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# Impact on the NHS and health of the UK's trade and cooperation relationship with the EU, and beyond

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(Received 4 May 2021; revised 10 January 2022; accepted 15 February 2022; first published online 28 June 2022)

## Abstract

The UK's relationship with the European Union (EU) is now embodied in two principal legal instruments: the EU–UK Trade and Cooperation Agreement, which formally entered into force on 1 May 2021; and the Withdrawal Agreement, with its Protocol on Ireland/Northern Ireland, which continues to apply. Using a 'building blocks' framework for analysis of national health systems derived from the World Health Organisation, this article examines the likely impacts in the UK of this legal settlement on the National Health Service (NHS), health and social care. Specifically, we determine the extent to which the trade, cooperation and regulatory aspects of those legal measures support positive impacts for the NHS and social care. We show that, as there is clear support for positive health and care outcomes in only one of the 17 NHS 'building blocks', unless mitigating action is taken, the likely outcomes will be detrimental. However, as the legal settlement gives the UK a great deal of regulatory freedom, especially in Great Britain, we argue that it is crucial to track the effects of proposed new health and social care-related policy choices in the months and years ahead.

**Key words:** Health policy; European Union; Brexit; trade

## 1. Introduction

The UK's relationship with the European Union (EU) is now embodied in two principal legal instruments: the Withdrawal Agreement (WA) with its Protocol on Ireland/Northern Ireland, which entered into force on 1 February 2020, and the EU–UK Trade and Cooperation Agreement (TCA) which formally entered into force on 1 May 2021. In addition, the 'Common Travel Area' (CTA), a set of arrangements that has evolved over time allowing largely free movement between the UK, Ireland and the Isle of Man and Channel Islands, profoundly affects the UK's relationship with the Republic of Ireland. These agreements governing the UK's relations with the EU have avoided some of the worst consequences for health and the National Health Service (NHS) (Fahy *et al.*, 2017, 2019, 2020). Although all forms of Brexit are bad for health, some (especially 'No Deal Brexit') would have been worse than others. However, these new arrangements fall far short of the benefits of being an EU member state. With the exception of the citizens' rights provisions in the WA, these instruments are primarily trade agreements. Health occupies a peripheral place in the relevant legal texts. Yet, all trade agreements have important consequences for health (Barlow *et al.*, 2017; Gleeson and Labonte, 2019; Van Schalkwyk *et al.*, 2021). These agreements are no exception.

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This final analysis in our ‘quartet’ concerns the position as of May 2021. This position is far from settled. Brexit is not ‘done’ and we expect the legal and political arrangements between the EU and UK to continue to evolve. At the same time, the UK has entered into some trade agreements with other countries, and is seeking further agreements.

Our focus is on health impacts across the UK. Brexit has important effects for health outside of the UK also, but these have been covered elsewhere (McHale *et al.*, 2020), as well as for the UK’s dependent territories. While in some instances the ‘trade and cooperation’ and regulatory aspects of the UK’s legal settlement with the EU will avoid adverse consequences for health in the UK, in several key areas the TCA either does not support a positive health impact, or actively undermines good outcomes for health. Without further intervention, the consequences for health and the NHS will be detrimental.

The regulatory freedoms associated with the EU–UK relationship post-Brexit mean that the UK now has considerably more space to make domestic legal and policy choices, unrestricted by obligations of EU membership. It is crucial to monitor the effects of such proposed regulatory changes to ensure that their impact is aligned with the best interests of health and the NHS in the four devolved health systems of the UK.

All four devolved health systems share the principle of access to health care free at the point of receipt, and an in-principle commitment to sufficient resourcing, predominantly through taxation, to achieve this goal. All ration health care through gatekeeping structures and, to differing extents, require co-payments from some patients for some health products and services. While much NHS hospital staffing is provided by direct NHS employees, primary care is offered through independent general practitioners.

There are, however, important differences (Doheny, 2015). In England only, there has been a move towards private ownership of NHS entities, and private provision of hospital and mental health services (Buckingham and Dayan, 2019). This pattern is even more pronounced in social care, where private provision dominates (Skills for Care, 2020). The February 2021 White Paper (Department of Health & Social Care, 2021) and NHS Long Term Plan (NHS England, 2019) envisage greater integration of health and care, which is already in place in Northern Ireland, Scotland (Stewart, 2016; Dayan and Edwards, 2017) and Wales (Greer, 2004). The White Paper, which has been broadly welcomed by the health sector (NHS Confederation, 2021), envisages a move away from requiring competitive tendering open to bids from private providers, set to be legally enabled by the removal of current rules under the 2021 Health and Care Bill before Parliament.<sup>1</sup> It also sets out greater direct control over the NHS in England by the Secretary of State, using powers included in the Bill, and pays little attention to public health, both aspects that have attracted criticism. In Northern Ireland, where health and social care come together within five geographically based Trusts, there are a number of all-Ireland initiatives, including cross-border health services and data sharing, many established with support from the EU and facilitated by the 1998 Good Friday Agreement and the Ireland/Northern Ireland Protocol to the WA (Department of Health, 2020).

The health of people in the UK is shaped by many factors beyond the NHS. These include public health measures (Flor *et al.*, 2021), the state of the economy (Banks *et al.*, 2020), availability and use of public spending and the ability to deal with health threats such as infectious disease. The UK’s departure from the EU will have wide-ranging impacts on many of these. Our focus here, however, is on the impacts of the UK’s new relationship with the EU on the health and social care system itself, as embodied in the relevant legal instruments, especially the TCA.

## 2. Method

Using our existing analytical framework (Fahy *et al.*, 2017), developed from the World Health Organisation’s (WHO) health system building blocks, and deploying a standard approach to

<sup>1</sup>Health and Care HC Bill (2021–22) [183].

**THE WHO HEALTH SYSTEM FRAMEWORK**



Figure 1. WHO health system framework.

interpretation of legal texts, we evaluate what the TCA, the WA and the provisions of the CTA mean for the NHS and social care across the UK. We draw on documentary data in the public domain, 23 semi-structured interviews and two online workshops, carried out under two related research projects, from February 2019 to December 2020. Ethical approval was given by the University of Sheffield (Reference 022929) and the University of Oxford (Reference R72072/RE001) (Figure 1).

Taking into account the stated aims of the NHS and social care across the UK, and using the WHO Health System Framework building blocks to structure our analysis, we evaluate the legal measures that now regulate the UK–EU relationship. Specifically, we determine the extent to which trade, cooperation and regulatory aspects of those measures support positive impacts for the NHS and social care. We categorise support according to a three-fold taxonomy: no positive health impacts arising from the trade, cooperation and regulatory aspects of the EU–UK relationships (red); some such impacts (yellow) and strong support for positive impacts (green) (Table 1).

Only if there is clear support from the legal provisions embodying EU–UK relationship can we expect positive outcomes for health. Yet, we find clear support in only one of the 17 building blocks. Consequently, we argue that further domestic action will be necessary to counter what will otherwise be detrimental impacts on the NHS and health in the UK.

As health is largely a devolved power, and applicable provisions differ among the constituent jurisdictions/health systems of the UK, we disaggregate effects in England, Northern Ireland, Scotland and Wales as far as is feasible at present. Certain aspects of the constitutional relationships within the UK are far from settled (Armstrong, 2020), and some are likely to be contested, so it is not possible to be definitive in all cases.

**3. Analysis**

**3.1. Health and social care workforce**

*3.1.1. Recruitment and retention of EU nationals in health and care*

While the WA provides some ongoing rights and protections for people within its scope,<sup>2</sup> and the CTA provisions secure equivalence of treatment for Irish and UK passport holders across

<sup>2</sup>WA, Articles 9–39.

**Table 1.** Impacts of the legal relationship between the UK and EU on health, trade, cooperation and regulation by health system components

Health system components	Building blocks	Current legal position in relationship between UK and EU and its trade, cooperation and regulatory impact	Health impact (in each of the UK NHSs)	TC&R impact supports positive health outcomes?
Workforce	Recruitment and retention of EU nationals in health and care	Settled status for EU nationals under WA Human migration vastly diminished under TCA Increased domestic policy scope <i>at UK level only</i> RoI and UK nationals treated equivalently for residence purposes under CTA	International recruitment not supported Differential impact by profession and sector, possibly geographically Requires monitoring to understand	Red
	Mutual recognition	Recognition ongoing for already qualified/qualifying under WA No mutual recognition under TCA, but potential to restore Increased domestic policy scope	Harder to recruit staff from EU unless mutual recognition restored	Yellow
Financing	Reciprocal health care	Access to cross-border health care continues on almost same basis UK increases control over costs of cross-border health care	More complex to understand and enforce but mainly continuity	Yellow
	Capital financing	No continued participation in EU structural and investment funds or EIB Increased domestic policy scope	Reduced scope for financing of health projects and capital investment	Red
	Indirect impact on NHS financing through public spending	Worse economic impact for the UK than deeper trade agreement	Likely long-term impact on funds available for NHS, but the extent is difficult to disaggregate from other economic decision making, especially COVID recovery plans	Yellow
Medical products, vaccines and technology	Pharmaceuticals, vaccines, medical devices, SOHO			
	For Great Britain	No mutual recognition of regulatory standards, except GMP medicines, in TCA; increased trade friction, so increased costs of supplying GB SOHO: not mentioned explicitly in TCA; still covered by CoE	Depends on policy choices made to attract suppliers to smaller GB market	Red

	For Northern Ireland	Must meet EU regulatory standards, but no EU recognition of NI regulatory processes Consequence of avoiding a 'hard' land border is that NI within scope of EU internal market law but NI regulatory decisions not recognised by EU Result is very small market in NI	Likely in practice to mean reduced access to health-related products given combination of very specific rules (creating higher hurdles) and relatively small market (reducing viability of supply for small volumes) Compounded by complex border rules, which UK has yet to fully implement	Red
	Medical radioisotopes	Covered by EU–UK Nuclear Cooperation Agreement Practical cooperation facilitates ongoing supply	Continued access for UK but outside strategic EU decision-making	Yellow
Information	Comparable data	UK now mainly outside EU structures for generating comparable health data	Impact limited as data sharing within, e.g. WHO and OECD continues	Grey
	Information exchange	No continued UK access to EU clinical trials info system or fitness to practice of health care professionals (particularly important in NI) in TCA	Reduced efficiency due to less information, making relevant areas harder (e.g. cross-border research, monitoring of safety of migrating EU health professionals)	Red
	Data protection	Data protection regimes now separate under TCA. Both propose recognising the other as adequate for now, but this may not continue, and if not then more burdensome contracts for each transfer will be required	Lack of overarching mutual recognition arrangements in the TCA makes cooperation more burdensome	Yellow
Service delivery	Working time and other work-related rules	Non-regression clause in the TCA, but increased domestic policy scope, and unclear what it will mean in practice	Changes to work-related rules permitted under TCA, but immediate impact on health unlikely in practice because of domestic considerations	Yellow
	Cross-border care	Possibility of cross-border services under the TCA, which may be particularly relevant for NI PEACE programmes continue under the WA (relevant for cross-border care coordination between NI and ROI)	Difficult to determine health effects of TCA provisions on services Possibility of alleviating to some extent restrictions on migration of natural persons by making use of TCA service provision	Yellow
	European Reference Networks	No continuation of UK participation in European Reference Networks in TCA	Specific negative impact for patients with rare diseases, where European Reference Networks have facilitated access to highly specialised care	Red

(Continued)

Table 1. (Continued.)

Health system components	Building blocks	Current legal position in relationship between UK and EU and its trade, cooperation and regulatory impact	Health impact (in each of the UK NHSs)	TC&R impact supports positive health outcomes?
Leadership and governance	Public health	TCA shifts public health standards from a requirement to an exception to trade, leaving UK standards to UK domestic policy Limited cooperation on antimicrobial resistance, and non-regression provisions on environmental protection in TCA, but unclear how much protection these provide Product standards in Northern Ireland continue to apply under WA	No obligation to 'mainstream' health so potential for UK to depart from EU public health standards in range of areas UK Internal Market Act in practice means reduced public health regulatory powers for Scotland and Wales	Yellow
	Competition and procurement	Competition and procurement rules now principally a matter for UK domestic policy; some additional commitments beyond WTO procurement rules but not as strong or detailed as EU rules	Creates scope for a different and lighter procurement regime and competition rules for health and care in the UK	Green
	Research	The TCA makes provision for the UK to participate in Horizon Europe	Inclusion in Horizon Europe better for health research than exclusion would have been, but still negative impact from exclusion from other health-related programmes	Yellow
	Scrutiny and stakeholder engagement	No provisions on scrutiny or stakeholder engagement related to these instruments (other than the specific provisions related to regular consent of the NI Assembly to the I/NIP)	Reduction in ability of health stakeholders to influence trade negotiations in comparison with EU process, although how much difference this makes in practice is unclear	Red

Key: Trade, cooperation and regulatory aspect of legal relationship EU–UK supports positive health outcomes: not at all (red); to some extent (yellow); considerably (green) or no change (grey).

the British isles, the TCA makes almost no provision for migration of labour. Coupled with the new British immigration regime, the legal position makes it significantly more difficult to recruit EU nationals into health, social care or biomedical research roles. Given the chronic shortages in certain roles and areas (Rimmer, 2020), this outcome is detrimental for the NHS and social care. Other than for Irish citizens, under the CTA, no free movement of labour pertains between the EU and the UK.

Migration entitlements are now determined by the UK's new immigration system, which generally prioritises salary and qualifications (HM Government, 2021b), with a specific route for qualified health care professionals (HM Government, 2021a). In practice, this means that while it will be straightforward to recruit doctors and nurses at any level, or higher paid roles in biomedical research, albeit with additional fees, it will be almost impossible to recruit lower paid health professionals without specific qualifications, or those needed to fill the vast majority of social care roles. Consequently, the removal of free movement entitlements associated with EU membership is likely to have the most serious impacts on social care, where salary levels are far too low to enable recruitment of staff from other countries, and nursing, which continues to have a high number of vacancies. These factors have been exacerbated by restrictions on migration more generally, because of the COVID-19 pandemic.

Turning to retention of staff already within the NHS, the new 'settled status' provides residence rights under the WA for EU nationals who were already resident in the UK on 31 December 2020, and their families, although these residence rights are not linked to remaining in a specific job.

Longer term, these measures will exacerbate the UK's longstanding inability to train or attract enough staff for its own health and care (Buchan *et al.*, 2014), and make it more difficult and expensive to rely on its long-standing solution of recruiting from abroad. What this means in practice will depend on both the UK's future immigration regime and the UK's future strategy for training, recruiting and retaining staff in the NHS and social care.

Although these detrimental impacts will be felt in the devolved health and care systems, with, for example, particular challenges in recruiting staff for remote areas in Scotland, devolved nations/administrations do not have control over migration policy that determines how completely and cost-effectively they are able to staff their health and care systems, and what balance between 'home-grown' and 'imported' talent to deploy. This responsibility without power arises because the immigration regime is reserved to the government in Westminster, with scant opportunities for devolved input, and because individuals securing a right to work in the UK can move within the UK. It is unclear what the legal settlement here will mean in terms of differential impacts on recruitment and retention of health and care staff in the different parts of the UK.

In this instance, the EU–UK relationship embodied in the TCA does not align with the needs of the health and care systems across the UK. Nor were the EU's and UK's negotiating objectives primarily about increasing trade: the TCA will *reduce* cross-border flows of labour, and increase the scope of domestic policy regulation. The impacts of domestic policy choices made under that increased scope for unilateral action will require careful scrutiny going forward, to ensure that detrimental impacts on the NHS and social care are minimised, both UK-wide and specifically in Northern Ireland, Scotland and Wales.

### 3.1.2. Mutual recognition

The TCA does not secure continuity of mutual recognition of qualifications between the EU and the UK. For those who have UK/EU qualifications recognised by the EU/UK before 31 December 2020, the WA<sup>3</sup> secures continued recognition. The UK has unilaterally decided to recognise EU qualifications on a temporary basis, but once this provision ends, health professionals from the EU whose qualifications are not already recognised will be required to comply with existing procedures on recognition by UK regulators of qualifications from other countries. This is likely to

<sup>3</sup>WA, Articles 27–29.

prove particularly challenging in Northern Ireland, where there is essentially an all-island health and social care workforce, especially in the north of the island.

For doctors in particular, this means longer and more burdensome procedures, rather than a more bespoke assessment as required for a specific post, both of which suggest the new legal regime will make recruitment of NHS staff more difficult. The lack of automatic recognition of UK qualifications in the EU will also make the UK a less attractive place for students and training professionals to work and seek qualifications, as the opportunities for future work are diminished in comparison with pre-Brexit. This also reduces the scope for UK-qualified professionals to move easily to the EU, so detrimental aspects of inward migration may be offset by more bureaucratic requirements for outward migration, although any effect is likely to be small as most migration of health professionals from the UK is to English speaking countries. In addition, the loss of free movement will create barriers for family members hoping to join EU citizens in the UK, especially where partners may seek employment.

The TCA includes the possibility of developing new mechanisms for mutual recognition of professional qualifications, led by the professions involved, which could in theory replicate most of the previous mutual recognition provisions under EU law. This approach is likely to prove particularly useful in Northern Ireland, where professional organisations already moved before the end of the transition period to formalise relationships outside the scope of EU law (Department of Health, 2020). However, proposals for developing new mechanisms under the TCA would have to demonstrate that mutual recognition of qualifications would have a positive *economic* value: improving health alone is not a justification for such a proposal. That said, the links between a strong health system and strong economic outcomes are well-established (Suhrcke *et al.*, 2007; McKee *et al.*, 2009), so demonstrating economic value may not prove much of an impediment. In the area of mutual recognition of health professional qualifications, therefore, the EU and UK negotiating objectives did not align with the needs of the UK's health system, although there is the potential in the TCA to reconstruct similar provisions of mutual recognition.

## 3.2. Financing

### 3.2.1. Reciprocal health care

One of the unusual features of the TCA is its social security coordination provisions,<sup>4</sup> which continue many aspects of reciprocal health care between the EU and UK which were not already covered in the WA (Verschueren, 2021). Coordination of social security is one of the three sources of EU law on reciprocal health care (the other two being the TFEU's provisions on free movement of services, and the Patients' Rights Directive<sup>5</sup>). The TCA's provisions are almost identical to EU law on social security coordination. The TCA<sup>6</sup> secures access to 'sickness benefits' (access to medical treatment in cash or in kind) on the basis of a legal requirement of non-discrimination between UK/EU nationals resident in or visiting the EU/UK. As with the EU provisions, the TCA does not cover 'medical assistance' or 'long term care benefits'<sup>7</sup> (although a 2016 Commission (European Commission, 2016) proposal would extend EU law to cover the latter). The TCA does not cover health care for visitors if the purpose of the travel is to receive health care.

For residents (UK nationals resident in the EU, EU nationals resident in the UK), access to health care continues on the same basis as before. It is residence, not nationality, that determines entitlement to access health care in the host state. For visitors, a form of entitlement similar to those associated with the European Health Insurance Card (EHIC) is preserved, securing access to necessary health care during a visit to the EU/UK.<sup>8</sup> Such necessary health care may be for pre-

<sup>4</sup>TCA, Articles 488–491, and the Protocol on Social Security Coordination.

<sup>5</sup>Directive 2011/24/EU, OJ L 88/45.

<sup>6</sup>TCA, Protocol on Social Security Coordination, Articles SSC.15–SSC.30.

<sup>7</sup>TCA, Article SSC.3 (4) (b) and (d).

<sup>8</sup>TCA, Articles SSC.16 and 17.



existing or chronic conditions, which extends entitlements beyond the access to emergency treatment that is offered by EU countries (and the UK) to anyone present who needs it, under their domestic rules. However, unlike in EU law, under the TCA, ‘vital medical treatment only accessible through a specialised medical unit’ (e.g. kidney dialysis; or oxygen therapy) requires prior authorisation.<sup>9</sup> It is currently unclear what UK rules will be on such authorisation, and is likely to remain so until COVID-related travel restrictions ease.

The TCA envisages that health care costs will be reimbursed by whichever state is ‘competent’ (usually the country in which the patient is ordinarily resident, but with specific rules for frontier workers and others in cross-border or complex situations). Reimbursement will be either on the basis of fixed amounts or waiver arrangements (e.g. patients moving between the UK and Ireland; patients moving between the UK and France for administrative costs but not for costs of medical treatment itself).<sup>10</sup> For residents of Northern Ireland and the Republic of Ireland, the CTA arrangements continue to apply: Irish or British citizens who live in, work in or visit the other state have the right to access health care there, on the same basis as citizens resident in that state (Ryan, 2001; Wilkins *et al.*, 2019). Ireland will also treat residents of Northern Ireland in the same way as its own residents in several ways, including extending coverage by the EHIC. This intention is underlined in a May 2019 Memorandum of Understanding (HM Government and Ireland, 2019) between the UK and Irish governments. It is, however, unclear whether the source of the rules securing access to health care for UK/Irish citizens in each other’s health systems is domestic law, or the TCA – the Irish government refers to the TCA in its advice to citizens (Department of Health, 2021), the UK does not. There has been criticism of the opacity and the insecurity of the legal position, with the CTA MoU described as ‘written in sand’ (Murray, 2019).

Mechanisms for enforcement of TCA rights to access cross-border health care are extremely weak (Hervey, 2020), unlike in EU law, and unlike the WA which has special enforcement measures for its citizens’ rights provisions (Smismans, 2018; Hervey *et al.*, 2020; Peers, 2020), which have been adopted into UK law by the EU.<sup>11</sup> From the point of view of individual patients, remedies for breaches of the TCA are in domestic law only.

In this instance, there is some alignment between the trade and cooperation impact of the TCA and its health impacts. The TCA retains facilitation of free movement pertaining to access to many, though not all, cross-border health care entitlements, although with much weaker enforcement opportunities. The TCA reduces potential obligations on the UK to pay for patients seeking care abroad on their own initiative.

### 3.2.2. Capital financing

As a relatively well-off country within the EU, the UK was not a main beneficiary of investment from EU structural and investment funds, though some significant projects were funded. These now risk substantial cuts as the replacement funds from the UK government may be less generous. One estimate suggests that Cornwall might receive only 5% of what it previously got from the EU (BBC, 2020). Even though health is not a specific objective of the structural and investment funds, there was still quite extensive use of these funds for health-related projects, from local projects addressing mental health and wellbeing in deprived areas (Ministry of Housing, Communities & Local Government *et al.*, n.d.) to supporting the development and translation of research into practice through networks such as the Academic Health Science Networks (NHS Confederation, 2018).

The UK has also left the European Investment Bank which has played an important role in providing low-cost long-term funding for health infrastructure investment amounting to over

<sup>9</sup>TCA, Article SSC.17, Appendix SSCI-2.

<sup>10</sup>TCA, Appendix SSCI-1.

<sup>11</sup>Withdrawal Agreement Act 2020, Section 5 (1).

€3.6 Bn (European Investment Bank, [n.d.](#)). This funding became particularly valuable in public-private partnerships used to fund health infrastructure such as new hospitals, for instance, the Royal Hospital for Sick Children in Edinburgh, though it was also used for other investments, such as to develop integrated primary care facilities in deprived urban areas.

This was another area where the UK's priority in negotiating the TCA was to increase the scope for divergence of domestic policy, rather than increasing trade or cooperation. The impact on health and care will depend on what domestic provision is made for infrastructure funding for health and care, either directly or by providing similar infrastructure lending. The planned UK Infrastructure Bank does include financing for health projects within its scope, although health and care are not identified as priority topics (HM Treasury, [2021](#)).

### 3.2.3. Indirect impact on NHS financing

Potentially the largest long-term impact of Brexit on health and care in the UK is its impact on the UK economy, and thus its ability to fund public services, though estimating this impact is difficult. The Office for Budget Responsibility (OBR) has evaluated the TCA, and maintained their preliminary evaluation that the agreement will reduce long-term growth of the UK by around 4%, with this taking around 15 years to be realised (Office for Budget Responsibility, [2021](#)).

The OBR has consistently found that the loss of revenue due to lower migration and economic growth will considerably outweigh the UK's net savings from no longer contributing to EU budgets. This means that Government budgeting now assumes leaving the EU means less available funding for the NHS and other public services, rather than more as was asserted during the Referendum campaign. There is evidence that periods of worse economic growth in the UK are also directly associated with more people suffering from chronic conditions (Janke *et al.*, [2020](#)).

Increased UK government expenditure related to COVID-19 may also create political pressure to restrain spending, despite a growing international consensus that global growth will recover much more rapidly than after the financial crisis (International Monetary Fund, [2021](#)). While these factors involve wider impacts beyond health, there are also additional health-specific pressures from the increased health demand that has built up during the COVID-19 pandemic, and potentially permanently elevated expenditure related to vaccination, if regular vaccination is required, for example. The combination of these factors is likely to mean sustained long-term pressures on health and care financing in the UK, though the difficulty of forecasting is compounded by the disruption caused by the COVID-19 pandemic.

## 3.3. Medical products and substances of human origin

### 3.3.1. Pharmaceuticals, medical devices and medical equipment

From 1 January 2021, the UK is no longer beneficiary of, or subject to the rules of, the EU's internal market for goods. The general rules on products moving from the UK to the EU are governed by the EU's external trade law, and products seeking access to that market must comply with EU customs duties, formalities and regulatory requirements needed to secure EU market access. The EU's common customs code (European Parliament and Council, [2013](#)) provides that most medicines are subject to relief from import duties. Since April 2020, that relief has been extended to devices and equipment necessary to combat COVID-19.<sup>12</sup> The EU was able to impose export controls on COVID-19 vaccines, including exports to the UK as a non-Member State, in March 2021, as part of its external trade law, so as to prevent or remedy a critical situation from arising on account of a shortage of essential products.<sup>13</sup>

<sup>12</sup>Commission Decision (EU) 2020/491 OJ L 103I/1; extended to April 2021 by Commission Decision (EU) 2020/1573 OJ L 359/8 and to December 2021 by Commission Decision (EU) 2021/660 OJ L 140/1.

<sup>13</sup>Regulation (EU) 2015/479 OJ L 83/1, Article 5; Commission Implementing Regulation (EU) 2021/521 OJ L 104/1.

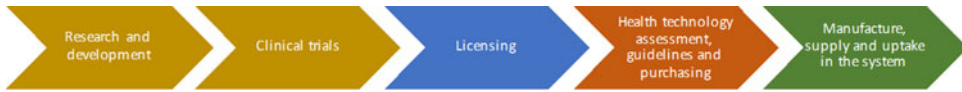


Figure 2. Regulatory life cycle for health-related products. Authors' own.

Relevant formalities for access to the EU's single market include most stages of the 'regulatory life cycle' of health-related products (Figure 2).

Likewise, products moving from the EU into the UK are generally subject only to UK trade law and trade agreements to which the UK is a party<sup>14</sup> and to UK regulatory standards. Medicines imported into the UK are subject to relief from customs duties (HM Revenue and Customs, 2018) and, since March 2020, customs relief applies to protective equipment, other relevant medical devices or equipment for the COVID-19 pandemic, as set out in the COVID-19 Commodity Code list (HM Revenue and Customs, 2020).

As a default, relevant regulatory standards applicable in the UK were those of EU law on 1 January 2021, as 'retained EU law'.<sup>15</sup> However, the EU (Withdrawal) Act gives significant ministerial power to amend retained EU law to remedy 'deficiencies'.<sup>16</sup> This regulatory freedom for product standards is the case for medicines (a category which includes vaccines), medical devices and equipment, as much as for other products. The UK has subsequently enacted a new Medicines and Medical Devices Act 2021, which gives Government ministers considerable latitude to change almost all aspects of regulation in this area through secondary legislation. In the short term, however, the UK will continue to recognise certification by qualified persons in the EU of batches of medicines for release to the market, and will give a 2-year notice period before making changes (Medicines and Healthcare Products Regulatory Agency, 2021c).

There is one exception to the UK's regulatory freedom here in the TCA. 'Good manufacturing practice' (GMP) for 'medicinal products', defined by reference to marketing, must be mutually recognised.<sup>17</sup> The definition is similar to the definition of medicinal products in EU law, but somewhat narrower as it appears to exclude, for instance, products marketed as foodstuffs (Dayan *et al.*, 2021). GMP is the stage of medicines regulation involving assurances that the production of medicinal products is safe, consistent and in line with what has been approved for sale. GMP is based on inspection by regulators, at a frequency determined by risk and when new products are being approved. In general, but with some possible exceptions, such as the power to suspend recognition,<sup>18</sup> EU and UK bodies will accept results of inspections carried out by those of the other party, and the certifications of compliance produced following that result. Contrary to the wishes of the pharmaceutical industry, which lobbied for the TCA to secure mutual recognition of a wider list of regulatory practices, including qualified persons, batch release and testing, these provisions eliminate just *one* non-tariff barrier to trade with the EU in medicines, by not requiring two sets of inspections. The costs of inspections are passed on to producers, and then to purchasers, so there will be a small direct financial benefit to the UK's NHSs, in addition to greater ease of trading.

However, this small element of mutual recognition is unlikely to counterbalance the potentially significant detrimental effects on the NHS flowing from costs associated with increased trade friction at every other stage of medicines, medical devices and equipment regulation. These (Figure 2) include: clinical trial requirements, the marketing authorisation of medicines; the assessment of medical devices as conforming to standards; the recognition of prescriptions;

<sup>14</sup>See Trade Act 2021.

<sup>15</sup>European Union (Withdrawal) Act 2018, Sections 2, 3, 7.

<sup>16</sup>European Union (Withdrawal) Act 2018, Section 8.

<sup>17</sup>TCA, Appendix 12-C.

<sup>18</sup>TCA, Appendix 12, Article 9.

the testing of batches of medicines to ensure they are fit for release; the tracing of medication within the EU to safeguard against falsified medicines and a wide array of requirements relating to customs, transport and border checks.

All of these processes would otherwise mostly be done once for the whole European Economic Area (EEA), and will now have to be done separately for UK and EEA markets. Research based on the experience of other free trade agreements, which would typically have this fairly low level of alignment for medicinal products, estimates this to drive a cost increase of over 5% for pharmaceuticals in the UK (Gasiorek, Serwicka, and Smith, 2018). The NHS may be able to avoid this by using cost control initiatives such as the ‘voluntary scheme’, but this would risk intensifying another probable dynamic whereby companies react to barriers by being less likely to introduce products to the UK market at all because to do so is not economically viable (Department of Health and Social Care, 2018).

Regulation of pharmaceuticals, medical devices and equipment represents another example where the TCA does not enable trade or cooperation, but prioritises the ability to diverge from the EU in domestic law and policy. This will be one of the areas where the UK faces important strategic choices about how to use its increased policy scope, which will affect the impact on health. Typically, smaller markets (meaning in practice, not the EU or the USA) see reduced access (meaning fewer products or later availability, or both). There may be potential for the UK to exercise domestic policy discretion to create a regulatory or purchasing regime that can offset this, but this is highly uncertain and may have wider impacts (e.g. speeding up adoption of innovative medicines would have cost implications for the NHS).

In the short term, the UK’s policy is to continue recognising EU regulatory processes (Medicines and Healthcare Products Regulatory Agency, 2020, 2021c) for nearly all the areas listed above for 2-3 years (Medicines and Healthcare Products Regulatory Agency, 2021a). This minimises added cost to industry and the NHS, but at the cost of removing regulatory autonomy for the UK and incentivising firms to focus compliance and research activities in the EU. Many UK-based pharmaceutical companies, including, for example, AstraZeneca (Elvidge, 2018), moved compliance processes to the EU when it became clear the UK was not seeking access to the single market (Neville, 2018) in its post-Brexit relationship with the EU.

There is one crucial exception to the points made above. The WA’s Protocol on Ireland/Northern Ireland imposes a fundamental limitation on possible regulatory divergence and imposition of customs duties, applicable to *Northern Ireland only*. Products imported from Great Britain into Northern Ireland, which are not at risk of being moved from Northern Ireland into the EU (either as they stand or after commercial processing, which means any alteration of the product, other than affixing a mark, label or seal), are not subject to customs duties.<sup>19</sup> But there is a presumption that goods brought into Northern Ireland from anywhere outside the EU (which of course includes from Great Britain) are at risk of being moved into the EU.<sup>20</sup> That presumption can be rebutted if it is shown that the product will not be subject to commercial processing in Northern Ireland, so long as it fulfils criteria set out by the Joint Committee, established by the WA.<sup>21</sup> According to a December 2020 Decision of the Joint Committee established under the WA, products not at risk of being moved into the EU include where processing is deemed ‘non-commercial’ because it takes place in Northern Ireland and is for the sole purpose of ‘direct provision to the recipient of health or care services by the importer in Northern Ireland’,<sup>22</sup> and (for goods imported from Great Britain) the customs duty payable under the EU’s common customs tariff is zero<sup>23</sup>; or (for goods imported from outside the EU

<sup>19</sup>Ireland/Northern Ireland Protocol, Article 5 (1).

<sup>20</sup>Ireland/Northern Ireland Protocol, Article 5 (2).

<sup>21</sup>Ireland/Northern Ireland Protocol, Article 5 (2) (a) and (b).

<sup>22</sup>Joint Committee, Decision 4/2020, Article 2 (b) (iii).

<sup>23</sup>Joint Committee, Decision 4/2020, Article 3 (1) (a) (i).

and GB) the EU customs duty is the same as or less than the UK's customs duty.<sup>24</sup> In the alternative, customs duties are not payable where the importer has been authorised, under terms set out in the Decision of the Joint Committee, to bring the product into Northern Ireland for its sale to, or final use by, end-consumers located in Northern Ireland.<sup>25</sup>

This means that, as things currently stand, no duties are payable on medicines or zero-rated devices/equipment brought into Northern Ireland and then altered, for example, repackaged in Northern Ireland, so long as these products are imported for 'direct provision to the recipient of health or care services by the importer in Northern Ireland'. This wording seems curious, as, with the exception of the small proportion of direct-to-consumer sales of medicines and devices, it is the Northern Irish Health Trusts which purchase goods used to provide health and care services for patients in Northern Ireland, not the patients themselves directly. Presumably, the intention is to secure continued supply into Northern Ireland of zero-rated health products, to avoid the increased cost of customs duties and associated regulatory burdens arising from paperwork falling on the Northern Irish NHS.

In terms of regulatory divergence, EU law regulating products in the internal market applies 'to and in the United Kingdom in respect of Northern Ireland'.<sup>26</sup> The EU law to which the Protocol refers includes almost all EU law regulating medicines and medical devices, as well as substances of human origin.<sup>27</sup> However, in principle, Northern Ireland is *not* counted as an EU Member State for the purpose of application of rules on mutual recognition of technical regulations, assessments, certificates, approvals or authorisations. So, although the geographical scope of EU law includes Northern Ireland, UK authorisations are not valid authorisations under the terms of the Ireland/Northern Ireland Protocol. This is the case *unless* the regulatory assessment is compliant with EU law,<sup>28</sup> in which case any conformity marking from a UK-based notified body must include 'UK(NI)'. UK(NI) marking is placed alongside CE marking. But such products, with both CE and UK(NI) marks, do not meet the regulatory requirements for the EU market.

The overall purpose of these provisions from the EU's point of view is so that the EU can treat the land border on the island of Ireland as a 'soft' border, like the borders within the EEA (Harvey, 2020; Weatherill, 2020). But the logical consequence is, the more British regulatory standards diverge from EU standards, the greater need for imposition of a 'hard' border between Great Britain and Northern Ireland (Weatherill, 2020; Hayward, 2021). The UK's Internal Market Act 2020 contradicts this logical consequence by seeking to secure a single regulatory space across the UK. Thus, the meaning and implications of the Protocol are disputed, especially in terms of implementation if the Joint Committee does not agree (Peers, 2020).

For medicines and medical devices/equipment, the Protocol requires that medicines placed on the market in Northern Ireland must meet all the regulatory requirements of EU law,<sup>29</sup> including having marketing authorisation for the EU or for Northern Ireland, held by an entity located either in the EU or Northern Ireland. Furthermore, any of the regulatory steps in medicines or medical devices/equipment supply which EU law requires to be carried out in the EU (e.g. testing for batch release) must be carried out either in the EU or Northern Ireland.

In the short term, taking into account the COVID-19 pandemic, both the UK and EU have adopted approaches that do not fully comply with the Ireland/Northern Ireland Protocol. The EU and UK made unilateral declarations in the Joint Committee in December 2020<sup>30</sup> to the effect

<sup>24</sup>Joint Committee, Decision 4/2020, Article 3 (1) (b) (i).

<sup>25</sup>Joint Committee, Decision 4/2020, Article 3 (1) (a) and (b) (ii).

<sup>26</sup>Ireland/Northern Ireland Protocol, Article 5 (4).

<sup>27</sup>Ireland/Northern Ireland Protocol, Annex 2, points 20, 21, 22.

<sup>28</sup>Ireland/Northern Ireland Protocol, Article 7 (3).

<sup>29</sup>Ireland/Northern Ireland Protocol, Article 5 (4) and Annex 2.

<sup>30</sup>Unilateral declarations by the European Union and the United Kingdom of Great Britain and Northern Ireland in the Withdrawal Agreement Joint Committee on human and veterinary medicines, 17th December 2020; MHRA. 2020. Supplying authorised medicines to Northern Ireland. Guidance, 31st December; Commission Notice 2021/C 27/08 OJ C 27.

that rules applicable to *medicines* under the Protocol will not apply until 1 January 2022. However, for *medical devices and equipment*, new rules apply to reflect that moving products from Great Britain to Northern Ireland constitutes an import in EU law, with all that follows for conformity marking (Medicines and Healthcare Products Regulatory Agency, 2021b). Furthermore, the new EU Regulation on medical devices,<sup>31</sup> implementation of which was delayed because of the pandemic,<sup>32</sup> will apply in Northern Ireland from May 2021.

To summarise, in terms of regulation, Great Britain is outside the EU and its single market, but Northern Ireland is only partially so. The effect of these rules is to create a small market, in terms of regulatory standards, in Northern Ireland, *unless* the UK chooses not to diverge from EU standards in Great Britain. The size of the Northern Ireland market, and the specificity of its rules, is likely to compound wider issues of access to medicines and devices/equipment for the UK, outside of the EU. The fact that it is now aligned to the EU and not aligned to Great Britain was a source of concern around disruption to pharmaceutical industry officials we spoke to, because 80% of medicines in Northern Ireland are currently supplied from elsewhere in the UK. In the medium term, without further intervention, this is likely to lead to later supply of new health technologies to Northern Ireland from Great Britain, and from the EU, and may lead to some entities ceasing to supply Northern Ireland at all.

### 3.3.2. Substances of human origin

Although they are covered by the WA, in the Ireland/Northern Ireland Protocol,<sup>33</sup> the TCA does not explicitly mention substances of human origin (blood, plasma, human tissue, cells or organs), so these are not part of the agreement between the EU and UK. However, the Council of Europe has long provided a reference point for regulation in this area (Roscam-Abbing, 2002; Pattinson, 2008), so any future divergence is likely to have limited impact in practice.

### 3.3.3. Medical radioisotopes

Medical radioisotopes fall outside the scope of the TCA, but are instead covered in the specific EU–UK Nuclear Cooperation Agreement (NCA),<sup>34</sup> which sets up a framework for cooperation on peaceful uses of nuclear energy. The Joint Committee established under that Agreement is explicitly tasked with ‘coordinating action for cooperation in non-power uses of nuclear energy, in particular, in order to minimise the risks of shortage of supply of medical radioisotopes, and to support the development of novel technologies and treatments involving radioisotopes, in the interest of public health’.<sup>35</sup> Much of the NCA is facilitative only (the Parties ‘may’ cooperate in various ways), but there is an obligation to ‘facilitate trade’,<sup>36</sup> and an obligation to set up administrative arrangements.<sup>37</sup> The NCA thus secures continued access, so no short-term problems of the type that would have been associated with a ‘no-deal Brexit’ are envisaged.

Longer term, the UK remains dependent on supply from the EU, which itself has a fragile supply of medical radioisotopes (Barańczyk *et al.*, 2015; McKee, 2017). The NCA does not involve the UK continuing to participate in the EU’s cooperation structures. As far as we are aware, there is no provision in the relevant EU legal framework for a third country to be part of the European Observatory on the Supply of Medical Radioisotopes. The Statutes of the Euratom Supply Agency,<sup>38</sup> within which the Observatory appears to sit, certainly make no such provision. The UK thus will not be involved in the EU’s long-term strategy for medical radioisotope supply

<sup>31</sup>Regulation (EU) 2017/745, OJ L 117.

<sup>32</sup>Regulation (EU) 2020/561, OJ L 130.

<sup>33</sup>Ireland/Northern Ireland Protocol, Annex 2, 23.

<sup>34</sup>UK-EURATOM Nuclear Cooperation Agreement, OJ L 445, 31.12.2020.

<sup>35</sup>UK-EURATOM Nuclear Cooperation Agreement, Article 19.

<sup>36</sup>UK-EURATOM Nuclear Cooperation Agreement, Article 9.

<sup>37</sup>UK-EURATOM Nuclear Cooperation Agreement, Articles 15 and 16.

<sup>38</sup>Council Decision 2008/114/EC, OJ L 41/15.

and therefore should consider how it can ensure a resilient supply if a detrimental impact on the NHS is to be avoided.

### 3.4. Information

#### 3.4.1. Comparable data

The UK is now largely outside the EU's structures for collecting comparable data, though continued participation in research projects may enable some ongoing comparable data to be generated (e.g. disease registries). There is scope through the TCA<sup>39</sup> for the UK to be involved in temporary cooperation on cross-border threats to health such as the COVID-19 pandemic, and this may lead to some limited cooperation with the European Centre for Disease Prevention and Control (ECDC) on infectious disease surveillance. For now, it is notable that the maps published by ECDC on the progress of the pandemic exclude the UK.

Measures to ensure comparable data are not generally a trade objective, except for trade in services which rely on comparable data. In the health context, data sharing tends to be between public entities, not on a trade or contractual basis, and so the impacts of the TCA are limited. A lack of comparable data will make it harder to benchmark performance of the NHS against that of other health systems, and this in turn may undermine long-term performance. However, any impact is likely to be limited, as the UK is still part of other relevant structures for comparable data (e.g. the WHO and OECD), and comparable data on health maintained by the EU is in any case very limited.

#### 3.4.2. Information exchange

Many of the regulatory structures of the EU are underpinned by information-sharing systems, and the UK's departure from the scope of the regulations also means leaving that flow of information. We highlight two that are particularly relevant for health. One is the Clinical Trials Information System (CTIS), which is being established in order to provide a single transparent overview of clinical trials for the EU.<sup>40</sup> Third country access to CTIS is very limited: the EMA's website notes that the overarching purpose of the CTIS is to provide for '[i]mproved collaboration, information-sharing and decision-making *between and within Member States*' (European Medicines Agency, 2018; emphasis added). Thus, access to the secure part of the database is predicated on EU membership. Under EU law, there is no full or partial access to the CTIS for any entity incorporated or established in a non-EEA country. Rather, access is on a trial-by-trial basis. Lack of access except on this basis will have a negative impact on UK involvement in health research (House of Lords European Union Committee, 2021, paragraph 270; Cancer Research UK 2021), though this may be mitigated by direct links between researchers.

Similarly, the lack of access to data on the fitness to practice of health professionals may be mitigated somewhat by information exchange via professional bodies (which may also cover countries beyond the EU, if it is successful). In both these instances, the effects of the TCA are greater inefficiency due to less knowledge in the UK about what is taking place in the EU. It will be more difficult for biomedical researchers to collaborate with EU partners, and there is a potential for an impact on patient safety if data sharing is inadequate to secure robust risk assessments and decision-making. The trade effects of this aspect of the TCA do not support positive health impacts, a point that has been repeatedly stressed by the biomedical research sector.

#### 3.4.3. Data protection

The EU–UK TCA includes a general 'right to regulate' digital trade clause,<sup>41</sup> for public interest reasons including public health protection, safety, privacy and data protection, which covers

<sup>39</sup>TCA, Article 702.

<sup>40</sup>Council Regulation (EU) 536/2014, OJ L 158/1.

<sup>41</sup>TCA, Article 198.

current and future regulation.<sup>42</sup> So the EU and the UK data protection regimes are now formally separate. The goal here for increased domestic policy scope runs counter to a trade goal, which would secure mutual recognition of data protection to support trade flows. The EU–UK TCA does include general, but quite vague, commitments to ensure cross-border data flows, as well as not creating restrictions through technical requirements,<sup>43</sup> but these fall very far short of membership of the EU’s single market.

In the case of data flow from the UK to the EU, the UK has amended its data protection law in effect to recognise the EU’s data protection regulation as consistent with UK law.<sup>44</sup>

The key concern associated with a ‘No Deal’ Brexit – the costly and burdensome personal data protection measures that would have been necessitated for data to move lawfully from the EU to the UK from 1 January 2021 – has been temporarily alleviated (though not removed) by the TCA, which provides that transmission of personal data from the EU to the UK ‘shall not be considered as a transfer to a third country under Union law’, for a period of 4 months, extendable by 2 months, from the date of entry into force of the TCA.<sup>45</sup> ‘Entry into force’ here means formal entry into force, which took place on 1 May 2021.<sup>46</sup> While the UK completed its formal requirements with the adoption of the European Union (Future Relationship) Act 2020, the EU’s requirements,<sup>47</sup> required the consent of the European Parliament, which was not forthcoming until late April 2021 (European Parliament, 2021). In the meantime, however, the European Commission proposed on 19 February 2021 that the UK’s data protection regime be deemed adequate, and this proposal will be considered in committee under the provisions of the EU’s General Data Protection Regulation 2016/679/EU, Article 45 (3) (European Commission, 2021). Personal data transfer from Iceland, Liechtenstein and Norway is also covered so long as those states expressly notify the EU and UK in writing of their acceptance. The grace period under the TCA (or *de facto* extension of the transition period) applies only as long as the UK does not amend its data protection law as it stands on 31 December 2020.<sup>48</sup> If the UK does so without the agreement of the EU secured through the Partnership Council, the grace period immediately comes to an end.

In that event, or if the European Commission (on behalf of the EU) ceases to recognise the UK as ‘adequate’ for data protection regulation in the future, alternative (and costly) measures would have to be put in place for data to be shared within the context of bio-medical or other health research projects that involve partners in the UK and one or more EU Member States (Phillips and Hervey, 2021). Over time, this distance of the UK from the EU’s data protection law and policy in general, and slowly emerging cooperation in the EU on health data more specifically (Elliott, 2013; Bogaert *et al.*, 2018), may have a chilling effect on bio-medical research in the UK. Any actions that the UK might take to position itself as a more favourable place for such research, of course, also run the risk of distancing the UK from the EU’s approach so far that the UK’s approach to data protection is no longer regarded as adequate. Some of the UK’s trade ambitions may already pose this risk: for instance, the UK is bidding to join the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), where signatories commit to less stringent data protection standards – and where both states and individual investors may challenge the UK’s approach. The UK is unlikely to secure an exception on data for itself as a newly acceding state, and would also compromise its position with the EU (Morita-Jaeger, 2021).

<sup>42</sup>TCA, Article 199.

<sup>43</sup>TCA, Article 201.

<sup>44</sup>Data Protection, Privacy and Electronic Communication (Amendments etc.) (EU Exit) Regulations 2019.

<sup>45</sup>TCA, Article 782.

<sup>46</sup>TCA, Article 783.

<sup>47</sup>TFEU, Article 217, in conjunction with TFEU Articles 218(6), 218(7) and the second subparagraph of Article 218 (8).

<sup>48</sup>TCA, Article 782.



### 3.5. Service delivery

#### 3.5.1. Working time legislation

EU legislation on working time became highly symbolic during the discussions that led to Brexit. Indeed, the European legislation on the working hours of doctors was the only specific example of legislative overreach cited by David Cameron in his speech in 2013 that led ultimately to Brexit (Cameron, 2013). In that context, it is perhaps surprising that the TCA's 'non regression clause' apparently constrains the degree of regulatory freedom regarding this and other employment-related law.<sup>49</sup> However, the non-regression rules on labour standards in the TCA give scant protection to individuals, relying only on domestic law for enforcement, and it is unclear what they mean in practice for the UK or the EU as parties to the Agreement (House of Commons Committee on the Future Relationship with the European Union, 2021).

As non-regression obligations apply only where the law or policy change affects trade or investment between the UK and the EU, those concerning the health workforce are likely to fall outside their provisions. So, for example, while a general change to working time rules across all economic sectors would at least arguably 'affect trade and investment' between the UK and the EU, if a change to working time applied only, for instance, to doctors working within the NHS, it may well be argued to not have an impact on trade and investment.

The impact on health and care is thus hard to evaluate, but overall, the provisions of the TCA are unlikely to prevent changes in rules on working time legislation, with domestic constraints (in particular the junior doctors' contract) likely to be a more relevant consideration (Fahy *et al.*, 2017). Of course, in the light of recruitment difficulties at all levels of health and care and the challenges to workforce recruitment and retention described above, the UK could seek to improve terms and conditions for health and social care employment. However, this would lead to increased costs, which would conflict with the financing constraints also described above. In the alternative, perhaps lower labour standards in UK health care contexts, leading to lower costs to providers, could drive investment in attracting private patients to the UK, rather than the EU.

Given these uncertainties, it is very difficult to determine the impacts of the TCA on NHS and social care staffing recruitment and retention.

#### 3.5.2. Cross-border health and care services

The services provisions of the TCA<sup>50</sup> apparently cover all four GATS modes of cross-border service supply. They would thus, in principle, apply where the service itself, but neither the provider nor the recipient moves (mode 1), for example where a patient in one state accesses, through telecommunications or postal infrastructure, medical treatment from a health professional established in another state; or a health institution such as a hospital in one state secures the services of a health professional established in another state through such communications. However, the TCA provisions are not organised in that way, nor does the TCA use the GATS wording, and therefore the exact correspondence between the instruments is unclear. Instead cross-border trade in services is defined as the supply of a service '(i) from the territory of a Party into the territory of another Party; or in the territory of a Party to the service consumer of the other Party'.<sup>51</sup>

Assuming that the TCA applies, it is worth considering the extent to which it supports mode 1 health service provision between the UK and EU. Examples of this include health services like diagnostic imaging functions, or laboratory functions, or even doctors sending notes to be typed up by someone in another country. So, for example, an image is taken in a UK hospital, which is sent electronically to a radiologist in Spain. The Spanish radiologist reads it, and

<sup>49</sup>TCA, Article 387 (2).

<sup>50</sup>TCA, Articles 123–126 and 134–158.

<sup>51</sup>TCA, Article 124 (e).

sends her interpretation/analysis/results electronically to the medical professionals in the UK hospital (Saliba *et al.*, 2012). When the UK was an EU Member State, this type of cross-border service provision was covered by the E-Commerce Directive.<sup>52</sup> For cross-border health service provision, the Patients' Rights Directive<sup>53</sup> also applies. These provisions are, at least for now (Department of Digital, Culture, Media and Sport and Home Department 2020), 'retained EU law' to the extent that they apply within the UK, but obviously the cross-border trade aspects of them are not covered by internal UK law.

There is nothing explicit in the main TCA text which excludes its application to this kind of cross-border service provision in health contexts. There is an exclusion for services supplied 'in the exercise of governmental authority'.<sup>54</sup> Services so supplied are 'supplied neither on a commercial basis nor in competition with one or more service suppliers'. How this to be understood is not always clear (Leroux, 2006), but in any event, would not be the case for the Spanish radiography services in this example, because the contract for this service has been agreed in a situation where the Spanish radiography provision has been chosen from several tenders, in competition with each other. As this illustrates, the predominantly public character of the NHS domestically does not exclude the application of trade rules in the case of cross-border care, especially as they are typically provided on a market basis.

There are a number of reservations to the services provisions applicable to health contexts. The UK's reservations include a right to regulate the provision of all established or cross-border health services. This reservation would permit the UK to insist on UK regulatory standards, including qualifications rules, for providers of cross-border health services, including the Spanish radiology service provider in this example. However, if the UK did not do so, then the Spanish regulatory standards, including qualifications rules, would continue to apply as is usual in 'mode 1' service provision (sometimes called 'home state control'). Of course, both sets of regulatory standards might apply, in which case, even if the standards were compatible with one another, there would be the additional costs associated with a dual regulatory burden. These matters will become more important if the UK departs from the EU's regulatory standards for health services workforce in the future.

The TCA services provisions may become important in the context of health and social care in Northern Ireland, as they may offer a way for health and care professionals established in Ireland, but not holding UK or Irish passports, and thus falling outside the protections of the CTA, to continue to offer services across the border, without meeting the UK's new migration requirements or professional standards. However, the lack of an explicit legal framework leaves uncertainty about associated questions such as oversight, liability or applicable standards, which would presumably have to be addressed contractually.

### 3.5.3. European Reference Networks

Although there is continued cooperation on cross-border care overall, there is no continued cooperation through European Reference Networks, which link together centres across Europe for certain highly specialised treatments or rare diseases. Although they have provided a mechanism for improving both understanding and treatment of such conditions, they are not funded through the research programme in which the UK is participating, but rather under the health programme, and are thus not included in the TCA.

Given the highly specialised nature of these networks, their removal only affects a small number of people. However, for those patients in the UK, the loss of access to this highly specialised expertise may be devastating (Tumiene *et al.*, 2021).

<sup>52</sup>Directive 2000/31/EU OJ L 178/1.

<sup>53</sup>Directive 2011/24/EU OJ L 88/45.

<sup>54</sup>TCA, Article 124 (o), (p) and (a).

### 3.6. Leadership and governance

#### 3.6.1. Global public health standards

The TCA includes only very limited references to global public health standards. There is a weak commitment to ‘dialogue and cooperation’ on antimicrobial resistance.<sup>55</sup> There is an intention to cooperate, including optionally through exchange of information using the European Early Warning Response System, on ‘health security’.<sup>56</sup> Like the labour and social standards ‘non regression’ rules, there is a commitment to maintain ‘environmental levels of protection’, defined as national rules ‘which have the purpose of protecting the environment, including the prevention of danger to human life or health from environmental impacts’.<sup>57</sup> Again, it is unclear what these rules will mean in practice (House of Lords European Union Committee, 2021).

In general, the TCA’s provisions on global public health standards illustrate the (lack of) ambition for this agreement. Health protection, rather than being an embedded aspect of the market between the parties<sup>58</sup> and an objective to be pursued in its own right, is conceptualised as a potential obstacle to trade. As such, public health standards in a range of areas are permitted as *exceptions* to the implied benefits of the free trade consequent upon the TCA. The UK is no longer tied into EU standards, which increases domestic policy scope for regulation, and so impacts on health will depend on how those powers are deployed.

To understand how these powers might be deployed, the government’s February 2021 White Paper offers very limited insight. The White Paper states that ‘the government will publish in due course an update on proposals for the future design of the public health system, which will create strong foundations for the whole system to function at its best’ (Department of Health & Social Care, 2021: 12). These proposals have the potential to be ambitious, given how they build on the momentum gained through a range of public health innovations at the local level that have emerged during the COVID-19 pandemic. The Local Government Association has documented innovations in local councils to facilitate contact tracing, and collaboration with schools and universities, businesses and care homes in analysing data, conducting public health risk assessments, and supporting vaccine rollout campaigns (Local Government Association, 2021). The establishment of the new National Institute for Health Protection, due to be operational in October 2021, shows evidence of attempts at institutional reform to make good on the government’s White Paper commitment, and capitalise on local innovations during the pandemic. However, its establishment has attracted criticism that establishing a new agency for public health is an unwelcome distraction for health practitioners from the ongoing need to respond to the pandemic (Rough and Kirk-Wade, 2021).

#### 3.6.2. Competition and procurement

As with other areas of the single market, the impact on the NHS of the UK’s freedom to depart from EU public procurement rules will depend on how those domestic regulatory powers are now used. The TCA includes some additional commitments on public procurement beyond WTO rules, such as on processes and ‘most favoured nation’ treatment but these are not as strong or detailed as the EU’s internal rules. They do not, for example, set out specific procurement procedures and when they must be followed by public bodies as the EU Public Contracts Directive does (European Parliament and Council, 2014). In addition, the TCA includes exemptions for activities necessary to protect human health,<sup>59</sup> and the relevant Title does not cover human health services, administrative health care services or supply services of nursing or medical personnel.<sup>60</sup>

<sup>55</sup>TCA, Article 85.

<sup>56</sup>TCA, Article 702.

<sup>57</sup>TCA, Articles 390 and 391.

<sup>58</sup>TFEU, Articles 9 and 168.

<sup>59</sup>Agreement on Government Procurement (GPA), Annex 25, Section A.

<sup>60</sup>GPA, Annex 25, Section B.

Overall, this means that there is scope for the UK to adopt a different approach to public procurement, that departs from the EU's core focus of using procurement to create a single market (Arrowsmith, 2020a, 2020b). This space is specifically opened by the removal of existing rules under the Health and Care Bill currently before Parliament, to be replaced by a specific post-Brexit regime for English NHS bodies purchasing health care, and by planned wider changes set out in the UK government's Green Paper (Cabinet Office, 2020). These suggest that the new regimes for procurement may well create a less burdensome regime for health and social care (Arrowsmith, 2020c). The situation is similar for competition rules more widely. The application of EU competition rules to health care had historically been limited, reflecting their primarily national character and the extent to which the public character of much health care puts it outside the scope of EU competition rules (Lear *et al.*, 2010). What difference the UK's increased discretion makes will depend on the UK's new competition regime. The Health and Care Bill would remove the jurisdiction of NHS Improvement and the Competition and Markets Authority for oversight of NHS trust mergers and cooperation in England, but given the otherwise highly regulated character of health care within the UK, changes in domestic competition oversight seem unlikely to lead to major immediate changes. Moreover, EU competition law will still also apply with regards to cross-border transactions involving EU countries, not least as these are more likely to be provided on a market basis.

### 3.6.3. Research

Research is one of the only two areas of substantive continued cooperation provided for in the agreement of relevance to health (alongside reciprocal health care arrangements). The TCA makes provision for continued participation in research and technological development programmes (though not other health-related programmes such as EU4Health). The TCA includes detailed provisions on what was likely to be the most contentious element, the calculation of the cost to the UK for participating, which removes the most likely roadblock to realising the UK's participation in practice.

What would have been a significant negative impact from being excluded from this platform for Europe-wide research has in principle thus been avoided. This will help to maintain the UK's relative strength in research and health-related research in particular, itself linked to substantial inward investment. This strength has been demonstrated during the COVID-19 pandemic, which has also illustrated the value of cross-country comparisons and learning.

However, in practice the situation for UK-based applicants has deteriorated substantially since the Brexit referendum, as shown in Figure 3. Even though the formal ability for UK-based applicants to access the programme remained, this shows that in practice, there has already been a substantial shift away from the UK in funding. The formal agreement of the TCA and continued UK participation in the research programmes may help this situation, but it already means that UK applicants start from a much weaker position overall for the next programme running from 2021, Horizon Europe.

There is also a risk that there will be an indirect negative impact on domestic research, if domestic funding decisions mean that participation in Horizon Europe comes at the cost of funding for research domestically (Universities UK, 2021). If this approach were followed, the UK's participation in Horizon Europe would mean effectively a cut of one billion pounds of research funding a year, which is the equivalent of the entire Medical Research and Science and Technologies Facility Councils combined. In the short term, the Government has made some additional funding available, but it is not sufficient to address the entire shortfall, and it remains unclear what the impact of UK participation will be on overall funding for health research in the UK (Kelly, 2021).

### 3.6.4. Scrutiny and stakeholder engagement

The WA and TCA include no provisions for scrutiny or for stakeholder engagement, with one exception: specific provisions for the ongoing consent of the Northern Ireland Assembly in

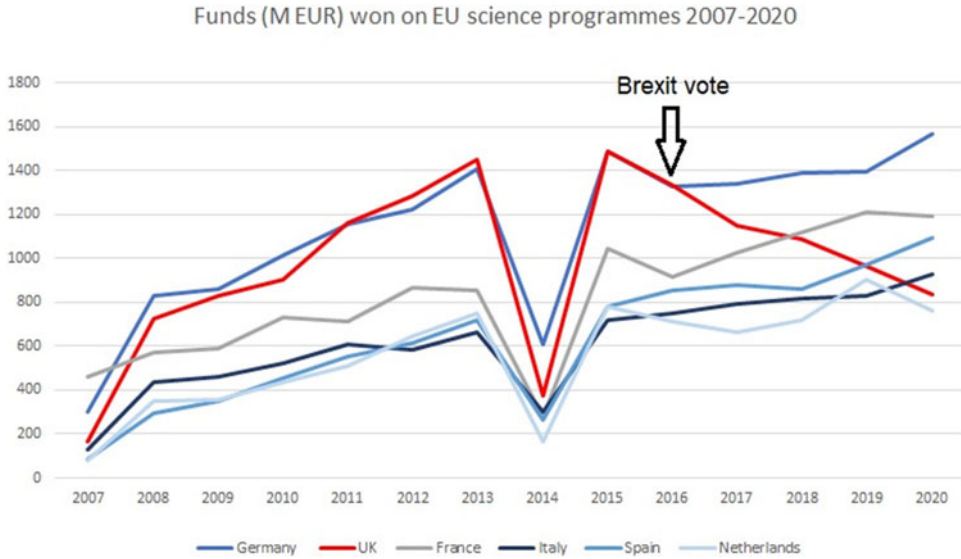


Figure 3. Funds awarded from EU Horizon 2020 research and technological development programme, by country of lead applicant. Author's own.

the Ireland/Northern Ireland Protocol (de Mars *et al.*, 2018; Harvey, 2020). This represents a significant reduction in scrutiny in comparison with trade negotiations by the EU, which are relatively transparent and which require the involvement and ultimately the agreement of the European Parliament (Jones and Sands, 2020).

Furthermore, the European Union (Future Relationship) Act 2020, that implements the TCA in UK law, has the effect of reducing even normal domestic Parliamentary scrutiny, with a very broad transfer of power to ministers to make laws directly, including primary legislation that would normally be made by Parliament. Moreover, many EU powers that have been returned to the UK in areas otherwise devolved to Scotland, Wales and Northern Ireland have been retained at the UK level.

In terms of the impact on health, this creates an increased risk of negative impacts from uninformed regulation on which there is a lack of stakeholder input; risks that will continue if similar trade deals in the future follow the same pattern (Van Schalkwyk *et al.*, 2021). The COVID-19 pandemic has shown the limits of government omniscience, especially in technical areas such as health. Quite apart from the impact on democratic legitimacy, scrutiny and stakeholder input helps to avoid unintended consequences and make choices based on all available evidence. However, the aim of the TCA in returning powers to the UK appears to have been to return powers to the national executive in London, rather than to the UK's institutions of government overall.

#### 4. Conclusion

The UK's relationship with the EU is now embodied in two key legal instruments: the Withdrawal Agreement (WA) and the Trade and Cooperation Agreement (TCA). The agreements do not aim to achieve nearly as much either trade or cooperation as EU membership does. As the analysis above shows, the priority for the EU was securing its single market, and excluding a large proximate non-Member State from the benefits of EU membership. The priority for the UK was sovereignty, and maximising the scope of action for domestic policy. The negotiated outcome means that much of the impact on the NHS, health and care will only emerge over time depending on how that scope of action is exercised.

The UK is now embarking on many years of trade negotiations to construct (or reconstruct) its trade arrangements with other countries. Even the TCA itself is not a final agreement; in order to reach agreement in such a short time, many areas have been left for continued negotiations. Mutual recognition of qualifications is one example that is important for the NHS, health and social care. As reflected in the TCA, the UK has very limited health-related objectives in its trade relations. The WA and TCA mitigated some immediate problems, such as access to health care for migrants and visitors, and a 'solution' for the island of Ireland that is as yet untested in the sense that the relevant rules are yet to be fully implemented. But in general, health is no longer an aspect of human thriving to be 'mainstreamed' into all policies, including trade-related policies, as it is in the EU's internal trade agreement.<sup>61</sup> Rather, health is an adjustment factor, an exception to the rule of trade and regulatory freedom. This is not what the health policy community sought in the UK's future relations with the EU, or with anywhere else.

It might be tempting to think that the COVID-19 pandemic will change patterns of globalisation that drive countries to enter into trade agreements. But travel restrictions aside, patterns of trade are still key to the protection of health: early in the pandemic, the UK was at pains to secure sufficient supplies of personal protective equipment; at present, vaccine supply is critical. These examples both illustrate the challenges of long supply chains. A move to shorten supply chains will re-emphasise the importance of domestic or at least local supply (and local means EU, for the UK). And of course, however the UK lives with COVID-19 going forward, people will still move – to some extent – for work and pleasure, and will have health care needs. The UK's settlement with the EU is a vastly diminished arrangement for human migration than what came before, and this has implications for the NHS, health and social care.

In 2017, we evaluated possible scenarios for the impact of Brexit on health and health services in the UK (Fahy *et al.*, 2017). Though we have updated those scenarios since then (Fahy *et al.*, 2019, 2020), overall the impact of the UK leaving the EU aligns fairly accurately with what we predicted for a 'Hard Brexit'. We envisaged major negative impacts for recruitment and retention of EU nationals in the NHS, social care and biomedical research workforce; for cross-border health service arrangements and for scrutiny and stakeholder engagement. These are either already occurring or the analysis above suggests there will be detrimental impacts on the NHS across the UK in these areas. We envisaged potential positive effects on professional qualifications rules, on working time, on competition and procurement and on public health regulation. These, as the analysis here shows, are possible future routes for the UK to deploy its new-found regulatory freedoms. It is, we argue, vital to continue the work of monitoring and analysing the emergent policy proposals, to provide an evidence base for difficult policy choices, and practical management of the consequences of change, to secure the best outcomes for the NHS, health and care across the UK.

In 2017, modelling a 'Hard Brexit', we envisaged moderately negative impacts for all other health systems building blocks. Here, the analysis above has shown that we were perhaps rather optimistic. The nature of the EU–UK relationship, as encapsulated in the legal texts we have analysed, is rather less close than we – and others in the health community – had hoped. Outside the EU's single market, Great Britain faces challenges in supply of medicines, medical devices and equipment. Some arise from the new formalities necessary for imports and exports, in the context of integrated supply chains. Many have not yet eventuated because of temporary rules put in place to manage the COVID-19 pandemic. The legal settlement for Northern Ireland (within the internal market's rules in some respects, but not others) is particularly challenging and there are real concerns about product supply with obvious consequences for the NHS, and for patients.

Longer term, the UK faces difficult decisions about how to optimise regulatory arrangements as a small market. Trade-offs between supporting domestic industries, securing supply from EU

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<sup>61</sup>TFEU, Articles 9 and 168.

and global markets, costs to the NHS and access to new technologies and maintaining the UK's considerable European and global influence in biomedicine are not new, but they take a different form for the UK going forward. Of course, the EU's regulatory arrangements will change over time too, so it will be important for health policy actors in the UK to continue to understand and respond to the EU's position in the years to come.

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