Health and the devolved regions and nations

Flear, M., Hayward, K., & Hervey, T. (2018). Health and the devolved regions and nations. In Brexit and the NHS (pp. 17-18). ESRC UK in a Changing Europe Initiative.

Published in:
Brexit and the NHS

Document Version:
Publisher's PDF, also known as Version of record

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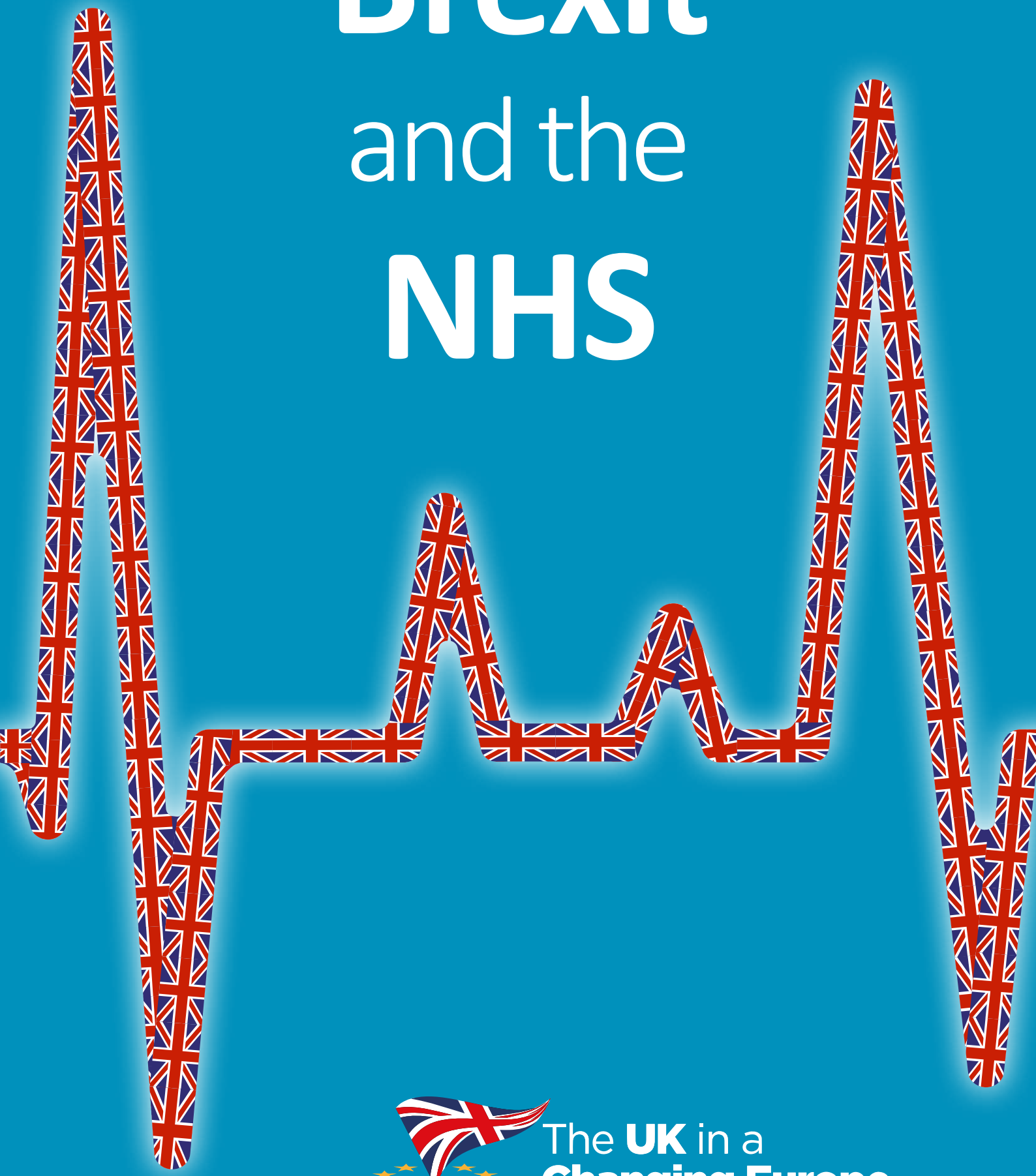

The UK in a Changing Europe

Foreword

The NHS was of course an issue during the EU referendum campaign. However, whilst its logo sat on the side of the Vote Leave bus, there was hardly what amounted to a proper debate about the possible implications of leaving the EU for the health service in the UK. Now, almost two years on, we need to address what Brexit might mean for the NHS and public health. This is no easy task.

The EU has little in the way of competence over health policy per se. Rather, membership and, by the same token, non-membership make themselves felt via a variety of more or less indirect routes, whether the implications of free movement, or of European health regulations, or the general economic situation of the country as mediated by our relationship with our EU partners. And of course we remain unclear as to what form Brexit will take, which merely adds to the complexity of the task at hand.

This report, written by academics from the team at the UK in a Changing Europe, attempts to respond to the question of how Brexit might affect the NHS and public health more generally. It was written by Catherine Barnard, Matthew Bevington, Nick Fahy, Mark Flear, Katy Hayward, Tammy Hervey, Peter Levell, Sarah McCloskey, Jean McHale, Martin McKee Jonathan Portes and George Stoye, and I would like to express my sincere thanks to all of them for their hard work.

Particular thanks are due to Jean McHale, Tamara Hervey and Mark Flear who provided much of the substance of what follows. Matthew Bevington put the report together and contributed to several parts of it, while Catherine Barnard went beyond the call of duty in checking over a draft at short notice. Navjyot Lehl, as ever, masterminded the design and production with her customary good humour and remarkable efficiency.

Professor Anand Menon
Director, the UK in a Changing Europe

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The UK in a Changing Europe promotes rigorous, high-quality and independent research into the complex and ever changing relationship between the UK and the EU. It is funded by the Economic and Social Research Council and based at King's College London.

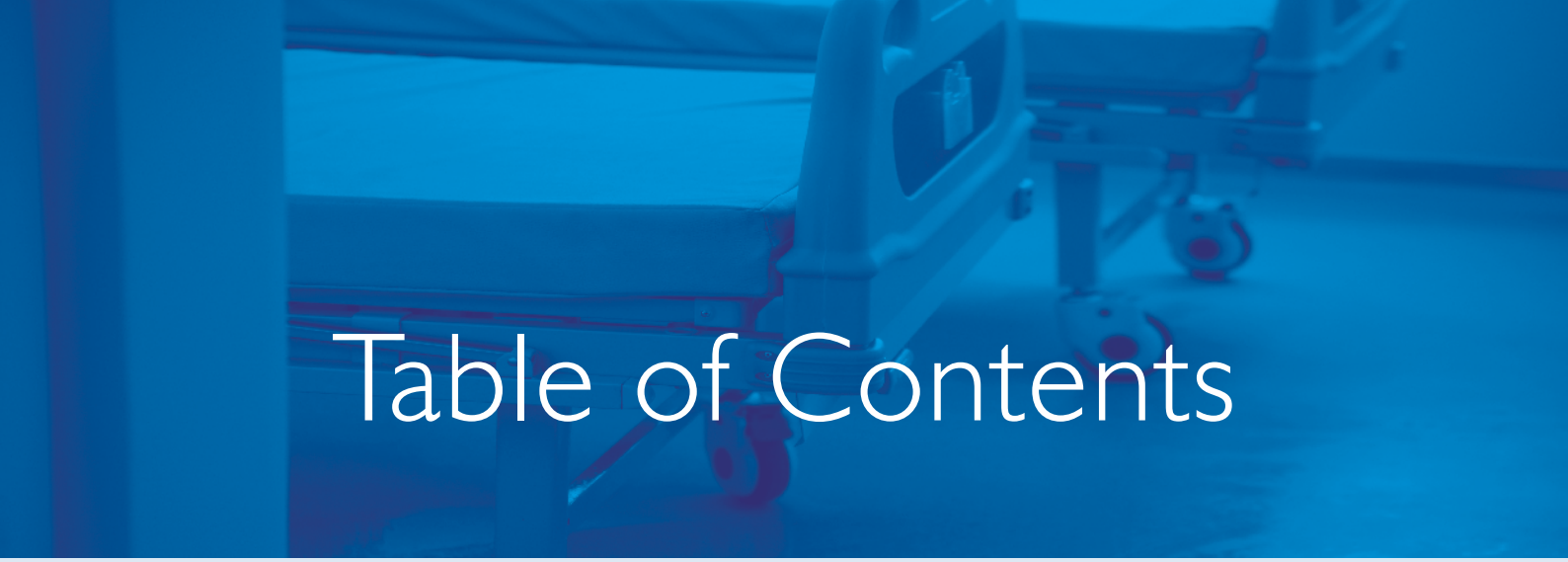


Table of Contents

Executive summary 4

Introduction 5

Brexit, the public finances and the NHS 6

Staff 8

Patients 10

Drugs and medical devices 12

Public health 15

Health and the devolved regions and nations 17

Conclusion 19

Executive summary

- **Public finances.** Brexit is forecast to mean less money for public services generally, including the NHS, due to lower economic growth and productivity. This of course comes on top of existing funding pressures. Should these pressures become more acute after Brexit, there will be direct knock-on effects on waiting times, and thus recovery rates, as well as the quality of care that can be delivered.
- **Staffing.** EU nationals play a crucial role in the health service, particularly in London, the south east of England and Northern Ireland. These are the areas most vulnerable to skills shortages should future immigration rules become more restrictive. The NHS, and social care, face the dual challenge of retaining skilled staff already in place and attracting sufficient numbers in future to fill vacancies. The government could decide to fund more training places for staff in the UK, but this will not be a quick fix and will face similar constraints from the public finances.
- **Patients.** Future arrangements will depend on a citizen's status. For UK citizens already resident in the EU, and vice versa, together with frontier workers, access to health services is likely to continue much as before. However, the potential loss of the European Health Insurance Card (EHIC) for UK citizens will mean increased costs for travellers, who in future may require health insurance. These costs are likely to impact most on the oldest and most vulnerable.
- **Drugs and medical devices.** Without special agreements on issues such as regulatory alignment and marketing approvals, the UK will lose access to many of the networks, approval systems and databases that allow these goods to flow freely between the UK and the rest of the EU. There is also a risk that the UK could become a lower priority market when it comes to the launch of new drugs. The result may be a delay in the ability of UK patients to access these products.
- **Public health.** The EU is committed to safeguarding public health. It has been influential in domestic tobacco control policy, for example, which has been critical in addressing the dangers of lung cancer. Brexit raises a concern that domestic commitment to such policies will be weakened in the future. There are also concerns about the UK's role in addressing communicable diseases across borders through participation in EU agencies. Blood, organ and tissue safety standards are facilitated by cross-border vigilance systems which the UK will not be a participant in unless specific agreements are put in place.
- **Devolved regions and nations.** Health policy is devolved to Northern Ireland, Scotland and Wales. These latter are anxious to ensure that those powers shared with the EU return to the devolved authorities after Britain leaves the EU. Brexit poses particular challenges for health policy on the island of Ireland, where healthcare integration is substantial. Changes in the wider UK-EU relationship could put at risk numerous cross-border initiatives that support public health in Northern Ireland.

Introduction

by Anand Menon and Matthew Bevington

Despite the infamous red bus, with its claim that leaving the EU would free up money for the health service, the potential impact of Brexit on the NHS received relatively little attention during the referendum campaign. The Leave side specialised in rather vague pledges of extra funding. For its part, the Remain side only managed to come up with one healthcare benefit of EU membership in its campaign leaflet: the fact UK citizens have the right to access free or cheap healthcare abroad.

Yet the campaign touched on genuine public concern. While healthcare was not an important direct determinant of how people voted, the decision by Vote Leave to link EU membership to NHS funding proved inspired. Dominic Cummings, seen by many as the mastermind of the Leave campaign, subsequently asserted that the referendum would have been lost without the £350 million per week claim on the bus.

Crucially, however, the salience of healthcare has risen since the referendum, not least because of severe winter crises. And given the all-pervasive nature of Brexit in contemporary political debates the two have, perhaps unsurprisingly, been discussed in tandem to a greater extent than prior to the referendum, albeit these debates have, in the main, been stubbornly superficial in nature.

The EU has limited direct competence over health policy, albeit that it is committed to considering the health impacts of its actions in all policy areas. Therefore, the effects of Brexit, whether positive or negative, will mostly be indirect. Changes to economic, trade and immigration policy in particular will have knock-on effects on healthcare provision and public health. Understanding these effects, and the interconnections between different policy areas, is vital if Brexit is to be a success from a health perspective. To take but one example, a malfunctioning immigration policy may lead to a malfunctioning health system.

Moreover, the sheer scale of the challenge that Brexit presents makes effective action in other areas of public policy much more difficult. Not least, the all-consuming nature of Brexit means real care must be taken to avoid falling into the trap, pointed out by the House of Lords, of allowing the political cycle to take precedence over long-term planning.

In what follows, we attempt to analyse the potential impact that Brexit will have on the National Health Service. We do not claim to be able to accurately predict the future, not least as the nature of Brexit itself remains stubbornly opaque. However, it is possible to analyse, based on the state of the negotiations and the positions of the two sides, what possible effect the decision to leave the EU will have on healthcare in this country.

Brexit, the public finances and the NHS

by Peter Levell and George Stoye

Regardless of Brexit, the NHS will face increasing demand and cost pressures. The Office for Budget Responsibility (OBR) recently projected that NHS spending would need to increase by 5.3% of national income over the next fifty years in order to meet increasing demand for its services and other cost pressures—a sum equivalent to about £110 billion in today's money. This includes meeting the challenges from a growing and ageing population, as well as the cost of new technologies and treatments, pressures that are common to public and private health systems across the world.

Such increases would be in line with historical increases in NHS spending, which rose from about 3% of GDP in the 1950s to about 8% in 2009-10, but would be far above those of the past seven years. Since 2009-10, real growth in NHS spending has averaged only 1.1% a year. Calls for greater funding have increased recently amid evident signs of strain, including longer waiting times and more cancelled operations.

The immediate effects of the referendum have increased these pressures. The depreciation of sterling has raised the costs to the NHS of goods and supplies that are imported, and the resulting inflation has eroded the real value of public-sector workers' pay. Simply compensating NHS staff for this increase in prices would cost around £1 billion in additional salaries. Indeed, in the November 2017 Budget the Chancellor announced that the public-sector pay cap would end for most NHS staff, at an expected cost of around £700 million in 2017-18. Finding additional funds to cover such increases in future will obviously affect the amount of healthcare that can be provided within a given budget.

Given this context, it is hardly surprising that NHS funding has not only been a consistently salient political issue but also figured prominently in the 2016 referendum campaign. This famously included claims that all of the UK's gross contribution to the EU budget—currently some £19 billion per year, or £360 million a week—could be diverted to the NHS.

However, these figures are misleading. There are a number of reasons why the full £19 billion will not be available. First, this figure includes the UK's rebate—currently about £5 billion of the full amount—which has already been allocated domestically to the government's priorities and simply cannot be spent again. The remaining £14 billion could theoretically be redirected to the NHS, but this figure also helps to fund EU spending in the UK (for example on farming subsidies) that the government has already pledged to maintain for some years.

The size of the UK's net contribution to the EU after taking into account both the UK's budget rebate and existing EU spending in the UK is about £8 billion. This represents a more realistic estimate of the sum that could be redirected to domestic priorities, including health spending. But even this does not take into account future payments that the UK may wish to make to the EU to ensure continued market access and participation in EU projects. In the short term, assuming some kind of transitional

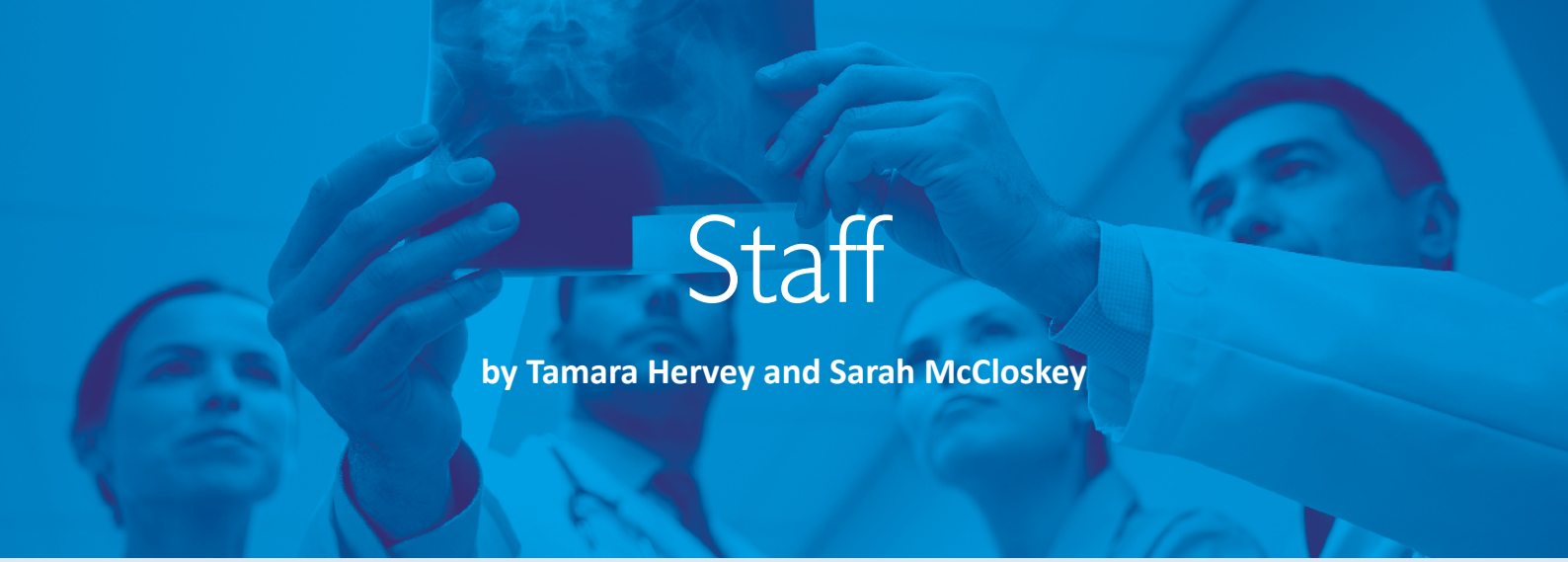
period is agreed, the UK will continue to contribute a significant amount to the European Union and there may also be some additional payments as part of a "divorce bill" to settle various bills.

Perhaps more importantly, the impact of Brexit on the wider economy is likely to have more bearing on the future funding of health services than any sum the UK might recoup from reduced EU contributions. Brexit represents a fundamental shake-up of the UK's relationship with its largest trading partner. If, as most economists expect, this reduces economic growth over the medium to long term, the loss to the Exchequer will almost certainly outweigh the reduction in our EU contributions. A reduction in GDP of just 1% translates to a fall in tax revenue of more than £8 billion (the amount that could conceivably be saved by ending budget payments to the EU).

The OBR has already incorporated some, but not all, of the potential impacts of Brexit into its forecasts. In the November 2016 Autumn Statement, it downgraded its forecasts for investment, productivity growth and immigration, and raised its inflation forecast relative to what it predicted in the event of continued EU membership. The implied hit to the public finances is about £15 billion per year by the early 2020s—about 10% of the NHS budget (and almost double any possible saving from ending budget payments to the EU). This is despite reduced investment having only a modest impact on tax receipts, as investment is taxed less heavily than consumption. Should this, over time, feed into lower company profits, the long-run increase in the deficit could be of the order of £3.5 billion. In other words, the potential macroeconomic impact of Brexit is such that it might reduce rather than increase the funds available for the NHS (and other public services), in both the short and long term.

Of course, all forecasts must be taken with caution. Growth since the original OBR forecast has so far been slightly stronger than expected (although the medium-term outlook is now gloomier than it was in November 2016). The fact we do not yet know what the UK's post-Brexit relationship with the EU will be also increases uncertainty about the longer term impacts. However, the OBR forecast is predicated on a relatively smooth transition, putting it at the optimistic end of the spectrum. In a 'no deal' scenario, in which the UK reverted to World Trade Organisation (WTO) rules in its trade with the EU, the economic dislocation would be much larger. Moreover, the OBR has not yet incorporated any longer-term negative impacts of Brexit on productivity, and some economists expect these to be significant.

In short, Brexit is likely to mean less money for public services, including the NHS, than otherwise would have been the case. Although the NHS budget may continue to rise in real terms, it is more likely than not that lower economic growth will take away funds that would otherwise have been available for additional spending increases. Even without Brexit, addressing the pressures on NHS funding would likely have required significant tax increases, extra borrowing or diverting more money away from other services. Brexit will make responding to these challenges even more difficult.



Staff

by Tamara Hervey and Sarah McCloskey

Free movement of people within the EU has had a significant impact on staffing within the NHS. Approximately 200,000 EU27 nationals work in the wider health and care sectors—about 5% of the total workforce. EU27 staff are pivotal to the operation of the NHS, especially in London, the South East of England and Northern Ireland.

The UK has never trained enough doctors for its own needs—some 28,000 doctors are non-UK nationals, around a quarter of the total. NHS England alone depends on some 11,000 doctors from the EU27, which amount to about 10% of all doctors. Add in the further 20,000 NHS England nurses and around 100,000 social care staff from the EU27 and the sheer scale of reliance on EU migrant workers becomes clear.

In anticipation of a 'Brexit effect', the NHS has already invited bids for a £100 million contract to recruit overseas doctors into general practice. And this in a context in which the NHS already has many unfilled posts. Restrictive rules on recruiting non-EU nationals are already causing problems for the NHS, and extending these to EU nationals will aggravate the situation.

The uncertainty posed by the Brexit negotiations to date has already affected staffing levels: the Royal College of Nursing reported a 92% drop in registrations of nurses from the EU27 in England in March 2017, and attributed this, at least in part, to "the failure of the government to provide EU nationals in the UK with any security about their future".

This is also a concern in the life sciences sector, which includes health and pharmaceuticals research and employs around 5,000 EU nationals. Should recruitment become problematic, this might in turn affect the pharmaceutical sector in particular, where access to necessary skills is a crucial factor in determining investment.

Prior to the 2017 election, the government promised to "make it a priority" during the Brexit negotiations to ensure that "staff from EU countries can carry on making their vital contribution to our health and care system." However, the Joint Report on progress in the Article 50 talks, published in December, provides protection merely for those already in post, not those who might be employed in future.

After Brexit, staff coming to work in the NHS may be subjected to the same citizenship rights criteria as the UK negotiates for all EU27 nationals. The UK's negotiating position outlines its intention ultimately to shift EU citizens simply to "non-UK" status. The Nuffield Trust has warned of potential damage if the UK's future immigration system is overly restrictive. This might mean that vacancies are not filled, and EU nationals already working in the health service will face ongoing uncertainty about their status. The imposition of additional barriers to potential NHS staff from the EU might also make it harder to recruit staff from these states. If European Economic Area nationals have to pay the immigration health surcharge – currently paid by non-EEA nationals staying in the UK for six months or more to allow access to the NHS – this will obviously represent an additional cost.

Whatever the promised new Immigration Bill provides, unless NHS and social care workers are placed in a special category, they will be vulnerable to measures designed to limit immigration. All depends on the definition of the proposed excluded category of "low-skilled migrants". Should this include Category 6 workers, such as senior care workers and nursing assistants, this might place extra pressure on the NHS. Moreover, such a restriction would also affect others indirectly involved in healthcare provision, including security guards, caterers, launderers and cleaners.

The government has said that in agriculture the case for a deal to facilitate the arrival of seasonal workers to support the needs of farmers is "compelling". There is clearly a difference between the arrival of temporary farm staff and what would be permanent NHS and social care staff, but this demonstrates that in principle it may be possible to secure a deal for certain health professions within the future immigration system.

However, potential threats to NHS staffing levels go beyond immediate concerns about immigration. Decisions about future regulatory alignment in services will determine whether the qualifications of medical professionals will continue to be mutually recognised between the UK and the EU27. Some see this as an opportunity to reset national standards. However, this is often based on a misunderstanding of the autonomy the NHS already enjoys. Rules related to English language capabilities have been in place to secure patient safety throughout the UK's membership of the EU. But there is clearly a trade-off between patient safety as served by restrictions on healthcare professions and patient safety as served by having a workforce sufficient to meet the country's needs.

Beyond staff numbers, Brexit may affect the working lives of health and social care professionals if changes are made to *EU-retained law* concerning working conditions. Currently, health and social care staff are protected by numerous employment rights derived from EU law, including non-discrimination at work, maternity and paternity leave, and security of rights where another employer takes over a contract to provide services.

The NHS Employers organisation sees this is as an opportunity to bring about positive change by replacing prescriptive rules that can hamper the efficient functioning of the health service. Others, including over a dozen Royal Colleges, insist these protections must be retained. The Working Time Directive has presented challenges in health and social care, and remains a source of controversy within the profession. It has attracted much criticism—including from former UK Prime Minister David Cameron—because of its perceived rigidity. Nevertheless, junior doctors have sought to guarantee its explicit inclusion in their new national employment contract.

Finally, pressures on staffing might pose a challenge when it comes to maintaining the UK's position as the European hub for life sciences. The success of this collaborative work hinges on the mobility of researchers and harmonisation of regulations.

Patients

by Tamara Hervey, Sarah McCloskey and Mark Flear

The current system for patients in the EU is based on reciprocal rights and freedom of movement. EU law seeks to remove any barriers that healthcare provision (or the lack thereof) could pose to EU citizens or their families visiting or living in another EU country. The government has acknowledged that it is attempting to achieve the same reciprocal healthcare benefits when the UK leaves the EU as currently exist.

Under current arrangements, each EU member agrees to reimburse any other EU member that treats people covered by its public health service. The principle is that visitors are treated in the same way as locals. The system covers migrant workers, border and frontier workers (those who live in one country but travel across a border for work) and people visiting for work and leisure. This rights-based cooperation facilitates access to healthcare for those with chronic health conditions, retirees and tourists. It also improves service efficiency.

Northern Ireland and Ireland provide perhaps the best example of how this works. Services designed for both sides of the Irish border meet collective healthcare needs in the area. Sexual health, diabetes and eating disorders are all treated in this way, with integrated services offered to patients in both Northern Ireland and Ireland. For instance, the radiotherapy centre at Altnagelvin Hospital in Derry/Londonderry is accessible to patients in County Donegal in the Republic who would otherwise have to travel long distances—to Dublin or Galway—to obtain the same treatment.

EU integration has also enabled economies of scale across the Irish border, such as the sharing of key healthcare services, particularly where specific expertise and facilities are not viable in a small region such as Northern Ireland. In 2014 the Northern Irish and Republic health ministers agreed that there would be a joint child heart facility established in Dublin. Between January and September 2017, 23 children travelled from Northern Ireland to Our Lady's Children's Hospital in Dublin. Such cooperation is facilitated by the EU Directive on the mutual recognition of professional qualifications and on EU rules on data protection that enable the sharing of patient details. It is possible that access to these shared facilities and similar ones (such as the North West Cancer Centre) can be facilitated by the future UK-EU relationship and even bilateral UK-Ireland arrangements under the Common Travel Area.

The European Health Insurance Card (EHIC) allows visitors to another EU country to access healthcare in that country. The EHIC applies even to those with disruptive chronic conditions. For instance, it allows the UK's 29,000 dialysis patients to arrange in advance to have treatment in any EU/EEA country, although this depends on the necessary resources being available. There are no official figures for the number of people who take up this opportunity, but Kidney Care Dialysis Freedom has arranged for around 1,700 patients to travel to the EU in the past two years. Kidney Care UK thinks this is likely to be an underestimation of the actual figure. People can also access specialist medical treatment in another EU country with the permission of their home state (S2 registration).

Most importantly though, EU nationals living in another EU country can access the treatment they need (S1 registration). Around 190,000 British pensioners live in the EU27 and rely on these reciprocal healthcare arrangements. The UK contributes about £500 million annually towards their care and receives £50 million for care provided to EU nationals in the UK. Average treatment costs for UK pensioners in the UK would be about double that of paying for their treatment elsewhere in the EU, mainly because of patient co-payments. If the UK did not conclude a Withdrawal Agreement with the EU, and were all these pensioners to return to the UK, the NHS would need some 900 additional beds to ensure sufficient capacity.

Under the terms of the Joint Report, those visiting another EU member state on exit day would still be covered by the EHIC. For everyone else, access to the EHIC will depend on the terms agreed with the EU under the Withdrawal Agreement and on the future relationship. It is not clear what will happen on the island of Ireland.

It is possible that the UK will negotiate access to the EHIC as part of the future UK-EU relationship. But should it fail to do so, UK nationals who want to travel to the EU in the future—some 53 million visits from the UK to the EU27 take place each year—will have three options: they could purchase private travel insurance, travel without insurance and risk significant healthcare bills or simply not travel at all. The Association of British Insurers (ABI) has estimated that, if the EHIC is withdrawn, the cost of treating UK citizens abroad will be about £160m.

For some, purchasing private insurance will not be an option. For example, any private travel insurance that is available to dialysis patients will be extremely expensive. For those who can get insurance, older people—who are already the biggest spenders on healthcare—will face the steepest costs. According to the ABI, the average cost of health insurance claims for those over 66 is almost three times higher than for those under 30.

The government could offset some of this by mandating a basic healthcare package for travel insurance, though there is no equivalent system for travel to other countries. Such a scheme is, however, used in the Netherlands for basic healthcare. Typically, there is a set fee for all customers, regardless of their age or risk profile, and all insurers must offer the same package and accept everyone who applies. However, such cover would not include more complex conditions, which older people are more likely to have, and consequently they would still incur additional costs.

The government may also be unwilling to intervene in the health insurance market, or to shoulder the fiscal cost of administering such a scheme. However, given that three-quarters of all visits abroad by UK residents are to the EU, a basic travel insurance package could cover the vast majority of UK travellers. But this would still be a cost that they do not currently have to meet while covered by the EHIC.

Drugs and medical devices

by Jean McHale and Matthew Bevington

EU law underpins the regulation of pharmaceuticals in the UK. Medicines are approved via one of two routes, a centralised or a decentralised process. Under the former, drug approvals are issued by the European Medicines Agency (EMA) and are valid across all member states. Under the latter, approval can be given by the equivalent authority operating within each member state. In the UK, this is the Medicines and Healthcare Products Regulatory Agency (MHRA).

Where medicines are subject to the decentralised process, the MHRA already has operating and approval systems in place. However, certain pharmaceuticals, such as orphan medicines, which are used to treat a relatively small number of patients who suffer from rare diseases, are not subject to the decentralised process. They must be authorised centrally by the EMA. Unless there are special agreements put in place post-Brexit, the implications would be serious.

First, unless this is subject to a specific sectoral deal, the UK would not have access to cross-EU monitoring and notification systems for pharmaceuticals. This loss of access is indicated in the Commission's draft Withdrawal Agreement of February 2018. Second, pharmaceuticals produced in the UK would not necessarily be approved for use across the EU. Third, the MHRA would need to establish its own specific measures to enable such approvals at the domestic level. It appears from evidence to the Health Select Committee in January that the MHRA is already planning for this. It is important that the UK government ensures that the MHRA has the necessary resources and support to undertake this increased workload.

Fourth, it would be in the UK's interests to ensure, as far as possible, alignment of standards with the EU to facilitate production and marketing of pharmaceuticals, at least for the near future. This is to prevent any adverse impact on patient safety and on the pharmaceutical industry. Such alignment has been strongly advocated by pharmaceutical companies operating in the UK in evidence to Select Committees. Linked to this, once the UK leaves the EU it will not be part of the EU pharmacovigilance networks, unless there is a specific sectoral agreement reached.

Practical concerns have also been raised about the future status of the UK as a market for new drugs. There is a danger that it would be regarded as a comparatively low priority market given its size relative to the EU and the US. New drugs might be less likely to be launched in the UK, therefore taking much longer to reach patients.

Health secretary Jeremy Hunt has suggested that drugs approved for sale in Europe would be automatically licensed in UK, but this would by no means guarantee equivalent treatment of UK-based products on the EU side. Nevertheless, such a move would speed up the process of getting new products onto the UK market.

However, such an arrangement would raise accountability issues. The UK would be entirely dependent on the regulatory procedures of the EU without any meaningful say over how they were designed and implemented. UK authorities would be responsible for any dangers to public health arising from the sale or use of EU-based products without any power to hold regulators to account, which might prove politically unsustainable.

The Prime Minister went further in her Mansion House speech in March, suggesting that the UK would be seeking access to the EMA, among other agencies, via associate membership. Whether this can be achieved in practice is not clear, as such third country status has not been afforded in the past.

If it can't be achieved, this would affect the 274 small and medium-sized pharmaceutical enterprises based in the UK that are registered with the European Medicines Agency, the EU's medicines regulator, and the 427 products that are centrally authorised and authorised for sale from the UK. For these products, without a comprehensive sectoral agreement that maintained current levels of regulatory alignment and mutual recognition of authorisations, all would have to be transferred to EU-based authorisation holders to continue being sold in the EU. The EMA has indicated that these transfers must be completed by the time the UK leaves the EU in March 2019.

Moreover, when it comes to trade deals with other states there is enormous uncertainty about what access foreign pharmaceutical companies might be granted to the UK and what access UK firms will enjoy abroad. Such questions will be the subject of negotiation during trade talks with third countries.

In terms of a future agreement with the US, there has been considerable criticism of the deal Australia signed with the US in 2004 particularly when it comes to the terms related to pharmaceuticals. That agreement contained greater protection for intellectual property (IP) rights, including patents, which benefitted those US pharmaceutical producers which held patents for the drugs they produced. This in turn impacted on those companies that produced generic drugs, limiting their ability to sell cheaper versions of the patented products.

The vast majority of drugs bought in the UK are generics, which account for 84% of the pharmaceuticals sold. Were similar provisions to be included in a future trade deal with the US—and a pharmaceuticals chapter would likely be included—then prices for both the public and the NHS could rise if rules favoured patent-holding firms over generics businesses.

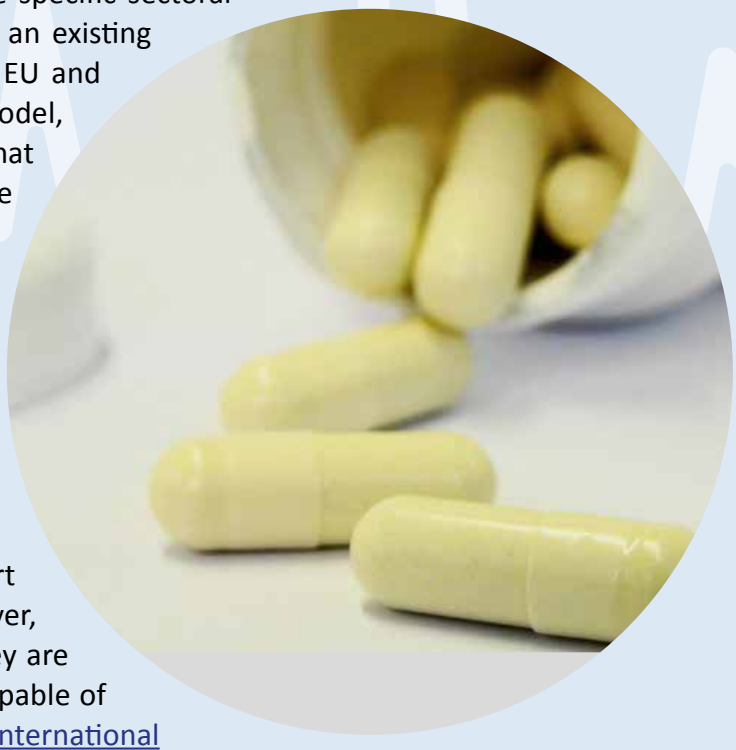
Clinical trials concerning pharmaceuticals are currently subject to the EU Clinical Trials Directive. This led to the first statutory requirement in the UK for a range of regulatory procedures in the area of clinical research on humans, including requirements concerning mandatory research ethics committee

approval and informed consent. This is due to be replaced by a new EU regulation, to be implemented in 2019, after the UK leaves the EU, although the terms of the transition period, or domestic legislative choice, will determine whether or not it is brought into UK law.

One aspect of this regulation is a new cross-EU computer database into which all clinical trial applications will have to be entered in order to be valid. Depending on the terms of a transition period, the UK may need to implement the regulation. Although this would ensure alignment post-Brexit in terms of approval criteria, it would not enable the UK to have access to the database unless a specific sectoral agreement was reached. The absence of such an agreement could jeopardise the work of UK researchers who want to undertake cross-EU clinical trials. However, the MHRA has indicated that it does not see this as a major issue, as international clinical trials are undertaken with collaborators across jurisdictions.

Turning from pharmaceuticals to medical devices, the approval of these is delegated to commercial companies, known as "notified bodies". These operate in different member states and provide approvals that are valid across the EU. The role and operation of these bodies has come under some criticism. Incidents such as the Poly Implant Prostheses breast implant scandal, when the use of unauthorised silicon in some implants led them to rupture, have helped to drive reform in this area. Medical devices regulation is due to be tightened through two new EU regulations set to come into force in 2020 (general devices regulation) and 2022 (in vitro devices regulation).

Part of these reforms will be accompanied by a new EU-wide electronic monitoring system, through the EMA, which will develop and expand existing databases. In addition, another database containing information on medical devices will be linked to the new EU Clinical Trials Database. Continued access to these databases post-Brexit would require specific sectoral deals. However, for medical devices there is an existing mutual recognition agreement between the EU and Switzerland that may provide a possible model, although the EU has so far remained firm that the Switzerland model is not on offer for the UK's future EU relationship.



Major uncertainties also remain in relation to access to other EU systems that affect patient health. For example, in leaving the EU the UK will be leaving Euratom, the EU atomic agency community. Concerns have been expressed as to whether this may result in problems in accessing radioisotopes used in cancer treatment, which have very short half-lives and cannot be stockpiled. However, the government has argued that because they are "not fissile nuclear material", and thus not capable of reacting, they would in any event fall outside international nuclear safeguards. Again, in her Mansion House speech, the Prime Minister made reference to the benefits of a close working relationship with Euratom but was unspecific about how this may be achieved.

Public health

by Jean McHale

Any departure from the EU approach to regulating health and social care will have significant consequences given the complex arrangements that are in place in these sectors. In biomedical research, for example, UK organisations are currently the largest beneficiaries of EU health research funds in Europe; EU research funding via the Horizon 2020 programme has benefitted the NHS; and EU collaboration in clinical research has generally been to the advantage of UK healthcare.

The EU's common legal frameworks—for instance, on data protection, human tissue regulation and the safety of clinical trials—underpin that collaboration. The Prime Minister in her Mansion House speech mentioned the prospect of a "far-reaching science and innovation pact with the EU, facilitating the exchange of ideas and researchers", with payment for access. Whether this will be welcomed by the EU is another matter. Its agreements with Switzerland over participation in such research programmes have been fraught, and it is questionable whether the EU would want to reciprocate the enthusiasm of the Prime Minister on this issue.

The EU has played an important role in the development of domestic public health law and policy. For instance, while some aspects of tobacco control policy are matters for domestic law—such as the ban on smoking in public places—tobacco control in general is affected by EU Law. The EU Tobacco Products Directive regulates a range of matters, including tobacco advertising and nicotine levels in tobacco. The Directive also addresses matters concerning trade in illicit tobacco, with measures directed at tracking and tracing tobacco products. It is important that the UK's commitment to tobacco control does not become weakened after it leaves the EU.

The safety and quality of donated blood, tissue, and cells and organs are also subject to EU regulation. The three main directives in this area, operating alongside a number of related directives, set out minimum quality and safety standards. Establishments dealing with blood, organs or tissue need to be accredited, designated, authorised or licensed, and inspected by the relevant authorities of member states (such as the Human Tissue Authority in the UK) for the procurement, testing, processing, preservation, storage or distribution of human blood, tissues and cells.

Further provisions relate to the clinical selection of donors, information and consent. The Directives have also led to the introduction of standard operating procedures for the donation, procurement, packaging, labelling and transportation of human materials. Some of these safeguards will remain in domestic law through the EU Withdrawal Bill, unless amended by ministerial action as the Bill will allow. A proposed amendment to the Bill seeks to secure that Brexit will 'do no harm' to health.

In other areas, however, reciprocity is required for the system to operate. For example, certain safety issues are targeted through specific cross-EU rapid alert systems, such as the Rapid Alert System for Human Tissues and Cells (RATC) and the Rapid Alert System for Blood and Blood Components (RAB). These enable information regarding adverse reactions to be shared quickly across member states.

The UK would not have access to these rapid alert and information systems unless there were specific sectoral agreements in place. The Commission's draft Withdrawal Agreement, published in February, indicates that the UK would not have access to such computerised databases post-Brexit.

The UK currently exports organs for transplant to other EU member states, with some organs being transferred across the border between Northern Ireland and the Republic of Ireland. It is important that steps are taken to maintain such exchange systems after the UK leaves the EU. The EU is also strongly against commercial dealing in human materials and parts. Provisions to this effect are contained in the EU Charter of Fundamental Rights and also in relation to the specific blood, organs and tissue directives. While at domestic level, in relation to organ transplants, the UK has also been opposed to commodification, it is important to ensure that such commitments are not weakened once the UK leaves the EU.

On communicable diseases, the EU has its own agency, the European Centre for Disease Prevention and Control (ECDC), which is concerned with identification, assessment and communication of threats. It undertakes a Health Security Initiative, which requires notification of health threats with the Health Security Committee, having a legal basis to act on such threats. The EU's role in this area is still evolving and the main instruments in relation to disease prevention derive from international law. Nonetheless, after Brexit the UK will not have access to such EU networks, which remains a major concern.

Data Protection is a further topic where the EU has been particularly influential. In UK domestic law there have long been commitments to safeguard the confidentiality of patient information through the equitable remedy of breach of confidence, which is today also bolstered by protection through the Human Rights Act 1998. However, data protection law also provides specific safeguards in relation to individual data access and control.

Currently, the law in this area is being reformed through the introduction of the General Data Protection Regulation and the Data Protection Bill 2017, implementing EU law. While initially the UK will therefore in many respects be aligned with EU law, the question is what happens longer term.

The structure of the legislation would enable comparatively straightforward amendments post-Brexit. In the Mansion House speech in March 2018, the Prime Minister emphasised the importance of Data Protection and the need for specific agreements and a role for the Information Commissioner. It remains to be seen to what extent the EU is prepared to accept the UK's proposals on this. It is important that commitment to patient autonomy and control of access to their own personal information is not put in jeopardy in the future.

Health and the devolved regions and nations

by Mark Flear, Katy Hayward and Tamara Hervey

Within the UK, public health and the NHS are largely the responsibility of the devolved regions and nations. England, Scotland, Wales and Northern Ireland (NI) have therefore developed their own distinct laws and policies. Some areas of England are also experimenting with forms of devolution.

The UK's withdrawal from the EU means that powers currently exercised at the EU level will be repatriated to the UK. The EU Withdrawal Bill had anticipated that even those EU laws currently implemented by the devolved institutions would, in the first instance, be returned to the UK government. However, David Lidington, the minister overseeing the devolution settlement from Brexit, has said that the Bill will be changed to ensure powers return to the devolved administrations initially. The Scottish and Welsh governments dismissed the offer out of hand. Negotiations are ongoing and there is still a lack of clarity about how these competences will be redistributed back to the devolved level.

This is extremely important given that health is a devolved matter that is currently deeply affected by EU law. The UK Government has found that there are 141 areas of overlap between EU and devolved powers in Northern Ireland, 111 in Scotland and 64 in Wales. The full lists are not transparent, but Institute for Government analysis suggests that a majority of these policy areas concern the environment and transport, while several cover matters for which the Department of Health is responsible.

Over the past twenty years, distinctive health policy in areas such as minimum alcohol pricing, obesity and tobacco regulation has developed in the devolveds. While the expectation had been that effective policy in these areas would require further devolution of powers, the trend towards centralisation indicated by the EU Withdrawal Bill means there are at least two significant shifts to bear in mind.

The first is a shift in the context for health policy in the devolved regions and nations in future. The Bill, in its current form, makes the UK level more important in that the powers repatriated from the EU will initially be placed there. There is the possibility that some of these powers could be 'released' to the devolveds, but this would be at the discretion of UK ministers. The second shift is that the devolveds will have less ability and scope for action where powers are not released to them. In addition, the use of UK-wide frameworks covering areas where EU and devolved powers currently intersect limits the devolveds' ability to act if it is deemed to undermine the UK 'common market'.

There are concerns that Brexit might have a negative impact on population health in the devolveds. In Wales, the withdrawal of EU funding might have a long term adverse impact on the determinants of health. In Scotland, several health projects have benefited from EU funding under the Interreg programme, which will cease by the end of any transition phase.

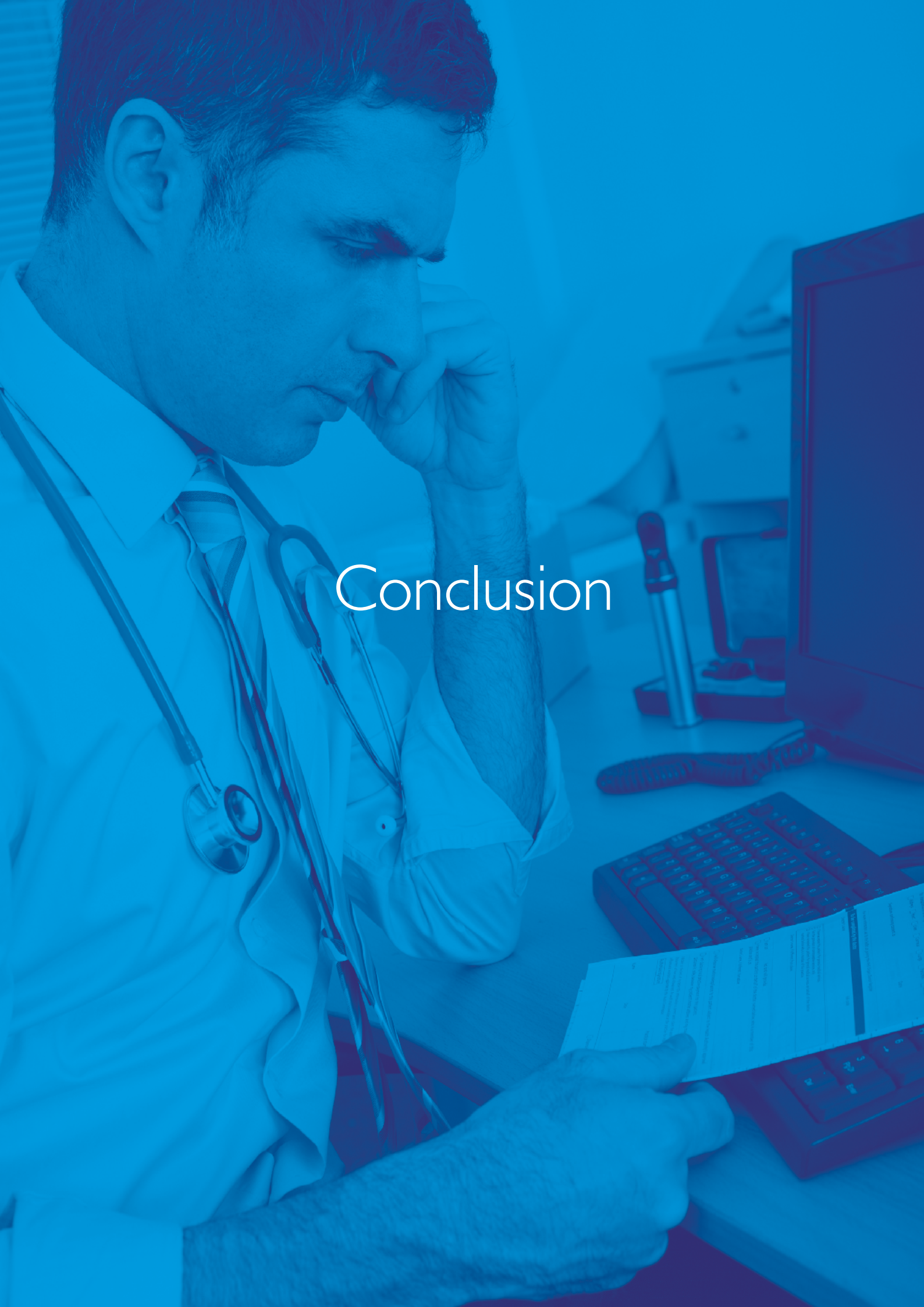
EU rules on reciprocal rights and the free movement of goods and people are currently vital for the provision and delivery of health services. Many of these rules are applied and administered at the level of the devolveds. The fact that EU27 nationals will become overseas nationals following Brexit

means that the rules that apply to them when they access NHS treatment (so-called overseas charging rules) will change. However, these rules currently differ in Scotland, Wales and Northern Ireland, and until there is clarity over which competences will return to the devolveds we have little idea what the future arrangements will look like.

Despite the different health systems in Northern Ireland and the Republic of Ireland, cross-border integration is clearly evident in healthcare. We have already discussed some of the aspects of this above, but the circulation of health-related goods and services, health professionals and patients, and the sharing of some facilities and funding across the Irish border will be challenged by Brexit. For example, unhindered by border checks and supported by reciprocal arrangements between healthcare providers in NI and the Republic of Ireland, an ambulance can travel to wherever is closest and best for any particular patient on either side of the border. Such arrangements would be in doubt if a 'hardening' of the customs border between the UK and the EU produced restrictions on the movement of pharmaceutical products or medical devices, or even medical staff.

EU funding under the Regional Development Fund and the PEACE programme has supported the provision and development of health-related services in NI, across the NI-Republic border and in Western Scotland. For example, Interreg Europe funding supports the cross-border partnership of Cooperation and Working Together (CAWT). Up to 2015 CAWT had delivered 12 large-scale projects and services, 121 new services had been implemented to the direct benefit of 53,000 people, and an additional €30 million had been invested in health and social care. The UK-EU Joint Report in December 2017 pledged that future support for NI through PEACE and Interreg would be 'examined favourably'. But this agreement is yet to see legal form and it leaves uncertainty for similar projects in Scotland.

The direct importance of the context, funding and laws of the EU for a wide range of health services and provision is evident in all of the devolved regions and nations. This adds a layer of complexity to the process of withdrawal that cannot be dealt with adequately on an all-UK wide basis.



Conclusion

The impact of Brexit on the NHS and public policy will hinge on a number of factors. Clearly, the state of the UK government's finances will be crucial in determining future health provision. In common with the broad consensus among independent economists, and the official forecasts produced by the OBR, our analysis does not foresee any dividend for the NHS from the UK leaving the EU.

On the contrary, there are likely to be further pressures on public-service funding more broadly from a hit to economic growth caused by Brexit. This will mean tough choices for the government. It could decide to increase healthcare funding, but this will have to come from raising taxes, borrowing or diverting funds from other priorities.

The UK's decision to leave the EU has not created the funding pressures on the NHS, but it is likely to exacerbate them. Similarly, should funding pressures become more acute after Brexit, there will be direct knock-on effects on waiting times, and thus recovery rates, as well as the quality of care that can be delivered.

Brexit is also likely to worsen existing staff shortages, potentially reducing service quality. There has already been a fall in the number of EU-origin nurses, attributed at least in part to uncertainty about their future status. Longer term, the NHS and the social care sector are dependent on immigration policy for fulfilling staffing needs, and it is as yet unclear what this policy will be. The risks, however, are evident.

The government may decide to put greater funding into training places for doctors and financial support for training nurses, as well as other support staff. However, the budget constraints alluded to above stand here too. The UK has benefitted greatly from importing skilled health workers that other countries have paid to train. There is a balance to be struck between an immigration regime that provides enough skilled workers on the one hand and training sufficient staff in the UK to fill vacancies on the other. However, the latter does not represent a quick fix, as training takes the better part of a decade.

Reliance on EU staff differs widely across the UK. This means that we should expect different areas to experience different levels of disruption, with London, the south east of England and Northern Ireland most likely to be affected. It should also be noted that our analysis does not cover social care in any depth, which will be particularly badly affected if future immigration requirements become more restrictive for key personnel in this sector.

For patients, there are likely to be disadvantages from leaving the EU, mainly by virtue of losing access to healthcare in their country of residence (especially for pensioners) or to the EHIC. Although the EHIC itself is by no means comprehensive, it does offer security to UK citizens travelling to the EU, who make up the vast majority of UK visitors abroad. This is not to say that some form of reciprocal healthcare agreement cannot be reached, but it would probably only cover current EHIC holders, and for future patients probably be more limited in scope than it is now. Although agreeing this individual measure may seem eminently achievable in isolation, dozens if not hundreds of such agreements will be required to maintain current benefits in the health policy area alone.

In sum, the effect of these changes is likely to increase costs for UK travellers to the EU by virtue of requiring health insurance, which itself will be more expensive than it would have been without the EHIC behind it. Those worst affected will be the elderly and those with serious underlying conditions, who may not qualify for health insurance or for whom it will be expensive.

Furthermore, Brexit might impact on the socioeconomic determinants of health, such as employment, income and living costs. A recent paper found that the life expectancy of a boy from the richest fifth of neighbourhoods in England was 8.4 years higher than that of a boy from the poorest fifth; for girls

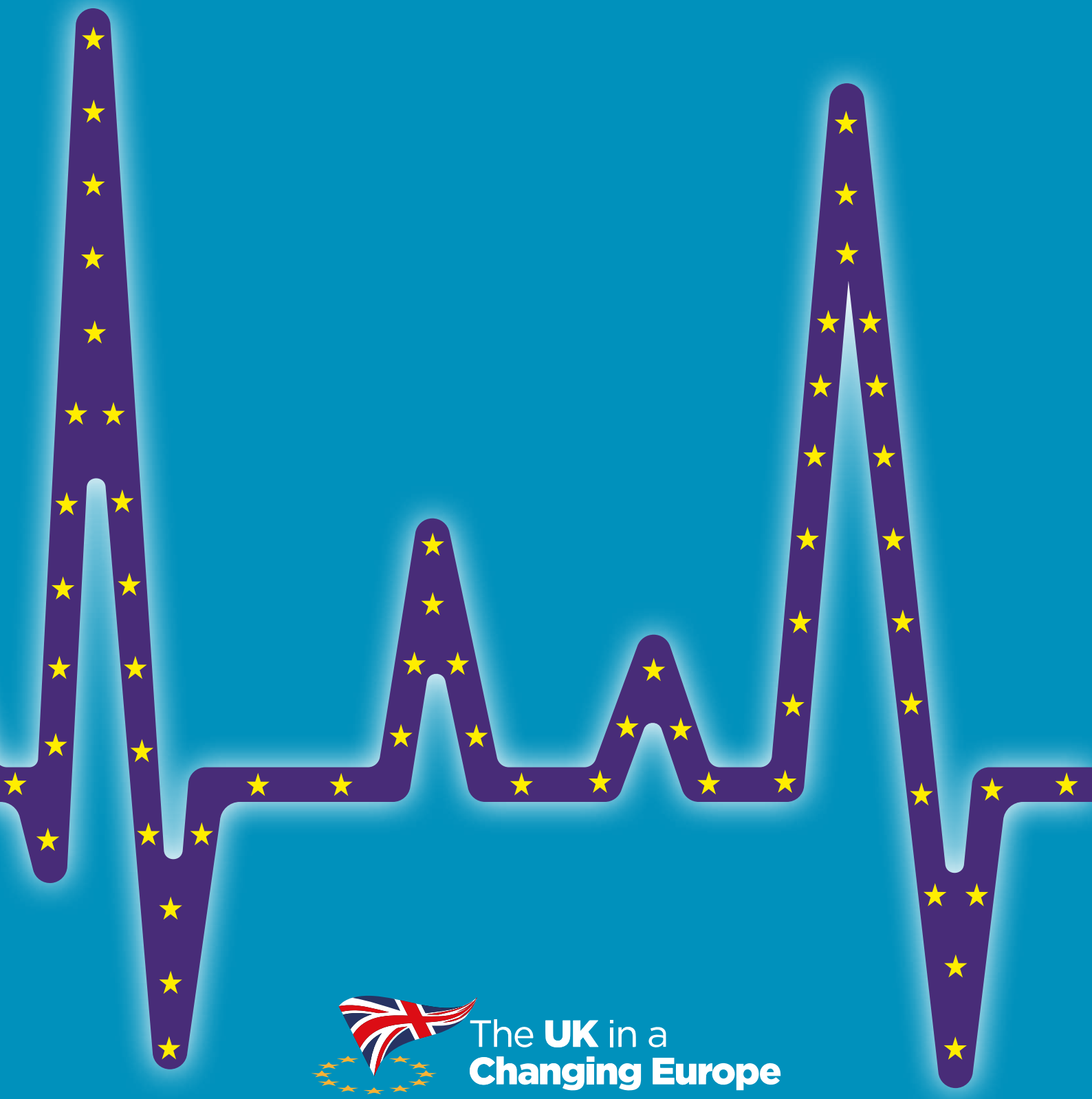
this gap was 5.8 years. Although this is a complex issue, and many other factors as well as the UK's relationship with the EU will drive changes, most economic analysis suggests that there will be a hit to the UK economy from Brexit, which will translate into worse health outcomes. Wealth and health are very closely connected, so it follows that if the population becomes less wealthy, then health outcomes will be affected.

It is too early to say what degree of alignment will exist between the UK and the EU after Brexit. There are numerous health systems and databases, such as the Clinical Trials Database and the Rapid Alert System for Blood and Blood Components (RAB) that will require specific agreements in order that the UK retain access. This issue is particularly acute on the island of Ireland, where the two healthcare systems are well integrated. Although specific agreements allowing, say, ambulances to operate across borders would conceivably be possible, any restrictions on the movement of healthcare goods, services and people will be to the detriment of patients on both sides of the border.

There are wider concerns from the devolved governments that areas of healthcare competence previously held at EU level being recentralised will shift the balance of policymaking powers, jeopardising existing projects funded through EU projects and having wider impacts on the socio-economic determinants of health.

Yet it will be the detail of the agreements that the UK will need to sign with the EU that will be decisive for public health and the NHS. We have set out what we consider the central areas that need to be addressed in order for the NHS to be successful and improve health outcomes after Brexit. What cannot be in doubt, though, is the complexity and scale of the task facing the government. Many of these issues can be resolved with political will and appropriate resources. When it comes to both, however, the pressure will be significant as the Government will need to deal with Brexit in tandem with pre-existing ones over long-term sustainability and social care provision.

Ensuring a well-functioning health service, and protecting public health, after Brexit is by no means impossible, but the challenges are significant.



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The UK in a Changing Europe promotes rigorous, high-quality and independent research into the complex and ever changing relationship between the UK and the EU. It is funded by the Economic and Social Research Council and based at King's College London.

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