

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



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All forms of Brexit are bad for health, but some are worse than others. This paper builds on our 2017 analysis using the WHO health system building blocks framework to assess the likely effects of Brexit on the National Health Service (NHS) in the UK. We consider four possible scenarios as follows: a No-Deal Brexit under which the UK leaves the EU on March 29, 2019, without any formal agreement on the terms of withdrawal; a 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; the Northern Ireland Protocol's backstop coming into effect after the end of that period; or the Political Declaration on the Future Relationship between the UK and EU. Our analysis shows that a No-Deal Brexit is substantially worse for the NHS than a future involving the Withdrawal Agreement, which provides certainty and continuity in legal relations while the Political Declaration on the Future Relationship is negotiated and put into legal form. The Northern Ireland backstop has varying effects, with continuity in some areas, such as health products, but no continuity in others. The Political Declaration on the Future Relationship envisages a relationship that is centred around a free-trade agreement, in which wider health-related issues are largely absent. All forms of Brexit, however, involve negative consequences for the UK's leadership and governance of health, in both Europe and globally, with questions about the ability of parliament and other stakeholders to scrutinise and oversee government 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,¹ considering possible scenarios for the future relationship between the EU and UK. That analysis was, of necessity, limited, because the objectives of the UK Government were unclear at that time—reflected in the oft-repeated statement, Brexit means Brexit. Although Theresa May provided some clarification on her Government's 12 objectives in her Lancaster House speech in January, 2017,² the speech 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,³ noted in a more 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 to be discussed later. The second document, which is not legally binding, is the Political Declaration on the Future Relationship, which sets out some broad intentions concerning a final relationship between the UK and EU. In theory, the details will be finalised during the transition period set out in the Withdrawal Agreement lasting until December, 2020, although given the absence of agreement within the UK and the slow speed of progress so far, it is likely 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 National Health Service (NHS) than any form of Brexit, we consider four possible scenarios: No-Deal Brexit; the Withdrawal Agreement, during transition; the Northern Ireland Protocol's backstop; and the Political Declaration on the Future Relationship between the UK and EU. We are not comparing these scenarios with the effects of remaining in the EU, because that was part of our previous analysis.

Under a No-Deal Brexit, the UK leaves the EU on March 29, 2019, without any formal legal arrangements in place. This will happen automatically, under the provisions of the EU (Withdrawal) Act 2018⁴ and Article 50 of the Treaty on European Union 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 (ie, a country that is not an EU member state), with all that entails.⁵

The detailed legal text of the Withdrawal Agreement⁶ 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 EU27 nationals (ie, nationals of any of the other 27 member states) 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 example, they will be able to achieve residence rights or 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,

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	No-Deal Brexit	Withdrawal Agreement	Backstop (Northern Ireland Protocol)	Political Declaration on the 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 or EEA nationals; Irish nationals in UK do not need new status but 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, free-trade agreements such as Canada-EU Comprehensive Economic and Trade Agreement do not involve enforceable employment rights provisions
Financing				
Reciprocal health-care arrangements	No rights in place because legal framework ceases immediately	Existing mechanism for coordination of social security continues; might lead to practical registration issues	No provision for continued reciprocal arrangements for social security	Potential for some weaker form of reciprocal health-care coordination than now, but linked to future free movement between the UK and 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; probably less capital financing than now
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 or 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	Legal framework continues and information exchange activities continue	Access only to information systems related to circulation of goods (ie, pharmaceuticals and 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 Northern Ireland Protocol level playing field rules	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 or 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 programme to promote peace and reconciliation	Cross-border health services not envisaged as part of the future relationship

(Figure continues on next page)

at the end of transition, no future agreement between the UK and EU is 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 and 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 UK, along with level playing field rules (eg, on 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

	No-Deal Brexit	Withdrawal Agreement	Backstop (Northern Ireland Protocol)	Political Declaration on 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 political will of government of the day	Legal framework continues but UK is outside EU institutional structures so loss of role in groups such as ECDC	Government reassurances to maintain EU standards, but scope to improve public health standards is contingent on political will; scarce or no participation in decisions by groups such as ECDC	Impact of EU rules dependent on depth of partnership; scarce or no participation in decisions by groups such as ECDC
	Existing protections can be removed by executive action	No mention in Withdrawal Agreement	Existing protections can be removed by executive action	Continued collaboration on public health at global level
Competition and trade	NHS England no longer operates in perceived shadow of EU competition and 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 Northern Ireland Protocol 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 is reduced (further); some existing protections could be removed by executive action			
Research	Collaborations and funding from EU ended; no access to Clinical Trials Registry's portal; loss of global influence	Collaborations and funding, plus legal framework, continue until end of December, 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 and influence
Scrutiny and stakeholder engagement	Volume of new legislation already limiting scrutiny and engagement and will continue	Volume of new legislation and executive powers under EU (Withdrawal) Act limits scrutiny and engagement	Volume of new legislation and executive powers under EU (Withdrawal) Act, plus new trade agreements, limits scrutiny and engagement	Volume of new legislation and executive powers under EU (Withdrawal) Act, plus new trade agreements, limits scrutiny and engagement

Broadly unchanged
 Moderate negative
 Positive
 Major negative

Figure: Impact of four different Brexit scenarios
 ECDC=European Centre for Disease Control. EIB=European Investment Bank. NHS=National Health Service.

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.⁷ Given that trade agreements take years to negotiate (the EU–Canada agreement took 5 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 has more than a thousand pages),⁸ and the Political Declaration is only 26 pages long, we should take seriously the possibility that the backstop in the Northern Ireland Protocol will come into effect. It might in fact become the future relationship between the UK and EU, at least for the medium term.

The Political Declaration on the Future Relationship between the EU and UK (from here on referred to as the Political Declaration) 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 points to a free-trade agreement (FTA) similar to the EU–Canada agreement,⁹ with some enhanced aspects, none of which is directly relevant for health. Unlike the Withdrawal Agreement and its Northern Ireland 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 quite easily, but of course only if political agreement is reached on a different model (such as Norway plus 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 on remains uncertain. It did not attract a majority vote in parliament on Jan 15, 2019, even after lengthy delays to win support.¹⁰ Theresa 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 2017 paper, our method is to use the WHO's health system building blocks¹¹ to assess the likely effects on each aspect of the NHS in the UK, under the four different future scenarios (figure). 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 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, which 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 more than 40 years of membership is an obvious limitation of our approach: no equivalent comparative situations exist. 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 implications might be addressed.¹² If the possible effects of Brexit for the NHS have been considered in detail, that information is not available for scrutiny or analysis.

Analysis and discussion

Health and social care workforce

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

The Withdrawal Agreement secures the position of EU27 nationals in the UK, with only some individuals who are currently protected by EU law not protected in the Withdrawal Agreement.¹⁵ 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. The administrative burden for EU or EEA nationals to reside in the UK and related uncertainty for individuals awaiting administrative decisions will increase. The Withdrawal Agreement does not specify the process of securing rights in detail, but it does provide a minimum core of enforceable rights.

The Northern Ireland Protocol backstop does not include protections for residency of EU or 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/1998 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. Although Irish citizens will continue to be able to rely on the provisions of the Common Travel Area between the UK and Ireland,¹⁶ other EU or EEA residents in the UK will no longer have their residency in the UK protected (other than any protections that the UK might choose to provide unilaterally). It is unclear how mutual recognition of qualifications between the Republic of Ireland and

Northern Ireland would operate.¹⁷ Free movement of people 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 March 29, 2019. Employment rights from EU law will initially be rolled over into UK law, but can be amended by executive action under the EU (Withdrawal) Act 2018. Mutual recognition of qualifications and the protections it gives stops immediately, which might affect recruitment of health workers from the EU or EEA and will restrict 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 or EEA nationals (except Irish nationals) in UK immigration law. How that general immigration law will develop in future is uncertain, but the Immigration White Paper¹⁶ indicates that it will be skills based. No proposed provisions exist to facilitate recruitment and retention of NHS workers. The proposed minimum salary threshold of GBP £30 000 per annum could seriously limit immigration of many health workers to the UK.

The Political Declaration also envisages an end to free movement and does not specify any specific conditions for entry and stay related to health in particular or public service in general (although it does for research, study, training, and youth exchanges). If the NHS is to employ staff from EU or EEA countries under the future relationship, it will be on the basis of UK immigration law only. Typically, FTAs such as the EU–Canada Comprehensive Economic and Trade Agreement 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 plus. 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 have increased autonomy and hence flexibility to set and assess requirements for health professions (eg, shorter training and different professional skills 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 and 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 FTA, which has not yet led to any substantive cooperation.

Financing

NHS financing after Brexit includes the direct effects of financing patient care under reciprocal health-care 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 after Brexit in which we can expect no change is for reciprocal health care under the Withdrawal Agreement. Existing mechanisms for coordination of social security would continue. These mechanisms include the European Health Insurance Card (EHIC), referral for planned cross-border care and health care for EU nationals living in another EU country (eg, 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 might 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, because 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 than a No-Deal Brexit, with the corresponding likely effect on NHS funding.

No-Deal Brexit means an immediate end to reciprocal health-care arrangements in March, 2019. The backstop makes no provision for continued reciprocal health-care arrangements, so under the Withdrawal Agreement, these would cease at the end of December, 2020. In the case of No-Deal Brexit, and, logically, in the absence of any future agreement, the UK Government has advised that visitors to EU or EEA countries need medical insurance because the EHIC might not be valid.¹⁸ It would be more accurate to say that the EHIC system will cease, along with the framework for administration or offset between UK and EU countries. Ceasing of this system will have major consequences for older UK residents, especially if they have pre-existing conditions, because insurance cover, which might not be available for those with the most severe conditions, could be extremely expensive.¹⁹ 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.²⁰ It is also unclear what will happen to UK pensioners living in EU27 states who are in the middle of a course of treatment there and are no longer entitled to cover, but who would be protected under the Withdrawal Agreement.

The Common Travel Area protects reciprocal rights for Irish nationals in the UK and UK nationals in the Republic of Ireland, but other EEA nationals who arrive after March, 2019, (if No-Deal Brexit) or 2020 (if backstop) have access to health care under UK domestic law only.¹⁶ The Immigration White Paper¹⁶ 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 EU27 countries who return permanently to the UK will have full access to the NHS on the same basis as those resident in the UK now.²¹

For the longer term, the Political Declaration is likely to mean a moderately negative impact. It envisages the possibility of a weaker form of reciprocal health-care coordination for visitors in the future than is now in place, but because 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 member states (eg, 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.²² These arrangements would sit outside the EU's infrastructure, which might create administrative and legal difficulties.

In our previous paper,¹ we noted that the consensus of economic forecasts was that Brexit would have a negative impact on the UK economy. This prediction 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, although 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.²³ However, many analyses predict a much slower rate of growth than if the UK remained in the EU, with the impact increasing as the UK-EU relationship becomes more disconnected.²⁴ Notably, the claim by the Chancellor of the Exchequer 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.²⁵

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, concerns about whether the Government can maintain its funding commitments for the NHS are warranted.

Indirect effects of Brexit in other areas that might impact health, such as food supply, are also important.²⁶ The UK is especially dependent on imports of fresh fruit and vegetables and a modelling study estimated that a No-Deal Brexit could lead to between 6000 and 23 000 excess deaths from cardiovascular disease between 2021 and 2030.²⁷

Further, many elements of UK laws on public health derive from EU legislation—eg, on air pollution, workplace health and safety, and trade within the single market in substances posing a risk to health, such as tobacco. Concerns exist that the UK might use Brexit to roll back some of these measures, especially because it has failed to meet some of the existing EU standards—eg, 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 socioeconomic groups where health is already worse than average. 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 to “do no harm”,²⁸ although they rejected enshrining it in legislation, thereby weakening the existing legal protections.

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 March 29, 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), because 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.²⁹ The Medicines and Healthcare products Regulatory Agency 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 might 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. What will happen to information sharing is unclear, but the Northern Ireland 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 indicates a 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.³⁰ 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,³¹ with launch dates of up to 24 months later.³²

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 because stockpiling arrangements cannot cope for more than a few weeks. The Government is proposing that general practitioners prescribe “best alternative medication”,³³ which can be distressing and confusing for some patients. Some products, such as radioisotopes, cannot be stockpiled. The UK would immediately be treated as a third country for licensing and manufacture purposes. Some firms might not have transferred licences to EEA-based entities in time.³⁴

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 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. No specific cooperation on health information is laid out in the Political Declaration, although other cooperation structures (in particular through WHO) could provide an alternative for some forms of information sharing, though not based on EU law.

Service delivery

Although in theory, under a No-Deal Brexit and the future relationship as indicated in the Political Declaration, scope exists for the UK to change aspects of NHS service delivery related to terms of employment such as working time legislation, the scope for change is small in practice, because 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 being relied on by health trusts in some areas of the UK to respond to long waiting times—eg, for elective knee operations. Patients are invited to pay upfront then are reimbursed.¹⁴ 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, established as part of the EU's programme to promote peace and reconciliation, under which much shared health-care infrastructure falls. Under a No-Deal Brexit, all these arrangements and possibilities would cease with immediate effect. Brexit will have especially important consequences for health services in Ireland (panel).

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 March 29, 2019, the UK is in principle excluded from EU institutions and agencies. It may not nominate, appoint, or elect members; participate in decision making; or attend meetings, including of expert groups, except where the Withdrawal Agreement explicitly provides otherwise. Such groups include the European Centre for Disease Control (ECDC), which is not specifically mentioned in the Withdrawal Agreement. As of March 29, 2019, the UK will be excluded from its decision making, although 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 health-care 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".⁶ However, after March 29, 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—eg, through the G7 and on health security through WHO. One of the few places where health-related matters are covered in the Political Declaration concerns security. Exclusion from EU

cooperation will result in a weakening of UK influence both in matters where the EU is concerned with health and 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 might 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.

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 market-oriented reforms to the English NHS, such as those in the 2012 Health and Social Care Act. EU law has often been considered to promote marketisation 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. The UK Government, not the EU, decided in the 2012 Act to impose EU competition law on health care in England.⁴⁵ 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.⁴⁶ It might 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 substantially from collaborative EU research funding in biomedical fields. For example, 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 marked 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 these arrangements continue under the Withdrawal Agreement.

Under the backstop, products in EU-based clinical trials could still be sourced from Northern Ireland, but the service of conducting 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 an FTA; 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 anticipated, but on worse

Panel: The Irish border

After 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 areas³⁵ and the Gibraltar economy is threatened by the loss of access to EU markets by financial services.³⁶ 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 because 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 (1932–38) when both countries imposed high tariffs on each other's exports. However, except briefly during 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.³⁷ 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 requirement is obviously incompatible with Northern Ireland leaving the EU's customs union and single market, because 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, meaning 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 and 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.⁷

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".³⁸ Maintaining the Common Travel Area is a priority for the UK Government.² 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.³⁹ 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.⁴⁰ EU law permits Ireland to continue to apply the Common Travel Area provisions to UK citizens⁴¹ and Ireland has committed to so doing.^{42,43} Thus, although the provisions for (most) people would continue under a No-Deal Brexit, 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. Although some Brexit supporters have advocated technological solutions,⁴⁴ in reality, none are 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.

terms for the UK, with negative consequences for the UK's global leadership and influence across a range of research areas.³² Ironically, collaboration on public health is specifically proposed at a global level, though not at a European one.

Under a No-Deal Brexit, all collaborations (eg, research, reference networks, shared health-care services, and cross-border treatment of patients) would immediately lose the legal basis on which they are conducted, 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 if 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, 2018.⁴⁷

Thus far, we have focused on the specific consequences of withdrawal for the health-care system. However, reflection on the wider implications for the machinery of government is crucial. In many government departments, planning for Brexit has involved notable loss of capacity for other work, given that hundreds of civil servants have been moved to Brexit-related work.⁴⁸ Even so, very little evidence indicates that the UK is prepared for any of the eventualities we have set out here. This absence of evidence 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, 2019.⁴⁹ Much has been done 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 no information exists 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,⁵⁰ 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”.⁵¹

Conclusion

In summary, our analysis suggests that leaving the EU under any of the four scenarios would be worse for the NHS than remaining. 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 enabling continuity in some areas (in particular for medical products, vaccines, and technology), but producing a negative impact in most other areas. The Political Declaration on the Future Relationship envisages an FTA similar to that between the EU and Canada; although it proposes going beyond that agreement in some areas, these are areas such as transport and energy that do not directly address health-related issues.

Contributors

The paper is based on a framework initially developed by all authors. NF and TH prepared the tables and, with MM, wrote the first draft, with

additional contributions from SG and HJ. All authors reviewed and revised the text.

Declaration of interests

NF and TH are 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 Economic and Social Research Council (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 non-governmental organisation (NGO) that 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 and MG is the programme director of NHS against Brexit, an NGO, unaffiliated with the National Health Service (NHS), which campaigns to remain in the EU. All other authors declare no competing interests. NF is supported by the National Institute of Health Research (NIHR) Oxford Biomedical Research Centre. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health.

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