Health law and policy, devolution and Brexit

McHale, Jean; Speakman, Elizabeth; Hervey, Tamara; Flear, Mark

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Introduction

Health provides a significant case study for multi-level governance and regulation approaches in the resolution of the challenges generated by Brexit. Although the NHS was a critical symbolic issue in the EU referendum, policy makers and health professionals alike underestimated how EU regulation impacts on public health and the delivery of health care. Health has been largely side-lined within negotiations for the withdrawal of the UK from the EU, and on future EU-UK relationship(s). The practical ramifications of Brexit on patients, professionals, health research and public health across the UK are significant (Fahy et al, 2017). But they play out in distinctive ways in each of the devolved nations/jurisdictions - Northern Ireland, Scotland and Wales - due to differences in the legal and regulatory arrangements for health care provision (Bevan, 2014).

Drawing on original empirical research (see appendix), we analyse the impacts of Brexit for health law and policy in the four UK national health systems. Alongside a review of literature and policy documents, our data comes from four closed stakeholder workshops across the devolved nations/jurisdictions and 37 semi-structured interviews with stakeholders in the UK and in EU27 member states carried out between November 2018 and February 2019. From these sources, we identify and

discuss six key challenges of Brexit for the devolved nations/jurisdictions, both now and in the future. In summary, these challenges are (1) formal allocation of powers for health post-Brexit; (2) public health as a key devolved power; (3) the impacts of Brexit on socio-economic disadvantage and health; (4)   NHS staffing and mutual recognition of professional qualifications; and (5   ) free movement and supply of medicines, equipment and consumables; and (6) the delivery of health care services in Northern Ireland. The starting point for these challenges is the formal allocation of powers: law is central to Brexit and to what comes after.

The nature of Brexit, and of future EU-UK relationship(s), will affect the manner in which the four nations/jurisdictions are able to respond to these challenges. Even though a   a Withdrawal Agreement was   eventually ratified, removing the particular vulnerabilities faced by devolved nations/jurisdictions in that 'no-deal' scenario, many uncertainties remain to be resolved in the period leading up to December 2020, and the possibilty of 'no-deal' in the sense of no future EU-UK relationship being in place at that time. Further uncertainties at present concern the nature of future EU-UK relationship(s).

We begin by outlining multi-level governance approaches and summarising their value to the resolution of the challenges generated by Brexit. We then discuss five key challenges outlined above: formal and de facto power allocation; public health; socio-economic disadvantage; staffing; medicines supply. As Northern Ireland is specific and significant, this is discussed separately as a sixth challenge. We then look across the six challenges to identify three key themes of health law and policy, devolution and Brexit.

Multi-level Governance and Brexit

Multi-level governance approaches offer an important contribution to decoding the practical and detailed effects of Brexit, and useful ways of understanding the challenges (and any potential opportunities) of post-Brexit futures. On an analytical level, multi-level governance raises the visibility of differentiated arrangements for sharing of power, especially in the case of legal and policy systems that are not federal hierarchies in a formalistic sense (Bache & Flinders, 2004a 2004b; Enderlein et al, 2010). The EU is of course one such system (Marks & Hooghe 1996; Stephenson 2013), but at least arguably so is the United Kingdom (Bache & Flinders, 2004b). Here we draw attention to places where the formal legalities associated with the borders of a nation state - whether or not the UK is a member of the EU, and what its formal legal relationships with the EU are, and are to be over time - do not match the realities on the ground (de Burca & Scott, 2006).

Multi-level governance is a flexible analytical tool, but also has normative purchase. Adopting a multi-level governance perspective is - at least implicitly - to push against 'one size fits all' narratives. In the context of health law and policy in the UK, such narratives have a tendency to articulate the hegemony of England: as, for instance, when the media talks of 'the NHS' where 'NHS England' would be more technically accurate. Such an approach raises awareness of, and thus renders visible, the relatively invisible positions and effects of a phenomenon such as Brexit, and its effects for health, in Wales, Scotland and Northern Ireland. In this regard, we not only give voice to the stakeholders on whose evidence we rely, but also express our view

that post-Brexit health governance cannot be properly understood from an Anglo-centric position.

Finally, as a future-facing approach, multi-level governance allows not only for comparison between legal and policy settlements at different levels within a system, but also facilitates isomorphic learning from differentiated regulatory experimentation (Sabel & Zeitlin, 2008). As noted in the discussion below on public health, there is evidence that this learning is already taking place, for instance in alcohol policies. By removing the UK from the regulatory constraints of EU membership, depending on future relationships, Brexit potentially offers scope for greater differentiation of legal and policy approaches to health within the UK. In this paper, therefore, we set a benchmark for subsequent discussion of health law and policy, in the upcoming phases of Brexit processes.

Formal allocation of legal powers for health governance within the UK

In some areas where Brexit will affect health in the four nations/ jurisdictions, there is a mismatch between their formal responsibilities and powers, and the ways in which Brexit (particularly if there is no legally agreed future relationship post 2020) is unfolding. This mismatch can occur in both directions. It occurs in one direction where a power is formally held at Westminster but specificities in the four nations/jurisdictions mean that differentiated approaches to health or the NHS post-Brexit would be merited. It occurs in the other direction where a power is formally held in the four nations/ jurisdictions, but the practicalities mean that de facto

responsibility for the effects of post-Brexit decisions on the four nations/ jurisdictions lies at Westminster.

Considering the former: free movement of persons within the EEA is currently a power reserved to Westminster (see Scotland Act 1998, schedule 5, part II s B6; Wales Act 2017, Head B; Northern Ireland Act 1998, schedule 2). Yet specific NHS staffing needs have already been part of the context in which it has been suggested that Scotland be enabled to develop its own immigration policy (Aitken, 2018). In Northern Ireland, the Common Travel Area forms the key legal context for migration of UK and Irish nationals. Depending on the form of the future EU-UK relationship(s), however, EU-26 nationals will only be able to rely on domestic immigration law.

Considering the latter: responsibility for the NHS is a devolved power in Wales, Scotland and Northern Ireland. These health systems are formally separate from NHS England. The health ministers in Cardiff, Belfast and Edinburgh are responsible for the health of their respective populations, and are obliged to secure adequate supplies of medicines within those separate systems. But the devolved nations/jurisdictions have no powers in trade agreements or medicines regulations (Scotland Act 1998, schedule 5. Part II SJ4; Government of Wales Act 2006, schedule 5; Northern Ireland Act 1998). Access to medicines post-Brexit, particularly in the case of reaching January 2021 without securing a trade relationship, is a concern, given the likelihood of multiple shortages taking place all at once, meaning that the normal responses to medicines supply shortages will be inadequate. The relative size of NHS England leads to concerns about how health professionals in Northern Ireland, Scotland and Wales will access necessary consumables. There are concerns about information flow and the

consequences if decisions are made at Westminster without the benefit of detailed knowledge of local practice and contexts.

Public health: a key devolved power

Public health operates through distinct structures in the four UK nations/jurisdictions. Single agencies (NHS Health Scotland, Public Health Wales, and the Public Health Agency in Northern Ireland) are responsible in the respective jurisdictions. In England, following the Health and Social Care Act 2012, while some powers have been given to a small, centralised Public Health England, public health is otherwise handled at local authority level (Greer, 2016).

Allocation of powers to the four nations/jurisdictions enables the prospect of increasing divergence in some public health policies. In some instances, the devolved nations/jurisdictions can be seen as regulatory pioneers, with policy isomorphism where the regulatory 'experiment' is seen as successful. Scotland's minimum alcohol pricing policy is a strong example. The policy arose because the Westminster government refused to create an excise tax on alcohol (Katikireddi et al, 2014). The Scottish approach to minimal alcohol pricing was challenged unsuccessfully in the courts, as an unjustified breach of the EU's internal market law. The specificities of health indicators in Scotland, evidenced by public health research (e.g. Meng et al, 2012), were a key determinant in judicial reasoning *(Scotch Whisky Association* [2017] UKSC 76). In short, the courts recognised that Scotland's public health needs are different. A similar approach has been followed recently in Wales (The Public Health (Minimum Price for Alcohol) (Wales) Act 2018).

Our interviewees revealed considerable concerns about the practical implications of Brexit for public health policy. The administrations in the devolved nations/jurisdictions have developed relationships with the EU beyond the formal EU structures. There is a degree of informal representation through their establishment of offices in Brussels (Birrell & Gray, 2017). Their elected representatives participate in networks such as the Confederation of Regions with Legislative Assemblies. These networks can be leveraged to secure EU-level support for desired regulatory approaches. EU regulation can play an important role in securing policies that are favourable to public health (or at least more favourable than a deregulated approach), and in limiting industry power, in a range of areas, especially EU food law and tobacco law:

> On the lifestyle side we're a little bit fearful about tobacco, and sugar … we're aware that those industries seem to be keen on Brexit, which is naturally what worries us. … [T]he EU has been very energetic on those topics so to lose that link and give us the freedom to diverge from that is not necessarily what we're after in public health terms. So we're worried about that. (Interviewee in Wales)

> Around food safety regulation or tobacco control, regulation labelling, [Brexit] could be positive because there could be an opportunity to strengthen legislation and regulation. And the devolved nations have the ability to do that. Or it could be potentially a negative because there could be deregulation. … [T]here are policy pathways that can have a direct impact and an indirect impact, and Brexit causes those things. (Interviewee in Wales)

Tobacco regulation has involved a mixture of domestic and EU law since 1986 (Hervey & McHale, 2015). The EU's controversial tobacco legislation (including the Tobacco Advertising Directive and Directive 2014/40/EU on tobacco use) was subject to considerable lobbying from the tobacco industry. The EU regulates emissions of tar, nicotine and carbon monoxide; and labelling and packaging of tobacco products, including health warnings. EU law also includes product control e.g. tracing systems/packs with 'unique identifiers', to address illicit dealing. One EU policy objective is to deter tobacco consumption by the young, by regulating additives, flavourings, and e-cigarettes. Additional domestic provisions, such as the ban on smoking in enclosed public places (Health Act 2006, Chapter 1), also promote public health. All the devolved nations/jurisdictions have taken steps to regulate smoking (Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016; Public Health (Wales) Act 2017; Health (Miscellaneous Provisions) Act (Northern Ireland) 2016).

EU regulatory standards for tobacco will be continued under the European Union (Withdrawal) Act 2018 through the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2019 SI No.41. However, Government Guidance outlines necessary new systems for tobacco producers to notify tobacco products/e-cigarettes as the reciprocal EU systems will not be in operation (Department of Health and Social Care, 2018). In addition, as pictorial representations on cigarette packets are copyrighted by the EU, in the absence of an agreement with the EU permitting their continued use , new warning notices and pictures would be needed.

Given concerns about the removal of the relatively protective EU regulation, it is unsurprising that there is also concern about where powers will be repatriated post-

Brexit. The EU's powers overlap with devolved powers in many areas in Northern Ireland, and, in some, albeit fewer, in Scotland and Wales (Institute for Government, 2018). Some of these overlaps cover public health matters. It remains uncertain whether the post-Brexit settlement will permit any regulatory divergence. Greer (2018) notes mixed signals from the UK Government, suggesting *both* post-Brexit strengthening of devolution, *and* limiting flexibility to protect 'the integrity of the UK' (see also Hervey & Speakman, 2018). The Withdrawal Agreement obliges the UK to continue to comply with EU product regulation (including for tobacco, alcohol and food) at least until December 2020 .

The statutory instruments approved to date in areas from tobacco to organ transplantation (e.g. The Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019 SI No.41), The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 SI No.481) do not appear to change the balance of power between Westminster and the devolved nations/jurisdictions. The question is rather what will happen longer term. To the extent that the post-Brexit settlement allows for regulatory divergence from the EU, the question of where those powers will be 'repatriated' is an open and contested one (Douglas-Scott, 2017; Doyle & Connolly, 2017; Hunt, 2017). Will it be at the level of the four nations/jurisdictions, or will the UK's 'internal market', and the desire for the UK to offer access to the whole UK market under future free trade agreements with countries outside the EU, require central regulation? These are questions where public health is likely to be subsumed in trade negotiations, rather than forming a distinctive legal and policy space. Within the EU, public health has slowly gained traction as such

a space (de Ruijter, 2019; Flear, 2015): the loss of this distinctive attention to public health within trade policy is one hidden and indirect potential effect of Brexit.

The impacts of Brexit on social-economic disadvantage and health

The empirical link between social disadvantage and health is well documented (Black, 1980; Marmot et al., 2010). Essentially, wealth equals health. Areas expected to be worse hit by broader economic consequences of Brexit overlap significantly with areas where health indicators are worse (HM Government, 2018a; ONS, 2014). This is reflected also in the devolved nations/jurisdictions, where several interviewees underlined the significance of broader economic and social contexts and their indirect adverse effects on health outcomes:

> We're also worried about mass unemployment events. This is now much broader – nothing to do with tobacco and sugar or alcohol or any of those. There are quite a lot of businesses in South Wales in particular that supply into the West Midlands especially, into the car industry, building components that go into cars. … [I]n the valleys, which are deprived areas … some of the most deprived areas in Britain, there's quite a concentration of companies supplying…things like moulded dashboards or the door panels and that kind of thing inside of cars, and all of that supplies into places like Toyota in Derby and also into the car plants in Birmingham and Coventry. And we're aware that those very same just-in-time delivery issues that affect the health service are critical for that industry. … So if they're undermined, although none of those are

in Wales … that's going to have a big effect on those component plants in Wales. (Interviewee in Wales)

In February 2019, the Swindon Honda plant announced its closure, with the loss of around 3,500 jobs. At the time, workers claimed that the closure was due to Brexit although this was disputed   (Walker, 2019).

The European Social Fund and the European Regional Development Fund have supported development in the devolved nations/jurisdictions (Birrell & Gray, 2017). Scotland and the border counties in Ireland have been awarded Interreg VA funding (EU funding for aspects of cross-border regions including health and social care, environment, research and innovation and sustainable transport). The Northern Ireland and Wales funding has contributed some £9 million to develop life sciences across five universities. In Northern Ireland, funding has been awarded through the Special Fund for Peace and Reconciliation. Interviewees expressed concern about the impact on the agricultural industry in Wales through the impact of the loss of EU structural funds:

We're also concerned about the fact that Wales got a lot of regional development funding, structural funds, from Europe, both for the valleys and for West Wales, so that would all disappear, and we hear the UK government say for the moment they'll match that but only till the next election. (Interviewee in Wales)

The economic impacts and their effects on the broader determinants of health can be also seen as exacerbating the existing impact of austerity policies.

> So the impact on the economy, … and the knock on impact on health inequalities, in some ways is very much a political choice. So there have been political choices in the last few years that have meant that economic inequalities have got worse and therefore social and health inequalities have got worse. But I don't really see that changing with Brexit. If anything I think Brexit's likely to make that worse, just because of the sort of toxic cultural effects. (Interviewee in Scotland)

The impact of Brexit, economically, socially and culturally, on the broader social determinants of health needs close attention by government at national and devolved levels. It has been suggested that some gaps in structural funding post-Brexit may be addressed through adjustments in the Barnett formula - the measure used to ascertain resources for devolved expenditure which includes health. There are, however concerns, not least that this approach could result in funding not necessarily being used for the highest priority needs (Birrell & Gray, 2017) in the devolved jurisdictions where particular risks of harm to health are consequent upon Brexit. Yet these discussions are embryonic at best: contrast Ireland, where the national press has carried explicit calls for government aid and investment to assist struggling economic sectors and areas (Taylor, 2019).

NHS staffing and mutual recognition of professional qualifications

NHS staffing shortages are a particular challenge   in Northern Ireland (see further below). But s   takeholders also spoke of areas in Scotland and Wales where the NHS relies to a greater degree on EU27 staff than the average UK figures suggest: one example is a hospital in the highlands of Scotland where 10/11 consultants were said to be EU27 nationals.

At present, professional movement is facilitated by the EU Mutual Recognition of Qualifications Directive 2005/36/EC. This enables recognition of professional qualifications of medical professionals. The European Professional Card includes doctors, nurses responsible for general care, pharmacists and physiotherapists (Commission Implementing Regulation 2015/983/EU). The powers to regulate health professionals are currently reserved to Westminster, but the impact on mutual recognition in the four nations/jurisdictions was nonetheless raised by our interviewees.

The Mutual Recognition of Qualifications Directive has proved controversial amongst some in the medical profession. Some see Brexit as an opportunity to require heightened standards in professional qualifications applicable to all health professionals practising in the UK. Concerns about the Directive and medical profession training were expressed by one interviewee:

> Overall the system allows the doctors to come into the country to satisfy our
> work force needs, but there is anecdotal evidence that perhaps some of the

qualifications aren't always up to the standard. And, interestingly, we know that some employers know this. … [T]hey have work arounds so they know if you have a specialist qualification in a certain specialty from a certain country you may put additional safeguards in place – one of the examples that we've stated is clinical oncology. In the UK if you're an oncologist, you've learned how to do chemotherapy … whereas if you have an equivalent qualification from another European country, … you've learned how to do maybe radiotherapy but not chemotherapy. It's just the different ways of organising medical training. But if a hospital would employ an oncologist from a European country with different training, they tend to know this … So we've heard that … hospitals … still employ the doctors but they're just aware that, 'right, you're an oncologist from X European country and can't actually do chemotherapy,' for example. (Interviewee from a UK wide organisation)

But what might be seen as an opportunity to amend approaches to reflect UK standards is also seen problematic for existing recruitment and retention of NHS staff across the UK:

The implication behind that [changing professional standards] is that somehow the bar that's set by the current European Directive could and should be raised. Well, that's implying that there's something defective in the current European Directive in terms of the standards that are required … If we're going to raise the bar even further, then clearly there are going to be implications of that for recruitment and retention. If we're expecting nurses to somehow meet some new UK standard which is above and beyond the existing UK standards defined

14

in the existing EU Directive I'm not sure that that's really helpful. (Interviewee from UK-wide organisation)

There would be a lot of cross-border provision of GP services, for example in Castleblaney in Monaghan, … so do they end up being regulated by two different systems? Are their regulation issues going to be the same? Do they have to take out two different sets of indemnities? Would that mean that people then wouldn't do that? So from an expense point of view, so you end up drawing down, working down on what is already a scarce workforce (Interviewee in Northern Ireland)

Several interviewees considered that a failure to continue the mutual recognition of professional qualifications would adversely impact on recruitment, and therefore upon staffing levels:

If there's no mutual recognition of professional qualifications, that will complicate matters for already qualified doctors seeking to come into the UK. Will it prevent them from coming indefinitely? Of course not. Agreements can be reached between the UK regulators and the regulatory authorities across Europe. [But] that will take some time, and in the meantime gaps in the workforce will not be filled. And will that then lead to … a chilling effect whereby doctors from across Europe start looking elsewhere and realise that there are other Anglophone countries …, which pay well, which have interesting and rewarding career opportunities? (Interviewee in UK-wide organisation).

The Directive will be initially carried over as 'retained EU law' by means of the European Union (Withdrawal) Act 2018. However, this will not extend to the reciprocal parts of the Directive. These include warning processes concerning unsafe practitioners. The Withdrawal Agreement will continue these during transition. Thereafter, unless a specific agreement is reached, the UK will be excluded from these EU systems:

> The alert mechanism is one of the key issues for us because Brexit will not stop pan-European medical migration. We want to know about doctors who come to the UK, who shouldn't be allowed to practise, likewise dentists etc, and vice versa … for patient safety reasons. (Interviewee from a UK-wide organisation)

Existing NHS staffing shortages and the time needed to train health professionals mean that for a considerable period it will be necessary for the NHS to recruit from abroad. Staffing shortages are differentially experienced in the devolved nations/jurisdictions, particularly in areas of geographical remoteness. In the past, it has been argued that visa arrangements for health and social care professionals are unduly restrictive where NHS Trusts wish to employ professionals from other non-EU nations (BBC News, 2018). The White Paper on Immigration (HM Government, 2018b) proposes no provisions facilitating recruitment and retention of NHS workers, and the proposed minimum salary threshold of £30,000 per annum could seriously limit the ability of the NHS to recruit many healthcare workers.

Free movement and supply of medicines, equipment and consumables

The supply of medicines, devices, vaccines, equipment and consumables in the NHS across the UK is dependent upon free movement of products within the EU's internal market, while protecting patients. A dense web of EU law on health service products supports long-standing and little understood supply chains, based on 'just in time' manufacture, storage, certification, distribution and delivery.

Concerns about supply shortages have been highlighted in the UK Parliament (House of Commons Health and Social Care Committee, 2018) and are echoed by interviewees:

> In normal times, if there was a critical supply shortage, because it's a UK market, that shortage would affect the Health Service UK-wide. They would take lead responsibility to work with the company to look for solutions which might involve working with other agencies – so importers, the Medicines Regulator – to try and find solutions to the problem and communicate that to the NHS via regional leads on Scotland. (Interviewee in Scotland)

> We're actually even more concerned about consumables ... We know that all those boring items – syringes, catheters, you name it, all the kinds of disposable equipment that's used in the health service – that's all just-in-time delivered, and those supply chains are pretty fragile and most of them involve Europe. (Interviewee in Wales)

The supply and distribution of medicines remains complex (House of Commons Health and Social Care Committee, 2018 paras 135-138). The Government have issued

notices on medicines supply in the event of a no-deal Brexit. While pharmaceutical companies were asked to stock 6 weeks supply of medicines, NHS trusts were told not to stockpile at local level (Hancock, 2018). Plans were also announced for airlifting medicines which cannot be stockpiled for longer periods (Kelso, 2018) and for a new logistics hub in Belgium to secure medicines supply for products supplied to the NHS on a 'short-lead' timetable (24-72 hours) (Brennan, 2018). The Human Medicines Regulations 2018 were also amended, to allow the Government to introduce serious shortage of supply protocols, permitting a pharmacist to dispense a different quantity, pharmaceutical form, strength or a generic or therapeutic equivalent of a prescription medicine, without reverting to the doctor prescribing it (Human Medicines (Amendment) Regulations 2019). These measures are untested as ensuring effective supply of consumables. There is awareness of challenges, but preparation, at least at the time of our interviews, appears to be at different stages:

> Generally in terms of medicine supply everyone in the supply chain has been working to draw out costs … So I think there is a general concern that over the years the medicine supply chain has become more and more fragile, so it's much easier if something unexpected happens to tip us over into a shortage situation.

> Shortages are a daily occurrence so at any time in the UK there will be hundreds of lines that are in short supply, though only a handful of those are going to be critical … that's why there is a kind of infrastructure in place to deal with that. I think the concern with Brexit is the number of potential products that could face

a problem at the same time, if there aren't sufficient contingency plans in place and our ability to cope with that, just the sheer volume. (Interviewee in Scotland)

Not only planning but also appropriate resource will be needed to ensure that supply chains operate effectively. As the Scottish interviewee notes, longer term changes in supply strategy, to reduce costs, may render supply chains vulnerable in parts of Scotland, and presumably elsewhere. Our interviews also revealed that different delivery of service models in Wales may pose different challenges, due to the role of microbiology laboratories which are run in hospitals, unlike in England. So while, overall, product supply is a UK-wide aspect of health service delivery that is particularly affected by Brexit, and especially by no-deal Brexit, the specificities of arrangements in the four nations/jurisdictions mean that UK-wide solutions may not be fit for purpose.

Northern Ireland and health care delivery: specific challenges

The health systems in some parts of the UK (particularly Northern Ireland) are more integrated with EU-27 countries (particularly Ireland) and this poses particular challenges in terms of patient care, service delivery, and above all NHS staffing.

There is a particular challenge of delivery of patient care in Northern Ireland post-Brexit. Recent years have seen increasingly integrated healthcare service provision on the island of Ireland. Much of this has been driven by economies of scale, and the geography of the north of the island. Some of this integrated provision has been facilitated through EU funding, and in particular the Cooperation and Working Together Partnership (CAWT), operational since 1992.

Bilateral agreements between the relevant health authorities facilitate provision of a range of patient services. For example, Irish children travel to Northern Ireland for ear, nose and throat treatment, reducing waiting times. Since 2015, children's cardiac services have been provided for the whole island in Dublin. The Irish Government contributed funds to the radiotherapy unit in the main hospital for the northwest of Northern Ireland, situated in Derry/Londonderry, at which cancer patients from both Northern Ireland and Donegal are treated. All these integrated services, and more, are facilitated by mutual recognition of professional qualifications, and shared standards, including for data sharing.

> We have what we call the National Ambulance Service of Ireland who would routinely, on a daily basis, cross the border, and each of the services would work together. … If you have an ambulance which just happens to be nearer to an accident or an emergency but it … belongs to the other jurisdiction, at this point in time, that ambulance will be sent to deal with the incident and transport the patient to the nearest A&E. … If there was a hard border, that would be more difficult. (Interviewee in Northern Ireland)

In effect, to a large extent, the island of Ireland also shares a healthcare workforce. Within the EU, it is relatively easy for staff to provide healthcare services across the Northern Ireland/Ireland border, and many do so:

> We have members who cross the border four, six times a day because they work in different hospitals, different clinics on both sides of the border. That's

facilitated by free movement, by the mutual recognition of professional qualifications, by the transfer of data via EU data protection regulations, so it's multi-faceted … given the cross-border nature within Ireland. (Interviewee in Northern Ireland)

Some hospitals have instituted staffing planning for a no-deal Brexit (Ord, 2018). Any practical impact on professional mobility in a no-deal Brexit with the potential for introduction of controls at the border is seen as a particular worry:

If they live in Donegal and they're travelling to Altnagelvin every day and sitting at a border for 20 minutes on the way over and … on the way back, they're not going to do that…There's a lot of people where that would have an impact. (Interviewee in Northern Ireland)

The Common Travel Area - a long standing arrangement between the UK, Ireland and the Crown Dependencies - established cooperation between respective immigration authorities enabling British and Irish citizens to move freely between, and reside in, these islands. It will secure free movement for UK and Irish nationals across the Northern Ireland/Ireland border, irrespective of the type of Brexit and future EU-UK relationship(s). However, this is not the case for nationals of the EU-26 (say, a Polish nurse working across the Northern Ireland/Ireland border). Although there are higher percentages of EU-27 national doctors (10%) in England (Baker, 2018) than in the devolved nations/jurisdictions, where General Medical Council (2018) figures show 5.8% in Scotland, 6.5% in Wales, and 8.7% in Northern Ireland (the vast majority of whom are believed to be Irish nationals), our interviews suggest that the overall figures

hide specific challenges of recruiting in remote areas or to particular specialties, weaknesses in workforce capacity planning, and availability of robust information on which to plan:

> Northern Ireland on its own can sustain ordinary specialties, but we don't have enough doctors within any given specialty and that is where the workforce planning comes in and that forms a big part of the Transformation Agenda.

> From a workforce planning point of view, I think what Brexit has shown, and it's always been a criticism, is that there hasn't been a great deal of medical workforce planning taking place in Northern Ireland. … [T]here has been a real absence of robust information and evidence on which to plan. (Interviewee in Northern Ireland)

Challenges to NHS staffing are not simply about Brexit, but interviewees expressed concerns that considerable existing staffing shortages would be exacerbated by the UK leaving the EU. A shortfall of at least 1,800 nurses in Northern Ireland is a particular concern.

> … [E]mployers of nurses are desperately struggling to compete on an international level for nurses. That's why we have the shortages that we do and the number of vacant posts. Trusts across the UK and here in Northern Ireland are currently investing a lot of time and energy and money in recruiting from overseas, particularly from countries like India and the Philippines. (Interviewee in Northern Ireland)

In short, none of our informants in Northern Ireland spoke of any potential benefits for health post-Brexit, and all had significant concerns.

Discussion

Considering the six key areas of challenge for post-Brexit health law and policy discussed above through a multi-level governance approach reveals three key themes of health law and policy, devolution and Brexit.

First: far from the effects of Brexit on health and the NHS being *uniformly* experienced across the UK, and across the health sector, multi-level governance calls attention to *differential* impacts. Differential impacts have both substantive and territorial dimensions. *Substantively*, some areas of the NHS involve greater integration with EU law and policy than others. For instance, maintaining a stable supply of health consumables such as medicines, vaccines and medical devices post-Brexit is a concern in the way that supply of whole blood or plasma is not. Moving away from the EU's multi-level system of governance implies significant risk in some areas, but less in others.

Furthermore, Brexit impacts on the NHS are felt differentially on a *territorial* basis. For instance, for recruitment and retention of health care professionals, Brexit exacerbates existing problems. Worsening NHS staffing pressures, especially in the context of ending free movement of EU26 nationals into the UK under EEA law entitlements, are

expected to be felt unevenly. Geographical remoteness poses particular challenges for recruitment and retention of NHS staff in Wales, Scotland and Northern Ireland, particularly of some specialities.

The specificities of a slowly emerging integrated health system and shared health workforce on the island of Ireland hold different challenges to those in England, Scotland or Wales. In Northern Ireland, there is greater integration of its health system with an EU-27 country –Ireland – which means that Brexit has a profoundly different impact to that in other parts of the UK. The integration of the all-island economy, especially since the Good Friday/1998 Agreement, relies in part on the UK and Ireland's EU membership and the legal structures implicated. While for people, the Common Travel Area will secure some aspects of the current situation into the future, this does not apply to EU-26 (non-UK and non-Irish) nationals working in the health sector in Northern Ireland and crossing the border, or their families. While the Withdrawal Agreement and the Northern Ireland Protocol   will provide legal continuity for people and products into the short and possibly longer term, the threat of a no-deal Brexit and uncertainty about a legally agreed EU-UK relationship post 2020 are worrying for the health sector. Longer term, patients' access to treatment across the Northern/Irish border is a particular concern.

Second, a multi-level governance approach draws attention to how health service delivery is nested within and interacts with broader economic, social and cultural policy fields and legal arrangements, and hence to the *indirect* implications of broad contexts of Brexit for health. These broader consequences of Brexit will be felt differently in different parts of the UK, territorially speaking. Many regions expected to suffer the

worst economic consequences are areas which already have poorer health indicators than much of the rest of the UK. For instance, while, in Wales, the impact of Brexit on health was slower to become visible in public and policy debate than in Northern Ireland and Scotland (Green et al, 2019; Welsh Assembly, 2018), there are particular concerns about the financial impact on Wales through withdrawal of EU structural funding, with its potential consequences on the social determinants of health. These concerns are shared by policy actors in Northern Ireland and Scotland, from their respective perspectives. Whether the UK has the requisite policy spaces to discuss the implications, and formulate concrete legal and policy responses, and redistribution of public resources, to these differentiated health impacts of Brexit is very much an open question.

Third, and finally, multi-level governance draws attention to the ways in which *formal legal responsibilities* for healthcare are a poor fit with the emerging *realities* of managing Brexit. The EU's multi-level governance arrangements, as mediated by the Court of Justice of the EU, leave open the possibility of distinctive approaches to some aspects of health, such as alcohol pricing. This flexibility and respect for national/regional difference mean that, in the UK context,   regulatory approaches tailored to the specific health indicators and circumstances of the UK's devolved nations/jurisdictions have been adopted. The continued legal viability of these is unclear in the medium term, given the deep uncertainties about both the EU-UK future relationship(s) and possible trade agreements with other countries, especially the USA, and whether those agreements would be as flexible as EU membership in this regard.

Legal and political accounts of multi-level systems typically involve a set of rules on competences and their allocation, and a set of political procedures through which disagreements about these are resolved, ultimately with legally binding processes behind them. Within the EU, these have worked more or less effectively for health. EU law's provisions for public health protection, for 'services of general interest', and its explicit exclusion of the organisation and delivery of health services from EU competence (Article 168 (7) TFEU) mean that Member States retain significant control over many health services regulatory choices, although EU-law-based challenges to aspects of health regulation have been successful since the 1970s (Hervey & McHale, 2015).

While these multi-level system rules work reasonably well while a country is *in* the EU, they do not appear to work so well when a country is *leaving* the EU. Emerging Brexit realities involve managing many health issues at Westminster level, even though legally speaking health services are devolved to Wales, Scotland and Northern Ireland. Medicines and consumables supply is a key case in point. Scope for the devolved nations/jurisdictions to respond to the challenges of Brexit, as well as to the negotiation of future trade relationships, has been in many ways fraught. For instance, in Scotland, whilst the prospect of enhanced powers post-Brexit in areas of public health could be an opportunity, there are major concerns regarding the impact of Brexit on staffing and clinical research. Yet calls for Scotland to respond to its need for inward migration to staff *inter alia* its NHS and biosciences sector by developing an independent migration law and policy have gained no traction at Westminster. The emerging realities of managing a future outside the EU leave little space for differentiated approaches in the devolved nations/jurisdictions, suggesting a rift

between formal legal responsibility and accountability and the locus of political decision-making, with obvious consequences for legitimacy and effectiveness of health law and policy.

Conclusion

Our informants saw many challenges and problems for health and the NHS post-Brexit, and very few opportunities. Resolving the challenges and ensuring a satisfactory reconfiguration of health competences post-Brexit is likely to provide a source of ongoing tension between Westminster and the devolved nations/jurisdictions. There is no easy way to identify challenges to health policy emerging from Brexit that are common to the UK as a whole, as opposed to those which are differentiated in the devolved nations/jurisdictions. Each 'level' (Westminster/Belfast, Cardiff, Edinburgh, and English regions) can legitimately articulate a claim. Greater integration of approach *within* the UK will be seen as necessary for negotiations of future UK trade relationships, both with the EU and with the rest of the world. Greater differentiation will be seen as an opportunity to benefit from being 'freed' from Brussels 'control', and respond to localized needs.

Understanding the post-Brexit UK health law and policy space through a multi-level approach raises the visibility of the claims of the devolved nations/jurisdictions to develop distinctive approaches, and to respond to the indirect consequences of Brexit's territorially differentiated effects on population health, especially among socio-economically worse-off groups. There could be space for mutual learning from approaches adopted within different parts of the UK, for instance integrated care

systems. Multi-level governance does not provide a normative roadmap to resolving disputed competences, but it does draw attention to the need for structures and processes to address the questions that they raise. As Brexit unfolds, it will be crucial to track its health effects not simply on the UK as a whole, but - critically - on its devolved nations/jurisdictions.

Acknowledgments

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