

Briefing October 2020

How will Brexit affect the UK's response to coronavirus?

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Coronavirus has demanded exceptional things of the NHS, and of health services across Europe. Now, the UK is scheduled on 31 December to make the biggest changes to its domestic and international legal system in 50 years during what may be a period of difficult containment – or of an ongoing and resurgent second wave.

This briefing will look at how leaving the single market might affect UK health and social care services in the short term as they try to deal with coronavirus while maintaining normal services. It will also look at what difference a deal might make, and the options that the UK and the EU have. It does not look at the longer term, at wider public health, or at possible implications for health services in the EU. The Nuffield Trust is exploring how to track these issues in the round in its Brexit Health Monitor project with a team of academics, funded by the Health Foundation.

Key points

- Leaving the single market will create new and wide-ranging problems for the majority of NHS medicines and medical devices which come from or via the EU. Measures such as stockpiling and planned delays in bringing in full controls will help, but data since the EU referendum shows medicines shortages have become more common and seem to fluctuate easily. The coronavirus wave and Brexit stockpiling both created spikes in imported supplies, and filling both requirements at once may be very difficult.
- Export blocks on medically vital supplies by the EU were used during the first wave of coronavirus and could cover the UK after 31 December.
- The UK will no longer have access to the European Centre for Disease Prevention and Control (ECDC), which collects and shares intelligence on pandemics and other infectious disease outbreaks. The UK is trying to negotiate access to the Early Warning and Response System, which shares information between ECDC and member states during pandemics, but this will depend on whether a deal is reached and whether this provision is secured.
- Based on negotiating documents, draft treaties, and briefing to date, the majority of the crucial issues for health which could have been secured in an agreement are not agreed upon by the two sides, or the outcome is uncertain. These should be given a higher priority in the context of the ongoing pandemic.
- Several important areas for responding to coronavirus depend on cooperative practices and favourable decisions across the EU and UK, beyond simply the presence or absence of a deal. These include allowances at customs on the EU side; the exchange of data and intelligence; and the UK being subject to blocks on exports. Bad relations will magnify the issues the NHS faces in trying to tackle coronavirus next year.
- Poor funding for public health and social care contributed to limitations in the UK's capacity to address coronavirus during the first wave. Leaving the single market will mean slower growth, making addressing these more difficult though the case to do so remains very strong.

What are the possible impacts of Brexit on the NHS in the time of coronavirus?

The effects of leaving the single market are likely to affect the immediate response to coronavirus most in the areas of supplies, management capacity, and workforce. Regulation, institutions and funding will also be permanently changed.

The supply of medical products

Leaving the single market and the customs union will create a variable but extensive burden of extra paperwork and requirements that must be satisfied to get medicines and medical devices into the UK.

On the regulatory side, separate UK processes for chemicals, medical devices, and medicines will potentially increase costs and complexity for companies needing to duplicate the processes and people which assure these products as being safe and effective. These processes previously only had to happen once to cover both the EU and the UK within the single market. They include having new medicines authorised, having devices assessed as conforming to regulations, and potentially assuring the standard of manufacturing.

The UK can unilaterally relax these rules and plans to do so for many in the short term, allowing the testing and release of batches of medicine to keep happening in the EU and giving importers some time to register for the licences they will need. These steps mean regulatory changes may be limited in their immediate impact.¹ Furthermore, the Withdrawal Agreement provides for goods that meet EU rules to keep being offered in Northern Ireland², and the UK Internal Market Bill means they can be accepted elsewhere. As of September 2020, this implies that the legal position may be that it will still be permanently possible for products to be sold anywhere in the UK as long as

- 1 www.gov.uk/government/collections/mhra-post-transition-period-information
www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brex-it-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brex-it-deal
- 2 https://ec.europa.eu/commission/publications/revi-sed-protocol-ireland-and-northern-ireland-included-withdrawal-agreement_en

they meet EU rules – depending on whether they are classified as qualifying for coverage under the Northern Ireland protocol.

Both unilateral changes and those relating to the Protocol mean the UK simply outsourcing key regulatory permissions to the EU, temporarily losing its capacity to regulate and control medicines and incentivising companies to locate elsewhere. This may not be permanently sustainable, but taking back control in the midst of a pandemic would carry significant risk.

When it comes to customs and checks at the border, the effect is likely to be more immediate and unpredictable. The concern here is that a huge increase in the volume of public and private paperwork and checking required across all sectors will cause bottlenecks that make it difficult to get any goods into the UK, especially from northern France to Kent. These routes accounted in 2018 for 73% of EU imported medicines, implying around half of the UK’s total medicines supply, and 90% of EU imported devices.³ The risks apply to some extent to the EU as well, where several countries have identified medicine lines which may see shortages if UK supply is disrupted.^{4,5}

The government has told suppliers to prepare for disruption on these routes particularly “during the first three months following 1 January 2021”. It notes that delays will partly be due to checks on the EU side slowing trade back and forth, suggesting the severity of disruption will depend on part on whether there is agreement in temporarily relaxing checks and sharing data, either through a deal or general close cooperation.⁶ A leaked letter to road hauliers noted that these EU checks could “reduce the flow rate to 60–80% of normal levels” leaving up to 7,000 lorries stuck in Kent rather than circulating normally. This also noted that, even after three months, passport controls

3 <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/exiting-the-european-union-committee/the-progress-of-the-uks-negotiations-on-eu-withdrawal/oral/91884.html>

4 www.bfmtv.com/economie/economie-social/union-europeenne/brexit-faut-il-craindre-une-penurie-de-medicaments-en-france-en-cas-de-no-deal_AN-201909200013.html

5 www.afmps.be/fr/brexit_information_pour_le_public

6 www.gov.uk/government/publications/letter-to-medicines-and-medical-products-suppliers-3-august-2020/letter-to-medicine-suppliers-3-august-2020

“could continue to cause disruption until the French relax checks or add more capacity”.⁷

The UK’s plans to phase in border controls means customs declarations and tariff payments can be deferred for up to six months on its side – but not on the EU’s.⁸ However, this explicitly does not apply to the special declarations needed for controlled medicines or to medical radioisotopes.⁹

As was the case ahead of a no-deal Brexit last year, the Department of Health and Social Care (DHSC) is asking suppliers to build up stockpiles equivalent to six weeks’ worth of usual levels, and is offering support for new routes to move around the short Channel crossings into Kent which are expected to be most affected.¹⁰ A particular concern may be if coronavirus causes demand for certain products to spike well above the usual level reflected in stockpiling and booking on new routes – for example, because they are discovered to be effective treatments.

Customs changes, regulatory changes, and any fluctuation in sterling are likely to result in substantial additional costs to medicines suppliers and, all else being equal, an increase in price. The University of Sussex’s Trade Policy Observatory has estimated that scenarios in which the UK leaves the single market will tend to drive up pharmaceutical and chemical costs by 5% to 7.5%.¹¹ A comparable estimate for medical devices is not available, but the UK government has estimated that ‘machines, equipment and energy’ imported from the EU would see a 6.1% increase in price even without any tariffs being applied.¹²

7 www.independent.co.uk/news/uk/politics/brexit-border-chaos-lorry-kent-dover-calais-eurotunnel-b547670.html

8 www.gov.uk/government/publications/the-border-operating-model

9 www.gov.uk/government/publications/the-border-operating-model

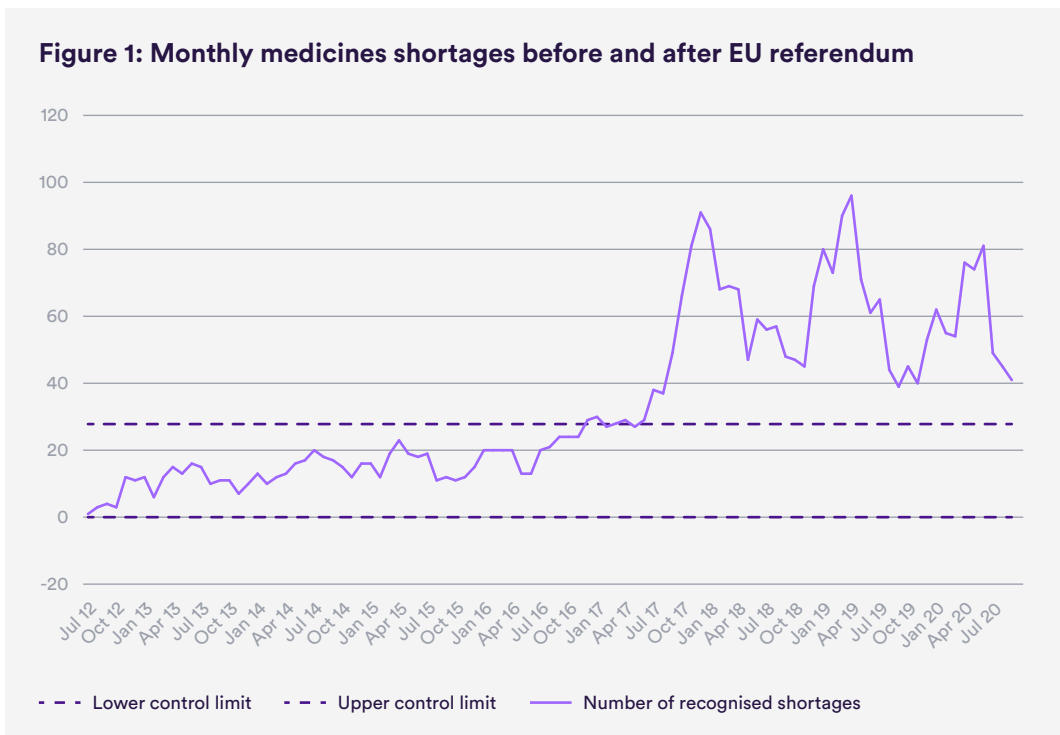
10 www.gov.uk/government/publications/letter-to-medicines-and-medical-products-suppliers-3-august-2020/letter-to-medicine-suppliers-3-august-2020

11 <https://blogs.sussex.ac.uk/uktpo/publications/which-manufacturing-sectors-are-most-vulnerable-to-brexit>

12 www.nuffieldtrust.org.uk/news-item/how-much-would-nhs-costs-rise-if-there-s-no-brexit-deal

Because the NHS has multiple levels of controls on the prices it will pay for medicines, price rises tend to be synonymous with shortages. The sensitivity of the system is illustrated by the patterns seen in off-patent ‘generic’ medicines since the 2016 EU referendum.

Generic medicines are paid for by the NHS against a fixed price list. For England and Wales a Pharmaceutical Services Negotiating Committee monitors whether that price is too low and is causing shortages for some products, and will apply to the DHSC for a waiver and a higher price if this seems to be the case. Beginning around the date of the referendum, the number of these ‘concessions’ began to climb, increasing very rapidly from the following winter and then fluctuating at a level much higher than before. The control limits shown in this Figure 1 reflect a level that would be reached on average about one month in every 30 years, based on numbers of shortages in the four years before the referendum. In 2018 a new Act of Parliament took effect to try to control prices by requiring more transparency, but this appears to have had limited impact.¹³



13 www.legislation.gov.uk/ukpga/2017/23/contents/enacted

The National Audit Office investigated this shift, finding that it cost the NHS an additional £315 million in the first year alone. They reported that a fall in the value of the pound and difficulties obtaining licences were likely contributing factors, though many changes remained unexplained.¹⁴ Both of these are plausible immediate risks of an exit from the single market.

In addition to price changes, the UK would also face being subject to any export blocks the EU introduced. The Commission responded to the first coronavirus wave by introducing controls on vital personal protective equipment which banned its export without specific permission¹⁵, and it has standing powers to make similar provisions again. The UK was on this occasion exempt because of its status under the transition agreement, but will not be in future. The EU does have the power to exempt countries, and did so for states in the Balkans.¹⁶

The UK would also lose rights to take part in EU procurement initiatives, which were used to procure vital supplies in a competitive global market during the acute phase of coronavirus. Some non-EU countries in the Balkans do take part in EU Joint Procurement Agreement¹⁷, but extraordinary purchases by the Commission may be made outside it. The recent bulk purchase of the coronavirus treatment Remdesivir was apparently only for EU states and the UK.¹⁸ A similar mechanism is being used to pay for vaccines from Sanofi at a European level.¹⁹ It does not seem to be clear whether the UK would suddenly be dropped if it left the single market part way through the delivery of these products.

The UK will rely significantly on goodwill from the EU in decisions relating to export bans, and to whether it can still be included in either type of joint buying exercise.

14 www.nao.org.uk/wp-content/uploads/2018/06/Investigation-into-NHS-spending-on-generic-medicines-in-primary-care.pdf

15 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0568&from=EN>

16 <https://trade.ec.europa.eu/doclib/press/index.cfm?id=2139>

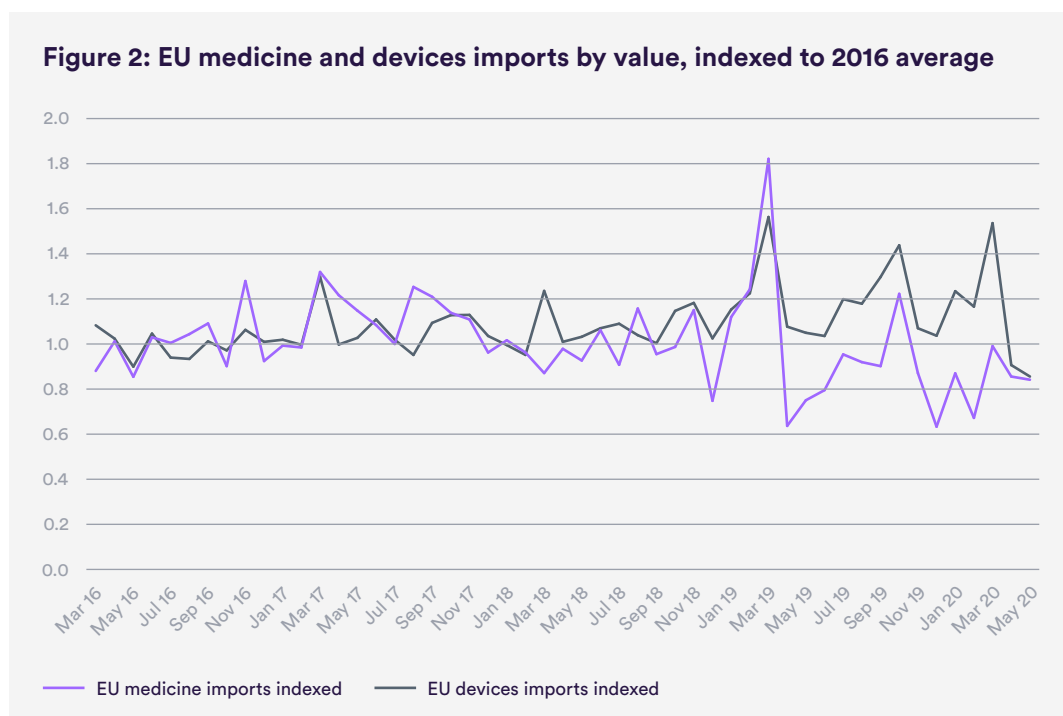
17 https://ec.europa.eu/health/preparedness_response/joint_procurement_en

18 https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1416

19 https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health/coronavirus-vaccines-strategy_en

Northern Ireland’s unique status under the Protocol agreed in 2019 means that it will effectively remain in the single market for many areas of regulation, greatly reducing the likely price and availability impacts for EU imports. However, this will mean new hurdles to importing medicines from the UK, including customs declarations for inbound goods and the need for goods to pass EU rather than UK regulatory standards if these diverge.

Any increase in prices or reduction in availability may be particularly challenging in a context which combines unusually high levels of demand, outright global shortages and sharp global price rises for certain products, as we saw during the acute phase of the coronavirus pandemic in March and April 2020. Figure 2 shows EU imports of medicines and medical devices by value, according to HMRC and indexed to the March 2016–March 2017 average.



March 2020 saw EU imports of medical devices spike to their highest ever level: the other highest spikes occurred around planned Brexit dates in March 2019 and October 2019, with stockpiling a likely factor.

Attempting to meet stockpiling requirements and exceptional demand at the same time, immediately ahead of the combined impact of added cost, regulatory change, and possible export bans would be an extremely difficult task for the NHS and its suppliers. The risk of shortages of the products most

desperately required would be high. If exit from the single market is likely to coincide with an ongoing second wave, there are strong cases for doing anything possible to improve this situation through negotiations with the EU, and for considering yet more radical measures around stockholding and regulatory exemptions.

Workforce

The end of free movement of labour will mean the UK can set its own migration policy. The Home Office's Policy Statement²⁰ lays out a single set of criteria to be applied to anybody wanting to work and live in the UK, whether from the European Economic Area (EEA) or beyond it.

For most graduate health care workers, the new system will be relatively permissive. Essentially any medical or nursing position in the NHS will meet the requirements to recruit internationally. However, the likely slump in international migration during the pandemic means there may be a requirement to accelerate recruitment next year if this is possible, from the already stretching figure of 10,000 a year needed to address immediate shortages in 2019.²¹ The new system, unlike free movement of labour, will require considerable paperwork and fees stretching into thousands of pounds. Despite the huge wage differences between the UK and many countries that typically provide clinical migrant workers, there is a need for caution about this having a deterrent effect.

In social care, the effect may be more pronounced. The new policy document would entirely rule out migration in order to take up most frontline social care roles. Before the pandemic, the social care sector in England, where records are most readily available, had been adding several thousand EEA migrant workers a year.²² Without a growth in the share of EEA workers from 5% to 8% over the past six years, the rate of vacancies could have been significantly higher than the 8% seen last year.

20 www.gov.uk/government/publications/the-uks-points-based-immigration-system-policy-statement/the-uks-points-based-immigration-system-policy-statement

21 www.nuffieldtrust.org.uk/research/closing-the-gap-key-areas-for-action-on-the-health-and-care-workforce

22 www.skillsforcare.org.uk/adult-social-care-workforce-data/Workforce-intelligence/documents/State-of-the-adult-social-care-sector/State-of-Report-2019.pdf

Social care is likely to struggle to increase domestic recruitment because (particularly in England) it entered the crisis in a very poor financial condition, and the extra demands of the pandemic appear to have worsened this. Just 4% of directors of adult social services felt they had sufficient funding to meet statutory duties in a 2020 round of surveying, down from an already low 35% the year before.²³ Hopes that unemployment due to the recession will make recruiting easier rest on the assumption that social care will fare relatively better than other sectors, such as retail and hospitality, but this seems very far from clear. Ongoing efforts to massively scale up testing and tracing capacity in the public and private sector^{24,25} will create a new source of competition for workers without a professional qualification interested in working within the health and care sector.

The sector also consists mostly of small businesses with less capacity to handle a complex and bureaucratic migration system: last year, most workers were in organisations employing fewer than 250 people.²⁶

Management and leadership capacity

The pandemic is also likely to mean that managers, leaders and policymakers have fewer people and resources free to plan for and respond to any disruption from leaving the single market.

Within NHS England, it is understandable but notable that recent board meetings and papers have not included any discussion of the end of the transition period²⁷, whereas EU exit featured regularly in late 2018 and 2019.²⁸ Many of the key personnel working on Brexit readiness have been transferred to work on the pandemic. At the civil service level, while most of the structures to manage Brexit remain in place, some have now switched their remit to focusing on coronavirus, including the National Supply Disruption Centre

23 www.adass.org.uk/media/7973/no-embargo-adass-budget-survey-report.pdf

24 www.gov.uk/government/news/new-lighthouse-labs-to-boost-nhs-test-and-trace-capacity

25 www.bmj.com/content/370/bmj.m3580

26 www.skillsforcare.org.uk/adult-social-care-workforce-data/Workforce-intelligence/documents/State-of-the-adult-social-care-sector/State-of-Report-2019.pdf

27 www.england.nhs.uk/about/board/meetings/previous

28 www.england.nhs.uk/about/board/meetings/previous

established to identify and monitor medicine shortages²⁹. The same is true for at least some key personnel in the Welsh and Scottish health systems. While there is no data, it seems likely that, within individual NHS trusts, leaving the EU has similarly moved down the list of risks to which resources are allocated.

The NHS also has fewer options to release pressure on staff and supplies than it might otherwise. The cancellation of planned care during the first wave of coronavirus has already resulted in large backlogs across the UK.^{30,31} Repeating it to focus scarce resources on emergency patients would risk dangerously long waits for some patients.

For social care, the Association of Directors of Adult Social Services in England described the pandemic as “all-consuming”.³² It seems probable that this may have weakened already limited capacity to handle the complex new migration system, discussed above, and any further shortages of supplies or staff.

For private sector suppliers, the Institute for Government notes across all sectors that “the devastating impact of the virus on many firms’ balance sheets means businesses are less likely to have the funds to invest in new systems, staff and training”.³³ It might be expected that medical suppliers would be an exception, but the stock market suggests this is not necessarily the case. Apart from AstraZeneca PLC, which has a promising vaccine in trials, shares in other major UK medicines and devices manufacturers – GlaxoSmithKline, Smith & Nephew and Convatec – are now considerably lower than they were before Covid-19.³⁴

29 www.gov.uk/government/publications/letter-to-medicines-and-medical-products-suppliers-3-august-2020/letter-to-medicine-suppliers-3-august-2020

30 www.nuffieldtrust.org.uk/news-item/nhs-performance-summary-july-august-2020

31 www.belfasttelegraph.co.uk/opinion/news-analysis/how-long-must-we-wait-for-reform-of-ni-health-and-social-care-39501492.html

32 www.adass.org.uk/adass-budget-survey-2020-part-one-covid-19-response

33 www.instituteforgovernment.org.uk/sites/default/files/publications/preparing-brexit-scale-task.pdf

34 www.londonstockexchange.com/indices/ftse-350/constituents/table?lang=en

Financing and funding

While the effect of the pandemic on the UK economy has been immediate and extreme, leaving the single market and customs union is likely to cause a slower, more permanent headwind to economic growth and state finances. In March, the Office for Budget Responsibility (OBR) assumed that a free trade agreement with the EU would lead to “around a 4 per cent loss of potential GDP over 15 years”, with around half of that felt within five years.³⁵

Particularly if a less close relationship with the EU than assumed by the OBR exists, this will mean an even greater pressure to control public finances at the forthcoming Spending Review and next year. This comes in the context of a level of deficit spending during the pandemic which has seen UK public debt exceed 100% of annual domestic product for the first time in 60 years.³⁶

Ministers have also committed to building 40 “new hospitals” across England, implying higher capital funding for the NHS (shared with Scotland, Wales and Northern Ireland through the Barnett formula).³⁷ This is likely to mean a very difficult context for other health budgets.

General public health funding has been cut by more than £1 billion in the past five years,³⁸ something which former scientists and policymakers have said contributed to the UK’s lack of capacity to deal with issues like tracing and testing during the first wave of Covid-19.³⁹ A small increase announced in March only very partially reverses this.⁴⁰

Social care accounted for a large proportion of cases and mortality of Covid-19 during the first wave. The Public Accounts Committee noted that “years of inattention, funding cuts and delayed reforms have been compounded by the government’s slow, inconsistent and, at times, negligent approach to giving the sector the support it needed during the pandemic”.⁴¹ The Nuffield Trust’s analysis of social care across the UK and overseas suggests that widespread

35 https://cdn.obr.uk/EFO_March-2020_Accessible.pdf

36 www.ft.com/content/57974640-8bea-448c-9d0b-32f34825f13e

37 www.conservatives.com/our-plan

38 www.kingsfund.org.uk/press/press-releases/reverse-cuts-public-health-funding

39 www.ft.com/content/e149101a-1c93-4b0a-bc12-14ca8bf11b0e

40 www.health.org.uk/news-and-comment/news/response-to-public-health-grant

41 <https://committees.parliament.uk/publications/2179/documents/20139/default/>

reform is needed to create a stable market for companies that provide care, and certainty among the public about what support they can get.⁴² This will have significant funding requirements.

Addressing both of these underlying structural weaknesses in the UK's ability to respond to future waves of a pandemic is likely to be made more difficult by the economic consequences of leaving the single market, although the case for action remains very strong nonetheless. Economists are almost unanimous that a deal, especially a more extensive one, would have a less dramatic effect than a no-deal exit.⁴³

Institutions and data sharing

The UK's full departure from the EU legal order will change how data, research and intelligence about pandemics can cross the English channel or Irish border.

Within the EU, data about individuals can be shared freely across borders due to the existence of shared protections, most notably the General Data Protection Regulation (GDPR). This will include some of the information necessary for the conduct of research, monitoring and trials. Transferring data outside the EU requires either a decision by the European Commission that a country has "adequate" protections, or special contracts being drawn up. This decision will not form part of the negotiations on a trade agreement; however, many commentators including Centre for European Reform director Charles Grant have suggested it may be connected in practice.⁴⁴ The overall cooperativeness of politics and institutions are likely to be relevant.

The UK will leave the European Centre for Disease Control (ECDC), which has provided more specific UK and EU intelligence on the pandemic. This will mean it no longer has access to the Early Warning and Response System (EWRS) which links ECDC to member states and institutions to share intelligence on outbreaks of infectious disease. Switzerland, not currently

42 www.nuffieldtrust.org.uk/news-item/a-social-care-cap-must-sit-alongside-reform-to-the-entire-system

43 www.bmj.com/content/363/bmj.k4767

44 www.theguardian.com/world/commentisfree/2020/jul/28/optimistic-brexite-deal-gloomy-outlook-free-trade-agreement

part of the ECDC, requested⁴⁵ and was granted⁴⁶ access to the EWRS during the pandemic. However, this was explicitly seen as part of negotiations across different sectors with the EU. Both the EU⁴⁷ and reportedly the UK⁴⁸ are considering some form of future cooperation after 31 December, though this cannot be full normal membership.

The EU is currently in the process, following long delays, of implementing a new system for the approval of clinical trials.⁴⁹ This will take several steps towards making it easier to run studies across borders, including:

- Having a single portal for applications to get trials approved
- Having harmonised standards for the conduct of trials
- A system where one member state looks at whether the trial meets standards first, allowing this to then be transferred to others.

Research by Cancer Research UK with scientists, industry, patient groups and officials in the UK and EU found that full UK involvement in this system was generally viewed as a positive and recommended seeking membership.⁵⁰ However, as discussed below, this does not seem likely. This means the UK will be left out of any improvement in the ease of running and monitoring trials across the EU next year. This could affect trials relevant to Covid-19, many of which need to be international to account for the fluctuating prevalence of the disease in different countries. However, the high priority placed on the disease does mean trials have been subject to accelerated approvals already in the UK⁵¹ and elsewhere.

45 www.reuters.com/article/us-china-health-swiss/swiss-look-for-access-to-eu-early-warning-system-as-coronavirus-spreads-idUSKBN1ZR24M

46 www.letemps.ch/opinions/suisse-lexperience-solidarite-favorise-rapprochement

47 www.researchgate.net/publication/341879996_Assessing_the_potential_impact_on_health_of_the_UK's_future_relationship_agreement_with_the_EU_analysis_of_the_negotiating_positions

48 www.theguardian.com/politics/2020/may/02/uk-seeks-access-to-eu-health-cooperation-in-light-of-coronavirus

49 https://ec.europa.eu/health/human-use/clinical-trials/regulation_en

50 www.cancerresearchuk.org/sites/default/files/future_of_clinical_trials_after_brexit.pdf

51 www.guysandstthomas.nhs.uk/research/studies/covid-19.aspx

How much difference will a deal make?

The 2017 Nuffield Trust briefing '*How will our future relationship with the EU shape the NHS?*'⁵² identified eight desirable features for the health service that would be possible within a future relationship agreement.

Repeated delays to planned negotiating timescales, due to both coronavirus and failure to reach agreement, mean that we know much less than would have been expected about the outcome. However, both sides have published draft treaties setting out their positions in some detail. A comprehensive analysis of negotiating positions and how they may affect health in a broader sense has been given in a recent *Health Economics, Policy and Law* paper.⁵³









Table 1 shows the extent to which the provisions we described in 2017 have been secured at this stage. A green rating indicates that agreement has been reached or both sides are proposing this feature. Red indicates a feature ruled out; amber that a feature has partly agreed, or neither agreed nor ruled out; and striped green and red that the two sides appear to be in direct disagreement over its inclusion or otherwise.

It should be noted that all the forms of Brexit proposed by UK governments since the 2016 referendum have fundamentally involved leaving the single market. This means that a significant degree of extra cost and bureaucracy relating to trade, an end to the free movement of labour, and UK exit from joint initiatives both during and outside periods of crisis, have always been guaranteed and are not on the table.

52 www.nuffieldtrust.org.uk/files/2017-11/1509990492_nt-future-relationship-with-eu-after-brexit-web.pdf

53 www.ncbi.nlm.nih.gov/pmc/articles/PMC7294072

Table 1: Desirable provisions in EU negotiations for health care in the UK and progress levels so far

Medicines approval alignment	
Minimal customs disruption	
Minimal regulatory barriers to supplies	
Cooperation on health programmes	
Continued access to science funding	
Continued reciprocal healthcare	
Data and experiments across borders	
Regulatory freedom where desirable	

Keeping medicines approvals aligned with the EU

Seeking continued participation in the EU’s system for the actual authorisation of new medicine products was always difficult to reconcile with leaving the single market, but was identified as a goal by the previous UK government.⁵⁴ This has now been entirely dropped in current UK policy documents⁵⁵ and is not being proposed by the EU, meaning it is entirely ruled out. Unless we simply accept EU decisions indefinitely, this may result in new medicines being introduced later in the UK, as happens in other smaller markets, and it will impose a degree of extra cost and bureaucracy on companies offering medicines.

Customs systems which minimise disruption and delays

The UK’s clear decision to aim for a departure from the customs union⁵⁶ means a certain degree of increased customs bureaucracy will be inevitable, including export and import declarations forms for products passing between

54 www.gov.uk/government/publications/the-future-relationship-between-the-united-kingdom-and-the-european-union

55 www.gov.uk/government/publications/our-approach-to-the-future-relationship-with-the-eu

56 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/868874/The_Future_Relationship_with_the_EU.pdf

the UK and EU – or Northern Ireland and other parts of the UK. Both sides in the negotiation have tabled proposals to streamline customs to some extent in view of this.

There are considerable differences: the UK text aims to lock in specific commitments to easier passage, like the right to submit paperwork electronically⁵⁷, whereas the EU text focuses more on just duties to work together and examine possibilities. While both sides envisage a zero-tariff agreement, they differ on the “rules of origin”, which would determine exactly which products are covered by this⁵⁸ – not usually a consideration for medical products, but possibly for their ingredients and precursors. The likely outcome is unclear.

Medical radioisotopes, which decay rapidly, are a product at particular risk from border congestion – in particular molybdenum, which is used to produce scanning materials for around 700,000 procedures each year. This cannot be produced in the UK and has a half-life of only 66 hours: a 2008 fire in the Channel Tunnel caused a rapid shortage and cancelled procedures.⁵⁹ Both the UK and EU draft texts suggest a framework for future cooperation and information sharing, but details are limited, especially in the EU text.^{60,61}

Minimal barriers to trade in health supplies

Leaving the single market means that many additional checks and requirements will be needed on medical supplies travelling between the UK and EU. Because the UK plans to relax many of these requirements in the short term, supplies going from the UK to the EU will be especially affected immediately. We called for these to be minimised by aligning them in a future

57 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/886010/DRAFT_UK-EU_Comprehensive_Free_Trade_Agreement.pdf

58 <https://commonslibrary.parliament.uk/research-briefings/cbp-8923/>

59 www.rcr.ac.uk/sites/default/files/rcrbrexit-medicinesmedicaldevicesandsubstancesofhumanorigin.pdf

60 www.gov.uk/government/publications/the-future-relationship-between-the-united-kingdom-and-the-european-union

61 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/886017/DRAFT_Civil_Nuclear_Agreement.pdf

relationship agreement, to minimise delays at the border and prices being pushed up for financially vulnerable hospitals and social care companies.

While mutual recognition of actual approval of medicines has been ruled out, the UK's draft treaty suggests that each side should accept approvals of batches of products done in the other country, and inspections of manufacturing facilities.⁶² This would be similar to EU arrangements with the United States.⁶³ However, these provisions do not appear in the EU draft treaty, and indeed in the wider context of negotiations the EU is reported to be actively opposed to these measures.⁶⁴

The situation for medical devices – including protective and testing equipment – is similar. The UK proposes wide-ranging mutual recognition, but the EU does not and is reported to oppose the idea.⁶⁵

'Substances of human origin', like blood plasma and organs, currently also benefit from EU legislation which imposes common requirements on safety and the traceability of origins and allows easier movement subject to these rules.⁶⁶ Neither side appears to consider these to fall within the scope of negotiations.⁶⁷

Ways to work with key European health programmes

The EU funds and arranges multiple international programmes which support public health, health research, and health care. As well as the ECDC and EWRS described above, these include cooperation programmes between Northern Ireland and the Irish Republic, and European Reference Networks connecting those who treat and research rare diseases.

62 <https://ec.europa.eu/info/sites/info/files/200318-draft-agreement-gen.pdf>
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/886008/DRAFT_UK-EU_CFTA_ANNEXES.pdf

63 www.ema.europa.eu/en/news/eu-us-reach-milestone-mutual-recognition-inspections-medicines-manufacturers

64 www.telegraph.co.uk/politics/2020/07/11/eu-accused-risking-lives-standoff-coronavirus-medicines-produced

65 www.ft.com/content/16a10238-2524-46ac-a659-a48c0b00c96b

66 www.nuffieldtrust.org.uk/research/brexit-relationship-eu-shape-nhs

67 www.ncbi.nlm.nih.gov/pmc/articles/PMC7294072/

The status of possible continued UK participation in these varies greatly. The EU and UK both envisage at least possible future cooperation in EWRS^{68,69} and both committed in the 2019 Political Declaration to work towards future cooperation in Northern Ireland. However, future participation in European Reference Networks and the ECDC itself is not under discussion.⁷⁰

Continued access to the EU's flagship science funding programmes

The EU's 'Framework Programmes', long-term international science funding programmes, support important life sciences research. Associate membership exists for countries which are not EU members. A recent letter from 100 leading research bodies to the UK and EU argued that future partnership will help tackle Covid-19 and future challenges, and both sides have this as an objective. However, it remains unclear whether agreement will be reached as part of any deal, with an array of stumbling blocks emerging in negotiations, including the nature of UK financial contributions and whether UK scientists can commercially exploit their findings.⁷¹

Protecting future travellers and pensioners against health care costs

If possible, it would be desirable that future generations of travellers and retirees can also benefit from having care costs covered when they go between the EU and the UK, as is the case today under initiatives like the European Health Insurance Card. Patient groups have argued that this is particularly important for individuals with very regular treatment needs – like people reliant on dialysis – which would otherwise make travel insurance prohibitively expensive.⁷²

68 <https://ec.europa.eu/info/sites/info/files/200318-draft-agreement-gen.pdf>

69 www.theguardian.com/politics/2020/may/02/uk-seeks-access-to-eu-health-cooperation-in-light-of-coronavirus

70 www.ncbi.nlm.nih.gov/pmc/articles/PMC7294072/

71 www.bhf.org.uk/what-we-do/news-from-the-bhf/news-archive/2020/july/uk-and-eu-research-leaders-urge-brexit-negotiators-to-compromise-on-horizon-europe-agreement

72 <https://publications.parliament.uk/pa/ld201719/ldselect/ldeucom/107/107.pdf>

Both the EU and UK draft treaties include language consistent with continuing rights for tourists and business travellers to access health care on the same basis of locals, with reimbursement from their home country.⁷³ Provisions for expatriate pensioners receiving health care are not included, though this arguably reflects a move away from the free movement of people which made such arrangements feasible.

Current retirees abroad are likely to be mostly covered by the existing Withdrawal Agreement⁷⁴, although the same is not necessarily true for other groups receiving health care coverage across the UK-EU border – especially where they change their country of residence or the country responsible for their care. A scenario paper for the NHS Confederation has been published examining different possible cases.⁷⁵

Provisions for data and experiments across borders

Several areas of EU law facilitate the execution of health research and analysis across borders. As discussed above, it remains to be determined whether the UK will be deemed to have ‘adequate’ protection for the continued free flow of data by the date of exit from the single market.^{76,77}

The new EU clinical trials system discussed above will streamline requests and approvals to run experiments across borders. Here the UK is proposing continued sharing of assessments and information in its draft treaty⁷⁸. This does not seem to be a bid for full continued membership, and it is probable the EU would not accept this if it was requested.⁷⁹ However, it could still help to facilitate the UK and EU countries to consider the approval of cross-border trials in a timely and fully informed way. It is unclear what the EU response to this will be.

73 www.ncbi.nlm.nih.gov/pmc/articles/PMC7294072

74 <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1580206007232&uri=CELEX%3A12019W/TXT%2802%29>

75 www.sheffield.ac.uk/media/17332/download

76 www.instituteforgovernment.org.uk/explainers/future-relationship-data-adequacy

77 www.gov.uk/government/publications/new-withdrawal-agreement-and-political-declaration

78 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/886008/DRAFT_UK-EU_CFTA_ANNEXES.pdf

79 www.ncbi.nlm.nih.gov/pmc/articles/PMC7294072/

Regulatory freedom if felt desirable

Our 2017 briefing noted that some NHS organisations wanted to be outside EU law in certain specific areas: procurement, working time and clinical trials. We recommended that the UK decide clearly on which, if any, areas more latitude might support health, then try to secure these. There has in fact been remarkably little policy debate in the UK over whether these freedoms are worth using and are worth associated costs – on clinical trials, for example, they are not reconcilable with the maximum degree of ease in working across borders. It is unclear whether currently proposed reforms to NHS procurement in England are supposed to be reliant on ending current EU law, or not.⁸⁰

Regardless of the lack of any clear decision about the value of these new powers, the overall picture is one of conflict. The EU has proposed ‘non-regression’ which rules out rolling back the working time directive: the UK is not openly accepting this.⁸¹ The UK can be interpreted as proposing aligned clinical trials, as noted above, which the EU is not. On procurement, while neither side seeks to maintain the existing EU rulebook, the EU proposes possibly extending the World Trade Organization’s procurement agreement, which does not currently cover clinical health care. The EU has not yet published proposals for what would additionally be covered.⁸²

Where this leaves us

Negotiations have not so far secured any of the provisions that are most important for the NHS, although there are promising signs for some. The UK appears to be more ambitious in looking for easier trade and science than the EU in several key areas which would benefit the response to coronavirus on all sides. Coronavirus strengthens the case for the UK to prioritise these demands more, and for the EU to adopt a more patient-focused mindset.

80 www.england.nhs.uk/wp-content/uploads/2019/09/BM1917-NHS-recommendations-Government-Parliament-for-an-NHS-Bill.pdf

81 www.ncbi.nlm.nih.gov/pmc/articles/PMC7294072

82 <https://ec.europa.eu/info/sites/info/files/200318-draft-agreement-gen.pdf>

Conclusions

Leaving the single market may cause significant disruption, especially to supply chains and the social care workforce. National and local leaders must remain aware of this alongside the immediate demands of Covid-19. This would not be a good moment to introduce very challenging new immigration rules for social care.

There are still important points yet to be decided between the UK and EU. Some are within the context of a formal deal. Agreements on medicines and devices regulation and on clinical trials could do much to help science and supplies cross borders in the fight against the virus.

But many are also simply about goodwill and cooperation between the two sides, whether through a formal agreement or not, with decisions the EU is free to make doing a great deal to set the context in which the NHS will operate in early 2021. These include whether the EU makes efforts to facilitate a smooth transfer to the new customs system, passport checks across the Channel, how the UK is treated in relation to joint procurement and export blocks, UK access to the European Warning and Response System, and the Commission's decision on data transfers.

The UK government needs to show commitment to health by making regulatory and scientific provisions a priority in the final stages of negotiations. It should not be tempted to de-emphasise them because they imply a somewhat closer relationship with the EU. Refusing to come to any agreement will damage the NHS and undermine the response to Covid-19.

The EU should show its commitment to health by seriously considering proposals that would benefit European patients. It should not be tempted to use them as a bargaining chip for concessions elsewhere, or to focus on the interests of its pharmaceutical sector which may benefit from a reduction in choice.

If there is a second or even third wave in process, particularly if there is no deal or the shape of any deal is unambitious, it is worth the UK and EU exploring a treaty to delay these changes.

Nuffield Trust is an independent health think tank. We aim to improve the quality of health care in the UK by providing evidence-based research and policy analysis and informing and generating debate.

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