The voice of NHS leadership

Health Select Committee inquiry into Brexit and health and social care

NHS Confederation submission, October 2016

1. Executive Summary

- Some of the consequences of Brexit could have implications for the commissioning, provision and development of healthcare interventions given the extent to which EU policy and legislation impact on the NHS.
- From an NHS perspective, possible implications for workforce, research and innovation, and health technology regulation are priority issues to be looked at during the withdrawal negotiations.
- On workforce, our priority will be to ensure a continuing 'pipeline' of staff for the sector, including by recognising health and social care as a priority sector for overseas recruitment.
- On research and innovation, our aim is that NHS organisations can continue to participate in EU collaborative programmes and are allowed to lead and be a member of European Reference Networks post-Brexit.
- On health technology regulation, our priority is that NHS patients can continue to benefit from early access to the wide range of innovative health technologies available on the EU market and that they do not miss out on the opportunities offered by participation in EU clinical trials.
- Alongside these priorities, we have identified public health, employment law, cross-border healthcare, and procurement as other areas in which risks or opportunities emerging from Brexit should also be considered.
- As the UK Government has not outlined its detailed negotiating position and negotiations have not started yet, it is difficult to be very specific on the measures which should be put in place to mitigate risks and to take advantage of opportunities.
- In the event that the UK were no longer part of the EU Customs Union and could therefore embark in the negotiation of trade deals with different economic regions across the globe, particular care will have to be paid to ensure that they will not lead to any lowering of public health or consumer protection standards.
- We also ask the Government to provide clarification as soon as possible that EU professionals who are already working for the NHS, or who will be recruited during the leave negotiations, will be allowed to remain after Brexit.

2. Most important issues during the withdrawal negotiations and outcome to be sought

2.1 The implications of UK withdrawal from the European Union are anticipated to affect all parts of the health system, including

the local clinical commissioners and provider organisations that we represent, including through NHS Clinical Commissioners, NHS Partners, and our Mental Health Network in England. This is in terms of the operational, financial and legislative uncertainty that may be faced by the service in the run up to and during negotiations, and in ultimately defining a body of domestic legislation that meets the ongoing needs of all parts of the NHS.

2.2 While the impact could span over a broad range of areas of NHS activity, we have identified implications on workforce, research and innovation, and regulation of healthcare technologies as primary issues for the withdrawal negotiations at the outset. For each of these three areas, we provide an overview below of why they are important and which outcome we would like to be pursued.

2.3 We also recognise that there is a range of other issues, including data protection, where the NHS will have particular views alongside other sectors and we will voice our fuller position on all those as the process to leave the EU formally gets under way.

Workforce

2.4 Across the UK, the NHS is heavily reliant on EU workers, with 57,604 staff in England alone coming from the EU, with around an additional 6,000 EU staff in independent health organisations. Our reliance on EU workforce has increased in the last few years, probably due to the tightening of UK immigration policy on non-EU workers. Looking at specific professions, around nine per cent of doctors and five per cent of nurses working in the NHS in England are EU migrants, with NHS trusts in London and the South East, as well as some health specialties, being particularly affected.

2.5 Similarly, the adult social care sector is also highly dependent on EU workforce, with approximately six per cent of their staff in England being non-UK EU nationals. If we take health and social care together there are approximately 144,000 EU nationals working in the combined sector in England, with additional staff working in services in Northern Ireland, Wales and Scotland.

2.6 While we welcome the recent announcement that more healthcare professionals will be trained domestically from now on, we are also aware that workforce planning is an inexact science and that it is extremely difficult to predict the number of professionals needed to ensure the smooth and safe operation of a health and care system in continuous change. Shortages in specific areas can take only 2-3 years to develop, but may need 10-15 years for the UK trained workforce to respond, by which time other solutions have usually been found and different workforce shortages may have emerged. It is to be expected, therefore, that our sector will need to continue to recruit overseas trained professionals, including from within the European single market, to operate smoothly and to offer safe and high quality services to patients in the future.

Desired outcome

2.7 Our **priority will be to ensure a continuing 'pipeline' of staff for the sector**.

2.8 If the UK continues to have full access to the single market in future, entailing freedom of movement for EU citizens to live and work in the UK and vice-versa, not much would change in terms of our ability to recruit from the EU.

2.9 At the other extreme, a total exit from the single market would leave the UK completely free to determine its own policies on immigration, with possibly much greater implications for the NHS. Under this latter scenario, it would be crucial to ensure that **any future UK immigration rules recognise health and social care as a priority sector for overseas recruitment, from both within and outside the EU.**

Research and innovation

2.10 Clinical research and innovation are key components of NHS activity and the NHS has a long tradition of EU collaborative research. Subsequent EU Research and Innovation funding programmes have acted as catalysts for this collaborative work, filling gaps in the research pipeline, and allowing researchers across Europe to gather forces to find responses to common challenges, both at clinical and operational levels, that confront health systems in Europe.

2.11 European programmes have, for example, supported research into health economics and the resilience of healthcare systems, for the public good. At the bottom line, the NHS wants to access research which brings affordable innovation and, most importantly, benefits to NHS patients. This is not possible, at least to the same extent, through participation in collaborative research with other regions of the world, such as the USA, where commercial interests are often the key driver of research.

2.12 EU research grants have also been crucial for the NHS's ability to attract and retain some of the most renowned clinicians in the world, who often decide to work for the NHS due to its reputation in leading EU collaborative medical research initiatives.

2.13 Furthermore, it is worth noting that the increased reputational value achieved by being awarded a highly esteemed and competitive EU research award cannot easily be replicated at national level.

Desired outcome

2.14 Collaboration at EU level has helped the NHS to develop new treatments, adopt innovation more quickly, and improve the quality of healthcare it provides. We would like to ensure that **the NHS can continue to participate in EU collaborative research programmes** post-Brexit for the following two main reasons:

- a national research programme will not have the same clout to attract and retain internationally renowned clinicians and researchers in the NHS, as EU research funding currently does;
- it will be extremely difficult to replicate a similar collaborative research approach with other parts of the world, as their systems are based on different values and traditions, and their research environment is more protectionist and commercially focused than the EU's.

2.15 We also want to ensure that after Brexit **the NHS can continue to lead and be a member of European Reference Networks for rare and complex diseases**, which are a new form of EU collaboration between specialised healthcare providers, to pool knowledge in selected clinical areas to increase the speed and scale at which innovation in medical science and health technologies is incorporated into healthcare provision[1].

2.16 Participation in these Networks is very important for the NHS's international reputation and for its access to clinical innovation and its early translation into clinical practice for the benefit of our patients. Given the NHS's level of expertise in the diagnosis and treatment of rare and complex diseases, we believe that it will also be in the interest of the EU to allow our continued membership of these Networks. Nevertheless, as participation is currently reserved to EU and EEA countries, **our future involvement will depend on this being specifically agreed upon during the leaving negotiations**.

Regulation of health technologies

2.17 The EU has competence to regulate health technologies, such as pharmaceuticals and medical devices, but also products of human origin such as blood, tissues and cells. This is because these products circulate in the EU single market and therefore a set of common standards and rules are needed to ensure their safety and quality.

2.18 Having a single EU regulatory framework has allowed new health technologies to be brought more quickly to the market for the benefit of patients. For example, pharmaceutical companies can make new medicines available everywhere in the EU through the single centralised marketing authorisation procedure provided by the European Medicine Agency, instead of having to apply for authorisation in each individual member state. Maintaining access to this centralised authorisation procedure is the main priority for the UK pharmaceutical/life sciences industry.

2.19 A single EU system has also allowed a higher level of patient safety and public health protection to be achieved through a close-knit network of competent authorities in member states and the European Medicines Agency, collaborating, exchanging information, and bringing their expertise to the table in a way that adds value, whilst avoiding duplication of effort.

2.20 The EU regulatory framework spans the full process needed to bring new health technologies to the market, starting from the clinical research phase. It is for this reason that the authorisation and conduct of clinical trials are also regulated by the EU. This is particularly relevant from an NHS perspective, given the vast amount of clinical studies conducted by the NHS.

[1] One quarter of the European Reference Networks are led by the NHS and the NHS is virtually a member of all Networks. For more information see: http://www.nhsconfed.org/regions-and-eu/nhs-european-office/brexit/can-the-nhs-maintain-its-international-leading-role-in-medical-science

2.21 It should be stressed that while the EU Clinical Trials Directive (Directive 2001/20/EC) has been widely criticised, including by the NHS, to improve things a new EU Clinical Trials Regulation (536/2014) is due to be enacted in 2018. Importantly, the new EU Regulation will introduce a number of flexibilities and simplifications which will make it easier for NHS trusts to participate in multinational clinical trials. An example of the practical impact of these positive changes is that it will soon be possible to launch a clinical trial with patients in several different countries through the submission of a single application dossier, instead of having to apply separately in each of the countries involved. This is a significant change that will certainly speed up the time for launching multi-country clinical trials, such as those looking into treatments for rare diseases which, by their very nature, require the participation of patients from several different countries.

Desired outcome

2.22 In the event that the UK continues to have full access to the single market in the future, the EU medical regulatory framework will continue to apply and thus not much would change. At the other extreme, an exit from the single market would leave the UK free to determine its own medical regulation, with possibly much greater implications for the NHS.

2.23 Under such a 'hard Brexit' scenario, it will be essential to **ensure that our patients can continue to benefit from early access to the wide range of innovative health technologies** which are available on the EU market. Similarly, it will be crucial that NHS patients do not miss out on the opportunities offered by participation in EU clinical trials.

2.24 This can be achieved by avoiding regulatory divergence between the UK and the EU in the future. A **system of mutual recognition of the respective medical regulatory systems** could, for example, be negotiated, to allow EU authorised products to enter the UK market and vice versa, in a smooth way. Ideally, this would also allow us to have access to the different EU mechanisms and infrastructure in this area. For example, **access to the new EU portal and database on clinical trials** which will be used to authorise new clinical trials and to share clinical trials' data and information at EU level.

3. Other risks and opportunities

3.1 In addition to the priority areas mentioned above, potential risks and opportunities of leaving the EU in other areas of health policy should also be highlighted:

Public health

3.2 A significant proportion of the domestic legislation in public health and consumer protection originates from the EU, as the EU has legislative competence in these areas. If EU rules were no longer enforceable in the UK after we leave the EU, we would recommend to **ensure that the same or higher level of safety is guaranteed through domestic standards and rules** in the future.

3.3 Furthermore, the EU has several mechanisms to respond to and combat major cross-border health threats, including communicable disease outbreaks. This has allowed considerable

improvement in the degree of information sharing and response coordination at EU level in cases such as Ebola, or swine flu pandemics. **Continued access to these EU coordination mechanisms and networks,** such as the European Centre for Disease Prevention and Control (ECDC)[2] should be sought during the negotiations, as it would be more difficult for the UK to tackle in isolation what are inherently transnational threats.

Employment law

3.4 The Government has already stated its intention to protect workers' rights after Brexit and, as the largest employer in the country, we very much welcome this. In the event of the UK no longer being bound by EU employment law in the future, we believe however that there are very **specific elements of EU law which could be looked at and reconsidered**. For example, we believe that while the European Working Time Directive has helped to protect staff from fatigue due to excessive working hours, and that therefore its founding principles should remain, the opportunity to change the rules on the timing of rest breaks and working patterns could permit greater flexibility to support seven-day working and integrated care, create better work-life balance for our workforce and potentially improve both training and staffing in healthcare settings.

Cross-border healthcare

3.5 As the right to receive healthcare in another EU country is regulated by the EU, leaving the EU may have consequences for NHS patients in terms of their ability to access cross-border healthcare. This could mean that, in the future, British citizens on holiday in Europe might no longer be able to use the European Health Insurance Card, which allows them to receive emergency or immediately necessary healthcare on the same terms as the residents of that country.

3.6 EU law also allows Britons who are abroad for a longer period of time – such as pensioners living abroad, or UK citizens who work in another EU country – to be entitled to receive healthcare in the country where they live on the same basis as the local population.

3.7 It should be stressed that these EU rules are reciprocal and therefore uncertainty also exists on whether EU citizens will be entitled to receive healthcare in the UK following Brexit.

3.8 If the UK were to leave the EU single market, these systems would in principle no longer apply in the future, unless bilateral agreements were negotiated. Consideration should be given by negotiators to possible implications for patients and how to ensure that a **fair alternative system is put in place,** either with the EU as a whole, or with those EU countries, such as Spain, which have high numbers of UK nationals living there.

Procurement

3.9 Nothing in EU law requires member states to open up public services to competition, as that is entirely a matter for domestic policy decision. However, when a member state decides to

[2] http://ecdc.europa.eu/en/Pages/home.aspx

introduce the market into the provision of public services, those activities then become subject to EU procurement law.

3.10 Whether procurement rules will continue to apply as now to the commissioning of NHS services, or might be amended post-Brexit, to allow for more flexibility, it will depend primarily on the type of relationship which the UK negotiates with the EU and the extent to which the UK continues to have access to the EU single market. Full access to the single market should normally entail the continued application of EU procurement legislation as now, while in the event of a 'hard' Brexit, some flexibility in this area would be possible.

4. How to mitigate risks and take advantage of opportunities

4.1 The risks and opportunities will largely depend on whether the UK will continue to have access to the EU single market, or not, in the future. As the UK Government has not outlined its detailed negotiating position and negotiations have not started yet, it is difficult to be specific on the measures which should be put in place to mitigate risks and to take advantage of opportunities. Nevertheless, we have the following main recommendations at this stage:

- In the event that the UK were no longer part of the EU Customs Union and could therefore embark in the negotiation of trade deals with different economic regions across the globe, particular care will have to be paid to respective public health policies and standards applied, as other trade blocks will be pushing for mutual recognition of their standards, which could be set at a lower level of safety compared to the EU's. International free trade deals are very complex and long to negotiate. While we recognise the UK Government may wish to agree deals quickly, for each trade pact it will also be crucial to ensure a high level of public health protection by conducting an in depth analysis of the standards applicable to each individual economic sector and ensuring that, whenever deemed necessary, reservations are agreed with our counterpart.

- Given the complexity of negotiations and the variety of policy areas that will be covered, we strongly recommend that organisations with specific expertise and knowledge in these respective areas are consulted by Government when drawing up the detailed approach to particular issues. This will allow a well-informed negotiating position to be shaped and avoid the risk that some of the implications could be overlooked.

- To reduce uncertainty in the run up and during the negotiations, whenever possible clarification should be provided by the Government. For example, the clarification given by HMT on EU funding programmes has been extremely helpful in reassuring our EU funding partners that it is safe to involve UK organisations in new funding bids. Similar clarification in other areas will be very welcome. In particular, reassurance by Government as soon as possible that EU healthcare professionals who are already working for the NHS, or who will be recruited during the leave negotiations, will be allowed to remain after Brexit, would be extremely helpful. Given the workforce shortages that the health service already faces, such reassurance is vital to enable us to recruit and

retain EU staff, who could otherwise be discouraged from coming/staying in the UK due to uncertainty over their employment rights after Brexit.

About us

The NHS Confederation represents NHS providers and commissioners. The organisation has nearly 500 members across health and social care, including hospitals, community and mental health providers, ambulance trusts and independent sector organisations providing NHS care in England, Northern Ireland and Wales. It is the only membership body to bring together and speak on behalf of the whole NHS.