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Article:

Fahy, N., Hervey, T.K. orcid.org/0000-0002-8310-9022, Greer, S. et al. (4 more authors) (2017) How will Brexit affect health and health services in the UK? Evaluating three possible scenarios against the WHO health system building blocks. The Lancet, 390 (10107). pp. 2110-2118. ISSN 0140-6736

https://doi.org/10.1016/S0140-6736(17)31926-8

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Hervey, TK orcid.org/0000-0002-8310-9022, McKee, M, Fahy, N et al. (4 more authors) (2017) How will Brexit affect health and health services in the UK? Evaluating three possible scenarios against the WHO health system building blocks. The Lancet. (In Press)



Elsevier Editorial System(tm) for The Lancet Manuscript Draft

Manuscript Number: THELANCET-D-17-03263R2

Title: How will Brexit affect health and health services in the UK? Evaluating three possible scenarios against the WHO health system building blocks

Article Type: Invited Review

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How will Brexit affect health and health services in the UK? Evaluating three possible scenarios against the WHO health system building blocks

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Word count: 4628

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Abstract (239 words)

The UK's process of leaving the European Union will have profound consequences for health and the NHS. In this paper, we evaluate the likely impact on WHO health system building blocks of three scenarios, a "soft Brexit", "hard Brexit", and "failed Brexit", where the UK leaves without a deal. Each scenario poses significant threats to all building blocks. The workforce of the NHS is heavily reliant on EU staff. Financing of health care for UK citizens in the EU and vice versa is threatened, as is access to some capital funds, while Brexit threatens overall economic performance. Access to pharmaceuticals, technology, blood, and organs for transplant are all at risk, with a particular concern about radioisotopes because of the decision to leave Euratom. Information used for international comparisons is threatened, by both exclusion from networks and non-conformity of standards. Threats to service delivery include aspects delivered through European Reference Networks and cross-border care, especially in Northern Ireland. Governance concerns relate to public health, competition and trade law, and research. However, we were able to identify a small number of potential opportunities, should a government choose to take advantage of them, in areas such as competition law and flexibility of training. Overall, a soft version of Brexit minimises health threats while failed Brexit is the riskiest. Effective parliamentary scrutiny of policy and legal changes will be essential, but the scale of the task risks overwhelming parliament and the civil service.

Introduction

Leaving the European Union (EU) is arguably the greatest peacetime challenge that the United Kingdom (UK) has ever faced. The future is especially uncertain following the 2017 General Election, which left the government in a minority in parliament.

The impact on heath and healthcare will be substantial, ¹ affecting how medical products are licensed, employment of EU staff in universities and the NHS, rights to healthcare of European citizens in the UK and vice versa, regulation of research, and much else. Yet the British government has not addressed these critical issues, while the civil service appears struggling to cope, especially within the Department of Health, which has experienced large scale redundancies. ² The Department for Exiting the EU had not initially considered reciprocal health care arrangements ³ and the Department of Health was excluded from the formal negotiating process. ⁴ We have no confidence that central government is yet in a position to address the consequences for health.

We employ the World Health Organisation's health systems building blocks (Figure 1)⁵ to evaluate the impact of Brexit on health and the NHS. Given the present uncertainty, we assess three possible scenarios: i) quasi-European Economic Area (with access to the single market but restrictions on free movement of people), or 'Soft' Brexit; ii) a free trade agreement, such as that between the EU and Canada, a— 'Hard' Brexit; and iii) falling back on World Trade Organization rules, a 'Failed' Brexit (Panel).

Health Impact Assessment

We identify a series of topics within each building block and score each as broadly unchanged (grey), positive (green), moderate negative (yellow), and major negative (red) in terms of health risk.

Table 1 summarises the likely consequences of the three scenarios of 'Soft' Brexit, 'Hard' Brexit and 'Failed' Brexit. We offer three key messages. First, Brexit affects all of the building blocks. Second, the impact of Brexit on health ranges from somewhat negative to very negative, with few opportunities. Third, the impacts depend on what type of Brexit is pursued; the harder the Brexit, the worse the impact, with no deal worst of all.

Health workforce

The health workforce is especially vulnerable, with major effects on recruitment and retention of EU nationals within the NHS and social care.

Recruitment and retention of EU nationals to the NHS workforce

The UK cannot be self-sufficient in NHS or social care workforce in the foreseeable future. Over 60 000 people from non-UK EU countries currently work in the NHS and 90 000 in adult social care.² One in ten doctors in the UK is a European Economic Area (EEA) graduate (the EEA comprises the European Union countries plus Iceland, Liechtenstein, and Norway).² The Association of UK University Hospitals notes that EU membership significantly enhances the attractiveness of the UK as a place to build a career in research/clinical roles.² These overall figures do not take account of professional, regional and sector-specific reliance on EU/EEA nationals, with London and the South East particularly vulnerable to a loss of labour. The island of Ireland effectively shares a health and social care workforce.

Brexit may make the UK less attractive to health workers from the rest of the EU as it could undermine their legal entitlements and those of their families (whether EU citizens or not). These include not only residence rights but the right not to be discriminated against on nationality grounds when entering the UK; access to employment, housing and other benefits, including access of their

children to primary, secondary and higher education; accumulation and transfer of pensions, social security and welfare; the right to health care anywhere in the EU on retirement and when visiting their home country (e.g. for childbirth); some democratic rights, such as to vote in local elections; and mutual recognition of qualifications from any EU country (subject to linguistic competencies). Where competence to practise is a concern, an EU-wide alert mechanism is in operation, bolstering trust in qualifications obtained elsewhere in the EU; there is no similar system covering the rest of the world.

These entitlements derive from EU law and are subject to minimal administrative formality. If rights are breached, enforcement is through UK courts. Save for symbols on their passports, these staff are treated as UK nationals. In March 2017, the Guardian newspaper reported a 92% drop in EU nationals registering as nurses in England, which the Royal College of Nursing blamed "on the failure of the government to provide EU nationals in the UK with any security about their future". ⁶

Mutual recognition of professional qualifications

One area where some see potential for improvement after Brexit is professional regulation, with regulators in the UK ⁴ uncomfortable with how mutual recognition of qualifications works. Specific skills, such as language, are assessed by employers, as they are most familiar with specific needs of the job and are best qualified to make that assessment. However, UK professional regulators (who have expanded their responsibilities beyond that in other EU Member States in recent years⁷) believe that they should have this role. They see potential for improvement by strengthening their requirements for recognising professionals' fitness to practise in the UK. Given the reciprocity principle in negotiations by the EU, this is likely to cause corresponding increased difficulties for mobility by health professionals from the UK to the EU.

Employment rights arising from EU law

Health and social care staff are protected by numerous employment rights under EU law. These include EU equality law (which protects against discrimination on sex, race, disability, other grounds); EU health and safety at work law (including maternity leave rights, working time); and EU employment law on restructuring (for instance security of rights when another employer takes over a contract to provide services). Although these will initially be 'rolled over' into UK law by the Great Repeal Bill, the protection that comes from interpretation of disputes by the European Court of Justice will cease.

Financing

The main impact of Brexit on financing affects individuals, who will lose coverage when abroad if reciprocal healthcare arrangements end. There are also impacts on capital financing for the NHS, as well as on the overall NHS budget.

Reciprocal healthcare arrangements

Free movement within the EU depends crucially on support from social protection systems of the Member States. In turn, access to them depends on mutual recognition of rights acquired in each country and a mechanism by which the country where the person is covered will reimburse the countries where the person receives care or support.

Whilst details are complicated, the basic principles are simple; rights are built up and passed on as you live and work in different countries. Anyone requiring healthcare in a different EU country is treated as if they lived there, with their home country reimbursing the country where care was provided. The EU-UK post-Brexit deal could continue this system and the UK government appears to want this, ² although how this can be reconciled with its wider Brexit objectives (in particular, leaving

the future jurisdiction of the EU's Court of Justice)⁸ is unclear. It is clearly a high priority for the EU and was reportedly invoked explicitly by the President of the European Commission when he met Prime Minister May but this issue does not yet seem to have reached the agenda of the Department for Exiting the EU.³

Leaving this system will jeopardise access for people covered by the NHS travelling to the EU for work, study or leisure. Around 27 million people hold European Health Insurance Cards (EHICs, used to show coverage by your home country) issued by the UK.² This has several important advantages over the alternative, of voluntary private insurance, which would transfer the cost to the individual. First, the EHIC does not exclude pre-existing conditions. Second, all existing private insurance schemes are priced according to individual risk, which would make coverage prohibitively expensive for older people or those with chronic conditions. Third, it would not replace some specific EU arrangements, such as provision for those requiring dialysis.⁹

The most profound impact is likely to be on UK nationals who now live elsewhere in the EU. There are around 190,000 people in receipt of British pensions living in other EU countries (in particular Spain, France, Ireland and Cyprus), who depend on these arrangements for healthcare. And Many are UK nationals who worked their whole lives in the UK, but who retired to warmer climates where their pension would go further. Others are not British, but have worked in the United Kingdom for much of their lives before retiring to their countries of birth.

The costs of EU-insured people receiving care within the UK are also covered by this system. They are fewer than UK nationals living abroad but again, the mechanism remains vital.

The UK pays about £650m per year for care provided to British people in other countries (of which about £500m is on pensioners), and receives about £50m for the care provided to EU-insured nationals in the UK (although because there is no easy or routine method to check a patient's eligibility for NHS care, the UK could in theory claim more, perhaps as much as £200m).² Financially, the amount paid by the UK is marginal in comparison to the total NHS budget (less than one-half of one percent),¹² and it also represents good value for money. The average cost of treating pensioners elsewhere in the EU under these arrangements is about half the cost of similar treatment within the UK.²

Capital financing for the NHS

The EU is the primary source of capital investment in healthcare infrastructure in poorer Member States through European Structural and Investment Funds, though this is not the case for the UK as one of the richer Member States. However, the European Investment Bank has provided over €3.5 billion in low-cost capital to the NHS since 2001,¹³ a major contributor to funding of public-private partnerships.

Indirect impact on NHS financing

The NHS is the largest discretionary part of UK public expenditure, ¹⁴ so anything that affects the UK economy is likely to impact substantially on NHS financing. With extra costs of recruiting scarce staff and higher prices of imported medicines, the Economist Intelligence Unit has estimated an increase in NHS costs of £7.5 billion a year, out of a total expenditure of £177 billion.¹⁵

Whilst some have drawn reassurance about the short-term performance of the UK economy since the referendum, this is unsurprising as no change in EU-UK relations has taken place. However, the overwhelming consensus of economic forecasts, including that of the Office for Budget Responsibility, is that Brexit will have a substantial long-term negative impact on the UK economy, and thus can be expected to put additional pressure on financing for the NHS.

Medical products, vaccines, and technology

A key concern relates to pharmaceuticals, where nearly EU law governs nearly every aspect of medicines licensing. Less visible, but equally important, is the impact on other medical products, including medical devices and radioisotopes.

Pharmaceuticals

The UK has benefited from hosting the European Medicines Agency (EMA), helping to consolidate its position as a leading location for the pharmaceutical industry in Europe. Particularly with a Soft Brexit, but even following a Hard Brexit, it may be possible for the UK to continue to pay to participate in the work of the EMA. However, the UK will become an observer at best at the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which is the global standard setter for pharmaceuticals.

If it leaves the European system of medicines licensing it will be excluded from the single process for authorising medicines across the EU. This offers substantial benefits in terms of cost and speed of bringing new products to market. The Association of the British Pharmaceutical Industry notes how this process has "not only greatly simplified the ... situation but also resulted in a system where medicines information such as the patient information leaflet are consistent across all EU member states, which is good for public health protection." In Switzerland and Canada, which have separate approval systems, medicines typically reach the market six months later than in the EU. It will therefore be necessary for the UK to develop its own regulatory system, unless it is willing simply to accept the decisions of other regulatory agencies such as the US Food and Drugs Administration or EMA.

Counterfeit medicines pose a major threat worldwide, both in terms of ineffective treatment and the emergence of antimicrobial resistance. ¹⁶ The EU is in the forefront of measures to address this problem and has created systems to monitor global supply chains and to share safety information on emerging problems. The UK might be able to opt in to this scheme, but with little or no input into policy.

The UK will need to strengthen the domestic Medicines and Healthcare Products Regulatory Agency. However, this will itself be challenging as the agency currently derives a substantial proportion of its income from the European Union, either as a contractor to the EMA or from European research funding and, as with universities and the NHS, it is likely to face difficulties in attracting specialised staff from other parts of Europe.

Other medical products, substances of human origin, and radiotherapy

Similar issues arise with medical devices (also licensed through a European system, though in a more decentralised one than for pharmaceuticals) and substances of human origin such as blood and organs. Again, the UK has the choice of either becoming a 'rule taker' of EU regulatory standards; deregulating the sector significantly, with all that entails for patient safety; or developing a new framework, which risks making the UK unappetising for companies through extra costs.

A 'Failed Brexit' would cause immediate disruptions to importing health products whose trade is not governed by WTO rules. There is a major threat to availability of radioisotopes for diagnosis and for cancer therapy, which the UK imports (mostly from the Netherlands). Generation, movement, and handling of these within Europe are governed by the Euratom treaty, one of the core European treaties agreed when the European Economic Community was created in 1957, so that some new legal structure will be needed if supplies of radioactive medical isotopes for cancer treatments are to continue.

Because so much current trade depends on EU regulatory structures and networks that make them 'friction free', it is difficult to assess how pharmaceuticals, medical equipment, and medical devices would continue be traded when these frictions return. More complex issues such as securing human blood, organs or tissue supplies, all the subject of specific provisions in EU law, are likely to face difficulties and short-term disruptions.

Information

Comparable information at EU level has been a substantial force for improvement in healthcare. For example, European comparative data on cancer outcomes, generated by the EU-funded EUROCARE studies, have had a profound impact on cancer care in the UK, highlighting variations in outcomes and scope for the UK to bring itself up to the level of better performing systems elsewhere in Europe. Yet producing this comparable data is enormously technically complicated, and it has taken decades to generate even the relatively limited datasets that are currently available. Similarly, in the area of communicable disease, the European Centre for Disease Prevention and Control (ECDC) in Stockholm has over 200 staff simply to ensure effective monitoring of that one relatively small domain¹⁸.

Though there is little reason in theory why cooperation on information sharing could not continue (provided that a regulatory framework for transfer of personal data is in place, and provided the UK gains 'adequacy status' as a non-EU country under the General Data Protection Regulation 2016/679), in practice this kind of work depends very much on sustained financing and investment in collaboration, as demonstrated by the EU's collaboration on health data being well in advance of comparable international data elsewhere in the world.

Service delivery

Though the EU Treaties leave primary responsibility for the organisation and delivery of health services and medical care with Member States, there are some areas where Brexit will impact on service delivery. Perhaps the highest profile example is the working time directive; alongside that, though, are less well-known networks for accessing specialist care for rare diseases throughout the EU, and the specific cases of cross-border care provision in Ireland and Gibraltar.

Working Time legislation

European legislation on working time and its application to doctors in training has been a long-standing controversy within the UK. Indeed, it was one of the areas identified as a problem by the former Prime Minister, David Cameron in 2013 as he launched the process that led to the Brexit referendum. Even now, views on the legislation are mixed. On the one hand, professional regulators see scope to improve flexibility by relaxing current rules on working time. On the other hand, junior doctors have insisted that the provisions of the Working Time Directive are included explicitly in their new national employment contract.

European Reference Networks

For rare diseases, it can be impractical or impossible to access care in every individual country; there may only be a handful of centres of expertise in the whole EU. The EU has set up European Reference Networks to bring together these highly specialised centres into networks around particular treatment areas, to enable patients to be diagnosed and treated using the best available expertise, even when in another EU country. These networks also facilitate research and clinical trials, drawing on the larger pool of patients than would otherwise be possible, and sharing of knowledge and development of guidelines. The UK currently has 33 hospitals participating in 22 of the 24 existing European Reference Networks.

Cross-border care

Two localities are likely to experience substantial disruption to service delivery because of Brexit; Northern Ireland and Gibraltar. In Northern Ireland, efforts to promote cross-border collaboration in health as part of the peace process have existed for decades, with active support from the European Union as well as the administrations in the UK and the Republic of Ireland. The projects deliver care for many with specific medical needs, including diabetes, sexual health, eating disorders and autism, and serve communities on both sides of the Irish border, thereby creating a sufficient critical mass of patients to secure the economies of scale necessary to justify provision. The matter of the UK-EU post-Brexit land borders is high in the EU's negotiating priorities, but attention to the health aspects of the negotiation, not solely to the security and trade aspects, will be crucial.

Leadership and governance

This 'building block' covers a wide range of system-level issues, such as regulation – where EU rules on the environment and public health are particularly relevant, as well as competition and trade rules – as well as supporting functions such as research, where again the impact of Brexit is substantial. It also covers processes of scrutiny and stakeholder engagement.

Public health

A series of directives designed to improve air quality have had a major impact on health. Thus, there has been an 80% decline in SO_2 emissions following restrictions on the sulphur content of fuel, virtually eliminating the problem of acid rain. However, the UK has often lagged behind its neighbours and, in 2015, only 2 London boroughs met European standards for NO_2 levels, leading the European Commission to initiate infringement proceedings. European directives on water quality have also been very effective, although again the UK has some way to go, with only 77% of British beaches rated as excellent, a figure well below that in many other Member States. This suggests that, in the absence of EU legislation, UK environmental standards could slip further.

The EU has been active in policies designed to tackle threats to health posed by products that cross borders, and especially tobacco. This is an area where the UK has been in advance of many other Member States. Currently, UK courts look to EU law in interpreting these rules. There is, however, a risk that the UK would be a prime target for the tobacco industry post Brexit, as is the case in Switzerland.²¹

The UK benefits greatly from its participation in EU specialised agencies, such as the European Food Standards Agency and the European Centre for Disease Prevention and Control. These agencies perform essential roles and, if the UK is unable or unwilling to continue participating in them, will have to find alternative arrangements. Working through and with the WHO or the UN *Codex Alimentarius* system as the UK, rather than as part of an entity the size of the EU, will inevitably entail a loss of influence. However, given the persisting threat of infectious diseases crossing borders, any lesser engagement poses a potentially serious threat to human and animal health.

Competition and trade

Competition law is one of the areas where the UK could have an opportunity to improve the policy environment for the NHS, should it choose to do so. The EU has a strong regulatory structure designed to prevent states from implementing industrial policies that might impede competition within the internal market. This includes anti-trust legislation that gives the Commission great authority to find and punish cartels, "state aid" law that blocks corrupt or unfair public subsidies to particular businesses, public procurement law that keeps governments from promoting particular businesses at the expense of the public purse, and competition law intended to create level playing

fields for companies established in different Member States. These bodies of law all create inconvenience and even some threats to the NHS.

The risk with state aid law, and competition law in general, is that sensible health policy might be interpreted as a subsidy to a particular (NHS) provider in a competitive market. If a private firm bids to provide NHS services and does not get the contract, it can challenge the decision in court, arguing that the process unfairly advantaged one set of competitors (NHS organisations) over another. These challenges have not been especially successful under EU law, with the ECJ consistently recognising the particular nature of health care, but the risk of expensive litigation drives behaviour within the NHS. Public procurement law creates administrative inconvenience since it demands that procurement be carried out in accordance with EU administrative requirements (or that contracts be split into smaller contracts that have a lower administrative burden). There is almost certainly scope to reduce administrative overhead here. However, this presupposes that the Government wishes to do this. While many European governments have insulated their health systems from these processes, the UK has explicitly decided not to, with the 2012 Health and Social Care Act opening the NHS in England (but not in Scotland) to further competition, invoking EU law as a justification for its own pro-competitive agenda. Consequently, it is far from clear that the UK will take this opportunity to structure the NHS to take it outside the scope of competition law.

A related issue is the scope for future trade deals to subject the NHS to investor-state dispute settlement mechanisms. This could allow corporations to contest domestic policies on health, the environment, and working conditions, for example, arguing that they are non-tariff barriers to trade or investment. This has been one reason for controversy over the proposed Trans-Atlantic Trade and Investment Partnership (TTIP), although the EU's negotiating position incorporated many safeguards, including for health systems and it seems likely that any arrangements outside the EU would not do so.

Research

The scientific community was one of the most vocal in the referendum campaign, reflecting the enormous importance of European Union membership for British research, and the leading role of British universities within the EU.

Although direct European Union funding accounts for only 17% of research contracts held by British universities, it accounted for almost three-quarters of the growth in funding in recent years. However, the consequences go far beyond funding. British researchers benefit from access to European networks and infrastructure and from the free movement of personnel within the European Union. An estimated 16% of the academic workforce in the United Kingdom comes from other parts of the EU. Additional benefits flow from the common legal frameworks and standards that underpin research, in areas such as data protection and clinical trials regulation. The UK Government has attempted to as assuage these concerns, offering to underwrite continued funding for existing EU projects, although without any commitment for long-term support. However, it has provided no reassurance about the other matters. There are at least six issues of direct relevance to health.²²

The UK already lags behind comparable economies in investing national funds in research and development. It is a net beneficiary of EU research funding, attracting substantially more than it contributes to the common pool. The loss of this funding would have severe consequences. It is thus critical that the UK finds a mechanism to continue to participate in the EU Horizon 2020 programme, as other countries such as Israel do, by paying into the scheme. Other sources of funding have also been important, such as the European Fund for Strategic Investment in support of exports.

However, there is more to continued research success than funding. Freedom of movement is also central; the UK attracts almost a quarter of researchers moving within the Marie Curie scheme, which supports mobility of researchers within Europe.²³ Health research in particular operates within an EU regulatory framework such as legislation on clinical trials (which, though initially overly burdensome, has been revised to strike a good balance between safety and administrative burden) ²⁴ Any divergence in standards would add greatly to the administrative burden of undertaking collaborative research and, potentially, to obtaining approval for new products that emerge from that research. Likewise, with the developing EU intellectual property regime, departure risks making it more difficult to protect intellectual property generated by UK research.

Scrutiny and stakeholder engagement

Whatever the form of Brexit, vast areas of previously European legislation will need to be adopted and adapted into national law, and then potentially revised; the harder the Brexit, the greater the volume of legislation needed. Given the sheer volume of legislation to be dealt with, this represents a challenge in itself, with the UK government likely to make substantial use of provisions that allow primary legislation to be amended directly by the Government through secondary legislation. ²⁵ A former Lord Chief Justice has recently argued that what he described as a "legislative tsunami" will prevent parliament for applying adequate legislative scrutiny²⁶, and thus also limit the potential for stakeholder engagement in the legislative process.

Conclusion

The impacts of Brexit on health are wide-ranging, touching every 'building block' of a health system as described in the WHO Health System Framework. This is a challenge for the Brexit negotiations, as the scale of the impact varies widely according to how the UK leaves the EU and then sets a basis of future EU-UK relations. It is also a fundamental challenge for health policy within the UK. Intentionally or not, Brexit will reshape the health system in the UK in a wide variety of ways, and much energy in the coming years will be required to stand still, as existing arrangements are reworked and adapted for the new situation. Although the impacts on the workforce and on people depending on reciprocal healthcare arrangements will be substantial (and potentially devastating for the individuals involved), the largest impact on the health system as a whole is likely to come from Brexit's impact on the wider economy and thus on the ability of the UK to finance the health service and on the ability of the state to function.

How effectively the UK deals with these challenges will be a governance challenge for the entire health policy system of the UK. Given the apparent lack of capacity of government to rise to this challenge, we argue that the wider health community within the UK must work together to address these issues.

Contributors: MM designed the initial structure of the paper and prepared the first draft. All authors then contributed drafts on different themes (Public Health, MM/DS; Research, MG; Health Services and pharmaceuticals, NF/TH; Competition, SG, Trade, HJ), which MM assembled prior to revision by all authors. The paper was then extensively revised by NF and TH, who prepared the table, prior to final revisions by all authors. The scorecard was discussed at a conference on Brexit hosted by the UK Society for Social Medicine.

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 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 were members of the advisory board of 'Healthier In', a NGO which campaigned to remain in the EU. Other authors have nothing to declare.

Figure 1: The WHO Health System Framework⁵.

LEADERSHIP / GOVERNANCE

THE WHO HEALTH SYSTEM FRAMEWORK SYSTEM BUILDING BLOCKS OVERALL GOALS / OUTCOMES SERVICE DELIVERY ACCESS IMPROVED HEALTH (LEVEL AND EQUITY) **HEALTH WORKFORCE** COVERAGE INFORMATION RESPONSIVENESS MEDICAL PRODUCTS, VACCINES & TECHNOLOGIES SOCIAL AND FINANCIAL RISK PROTECTION QUALITY IMPROVED EFFICIENCY FINANCING SAFETY

Panel Three possible scenarios for Brexit

'Soft' Brexit: continued integration with the single market

This scenario represents the closest continuing relationship with the EU, with a high degree of integration with the single market, though as restrictions on free movement of people seem inevitable, ^{8,27} there would also have to be limits on access to the single market. This could be based on the European Economic Area model, used by Norway, Iceland, and Liechtenstein. Given the importance of avoiding tariffs and quotas on goods with the EU, one obvious counterbalance for the UK would be to offset limits in free movement with limits on trade in services, though this would have a significant impact on the City of London in particular, and thus on tax revenues. Some rights of people from the rest of the EU who are already in the UK could be settled in the UK's withdrawal agreement, although major questions would remain about how they would operate, be enforced and, in the case of disputes, adjudicated.

The legal implications of Soft Brexit include that much of EU law would continue to apply in the UK, albeit without the UK participating in making that law, and without access to the EU's Court of Justice (ECJ) to interpret and enforce that law. Formally, EU law would no longer be a source of UK law, but de facto much of it would continue to be so, through the continued reference to EU regulatory standards necessary to secure access for UK firms to EU markets, and through the interpretation and application of 'ex-EU law', as proposed under the Great Repeal Bill, which would transpose all existing EU legislation into domestic UK law (although many practical questions remain unanswered). In practice, much would depend on what dispute resolution mechanism replaced the ECJ, as a tribunal system is unlikely to maintain the transparency and commitment to a high standard of health enshrined in the European Treaties and upheld repeatedly by the ECJ.

'Hard' Brexit: free trade agreement

This scenario involves a wide-ranging EU-UK free trade deal, perhaps similar to the recently signed free trade agreement (FTA) between the EU and Canada. The position set out in the Government's White Paper on Brexit⁸ is not compatible with remaining within the single market in any way, given in particular the Government's insistence on avoiding any judicial oversight of an agreement. A FTA would be the closest likely future relationship with the EU consistent with the White Paper's negotiating approach. By creating an entirely new agreement, though, it would also probably be the most time-consuming, most likely taking up to a decade to reach agreement.³⁰

The legal implications include that the EU-UK FTA is not in any way part of UK law. At present, individuals have recourse to EU law if their rights are violated. Under the EU-UK FTA they would lose this entitlement. This was a central issue in the government's attempt to void seeking Parliamentary approval for triggering Article 50, signifying its intention to withdraw from the EU. Instead, an investor-state dispute resolution system might be included.

'Failed' Brexit: falling back on WTO rules

This is the scenario if the UK and the EU cannot reach agreement, and the UK falls back on WTO rules for its trade with the EU. From a trade point of view, this poses technical and substantive challenges. Technically, the process of updating the UK's terms of trade under the WTO is likely to be far from straightforward. The challenges involved have been illustrated by a case study that examined the superficially simple rules on trade in lamb and mutton. In practice these rules were so complex that they had not been updated since before the EU's 2004 enlargement. Substantively,

the UK will abruptly face additional tariffs and, arguably more importantly, quotas on goods of all kinds with the EU and the other countries with whom we currently trade under free trade agreements through the EU. There are also many aspects of trade which are governed within the EU legal framework but which do not have corresponding agreements through the WTO, meaning that further individual agreements would still need to be found in this scenario.

Table 1: The risk to different health-related issues (organised by health system building blocks) of three scenarios for Brexit

Health system building blocks		'Soft Brexit' – EEA-minus	'Hard Brexit': FTA		'Failed Brexit': WTO rules		
Workforce	Recruitment and retention of EU nationals in the NHS	Even this scenario includes some restrictions on migration	Likely to include restrictions on migration. EU nationals have 'foreigner' rights and status		Lack of legal framework for mobility likely to impact severely on migration.		
	Mutual recognition of professional qualifications	May remain unchanged.	Potential for professional regulators to improve system.	Likely to make mutual recognition more difficult.	Potential for regulators to improve system.	Likely to make mutual recognition much more difficult.	
	Employment rights for health workers	If mostly in EEA, existing rights likely to remain.	Existing rights likely to be at least somewhat diminished.		No protection of existing rights.		
Financing	Reciprocal healthcare arrangements	Likely to continue with current arrangements.	Replacement arrangements unlikely to provide fully equivalent protections. EU funds through European Investment Bank likely to be stopped.		Lack of legal framework means no rights in place.		
	Capital financing for the NHS	Likely to continue through European Investment Bank.			Chaotic exit likely to undermine capital financing more generally.		
	Indirect impact on NHS financing	Even this scenario likely to impact wider economy and thus NHS financing.	'	kely to impact adversely on wider conomy and thus NHS financing.		Likely to severely impact wider economy and thus NHS financing.	
Medical products, vaccines, and technology	Pharmaceuticals	Likely to continue with current arrangements. Loss of global influence through ICH.	A new licensing regime needed, with impact on timely access. Loss of global influence.		Lack of legal framework likely to impact severely on the UK as a market. Loss of global influence.		
	Other medical products	Likely to continue with current arrangements.	A new licensing regime needed, with impact on timely access.		Lack of legal framework likely to impact severely on the UK as a market, in particular for radiotherapy.		
Information		Likely to continue with current arrangements. Will need	External position likely to undermine information Lack of agreements likely to mean end of information				

		recognition of 'adequacy'	collaboration, so long as 'adequacy' recognition secured.		collaboration.	
		under Data Protection Reg.				
Service delivery	Working Time legislation	Likely to continue with current	Potential to	Existing	Potential to	Existing
		arrangements.	improve on current	protections	improve on	protections
			rules.	likely to be	current rules.	removed.
				diminished.		
	European Reference Networks	Likely to continue with current	undermine collaboration.		Collaboration stopped without	
		arrangements.			a legal framework.	
	Cross-border care	Likely to continue with current	Unless 'deal' includes specifics, likely to cause severe problems with current collaborations.		Lack of deal will cause severe problems with current	
		arrangements.				
					collaborations.	
Leadership and	Public health	Likely to continue with current	Potential to	Existing	Potential to	Protections
governance		arrangements.	improve on current	protections	improve on	likely to be
			rules, if political will	likely to be	current rules,	diminished,
			exists.	diminished.	if political will	under guise
					exists.	of 'red tape
						cutting'.
	Competition and trade	Trade likely to be impacted as	Potential to adapt	Trade likely	Potential to	Trade likely
		part of negative consequence	competition rules	to be	adapt	to be
		of leaving the EU.	better to the NHS, if	somewhat	competition	severely
			political will exists.	affected.	rules better to	affected.
					the NHS, if	
					political will	
					exists.	
	Research	Likely to continue with current	likely to be diminished. Loss of		Research collaborations with	
		arrangements.			and funding from EU ended.	
	Continue de la	Note that the second se	global influence.		Loss of global influence.	
	Scrutiny and stakeholder	Volume of new legislation	Volume of new legislation likely to		Volume of new legislation	
	engagement	likely to limit scrutiny and	severely limit scrutiny and		likely to severely limit scrutiny	
		engagement	engagement		and engagement	

This table is colour coded to indicate likely impacts as: broadly unchanged in grey; positive in green; moderate negative in yellow; major negative in red.

References

- 1. McKee M, Galsworthy MJ. Brexit: a confused concept that threatens public health. *J Public Health (Oxf)* 2016; **38**(1): 3-5.
- 2. Health Committee. Oral evidence: Brexit and health and social care, HC 640 (2016-17): House of Commons, 2017.
- 3. Trend N. Will Brexit see UK travellers lose their European health privileges? 2017. http://www.telegraph.co.uk/travel/comment/ehic-cards-after-brexit/ (accessed 8th May 2017).
- 4. Health Committee. Brexit and health and social care people & process (Eighth Report of Session 2016-17; HC 640). London: House of Commons, 2017.
- 5. World Health Organization. Everybody's business: strengthening health systems to improve health outcomes: WHO's framework for action. Geneva, Switzerland: World Health Organization; 2007.
- 6. Boffey D. Record numbers of EU nurses quit NHS. 2017. https://www.theguardian.com/society/2017/mar/18/nhs-eu-nurses-quit-record-numbers (accessed 13th May 2017).
- 7. Sole M, Panteli D, Risso-Gill I, et al. How do medical doctors in the European Union demonstrate that they continue to meet criteria for registration and licencing? *Clin Med (Lond)* 2014; **14**(6): 633-9.
- 8. UK Government. The United Kingdom's exit from and new partnership with the European Union (Cm 9417). London: Her Majesty's Stationery Office, 2017.
- 9. Footman K, Mitrio S, Zanon D, et al. Dialysis services for tourists to the Veneto Region: a qualitative study. *J Ren Care* 2015; **41**(1): 19-27.
- 10. Legido-Quigley H, Glinos IA, Baeten R, McKee M, Busse R. Analysing arrangements for cross-border mobility of patients in the European Union: a proposal for a framework. *Health Policy* 2012; **108**(1): 27-36.
- 11. Legido-Quigley H, Nolte E, Green J, la Parra D, McKee M. The health care experiences of British pensioners migrating to Spain: a qualitative study. *Health Policy* 2012; **105**(1): 46-54.
- 12. Organisation for Economic Cooperation and Development. OECD Health Data. 2016 (accessed 6/5/2017.
- 13. European Investment Bank. Projects financed on health in the UK. 2017. http://www.eib.org/projects/loan/list/?from=®ion=§or=5002&to=&country=GB (accessed 3/5/2017.
- 14. Office for Budget Responsibility. Fiscal sustainability report. London: OBR; 2017.
- 15. Paton J. Health Care Faces Funding Strain if Britain Chooses Hard Brexit. 2017. https://www.bloomberg.com/politics/articles/2017-06-05/hard-brexit-seen-adding-to-strain-on-u-k-s-tight-health-budget (accessed 7th June 2017).
- 16. Attaran A, Barry D, Basheer S, et al. How to achieve international action on falsified and substandard medicines. *Bmj* 2012; **345**: e7381.
- 17. Ward A, Barker A. EU exit spurs call for deal on radiotherapy. Financial Times. 2017 23/2/2017.
- 18. European Centre for Disease Prevention and Control. Annual Report of the Director. Stockholm, Sweden: ECDC; 2016.
- 19. Cameron D. EU speech at Bloomberg. 2013. https://www.gov.uk/government/speeches/euspeech-at-bloomberg (accessed 3/5/2017.
- 20. Vaughan A. Almost all London boroughs failed EU air pollution limit for toxic NO2 gas. 2015. https://www.theguardian.com/environment/2015/jul/07/almost-all-london-boroughs-failed-eu-air-pollution-limit-for-toxic-no2-gas (accessed 9th June 2017).

- 21. Lee C-Y, Glantz SA. The tobacco industry's successful efforts to control tobacco policy making in Switzerland. San Francisco: Center for Tobacco Control, Research and Education, Tobacco Control Policy Making: International (University of California); 2001.
- 22. Galsworthy M, McKee M. A plan for U.K. science after the European Union referendum. *Science* 2017; **355**(6320): 31-2.
- 23. European Commission. Statistics Marie Skłodowska-Curie actions research fellowships. 2016: http://ec.europa.eu/research/mariecurieactions/funded-projects/statistics/index_en.htm.
- 24. McKee M. Europe's framework for clinical trials is good news for UK scientists and patients. 2016. https://www.theguardian.com/science/political-science/2016/feb/19/europes-framework-for-clinical-trials-is-good-news-for-uk-scientists-and-patients (accessed 8th May 2017).
- 25. Parliament. Henry VIII clauses. 2017. http://www.parliament.uk/site-information/glossary/henry-viii-clauses/ (accessed 8/6/2017 2017).
- 26. Bowcott O. Brexit may cost MPs and peers the power to pass laws, says former judge. 2017. https://www.theguardian.com/law/2017/may/03/brexit-parliament-oversight-mps-peers-laws-legislation-lord-judge (accessed 7th June 2017).
- 27. The Labour Party. Keir Starmer speech on Labour's approach to Brexit. 2017. http://press.labour.org.uk/post/159971207604/keir-starmer-speech-on-labours-approach-to-brexit (accessed 25 April 2017 2017).
- 28. Department for Exiting the EU. White Paper on Legislating for the UK's withdrawal from the EU (Cm 9446). London: Her Majesty's Stationery Office; 2017.
- 29. McKee M, Stuckler D. Current models of investor state dispute settlement are bad for health. The European Union could offer an alternative. *Int J Health Pol Management* 2017; **6**: 177-9.
- 30. Khan M. Brexit negotiations will be a 'humongous' task warns ex-EU ambassador Rogers. 2017.
- 31. Ungphakorn P. The limits of 'possibility': Splitting the lamb-mutton quota for the UK and EU–27. 2017. https://tradebetablog.wordpress.com/2017/01/06/limits-of-possibility/ (accessed 9th May 2017).