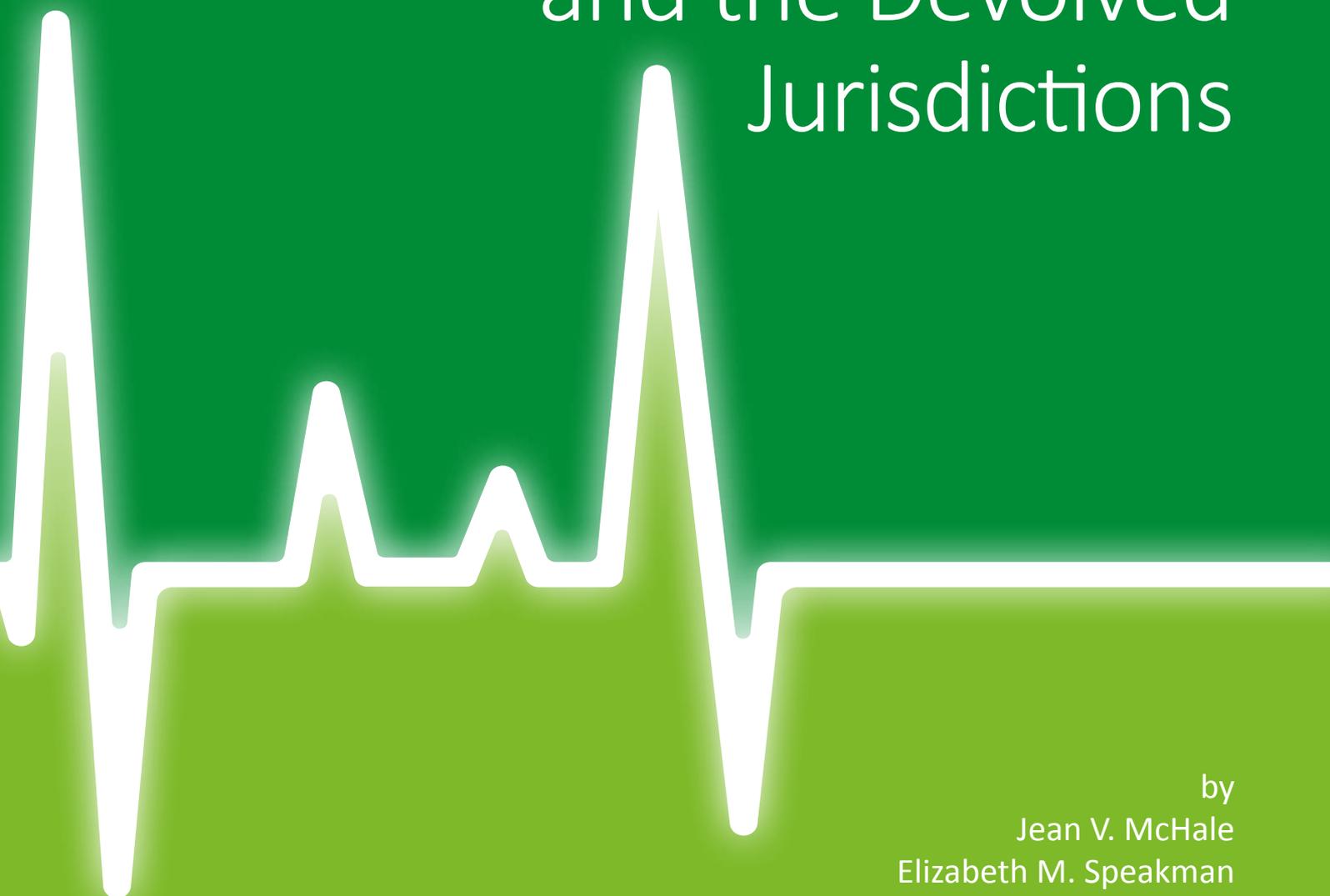


The NHS and Health Law Post Brexit:

Views from Stakeholders
and the Devolved
Jurisdictions



by
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Executive summary

The NHS has played an important role in the Brexit debate since the Referendum and the Big Red Bus. This report, from a ESRC UK in a Changing Europe project “Health Law Outside the EU: Immediate, Intermediate and Long Term Impacts”, considers the impact of Brexit on the NHS in the devolved jurisdictions, from the perspectives of professionals and patients, pharmaceuticals and public health. Drawing upon 22 semi-structured interviews with key stakeholders in the health sector in England, Northern Ireland, Scotland and Wales, we show that experts on the ground are concerned about many aspects of health post-Brexit. There are particular worries about a No-Deal Brexit, especially on the island of Ireland; in terms of supply of basic consumables to hospitals; and in how robust current practices for responding to shortages would be.

KEY FINDINGS

- 1.** Health co-operation on the island of Ireland is facilitated by a combination of EU law and bilateral agreements. Major concerns were expressed by interviewees as to the position of cross-border care in the border regions.
- 2.** Exclusion from the EU Patients’ Rights Directive may impact on patient care in Northern Ireland where currently some patients have been referred to other EU member states for treatment. It is uncertain whether there will be attempts to continue such referrals post Brexit. While bilaterals with other EU Member States may still be utilised as a means of addressing waiting lists this may incur greater costs.
- 3.** Staffing remains a major issue to be resolved. Brexit is occurring in the context of a chronic shortage of healthcare professionals throughout the UK, but particularly severe in Northern Ireland. There is a different distribution of EU nationals working in the NHS across the devolved jurisdictions. While some of the staffing issues relate to Brexit, others concern a range of other policies. In the context of Northern Ireland there is particular concern about staffing planning and resources. Further adverse impacts on staffing relate to long term UK medical training policy and availability of bursaries for nursing students.
- 4.** Policy in relation to mutual recognition of qualifications is likely to be a continued issue of debate. There were different views expressed by stakeholders as to the appropriateness of continuing with the present system.

5. The prospect of shortages in access to medicines but also to a range of other consumables is a matter of concern. Normally responses to shortages are centrally run and there is clearly an interface with the devolved jurisdictions. The key issue is the likelihood of multiple shortages taking place simultaneously, meaning that the normal responses are inadequate. The size of NHS England compared to that of the devolveds leads to concerns about how professionals in Northern Ireland, Scotland and Wales will access consumables they need to treat patients, especially in the event of a no-Deal Brexit. Some of the stockpiling issues are different in Wales due to different organisational structures e.g. microbiology labs being centrally run in NHS Wales.
6. Public health remains a concern amongst stakeholders across the devolved jurisdictions. There are perceived dangers that standards may be weakened due to the influence of commercial considerations, particularly in tobacco regulation.
7. Future regulation of E-cigarettes and its impact on public health policy remains a matter of debate within the UK.
8. Concerns were raised as to the impact on the EU of the UK no longer being part of EU public health networks. It is suggested that the relationship with ECDC should be pursued by the UK Government.
9. As a number of interviewees noted, the UK through its membership of the EU is involved in a range of vigilance systems which operate in relation to health professionals, pharmaceuticals, medical devices and blood and tissue which facilitate the protection of patient safety. Without a specific agreement, the UK will be excluded from these systems. Some of these questions are being addressed by the MHRA with regard to domestic systems of pharmaceuticals and devices in its Autumn No Deal Brexit consultations and the Department of Health in relation to blood and tissue safety with the devolved jurisdictions. However access to EU systems remains uncertain and will need to be subject to future negotiation.
10. The social determinants of health and the potential adverse economic impact of Brexit through the loss of EU structural funding support and damage to industry has been particularly highlighted in Wales and Northern Ireland. The potential negative impacts on health of social and economic disruption need to be addressed by policy makers in the immediate, intermediate and long term period of Brexit.



Brexit and the Devolved Jurisdictions: Impacts for the NHS and Health Law¹

by Jean V. McHale², Elizabeth M. Speakman³, Tamara K. Hervey⁴ and Mark Flear⁵

A notable development in health law and policy in recent years has been the impact of devolution on Wales, Scotland and Northern Ireland. Health as a devolved power means that the devolved jurisdictions are able to develop their own health policy on a range of issues.⁶ This can be seen as reflective and responsive to the different demographics which can bring their own health challenges. Yet where questions of regulation and patient safety are concerned it is unrealistic to regard devolved powers as distinct and different. Brexit raises specific challenges in relation to health due to the impact of the EU upon domestic health law.⁷ However, many issues concerning health and the EU are not left directly as matters for the devolved jurisdictions, instead they are “reserved” for Westminster.⁸ Reserved powers include the regulation of health professionals, product safety and labelling, employment rights and duties such as the Working Times Regulations 1998, medicines, medical devices and biological substances. Nevertheless, there will be specific and at times different impacts of Brexit on the devolved jurisdictions in situations in which the powers are not reserved to Westminster.

In this report we consider the impact of Brexit on the NHS and the devolved jurisdictions from the perspectives of people – healthcare professionals and patients – public health and pharmaceuticals.⁹ We draw upon the first part of our study from 22 semi-structured interviews conducted so far with key stakeholders in the health sector across a range of health areas and in each of the four UK regions and Europe. Interviewees were asked for their perspectives of the impact of Brexit on their particular health areas, challenges and also whether they saw any opportunities. The research conducted was approved under the University of Birmingham Research Ethics approval process. Many of the issues discussed below are highly politically sensitive, to such an extent that many people approached felt unable to be interviewed while negotiations were ongoing. We are extremely grateful to those stakeholders who did speak to us and have respected both their anonymity and that of their organisations. Our analysis was also informed by three closed stakeholder workshops held in Edinburgh (November 2017), Belfast (December 2017) and Cardiff (January 2018) and we are also very grateful to those who participated. This report examines the key issues highlighted through the prisms of the immediate, intermediate and long-term impacts of Brexit on health law.¹⁰

1 This report is funded by the ESRC under their UK in a Changing Europe initiative. Grant Number ES/R002053/1.

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6 These include in relation to the regulation of blood, organs and tissues.

7 See further T.K.Hervey and J.V.McHale • *European Health Law: Themes and Implications* Cambridge University Press: 2015.

8 Scotland Act 1998, schedule 5; schedule 1 inserting New Schedule 7A to the Government of Wales Act 2006, implemented from 1st April 2018.

9 See also in relation to Wales- <http://amrcw.org.uk/portfolio/brexit-and-the-implications-for-healthcare-in-wales-2/>.

10 See also the UK in a Changing Europe Report Brexit and the NHS (March 2018) – including contributions from McHale, Hervey, Flear. T. K.Hervey <http://ukandeu.ac.uk/wp-content/uploads/2018/03/Brexit-and-the-NHS-.pdf> and E. M Speakman, ‘The Immediate Futures Of Health Law After Brexit: Law, ‘A-Legality’ And Uncertainty’ [2018] *Medical Law International*. <https://journals.sagepub.com/doi/full/10.1177/0968533218810746>.

People: The Impact of Brexit on Patients and Staffing

In the UK as a whole there are currently some 10% registered medical practitioners drawn from other EU member states. In England there are 10% of doctors and 7% of nurses from other EU member states.¹¹ In other parts of the UK, General Medical Council figures record that the percentage of doctors with a primary medical qualification from the EEA are Wales: 6.4%, Scotland: 5.7%, Northern Ireland: 8.8% (mostly from the Republic of Ireland).¹²

Northern Ireland, as in relation to other aspects of Brexit, faces specific challenges. The UK Government has stated that “The UK wants to ensure continued collaboration on healthcare with Ireland and [to ensure] that there are no barriers to the movement of patients, staff or resources on the Island of Ireland.”¹³ Northern Ireland is the place where our interviews to date indicate that there is a key challenge to staffing and delivery of patient care¹⁴. Recent years have seen increasing integrated healthcare provision in the island of Ireland, much of it driven by economies of scale.¹⁵

This has been facilitated through EU funding and the development of CAWT - the Co-operation and Working Together Partnership - operational since 1992. There is currently a range of cross border provision of services facilitated through existing bilateral agreements. So, for example, children travel to Northern Ireland for ear nose and throat treatment to avoid waiting lists of up to four years in the Republic of Ireland. Children’s cardiac surgery stopped being provided at Belfast Royal Victoria Hospital in 2015. Instead children from Northern Ireland and from the Republic of Ireland are treated in Our Lady Children’s Hospital in Dublin. The Irish Government has contributed funds to the Radiotherapy unit at Altnagelvin which is the main hospital for the north west of Northern Ireland and which provides treatment for cancer patients from both Northern Ireland and Donegal. The practical day to day nature of such cross-border care provision was raised by a Northern Irish interviewee from a health professional organisation:

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, and it’s all magnified given the cross border nature within Ireland. (Interviewee in Northern Ireland)

11 Latest statistics in C.Baker “NHS staff from overseas: statistics” House of Commons Library Briefing Paper Number 7783, 10 October 2018.

12 Latest GMC Figures (2015) Our data about doctors with a European primary medical qualification, Working Paper 1 February 2017.

13 Department of Health and Social Care Government response to the House of Lords European Union Committee, 13th report of session 2017-19, ‘Brexit: reciprocal healthcare’.

14 Note also there have been concerns raised from the perspective of Ireland as to the impact of Brexit on health. See Health Manager “The impacts of Brexit on healthcare staffing and services” <https://www.healthmanager.ie/2017/10/the-impacts-of-brexit-on-healthcare-staffing-and-services/>.

15 The House of Lords report: Brexit: Reciprocal Healthcare (2018) strongly urged the Government to maintain this cross-border cooperation in the Brexit negotiations as to do otherwise “would be highly detrimental to healthcare for patients on both sides of the border, including children and other vulnerable patients”. HL Paper 107 at page 4.

While staffing and the broader uncertainties that Brexit poses is a key issue specifically raised by interviewees, this has to be set against a backdrop of what are already considerable existing staffing shortages in Northern Ireland:

In Northern Ireland we know that there are currently at least 1,800 – and we actually believe it to be significantly more than that – at least 1,800 vacant nursing posts in the health service in Northern Ireland, and probably almost the same number out in the independent sector. So clearly the implication with leaving the European Union is the question mark over the status of those nurses working here who have come from other European Union countries, EEA countries. The number of those nurses has declined quite significantly over the last couple of years.



That really adds to the concerns about the sustainability of the nursing workforce and the need for proper planning. That takes in making sure that we train enough nurses at a pre-registration level, that we take on enough student nurses. But it also goes into other areas such as pay and terms and conditions of service, because obviously one of the ways in which you can retain nurses in the service, or even entice those back who've left nursing, is by offering a reasonable and decent pay and terms and conditions' strategy.

So that's very much been the focus of what we've been looking at over the last two years. It's developing a workforce strategy that will take into account and compensate for the inevitable loss of nurses from other European Union countries. But also doing what we can to safeguard the status and the right to work in the UK post-Brexit of those nurses. In simple terms we think we really can't afford to lose them. (Interviewee in Northern Ireland)

Many Northern Irish doctors and medical students have been trained in the Republic of Ireland, a situation which might be jeopardised if mutual recognition of professional qualifications does not continue post-Brexit:

We have probably less of a reliance on EEA qualified doctors in Northern Ireland. About 9% of our doctors in Northern Ireland qualified outside of the UK. However 73% of that 9% actually qualified in the Republic of Ireland.

One of the concerns would be the mutual recognition of professional qualifications. We have, relatively speaking, a large number of medical students from Northern Ireland who train in the Republic, bearing in mind it could be half an hour or an hour journey for some people to go from Belfast to Dublin or from Newry to Dublin or wherever to do medicine.

In the event of the mutual recognition of professional qualifications not being honoured it means that those people wouldn't be able to come back home to practice medicine without potentially having some sort of barrier or some sort of process to go through. We would hope that wouldn't be the case because it may create a barrier so people would just opt to continue to work either in the Republic or in some of the other EU countries. (Interviewee in Northern Ireland)

Particular concerns were raised about a perceived impact of Brexit upon the recruitment of nurses:¹⁶

Employers within healthcare and employers 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.

The loss and the accelerated loss because of Brexit of nurses from other European Union countries, that's happening on the back of a situation where we already have shortages... if nurses trained in other European Union/EEA countries are going to leave the UK, then that's simply going to exacerbate the existing shortages. That's really the issue. (Interviewee in Northern Ireland).

Another interviewee suggested that there were particular systemic problems in Northern Ireland:

In Northern Ireland it's also due to the absence of any systemic workforce planning. This is something that we've been raising for many years in Northern Ireland, that there is no process whereby the health needs of the people of Northern Ireland are assessed. And obviously some elements of future gazing into that. In other words, what are the health and social care needs of the people of Northern Ireland going to be over the next ten years. Then on that basis, how many nurses and what kind of nurses do we need to meet those needs, as well as obviously all the other health and social care professional groups. Then how are we going to make sure that we have a workforce that will meet those needs. That's a combination of training enough nurses in the first place, and obviously having the facility for overseas recruitment if that's required. (Interviewee in UK - wide organisation).

Concerns about workforce planning in Northern Ireland are likely to be exacerbated in the case of a no-Deal Brexit:

For particular specialties, there would be an issue for example with the cancer and radiotherapy unit in Altnagelvin and the joint paediatric cardiac service based in Dublin, two models of practice that show that they have got the capacity and the demand that is necessary to sustain it, but it's on an all-Ireland basis.

Northern Ireland on its own can sustain ordinary specialties, but we don't have enough demand or doctors to sustain niche specialties which is why the all-island provision of services is so crucial. Workforce planning is a huge part of this and 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. In recent times they have looked at it, but the issue seems to be that there has been a real absence of robust information and evidence on which to plan. (Interviewee in Northern Ireland)

¹⁶ "Number of EU nurses drops sharply" - Financial Times, November 2017. 1,107 nurses joined NMC register in 2017- drop of 89% on previous year. Nursing and Midwifery Council News. "Increasing number of nurses and midwives leaving profession 'highlights major challenges faced by health and care sectors'" <https://www.nmc.org.uk/news/news-and-updates/increasing-number-nurses-midwives-leaving-profession-major-challenges/>.

While it has been suggested that the shortage could be addressed through training of more clinicians, there was scepticism from interviewees as to how realistic this was as a strategy. This would moreover obviously be a long-term strategy given the timeline which it takes to train medical practitioners, particularly up to consultant level.

Concerns were expressed as to the impact of the no-deal scenario on medical professional mobility:

The argument has always been that the Common Travel Area precedes any European involvement or any EU membership by either UK or the Republic and so that would be reciprocal. The CTA is based on informal goodwill and although it's a unilateral agreement between the UK and Ireland, there isn't actually any legislative underpinning of it, or any legislative underpinning has been strengthened by our EU membership. If that relationship was to deteriorate, then that could cause a problem for the CTA.

So our issue had been that even if the freedom of movement with the CTA continued, in the event of a no deal scenario, people would again vote with their feet.

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

The question of regulation and insurance was raised was also raised by one respondent:

There would be a lot of cross-border provision of GP services, for example in Castleblaney in Monaghan, that would go across the border, 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)

These are further practical issues which will need urgent resolution in the event of a "no-deal" Brexit or if no agreement is reached at the end of the transition period.

In Wales and Scotland the staffing questions in relation to doctors from other EU Member States are not as pronounced at one level as there are fewer clinicians overall from other Member States. However, as groups of clinicians appear to be concentrated in specific areas, such as the larger cities, this may have a particular impact on those regions. As one interviewee from a professional organisation commented:

In terms of Wales and Scotland there are the extremities of those countries, so rural areas that are maybe quite dependent on European doctors. When you look at the figures you may say, oh, but it's only 5.8% of doctors in Scotland with a European qualification but all of them may be in the Highlands and Islands and without them there are simply no doctors. And it's similar in Wales: there are areas, yes, it's 6.5% of doctors in Wales are European or have a European qualification but often they're all centred in one specific area where other doctors maybe don't want to work: maybe it's a very deprived area, maybe it's a very rural area. So there are workforce issues. (Interviewee from UK-wide organisation)

Interviewees also raised questions of patients' rights. EU reciprocal health rights under the EU Patients' Rights Directive which enables patients to obtain some treatment in another European Economic Area (EEA) country (excluding Switzerland) and obtain reimbursement of cost from the NHS¹⁷ has led to patients being referred for treatment in other EU Member States:¹⁸

There's been a huge upsurge [in use of the Patient's Rights Directive] in all of the UK. In Northern Ireland particularly as they have got the largest waiting lists. There is a EU cross-border directive whereby, if for example you are sitting on a Northern Ireland waiting list waiting for a knee replacement you can go somewhere. Lithuania I think is the latest hot place I think to go.

You have to pay up front and claim it back. You won't get your travel costs and you won't get your hotel costs reimbursed but you would get a set fee. It may cost you slightly more depending on what country you go to. I can't remember the exact figure, but millions of pounds have been reimbursed to patients from Northern Ireland to have procedures done because they have been on the waiting list for so long. That's had a big surge this side of Brexit because there's no guarantee, and it's very unlikely, that that will continue post-March. (Interviewee in Northern Ireland)

The use of the EU Patients' Rights Directive has not to date been seen as a major issue in the debates concerning patients' rights and reciprocal healthcare. However in Northern Ireland at least it appears to have had a considerable impact. If the Withdrawal Agreement is adopted, application of the Directive as with other reciprocal health care rights would continue during transition.¹⁹ However there is no guarantee what will happen post December 2020. If there is a No Deal Scenario then there have been assurances in terms of safeguarding the position of EU citizens in relation to access to health care. While NHS emergency treatment is free to residents and visitors alike, outside the emergency situation and once patients leave A&E, unless they are "ordinarily resident" or fall within one of the exceptions provided under the relevant Statutory instruments they may find themselves without protection. Different approaches are taken across the devolved jurisdictions in relation to charging overseas visitors for health care with England having notably tightened up its guidelines under the previous Secretary of State for Health and Social Care, Jeremy Hunt.²⁰

17 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

18 See also discussion of this in the House of Lords European Union Committee, 13th report of session 2017-19, 'Brexit: reciprocal healthcare'

19 See further T.K.Hervey and N. Fahy "Briefing note for House of Commons Health Committee on the Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (WA), and the Outline of the political declaration setting out the framework for the future relationship between the European Union and the United Kingdom of Great Britain and Northern Ireland (Dec FR), as agreed at negotiators' level on 14 November 2018, from the point of view of health and the NHS".

20 The National Health Service (Charges to Overseas Visitors) Regulations 2015, SI 2015/The National Health Service (Charges to Overseas Visitors) (Wales) Regulations 1989 SI 2009/ 1512; The National Health Service (Charges to Overseas Visitors) (Scotland) Regulations 1989 No. 364; Health and Personal Social Services Provision of Health Services to Persons not Ordinarily Resident Regulations (Northern Ireland) 2015, 2015/2.7

People: The Impact on Health Care Professionals and Recognition of Professional Qualifications

Professional movement is facilitated by the EU Mutual Recognition of Qualifications Directive²¹ and the European Professional Card.²² These are currently powers reserved to Westminster but the impact on mutual recognition has been raised in the devolveds. Here we consider first some general issues about mutual recognition and then secondly possible specific impacts in the devolveds. The Mutual Recognition of Qualifications Directive has in the past proved controversial amongst some in the medical professions who argue that one opportunity post-Brexit will be the ability to require heightened standards in relation to professional qualifications from other EU Member States. Currently, international medical graduates sit a language exam and there is a Primary Source Verification for Documents but this cannot be where EU qualifications are at issue. Concerns were expressed by one interviewee about the Directive and medical profession training:

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.

I think what the employers have done is they 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, all the different types and ways of treating the cancer, whereas if you have an equivalent qualification from another European country, I can't remember off the top of my head but 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 that would not ask the oncologist to learn about, for example, the chemotherapy that they haven't covered in their education. So we've heard that doctors and hospitals and employers, they 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.

The only other opportunities are potentially around education and training. So in the MRPQ Directive in Annex 5 it lists what constitutes GP specialist training and specialty training, and some of the rules – this is all based on the length of time served, like the length of time you've trained rather than what you've learned, and it's not quite as flexible as it could be. So for education and training if we no longer have the constraints of the MRPQ Directive in terms of medical education governing what we can and can't do with medical education,

²¹ Directive 2005/36/EC.

²² Commission Implementing Regulation (EU) 2015/983.

that might be an opportunity but that's been the sort of main opportunity. Also, maybe getting rid of some of the constraints that govern medical education that are in the Directive. (Interviewee from a UK-wide organisation)

But others see the prospect of amendment to the system of mutual recognition of qualifications at domestic level as potentially problematic in the context of nursing training:

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

The existing provisions of the Directive will be initially carried over by means of the European Union (Withdrawal) Act 2018. However this will not extend to the reciprocal parts of the Directive. These include the warning processes in place in relation to unsafe practitioners. The Withdrawal Agreement would, if adopted, continue these during transition. Unless a specific agreement is reached, the UK will be excluded from these EU systems in the future:

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. Some of those 21,000 doctors in the UK will return home; some will have issues with fitness to practice, and we want the information to be shared via the alert mechanism with our European partners, for patient safety reasons. (Interviewee- from a UK-wide organisation)

Concerns have also been expressed about the position of European medical students trained in the UK:

If you look at the draft text of the current Withdrawal Agreement – which could be being rewritten as we speak – it will continue to respect the mutual recognition of professional qualifications gained before the end of the transition period, so December 2020. If you're one of the approximately 700-plus European medical students in the UK who will graduate after that date, your qualification won't be recognised automatically in your home country, which is at a very basic human level unfair. Because you chose to come to the UK in the expectation that you could practise medicine in your home country and across the rest of Europe. That's not currently the case and is of course a very real concern for us, for the individuals, for the UK government and, interestingly, less so for the EU side because they view this very much as a sequencing process and they want to deal with that in the next stage. (Interviewee from a UK wide organisation)

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. The issue will be that that will take some time, and in the meantime gaps in the workforce will not be filled. And will that then lead to a, shall we say, a chilling effect whereby doctors from across Europe start looking elsewhere and realise that there are other Anglophone countries in the world, which pay well, which have interesting and rewarding career opportunities – America, again, and Australasia?. (Interviewee in UK-wide organisation).

A no-deal scenario is thus particularly likely to have an adverse impact on staffing. There is already some evidence that some hospitals have instituted planning for no-deal scenario if staff levels are impacted by no-deal Brexit.²³

Existing NHS staffing shortages and the time line needed to train health professionals means that for a considerable period of time it will be necessary for the NHS to recruit from abroad. How easy this will be remains uncertain. 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.²⁴



²³ "Oxfordshire Hospitals told to plan for No Deal Brexit" Oxford Mail 15th October 2018- concerns re number of staff to care for patients as "scores of EU staff" having already left.

²⁴ BBC News "NHS groups welcome immigration change for doctors and nurses", 14th June 2018.



Pharmaceuticals and Medical Devices: Access and Regulation

Domestic law concerning the regulation of pharmaceuticals and medical devices is highly dependent upon EU law.²⁵ These regulatory powers are reserved to Westminster, however some of the concerns have been raised by interviewees about the impact on the devolveds. There are two routes for the authorisation of medicines - the centralised or a decentralised process. Under the centralised process drug approvals are given by the European Medicines Agency (EMA). Once given, an approval will apply across all Member States. Certain drugs such as paediatric medicines and orphan medicines have to be approved through the centralised process. For the decentralised procedure, approval can be given by the competent authority at member state level, which in the UK is the Medicines and Healthcare Products Regulatory Agency (MHRA). Post-marketing safety issues are addressed through EU wide pharmacovigilance networks. Without a specific sectoral agreement we will no longer have access to the European Medicines Agency approval systems and vigilance databases.

Concerns have been expressed already as to the potential adverse impact on delays of access to medicines with the UK no longer being a “primary launch market” when it becomes as “third country”.²⁶ The Secretary of State Matt Hancock in evidence to the House of Commons Health Select Committee on 27th November 2018 assured the Committee that there would not be any additional regulatory burdens for companies seeking to license new medicines.²⁷ He also suggested that the MHRA may even be able to accelerate licensing outside the EU. This however does not address the broader question of whether the UK will be seen as a desirable launch market by industry and the current situation remains very uncertain as to the impact ultimately on patients.

The safety of medical devices is a current concern.²⁸ Device regulation is driven through the EU. It involves devices being awarded a C.E. mark by “notified bodies” which are private companies undertaking this role having been authorised to do so by a competent body of a member state. The operation of these bodies has been controversial and those seeking device approval have been able to “shop around” between them.

One of our interviewees raised concerns as to the impact of a Brexit which takes the UK outside the EEA:

Our status will hugely affect whether or not we're involved in medical devices regulation in the future. The European Medical Device Regulatory System is shared by 31 or 32 countries. It's the current 28 Member States, plus the four EFTA members: Liechtenstein, Iceland, Norway and Switzerland...But unless we are members of EFTA, then we wouldn't even be invited. And it's not clear whether or not we would recognise European Union approved medical

25 Directive 90/385/EEC Directive 93/42/EEC, Directive 98/79/EC.

26 And see also reference to the evidence of Johnson and Johnson to the House of Commons Health and Social Care Committee Brexit: medicines, medical devices and substances of human origin Fourth Report of Session 2017-9 HC 393 at para 62.

27 <https://www.parliamentlive.tv/Event/Index/ef9626de-d393-4bd7-af5b-bee83b5ca5d7>.

28 See further J.V.McHale “Health Law, Brexit And Medical Devices: A Question Of Legal Regulation And Patient Safety” [2018] Medical Law International <https://journals.sagepub.com/doi/full/10.1177/0968533218807255>.

devices and have the ability to import them without tariffs. I think it would be sensible to accept those standards, because we set up the system on which the standards are going to be based, we were party to that. But it would again be an example of the UK choosing to accept legislation from elsewhere without contributing to it, which in my opinion is not a sensible plan. (Interviewee in Wales)

As with other areas, the European Union Withdrawal Act 2018 would ensure that the basic regulatory provisions concerning medical devices regulation will be continued in the short term. The Withdrawal Agreement secures continuity for products during the transitional period.²⁹ Currently the UK has access to EU databases which provide warnings of harm to patient safety: this will also continue if the Withdrawal Agreement is adopted.³⁰ But after that, there are no guarantees:

The data from post market surveillance is all supposed to be loaded on the EUDAMED database that's being developed by the Commission. They have a closed section for regulators, which will include all the annual surveillance reports and any field safety corrections, actions or concerns of regulators to voice aloud. It's not currently envisaged that that is going to be available to the public, so it would only be available to EU regulators, in which case indeed the UK MHRA might be excluded. In my opinion, and I put this in my statement to the committee in Parliament last week, that could mean a delay in the UK hearing about alerts, and therefore patients potentially waiting longer to get risky devices removed from the market. (Interviewee in Wales).



Moreover the EU law in this area is changing. New EU Medical Devices Regulations have now been agreed but full implementation will not occur until 2020 for the main devices Regulation and 2022 for the In Vitro Devices Regulation. It appears from the assurances of Lord Shaughnessy that the Government intends to transpose these into domestic law.³¹

Clinical trials of pharmaceuticals are currently underpinned by the EU Clinical Trials Directive, transposed into domestic law through the Medicines for Human Use (Clinical Trials) Regulations. EU law in this area will be reformed by a new EU Clinical Trials Regulation.³² The full implementation of this Regulation has been delayed. It is dependent on a new computer database which will not be operational until 2020. The Government has again indicated its intention to implement the Regulation, including aspects such

²⁹ Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, November 2018, Part Three, 'Separation Provisions', Title I 'Goods placed on the market'.

³⁰ Draft Withdrawal Agreement, Article 43.

³¹ Lord O' Shaughnessy on medical technologies and Brexit, 14th September 2017, Department of Health and Social Care.

³² See E. Cave, 'EU Clinical Trials Regulation 2014: Fetter Or Facilitator?' [2018] Medical Law International. <https://journals.sagepub.com/doi/full/10.1177/0968533218799535> and see also in relation to research regulation post "Brexit G. Laurie, 'How Do We Make Sense Of Chaos? Navigating Health Research Regulation Through The Liminality Of The Brexit Process' [2018] Medical Law International. <https://journals.sagepub.com/doi/full/10.1177/0968533218799533> and on the question of standards setting M. Flear, 'Charting A Roadmap Towards Membership And Formal Voice In Global Bioethics Standard-Setting: Health Research And The Case Of The International Council On Harmonisation' [2018] Medical Law International. <https://journals.sagepub.com/doi/full/10.1177/0968533218804598>.

as access to the database, but again this depends entirely upon reciprocal sectoral (or other) future agreement(s) with the EU.³³

The Department of Health and Social Care has issued “No Deal” notices for medicines, trials and devices.³⁴ While there is the aim of continuity under the EU Withdrawal Act 2018, the MHRA has undertaken consultations during autumn 2018 on the new regulations that would be needed in a no-deal scenario. In such a situation it is intended that the MHRA would undertake all marketing authorisations and consult on new authorisations such as paediatric medicines. Batch testing of medicines carried out in countries on a list from MHRA will be accepted. A UK/EU/EEA qualified person will be required to certify batch testing. The UK government has indicated it intends to continue current medical devices regulation and also to impact the new Devices Regulations. But, unless this is agreed in the future EU-UK relationship, CE marks from UK-based “notified bodies” would not be automatically recognised across the EU.³⁵

Some service provision such as the supply of medicines operates across the devolved jurisdictions. Concerns regarding the impact of supply were highlighted by the House of Commons Health Select Committee earlier in 2018.³⁶ Interviewees in our study in different jurisdictions within the UK highlighted concern about the implications of Brexit on stocks of medicines and other products for use in the clinical setting:

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, boring things like syringes and that sort of thing. 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. A little bit like the tanker drivers' strike, we didn't realise the fragility of that system until there was a short strike, if you remember? (Welsh Interviewee)

The supply and distribution of medicines remains complex.³⁷ Various government statements have been made about planning for a “no-deal Brexit”. On 23rd August 2018 Matt Hancock, Secretary of State for Health and Social Care stated that pharmaceutical companies had been told to stock 6 weeks supply of medicines.³⁸ But NHS trusts have been told not to stockpile at local level. Plans have also announced for airlifting medicines which cannot be stockpiled for longer periods.³⁹ On 23rd October 2018 Matt Hancock announced that a tender has been issued worth “tens of millions of pounds” to provide extra storage

33 Lord O'Shaughnessy on medical technologies and Brexit and see House of Commons Health and Social Care Committee Brexit: medicines, medical devices and substances of human origin Fourth Report of Session 2017-9 HC 393 at para 62.

34 “How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal”, updated 14th September 2018 <https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexite-deal/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexite-deal>.

35 There are provisions in the Northern Ireland Protocol about a new UK(NI) conformity marking, which would come into effect in event the ‘backstop’ is triggered, see Northern Ireland Protocol, Article 8.

36 House of Commons Health and Social Care Committee Brexit: medicines, medical devices and substances of human origin Fourth Report of Session 2017-9 HC 393.

37 See also House of Commons Health and Social Care Committee Brexit: medicines, medical devices and substances of human origin Fourth Report of Session 2017-9 HC 393 at paras 135-138.

38 Letter from the Secretary of State for Health and Social Care “Governments Preparations for a March 2019 No-Deal Scenario”.

39 <https://news.sky.com/story/medicine-stockpiles-and-emergency-airlifts-in-the-event-of-no-deal-brexite-11480185>.

in the case of no-deal.⁴⁰ On 27th November Matt Hancock gave further evidence to the Health and Social Care Select Committee indicating that continued planning was in progress.⁴¹ It remains to be seen how this translates out relation to ensuing effective supply of consumables as noted by the interviewee above.

In the devolved there is awareness of the challenges but preparation appears from our interviews to be at different stages:

Generally in terms of medicine supply everyone in the supply chain has been working to draw out costs, or for manufacturers it's reducing the number of wholesalers for example with the supply of medicines. For wholesalers, for pharmacies, it's reducing the amount of stockholding because that's all capital cost. 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. And so I think 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)

We've also been raising the issue of the implications of it for the NHS more broadly; the primary duty for that lies with each of the health boards. So we've got quite substantial ramping up of operational planning for no-deal Brexit, though if I'm honest we haven't really committed financial resource to that yet, such as stockpiling. We run the microbiology laboratories, most of them in Wales, across each of the hospitals as well, which is another difference from England, and so we're aware, taking them as an example, that most of the reagents, most of the equipment that they use is involved in just-in-time supply chain deliveries, and we would actually have to stockpile some of those potentially in a no-deal. So we haven't actually done that. We've started the planning towards it but we haven't actually committed resource. (Interviewee in Wales)

It is clearly a matter of concern to ensure that not simply planning but effective resource is devoted to ensuring that such supply chains operate. As the Scottish interviewee notes, changes in supply strategy to reduce costs longer term may render these vulnerable in the event of multiple simultaneous shortages. Different delivery of service models in Wales may pose different challenges to those in other parts of the UK due to the role of the microbiology laboratories.

40 <https://www.hsj.co.uk/policy-and-regulation/brexit-ministers-launch-tens-of-millions-bid-to-stockpile-medicine-/7023652.article>.

41 <https://www.parliamentlive.tv/Event/Index/ef9626de-d393-4bd7-af5b-bee83b5ca5d7>.

Public Health

The central importance of public health to the EU is reflected in Article 168 of the EU Treaty:

Union action which shall complement national health policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating causes of danger to physical and mental health. Such action shall cover the fight against major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education and monitoring early warning of and combating serious cross-border threats to health. The Union shall complement Member States action in relating to reducing drug related health damage, including information and prevention.

The Faculty of Public Health led an attempt to incorporate this via a legally binding “Do No Harm” amendment during the passage of the EU Withdrawal Bill through the House of Lords. Although this was unsuccessful, the Government did make certain assurances during the 3rd reading debate.⁴² Lord Duncan stated that:

The Government fully expect that, after exit, Article 168 will continue to be influential to the interpretation and application of retained EU law. This may include the determination of legal challenges to which Article 168 is relevant, including the consideration of public health legislation before exit day. As was noted on Report in this House, although Article 168 is not a directly enforceable provision of the TFEU, it has nevertheless been influential on EU and domestic law in the area of public health.

EU law plays an important role in public health, including cross-border control of infectious diseases, regulation of tobacco, food and alcohol, and blood/organ/tissue safety.

Across the UK, discernible differences have been developing in public health policies. The devolved jurisdictions can be seen as pioneers in some areas. So for example Scotland has taken the lead in relation to minimum alcohol pricing. Stakeholders in Wales also have considerable concerns as to the practical implications of Brexit for public health policy:

On the lifestyle side we're a little bit fearful about tobacco, and sugar for that matter, in that we're aware that those industries seem to be keen on Brexit, which is naturally what worries us. And we know that the 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)

42 [https://hansard.parliament.uk/lords/2018-05-16/debates/98F7DF3F-ACE5-42E4-9FF6-F2BB1027EFA5/EuropeanUnion\(Withdrawal\)Bill](https://hansard.parliament.uk/lords/2018-05-16/debates/98F7DF3F-ACE5-42E4-9FF6-F2BB1027EFA5/EuropeanUnion(Withdrawal)Bill).

Communicable disease control

All EU Member States are signatories to the International Health Regulations (IHR),⁴³ the key legal instrument for addressing public health emergencies of international concern, such as pandemics. As the IHR is an instrument of international law rather than EU law, this will continue to operate regardless of Brexit. The UK is also seeking to strengthen its links with bodies such as the European office of WHO.

However, as matters stand, the UK will no longer be a member of the European Centre for Disease Control – ECDC – nor of the various vigilance systems, committees and databases by means of which Member States share information of public health threats. Respondents expressed concern about this:

Over the last 20 years or so, the UK has developed a considerable relationship with the wider EU and European countries. The UK has punched way above its weight in many respects and has been strong in the development of networks across Europe, and a very strong supporter of the development of the European Centre for Disease Control. We have been a major contributor to the work of that centre. So, naturally, we have some concern about the possibility that we will end up with a lesser degree of involvement or, indeed, no involvement with other structures, including the Health Security Committee: the European Commission body that is convened to help coordinate cross-Europe threats, and enables countries to talk about what they understand the threat to be and what they're doing.

One possibility is that we will remain with essentially the same type of relationship, involved with the Health Security Committee as we currently are by way of some kind of honorary membership of it. If that's the case then, in a way, nothing changes. The second and perhaps more likely possibility, is that we still have the opportunity to join the Health Security Committee but on an ad hoc basis as an observer, rather than a full member, which would mean we wouldn't have the voting rights. Now, in many instances, that's going to be good enough. The purpose of the Health Security Committee is very much information sharing and helping to coordinate responses, rather than political voting on things.

(Interviewee in England)

Concerns were expressed by our interviewees that Brexit might have an adverse impact on communicable disease work in both the EU and the UK. This was highlighted by an interviewee from the Republic of Ireland:

It would be to the detriment of ECDC if the UK are not properly involved. But, you know, it's difficult to imagine how they can be...we already have non-EU members involved in terms of the Norwegians, Iceland, etc. But...the UK doesn't appear to want to have any of those models. So, how can it still be involved?

To a degree you can technically get away with International Health Regulations doing that for you. It's the International Health Regulations [that] would be the saving grace. (Interviewee in the Republic of Ireland)

I think it's actually damaging to ECDC and to Ireland. Public Health England is still probably one of the international leaders on chemical issues. That's not totally ECDC. But also on certain other non-chemical issues. There's a lot of expertise that even the other big countries in Europe just don't have. (Interviewee in the Republic of Ireland)

43 International Health Regulations (2005).

There have been suggestions that it would be desirable for the UK to continue involvement with ECDC in the future:

It's possible that we could still end up with a relationship with ECDC that is hardly different to the present, in which case it would be great. It's clearly not for me to say because there's a political process involved in the agreement. The second and perhaps rather more likely possibility, is that we end up with some kind of agreement which includes agreement around health and health security. That would be a continuing relationship with ECDC but based on an observer status and a pay for play basis, so it would mean that we wouldn't have voting rights. There are two senior oversight committees of ECDC: the management committee and the advisory forum and the UK sits on both of those. We'd probably end up with an observer status on the Health Security Committee, and an awful lot can be achieved through observer status. In practice, one gets to contribute every bit as much and hear what's being said, just wouldn't have the vote. So we'd have observer status and then we would likely have to pay through some mechanism in order to remain part of a series of the networks and other initiatives that ECDC run that we would want to stay part of. (Interviewee in England)

As the ECDC is not expressly covered in the Withdrawal Agreement, as things stand, the UK will be formally excluded from the ECDC's decision-making processes from 29 March 2019.⁴⁴ Although as the interviewee notes there may be the prospect of further participation in ECDC as allowed in the EU Treaty.⁴⁵

Others expressed concern that the UK will not be involved/consulted on matters on a more informal basis after it leaves the EU:

We've visited and seen – for a number of different reasons, colleagues around Europe about certain

issues, whereas historically we probably would have been more likely to have visited in the first instance the UK. Because that's our future now. (Interviewee in the Republic of Ireland)

Tobacco and e-cigarettes

All the devolved jurisdictions have taken steps to regulate smoking.⁴⁶ Tobacco use, for instance, is regulated via the EU Tobacco Directive 2014/40/EU which is a reserved power. This is a Directive which proved particularly controversial at EU level and was subject to considerable lobbying from the tobacco industry. The Directive regulates emissions of tar, nicotine and carbon monoxide. Tobacco advertising is regulated. The Directive includes specific requirements as to the warnings given and labelling and packaging of tobacco products. The Directive also includes provisions concerning product control e.g. tracking and tracing systems/packs with “unique identifiers”. Such mechanisms were introduced to address illicit dealing. One of the policy objectives behind the Directive was to deter tobacco

⁴⁴ Draft Withdrawal Agreement, Article 7.

⁴⁵ The route to participation as a third country from the Founding Instrument of ECDC Article 30 Participation of third countries.

1. The Centre shall be open to the participation of countries, which have concluded agreements with the Community by virtue of which they have adopted and apply legislation of equivalent effect to Community legislation in the field covered by this Regulation.

2. Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries are to participate in the Centre's work, including provisions relating to participation in the networks operated by the Centre, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Centre, financial contributions and staff. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004R0851&from=EN>

⁴⁶ Health (Tobacco, Nicotine etc and Care) (Scotland) Act 2016.

consumption by the young. Consequently there is regulation of the use of additives and flavourings. The Directive also for the first time regulates the use of e-cigarettes. Current EU regulation in this area is set to be continued under the European Union (Withdrawal) Act 2018 through the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2018. However, as Government has noted in its Consultation on amending Tobacco Products and Nicotine there will need to be new systems for tobacco producers to notify tobacco products/e-cigarettes as the reciprocal EU systems will not be in operation⁴⁷. In addition, as the pictorial representations etc on cigarette packets are copyrighted by the EU, in the event of a “no deal” Brexit new warning notices/ pictures would need to be included on packaging. Notification has been given to the devolved administrations in relation to these Regulations.⁴⁸

E-Cigarettes: an area for future divergence?

E-cigarettes is something which is currently regulated under the EU Tobacco Directive.⁴⁹ Although the Directive leaves some scope for national policy making, post-Brexit that scope may be increased. The question is where that power will be ‘repatriated’. Will it be at the level of the devolveds, or will the UK’s ‘internal market’, and the desire for the UK to offer access to the whole UK market under trade deals, require central regulation? The UK Government have stated that post Brexit there will be needed to “reflect the new environment in which tobacco control will be delivered”.⁵⁰ Some see e-cigarettes as a tool to encourage smoking cessation, and deregulation as a public health opportunity⁵¹. Others regard e-cigarettes as a dangerous gateway towards smoking in general.⁵² There have already been suggestions that this may be an area where Brexit can be seen as an “opportunity”.⁵³ But the tensions in policy in e-cigarettes in the literature are reflected in different approaches being taken in the devolveds. Our research however highlights what appears to be the divergence of approach between England and Wales on this issue:



Wales has been strong on e-cigarettes; Public Health Wales has a different opinion than Public Health England. I’m not sure who’s necessarily right on it. Because we introduced in Wales the ban on smoking in public places before England did, we feel fairly committed to it and we’ve not wanted that watered down for e-cigarettes either. This is all before

47 “Consultation on the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2018, <https://www.gov.uk/government/consultations/tobacco-products-and-nicotine-inhaling-products-amendment-eu-exit-regulations-2018/tobacco-products-and-nicotine-inhaling-products-amendment-eu-exit-regulations-2018>.”

48 See for example, http://www.parliament.scot/S5_HealthandSportCommittee/General%20Documents/20180926_Letter_OUT_to_MinisterPHSW_-_Tobacco_Products.pdf.

49 See also consideration of this by the House of Commons Science and Technology Committee E-cigarettes Seventh Report of Session 2017-19 HC 505.

50 Department of Health Towards a Smokefree Generation A Tobacco Control Plan for England, July 2017.

51 D. T Levy, R. Borland, E. N Lindblom, M.j L Goniewicz, Rafael Meza, T. R Holford, Z. Yuan, Yuying Luo, .R J O’Connor, Niaura, D. B Abrams “Potential deaths averted in USA by replacing cigarettes with e-cigarettes” (2018) 27 Tobacco Control 18.

52 See discussion in S, Glantz and D W. Bareham “E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications” (2018) 39 Annual Review of Public Health 215.

53 HC Science and Technology Committee Report E-cigarettes 9 May 2018.

Brexit came along but we are very concerned about any weakening of the position or the momentum we've had. And we are a bit queasy about e-cigarettes...

I think the jury's still out, but Public Health Wales has tended to oppose things like allowing or facilitating e-cigarettes in public places whereas Public Health England has been a bit more inclined to think that e-cigarettes could be a partial good news story, you know, kind of where the market helps tobacco control. (Interviewee in Wales).

Such diverse approaches and potential tensions are concerning. It is also the case that any perceived division on tobacco control policy within the UK may have the longer term effect of the UK being seen as more vulnerable as a target by the tobacco industry.

Blood, organ and tissue safety

Our second stage of interviews will consider further issues concerning blood, organ and tissue safety. These are all currently regulated under EU Directives which have been implemented into domestic law.⁵⁴ These are to be the subject of three new regulations following the European Union (Withdrawal) Act 2018 the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations, Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations and Blood Safety and Quality (Amendment) (EU Exit) Regulations.⁵⁵ The intention as in other areas is to transpose EU law into domestic law. In correspondence between the Chair of the Scottish Parliament Health and Sport Committee and the MHRA Chief Executive Office Dr Ian Hudson, Dr Hudson stated that:

We understand our Department of Health and Social Care colleagues have engaged with the devolved administrations with the aim of producing a memorandum of understanding to facilitate the joined-up approach for blood safety and quality regulations across the UK. We would wish to collaborate on this and involve the relevant colleagues both from the agency side and the DHSC and move this vital piece of work forward.⁵⁶

At the time of writing this memorandum of understanding was not published. The area of safety of blood, blood products and contamination scandals provided the backdrop to the EU Directives in this area. At domestic level blood contamination scandal controversies are the subject of consideration of an on going UK inquiry⁵⁷ and also has been the subject of a separate inquiry- the Penrose Inquiry in Scotland.⁵⁸ The EU system provides as with other areas a series of alert systems (Rapid alert platform for substances of human origin (SoHO) Rapid Alert system for human Tissues and Cells [RATC], Rapid Alert system for Blood and Blood Components [RAB]). Rapid alerts include quality and safety defects, information notices, epidemiological notices and bilateral inquiries)/ additional type of rapid alert exists for tissues and cells: illegal and fraudulent activities. There is also a Single European Code which facilitates the traceability of tissue/cells linked to a specific EU database.⁵⁹ Without specific agreements the UK will be excluded from these systems.

54 Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC; Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells; Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

55 See further in relation to correspondence by the Scottish Parliament Health and Sport Committee on this issue <http://www.parliament.scot/parliamentarybusiness/CurrentCommittees/110131.aspx>.

56 Letter from Ian Hudson, Chief Executive MHRA to Lewis Macdonald MSP Convener, Health and Sport Committee Scottish Parliament.

57 <https://www.infectedbloodinquiry.org.uk/>.

58 <http://www.penroseinquiry.org.uk/>.

59 Commission Directive (EU) 2015/565 of 8 April 2015.

Potential economic impacts of Brexit and Health

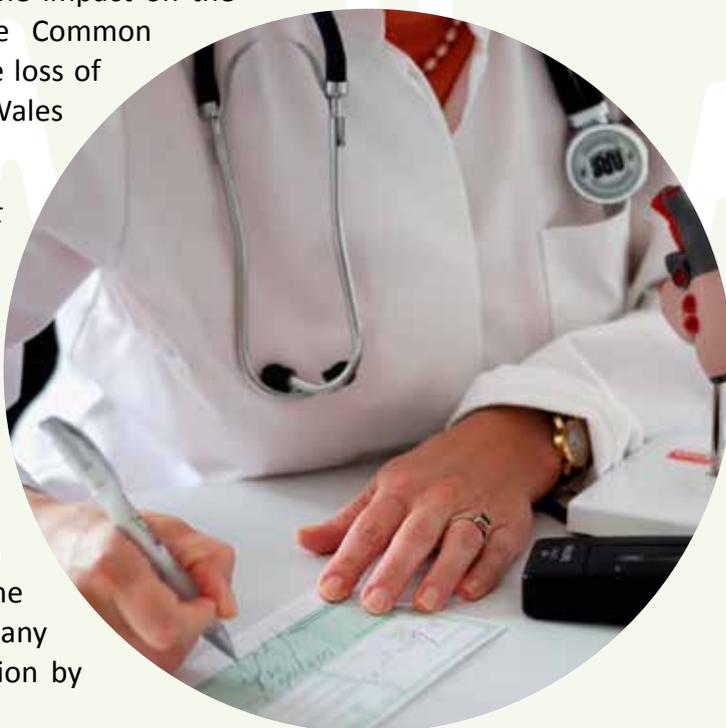
In public health literature there has long been discussion of the empirical link between social disadvantage and health from the Black Report⁶⁰ to the work of Sir Michael Marmot.⁶¹ Essentially wealth equals health. In Wales, public health interviewees expressed concern as to the potential adverse economic impacts of Brexit which could in turn have adverse impacts on health:

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. So we've already noticed a German company's already decided to close one plant just last week here in Wales. But in the valleys, which are deprived areas, as you're well aware I'm sure, some of the most deprived areas in Britain, there's quite a concentration of companies supplying often 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. These plants also supply into the Honda plant at Swindon as well. So if they're undermined, although none of those are in Wales, you know, if car manufacturing is not viable on the current basis then that's going to have a big effect on those component plants in Wales. So that's one thing that we're concerned about. (Interviewee Wales)

Interviewees also expressed concern about the impact on the agricultural industry in Wales through the Common Agricultural Fund regarding the impact on the loss of structural funds from the EU, which support Wales in regional development:

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.

Public health has very particular dimensions in different parts of the UK and the impact of the broader social determinants of health and any consequent Brexit impacts need close attention by Government at national and devolved level.



60 Report of the Working Group on Inequalities in Health (chair Sir Douglas Black) DHSS (1980).

61 Fair Society: Healthy Lives (The Marmot Review) (2010). <http://www.instituteofhealthequity.org/resources-reports/fair-society-healthy-lives-the-marmot-review/fair-society-healthy-lives-full-report-pdf.pdf>.



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The **UK** in a
Changing Europe

Professor Jean V. McHale

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She is currently writing a book " *The Regulation of Cosmetic Procedures: Legal, Ethical and Practical Challenges*" with Dr Melanie Latham Reader in Law, Manchester Metropolitan University which will be published by Routledge in Spring 2019.

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