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Dear EAHL members,

This year is coming to an end, and 2020 has for all been an extraordinary year. The pandemic is first and foremost a tragedy for those personally affected by the disease being severely ill or having suffered loss of their beloved ones. Many persons have also experienced financial hardship due to unemployment. For health law lawyers, one may say that a rather unexplored part of the field came to the forefront. In all countries, health law is used as a tool to control the pandemic, e.g. by introducing social distancing and prioritization access to health care and vaccination. You can read more about this in our previous newsletter, which was highly welcomed by the EAHL members and reminds us about what EAHL can do if we join or academic forces.

This special issue of the newsletter contains abstracts from the PhD seminar that EAHL organized earlier this month. The original idea was to have a seminar in Brussels, but it was during the summer clear that plans had to be changed and the event moved online. It was inspiring to listen to the discussions between the PhD students and the abstracts are the main content of this newsletter. You can see that the projects cover various topics within health law, both classical and contemporary issues, and indicates a bright future for European health law.

Stay safe, keep distance and all the best for 2021,

Karl Harald Søvig
The patient’s right to access to psychiatric records: doctrine and jurisprudence

Anatoliy A. Lytvynenko

Access to medical records is well-recognized as one of the basic rights of the patients. Despite medical legislation is relatively young, the worldwide case-law has witnessed actions for medical records production for already a century, despite it has been widely known for a couple of decades. The purposes for an insight into medical data may be different – from preparing medical malpractice actions or recovering an insurance policy to challenging a testament, divorce proceedings and various private needs. Though all the medical records are deemed as sensitive data, the records concerning a patient’s psychiatric treatment, diagnosis and prognosis are considered even more highly confidential. However, psychiatric records are also not bound to be inspected by the patients. The regime of such access is mostly far more strict than of ordinary medical records, but the legislation of many states is silent towards the distinction between these records and the possibility of insight to them, remaining this complicated issue for the courts to decide. The purposes for access to psychiatric records may considerably vary from insight into ordinary medical records and the hospitals are frequently reluctant to produce them finding it could endanger the health of an ex-patient, or resurrect his old ailments. The current position of the courts is for allowing the production of such records though not disregarding the necessary precautions: some courts found that the insight must be limited, justified by the plaintiff and the records should be inspected in the presence of physicians. The right to access to psychiatric records may also arise more complexified aspects, such as disposal of minor psychiatric records, or a plea to expunge psychiatric records in an analogy with criminal records. Civil or administrative proceedings in respect with access to psychiatric records are relatively rare and the courts often substantiate their judgments upon the trial facts regarding the health and mental condition of the patient as well as his justification to inspect such records.
Big Data in IoE in healthcare emergencies: analysis of autonomous emergency response systems in healthcare emergencies

Aiste Gerybaite

Sophisticated IoT devices are now able to process and monitor real-time undesirable events and provide real-time alerting in accidents involving elderly people, predict outbreak of the diseases, or provide emergency response management in pandemics such as the current Covid-19 crisis. Due to the multidimensional nature of healthcare emergencies, the use of Big Data in such emergencies poses a number of questions, not only with respect to the precise definition of an emergency, the agencies involved, the procedures used, but also questions with respect to securing data protection, privacy, and the right to health in such emergencies without hindering the potential benefits of the development of Big Data solutions within healthcare sector.

Currently, the research in the healthcare sector focuses either on the development of the ICT solutions for the sector (e.g. various medical devices) or on the regulatory requirements applicable to the sector. Yet, Big Data, privacy and data protection issues tend to be overlooked. In particular, the healthcare sector tends to overlook the two dimensions of healthcare emergencies, the public healthcare and the individual healthcare emergency dimension, and its implications to data protection and privacy. The public dimension of healthcare emergencies refers to emergencies such as global outbreaks of diseases (such as Covid-19, SARS etc.). The latter, instead, refers to loss of vital signs by an individual which would not qualify as a public health emergency but, nonetheless, could have a devastating impact on an individual’s wellbeing.

Further, the current state of the art undoubtedly indicates a gap between the appropriate translation and application of fundamental legal research into concrete scenarios with specific ICT technologies used in healthcare sector. As the ethical-legal research world focuses on fostering a high-level discussion on Big Data, healthcare and IoE, the ICT sector wonders what all this means to their specific scenario.

The research topic therefore aims at exploring the complex relationship between Big Data tools used in healthcare emergencies, specifically, emergency response systems, and the right to privacy and data protection and how the change of such notions in the digital environment affects Big Data tools. The aim of the research is to analyse how the ICT tools used in such healthcare emergencies allow to strike the balance between sometimes competing interest of the right to health and the right to privacy. Specifically, the research focuses on the analysis of the ICT tools used for public healthcare emergencies, taking as an example tools used for Covid-19, such as the contact tracing apps and immunity passports. On the other hand, the research shall look at the individual dimension of healthcare emergencies, taking as a practical examples heart rate monitors, pacemakers and in-vitro vital sign monitoring tools.

Acknowledgment

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To what extent does international law play a role in addressing obesity?
Lessons from tobacco control.

Citta Widagdo

Obesity is one of the greatest public health challenges of the 21st century. Its prevalence has tripled in many countries of the European Region since the 1980s and the numbers of those affected continue to rise at an alarming. Current Covid-19 pandemic has further exacerbated the obesity epidemic to ultimately become a political concern.

This research aims to explore the role of international law as a response to the epidemic. I use the World Health Organisation Framework Convention on Tobacco Control (WHO FCTC) as a model of a powerful legal instrument used by countries to implement tobacco control measures and as a substantial tool to defend them against legal challenges initiated by the industry. In addition to the 167 nation states that have become parties to the Framework Convention, the European Union is the only and first-ever regional economic and political organisation that has become a full signatory member and party to the WHO FCTC. This research also uses landmark legal cases to see the impact of WHO FCTC in implementing public health policies in domestic courts.

The current global health law approach to obesity prevention is at an early stage of development. While non-binding instruments have been adopted, they are insufficient, rely heavily on voluntary self-regulation, and cannot establish the primacy of the right to health against lack of policy coherence. Examples will be taken from various reports in domestic countries, such as the year-long investigation by the UK House of Lords Science and Technology Select Committee that examined the effectiveness of nudges in the UK, demonstrating ineffectiveness of non-regulatory measures. A treaty has the greatest potential for creating powerful norms to implement due to its legally binding nature that can strengthen enforcement possibilities whilst increasing political pressure to comply, as well as uniting nations through stronger global health leaderships.

This research seeks whether the WHO or the United Nations need to implement a new global health treaty, modelled by previous tobacco control. It will ultimately conclude that a binding international agreement, rooted in the right to health and the right to food, has untapped potential to improve global health by establishing norms, targets, specific obligations, and accountability mechanisms in addressing obesity.
The promotion of public health in EU external relations

Elisabet Ruiz Cairó

At a time where public health makes all the headlines and multilateralism is increasingly contested, this research examines how the European Union promotes public health standards in its foreign policy and evaluates the effectiveness of such action. The study aims at two sub-objectives: an examination of the constitutional framework governing EU public health, with a particular emphasis on its external dimension, and an assessment of the factors influencing the effectiveness of the promotion of EU public health standards at the global level.

EU public health is characterised by a fragmented constitutional framework. The European Union adopts public health legislation on the basis of several provisions in addition to Article 168 TFEU, notably the internal market and the environmental policy. EU public health actions are undertaken under a complex institutional setting characterised by the varying role of EU institutions depending on the legal basis of the measure under scrutiny. The limited EU competence in public health implies the need to coordinate national and EU measures. The increasing role of EU agencies adds a layer of complexity by bringing additional actors to the scene. In its global health action, the EU status in health-related international organisations and agreements strongly varies on a case-by-case basis.

Under these circumstances, the research reveals that several factors influence the successful promotion of EU public health standards at the global level. The alignment between EU interests and those of its negotiating partners is crucial in the outcome of the negotiations. The Union’s competence in a certain area, its status in the international organisation concerned, the existence of an attractive bargaining tool in the negotiation or the expertise previously developed by the Union in a certain area will also be determinant in the effective promotion of public health standards by the European Union.

While the research attempts to undertake a horizontal study of EU public health, it is illustrated by numerous case studies. These include the Union’s external promotion of tobacco-control legislation, its role in the fight against cross-border health threats, the balance of trade interests and public health in bilateral trade and investment agreements, and the position of the Union towards intellectual property rights and public health at the WTO.

This work lastly proposes a number of measures that could enhance the EU external public health action and points at several aspects of this area that should be further researched. A strengthening of EU public health competences, an effective application of the principle of sincere cooperation between the Union and its Member States, and a clarification of the relationship between public health and EU principles should be the main priorities in this area.
Late-term abortion: 
A comparative analysis of regulatory frameworks and legal challenges

Fien De Meyer

Abortion of a viable foetus (henceforth late-term abortion) continues to be a highly contentious topic. This doctoral research is the first to systematically, and by way of international comparison, analyse the challenges that late-term abortions pose for medical, criminal, and human rights law. The focus will be on the legal tension that may exist between the legal recognition of the interests of the viable foetus and the rights to self-determination of the pregnant woman, which may impact significantly upon the physician’s duty of care. The research will give particular attention to the Belgian context, motivated by the new Belgian Abortion Law (2018) and the recent Belgian legislative proposal to amend the Abortion Law (2019-2020). In light of these legislative developments, particular attention will be paid to the concept of *comprehensive decriminalisation* and its implications for the legal status of late-term foetuses. To inform the legal analysis and resulting recommendations on abortion legislation, socio-legal qualitative interviews will be conducted with Belgian gynaecologists performing abortions after the legal limit for abortion on request (12 weeks post-conception).

Summarised, the research will aim to answer the following questions:

- What legal challenges does the Belgian law on (late) termination of pregnancy currently pose, and (how) are these addressed by other countries (the United Kingdom, Ireland, the Netherlands)?
- How do Belgian gynaecologists interpret and apply the current law on later termination of pregnancy in practice?
- What would comprehensive decriminalisation and medicalisation of abortion mean for the Belgian law and practice relating to late-term abortion (drawing on lessons from the decriminalised abortion law frameworks of Australia, Canada, and New Zealand)?

The research will result in general recommendations on the regulation of late-term abortion in Belgium, which may inform and inspire other states that are considering abortion law reform.
EU regulation of algorithmic decision-making in health: safeguarding patients’ rights in the era of artificial intelligence

Hannah van Kolfschooten

Artificial intelligence (AI) is often referred to as “the new electricity”,¹ as it holds the potential to transform society in the same way electricity did. It seems indeed inevitable that the growing use of computer systems that are capable of exhibiting or simulating human-level intelligence will profoundly affect our lives.² AI is the umbrella term for systems designed by humans that display rational behaviour by analysing their environment through the collection and interpretation of data and subsequent reasoning and processing of information derived from this data, then deciding on the best action to achieve a given goal, and acting accordingly.³

The European Union (EU) is on the brink of an AI revolution in the health sector. AI technologies can be deployed for arguably every aspect of healthcare and public health: from AI-software to detect breast cancer in screening mammograms⁴ and AI-algorithms predicting outbreaks of infectious diseases,⁵ to fully autonomous robotic surgeons.⁶ AI-driven technologies will likely change the patient-physician relationship.⁷ AI holds the promise to save billions of lives by improving the quality of healthcare, reducing costs, increasing accessibility of healthcare and anticipating health emergency threats.⁸ However, while its potential benefits are tremendous, the emergence of AI-technology in the sphere of health harbours numerous threats to individual fundamental rights of EU citizens. Known hazards associated with AI such as discrimination, diminished privacy and opaque decision making are exacerbated in the context of health.⁹ A lack of adequate regulation of health AI may compromise patients’ rights.

An important part of the regulation of AI in the health sector will take place at the EU level. The European Commission has recently put forward a European approach to AI, with special emphasis on ensuring a solid European ethical and legal framework.¹⁰ It is assumed that the current EU regulatory and legislative

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² This definition was based on the definition of ‘artificial intelligence’ in the Oxford English Dictionary.
³ Independent High Level Expert Group on Artificial Intelligence, ‘A Definition of AI: Main Capabilities and Disciplines’ (2019).
⁸ M Matheny and others (eds), Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril. NAM Special Publication. (National Academy of Medicine 2019).
framework for health technology is not adapted to the specific challenges AI brings about. The approach states that, in order to make AI part of the EU society, it is necessary to “create a unique ecosystem of trust”. It is however questionable whether this approach for AI, based on the value of trust, is suitable for implementation in the healthcare and public health sector in terms of patients’ rights protection. Therefore, this thesis aims to address the following question: How can EU regulation of algorithmic decision-making in public health and health care be designed in a manner that sufficiently safeguards patients’ rights, the right to health privacy and informed consent in specific?

This thesis will map current efforts of the EU to regulate AI in relation to health. In this context, particular attention will be paid to the constitutional aspects of this regulation. It will conduct three case studies: the use of AI in public health surveillance, AI-driven medical imaging for diagnostics and the use of AI in assisting clinical decision-making. All case studies will be considered from the perspective of patients’ rights and placed within the normative framework of “trust in AI”.

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11 ibid.
12 ibid.
Leveraging of Big Data to improve Healthcare decision-making

Kaat Van Delm

My research is part of an interdisciplinary FWO project concerning the “Leveraging of Big Data to improve Healthcare decision-making”, a cooperation between the KU Leuven, Ghent University and the Ghent University Hospital. In the framework of my PhD, a legal analysis is performed of the opportunities which big data, and specifically routinely collected data (RCD), contain for the improvement of EU healthcare decision-making. A comparative analysis is performed with U.S. health law where relevant. The main research questions are the following:

Can the EU health law framework be applied to the use of RCD in all phases of the medicines and medical devices lifecycles, and does such application align with the regulatory objectives spulated in such legislation?

What are the implications of the use of RCD on the liability regimes in place, especially when relied upon in the context of accelerate access to new medicinal products, and what are the implications for the EU institutions’ role and responsibilities?

How should liability be determined in the context of the manufacture or use of autonomous healthcare systems relying on RCD in the EU?

So far, a first exploration has been performed of the EU regulatory health law framework and its applicability in an RCD context. In addition, the various procedures available for accelerated access to new medicinal products have been analysed as well at EU level, as at U.S. federal level. This topic proved to be especially interesting in the context of the Covid-19 crisis.
Test tube law to the test

Lina Oplinus

In varietate concordia (united in diversity). This motto of the European Union is certainly true regarding the regulations of the (ex-)member states on assisted reproductive technologies. Zweigert and Kötz would have been hesitant to comparative legal research in such an ethical sensitive field. However, this presentation puts the laws on assisted reproductive technologies of Belgium, the United Kingdom and France to the test.

The comparative analysis is embedded in a wider PhD-project. It investigates how the Belgian legal framework governing assisted reproductive technologies can be made more appropriate. A legal framework is appropriate when it is:

- Certain: it ensures that practitioners as well as patients know which techniques are allowed under which conditions,
- Durable: it is able to cope with new assisted reproductive technologies,
- Consistent: it deals with all relevant factors of the assisted reproductive technologies and no conflicting rules apply,
- Coherent: it regulates all assisted reproductive technologies in the same way.

The first part of the research revealed that the Belgian legal framework is inappropriate on certain points. The second part of the research aims at fixing those points. One way to do this, is to look into the legal frameworks on assisted reproductive technologies of other jurisdictions. The focus on the legal frameworks i.e. the structure of the regulation and not on the content of the rules itself, circumvents the criticisms from comparative lawyers. It is, for example, not the aim of the PhD-project to determine what an appropriate age limit for assisted reproductive technologies is and if such a limitation to reproductive freedom is allowed, but how those rules can be framed in a certain, durable, consistent and coherent way.

The legal frameworks of the United Kingdom and France are tested in order to determine if they are more certain, more durable, more consistent and more coherent and as a consequence can help to ameliorate the Belgian framework. Both jurisdictions were carefully selected. The French Loi Bioéthique obliges the regulator to review its provisions after a certain period of time. Hence, it is to be expected that the French legal framework is more durable than the Belgian which lacks such rule. The legal framework in the United Kingdom is remarkable, because it established an at arm’s length body in order to monitor and license certain assisted reproductive techniques, the Human Fertilisation and Embryology Authority (HFEA). The HFEA has a statutory duty to publish a Code of Practice which contains detailed rules which the fertility centres need to abide in order to obtain and keep their license. The Code of Practice is regularly updated. As a result, it is not unreasonable to assume that the legal framework of the United Kingdom is more certain and durable.

The presentation reveals the results of the tests of the legal frameworks of Belgium, France and the United Kingdom in light of post mortem reproduction. Who will pass and who will fail this competition?
Health Technology Assessments and the international right to health

Luciano Bottini Filho

Health systems always have to respond to scarce resources. One measure that has become central to address this problem is Health Technology Assessments (HTA), a comprehensive multidisciplinary study of the economic, medical and social aspects of health treatments to determine the best healthcare alternatives. This process has largely relied on scientific and economic research, but recently scholars have become more aware of the need to include ethical, social factors and, not least, legal matters. An HTA institutionalisation normally requires legislation and internal regulations that will impact on the introduction of new technologies, with Courts also involved in reviewing the validity of those recommendations. Internationally, those legal frameworks and subsequent judicial challenges will impact upon the right to health. This research, therefore, aims to examine whether the international right to health can provide a normative foundation for HTA.

This main question lead to a range of sub-questions: 1. which legal aspects of HTA can be related to an HRBA regarding to a) procedures and b) substantive criteria? 2. how can law and human rights be generally represented within HTA recommendations? 3. how to set priorities in HTA with multiple growing frameworks such as the Sustainable Development Goals and Global Health Law?

To address these topics, I employ basic socio-economic rights norms under the International Covenant on Economic, Social and Cultural Rights (ICESCR) in the context of HTA. Comparing the grounding rules of resource allocation for socioeconomic rights with other instruments now available broadly under the banner of Global Health Law, including the Sustainable Development Goals, I pursue an interpretation focused on Article 2.1 of the ICESCR as the best basis for an HRBA in resource allocation. Fundamental to this analysis are general socio-economic rules, such as progressive realisation, maximum available resources, and international cooperation and assistance.

Despite its developing importance to global health and health system capacitybuilding, no specific study has systematically analysed the role of law in HTA, save for examining judicial decision on healthcare rationing. The right to health has commonly been associated with procedural fairness in HTA and procedural review by courts.

My argument is that law has also a substantive effect on resource allocation in HTA not only limited to procedural principles (transparency, participation, review of a decision or reasonable criteria). Because scarcity is a result of substantive policies influenced by law (procurement, market regulation, price negotiation, taxation, etc.) it is impossible to determine the fairness of a decision only through compliance with a fair process in HTA. I maintain that the international right to health (under Article 2.1 of the ICESCR) offers the grounding principles to an alternative stance based on the notions of “maximum available resources” and “progressive realisation” of socio-economic rights. In this sense, an HRBA to HTA refers to a fair process that also engages with the causes of scarcity with coordinated policies conditioned to law in areas such as procurement, price regulation and product development agreements.
Do people living with HIV enjoy on an equal basis with others their right to health in Spain?

*Maria del Val Bolívar Oñoro*

The thesis is premised on a broad understanding of the right to health that includes the non-discriminatory access to healthcare as established by the Committee on Economic, Social and Cultural Rights on their General Comment No. 14. The right to protection of health is a widely recognized right in the international context, but its nature is socioeconomic. This classification has led to the establishment of the obligation of the States to converge towards the full realization of this right, but only within the limits of available resources. This formulation has granted sufficient flexibility so that, in crisis contexts, such as the one that Spain has been experiencing, regressive measures have been taken in terms of health care, such as the elimination of subsidization of thousands of drugs. In this context, people have been forced to decide whether to pay for some health services and products to obtain them. To escape from this situation of insecurity, since it is not possible to predict when the next regressive measures in health care will take place, the population has been contracting private health insurance.

Against this background, in order to answer the main research question, my thesis examines first to what extent people living with HIV are discriminated against when trying to purchase a private health insurance on the basis of their health status. It then examines the role played by the freedom to conduct a business in this context, and, ultimately, how a human rights-based approach could help guarantee the highest standard of health protection for people living with HIV.
Mind the gap: Legal governance of emerging health technologies from a human rights perspective

Renée Dekker

Due to medical-technological developments, the use of wearables, big data, AI, and bionic services is rapidly increasing, and healthcare is only a small step away from providing generally accessible human enhancement services. In regard to these developments technology companies have become healthcare providers and in their new role the "healthcare treatment" is provided without intervention of a traditional GP or hospital. However, existing laws and regulations are still geared to traditional healthcare "acts in the field of medicine". As it stands, emerging medical technology services will come with a "legal gap" with respect to upholding relevant national, European and international rules that aim to protect the human right to self-determination. This gap manifests itself in how the recipient of the service of the medical-technology company finds him/herself in a similar dependent position as would have been the case under traditional healthcare, but without the traditional legal protection. In addition, the nature of the aforementioned companies is transnational, so legal rules need to be set at above national level.

This leads to the following research question: How can legal safeguards for a proper healthcare level under international and European law be effectuated in respect of new medical technology healthcare services, as a safeguarding system of legal healthcare governance that balances between the future tech-med potential of the 'healthcare companies’ and the need to protect the recipients right to self-determination?

Main subquestions to answer the research question:

1. What are the main legal implications of the medical-technological developments in regard to the legal relationships between the careworker, careprovider and the patient at a national, European and international level?

2. Which legal principles of health law and other related advice and guidelines determine the (minimum) level of protection that the recipient is entitled to under international and European law?

3. To what extent have European and international principles of law been effectively implemented at national level in terms of safeguarding human rights with an eye on the new dynamic in healthcare (due to medical-technological developments)?

4. To what extent can human rights be safeguarded at national level in view of the newly created relations between the recipient and the (care)provider of the new medical-technical care services, in view of their multinational and transnational character?

5. What alternative safeguard mechanisms can be found? (for effective protection of human rights on the one hand and is able to support medical-technological developments on the other hand?)
Internet of Healthcare (Law):
Privacy and Data Protection Aspects in an Internet of Everything

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The promise of an Internet of Everything in healthcare (‘Internet of Healthcare’) is that smart devices and intelligent connections can leverage health-related data to deliver the right information to the right person (or machine) at the right time and in the right place. Enhancing sharing of health-related data could generate increased value for stakeholders across the health data ecosystem by fuelling innovation and driving better health outcomes. Despite its potential to increase medical intelligence and support decisions affecting health, the possibility of tracking and analysing the health of citizens/patients raises significant legal, ethical, security and trust concerns due to risks posed by unjustified interferences with privacy and/or illicit access to or processing of personal data. With regard to the foregoing, the aim of this research project is to study risks and benefits associated with sharing health-related data in an emerging Internet of Healthcare. Accordingly, the thesis asks: what legal tools and supplementary measures are available to facilitate the benefits of sharing health-related data while ensuring respect for privacy and adequate protection of personal data in telehealth?

The thesis explores the research question from multidisciplinary (normative, ethical, technological, data governance and stakeholder) viewpoints and under the scope of European (EU/EEA/CoE) jurisdiction. The research builds on the paradigm of an Internet of Everything to conceptualise health-related data sharing practices in telehealth. This framework offers new perspectives for a critical analysis of whether privacy and data protection rules relevant to the sharing (including international transfers) of health-related data provide adequate and effective safeguards for citizens/patients (data subjects) in telehealth. The theoretical background also helps to map current privacy and data protection risks and identify possible mitigation strategies concerning the use of telehealth technologies and applications for the purpose of sharing health-related data.

The thesis conducts research analyses across four dimensions and use cases of telehealth. First, by analysing the objectives and data strategies of key stakeholder groups in the telehealth market and by outlining underlying data value chains. Second, by examining data protection and data governance challenges relating to the connection of national eHealth infrastructure with public and third-party telehealth services on the basis of ongoing developments in the Electronic Health Service Space of Hungary. Third, by investigating legal interoperability challenges arising in relation to the use of citizen/patient-centred digital health passport applications and smart electronic health datasets. And finally, with regard to the recent uptake of telehealth technologies and applications in human resource management, by studying what a reasonable expectation of privacy should be in case of being subject to the monitoring of employee health and well-being. These research findings will facilitate progress towards the identification of best practices concerning the sharing of health-
related data in telehealth, which could help to strengthen the legal protection of citizens/patients and the trust of relevant stakeholders in exploiting the potential benefits of an Internet of Healthcare.

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Sarah von Droste

Human health is the ultimate guarantee for a thriving union, for a stable economy and for a living solidarity thus it is a vital pillar of the European Union, even though health lies within the sovereignty of each Member State of the EU. The recent pandemic outbreak of the COVID-19 virus has shown us the limits but also the possibilities of the European Union. In these past months the EU as well as the actions of each Member States have been under close observation, we witnessed how solely some acted but also how solidarity was lived amongst those countries who needed help. However, due to these seemingly uncoordinated events on the part of the EU, Euroscepticism has risen again, but we have to ask ourselves, is this even a valid scepticism? Is it based on legal truth? Is the EU doing all what is in its powers or is it using just half of its potential? And does the EU need more competences?

Currently the EU Member States are coordinating their responses and the EU is expanding its involvement in human health, despite its limited legislative competences. However, there are a number of legal, institutional instruments and informal mechanisms available at EU level to respond to a public health crisis. Therefore, this thesis aims to analyse the competence framework of the EU with regards to health and then more detailed with regards to its competences during a crisis management of a pandemic outbreak. The possibilities which are given within the Treaty of Lisbon and in particular with the Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health will be thoroughly examined. Past pandemics as the swine flu and the Ebola virus will be under closer examination with regards to the reactions and actions in comparison to COVID-19 to identify which mechanisms are needed. Consequently, the scope of the EU will be analysed and if all existing measures have been used by the EU to tackle this crisis or if the EU is in need to rethink its competences with regards to health.
The legal issues involved in cross-border access to end-of-life services in Europe

Sien Loos

Due to the increased globalisation of healthcare, medical tourism has become a multibillion-euro industry and several countries have become hubs that provide specific types of healthcare services. Although medical tourism has attracted a lot of attention from legal experts, there is one controversial form of medical tourism that has not yet been the subject of a thorough legal analysis: patients travelling across borders to access end-of-life services. Within Europe, cross-border access to end-of-life services is quickly gaining in importance. Around the year 2000, the first media reports appeared of patients travelling to get assistance in terminating their lives. These involved German and UK citizens travelling to Switzerland for assisted suicide by making use of the services of right-to-die organisation Dignitas. More recently, at the end of 2016, the first reports appeared of – mainly French – patients travelling to Belgian hospitals for euthanasia. By now, Belgium has become the main country of destination for EU citizens who wish to be euthanised.

Currently, considerable legal research is being devoted to comparing the national regulatory frameworks of assisted suicide, euthanasia, and palliative care. Similarly, the conformity of national regulations with international human rights law receives extensive attention. What is lacking is a systematic analysis of the legal challenges that arise when EU citizens want to access end-of-life services in another EU Member State. My research therefore aims at filling the gaps in the existing literature by providing such an analysis. The ultimate goal of this research project is to provide an overview of legal measures that may constitute legitimate restrictions to cross-border access to end-of-life services, as opposed to measures which cannot be justified in light of human rights law, EU law, and/or international private law.

During this seminar, I will analyse the phenomena of euthanasia and assisted suicide from the perspective of both human rights law and EU law. First, I will shed a light on the human rights framework concerning assisted dying, which will be established through an assessment of a handful of high-profile cases that have come before the European Court of Human Rights. More specifically, I will address the question as to what margin of appreciation is awarded to states: (1) to restrict foreigners from accessing assisted dying services on their territory; and (2) to restrict their citizens from accessing these domestically prohibited end-of-life services abroad. This will result in a general conclusion, laying down the human rights principles that EU Member States have to abide by when regulating assisted dying.

Second, I will delve into secondary EU law and the case law of the Court of Justice of the EU in order to determine whether euthanasia and assisted suicide fall within the scope of EU law. The main question to be answered here is whether these interventions can be classified as a service under the Treaty on the Functioning of the European Union and thus whether free movement law must be respected by the national authorities of the Member States when restricting cross-border access to euthanasia and assisted suicide.
New Realities of Clinical Research: Fair Allocation of Data Control and Responsibility

Teodora Lalova

The clinical trials field is highly complex and requires the shared efforts of a multitude of actors: sponsors, investigators, patients, biobanks, ethics committees, regulators. Rapid developments of new technologies (AI, precision medicine) are currently putting the system to the test. Clinical trials have to be conducted more frequently on a pan-European scale, as the genetic mutations that would respond to precision medicine in new therapies would often be rare, hence patients would have to be recruited cross-border. The COVID-19 pandemic and the national lockdowns provided another example of the novel challenging contexts in which clinical research has to be conducted. In the EU, the applicable legal framework consists of highly divergent Union and national laws, most of which were not created with the new realities of clinical research in mind.

From a theoretical perspective, the focal point that permeates them all is control over health data, thus positioning the interplays with the data protection rules at the centre of the PhD project. The study sets out to investigate the preparedness of the EU legal framework for the new realities of clinical research. To that end, it aims to situate clinical research in precision medicine and pandemic contexts, as two of the main examples of change; and to identify the main challenges when it comes to control over health data. The final goal is to evaluate the findings and propose adjustments to the current legislation. The project employs a mixed-methods design. Traditional desk research is complemented with empirical research (semi-structured interviews and surveys). At the current stage of the PhD, cross-border access to clinical trials has been investigated via the conduct of 38 interviews and a survey with 396 responses from key stakeholders. In addition, the interplay between the General Data Protection Regulation and the Clinical Trials Regulation have been investigated, with a particular focus on issues concerning secondary use of personal data.

Sharing of health data for healthcare and health research

Tjaša Petročnik

Tjaša Petročnik is a 2nd year PhD researcher at the Department of Law Technology, Markets, and Society at Tilburg Law School. She focuses on sharing of health data for innovation, in particular on the role of large consumer technology corporations in the health sector, applying an economic regulation angle.
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**Women’s Birthing Bodies and the Law**
Unauthorised Intimate Examinations, Power and Vulnerability
Edited by Camilla Pickles and Jonathan Herring

This is the first book to unpack the legal and ethical issues surrounding unauthorised intimate examinations during labour. The book uses feminist, socio-legal and philosophical tools to explore the issues of power, vulnerability and autonomy. The collection challenges the perception that the law adequately addresses different manifestations of unauthorised medical touch through the lens of women’s experiences of unauthorised vaginal examinations during labour. The book unearths several broader themes that are of huge significance to lawyers and healthcare professionals such as the legal status of women and their bodies.

The book raises questions about women’s experiences during childbirth in hospital settings. It explores the status of women’s bodies during labour and childbirth where too easily they become objectified, and it raises important issues around consent. The book highlights links to the law on sexual offences and women’s loss of power under the medical gaze.

*Women’s Birthing Bodies and the Law* includes contributions from leading feminist philosophers, healthcare professionals, and academics in healthcare and law, and offers pioneering analysis relevant to lawyers and healthcare professionals with an interest in medical law and ethics; feminist theory; criminal law; tort law; and human rights law.

*Camilla Pickles* is Assistant Professor at Durham Law School, Durham University.
*Jonathan Herring* is Professor at the Faculty of Law, University of Oxford.

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A Comparative Perspective
Edited by Imogen Goold, Cressida Auckland and Jonathan Herring

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Contextualising the differences and similarities, and drawing out the cultural and social values that inform the approach in different countries, this volume is highly valuable to scholars across jurisdictions, not only to inform their own local debate on how best to navigate such cases, but also to foster inter-jurisdictional debate on the issues.

The book brings together commentators from the fields of law, medical ethics, and clinical medicine across the world, actively drawing on the view from the clinic as well as philosophical, legal and sociological perspectives on the crucial question of who should decide about the fate of a child suffering from a serious illness.

In doing so, the collection offers comprehensive treatment of the key questions around whether the current best interests approach is still appropriate, and if not, what the alternatives are. It engages head-on with the concerns seen in both the academic and popular literature that there is a need to reconsider the orthodoxy in this area.

*Imogen Goold* is Associate Professor and *Jonathan Herring* is Professor, both at the Faculty of Law, University of Oxford.
*Cressida Auckland* is Assistant Professor in the Department of Law at the London School of Economics and Political Science.

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Prue Vines is Co-Director of the Private Law Research and Policy Group at the Faculty of Law, University of New South Wales.

Arno Akkermans is Director of the Amsterdam Law and Behaviour Institute at the Vrije University, Amsterdam.

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