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How will Brexit affect health services in the UK? An updated evaluation.

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## Abstract

All forms of Brexit are bad for health, but some are worse than others. This paper builds on our analysis using the WHO health system building blocks framework to assess the likely effects of Brexit on the NHS in the UK. We consider four possible futures: (1) a “No Deal” Brexit under which the UK leaves the EU on 29 March 2019 without any formal agreement on the terms of withdrawal; (2) the Withdrawal Agreement, as negotiated between the UK and EU and awaiting (possible) formal agreement, which provides a transition period until the end of December 2020; (3) if the Northern Ireland Protocol’s ‘Backstop’ comes into effect after the end of that period; and (4) the Political Declaration on the Future Relationship between the UK and the EU. Our analysis shows that a No Deal Brexit is significantly worse for the NHS than a future involving the Withdrawal Agreement, which provides certainty and continuity in legal relations while the Future Relationship is negotiated and put into legal form. The Northern Ireland ‘Backstop’ has variable impact, with continuity in some areas, such as health products, but no continuity in others. The Political Declaration envisages a future relationship which is centred around a free trade agreement, in which wider health-related issues are largely absent. All forms of Brexit, however, involve negative repercussions for the UK’s leadership and governance of health, both in Europe and globally, and significant harmful consequences for the ability of parliament and other stakeholders to scrutinize and oversee governmental actions.

## Introduction: the current position

All forms of Brexit are bad for health, but some are worse than others. This was the conclusion of our previous analysis,<sup>1</sup> considering possible scenarios for the EU-UK's future relationship. That analysis was, of necessity, limited as the objectives of the UK government were, at that time, unclear, reflected in the oft-repeated statement that "Brexit means Brexit". While Theresa May provided some clarification on her government's 12 objectives in her Lancaster House speech in January 2017,<sup>2</sup> this offered few details as to how they might be achieved. Moreover, some seemed difficult to reconcile, such as free trade with the EU and the ability to do separate trade deals with the rest of the world. As Sir Ivan Rogers, the UK's Permanent Representative to the EU who resigned just before the Lancaster House speech,<sup>3</sup> noted in a recent speech, May's approach to negotiations made it impossible to achieve her first and last objectives, to provide certainty and arrange an orderly exit from the EU.

Yet, by December 2018, two documents were negotiated. The first, which would be legally binding, is the Withdrawal Agreement. This covers many, but not all, aspects of the UK's exit from the EU, including continued payments, citizens' rights, and the status of the border in Ireland. Some especially contentious areas, such as fisheries, have been left for later. The second text, which is not legally binding, is the Political Declaration on the Future Relationship. This sets out some broad intentions concerning a final relationship between the UK and EU. In theory, the details will be fleshed out during the transition period set out in the Withdrawal Agreement lasting until December 2020, although given the lack of agreement within the UK and the speed of progress so far, many commentators believe that this will take a much longer time.

Given these developments, we are now able to provide an updated evaluation. Leaving aside remaining in the EU, which is better overall for the NHS than any form of Brexit, we consider four possible future relationships between the UK and the EU:

- (1) "No Deal" Brexit;
- (2) the Withdrawal Agreement, during transition;
- (3) if the Northern Ireland Protocol's 'Backstop' comes into effect; and,
- (4) the Political Declaration on the Future Relationship.

We are not comparing these scenarios with the effects of remaining in the EU as that was in our previous analysis.

Under a 'No Deal' Brexit, the UK leaves the EU on 29 March 2019 without any formal legal arrangements in place. This will happen automatically, under the provisions of the EU (Withdrawal) Act 2018<sup>4</sup> and Article 50 of the Treaty on European Union (TEU) unless the UK, with the agreement of the EU and its Member States, acts to stop it. This is uncharted territory, but the EU has been clear that the legal status of the UK will be that of a 'third country', with all that entails.<sup>5</sup>

As noted above, the detailed legal text of the Withdrawal Agreement<sup>6</sup> brings into effect a transitional period, to the end of December 2020, during which the UK is no longer an EU Member State, but many aspects of EU law continue to apply in the UK. The Withdrawal Agreement makes specific provision to protect the rights of EU-27 nationals in the UK, and vice versa, up until the end of transition, and beyond, for citizens from the UK and EU27 who

are in each other's territory in December 2020. For instance, they will be able to achieve residence rights/settled status in the UK; continue to benefit from social security entitlements, such as pensions already accrued; and have personal data protected.

The Northern Ireland Protocol (the 'Backstop'), a binding part of the Withdrawal Agreement, will come into force if, at the end of transition, no future EU-UK agreement(s) is/are in place to resolve the challenges associated with the land border between the UK and EU on the island of Ireland. Because the Common Travel Area arrangements, permitting unimpeded movement between the UK, Ireland, and the Crown Dependencies (Channel Islands, Isle of Man) will continue for people, but not for goods and services, the Protocol's focus is on products crossing that border. The Protocol establishes a single customs territory between the EU and the UK, along with 'level playing field rules' (on things like environmental protection and labour standards) for all trade in products between the UK and EU. Where products are imported into Northern Ireland from the EU, unjustified non-tariff barriers are forbidden, and EU legislation on marketing and safety standards for products applies in Northern Ireland. The Protocol itself does not require the same standards for products being produced or marketed in the rest of the UK, but if the UK wants to keep a single regulatory market including Northern Ireland, and avoid an internal border in the Irish Sea, then in practice the UK will need to align with EU standards.<sup>7</sup> Given that trade agreements take years to negotiate (the EU-Canada agreement took five years to negotiate and the EU-Japan and EU-Singapore agreements took almost as long), and run to hundreds of pages (the EU-Canada agreement is over one thousand pages),<sup>8</sup> and the Political Declaration is only 26 pages long, we should take seriously the possibility that the Backstop in the protocol on Northern Ireland comes into effect. It may in fact become the future relationship between the UK and the EU, at least for the medium term.

The Political Declaration on the Future Relationship is not formally contingent on the Withdrawal Agreement, although its negotiation will surely be affected politically by the terms under which the UK leaves the EU, as a No Deal Brexit will be harmful for the EU as well as for the UK. The Political Declaration currently points to a free trade agreement (FTA) similar to the EU-Canada agreement,<sup>9</sup> with some enhanced aspects, none of which is directly relevant for health. As noted above, unlike the Withdrawal Agreement and its Protocol, it is a political statement only. The details are yet to be agreed, and it is in the nature of a political text that it could be changed relatively easily, but of course only if political agreement could be reached on a different model (such as 'Norway+' or 'Norway for now', both of which would involve a closer alignment than is the case with the EU and Canada, and which would include free movement of people).

Whether the Withdrawal Agreement will be agreed remains uncertain. The Agreement did not attract a majority vote in Parliament on 15 January 2019, even after lengthy delays to win support.<sup>10</sup> May is now seeking some changes to the Withdrawal Agreement. However, it is difficult to envisage how it could be changed substantively without altering either the UK's so-called "red lines", of which the most important are ending freedom of movement for people and withdrawal from the authority of the EU's Court of Justice, or the EU's negotiating position which includes the integrity of the single market.

## Method

As in our previous article, our method is to use the WHO's health system building blocks<sup>11</sup> to assess the likely effects on each aspect of the NHS in the UK, under the four different futures we envisage. These are set out in Table 1. For each, we categorise effects as broadly unchanged (grey); positive (green); moderate negative (pale red); or major negative (red). We offer a timely analysis, based on the current likely futures for the UK, and so we are working from the available legal and political texts. At this time, of course, the meanings and significance of those texts have not been tested. This is an inherent limitation of the standard methods of legal and policy analysis that we adopt here. The unprecedented nature of a Member State leaving the EU after over 40 years of membership is an obvious limitation of our approach: there are no equivalent comparative situations. The scale of the challenge can be inferred from the fact that the Long Term Plan for the English NHS mentions Brexit only twice in 136 pages, neither offering any detail of what it might mean or how any threats might be addressed.<sup>12</sup>

## Analysis and Discussion

### 1. Health and social care workforce

Perhaps the most important challenge for the NHS post-Brexit concerns the health workforce. Existing shortages will be exacerbated if Brexit results in an exodus of health professionals from other EU/EEA countries, and promised future investments in UK-trained healthcare staff cannot resolve this in the short term.<sup>13</sup> Overall average figures (some 10% of doctors in the NHS in England, for instance) hide specific areas of greater concern, with some regions especially reliant on EU/EEA staff.<sup>14</sup>

The Withdrawal Agreement secures the position of EU nationals in the UK, with only some individuals who are currently protected by EU law not protected in the Withdrawal Agreement.<sup>15</sup> The existing provisions for mutual recognition of professional qualifications and the related alert mechanisms, which provide for exchange of information on health professionals who have been subject to disciplinary proceedings, as well as employment rights, will continue until the end of December 2020. There will be a greater administrative burden for EU/EEA nationals to reside in the UK, and related uncertainty for individuals awaiting administrative decisions. The Withdrawal Agreement does not specify the process of securing rights in detail, but it does provide a minimum core of enforceable rights.

The Backstop does not include protections for residency of EU/EEA nationals, or mutual recognition of qualifications. It does, however, include some 'level playing field' rules in employment law, particularly equality rights under the Good Friday Agreement. These include equal treatment in employment on the basis of sex, race, religion or belief, disability, age or sexual orientation, and on the basis of sex for social security, but, importantly, nationality is not a forbidden ground for discrimination under these laws. While Irish citizens will continue to be able to rely on the provisions of the Common Travel Area between the UK and Ireland,<sup>16</sup> other EU/EEA residents in the UK will no longer have their residency in the UK protected (other than any protections that the UK may choose to provide unilaterally). It is unclear how mutual recognition of qualifications between the Republic of Ireland and Northern Ireland would operate.<sup>17</sup> Free movement of persons would end, with recruitment

and retention of EU nationals into the NHS after December 2020 under UK immigration law only.

Under a No Deal Brexit, entitlements of EU nationals in the UK would be based on UK domestic law only from 29 March 2019. Employment rights from EU law will initially be rolled over into UK law, but can be amended by executive action under EU (Withdrawal) Act 2018. Mutual recognition of qualifications and the protections it gives stops immediately, which may affect recruitment of health workers from the EU/EEA and will limit information exchange about health professionals moving across Europe. The Immigration and Social Security Co-ordination (EU Withdrawal) Bill 2019 removes the special status of EU/EEA nationals (except Irish nationals) in UK immigration law. How that general immigration law will develop in the future is uncertain, but the Immigration White Paper indicates that it will be skills-based. There are no proposed provisions facilitating recruitment and retention of NHS workers. The proposed minimum salary threshold of £30,000 per annum could seriously limit immigration of many health workers.

This is also the case for the Political Declaration on the Future Relationship. The Declaration envisages an end to free movement, and does not envisage any specific conditions for entry and stay related to health in particular or public service in general (though it does for research, study, training and youth exchanges). If the NHS is to employ staff from EU/EEA countries under the future relationship, this will be on the basis of UK immigration law only. Typically, FTAs such as the EU-Canada Comprehensive Economic and Trade Agreement (CETA) do not involve enforceable employment rights provisions, although this depends on the degree of integration and 'level playing field' requirements, which would be deeper under 'Norway+'. Access to the EU market will be contingent on alignment in a range of areas of which employment rights is one, as well as agreement on dispute settlement.

Under a No-Deal Brexit, or with the envisaged future relationship, in theory the UK will enjoy increased autonomy and hence flexibility to set and assess requirements for health professions (eg: shorter training, different professional skill mix), as well as general employment law standards. But in practice, if standards make it *more* difficult to recruit staff, it will be even harder to recruit from outside the UK. If standards are lower, there is a consequent trade-off for patient confidence/safety. Furthermore, if the UK chooses to remain aligned with the EU, it will lose the ability to inform regulatory standards as it has as an EU member. The Political Declaration indicates a weak ambition for arrangements on mutual recognition of professional qualifications; but this is already less ambitious than the Canada-EU Free Trade Agreement, which has not yet led to any substantive cooperation.

## 2. Financing

NHS financing post-Brexit includes the direct effects of financing patient care under reciprocal healthcare arrangements; access to capital financing for NHS infrastructure; and the broader effects of the post-Brexit economy on NHS financing generally.

The only aspect of NHS financing post-Brexit where we can expect no change is for reciprocal health care under the Withdrawal Agreement. Existing mechanisms for coordination of social security would continue. These include the European Health Insurance Card (EHIC), referral for planned cross-border care and healthcare for EU nationals resident in another EU country (e.g. UK retirees in Spain). However, these rights depend on patients

being correctly registered; and given discrepancies between the number of British people resident in Spain and those formally registered, this may cause problems in practice.

All other aspects of NHS financing are negatively affected. The Withdrawal Agreement will secure continuity for current European Investment Bank-funded projects, but no new projects after March 2019, as these are reserved for Member States. The certainty and continuity secured under the Withdrawal Agreement and the Backstop mean less of a negative effect on the economy as a whole than a No Deal Brexit, with the corresponding likely effect on NHS funding.

No Deal Brexit means an immediate end to reciprocal healthcare arrangements in March 2019. The Backstop makes no provision for continued reciprocal healthcare arrangements, so under the Withdrawal Agreement, these would cease at the end of December 2020. In the case of No Deal, and, logically, in the absence of any future agreement, the UK government has advised that visitors to EU/EEA countries need medical insurance as the EHIC 'may not be valid'.<sup>18</sup> It would be more accurate to say that the EHIC system 'will cease', along with the framework for administration/offset between UK and EU countries. This will have major consequences for older UK residents, especially if they have pre-existing conditions, as insurance cover, which may not be available for those with the most severe conditions, could be extremely expensive.<sup>19</sup> Some other groups will be particularly affected, such as patients on dialysis who benefit from provisions that allow them to receive it in centres in other Member States.<sup>20</sup> It is also unclear what will happen to UK pensioners living in the EU27 who are in the middle of a course of treatment there and are no longer entitled to cover, who would be protected under the Withdrawal Agreement.

The Common Travel Area protects reciprocal rights for Irish nationals in UK and UK nationals in the Republic of Ireland, but other EEA nationals who arrive after March 2019 (if No Deal) or 2020 (if Backstop) have access to healthcare under UK domestic law only.<sup>16</sup> The Immigration White Paper<sup>16</sup> proposes an extension of the Immigration Health Surcharge, typically £400 per year, to EEA nationals. The UK government has recently confirmed that in a no-deal scenario, UK nationals resident in EU-27 countries who return permanently to UK will have full access to NHS on same basis as those resident in the UK now.<sup>21</sup>

For the longer term, the Political Declaration is likely to mean a moderately negative impact. It envisages the possibility of some weaker form of reciprocal healthcare coordination for visitors in the future than currently, but as this is linked to future free movement provisions between the UK and the EU, taken together with wider plans on immigration it seems unlikely to be realised in practice. Some individual EU MS (e.g. Spain) have indicated willingness to enter into bilateral reciprocal arrangements, and the UK Secretary of State will be given power to enter into such agreements.<sup>22</sup> These arrangements would sit outside the EU's infrastructure which might create some administrative and legal difficulties.

In our previous paper we noted that the consensus of economic forecasts was that Brexit would have a negative impact on the UK economy. This has been borne out; the latest report on Brexit from the independent Office for Budget Responsibility (OBR) concludes that cumulative economic growth has been between 2 and 2.5 percentage points less than it would otherwise have been since the referendum. Looking ahead, while all forecasting is difficult, the situation with Brexit is especially so. The OBR's most recent analysis was unusually critical of the government's failure to provide any "meaningful basis for predicting the post-Brexit relationship between the UK and EU" on which to base its estimates.<sup>23</sup> However, all serious analyses predict a much slower rate of growth compared to remaining,

with the impact increasing as the UK-EU relationship becomes more disconnected.<sup>24</sup> Importantly, the claim by the Chancellor of the Exchequer's that the agreement reached with the EU in December 2018 would yield a "deal dividend" has been described as "not credible" by the parliamentary Treasury Committee.<sup>25</sup>

As one of the largest areas of public expenditure, any negative impact on the UK economy will put additional pressure on NHS financing, even though the exact impact will depend on the form of Brexit and on policy responses, including the extent to which the government is willing to raise taxes, increase borrowing and prioritise different sectors. Given looming crises in several other sectors, including welfare and the criminal justice system, there must be concerns about whether the government can maintain its funding commitments for the NHS.

Indirect effects of Brexit in other areas that may impact health, such as food supply, are also important.<sup>26</sup> The UK is especially dependent on imports of fresh fruit and vegetables and a recent modelling study estimated that a No Deal Brexit could lead to between 6,000 and 23,000 excess deaths from cardiovascular disease between 2021 and 2030.<sup>27</sup>

Further, many elements of UK laws on public health derive from EU legislation, for example on air pollution, health and safety, and trade within the single market in substances posing a risk to health, such as tobacco. There are concerns that the UK may use Brexit to roll back some of these measures, especially as it has failed to meet some of the existing EU standards, for example on air quality. Changes to these broader determinants of health would have indirect implications for the NHS and its resourcing, if population health worsened, particularly in geographic areas or socio-economic groups where health is already worse. Following a sustained campaign by the Faculty of Public Health to translate the obligation on the EU in the Treaties to ensure a high level of human health in its policies, Ministers gave a verbal assurance that they would maintain standards so as to "do no harm",<sup>28</sup> although they rejected enshrining it in legislation, thereby weakening the existing legal protections.

### 3. Medical products, vaccines and technology

The Withdrawal Agreement would mean continued application of EU law to products circulating between the UK and the EU. Products manufactured in either the UK or the EU will continue to be able to be marketed in either territory without unjustified restrictions. This continuity of legal relations will secure supply chains for medicines, vaccines, medical devices and equipment and other health consumables, on which the NHS relies, after 29 March 2019, until the end of December 2020, and longer if the Backstop comes into effect. Information sharing through EU databases continues. After March 2019, the UK becomes a rule-taker in terms of licensing of medicines through the centralised procedure (which applies to all biotechnology and similar innovative medicines), as it must accept the European Medicines Agency's authorisations but cannot lead on such licensing itself. Under any form of Brexit, the UK will no longer be part of the European Medicines Agency, entailing loss of global influence unless the UK can gain a status in the International Council on Harmonisation.<sup>29</sup> The MHRA will, however, be able to continue to licence medicines subject to the decentralised procedure, and the EU will recognise that licensing, and vice versa. UK-based 'notified bodies' that certify safety requirements are met for medical devices will continue to be recognised in the EU, and vice versa. By December 2020, such notified bodies are required to have shared their information so that medical device manufacturers

can transfer to an EU-based notified body if they wish to continue to sell in the EU after that date.

If the Backstop comes into effect, medicines for the EU market may be manufactured in Northern Ireland, but medicines manufactured in the rest of the UK will be treated by the EU as coming from a 'third country'. It is unclear what will happen to information sharing, but the Protocol makes provision for administrative structures within which such questions could be resolved. UK medicines licenses would no longer be recognised by the EU.

The Political Declaration on the Future Relationship indicates potential for weaker cooperation with the EU on licensing and regulation of medicines than is currently in place. Radioisotope cooperation is also envisaged, although the practical arrangements remain uncertain and the UK is likely to have low priority should shortages arise.<sup>30</sup> In the medium term, without laws in place to secure regulatory alignment, the UK would become less attractive for launch of new medicines by global pharma<sup>31</sup> with launch dates of up to 24 months later.<sup>32</sup>

Under a No Deal Brexit, the absence of a legal framework for imports and exports is expected to have an immediate and drastic effect on supply chains. The UK government has sought to reassure patients that its contingency plans with the pharmaceutical industry are robust, but shortages are likely as stockpiling arrangements cannot cope for more than a few weeks. The government is proposing that GPs prescribe 'best alternative medication',<sup>33</sup> which can be distressing and confusing for some patients. Some products, such as radioisotopes, cannot be stockpiled. The UK would immediately be treated as 'third country' for licensing and manufacture purposes. Some firms may not have transferred licences to EEA-based entities in time.<sup>34</sup> Information

A No Deal Brexit would involve an abrupt end to information sharing and collaboration based on EU law. This would immediately affect cooperation in areas such as cross border movements of patients, disease surveillance, cross-border clinical trials and other health research, registries, monitoring of the safety of pharmaceuticals and medical devices, and of the fitness to practise of health professionals. The Withdrawal Agreement would secure continued access to information and cooperation until the end of December 2020; and the Backstop would secure information sharing on products and substances of human origin thereafter. There is no specific cooperation on health information envisaged under the Political Declaration on the Future Relationship, although other cooperation structures (in particular through the World Health Organization) could provide an alternative for some forms of information sharing, though not based on EU law.

## 5. Service delivery

Although in theory under a No Deal Brexit and the future relationship as indicated in the Political Declaration, there is scope for the UK to change aspects of NHS service delivery related to terms of employment, such as working time legislation, in practice the scope for change is limited, as key provisions of existing European law are written into existing contracts, in particular those of junior doctors. Under the Withdrawal Agreement and the Backstop, much of the EU's legal framework for employment law continues to apply in the UK.

Provisions of EU law (particularly the Patients' Rights Directive) are currently being relied on by health trusts in some areas of the UK in order to respond to long waiting times, for

instance for knee operations. Patients are invited to pay upfront, but then are reimbursed.<sup>14</sup> These arrangements would continue under the Withdrawal Agreement. The Northern Ireland Protocol does not explicitly cover service provision, but it seeks to continue all-Ireland activities and structures, such as Cooperation and Working Together (CAWT), established as part of the EU's programme to promote peace and reconciliation, under which much shared healthcare infrastructure falls. Under a No Deal Brexit, all of these arrangements and possibilities would cease with immediate effect.

Brexit will have especially important consequences for health services in Ireland (Panel).

## 6. Leadership and governance

Some effects of Brexit for leadership and governance in health will have indirect effects on the NHS, in that the UK's European and global health leadership position will be diminished. Under the Withdrawal Agreement, from 29 March 2019, the UK is in principle excluded from EU institutions and agencies. It may not: nominate, appoint or elect members; participate in decision-making; attend meetings, including of expert groups, except where the Withdrawal Agreement explicitly provides otherwise. This includes the European Centre for Disease Control (ECDC), which is not specifically mentioned in the Withdrawal Agreement. As of 29 March 2019 the UK will be excluded from its decision making, though it will participate in information exchange until the end of the transition. The ECDC, like the network that coordinates health technology assessment, has been strongly influenced by the UK and the end of participation in these networks will diminish the UK's international influence on standard setting in health.

Under the Withdrawal Agreement, the UK may observe and send an advisory representative to the Administrative Commission for coordination of social security, which oversees reciprocal healthcare arrangements. The Withdrawal Agreement also covers meetings of EU agencies involving experts, which includes the decision-making procedures of the European Medicines Agency. UK experts may be invited to attend, but may not vote in, meetings or parts of meetings where either the decisions apply to the UK or entities in the UK, or 'the presence of the UK is necessary and in the interest of the Union'. However, after 29 March 2019, the UK is excluded from acting as lead authority in 'risk assessments, examinations, approvals or authorisations'.

The Withdrawal Agreement does not explicitly mention public health collaborations between the UK and EU, but this is likely to continue at global level, for instance, through the G7 and on health security through the WHO. One of the few places where health-related matters are covered in the Political Declaration concerns security. Obviously, exclusion from EU cooperation will result in a weakening of UK influence both in matters where the EU is concerned with health, and also where the EU interacts through global health entities such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use or WHO. The UK may be able to exert some influence through these global entities, but doing so as a smaller economic entity than as part of the larger EU is likely to have the obvious implications.

It has been suggested that leaving the EU might free the NHS from some of the obligations of EU competition and public procurement law, thereby making it possible to roll back recent market-oriented reforms to the English NHS, such as those in the 2012 Health and Social Care Act. EU law has often been seen as promoting marketization and competition in health

services. However, the magnitude of concerns is not matched by the reality of EU law in this area. EU law provides many exemptions for public services, in particular under the description of 'services of general interest', and in most cases it is a matter for national governments as to whether they do open their health systems to competition, although if they do they must then abide by relevant EU law. It was the decision of the UK government in the 2012 Act, not the EU, to impose EU competition law on health care in England.<sup>35</sup> Importantly, the Treaties and a succession of rulings of the EU's Court of Justice have served to protect health services in several Member States from potential consequences of internal market provision. It is very unlikely that these protections would be replicated in any future trade deals with, in particular, the USA.<sup>36</sup> It may be, though, that being formally removed from the application of EU competition and procurement law might reassure perceived concerns in a way that would create scope for more efficient organisation of the NHS.

The UK has played a key role in the EU's regulation of biomedical research, and has benefited significantly from collaborative EU research funding in biomedical fields. For instance, many EU-funded rare diseases networks are led by UK-based clinicians. EU law underpins information exchange in cross-border clinical trials, as well as setting regulatory standards and broad requirements for ethical oversight, although significant discretion remains at national levels. The new Clinical Trials Regulation will provide centralised infrastructure in a single EU portal, facilitating access to the EU market for new drugs. All of these arrangements continue under the Withdrawal Agreement.

Under the Backstop, it will remain possible for products in EU-based clinical trials to be sourced from Northern Ireland, but the service of carrying out a clinical trial is not covered by the Protocol, and so access by UK entities to cross-border clinical trials within the EU would end.

The Political Declaration envisages a relationship centred around a free trade agreement; how far the EU's rules on trade and competition would continue to apply to the UK would thus depend on the depth of that agreement. Continued participation in EU programmes such as research and technological development is envisaged, but on worse terms for the UK, with negative consequences for the UK's global leadership and influence across range of research areas.<sup>32</sup> Ironically, collaboration on public health is specifically envisaged at a global level, though not at a European one.

Under a No Deal Brexit, all collaborations would immediately lose the legal basis on which they are carried out, making data sharing across borders impossible unless the EU formally recognises the UK's data protection laws as compliant with EU law (which they would be as 'rolled over' into retained EU law under the EU (Withdrawal) Act 2018, unless amended), and access to funding would end, presumably with immediate effect. Regulatory uncertainty under No Deal has already halted one clinical trial in Scotland in December 2018.<sup>37</sup>

So far, we have focused on the specific consequences of withdrawal for the healthcare system. However, it is important to reflect on the wider implications for the machinery of government. Planning for Brexit has involved moving hundreds of civil servants to other government departments, while many remaining in their departments have been moved to Brexit-related work. Even so, there is very little evidence that the UK is prepared for any of the eventualities set out above. This applies both to the machinery of government and to Parliament, which faces the virtually impossible task of scrutinising and passing several major pieces of legislation and up to 600 Statutory Instruments, some of great complexity, all

by the end of March 2019.<sup>38</sup> Much has been undertaken in great secrecy, limiting scope for either Parliament or other stakeholders to assess what is being done. Thus, the Secretary of State for Health has reported the scale of the additional capacity obtained for storing medicines but there is no information on the planning assumptions underlying the decision, or its costs and where they will fall. Where information has become available, as with the (now rescinded) contract for additional ferry capacity awarded to a company with no ferries,<sup>39</sup> it has raised many unanswered questions. Meanwhile, other important legislation, such as that concerning social care, has suffered prolonged delays. Jonathan Powell, a former Downing Street Chief of Staff, has stated that “When the inquiry is eventually held into Brexit it will ... focus not just on individual failings but the whole system – the government, the opposition and even the civil service”.<sup>40</sup>

## Conclusion

In summary, our analysis suggests that leaving the EU under any of the four scenarios would be worse for the NHS than staying. However, by far the worst option would be a No Deal Brexit. The Withdrawal Agreement is likely to have many adverse consequences, but will also allow much to remain as it is until December 2020. The impact of the Backstop is likely to be uneven, effectively continuing the current position in some areas (in particular for medical products, vaccines and technology), but with a negative impact in most other areas. The Political Declaration on the Future Relationship envisages a free trade agreement similar to that between the EU and Canada; although it proposes going beyond that agreement some areas, these are areas such as transport and energy that do not directly address health-related issues.

### Panel: The Irish border

Following Brexit, the EU will have three land borders with the UK: in Cyprus, where the UK has two Sovereign Base Areas; between Gibraltar and Spain; and on the island of Ireland. A No Deal situation would create major problems for all three. For example, it would remove the legal basis for free movement of the 11,000 Cypriot nationals living in the base areas<sup>41</sup> and the Gibraltar economy is threatened by the loss of access to EU markets by financial services.<sup>42</sup> But it is the Irish border that has proven most challenging. Created in 1922, that border is 499 km long and is crossed by 270 public roads. Its creation severely disrupted historic trading arrangements as many of the roads were closed or designated as “unapproved crossings” and customs posts were erected to conduct checks on all goods in transit and to collect duties. These checks became especially important during the Anglo-Irish Trade War (1932-1938) when both countries imposed high tariffs on each other’s exports. However, except briefly in World War 2, free movement of people continued without the need to show a passport. The customs posts were removed when both countries joined the EU in 1973 but by then their locations had been replaced by military checkpoints in response to the growing violence in Northern Ireland. At that time many of the minor roads were blocked with concrete barriers or cratered by explosives. The Good Friday/1998 Agreement, endorsed overwhelmingly by referendums in both jurisdictions, paved the way for extensive cross border collaboration, based on shared institutions. Since then, the economies on either side of the border have become integrated. Health has been an important element of these developments, including the Co-operation and Working Together (CAWT) programme, which facilitates cross border collaboration and sharing of health infrastructure, especially in the geographical north, taking advantage of economies of scale. Thus, patients in border areas will often be referred for specialist care in a facility in the other jurisdiction if it is more convenient.<sup>43</sup> Large numbers of health workers cross the border every day, with some working part time on both sides of it.

As an international treaty, the Good Friday/1998 Agreement requires the UK government to keep the border open. However, this is obviously incompatible with Northern Ireland leaving the EU’s customs union and single market, as that would leave a large gap in the EU’s external border. The Withdrawal Agreement’s ‘Backstop’ in its Northern Ireland Protocol comes into effect if the UK fails to agree a future trade agreement resolving this problem. The Protocol’s objectives include avoiding a hard border, protecting the Good Friday/1998 Agreement and maintaining the necessary conditions for continued North-South cooperation, implicitly including CAWT.

The ‘Backstop’ establishes a single customs territory between the EU and the UK. This means that no tariffs or taxes could be imposed on products moving between the UK and the EU, and the same external tariffs would apply to products from other countries coming into the UK and EU. In this way, the UK government meets the obligation in the Taxation (Cross-Border Trade) Act 2018 not to ‘enter into arrangements under which Northern Ireland forms part of a separate customs territory to Great Britain’. For the regulation of products (non-tariff barriers), the Protocol extends the application of all relevant EU law (product standards, marketing and product safety, listed at length in Annex 5 of the Protocol) to Northern Ireland. The Protocol itself does not directly or formally require the same standards for products being produced or marketed in Great Britain, but if the UK wants to keep a single regulatory market including Northern Ireland, and avoid an internal border for products in the Irish sea, then in practice the UK will have to align with EU standards.<sup>7</sup>

It is far from clear what would happen in a No Deal Brexit, although a leading Northern Ireland general practitioner has described it as a “potential disaster”.<sup>44</sup> Maintaining the Common Travel Area is a priority for the UK government.<sup>2</sup> The Common Travel Area is not an international agreement, but a relatively complex series of national laws in the UK and the Republic of Ireland, which have the effect of treating UK and Irish nationals almost identically in both states.<sup>45</sup> The UK has confirmed that its recognition of the rights of Irish nationals will continue even in the event of a No Deal Brexit, and that Irish nationals will not be required to acquire the new ‘settled status’.<sup>46</sup> EU law permits Ireland to continue to apply the Common Travel Area provisions to UK citizens,<sup>47</sup> and Ireland has committed to so doing.<sup>48, 49</sup> Thus, while the provisions for (most) people would continue under No Deal, arrangements for products and services pose a major challenge. The Irish government would be required to impose some sort of frontier for products and services, with an inevitable risk of attacks on border infrastructure. While some Brexit supporters have advocated technological solutions, in reality none are currently sufficiently developed. The consequences for cross border collaboration in health services would be profound, because the legal basis for much of what now happens would be removed. These include rules on recognition of qualifications of cross-border health workers, their rights (for example a Polish doctor living on one side of the border and working on the other), the movement of blood products and morphine across borders in ambulances, and service contracts to maintain equipment.

Table 1 Impact of four different Brexit scenarios

		No Deal Brexit	Transition (the WA)	Backstop (NI Protocol)	Future relationship
Workforce	Recruitment and retention of EU nationals in the NHS	No provisions facilitating recruitment and retention of NHS workers.	Legal framework continues with some changes, retention and recruitment continues. Uncertainty over administrative arrangements.	The Backstop does not include protections for residency of EU/EEA nationals. Irish nationals in UK do not need new status; all other EEA nationals do.	No provisions facilitating recruitment and retention of NHS workers.
	Mutual recognition of professional qualifications	Theoretical potential to improve standards likely to be hampered in practice by recruitment needs.	The existing provisions for mutual recognition of professional qualifications and the related alert mechanisms will continue.	Theoretical potential to improve standards likely to be hampered in practice by recruitment needs.	Declaration indicates weak ambition for arrangements on mutual recognition of professional qualifications; but this is already less ambitious than the Canada-EU Free Trade Agreement, which has not yet led to any substantive cooperation.
		Mutual recognition and protections it gives stops immediately, and will limit information exchange about health professionals moving across Europe.		No provisions for mutual recognition beyond end of transitional period.	
Employment rights for health workers	No protection other than in domestic law of existing rights.	Legal framework continues.	Legal framework continues under some 'level playing field' rules in employment law. Nationality is not a forbidden ground of discrimination under these laws.	Typically FTAs like CETA do not involve enforceable employment rights provisions.	

Financing	Reciprocal healthcare arrangements	No rights in place as legal framework ceases immediately.	Existing mechanism for coordination of social security continues. May be practical registration issues.	No provision for continued reciprocal arrangements for social security under the Northern Ireland Protocol.	Potential for some weaker form of reciprocal healthcare coordination than currently, but linked to future free movement between the UK and the EU.
	Capital financing for the NHS	Access to EIB stopped and capital financing generally undermined.	Legal framework continues for existing EIB financed projects but no new financing from the EIB.	Access to EIB stopped and capital financing generally undermined.	Potential to participate in and receive funding from the EIB; likely lower level of capital financing than currently.
	Indirect impact on NHS financing	Severe effect on wider economy and thus NHS financing.	Some effect on wider economy and thus NHS financing.	Some effect on wider economy and thus NHS financing.	Some effect on wider economy and thus NHS financing.
Medical products, vaccines, and technology	Pharmaceuticals	Absence of legal framework for imports/exports drastically affects supply chains. Major disruption expected.	Continued application of EU law to circulation of medicinal products. For regulation and licensing, the UK becomes a rule-taker. Loss of global influence through role in European Medicines Agency	Continued application of EU law to circulation of medicinal products. Special arrangements for medicines manufactured in Northern Ireland. For regulation and licensing, the UK would not be able to license products for the EU.	Potential for some weaker cooperation with EU on licensing and regulation of medicines than currently.
	Other medical products	Major concerns about timely access to radioisotopes	Continuity of supply secured	As for pharmaceuticals.	As for pharmaceuticals.

Information		Absence of legal framework means end of information collaboration based on EU law.	Current legal framework continues, current information exchange activities continue.	Access only to information systems related to circulation of goods (ie: pharmaceuticals, medical devices) and substances of human origin (eg: blood). Access to other health-related information systems ends.	No specific cooperation on health information envisaged.
Service delivery	Working Time legislation	Regulation of working time and other conditions of work formally returns to the UK. But scope to change in practice is limited	Legal framework continues.	Legal framework continues under level playing field rules in NI Protocol.	Regulation of working time and other conditions of work formally returns to the UK. But scope to change in practice is limited.
	Cross-border care	No framework for cross-border care to cope with long waiting times and administration/offset between UK and EU countries	Legal framework continues.	Not covered, except for island of Ireland implicitly and as part of the Co-operation and Working Together (CAWT) to promote peace and reconciliation.	Cross-border health services not envisaged as part of the future relationship.
Leadership and governance	Public health	The government has offered reassurances to maintain EU standards but refused to enshrine them in legislation. Absence of EU law means that upholding public health standards in future depends on	Legal framework continues but UK is outside EU institutional structures so loss of role in e.g. ECDC	Government reassurances to maintain EU standards, but scope to improve public health standards is contingent on political will. Limited or no participation in decisions by e.g. ECDC.	Impact of EU rules dependent on depth of partnership. Limited or no participation in decisions by e.g. ECDC.

		on political will of government of the day			
		Existing protections can be removed by executive action	No mention in WA	Existing protections can be removed by executive action	Continued collaboration on public health at global level
	Trade and competition	NHS (England) no longer operates in perceived shadow of EU competition & public procurement law provisions which are felt to drive inefficient behaviours in context of NHS	Legal framework continues but UK is outside EU institutional structures so loss of role	Legal framework continues under NIP level playing field rules	Impact of EU rules dependent on depth of partnership
		Outside EU trade structures, UK's global influence over health in trade deals reduced (further). Some existing protections could be removed by executive action			
	Research	Collaborations and funding from EU ended. No access to Clinical Trials Reg's portal. Loss of global influence.	Collaborations and funding, plus legal framework, continue until end 2020	Product access, but otherwise collaborations and funding from EU ended. Loss of global influence	Continued participation in research envisaged, but on worse terms for the UK. Loss of global leadership & influence

	Scrutiny and stakeholder engagement	Volume of new legislation already limiting scrutiny and engagement, will continue	Volume of new legislation and executive powers under EU (W) Act limits scrutiny and engagement	Volume of new legislation and executive powers under EU (W) Act, plus new trade agreements, limits scrutiny and engagement	Volume of new legislation and executive powers under EU (W) Act, plus new trade agreements, limits scrutiny and engagement
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Grey = broadly unchanged; Green = positive; pale red = moderate negative; red = major negative

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Competing interests: NF and TH have acted as advisors to the House of Commons Health Committee, to which MM gave evidence. NF is a former employee of the European Commission. TH is a Jean Monnet professor, formerly partially funded by the EU, and is principal investigator in an ESRC Governance after Brexit Grant ES/S00730X/1 and co-investigator in an ESRC Brexit Priority Grant ES/R002053/1. MG is the Programme Director of Scientists for EU, a NGO which campaigned to remain in the EU. MM is the immediate past president of the European Public Health Association and a member of the European Commission's Expert Panel on Investing in Health. MM and TH are members of the advisory board of 'NHS against Brexit', a NGO unaffiliated with the NHS which campaigns to remain in the EU. Other authors have nothing to declare.

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