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City Law School Research Paper 2021/04

**Health 'Brexternalities':
The Brexit effect on health and health care outside the UK**

Tamara Hervey, City, University of London; Ivanka Antova, Queen's University Belfast; Mark Flear, Queen's University Belfast; Jean McHale, University of Birmingham; Elizabeth Speakman, Edinburgh Napier University; Matthew Wood, University of Sheffield

2021

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Abstract

The principal effects of Brexit on health and health care will fall within the United Kingdom, and all forms of Brexit have overwhelmingly negative implications for health care and health within the UK. This article focuses on the *external* effects of Brexit ('Brexternalities') for health and health care. The EU is a particularly powerful institutional and legal arrangement for managing economic and political externalities, in health policy as in any other policy. Equally, when a state leaves the EU, the manner of leaving will result in better or worse management of relevant externalities. 'Brexternalities' thus involve questions about policy legitimacy and accountability. Health 'Brexternalities' do not fall equally in all EU countries. They are felt more distinctly in the context of those elements of health policy that are most closely entwined with the UK's health policy: for instance, on the island of Ireland; certain areas of Spain and other parts of southern Europe. Some health 'Brexternalities', such as in medicines safety, will be imposed on the whole population of the EU. And some health 'Brexternalities', such as communicable disease control, will be felt globally.

Keywords: [European Union](#), [health policy](#), [Brexit](#), [health and trade](#), [health staffing](#), [Northern Ireland](#), [Malta](#)

Introduction

The principal effects of Brexit on health and health care will fall within the United Kingdom. Far from the promised extra funding for the NHS, any form of Brexit will have overwhelmingly negative implications for health care and health within the UK (Fahy et al 2017, 2019; Hervey and Speakman 2018). But what about the *external* effects of Brexit for health and health care, or its ‘Brexternalities’ (Armstrong 2019a 2019b; Greer and Laible 2019)?

The EU is a particularly powerful institutional and legal arrangement for managing economic and political externalities (Weatherill 2016). Of course, such arrangements are incomplete, but compared to other trade agreements or international institutional infrastructures, the EU’s decision-making processes, including their reviewability by national and EU courts, do a relatively good job of including within policy decisions those entities and people who will be affected by such decisions. Not every ‘outsider’ is so included, but the EU manages inclusion through a range of legitimacy and accountability processes (Schmidt and Wood, 2019), all of which are legally mandated, in that the EU is itself a creature of law, and operates on a substantively and procedurally constitutionalised basis, constrained by legal competences.

This legally-mandated and -secured inclusion of those who would otherwise be ‘outsiders’ is in place for health policy as much as for any other policy area in which the EU is involved. To give a flavour: EU health legislation is adopted according to processes that include the directly elected European Parliament. Parliament has been quite effective in the health policy domain at securing legislative change – in recent years, for instance, in medical devices regulation, data protection, clinical trials regulation, and patients’ rights. Sometimes the Parliament has relied on its *locus* before the CJEU to challenge legislation in the health policy domain that is outside the scope of the EU’s competences – for instance, in protection of intellectual property rights in substances of human origin used, among other contexts, in biomedical research (Hervey and McHale 2004: 260-270). Administrative acts of the EU institutions are also subject to judicial review, either before national courts (if national institutions have sufficient discretion in implementing those decisions), or before the European courts (in particular the General Court). Economic actors, and human beings with appropriate standing, can also seek judicial review of EU health law and policy – as for instance the case in tobacco regulation (Hervey and McHale 2004: 96-105; Hervey and McHale 2015: 390-394), or privacy rights to health information (Hervey and McHale 2015: 173-176). And where EU law is relied upon to open up markets in ways which might be deleterious to health, the CJEU can hear references from national courts charged with determining whether the relevant balance of interests is appropriate. A great deal of internal market litigation on free movement of products involves

arguments about proportionate public health protection measures. The balance between opening up opportunities to work or provide services in other Member States, through legally-mandated mutual recognition of professional medical qualifications, and securing patient safety and sustainability of domestic health systems, is also subject to oversight by courts. And so on.

Equally, therefore, when a state leaves the EU, the manner of leaving will result in better or worse management of relevant externalities. Notions such as state sovereignty, or ‘taking (back) control’, which have dominated UK discussions about Brexit, in and of themselves discount externalities. They assume closure of the space within which political decisions are made (at the level of the UK), and the economic, social or other effects those decisions might have. They leave out accountability to those who are affected, whether *within* the state concerned (for instance, the question of where EU-held powers are repatriated (McHale et al 2020), or beyond it. Decisions are subject neither to input, output, nor through-put legitimacy (Schmidt 2013; Schmidt and Wood, 2019) in terms of their external effects: the sovereignty of the nation state (the UK) is here a cipher for appropriate decision-making.

‘Brexternalities’ thus involve questions about policy legitimacy and accountability. For (some) supporters of Brexit, EU membership by definition dilutes legitimacy and accountability, so leaving the EU can only improve it. But if we accept that legitimacy and accountability go beyond the electorate of the state whose government takes acts of state sovereignty – and being a Member State of the EU by definition entails accepting that – then we logically also should accept that the consequences of *leaving* the EU cannot be legitimized internally alone, and at least some outsiders should be included in legitimate decisions about whether – and crucially *how* – to leave the EU. It follows that some forms of Brexit – particularly those which involve on-going legal entitlements, and legally mandated institutional structures for dispute resolution – will secure better inclusion of those excluded from the decision to leave the EU than others.

This article explores the ideas articulated above through the principal ‘Brexternalities’ in the health policy domain. It characterizes those health ‘Brexternalities’ on the basis of their spatial extent: those affecting sub-sets of the EU; those affecting the EU as a whole; and those having a global effect. On the basis of the notion of legitimacy articulated above, it argues that ‘better’ Brexits are those which at least attempt to secure some protection for ‘outsiders’ who suffer detriment from a decision made by the ‘insider’ population of the UK who were entitled to vote in the referendum, and from the acts of the ‘insider’ UK governments that followed. As will be seen, the concepts of ‘insider’ and ‘outsider’, critical to the definition of an ‘externality’ are

problematic in the context of Brexit as it has unfolded. The article proceeds as follows: after a short methods section, the article explores the concept of 'Brexternalities', seeking to problematize the notions of 'insider' and 'outsider' using a temporal frame. Focusing on health, it tracks how we might conceptualise 'insiders' and 'outsiders' at different moments in the Brexit processes. The article then turns to the spatial. It outlines three types of health 'Brexternality': those affecting part of the EU; the EU as a whole; and with global effect. As almost none of our data points to any benefits, the article focuses mainly on the costs of 'Brexternalities'.

Methods

This article draws on data from two separate projects, led by McHale and Hervey respectively. Hervey and Flear are involved in both projects; McHale, Speakman, Wood and Antova are involved in one of the two. Both involve desk-based research on health law and policy post-Brexit, drawing on a wide range of legal texts, policy documents, Parliamentary records, media reporting and literature. Our analysis of that data sought to determine the likely consequences of Brexit in various health domains: patients, health professionals, health-related products and services, and public health.

That data is supplemented as follows. McHale's project involved closed stakeholder consultation workshops held in Belfast, Brussels, Cardiff and Edinburgh, between October 2017 and January 2018), bringing together around 35 experts from different health policy contexts. McHale and Speakman collected data through 37 semi-structured interviews¹ conducted by telephone between November 2018 and February 2019. Hervey's project included 11 in-person semi-structured interviews carried out by Flear, Hervey and Wood between February and May 2019. In both projects, interviewees were identified from the workshops, government and health websites, published literature and recommendations. They represent a wide range of organizations in the health sector across the key areas of the UK health system broadly defined (patients, professionals, pharmaceuticals and medical devices, health research, and public health). Some interviewees are based outside the UK, or work within pan-EU health structures. Interviews focused on the effects of Brexit from the point of view of the interviewee's particular health policy expertise. Because of the political sensitivity of the information, in the context of on-going Brexit negotiations, we have

¹ Research ethics approval was granted by the University of Birmingham, for McHale's project, in advance of the telephone interviews, and by the University of Sheffield, for Hervey's project, in advance of the in-person interviews. Before each interview, informants were provided with an interview protocol and required to sign a consent form. Interviews were recorded, transcribed, and further consent was obtained for the use of quotations.

maintained the anonymity of interviewees and their organizations. Interviews ranged from 30 minutes to over 2 hours in length, with most taking around an hour.

Health ‘Brexternalities’ through time

In economics (OECD 1993), an ‘externality’ is a situation where the effect of production or consumption of goods and services imposes costs or benefits on others which are not reflected in the prices charged for those goods or services. Economic externalities are particularly prevalent in health and health care (Mankiw 2017), where, for instance, especially if health care is privatized, the benefits of herd immunity are enjoyed by those beyond the group who bear the costs of individual acts deciding to be vaccinated; and the benefits of health research are felt by those outside the group of those funding it.

By extension into politics, a ‘political externality’ occurs when actions attributable to a group of people determine policy or law (or both) that applies to and imposes costs or benefits on individuals outside of that group. An ‘externality’ is more pernicious than a mere ‘repercussion’ because of its excluding effects, which de-legitimize the decision made, in the context of a democracy where decisions are supposed to involve those affected through political processes, and interests are supposed to be protected by legal means of accountability. Members of the ‘insider’ group determine the political and regulatory environment within which ‘outsiders’ must operate, without any (direct) way for the outsiders to be involved in the decision-making, or to negotiate the terms on which the decision is taken. Furthermore, ‘outsiders’ have no means by which to hold the decision-makers legally or politically accountable for the effects of the decision.

In order to understand externalities, and their relationship with legitimacy and accountability, therefore, we need to understand who are ‘insiders’ and who ‘outsiders’ when a particular decision or set of decisions is/are made with external effects. And we also need to have a conceptualization of what counts as ‘inclusion’ in a decision: representation, voice, output, input, thought-put/process, consideration of relevant interests, accountability for results, and so on? Finally, we might want to pay attention to the ways in which law structures inclusion – in this regard, socio-legal discourses suggest an inclusive aspiration, which is difficult both logistically and normatively: especially at a moment where state sovereignty is expressed unilaterally, such as Brexit. In all these, attention to the temporal is essential (Armstrong 2017).

Any state policy that has extra-territorial effects in principle involves externalities, as the electorate of other states cannot participate in the policy decision. International organizations

like the EU seek to manage externalities (Weatherill 2016). The EU manages externalities in part by using law in at least three ways. Law determines processes by which the external effects of state decisions are managed within the EU's internal market. Legal processes seek to include the whole affected population (*within* the EU) in electing representative institutions which are part of the EU's decision-making process (although of course affected populations outside the EU are excluded). The EU gives outsiders access to judicial oversight of legal and policy decisions. In none of these is the EU complete in its inclusion of those excluded, but the EU achieves greater inclusion than mechanisms of ordinary international (trade) law.

At the moment when the Cameron government called the EU referendum, the European Union Referendum Act 2015 determined the 'insiders' (and, by definition, the 'outsiders') for the recommendation to the UK government as to whether the UK should leave or remain in the EU. The eligibility to vote in the EU referendum was determined by reference to the UK's general election franchise, framed by domestic (constitutional) law. This involved the exclusion of several groups which have come to be seen as particularly affected by Brexit: 16 and 17 year olds; UK-resident EU citizens except Irish citizens; and UK citizens resident abroad. 16 and 17 year olds had been eligible to vote in the earlier Scottish independence referendum. UK-resident EU citizens are particularly affected by the loss of rights derived from EU citizenship, which include ability to work within the NHS, and to have medical qualifications from other Member States recognized in the UK; as well as access to healthcare, along with other social benefits, on the same basis as resident UK nationals.

In the case of UK citizens resident abroad, attempts to use legal means to challenge exclusion were unsuccessful (*Shindler and MacLennan* [2016] EWHC 957; see Armstrong 2017). This legally-blessed configuration of 'insiders' was in effect continued in the *Miller* ruling ([2017] UKSC 5) of the UK Supreme Court, to the effect that the decision to trigger Article 50 TEU could not be taken by the government alone, but required an Act of Parliament (the European Union (Notification of Withdrawal) Act 2017). The question here concerned the legal category of the UK's 'own constitutional requirements', as mandated by Article 50 TEU: in other words, the legal frame is a combination of domestic and EU law.

But after the triggering of Article 50 TEU, the way the decision-makers were understood changed to an international law/intergovernmental relations frame. This move was critical to any arguments about the position of 'outsiders'. The UK as the departing Member State was the key decision-maker on one side of a negotiation; and the Council of the EU-27 was the key decision-maker on the other side. Neither negotiating position was the subject of legal challenge. The Council-27's negotiating mandate (European Council 2017) authorized the

Barnier negotiating team to negotiate on behalf of the EU-27. Several aspects of it could have been legally challenged, such as the way in which Council-27 interpreted Article 50 TEU as mandating a particular phasing of negotiations (Withdrawal Agreement before Future Relationship), or Council-27's particular interpretation of the EU's internal market (its indivisibility), leading, for instance, to the Barnier (2017) 'steps of doom' position.

UK domestic constitutional law precludes such a challenge. But we can infer from the *Wightman* ruling (Case C-621/18) that the decision to withdraw from the EU was a unilateral act of the UK state, acting in an intergovernmental frame as the sovereign government representing the UK population. The reality was, of course, that decisions taken by UK governments as part of the negotiating process could not be said to be legitimated by the whole of the UK population (given the EU referendum franchise and the closeness of the Leave vote); nor could anything about the *way in which* the UK sought to leave the EU be said to be legitimated by the referendum result, given that the question asked the electorate nothing about *how*, only *whether* or not to leave, and neither the 2017 nor the 2019 General Elections offered voters a clear perspective on what type of Brexit each political party would seek to deliver if in power. The UK's negotiating positions for the Withdrawal Agreement and future EU-UK relationship(s), the executive agreement of the Withdrawal Agreement, even the European Union (Withdrawal Agreement) Act 2020: all are acts which are not subject to any/much legitimating control involving any outsiders, and certainly none by judicial review.

At the point of the referendum, Remain voters and Leave voters (and those who abstained) were all 'insiders' in the sense that they had the opportunity to vote in the referendum. But unlike the ordinary political process in the UK, where those whose political party (and preferred policies) are on the losing side have another opportunity to influence decisions at the next general election, the EU referendum was constructed in UK political and constitutional narratives of the main political parties as a one-off vote. This could be seen as imposing externalities not only on those who are now in the electorate and who will be affected by said one-off decision (for instance, those who, in June 2016, were aged 14-17, or were yet to secure UK citizenship) (some of whom may have voted Leave), but also on those who did and/or would now, vote Remain.

The *Millar* ruling confirmed that the devolved governments are also outsiders, in that they have no legal entitlement to resist Brexit within their territories. At least arguably, they ought to be included, given the ways in which the UK's constitutional settlement has evolved over the last few decades (Fabbrini 2017). The First Minister of Scotland, Nicola Sturgeon's moves indicating a possible future Scottish 'independent and seeking EU Membership' referendum

could be constructed as a legitimate and potentially legitimating attempt to reassert the powers of insiders for the Scottish population, who voted to Remain.

Not one of our interviewees from outside the UK, and very few from within (for examples, see McHale et al 2018, McHale et al 2020), saw anything other than very minor health benefits from Brexit, and the vast majority of our data regards Brexit as fundamentally detrimental to health and the NHS. Indeed, the majority of interviewees focused on how EU-UK relations in health policy fields could be structured so as to secure as much continuity as possible with the *status quo*. Health experts (among experts in general) can be constructed as ‘outsiders’ in the referendum process (which excludes any special claims to expertise, giving only one person one vote), and in processes that unfolded after the referendum about the form that Brexit would take. Political narratives about the referendum result – for instance to the effect that ‘this country has had enough of experts’ (Mance 2016) – excluded from policy decisions stakeholders who would normally have been included on account of their policy expertise. For instance, the UK government’s decision to authorize the Secretary of State for Health to permit the substitutability of medicines by pharmacists, without reference to the prescribing medical professional, in the event of medicines shortages following a ‘No-Deal’ Brexit, excluded many stakeholders, such as patients groups and medical professional organizations, whom some of our interviewees told us would normally have been included in such a policy process. Rather, the ‘will of the people’ as understood as expressed in the referendum vote, displaces inclusion of expertise. That exclusion did not, however, found a basis for judicial review (The Good Law Project 2019).

Moreover, as time passed, the position of the UK Parliament vis-à-vis its government became more and more difficult to square with any notion of accountability or legitimacy through ordinary processes of parliamentary representative democracy. The way in which both main parties (Conservatives and Labour) were split between Leave and Remain *de facto* precluded effective parliamentary opposition, which is crucial in the UK constitution to secure the inclusion of those voters whose preferences are not reflected in any particular government. Indeed, various moves by the House of Commons, such as ‘indicative votes’ or the Cooper Bill 2019, could be seen as MPs as ‘outsiders’ trying to become ‘insiders’. In the health domain, even the Secretary of State for Health was an ‘outsider’ to Brexit negotiations under the May and Johnson governments, as he was not one of the ministers ‘around the table’ when decisions on the UK position were taken. Further, our MP interviewees expressed concern over the perceived inability of MPs to hold government to account in even the most rudimentary ways, such as by securing transparent access to relevant information (Health and

Social Care Committee 2017, 2018a, 2018b). Interviewees saw this as an example of how far removed from the ordinary political realm the Brexit process had become.

To summarise: the way in which questions of *how* to leave the EU were resolved as time unfolded resulted in 'othering' increasingly significant groups *within* the UK, even though those groups were insiders in the original referendum decision.

But of course, the effects of the decision *whether* to leave the EU, as well as *how* to do so, ripple far beyond the UK, EU nationals resident in the UK, and UK nationals who have been resident in the EU for over 15 years.

UK-based companies, which supply products across the EU, need to shift regulatory interactions to other Member States, so as to secure continued access to the EU's internal market. Medicines and devices regulation is a case in point, where the UK was/is a highly reputable place to undergo regulatory oversight, securing certainty for industry operators as well as patient safety. CE certificates need to be 'migrated' to BSI's Dutch entity, or to another EU-established notified body. 99% of centrally authorized medicines had been brought into regulatory conformity by 12 April 2019 (European Commission 2019b), and a relocated European Medicines Agency completed this work, alongside ongoing work on UK-nationally authorized medicines. The costs of relocation of the EMA include the physical costs of moving, but also the delays caused to the EMA's work.

National administrative capacity had to be expanded, for example in the Dutch and French ports, and in airports. Pharmaceuticals batch-testing facilities needed to be transferred from the UK to the EU. Companies such as AstraZeneca, and organizations like the European Federation of Pharmaceutical Industries and Associations, warned of the complexities of securing supply of medicines, especially to countries such as the Netherlands and Belgium. Even though supply was secured (Guarascio 2019), there are obviously cost implications. Legal changes were also necessary, for example Spain's No-Deal legislation, which included an attempt to secure health care access for UK pensioners in southern Spain. All of these activities involved negative implications not least in the form of lost opportunities for the public and private expenditure which could otherwise be used for other purposes.

Even if Council-27's negotiating position might have been said to be representing interests of firms and people in the EU27 at a broad brush level, that cannot account for the more granular decisions being taken at both EU and national levels. And those types of decisions have significant effects, *inter alia* in the health policy domain.

To summarise, a 'health Brexternality' has the following features: the effects of leaving the EU impose costs on the health of others who were unable to be involved in the decision to leave the EU, and/or in decisions about the manner in which the UK left the EU. 'Brexternalities' thus involve questions about policy legitimacy and accountability of post-Brexit health governance. Health 'Brexternalities' are not, however, evenly felt: their impact is differential on the basis of spatially-determined modalities.

Spatially differentiated health 'Brexternalities'

Where health services or products provision is particularly closely tied to the UK, health 'Brexternalities' are most severe. The prime example of this is in the Republic of Ireland, which is the EU state with the closest historical, political and economic ties with the UK. It is discussed below. But other examples also emerged from our research: both from the desk-based analysis and especially from the interviews. These involve countries like Spain, with a high concentration of UK nationals receiving health care, due to the climate; Malta, which has been closely integrated with the UK in terms of medicines supply, and regulatory capacity building; and Central and Eastern Europe, where the UK was seen as the ideal place to train as a medical professional.

Southern Europe (Spain)

In certain areas of Spain and other parts of southern Europe, significant communities of UK nationals have chosen to reside post-retirement. Estimates suggest around 190 000 UK pensioners are in this situation (House of Lords, 2018), although official figures probably hide significantly more people who in effect live between the UK and, say, Spain, spending some of each year in either place (Benson, 2018; Menon 2018). Sometimes, this is on medical advice: the warmer climate suits certain chronic conditions. These people relied on EU law rights to access health care. Removing those entitlements, unless replaced with something else, would mean they would need to have private health insurance, a significant cost and burden, especially for those with chronic or multiple conditions for whom insurance might be unaffordable or simply not available (McKee and McKee 2018)

Under the Withdrawal Agreement (WA), Article 32, entitlements to access medical care will continue as long as UK nationals in EU countries continue to be in a cross-border situation after 31 December 2020. The European Commission's view is that Article 32 WA *also* extends entitlements to access medical care relying on EHIC to EU nationals resident in the UK, on visits to the EU. This is one of the aspects of the Withdrawal Agreement in which rights and obligations continue past the Agreement's transition period. According to Articles 126 and

132 WA, this period ends on 31 December 2020, unless the WA's 'Joint Committee' (an institution comprising representatives of the EU and UK, which supervises implementation of the WA, see Article 164 WA) agrees otherwise before 1 July 2020. 'Brexternalities' are significantly reduced with this type of Brexit (Armstrong 2019b), although the cross-border situation would be disrupted, and hence rights lost, if a UK patient returned to the UK and then sought to go back to Spain, or if an EU national left the UK in such a way as to lose the 'ordinary residence' that entitles access to the NHS (and hence responsibility of the UK's NHS for necessary health care on a visit to an EU country).

Some UK nationals in EU countries could rely on EU law covering 'third country nationals', which grants some rights, including potentially to health care, to those resident for more than 5 years (Long Term Residents Directive 2003/109/EC). The Long Term Residents Directive, Article 11 (1) requires Member States to treat those within its scope on an equal basis as nationals in terms of, *inter alia*, access to services available to the public, and to social protection and social assistance. However, Member States may restrict this entitlement to 'core benefits' only (Article 11 (4)). The CJEU has defined such core benefits in a housing case (*Kamberaj*, see also European Commission 2019a), as those which enable individuals to meet their basic needs, such as food, accommodation and health. But the scope of this provision is untested in the context of healthcare.

In addition to the Withdrawal Agreement, effects of Brexit on health outside the UK need to take into account domestic law responses. Spain, along with several other EU countries, took steps to reduce the negative effects of a No-Deal Brexit on resident UK nationals. Its Royal Decree-Law 5/2019, 1 March 2019, sought to grant UK nationals in Spain the same rights that they previously enjoyed, including access to healthcare (Articles 2 and 13). On its face, this approach would significantly reduce health 'Brexternalities'. But there are a number of potential problems.

First, these legal measures are subject to the principle of reciprocity. In other words, for UK nationals to continue to enjoy rights in Spain, Spanish nationals in the UK would need to be given the same rights that they previously enjoyed. The text of Decree-Law 5/2019 provides that the UK has to guarantee rights 'on the same terms and subject to the same conditions' as pre-Brexit. It is not clear whether the 'terms and conditions' concern only the substantive content of the rights at issue (access to healthcare as if a UK national), or whether they are also to do with the enforceability and/or the legal source of the right. Interpreted literally, the 'terms and conditions' of the current position include the qualities of EU law, such as its enforceability before national courts, its primacy over conflicting domestic law, and the ability

to refer questions to the CJEU on authoritative interpretations of relevant rights. These are all guaranteed by the Withdrawal Agreement. However, looking at the substance of the relevant rights, the terms on which Spanish nationals will access the NHS post-Brexit are under the new 'settled status' regime, which involves some small substantive differences (mainly concerning family members) to EU citizenship entitlements, but crucially significant procedural differences. And, if the UK were to move post-2020 to impose any new administrative constraints on access to the NHS for Spanish nationals in the UK, either visitors or people there longer term, that were not in place before, that would jeopardise the condition of reciprocity in the Spanish law.

Second, the Spanish law only involves an undertaking to treat 'persons entitled to healthcare in the UK or Gibraltar by the relevant British entities'. Entitlement to non-emergency secondary-care medical treatment in the UK is on the basis of ordinary residence, not citizenship. So someone who is not 'ordinarily resident' in the UK (because they are resident in Spain) would not be covered by this Decree-Law. So there is a potential gap in protection for those who have not been resident in Spain long enough to fall under the EU's Long Term Residents Directive, but have been resident in Spain too long to be 'ordinarily resident' in the UK for the purposes of accessing healthcare.

Third, on a practical level, the UK also has to reimburse the Spanish authorities for the health care undertaken. This is covered by the Withdrawal Agreement, Article 34. The costs of putting this new reimbursement system in place are among the health 'Brexternalities' at issue.

Small states with close UK health ties (Malta)

Historic ties in the health domain between the UK and small states, especially English-speaking states, like Malta, affect the way health 'Brexternalities' will be felt in different parts of the EU. Small states often have close economic ties with large states with whom they have historic or colonial legacies, working closely in similar regulatory frameworks and traditions (Corbett and Veenendaal, 2018). Malta's health care system worked with the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), which authorizes pharmaceuticals for market access, even before Maltese accession to the EU. Many medical professionals, particularly specialists, practising in Malta, qualified in the UK. The MHRA trained the Maltese health inspectorate.

Some 60-70% of medicines used in Malta come through the UK, supplied by UK-based agents. Maltese doctors are accustomed to prescribing them and patients to using them. Security of medicines supply is therefore a huge potential 'Brexternality' for a country like Malta

(Musazzi et al 2020). The Maltese authorities sought to mitigate these problems by working with stakeholders to stockpile and to convince them to secure different supply chains, from other EU Member States, or at least from a supplier which holds a marketing authorization in another EU Member State.

This is far from easy, because medicines need to be labeled and product information leaflets supplied in one of Malta's official languages. The market in Malta is too small (450 000 patients) to justify relabeling in Maltese, and English is an official language, hence the current practice of using packaging that is also used in the UK. Multilingual labeling is another possible approach, but many EU countries do not accept English on their pharmaceutical packaging as an additional language. Our interviewees suggested that some pharmaceutical companies, particularly the larger ones, were reluctant to undertake the costs of securing regulatory compliance, in order to supply the Maltese market. They expressed concerns that these costs would end up with the end-users (patients), and that this burden would fall disproportionately on the older population, with chronic conditions. They also suggested that these health 'Brexit externalities' are largely hidden from the public domain, and that public knowledge about these costs of Brexit in Malta is scarce.

States with ties to UK health workforce (Central and Eastern Europe)

The UK labour market and market for services offers a particular draw for EU nationals, especially those from Central and Eastern European states, because of its relative openness, flexibility and light regulation (Greer in Greer and Laible 2019). This is the case in the health care domain as much as in other contexts more associated with such labour and service mobility, such as fruit-picking or plumbing. The Standing Committee of European Doctors (2017) strongly urged the Barnier negotiating team to secure future mutual recognition of UK medical qualifications in the EU. This has been achieved in part in the Withdrawal Agreement, for ongoing recognition of qualifications that were recognized before the end of December 2020. At the time of writing, information on the arrangements under the proposed future EU-UK trade relationship suggest they will fall far short of that.

There are particular concerns for medical professional capacity building in Central and Eastern European states, where the opportunity to qualify in the English language provides a strong incentive for medical professionals to spend part of their career in the UK, particularly benefiting from the ability to secure specialist qualifications (Kuhlmann et al 2017). Future health workforce planning in those states is thrown into jeopardy by these health 'Brexit externalities'. The Netherlands, Ireland or Sweden may offer alternative opportunities, but none is as large or as open as the UK as a labour market (Greer in Greer and Laible 2019).

Some of our interviewees suggested that Australia or the USA are likely alternative destinations. They also warned that there is unlikely to be a benefit to Central or Eastern European states of less outward migration of medical professionals: salary levels in those states are insufficient to suggest that UK-based medical professionals will return to their home state.

Ireland

It is probably impossible to estimate the risks in general of Brexit to the island of Ireland, and we do not attempt to do so here. As de Mars et al (2018) show, the particular fragility of the 'bordering', and 'de-bordering' of Ireland, is profoundly affected by the potential 're-bordering' entailed in Brexit. Ireland is closely integrated with the UK through integrated supply chains; Britain accounts for 30% of Irish imports; most analysis shows substantial sector-specific economic losses in Ireland as a result of Brexit (Egan in Greer and Laible, 2019; Copenhagen Economics 2018).

Health is only one domain – but an important one – in which the island of Ireland has essentially become an integrated entity, albeit an entity which takes a formal form of Ireland, and Northern Ireland, as a devolved part of the UK (McHale et al 2020). Not all of the legal and political mechanisms supporting that integration come directly from EU membership, which makes it hard to disentangle effects of Brexit on health (or anything else) in Ireland. The Good Friday Agreement's power-sharing model is based on cooperation and working together (CAWT) in both North-South (Northern Ireland and the Republic of Ireland) and East-West (Republic of Ireland and the UK as a whole) dimensions. CAWT supports integrated health care systems across the island of Ireland, and also with other parts of the UK, such as Scotland, through INTERREG funding (Commons Health and Social Care Committee 2017). Health is thus one of the successes of the Good Friday Agreement (de Mars et al 2018: 4). Pharmaceuticals, devices and consumables supply chains are deeply integrated on the island of Ireland, and this is supported by EU law on free movement of products. The health workforce, especially in the geographical north of the island, is essentially shared. Some of this is supported by EU law (such as on mutual recognition of qualifications). But other aspects are embodied in the 'Common Travel Area', which takes legal form in a set of parallel rules within UK and Irish law (Ryan 2001; McGuinness & Gower 2017; de Mars and Murray 2020).

Any division of the island of Ireland through 're-bordering', even of the lightest nature, involves 'Brexternalities' for health in both Northern Ireland and Ireland. These will be felt predominantly in access to medical products such as pharmaceuticals and medical devices, as well as provision of health services and the health workforce. The UK and Irish governments intend

that the Common Travel Area secures continued access to emergency, routine and planned publicly funded health services of British patients residing in Ireland and Irish citizens residing in the UK (Lidington and Coveney MoU 2019), but this is yet to be tested in administrative or judicial contexts.

Although formally Ireland and Northern Ireland have separate health systems, in practice the two systems are highly integrated. One potential health 'Brexituality', recounted in our interviews, is the possible return to a situation in which an ambulance can no longer freely cross the border, supported by reciprocal arrangements between the two health systems, EU law on free movement of products and mutual recognition of qualifications of medical staff (Flear et al 2018; McHale et al 2020). Thirty years ago, critically ill patients had to be transferred between ambulances on the border. This involved inefficiencies, as two ambulances and associated staff would be tied up in one incident. For a patient in an acute situation, it could represent the difference between life and death. One of our interviewees described how over 100 patients, including a close family member, who would otherwise have died, have been saved by these arrangements. But the arrangements under the Withdrawal Agreement, and in particular the Northern Ireland Protocol, secure continued access for ambulances across the border on the island of Ireland, removing the potential threat to life itself as a particularly poignant health 'Brexituality'.

Significant costs for the Irish health service would have been entailed in dismantling the health facilities that are shared across the border, including the North Western Cancer Centre at Altnagelvin Hospital in Northern Ireland, which serves patients in the western part of Northern Ireland and north and west Donegal; Our Lady's Children's Hospital in Dublin, which provides heart surgery for children across the island of Ireland; or the EU-funded €7.6 million project on mental health for Northern Ireland and the Republic of Ireland, supported by the health strand of the CAWT (Belfast Telegraph 2018). Shared training, for instance under the EU's INTERREG programme involving paramedics in Scotland, the Republic of Ireland and Northern Ireland, allowed for economies of scale. To recreate these for Irish patients only could be beyond the capacity of the Irish health care system (Health and Social Care Committee 2017).

And the potential costs go further than mere health care capacity. Health care integration has taken place within the broad parameters of the peace process, following the Good Friday Agreement. Healthcare thus plays a (small) role in security, peace and stability on the island of Ireland (Hervey and Speakman 2018). The health 'Brexitualities' of a post-Brexit border

on the island of Ireland thus could extend to violence and loss of life, a point noted in some of our interviews.

Around 30 000 workers cross the Irish border daily (NIAC 2018a, paras 5-7 in de Mars et al 2018: 76), of whom many work in health and social care (BMA 2018). (For data from 2009 on frontier working across the EU generally, which shows health and social care is one of the significant industries at issue, see European Commission 2014.) The Common Travel Area (Ryan 2001; de Mars and Murray 2020) effectively secures rights to work in this way for British and Irish nationals. We do not have exact data on how many of these workers are EU-26 nationals. Overall, around 275 000 non-UK EU nationals are resident in Ireland (Central Statistics Office, 2011) and nearly 47 000 in Northern Ireland (Northern Ireland Statistics and Research Agency, 2011). Given reliance in the sector generally across the UK, the number is likely to be not insignificant. The Withdrawal Agreement reduces the potential 'Brexit externalities' here significantly during the transition period, where the practices of frontier workers in settled patterns of working are secured in legal rights. After December 2020, though, the health 'Brexit externalities' entailed in introducing more checks on workers and increased barriers to working across an EU Member State and a 'third country' will make it more difficult to recruit EU-26 nationals to serve the health needs of border communities (Connelly 2018: 44, cited in de Mars 2018: 78).

Our interviewees in Ireland expressed concerns that medical professionals working across the border would, if forced to choose, elect to relocate to Northern Ireland and the UK more generally. Pay, especially for post-2012 entrants when a 30% austerity pay cut was imposed, working conditions and over-crowding in the Irish hospital sector do not offer the opportunities that places such as Australia, Canada, New Zealand and the UK can offer, so Irish medical graduates emigrate, leaving Ireland with unmet healthcare needs. Further, our interviewees suggested that the post-Brexit reduced pool for the UK to recruit to NHS positions, and the departure from the UK of EU-26 nationals to other parts of the EU, leaves Ireland vulnerable to attempts by the UK to entice Irish medical professionals to the UK, given the shared language and very closely aligned qualifications programmes. The ability of Ireland to persuade UK-trained Irish national doctors back would be further reduced if the mutual recognition of professional qualifications ceased under the future EU-UK relationship.

Ireland shares the vulnerabilities of countries such as Malta when it comes to medicines supply. It is a small, English-speaking market, and reliant on UK supply chains for pharmaceuticals, medical devices and consumables. The Withdrawal Agreement guarantees free movement of products not only during the transition period, but also thereafter. The

Northern Ireland Protocol is supposed to move all practical administrative aspects involved (customs duties, regulatory controls) to a *de facto* border in the Irish sea, so that there is no land border on the island of Ireland.

The Withdrawal Agreement's Northern Ireland Protocol (NIP) in effect assumes that Northern Ireland is within the EU's customs territory (NIP Article 6; Weatherill 2020; Harvey 2020). More importantly for pharmaceuticals, which are zero-rated in any event, but also relevant to medical devices, equipment and consumables, the NIP extends the application of EU goods law (product standards, marketing and product safety rules) to Northern Ireland. EU law on marketing and safety standards for goods (all listed at great length in NIP Annex 5) will apply 'to and in the United Kingdom in respect of Northern Ireland' (NIP A6(2)).

Although the NIP's stated objective is to be temporary (NIP A1(4)), the amount and depth of detail suggests that this has been drafted in a way that it can actually be used. And it is not time-bound: it applies until it is superseded by (a) subsequent agreement(s) (NIP A1(4)). The health 'Brexit externalities' of a Brexit involving the Withdrawal Agreement are thus significantly less than would have been the case under a 'No-Deal' Brexit.

But problems remain to be solved, and these will be costly as well as disruptive to existing patterns of trade in medicinal products, devices and medical equipment. The idea is to move as many checks as possible away from the border, to factories, distribution centres and at the end consumer point. But for instance for food safety and animal health, key elements of public health protection, the EU will want to be satisfied that the UK is upholding the standards agreed in the NIP. This assurance will be especially important if the UK's regulatory standards diverge from the EU's (Hayward and Phinnemore 2020). In that case, the EU needs to be able to act quickly, (De Mars et al 2018: 38-29). All of these changes imply costs, and many will fall disproportionately on Ireland.

Although the European Commission acts on behalf of the whole EU, the 'Brexit externalities' of this position will not be felt evenly across the EU, and will be felt much more profoundly in Ireland.

EU population-wide health Brexit externalities

The health 'Brexit externalities' discussed so far involve spatially differentiated effects. But some health 'Brexit externalities' will be felt across the whole EU. These concern in particular the significant contributions that the UK has made to the overall EU capacity for EU-level regulatory decisions in health domains, as well as UK contributions to biomedical research.

The size of the UK, its extensive governmental, technical/scientific, educational and research resourcing, and its centuries of public investment in scientific education and regulatory capacity all make it a significant player in the EU (Greer and Loblovà in Greer and Laible 2019). The UK's contributions here fall into two main types: expertise and leadership, with overlaps between the two.

Both research and regulatory expertise from the UK have contributed significantly to EU decision-making in the health domain (Greer and Loblovà in Greer and Laible 2019). The House of Commons Health and Social Care Committee (2018a: para 38) found that, in 2016, the UK's Medicines and Healthcare products Regulatory Authority took the lead in nearly half of EU regulatory procedures and on 20-35% of the European Medicine Agency's licensing and vigilance work. The UK was extremely active in the European Medicines Agency's committees and working parties. Replacing that capacity entails costs. The EMA has brought central marketing authorizations involving the UK into regulatory conformity (European Commission 2019b). However, there are obviously also opportunities here too. The Netherlands embraced the relocation of the EMA to Amsterdam enthusiastically for that reason. Without the inclusion of UK capacity in its delegations, the EU's influence in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or the International Medical Device Regulators Forum is diminished. More broadly, if the UK drifts towards the USA in terms of global standards, e.g. in medicines, or food safety, the EU may find it harder to promote its position in global contexts such as the WTO (Jarman, in Greer and Laible 2019)

There are also health 'Brexternalities' for the EU in terms of medicines supply. Each month, some 45 million boxes of pharmaceutical products go from the UK to the EU (and some 37 million from the EU to the UK). This trade is facilitated by marketing authorizations recognized by EU law. For access to the EU market, such pharmaceuticals marketing authorizations will need to be held by companies in EU Member States, and the process of transferring such authorizations entails costs and takes time. Our interviewees expressed some concern that, in the event of a 'No-Deal' Brexit, there might have been insufficient time for legal processes to be completed, potentially leaving patients across the EU-27 vulnerable to interrupted supply. But delays to Brexit mitigated these time-critical health 'Brexternalities'. By June 2019, some six months before the UK left the EU, the European Commission (2019a) reported that 99% of centrally authorized medicines in use in the EU27 had been 'Brexit-proofed'.

Removing the UK from the EU's biomedical research capacity also entails significant 'Brexternalities' (Cancer Research UK 2020). It may be that the UK is able to negotiate

continued access to EU biomedical research funds as a 'third country'. But this may prove politically unappealing, either to the EU, or to the UK, or both. At the simplest level, the EU will lose 12% of its population on Brexit, with implications for the potential scale of clinical trials and other biomedical research. Of course, many such trials take place using populations drawn from outside the EU, and this will continue. But for clinical trials taking place within the EU, the loss of the UK population is likely to be particularly starkly felt in the case of rare diseases, where EU-scale research is viable because of the scale of the EU population and its ability to invest.

Furthermore, our interviewees estimated that some 60% of products used for clinical trials come from the UK, so imposing border controls would necessitate changes to the practicalities of EU-wide clinical trials: it will not be possible to continue in the way that these trials currently work. The UK was vastly over-represented in leadership of European Reference Networks, which are EU-funded consortia of scientists focusing on a particular rare disease. Our interviewees told us six of the current 24 Networks were UK led, and these positions are occupied on the basis of peer review and assessment. By August 2019, all Networks were listed on the relevant website as led from other EU Member States (European Commission 2019b). The EU is losing the leadership and research expertise of some of its (and the world's) best biomedical scientists. One of our interviewees told us that one such Network had extreme difficulty finding a non-UK expert to take over its leadership. All of these losses involve health 'Brexternalities', particularly for sufferers of rare diseases.

Global health Brexternalities

Finally, some health 'Brexternalities' will be felt globally. The obvious example here is communicable disease control. Greer and Loblovà (2019) contrast the position of EFTA/EEA countries and Switzerland as they relate to the EU's European Centre for Disease Control and Surveillance (ECDC). The difference is striking. For functional purposes, where the key granular decisions are made, Norway, Iceland and Liechtenstein are in effect treated as EU Member States. Switzerland is not. This is so even though the geography and the dense interconnections between Switzerland and the EU suggest that coordination with Switzerland would be desirable. This is not, therefore, a functionally driven matter, and we can expect that the UK will be treated similarly once outside the EU. The Withdrawal Agreement does not include any provision about the ECDC. Indeed, the UK excluded itself from even those collective responses to COVID-19 in which it could have participated, for instance joint procurement of medicines, vaccines and equipment (McKee et al 2020).

Our interviewees were universally concerned about UK exclusion from the ECDC. They point to Public Health England's huge contribution to ECDC's work, noting that 'nobody has as good scientific input' as the UK, that the UK 'punches way above its weight' (McHale et al 2018), and the UK's leadership on all kinds of communicable and non-communicable disease surveillance and research. Even the other big EU countries do not have that capacity and expertise, and so it is unclear who is going to take up the slack post-Brexit. They note that, unless the UK seeks a 'Norway'-type future relationship, it is difficult to see how the UK can be involved in the future. They express some hope that the detriments could be mitigated by working through the WHO's International Health Regulations, but note that this will be sub-optimal. One interviewee distinguishes between 'high level' and global threats, where it will remain possible to work with the UK through the WHO mechanisms, and 'the daily things', threats that are more specific to the EU, which are discussed in the EU context through ECDC, for example an outbreak of Hepatitis A in men who have sex with men, involving the UK and a few other countries. These will not be possible to carry out using UK capacity post-Brexit, and that will be to the detriment of the EU, and the rest of the world, in terms of communicable disease data gathering, surveillance and response. Another interviewee notes that not easily being able to share data through the ECDC's early warning system on what is happening in the UK will be detrimental to public health across the EU. This is also a concern for the food, medicines and chemicals agencies and others with 'early warning' mechanisms. The IHR mechanisms do not in themselves cover this kind of information-sharing.

Summary and conclusions

The EU is a particularly effective (though of course far from perfect) institutional and legal arrangement for managing political and economic externalities. Other mechanisms or relationships between the UK and the EU are likely to be sub-optimal in that regard at least in the short to medium term.

Different levels and types of integration of health law and policy mean 'Brexit externalities' are felt differently in different contexts in the health law and policy domain. Although some are felt by certain groups in the UK, such as rare disease sufferers who were excluded from the referendum vote, health 'Brexit externalities' fall mainly in EU countries.

But health Brexit externalities do not fall equally in all EU countries. They are felt more distinctly in the context of those elements of health policy that are most closely entwined with the UK's health policy: for instance, on the island of Ireland; certain areas of Spain and other parts of southern Europe; small English speaking countries who rely on the UK for medicines supply; under-capacitated countries, for instance, in Central and Eastern Europe who rely on the UK

for medical professional training. Some health Brexternalities, such as in medicines safety, are imposed on the whole population of the EU. And some health Brexternalities, such as in communicable disease control, will be felt globally.

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