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# EAHL Newsletter

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EAHL  
EUROPEAN ASSOCIATION OF HEALTH LAW



Message from the President



Dear EAHL members,

This issue of the newsletter is dedicated to the abstracts presented during the PhD workshop of the 8th EAHL Conference in Ghent in April.

Many of you were present and it was such a pleasure to see you all in person. I don't think that I have ever seen so many happy faces at a conference.

The conference was a success. We had more than 200 participants and it was very well organized. We had insightful keynote speeches, fruitful workshops, inspiring presentations and interesting discussions. Just as important as the formal program, is the social gathering. Old friends met and new relationships were created. Thanks to all who took part in organizing the event. You were a great team!

The conference was held during special times for Europe. The covid-19 pandemic is not yet over, and Ukraine is at war. When EAHL had the call to host the conference, we had four applications. In the final round two applicants were left, Ghent and Lviv. You all know the outcome, but it was a close race. It is unbelievable that we almost decided to host the conference in a city that currently is under attack. The war is first of all a human tragedy, with loss of so many lives. The underlying conflict is a battle of values. EAHL aims to strengthen the health and human rights interface throughout Europe. Ukraine is attacked due to the fact that the country wants to connect closer to Europe and to develop the values that we believe in: democracy and human rights. EAHL condemns the Russian invasion but not the Russian people, and members that share the values of EAHL are always welcome regardless of the politics in their home country.

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EAHL will during June announce the call to host the next EAHL conference to be held in the spring of 2023. Before that, EAHL will organize a PhD workshop in cooperation with the university of Göttingen, Germany in the spring of 2022. I look forward to these events and I think that we all have realized during the pandemic the importance of meeting in person.

Thanks to the PhD students for submitting your abstracts and in this way sharing your research. The many abstracts cover several fields of health law and indicates a willingness to explore the many issues that are still under-explored. The EAHL has a bright future, and we thank our young researchers for being part of this and bringing our association forward.

*EAHL President*

*Karl Harald Søvig*



*Conference in Ghent*

## Awards provided during the Conference

Best abstract for the PhD seminar:

- **Danaja Fabric Povse**, “Are covid certificates a proportionate measure to restrict freedom of movement during the omicron wave?”

Best poster at the conference:

- **Noémi Dubruel and Emmanuelle Rial-Sebbag**, “Legal challenges raised by in silico clinical trials: between optimizing access to treatments and safety requirements”

Both the prizes are of 100 Euros and two years free membership E AHL and two years subscription of the European Journal of Health Law. Thanks to Brill for sponsoring the subscription!



*Conference in Ghent*

## *Honorary memberships:*

**Anne-Marie Duguet** and **Herman Nys** were announced as honorary members due to their dedication to the field of health law in Europe and to the Association.



*Honorary members and EAHL President*

## PhD Workshop session 1

### “Covid-19 and its Implications on Health Law in Europe”

Chair: Prof. Joaquin Cayon De Las Cuevas

#### **Assessment of decision-making capacity of patients with capacity disorders during the Covid-19 Pandemic in Latvia –**

*Laura Kadile, PhD at University of Latvia*

Decision-making capacity is a fundamental prerequisite for honoring health-care decisions in health care. It is assumed that every adult patient has a decision-making capacity. Often, human understanding and decision-making capacity is temporarily or permanently affected by illness or injury. Data from studies carried out abroad indicated that in health care institutions 34% of cases, but in psychiatric institutions 45% of cases, patients are characterized by decision-making capacity disorders (Lepping P., et.al. 2015). There are no data on the prevalence of such patients in Latvia. In circumstances where the decision-making capacity of the patient is limited, it is necessary to provide special protection of such patients and their rights, especially during pandemic.

The aim of this study is to develop a unified, capacity-based approach for the assessment of decision-making capacity for patients unable to provide consent during the Covid-19 Pandemic in health care institutions in Latvia, introducing the decision-making capacity concept in Latvian law.

As the result of the study, key challenges in capacity assessment during a pandemic is being assessed. Necessary improvements in assessment and communication between health care practitioners and patients are being discussed.

This paper first explores the prerequisites for the assessment of the capacity of such patients in health care institutions. Secondly, it will be determined in which cases, failure to comply with such a principle and restriction of the rights of patients in a democratic state governed by the rule of law in Times of Pandemic would be permissible and compliant with the Constitution of the Republic of Latvia. Thirdly, it highlights the necessity to develop a human-rights based approach assessing decision-making capacity in health care institutions in Latvia.

This abstract is prepared in the framework of research projects:

- 1) “Towards a human rights approach for mental health patients with a limited capacity: A legal, ethical and clinical perspective”, No. lzp-2020/1-0397;
- 2) "Strengthening of the capacity of doctoral studies at the University of Latvia within the framework of the new doctoral model", identification No. 8.2.2.0/20/I/006.

## **Are covid certificates a proportionate measure to restrict freedom of movement during the omicron wave? –**

*Danaja Fabcic Povse, Health and Aging Law Lab, LSTS – Vrije Universiteit Brussel*

**Context.** Digital covid certificates (DCCs) were put in place under Regulation 1021/953 to facilitate the exercise of freedom of movement when member states place entry restrictions. The DCCs are based on the presumption that certain people pose less risk to public health: vaccinated, recently infected or tested negative on a biochemical test. On principle, holders of DCCs should not be subject to additional requirements to enter a country. However, with the advent of omicron variant of concern which has a very high rate of transmission compared to previous variants, and considering its public health impact, it may be time to question the proportionality of DCCs as a measure.

**Aims & objectives.** The findings of this paper will feed into my PhD project on the interaction of public health and non-discrimination law in the context of digital covid certificates. It will help me determine fundamental parameters for evaluating the effectiveness of public health measures, as well as provide an important public forum to discuss the outcomes of the first year.

**Methodology & initial findings.** I will answer the following research question: “are covid certificates a proportionate measure to restrict freedom of movement during the omicron wave?”. In order to answer it, I will take into account primary EU law, which allows public health to be invoked as grounds to restrict freedom of movement, insofar as the measures are proportionate. I will evaluate the certificates in the light of the proportionality principle, following criteria of justifiability, suitability, necessity and proportionality. Especially suitability and necessity of the measure will be examined in the light of limited access to free testing, immune escape and high transmission rates in the community. Taking into account the persuasory nature of the measure rather than a “hard” vaccination obligation and the different member state exist strategies, I also evaluate proportionality *sensu strictu* of the measure.

## Medical Liability and Compensation in Poland vis-a-vis COVID-19 Pandemic –

*Karolina Harasimowicz, PhD at Lazarski University Warsaw*

The COVID-19 pandemic affected Poland's citizens as much as any other citizen of other countries. However, unlike many other countries which brought forth compensation mechanisms for negligence and fault towards patients being hospitalised during COVID-19, Poland failed to enact any such policy measure or law.

Rather, Poland's medical liability and compensation regime for patients affected due to injury sustained during COVID-19 treatment is encompassed in its Civil Code where the medical liability hinges mainly on the wrong being proved by the affected person, and it is favourable to healthcare professionals. Poland enacted the bill called the COVID-19 Act which provided for the emerging COVID-19 Situation, however, not for compensation for COVID-19 casualties and affected patients.

As regards Compensation, the value is determined by comparing the condition the patient would enjoy had the physician not failed and the condition which occurred as a result of medical malpractice of the physician.

As regards Vaccine Injury Compensation regimes VICPs are no-fault liability regimes established to compensate individuals who experience serious vaccine-related harm/vaccine injury. In Poland, a contemplated Act for VICPs provided that it did not require injured patients to prove negligence or fault by the vaccine provider, health care system, or the manufacturer before compensation. However, the same failed to be passed. The Act was said to provide an expedited path to obtain compensation in case a patient suffers adverse effects because of a vaccine (e.g. a COVID-19 vaccine) that is either obligatory or voluntary. Thus, the status quo remains that any person who has suffered damage (including as a result of administering a vaccine) can claim compensation under the general provisions of the Polish Civil Code. Despite the reluctance of lawmakers in Poland to bring about legislative change for the fast disposal of claims of medical liability and compensation, considerable efforts are being made to ensure extra judicial procedure for affected patients for patients' personal injury claims.



## **Investigating challenges related to data protection in clinical research during the COVID-19 pandemic: results from a mixed-methods empirical study –**

*Teodora Lalova, KU Leuven*

**Background:** The COVID-19 pandemic brought global disruption to health, society and economy, including the conduct of clinical research. In the European Union (EU), the legal and ethical framework for research is very complex and highly divergent. Many challenges exist in relation to the interplay of the various applicable rules, and in particular with respect to the compliance with the GDPR. It has not yet been investigated how the GDPR affected the conduct of research during the pandemic. Moreover, empirical research on the application of the GDPR in health research is still scarce.

**Objective:** To gain insights into the experience of key clinical research stakeholders (investigators, ethics committees, and data protection officers (DPO) and legal teams working with clinical research sponsors) across the EU and the UK on the main challenges and related solutions prior to and during the pandemic, and to inform the clinical research community about possible novel ways forward.

**Method:** Online survey and follow-up semi-structured interviews. The survey was widely disseminated between April and December 2021 by international organizations and consortia, such as the European Network of Research Ethics Committees, the European Organization for Research and Treatment of Cancer, and the Innovative Medicines Initiative: Corona accelerated R&D in Europe, as well as via social media. Interviews were conducted between July and December 2021. The survey will be analyzed descriptively. Interviews will undergo a framework analysis.

**Results:** In total, 190 respondents filled in the survey. Of them, more than half were investigators (53%). The groups of ECs (24%) and DPO/legal experts (23%) demonstrated a relatively equal interest in the survey. Out of the targeted 28 countries (EU and UK), 25 were represented in the survey. The majority of stakeholders were based in Belgium (17%), the UK (11%), Italy (11%), Germany (8%) and the Netherlands (8%). The study aimed to investigate in-depth the experience of the respondents on several key topics, namely: 1) primary use of personal data for clinical research, 2) secondary use of personal data for clinical research, 3) compliance with the transparency obligation, 4) communication between researchers and ethics committees (specifically the indirect role that ethics committees may play as regards compliance with data protection rules in clinical research), and 5) the main challenges experienced by key stakeholders prior to and during the pandemic. At the moment of submission of this abstract, analysis is ongoing, however preliminary results suggest that there are diverging perceptions on key topics, such as what should be the role of ethics committees in GDPR compliance. The majority of participants hold an aligned view on the biggest challenge for clinical research, namely the lack of legal harmonisation for pan-European studies.

## “So help me God”

### **The uncertain future of religious exemptions from mandatory vaccination –**

*Rogier Simons, Amsterdam University Medical Centers*

Since the entry of vaccines against COVID-19, many medical, ethical as well as legal questions arose on the subject of vaccination and its policy. More specifically, the question of making vaccination policy more coercive has heated the debate in many countries across the globe. One particularly remarkable judgment has been done by the Supreme Court of the United States in late October 2021 – *Does v. Mills*. In the judgment, the Court allowed a vaccine mandate for health care workers in the State of Maine to remain in effect. Prior to the judgment of the Court, Maine health officials declared that vaccination against COVID-19 should be mandatory with only allowing exemptions for people for whom a vaccine would be medically inadvisable. The mandate led to great dissatisfaction amongst health care workers, who argued that they were entitled to religious exemptions under the First Amendment’s free exercise clause as well as the federal employment law. Strikingly, religious objections against mandatory vaccination are not to be exempted from the mandate; this whilst in related COVID-19 contexts the Court ruled that religious exemptions must be allowed – if policies too allow for non-religious exemptions.

Although many COVID-19-vaccination cases were decided upon by the Court in the past 1.5 years, the case of *Does v. Mills* involved the first claims of religious freedom. Looking at the judgment from a European perspective raises the question as to how the right to freedom of religion in similar cases would be judged upon by the European Court of Human Rights (ECtHR). What is the scope of the right to freedom of religion ex article 9 ECHR in cases concerning (mandatory) vaccination and what can be learned from the ruling of the US Supreme Court? With growing numbers of rulings from the ECtHR regarding (mandatory) vaccination, it is interesting to see what arguments led to the judgment of the US Supreme Court in relation to those of the ECtHR. Therefore, in this oral presentation, the relation between the right to freedom of religion and mandatory vaccination will be discussed.

## Session 2 “Health Law and AI – European Perspectives“

Chair: Prof. Annagrazia Altavilla

### **Balancing Transparency of AI in Healthcare with Safety and Quality from Legal and Technical Perspective**

*Anastasiya Kiseleva,*

*Vrije Universiteit Brussel (LSTS and HALL research groups),*

*CY Cergy Paris University (ETIS research lab)*

The PhD research submitted to be presented at the workshop is based on the following hypothesis: transparency of AI in healthcare is important but not an absolute requirement and shall be always balanced with its safety and quality. According to data scientists, the most advanced algorithms are often the most accurate and at the same time least explainable. Thus, the safety and performance of AI might be the trade-offs of its full transparency. Additionally, healthcare itself is the domain where the highest level of transparency is hardly achievable. Any treatment is always a complex, risky and unpredictable process. While transparency is a crucial element for building trust in the use of AI in healthcare, requiring full transparency would put a too extensive burden on AI that might diminish its benefits.

Instead of requiring full transparency from AI's decision-making process, the right balance between accuracy (which equals safety and performance) and transparency of AI in healthcare is needed to be found. To find the mentioned balance, I explore transparency taking into consideration all the stakeholders involved in the process of AI's application: AI's developers and operators, healthcare providers and patients. At the same time, the measures to achieve the right level of AI's transparency shall be found. For that, I am investigating both the legal framework regulating transparency as a general principle and its specific regulation in the healthcare domain. Importantly, the measures are technically limited due to the restricted explainability of AI. Due to that, in my interdisciplinary research I also explore and assess the measures to achieve AI's transparency suggested by data scientists and correlate them with the identified legal requirements. This will enable us to develop a solution working not only for policy-makers but also for data and AI scientists.

**Research Question:** To what extent shall performance transparency of AI in healthcare be achieved and ensured for all the stakeholders involved without rendering the process technically infeasible? What are the available technical measures to achieve AI's transparency and how do they correlate with legal requirements? Does the relevant legal framework provide enough tools to balance AI's transparency with its safety, accuracy, and efficacy? If not, how shall the law address that?

## Professional Responsibility in Artificial Intelligence Health Decision-Making

*Saar Hoek, PhD at University of Amsterdam*

Automatisation and digitisation play an increasingly big part in all facets of life. Emerging sophisticated models and methods yield promising results and could be a great asset in many fields. In healthcare, the hope is that the application of novel technologies – such as deep neural networks – could aide physicians in tasks ranging from automated diagnosis to robotically performed surgeries. Though this prospect is undeniably attractive, some legal and ethical concerns that come with the introduction of automatisation have yet to be properly addressed. In healthcare, medical decision-making is buttressed by both medical professional autonomy and patient autonomy. On the one hand, a patient should have rights pertaining to i.a. their treatment and accessibility of information. On the other hand, the physician is responsible for a good standard of care and is accountable for her actions. The relationship between the physician and the patient relies on safeguarding autonomy for both parties, so as to build and maintain trust. However, the introduction of new technology could potentially impact this trust and this relationship. This research will investigate the impact of automated decision-making (through methods such as AI and RPA) on the professional autonomy of the physician, seen through the lens of the patient-physician relationship from the perspective of the medical professional. Herein, the research will inform a legal analysis on the impact of such AI health decision-making on good care and liability for malpractice, (perceived) privacy and data protection and trust. The results will provide insights for the future development of new AI models and their clinical implementation.

## **Building Trust in Artificial Intelligence in Medicine:**

### **A European Union Legal Perspective**

*Hannah van Kolfshoeten,*

*Law Centre for Health and Life, University of Amsterdam*

Artificial Intelligence (AI) is slowly transforming the healthcare sector in the European Union. In order to speed up innovation while minimizing risks and protecting fundamental values and rights, the European Commission proposed a new legal framework for AI. Its main objective is to create an ‘ecosystem of trust’. Patients may benefit from a regulatory approach to AI that centres on building trust. Trust is considered crucial for the doctor-patient relationship, and far-reaching technological changes in the healthcare system may undermine trust.

The use of trust as a regulatory objective for AI raises three crucial questions: 1) What does the European Commission mean with ‘trust’ and ‘trustworthiness’? 2) To what extent does AI as such has the capacity to be trusted? And 3) How can trust in AI be achieved through legal regulation? Because of these uncertainties, it is unclear whether ‘trustworthy AI’ as a foundational policy ambition also enhances the protection of patients’ rights, despite the shared value of trust.

In light of the common foundational value of trust, this article analyses the role of the notion of trust in the legal Europeanisation of health AI through a patients’ rights lens. The primary aim of this study is to evaluate the consequences of the EU policy objective of trust for AI used in the health sector. The outcome of this article will permit to shed light on shortcomings in the current legal framework on health AI and patients’ rights in Europe in view of the algorithmic turn in healthcare.

***Shrek's perspective: a narrative on equity, health and AI – Sofia Palmieri, PhD at Gent University***

The concept of equity is an ethical principle and is consonant with human rights principles. Equity in the specific context of health is generally defined as the absence of systematic inequalities between groups with different underlying social advantage or disadvantage levels. However, given its ethical nature and the inherent fluidity of the concept itself, equity can be interpreted differently depending on the context. When it comes to health and AI, the concept of equity can be translated differently, taking on different meanings and implying the need for different regulatory interventions.

Aware of the possible discrimination arising from the use of AI, the recent AI Act elaborates the principle of "Diversity, non-discrimination and equity" conceived by the High-Level Expert Group on Artificial Intelligence (HLEG). In this sense, in its proposal for AI Regulation, the EU Commission has presented requirements to promote the elimination of prejudice and biases, protecting, *latu sensu*, the equity principle. With a narrative *escamotage* and an exceptional character (Shrek), we will explore the various meanings that

equity can assume when AI is used in Healthcare. Furthermore, elaborating on Shrek's position, we will analyse how the AI Act protects the principle of equity and the right to non-discrimination through the elaborated requirements.

## **The Evolution of the Right to Health in a Context of Innovation: The necessary emergence of a right of access to medical innovations**

*Edouard Habib, PhD at Aix- Marseille University*

### I. Introduction: Right to Health and Disruptive Innovation in Health

First proclaimed in 1948 by article 25 of the Universal Declaration of Human Rights and further elaborated in 1966 by Article 12 of the International Covenant on Economic, Social and Cultural Rights, the right to health remains today a particular object of international and national law. Indeed, as the COVID-19 pandemic and the access to RNA vaccines brutally reminded us, the protection of everyone's health, and therefore the application of the right to health, can depend greatly on the access to medical innovations. However, nowadays, the disruptive nature of medical innovations, their complexity, as well as the exponential rate of their development represent a real challenge to the right to health, which should guarantee access to state-of-the-art, quality healthcare to all. These disruptive medical innovations which are changing the face of medicine (gene and cell therapy, tissue engineering etc.) all have at least two things in common, which are not unrelated, that make them difficult for everyone to access, namely their exorbitant prices and the complexity of the development and manufacturing process. The question that then arises is: **should the right to health evolve to include a right of access to medical innovations to ensure access to quality care?**

### II. Material and Methods: A Dual Comparative Approach France-Canada and Innovation Law-Health Law

To answer this question, it is first necessary to define a geographical and therefore legal scope for the right to health to be studied properly. In fact, although there is a more or less common understanding of the right to health in international law, it is not the case in national laws where it is implemented in different ways. Some states have enshrined the right to health in their constitutions, some not; for some the right to health is limited to ensuring access to primary health care, while others include the right to a complete health insurance for every citizen. It has thus been chosen to compare two countries that have almost the same conception of the right to health and how it should be implemented in order to study the impact of today's medical innovations on it. These two countries are France, as a member-state of the European Union, and Quebec as a province of Canada which both have a relative extended conception of the right to health and the same political will to transform their healthcare systems through innovation.

Second, once the right to health is defined in France and Quebec, it is necessary to study the law that regulates the development of innovations, and more specifically medical innovations, to identify and understand possible legal barriers to their access and thus, to the enforcement of the right to health. Every step of medical innovation, from its invention through its diffusion to its societal acceptance, is regulated by a legal framework that can be divided into two branches. Those two branches are the law *for* innovation, which consists of

regulations supporting and fostering innovation, and the law *of* innovation which aims to regulate it. It is therefore essential to check whether this legal framework, composed by two branches potentially conflicting, is compatible with the right to health as it exists in France and Quebec.

### III. Results and Discussion: Right to health and right to access innovation

To conclude, it is important to note here that the work of defining the right to health in France and Quebec is essential to this study. Indeed, its very existence is still controversial in the legal community. It was therefore chosen to talk about the right to health as a translation into national law of international commitments made under the aegis of the United Nations.

Finally, by studying both the right to health and the right to innovation while comparing their application in France and Quebec, it will be possible to say whether it is necessary to integrate a right of access to medical innovations into the right to health or not.



## Legal and ethical issues of using digital and data science methods in the development of health products

*Noemie Dubruel, PhD University of Toulouse*

The emergence of data science and digital technology is transforming many fields, including health and biomedical research. The development of health products is thus impacted by the use of innovative methods that offer undeniable advantages for its optimization and acceleration. Health law provides a framework that ensures quality biomedical research allowing safe and reliable care. However, this framework antedates the technologies it is supposed to govern. Therefore, this issue, which is the subject of this thesis, raises legal and ethical questions about the capacity of health law to adjust to technical developments and innovation, which need to be deeply analysed by legal scholars.

Among the methods involved in data science, we study the implementation of *in silico* clinical trials. These virtual clinical trials are carried out on computers by digitalization and simulation in order to complete the two current pillars of biomedical research, namely *in vivo* and *in vitro* research. It should be underlined that this method can be used to fill the under-representation gaps of vulnerable patients in clinical trials. Furthermore, *in silico* clinical trials constitute an additional tool for personalized medicine, via the development of “digital twins”, allowing the creation of targeted therapies adapted to an individual.

In this context, the issues inherent to biomedical research are associated with those concerning data collection, their sharing, their security and the protection of individuals’ privacy. Therefore, the emergence of data science and digital technology in biomedical research implies new concerns about the respect of human rights, data protection and respect for privacy. These concerns are reinforced by the identification of limits in using these methods in practice, in particular regarding some risks such as scientific bias, difficulties in guaranteeing the quality and security of data, or discrimination that could compromise access to safe and reliable care. Furthermore, the lack of uniformity in the qualification and use of these methods is reinforced by the absence of standards for their evaluation. This evaluation is currently limited to a scientific evaluation at the detriment of an ethical reflection, which needs to be further analysed.

The elaboration of a legal and ethical framework adapted to the deployment of these methods, their use and validation, thus appears necessary. However, French and European legal frameworks, designed to regulate "classic" biomedical research, are now challenging the protection of individuals in a context of digitalization and massive use of personal data. Indeed, the deployment of these new methods is at the crossroads of several fields, they are regulated *in silos* through separated legal frameworks. More specifically, these methods fall within the scope of data research which is primarily framed by Regulation (EU) No. 2016/679 on the protection of natural persons with regard to the processing of personal data. The results obtained by using these methods are intended to be correlated with the implementation of interventional research, notably framed

under the Regulation (EU) n°536/2014 on clinical trials of medicinal products for human use, as well as by the recommendations of good clinical practice. This situation reinforces legal insecurity for the various stakeholders and it would be necessary to provide means to clarify the regulatory framework for digital and health technologies.

The objective of this work is to question and analyse how the existing frameworks can be adjusted in order to provide for an appropriate and harmonized framework for the acceptable deployment of these methods.

This adjustment is notably thought to be applied to the role of law and bioethics for the supervision of innovation in health. This analysis is also conducted regarding professionals' practices, as well as issues for economic and competitive issues for innovation in health. Moreover, the consideration of European policies for the development of health products is not negligible. Finally, we intend to analyse the influence of European Health Law in the international environment and its impact on health research and innovation.

## Session 3 “Digitalisation and Health Law in Europe”

Chair: Prof. Steven Lierman

### **Ethical and legal reflections on patient involvement in the eHealth era-**

*Daniela Spajić, PhD at Leuven University*

The engagement of patients is increasingly being considered as a cornerstone for the provision of care and, beyond one's personal care, has even been said to make the healthcare system more sustainable in the long run. To this end, the European Commission considers digital solutions to form a key pillar for citizen empowerment and a successful transformation towards patient-centered care. The reason for this is the digitalization of healthcare, which is said to maintain high-quality healthcare services for which, subsequently, data is the facilitator. Personal data and health-related data form an essential part for the personalization and improvement of care services. Although the existing data protection, privacy, and confidentiality legislations allow the sharing of health-related data under certain circumstances, they have been said to also impede the (re-)use of such data. Additionally, the concept of “patient empowerment” or “citizen empowerment” is highly debated in the literature and has been subject to criticism due to the responsibilities that come with the use of eHealth tools, often to the detriment of the individual. With that in mind, the question arises if and how the current confidentiality, privacy, and data protection legislation relates to the idea of patient empowerment, aiming to improve healthcare quality, and which potential conflicts occur in relation to this notion. Therefore, the presentation seeks to offer an interdisciplinary discussion on some preliminary legal and ethical considerations in the context of patient engagement and the use of eHealth technologies.

## The role of automatic complaints in enhancing the quality of care

*Paulien Walraet, PhD at Gent University*

Setting up a reliable and transparent complaints system in hospitals is indispensable in assuring a qualitative healthcare system. The possibility to file a complaint is accordingly considered as one of the essential patients' rights. However, the existence of a *right* implies a certain degree of freedom on the part of the patient. In other words, the possibility exists that no complaint is lodged even though the quality of care is proven inadequate. This can have various reasons: the patient is not aware of any wrongdoing, the patient experiences the possible financial or burdens of initiating a procedure as too hard, or the patient does not know that a complaints mechanism exists, and so on. As a result, existing shortcomings in healthcare may not always be addressed. This is not only detrimental to the patient as an *individual*, but also to healthcare in *general*. The reporting and analysis of complaints on a large scale shows where changes need to be made in order to improve the quality of care for society as a whole.

The implementation of an automatic and artificially driven complaints procedure might help resolving this situation. The possibilities offered by technology today allow us to indicate where quality is lacking in individual cases, and even to automatically file a complaint against a healthcare institution. In doing this, quality could not only be met for an individual patient who does not file a complaint for whatever reason, but could ideally improve the entire health care system.

This development necessitates a legal analysis of the position of technology in the filing of a complaint. This presentation will specifically elaborate on how the legal position of technology relates to the role of the individual patient in filing a complaint against a healthcare institution.

## Regulating mHealth to guarantee quality and inclusive healthcare –

*Giulia Re Ferrè, PhD University of Milan*

During the pandemic, the use of health apps and wearable devices such as smartwatches, smart-rings, etc., has grown exponentially, creating new ways of taking care of oneself which have carried not only benefits but also risks and concerns that need to be addressed, both on a national and European level. This contribution aims to give an overview of the problematics related especially to the implementation of the so-called mobile health and will focus mainly on two topics: on one side the need to guarantee the quality of the healthcare provided through apps and wearable devices and on the other the goal to assure an inclusive healthcare system by ensuring equal access to technologies. Both aspects contribute to the concretization of the right to health, enshrined in the Constitutions of the member States and recognized by the EU.

Wearable and mobile health technology have the potential to revolutionize patients' care, especially for chronic patients, if reliable data can flow into the Electronic Health Record. This process implies control by the public power on devices and software, first of all, to assure the quality of the data self-gathered by individuals. Data reliability is the necessary precondition to be able to use the information in the public healthcare system through an integrated EHR, but the uncertain application of the Medical Device Regulation to *mHealth* devices together with the lack of special regulation could result in a gray area; in fact, often instruments potentially able to provide personalized care, assisting both the patients and the medical staff and integrating the public healthcare system are just considered as commercial apps.

On the other hand, the intervention of the public power should aim to guarantee inclusivity. As a matter of fact, quality health cannot result in a sort of elitist health system, where only those who can afford the best technologies can get proper treatments. On this particular aspect the new German Digital Healthcare Act, which introduces a large-scale reimbursement system for health applications, represents an interesting case study.

## Law and Biocapitalism: Regulating Biomedicine and the Case of Bioprinting of Human Tissues

*Mirko Đuković*

*SJD/Ph.D. Candidate, Central European University*

*Visiting Research Fellow, Max Planck Institute for Comparative Public Law and International Law*

3D bioprinting is a novel technology that uses the technique of 3D printing technology to mimic and produce viable human tissues and organs for transplant surgeries. The topic of this research can be approached from different angles. Both private and public law perspectives are valid at this juncture as the technology is in its nascent stage and only applied to small-scale surgeries. What in particular drew my attention was that under half out of 1,555 Verdict Medical Devices readers expect that bioprinting will become a routine part of healthcare by 2040. The question we should ask following this is, routine for whom and if so, whether everyone will have equal access to it, thus being able to exercise their right to health in full capacity, if they choose to do so.

To answer this, the approach that I take in my research questions how the law is used not only to regulate and govern technologies - but also our bodies. I hypothesize that such technologies transform the human body into a conduit of natural and legal processes which turn our bodily products into “fictitious commodities”. Those processes are predominantly controlled by the interests of the market. Thus, the bioprinting of human tissues changes the paradigm of self-ownership. The preliminary research into other similar biomedical technologies shows that instead of alleviating our health rights and access to advanced medical treatments, technology is being protected by the proprietary laws of the market, thereby defeating one of the purposes of its advancements and innovations.

The ethical, legal, and social implications (ELSI) of bioprinting point to proprietorship in bioprinting technology as a key issue, which comes from the fact that the neoliberal sacralization of property inevitably led to the profound desacralization of the human body, even at the very molecular level. This phenomenon is thoroughly researched in Dickenson’s scholarship, where she questions who the players are that provide legitimacy to body commodification. Similarly, Waldby and others discuss the issue of “biovalue” and the influence of capitalism on the regulation of our bodies. Rose notices that over the past few decades, the biopolitical has been replaced by bioeconomic. The cumulative effect of these scholarships is to demonstrate how the value or worth of bodies in a civilized society has been instrumentalized to the point of costs and benefits analysis, an economic unit of measurement. Such theoretical work, therefore, influenced my use of the law and political economy approach. Thus, I navigate through international biomedical law, human rights, and

(bio)constitutional and regulatory approaches predominantly in the EU and the U.S. markets in my research.

Law is observed as political and social practice and as rights. The legal method is doctrinal and comparative. However, as the research is multidisciplinary, where my theoretical framework is built on the Foucauldian approach to governmentality and biopower and Marx's theory of value. It is on these Foucauldian and Marxist epistemologies that I build my theoretical and methodological inquiry into law as regulation. My arguments follow the research in medical anthropology and ethnographic studies that reveal how biomedical practices are formed and organized and in particular how they depend on the market rationales, especially in the context of a neoliberal economy. Following the law and political economy approach, I posit that biomedical science coupled with market rationales creates new taxonomies such as knowledge-economy and know-how value.

Finally, my thesis intends to demonstrate vis-à-vis the framework of distributive justice, that new technologies can only advance justice when they benefit the marginalized and impoverished. Tissue transfer follows the rules of power and wealth. Relying on the research that indicates that ideology has an effect on regulation, where exploitation of regulatory gaps turned the body into a commodity, I employ Marxist and feminist theory to deconstruct political economy around the human body and to show how neoliberal market rationalism damages healthcare. Omitting the ontological value of the human body leads to the commodification of the body, and changes the conceptual framework of body property. This, in turn, contributes to the deep social disparity that affects the aim of distributive justice.

## **Quantified Self devices and the GDPR: Determining the essence of the data –**

*Anni-Maria Taka, Helsinki University*

In my article-based doctoral dissertation, I analyse the processing of personal data in connection with the use smart devices for health and wellness. In the PhD seminar I would like to present my thoughts about my article (draft, not yet published), in which I analyse the nature of the personal data collected and processed by the so called Quantified Self apps and devices. Smart watches, rings and other similar devices are used to measure and monitor different aspects of the user's wellbeing, such as activities, sleep and recovery. Depending on the functionalities of the device, it may make suggestions to the user, such as to be more active or to rest. The suggestions and other information provided to the user are based on the user data, such as physical exercises, heart rate and body temperature. Typically, these consumer products are not manufactured for medical purposes and are therefore not considered medical devices. However, the Quantified Self apps and devices may also be used in a medical context.

As the user data collected and processed is typically personal data, EU's General Data Protection Regulation (2016/679, 'GDPR') is very relevant. In my article, I study the concept of 'data concerning health', which is introduced and defined in the GDPR. I use legal dogmatic research methods to analyse whether the user data processed in the context of Quantified Self apps and devices is, according to the GDPR, data concerning health. Based on relevant EU case law, authority guidelines, legal literature and other relevant sources, I seek to come up with a structured method that can be used to determine the nature of the data.



## Session 4 “Actual challenges in European and International Health Laws”

### Chair: Prof. Karl Harald Søvig

#### Ensuring global equitable access to vaccines through the notion of ‘state capabilities’ of low-and-middle-income-countries

*Pramiti Parwani, PhD at Amsterdam University*

The COVID-19 pandemic has brought into public focus, more sharply than ever, the pressing problem of global vaccine inequity. As of February 21, 2021, only 7.81% of the population in low-income countries have been fully vaccinated, while almost 73% of the population in high-income countries has received the complete dose of the vaccines.<sup>1</sup>

As countries scramble to get vaccines, often at the cost of another nation’s access to the same vaccines, wealth and power imbalances between countries have an undeniable effect on their population’s access to vaccines.<sup>2</sup> Moreover, international institutions and private actors (for instance, pharmaceutical companies) can further reinforce these power imbalances.<sup>3</sup>

However, within international law, discussions on access to vaccines (often encompassed within the broader context of access to medicines) focus almost exclusively on the rights-based approach- in particular the right to health as enshrined within the International Covenant on Economic, Social and Cultural Rights (ICESCR). Access to essential medicines has been recognised as a minimum core obligation of the right to health.<sup>4</sup>

The ICESCR focuses its obligations squarely on States Parties, requiring them to protect, fulfil and respect socio-economic rights within their own territories. Beyond some duties on states to provide international assistance and cooperation “to the maximum of its available resources”, the ICESCR does not aim to impose obligations on foreign states to target socio-economic deprivation outside their territories, even where it is possible to draw a link between deprivations in one state and actions of foreign states.<sup>5</sup> In the first section, I lay down the existing legal framework on access to vaccines within international law.

In the second section, I turn to Third World Approaches to International Law (TWAIL) to highlight critical drawbacks of mainstream international human rights law. TWAIL is a critical strand of international legal

<sup>1</sup> Our World in Data, Coronavirus (COVID-19) Vaccinations, <https://ourworldindata.org/covid-vaccinations> (accessed 21 February 2022)

<sup>2</sup> A. Kayum Ahmed, Oxford, AstraZeneca Covid-19 deal reinforces ‘vaccine sovereignty.’ We need a people’s vaccine instead, Stat, June 4, 2020; Michael R. Millar *et al.*, Ethics of vaccination: Should capability measures be used to inform SARS-CoV-2 vaccination strategies? (2021) *British Journal of Clinical Pharmacology*, 1-9, available at <https://bpspubs.onlinelibrary.wiley.com/doi/10.1111/bcp.14875> (accessed 17 December 2021).

<sup>3</sup> *Ibid.*

<sup>4</sup> Office for the High Commissioner for Human Rights, CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12). ¶43(d).

<sup>5</sup> Monica Hakimi, Human rights obligations to the poor in POVERTY AND THE INTERNATIONAL ECONOMIC LEGAL SYSTEM: DUTIES TO THE WORLD’S POOR (Krista Nadakavukaren Schefer, ed.) (2013) Cambridge University Press.

scholarship which seeks to highlight the colonial roots of international law, arguing that this colonial past is still very much manifest within the international legal regime and its structures and institutions.<sup>6</sup>

In particular, TWAIL laments that the *exclusive* focus on human rights can act as ‘blindness’,<sup>7</sup> obscuring the role of foreign states, international institutions and private actors in creating and perpetrating conditions of socio-economic deprivation (including inadequate vaccine access) in low-and-middle-income countries (LMICs). IHRL imposes legal obligations on states to ensure that their population has access to essential medicines, without adequate consideration of the structural barriers that may make it impossible for states to actually do so. In this manner, IHRL can prevent us from discerning and challenging the wider neo-liberal agenda which impacts peoples’ capabilities.

Any meaningful discussion on global equitable access to vaccines must thus necessarily go beyond the rights of people (and corresponding obligations of the state) as enshrined in law, and consider the effective freedom available to LMICs to actually develop or procure vaccines for their populations. Therefore, in Section 3, I introduce the notion of *STATE CAPABILITIES* and propose that it be used as an important component for policy making for ensuring global equitable access to vaccines.

The notion of state capabilities is based upon the Capabilities Approach, which was developed by Amartya Sen and Martha Nussbaum and primarily focuses on the genuine freedom and opportunity available to *individuals* to achieve well-being. However, in light of the vital role played by states in first accessing vaccines (before they can attempt to ensure access to vaccines for their populations) I seek to expand the Capabilities Approach beyond its traditional individualistic contours, and propose the notion of State Capabilities to emphasise the potential or effective freedom for states to genuinely protect their nationals’ well-being.

Group capabilities help us understand and explain ‘horizontal inequalities’ amongst groups (or states) in their power and resources.<sup>8</sup> This is directly applicable to the present issue of equitable access to vaccines, with different countries being unequally placed in their access to these resources. The language of state capabilities can help create space within legal/policy discussions to highlight the role played by external actors – foreign states, international organisations and private actors- in constraining or facilitating a state’s capabilities to access vaccines for its population.

<sup>6</sup> Antonius R Hippolyte, Correcting TWAIL’s Blind Spots (2016) *International Community Law Review*, 18 at 3; Nneamaka Ifunanya Vanni, Narratives and Counter-Narratives in Pharmaceutical Patent Law Making: Experiences from 3 Developing Countries (2016) A Thesis Submitted for the Degree of PhD at the University of Warwick, available at <http://wrap.warwick.ac.uk/90970> (accessed 17 December 2021)

<sup>7</sup> Amy Kapczynski, The Right to Medicines in an Age of Neoliberalism (2019) *Humanity* 10(1), 79-107 at 95; Susan Marks, Human Rights and Root Causes (2011) *Modern Law Review* 74: 1 at 59.

<sup>8</sup> Stewart, *supra* note 8.

## **Financial penalties of the Patients' Rights Ombudsman for infringement of collective patients' rights**

*- Karolina Wierzbicka, University of Lodz*

The aim of the presentation is analysis and evaluation of the mechanism of protection of collective patient rights. Patients' Rights and Patients' Rights Ombudsman Act (2008) introduced new legal measures in cases of infringement of collective patient rights. There were no such solutions in the healthcare sector in previous Polish legislation. The Ombudsman is entitled to impose heavy financial penalties in cases where its decision has not been implemented by healthcare providers. According to article 68 of the act, the Ombudsman by way of administrative decision, imposes a penalty of 500.000 zloty where actions defined in previously issued administrative decisions have not been implemented, which aims at removing the effects of violating the warrant of abandoning the violation of rights. In cases where documentation and information on actual practices required by Ombudsman has not been provided, the penalty is 50.000 zloty. Article 68 leaves the Ombudsman a discretionary determination of the amount of the fine to be imposed. The speech will include court cases in which a high fine was imposed. The literature emphasizes that "due to the nature of collective patients' rights, the penalties should be severe. Their height plays a preventive role in this case ". The aim of the legislator in Art. 68 was to force the addressee to implement the ombudsman's decision. A one-off fine is not an effective disciplinary mechanism, as after it is imposed in a specific amount of money, the addressee loses the incentive to quickly remedy the ongoing infringement. From this perspective, a more appropriate solution would be to introduce a penalty for the delay in the execution of the decision. The provisions sanctioning infringement of collective patient rights, although modeled on the provisions on the protection of collective consumer interests, were shaped inconsistently, and the function and purpose of the fine under Art. 68 is ambiguous.

## **Liability for Healthcare - Associated Infections: between public health and patient safety**

*Mariya Sharkova, PhD at Alberta University*

Healthcare-associated infections (HAI) are among the most common hospital adverse events worldwide, affecting healthcare quality significantly. HAI affects patients by causing additional suffering and prolonged hospital stay or even death. Their treatment also represents an enormous financial burden to healthcare systems and leads to antimicrobial resistance.

The oral presentation gives a short overview of the legislation of HAI in Bulgaria and its shortcomings. It argues that public health and liability are interconnected as HAI directly reflects the quality of healthcare provided to patients and leads to the liability of healthcare facilities and medical specialists. At the same time, the fear of liability can significantly deter HAI reporting and registration and therefore undermine public health measures against HAI.

The study includes research based on case law in Bulgaria regarding HAI related hospital liability as a determinant of HAI burden. It argues that public health measures should be introduced together with reforms in liability to reduce HAI and improve the quality of healthcare and patient safety. The study compares traditional redress systems based on tort and contractual liability with alternative compensation systems and their effect on HAI prevention.

## **Citizen science for improved healthcare: where does the law stand?**

*Olga Gkotsopoulou, Vrije Universiteit Brussel*

Healthcare in citizen science projects is relatively under-explored, despite citizen science's potential to strengthen health literacy and improve inclusion in healthcare, by boosting participation at the general population level. The Covid-19 pandemic and the urge for fast, interdisciplinary, scientific studies to address an unprecedented global health emergency and to contain effectively the virus have functioned as catalyst for citizen engagement in healthcare the last years.

During the pandemic, citizen involvement has been simplified and encouraged through technology, especially every-day devices and digital platforms. For instance, we witnessed the deployment of smartphone applications for the live self-reporting of potential Covid-19 symptoms, including features such as coughing sound recordings and quick feedback rounds. Those initiatives permit for wider and faster data collection, as opposed to more traditional ways of healthcare research, follow-up and analysis work.

In Europe but also worldwide we observe an emerging tendency towards data altruism for the common good, remarkably in the field of health. Taking as starting point a compilation of citizen science projects in the European Union (EU), including as well the United Kingdom, with a focus on health and healthcare, we explore the different types of projects, their operational frameworks as well as their supporting mechanisms, be it private or public entities, non-governmental organizations and other working groups – internal or external to the projects.

Departing from the challenges faced by citizen science projects in healthcare, including the lack of a commonly accepted definition of citizen science, we investigate how the pandemic has led to an increase in citizen science projects in the sector of healthcare research. Specifically, we explore the role of law and policy and the respective discourse. We look into EU's policies and current regulatory debates regarding citizen engagement in healthcare research in general (before Covid-19) and in Covid-19 research in particular, and we identify differences and changes, for example derogations, which facilitate innovative types of research in the context of an epidemiological emergency. We conclude with comparative insights from other more popular types of citizen science projects, for instance from the sector of environmental action.

## **Evaluation of the necessity-based model and consent-based model for the processing of biosamples and health data in clinical biobanks**

*Noemi Conditì, PhD at Bologna University*

As collections of biosamples and related (health) data, biobanks are essential infrastructure for developing personalised medicine and conditions for realising the highest attainable standard of health. However, it is important to carefully balance public interests in conducting scientific research and the patients/data subjects' rights, especially the need to respect for privacy and autonomy.

When it comes to biobanks and bio-banking research, among the legal basis set forth in the GDPR, two main models might be identified to ensure lawfulness of the processing of samples and health data (i.e. special categories of personal data as per art. 9 GDPR) for scientific research purposes: the necessity-based model and the consent-based model.<sup>1</sup> In the first case, the processing is necessary “for archiving purposes in the public interest, scientific or historical research purposes” (art. 9(2)(j) GDPR) or “for reasons of public interest in the area of public health” (art. 9(2)(i) GDPR), while in the second data and samples are processed after prior consent has been given by the patient.

The aim of my presentation is to evaluate advantages and disadvantages of each of the proposed models in the context of the development and management of clinical biobanks. Indeed, these biobanks usually contain biosamples collected in the course of medical treatment and are placed at the interface between clinical practice and scientific research, whose results might be used to improve the health care of those patients that provided samples and data to that purpose.

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