GUEST EDITORIAL

Towards more comprehensive health law and policy research

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Abstract
In this comment, and drawing on the papers in the special issue, we ask: what are the core questions for the future of research into health law and policy, and European health law and policy more specifically? We first sketch the general functions and values of health law and policy. We then outline how these functions and values are affected by globalisation and Europeanisation, on the one hand, and technological change and digitalisation, on the other. In light of these developments we carve out some questions for future research and the implications of this agenda for the academic community that is working on European health law and policy.

1. Introduction

When we started writing this short overview of the direction and scope of health law and policy research as it relates to and involves Europe – including the EU, the World Health Organization (WHO) Europe Office and the European Court of Human Rights (ECHR) framework – COVID-19 was nowhere on the horizon.[1] The policy backdrop for the meetings of scholars working in this field was that, in light of Brexit, changes under the Juncker Commission and the aftermath of the financial crisis, we felt that there may be a need to reconfigure or reassess the research agenda regarding the EU's laws and policies for human health.[2] Now, in the throes of COVID-19, transnational and EU solidarity is being tested seemingly to its limit – even more than during the financial crisis in 2008 – and calls for more central roles for the EU and the WHO suggest that the need to look beyond the state, to European, global and transnational sources of governance, is increasingly recognised. In short, the field seems to be as alive as ever.

Those of us who have been working on this topic for 10 years or more are observing an unprecedented, seemingly overnight expansion of the research space and of scholarly interest in the field of EU and global health law and policy. This increased interest is something that we can expect to last for the next few years, but there will be a time – we are sure of this – where health will not be as high on the EU political and research agenda. To some extent, this does not matter. Research into the nature and implications of EU health law and policy does not necessarily need to sync up with the agenda of international organisations generally, or the objectives of the EU Commission and the transnational legislative agendas of the member states, specifically. However,

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[1]'European health law' refers to the broader scope beyond the EU (including ECHR), 'EU health law' refers to the law and regulations that originate in the EU, where the ECHR is also an important legal source.
[2]This discussion took place as part of the *EU Health law and Policy – Shaping a Future Research Agenda* project.

it is clear from the history of the field, and work done prior to the current, salient moment, that this is not a topic of temporary relevance.

The impact of developments at the global and regional, as well as the national and local, levels for the functioning of health systems and the health of populations is well established. Much of the commentary emerging from the current 'bubble' in interest, mirrors that which has preoccupied the field for decades previously – namely, where authority in health lies and whether this is the right location. Whilst these are important questions, we posit here that the challenge for the field of health law and policy is to accept multi-level authority as a given. As the discussions on the future of research into European health law and policy that led up to this special issue illustrate: the location of authority in health governance – whether institutionally embedded 'where it belongs' (de Ruijter, 2017a, b) at the local, national or regional level – is important for implementation and accountability. However, in the end it makes no difference to the reality of the deep impact that health law and policy generally has upon health systems, their governance and, ultimately, the individuals' experience of health care (Hervey and McHale, 2015; de Ruijter, 2019, Gostin, 2019).

In this comment, and drawing on the papers in the special issue, we ask: what are the core questions for the future of research into health law and policy, and European health law and policy more specifically? This question, for the short to medium term, cannot be answered without taking into account the implications of COVID-19, and we consider some of these here. In taking a broader approach to the objectives of the special issue, we first sketch the general functions and values of health law and policy. The purpose of this is to present the foundations of the field and, therefore, to help draw the scope of possible future research endeavours. We then outline how these functions and values are affected by globalisation and Europeanisation, on the one hand, and technological change and digitalisation, on the other, whilst keeping in mind that many of these issues are touched on much more elaborately by the contributions of the special issue. In light of these developments we carve out some questions for future research and the implications of this agenda for the academic community that is working on European health law and policy.

2. Values and functions of health law and policy

Health[3] law and policy developed over the course of the 20th century partly in response to the atrocities of the Second World War (Marrus, 1999; Frewer, 2010), but also in tandem with human rights and bioethical developments, where the principles of patient autonomy, self-determination and solidarity were central to re-shaping both horizontal and vertical relations between doctors, patients, payors and governments (Hervey and McHale, 2015; de Ruijter, 2017a, b, 2019).[4] However, it was certainly not a new phenomenon; public health and sanitary regulation were already in place, and international legal instruments governing health were in existence, long before the 20th century (Rosen, 1958; Frewer, 2010; Freeman, 2014). The academic recognition of health law and policy as a separate legal field is more recent (Giessen, 1988; Burris and Anderson, 2013). In the European context, it has revolved around various interrogations as to why health is such a special case of transnational policy, and how it has fared among the changing dynamics of global and EU (dis)integration. In the case of the EU, our concern has centred on the impact of EU governance upon national health systems, the role of EU law in shaping this impact, and the accompanying political dynamics (Hervey and McHale, 2004; Steffen, 2005; Greer, 2009; Mossialos *et al.*, 2010).

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[3]'Health' as a concept, besides health law and policy, is part of the current conceptual framing of the research agenda. For its purpose here we refer to de Ruijter (2019: 52–58), and the discussion of 'health' in the WHO and EU contexts.

[4]Our focus here is on health law and policy in the European region but it is important to note that this account is very different from that which applies elsewhere. A number of illuminating critiques chart the very different trajectory of health law and policy in countries that were formerly under colonial rule. See, inter alia, Iyioha and Nwabueze (2016), Bennett (2008), Gadd (2005), Sehrawat (2013), Ncube (2012) and Adu-Gyamfi *et al.* (2017).

We commonly explain governments' reluctance to cede power to the EU in the field of health by reference to the latter's economic significance and socio-political consequence. Health services form the centre of nation states' welfare provisions, and in most EU member states health spending is one of the largest single chunks of the national social welfare budget (Przywara, 2010). Moreover, and more so than any other area of public policy, health policy 'often involves matters of life and death… [and thus] is often accorded a special position in comparison to other social issues' (Buse *et al.*, 2012: 5). It has '…a considerable social-psychological dimension when it comes to establishing bonds of trust between citizens and states and maintaining strong state-society relations' (Steffen *et al.*, 2005: 2). This 'special position' means that the State has primary responsibility for the health of its population, and that the population can legitimately expect the State to provide for its health (Gostin and Wiley, 2016: 6). The State fulfils this responsibility by enacting various health laws and policies.

These have two central functions. On the one hand, they regulate the field of health care which, depending upon the nature of the health system, primarily involves horizontal relationships (between health professionals, hospitals, insurers and patients). On the other hand, in the field of public health, laws and policies regulate mostly vertical relationships, such as those between the citizen, public authorities and market actors (communicable disease control, public inoculation programmes, health and safety for products and services, professional disciplinary law and criminal law, in certain countries). These regulatory functions gain legitimacy through enactment of a political process; a democratically elected government acts to protect or promote the health of its population (Gostin and Wiley, 2016: 6).

However, health law and policy is not a neutral site of regulation. Its regulatory function requires it to continuously balance collective rights and benefits against individual freedoms and preferences. A decision that the collective or the individual is more important, and is thus more worthy of protection in the given instance, says something about the values that underpin the health system. These might involve quite specific rights, such as to informed consent or access care services, or much broader values such as universality, solidarity, dignity or democracy. The health law and policies adopted within a given territory are based upon the values that society holds central. As such, through its regulatory function, health law and policy formulates, embodies and makes explicit the goals, values and ethics that underpin national health regimes. The WHO envisages health policy as the tool which specifies the health goals of a society, defines a 'visions for the future' and, perhaps most importantly, builds consensus around that vision (WHO website).

In this sense then, the location of authority in health *is* important. It is important not only economically, since allocation of authority to particular levels will result in more or less efficient system outcomes (Adolph, Greer and Massard da Fonseca, 2012), but also socially, politically and ethically, because shifts in the location of authority raise questions about the legitimacy, substance and underlying principles of health law and policy.

3. Challenges to the function and values of health law and policy: multi-layered sources of authority in the digital, technological age

The normative grounding of health law and policy – its values and functions as introduced above – is not unmoving, but rather has undergone significant change. The world has become increasingly interlinked through the digital revolution and globalisation and, as COVID-19 evidences, society is more populated, interconnected and globalised than ever, which has deep impacts for human health (Huynen *et al.*, 2005). Infectious disease was the founding catalyst of global health governance, and has played both a dividing and a connecting role in the world's human history. For hundreds of years it gave authorities reason to divide, close borders and weaponise infectious diseases, whilst at the same time connecting populations in the common struggle towards health and a good life. In more recent times – as in all other areas of society – globalisation and digitalisation have had important implications of transnational health law and policy.

Global health law and policy scholars have long argued about the public health harms and benefits of globalisation (see Feachem (2001) and critique by, *inter alia*, Lee *et al.*, (2002)). What is clear is that trade, Europeanisation and globalisation more generally have increasingly blurred the lines regarding the authoritative sources of health law and policy (Garcia and Gostin, 2012; Cohen, 2014; Jarman and Koivusalo, 2017). Where states were once the only sources of public authority, commercial actors, non-governmental actors and international organisations, from sectors as diverse as transport, agriculture and security, are now active stakeholders in health law and policy (Kruk, 2012; Hanefeld, 2015). The very fact that 'health diplomacy' has entered the disciplinary lexicon is a signal of the impact of globalisation upon health (Novotny *et al.*, 2013; Poku and Sundewall, 2018) and an indicator of how globalisation transfers ideas and values across borders, reshaping power structures as it goes (Frenk *et al.*, 1997; Thomas and Thiede, 2004).

The EU, as a specific case of regional globalisation, is a prime example of this evolution. Now a significant health actor, it is increasingly constraining and shaping the national health policy space, and creating sources of individual rights that affect access to health care and public health (Greer, 2014; Gostin *et al.*, 2019). The papers in this special issue attest to the diversity and depth of the EU's influence, spanning almost everything from medical device regulation and access to pharmaceuticals, to the fight against antimicrobial resistance and the scourge of mental ill-health. This regulatory influence extends across horizontal, health care relationships and vertical, public health relationships, and is underpinned by a battle between the EU's market-promoting purpose and its stated to commitment to solidarity (Hervey and McHale, 2015). The reality of the Europeanisation of health policy and law is that whilst national governments retain formal control over health, the web of EU health governance continues to grow and to delimit the scope of state control (Hatzopoulos, 2005; Greer *et al.*, 2013; de Ruijter, 2019).

Driving and facilitating this process of globalisation, and changing the face of the delivery and access to medical care and public health, is the rapid evolution of technology (Milio, 2001; Piot, 2012). Patients can access information online and have often already diagnosed themselves before going to a doctor, whilst the possibilities of eHealth in facilitating remote and automated care, for example, are expanding each day. Digitalisation is shaping not only health care, but also public health, where big data and surveillance technology plays an increasingly large role. We only have to think about the discussions around contact-tracing apps in the current pandemic of COVID-19 to see the significance of these developments.

Such changes in the delivery, access and organisation of health care and public health must be met by study of how to safeguard patients from the negative side-effects of these technologies, and how regulation can react to these developments. How can the health provider–patient relationship, as well as the underpinning values of human dignity and fundamental rights, be safeguarded? Health technologies, like the forces of globalisation, change power structures, bridging the public–private divide as never before and elevating the role of transnational and private actors. Health law and policy, at whichever level it is created, needs to protect and promote the positions of vulnerable populations and individual patients in this regard. Technological advances need to be met by adequate governance, supported by a resilient and strong field of health law and policy research, so as to reap the benefits of technology with the utmost care (Flear *et al.*, 2013; Richman, 2018).

4. Implications for health law and policy research: towards a more inclusive and comprehensive field

When we look to the future of health law and policy research, Europeanisation, globalisation and digitalisation are central developments. The COVID-19 outbreak is an unfortunate yet illuminating example of how these various pressures interact, whilst the articles in the special issue remind us that this interdependence is not a new phenomenon.

This reality has clear implications for the practice of health law and policy, but also for the research community. From a practical perspective, the shifting allocations of authority in health governance mean that national health lawyers will not be able to help their clients fully, and health policy-makers will fail to govern effectively, if they do not take into consideration or take advantage of global and EU normative frameworks as they pertain to health. At the same time, a lawyer or a policy-maker that is well versed in the global or European health instruments would not be able to see the full impact of these norms without an understanding of how these interact and play out at the local level.

Hence, although it remains of importance to identify the sources of authority, to speak of transnational or global health law and policy, or even EU health governance, may not be helpful for determining the legal or policy scope, or the appropriate subject of our research endeavours. In order to fully grasp the interrelations, we need to tie the different discourses of practitioners and scholars working on health law and policy together. We need to focus on how values (rights and obligations) are allocated with respect to human health, through law, regulation and policy, by global, regional, national and local health authorities collectively. In so doing, a more comprehensive approach to health law and policy should not lose sight of the fact that its underlying normative remits are not necessarily universal, and that the study of health law and policy is never a value free exercise. As always, researchers need to be explicit about their normative to theoretical perspective.

For the academic community studying European health law and policy, this means that we should seek to work more closely and consistently with colleagues in the field of global health or those that do research at the local level. Markets, people and their related health challenges also do not stop at borders and so research into health law and policy and should be open and inclusive, and not be limited by institutions and borders. This presents a challenge because of our tendency to work in silos. We split ourselves into those with expertise in global, European or national level health law and policy, instead of thinking of health law and policy as naturally involving all three of these levels (as well as the local and regional levels). We collaborate in specific instances but our default understanding is of a field divided into global health, European health, EU health and national health. The challenge for health law and policy is to reconfigure this perception, and to understand ours as a single, multidisciplinary field which embodies authority sourced from all levels.

What defines the scope of the broader research field and its future agenda, in the end, are questions of how law and policy can impact human health as a social determinant and, *vice versa*, how advances in the field of health affect health law and policy. More narrowly, the conundrum is whether, in the context of change and evolution, it is possible to adhere to the connecting and underlying factors that shape European health policy and law: a commitment to human dignity and solidarity in the face of health, disease and mortality.

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