consent currently mandated under Irish law for healthcare providers and institutions with the lens of the CHI (Children Health Ireland) scandal to highlight the pitfalls of the system.

Methodology

This paper will use doctrinal analysis to review the legal regulations on informed consent and open disclosure obligations that provides the doctrinal foundation for analysing Irish statutory and case law.

Additionally, as Irish healthcare law and governance is relatively new, this research will heavily rely on comparative analysis to review the similarities, differences and in particular the actions taken to prevent future similar events and to view the research question not just from a distance policy perspective but to adapt functional regulations within the practical operation of Irish healthcare institutions. This comparison will involve CHI events (Ireland), Mid Staffordshire NHS Foundation Trust scandal (United Kingdom), Johns Hopkins Hospital Paediatric Cardiac Surgery Scandal (United States), Bundaberg Hospital Scandal (Australia) and Winnipeg Pediatric Cardiac Surgery Inquest (Canada).

Results

The analysis demonstrates that while Irish law formally recognises the duties of consent and transparency, which were initially grounded in constitutional protections of bodily integrity and patient autonomy and then statutorily established Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, significant gaps persist between the legal doctrine and institutional implementation.

The United Kingdom (UK) is the most similar jurisdiction that the Irish Healthcare system can adopt from and both jurisdictions operate under common law. While there are legislations surrounding open disclosure and consent, there is little in terms of safeguarding these rights. Through comparative analysis with the UK's Mid Staffordshire NHS Foundation Trust scandal steps can be taken regarding penalties for non-compliance, strengthening requirements for documentation and audit trails.

Another aspect of implementing these regulations involves the management of healthcare providers and the different privileges among them. For consultants with independent privileges, stronger emphasis on their role as conductor of the patient's care needs to be established. This requires a more active role from their insurance providers to assist and support those healthcare providers that act as a sole trader.

For employees of the hospital, a stronger review of patient care and consents needs to be adopted by institutional providers.

Conclusions

Irish legislation needs to adopt a practical operational approach to laws relating to healthcare, with involvement of healthcare providers, healthcare institutions and insurance providers.

FR-I-S13-P02

Session: Minors II · **Room:** R.007

When Protection Causes Harm: Structural Injustice and Children's Rights in Anti-FGM Interventions

Senior Lecturer Lotta Wendel PhD, LL.M

Department of Criminology, Malmö University, Malmö, Sweden

Background

Efforts to eradicate female genital mutilation (FGM) are firmly embedded within global health, human rights, and legal frameworks, and are widely framed as necessary to protect girls from harm.

However, a growing body of research—including studies to which I have contributed—points to significant unintended consequences of current interventions. These developments raise critical questions for health law, particularly regarding the risks of structural injustice, limitations on children's rights, and forms of iatrogenic harm produced within systems designed to protect.

Research Question

How do anti-FGM policies and practices generate unintended harms—such as structural injustice, constraints on children's participatory rights, and iatrogenic effects—within national and global health law contexts?

Methodology

The paper draws on three recent empirical and analytical studies in which I have been involved. The first examines genital examinations conducted in Sweden between 1982 and 2022 in cases of suspected FGM, analysing legal justifications and clinical practices. The second investigates the role of special representatives for children in such cases, with a focus on how the child's right to be heard is interpreted and implemented in practice. The third study offers a critical analysis of global anti-FGM campaigns, with particular attention to dominant "zero tolerance" approaches and their broader implications.

Results

Taken together, the studies reveal several interrelated forms of unintended harm. In the Swedish context, legally sanctioned genital examinations—while intended as protective measures—often disproportionately target migrant communities and may involve invasive procedures carried out without clear medical necessity. This raises concerns regarding bodily integrity, proportionality, and non-discrimination, and illustrates how legal mandates can contribute to structural injustice in clinical settings.

Further, the analysis of special representatives shows that children's participatory rights are frequently constrained in practice. Although the legal framework emphasizes the child's right to be heard, children's voices are often mediated, filtered, or marginalized within formal procedures, resulting in a gap between legal ideals and lived realities.

At the global level, dominant anti-FGM strategies are shown to risk producing iatrogenic effects, including the reinforcement of stigmatizing narratives about affected communities, and the erosion of trust between patients and healthcare providers. These dynamics may ultimately undermine both healthcare access and the legitimacy of legal interventions.

Conclusions

The findings highlight a fundamental tension in health law between the obligation to protect individuals from harm and the risk of harm caused by protective interventions themselves. Drawing on my involvement in these studies, the paper argues for a more reflexive and context-sensitive approach to anti-FGM regulation. This includes stronger safeguards surrounding medical examinations, more robust implementation of children's participatory rights, and greater attention to cultural competence and community engagement.

A key takeaway is that legal and health interventions must be evaluated not only in terms of their intentions and formal legitimacy, but also in relation to their practical effects. Ensuring that anti-FGM efforts are equitable, proportionate, and respectful of the rights and dignity of those they aim to protect is essential for both ethical and effective governance.

FR-I-S13-P03

Session: Minors II · **Room:** R.007

Discreet Childbirth in Belgium? Towards a Legal Balance Between Access to Healthcare and the Right to Ancestry Information

Meester Lieselotte Bruynseels Master's degree in Law

Law firm Dewallens & partners, Leuven, Belgium

Background

Discreet childbirth means that women leave their information at childbirth, but this information does not appear on the child's birth certificate. These data are kept in a register accessible only to the child, enabling potential contact with the biological mother later in life. Although discreet childbirth has long appeared on the Belgian political agenda, it has not yet resulted in legislation. The new federal government included the measure in its coalition agreement, and a legislative proposal was submitted in March 2025. The debate sits at the intersection of two concerns: ensuring access to safe perinatal care

for women in vulnerable circumstances, and guaranteeing the child's right to ancestry information.

Research Question

How can a legal framework for discreet childbirth in Belgium achieve a proportionate balance between, the need for safe and accessible care for women in vulnerable situations, and the child's fundamental right to ancestry information?

Methodology

This study starts from a classical sources analysis, beginning with the recent Belgian legislative proposal submitted at the start of the new legislature. It then conducts a comparative legal analysis, with particular attention to "*accouchement sous X*" in France. The case law of the European Court of Human Rights is examined. Finally, the analysis is placed within the European evolution toward a more firmly anchored right to ancestry information.

Results

Regulating discreet childbirth in Belgium can be legally defensible to broaden access to safe (perinatal) care, provided strict safeguards for the right to ancestry information. While the pending legislative proposal offers a first normative framework, it requires further refinement—particularly regarding data protection, the functioning of the confidential register, and procedures through which children can request information. Regulation can ideally be aligned with the planned reform of the Law on Medically Assisted Reproduction, since by 2027 the legislator must establish access to ancestry information for children conceived with donor material. Follow-up research is therefore advisable to refine this legal framework.

Conclusions

Discreet childbirth can expand access to safe healthcare in Belgium for women who would otherwise give birth in risky circumstances. At the same time, it requires clear safeguards for the child's right to ancestry information, such as a confidential, legally anchored register. In this way, a legal framework can be developed that balances care accessibility and identity rights.

FRI-S13-P04

Session: Minors II · **Room:** R.007

Repenser l'Accès des Mineurs aux Soins de Santé Mentale: Lacunes Normatives et Nécessité d'un Modèle Fondé sur la Maturité

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University of Warsaw, Warsaw, Poland

Contexte

L'accès des enfants et des adolescents aux soins psychiatriques et psychologiques constitue l'un des angles morts les plus préoccupants du droit de la santé mentale en Europe et au-delà. La plupart des systèmes juridiques subordonnent cet accès au consentement parental, sans prévoir de mécanismes adaptés aux situations dans lesquelles l'autorité parentale fait obstacle aux soins ni de solutions claires et efficaces lorsque l'urgence clinique impose d'agir sans délai. Le cadre normatif demeure ainsi fragmenté, lacunaire et souvent déconnecté des réalités de la pédopsychiatrie contemporaine.

Question de Recherche

Cette communication vise à déterminer dans quelle mesure les cadres juridiques existants garantissent aux mineurs un accès effectif et autonome aux soins de santé mentale, et à identifier les réformes nécessaires au regard des obligations découlant de la Convention relative aux droits de l'enfant et de la Convention européenne des droits de l'homme.

Méthode

L'analyse repose sur une approche comparative entre le droit polonais et un aperçu des systèmes européens, avec une attention particulière portée au modèle britannique, fondé sur une évaluation individualisée de la capacité de discernement du mineur en matière de traitement médical. Elle est complétée par l'examen des standards internationaux de protection des droits de l'enfant. S'agissant de la Pologne, une attention particulière est accordée aux réformes législatives récentes relatives au statut du psychologue clinicien et à l'accès des adolescents aux soins psychologiques, dont l'une a été acceptée et l'autre rejetée.

Résultats

L'étude met en évidence une forte hétérogénéité des seuils d'âge et des critères d'évaluation de la capacité décisionnelle des mineurs, une application incohérente de la notion de *periculum in mora* (péril en la demeure) en situation d'urgence psychiatrique, ainsi que l'absence quasi universelle de mécanismes garantissant un accès confidentiel et autonome aux soins. Les réformes se heurtent fréquemment à des résistances corporatistes et à des considérations idéologiques.

Conclusions

Le respect de l'intérêt supérieur de l'enfant et de son droit à la santé impose un réexamen des conditions d'accès autonome aux soins de santé mentale. Cette contribution postule un modèle de consentement gradué fondé sur la maturité du mineur et sur des standards harmonisés d'évaluation de sa capacité décisionnelle. Le droit ne peut rester en retrait d'une crise de santé mentale juvénile dont l'ampleur est désormais documentée à l'échelle internationale.

FRI-S13-P05

Session: Minors II · **Room:** R.007

La Nouvelle Procédure de la Modification de la Mention du Sexe dans les Actes de l'État Civil en Pologne à la Lumière des Solutions Adoptées par d'Autres Pays

Krzysztof Ślaski MA

University of Warsaw, Warsaw, Poland

Contexte

En 2025, la Cour Suprême polonaise a rendu une décision révolutionnaire, modifiant en profondeur les procédures judiciaires relatives à la reconnaissance du sexe légal, restées inchangées pendant plusieurs décennies. L'ancien système avec un procès contradictoire, a été remplacé par une procédure non-contentieuse. Ce changement emporte des conséquences importantes, notamment quant aux personnes habilitées à demander la modification, à celles autorisées à participer à la procédure, ainsi qu'aux preuves à présenter pour obtenir une décision favorable. La décision judiciaire ne « détermine » plus désormais le sexe d'une personne adulte, mais « corrige » l'erreur commise lors de la détermination du sexe de l'enfant à la naissance — une distinction qui redéfinit la nature de cette institution juridique.

Questions de recherche

Dans ce contexte, trois questions méritent d'être posées. La « nouvelle » procédure doit-elle être considérée comme plus favorable à la protection des droits de l'homme et à l'autonomie individuelle que les règles précédentes ? Quels autres modèles de changement de sexe légal ont été adoptés dans d'autres pays, et peuvent-ils garantir une meilleure protection des droits individuels ? Enfin, la primauté doit-elle être accordée aux formalités administratives ou au droit à l'autodétermination de l'individu ?

Méthode

Les recherches sont principalement menées à l'aide d'une méthode d'analyse de la législation, de la jurisprudence et de la littérature juridique. La méthode comparative est également utilisée, ainsi que, à titre subsidiaire, la méthode historico-juridique.

Résultats

Les recherches permettent de conclure que la modification opérée par la Cour Suprême en 2025 a amélioré la situation des personnes transgenres. La participation du procureur a été exclue de la procédure, ce qui a renforcé la position de la personne concernée ; il convient également de saluer le fait que seule celle-ci peut désormais initier la procédure. L'autonomie individuelle semble ainsi mieux protégée qu'avant 2025. Cependant, dans d'autres pays, la procédure est encore plus simple. Après examen de plusieurs législations européennes — notamment française et italienne — c'est la régulation suisse qui apparaît comme la plus aboutie : fondée sur le principe d'autonomie totale, elle se limite au dépôt d'une demande auprès de l'administration, avec des exigences probatoires nettement moins strictes.

Conclusions

La Cour Suprême polonaise a renforcé la protection des droits des personnes transgenres en Pologne, mais les règles établies ne garantissent pas encore une autonomie pleine et entière. La Pologne pourrait utilement s'inspirer de l'expérience d'autres pays afin de remédier aux lacunes de la procédure adoptée.

A Comparative Approach to Patients' Identity-Based Preferences for Healthcare Providers

Naoual El Yattouti PhD

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Background

In many countries patients have the right to choose their healthcare provider freely, at least to a certain extent. Considering each person's right to physical integrity and the importance of trust in a care-relationship, this is not surprising. These patient's choices may sometimes be based on the healthcare provider's identity, for instance on the basis of their gender, race, ethnic background or religion.

Research Question

Depending on the elements of the case, it may raise ethical questions, and especially relevant for this contribution, legal ones. The question arises whether non-discrimination law may form boundaries to the patient's rights to choose their healthcare provider, or what should be done exactly with patient's requests for different healthcare providers based on the personal characteristics of the healthcare provider that are protected grounds. When involving the health institution's approach to these patient's requests, and their duty to protect their employees against discrimination by third parties, while at the same time balancing patient's rights, the question becomes more complicated. It also prompts the question: Are all these requests to be treated the same legally or are they to be differentiated, for example for reasons of providing gender or culturally sensitive care? And is equality law equipped to allow such exceptions, perhaps as measures of affirmative action, to compensate health disparities caused by racial or gender discrimination against minoritised patients?

Methodology

This contribution will start by describing the patient's free choice of healthcare provider, diving into the national frameworks of Belgium, the Netherlands, France and the United Kingdom. Next, the scope of protection of discrimination law in these States will be examined. This part aims to provide answers to the questions whether healthcare providers can invoke some sort of protection derived from discrimination laws against patient's care refusals, and whether health institutions are obliged to protect their staff in such situations. The consideration of the patient's right to healthcare and the potential rights to gender sensitive and culturally appropriate healthcare, will be weighed against the necessity and possibility of protecting healthcare providers against discriminatory requests. This contribution draws from insights gained in sociological research and an own qualitative empirical study in Belgium, where nurses were interviewed on their experiences with discriminatory patient requests.

Human Rights and Legal Liability in AI-Assisted Clinical Decisions: A Risk-Based Medico-Legal Framework for Accountability, Safety, and Patient Protection

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Background

The integration of artificial intelligence (AI) into healthcare is reshaping clinical decision-making, particularly in diagnostics, risk stratification, and treatment planning. While AI systems may improve efficiency and clinical accuracy, their deployment introduces concrete risks to fundamental rights, including the right to health, non-discrimination, and patient autonomy. In many clinical environments, AI-assisted outputs are incorporated into decision-making processes without clearly defined requirements for clinical validation, transparency, or human oversight. From a European regulatory perspective, such systems may qualify as high-risk technologies and, in certain cases, as medical devices, thereby requiring compliance with safety, performance, and post-market surveillance standards. The absence of clearly operationalized safeguards increases the risk of harm resulting from uncritical reliance on algorithmic recommendations.

Research Question

How should legal liability be allocated in cases of AI-assisted clinical harm, and what risk-based regulatory safeguards are necessary to ensure protection of fundamental human rights and patient safety?

Methodology

This study applies doctrinal legal analysis combined with scenario-based evaluation of AI use in clinical practice. It examines three recurrent medico-legal scenarios:

- (1) physician reliance on inaccurate AI-generated diagnostic output;
- (2) algorithmic bias resulting in unequal or discriminatory clinical outcomes;
- (3) institutional deployment of AI systems without adequate validation, monitoring, or human oversight.

The analysis is informed by international human rights standards, European risk-based regulatory approaches to AI, and comparative principles of medical liability, health legislation, and medical device regulation.

Results

The analysis demonstrates that existing legal frameworks remain insufficient to address distributed responsibility in AI-assisted healthcare. Liability cannot be attributed to a single actor. Physicians retain responsibility under established standards of care when relying on AI without critical evaluation. However, where harm is linked to algorithmic bias, data limitations, or system design defects, responsibility may extend to developers and manufacturers. Institutional liability arises where healthcare providers fail to ensure proper validation, training, and oversight mechanisms. For example, in AI-assisted radiology, diagnostic errors may occur when algorithmic outputs are applied without independent clinical verification. The absence of enforceable requirements for transparency, auditability, and human control increases the risk of rights violations and limits patient access to effective remedies.

Conclusions

AI-assisted clinical decision-making should be regulated as a high-risk medical activity within a risk-based legal framework that combines medical law, product safety regulation, and human rights protection. Physicians must retain final responsibility for clinical decisions, while healthcare institutions and AI developers should bear clearly defined legal responsibility for system safety, validation, and performance. Regulatory frameworks should require ex-ante clinical validation, conformity assessment where applicable, continuous post-market monitoring, algorithmic transparency, and independent audit mechanisms. Embedding these safeguards into health legislation and medical device regulation will ensure that AI systems are deployed as accountable clinical support tools, strengthening patient protection, legal certainty, and public trust in healthcare innovation.

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