‘No Deal’ Brexit – how might it impact urological practice in the UK?

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On 29 March 2017, the Government of the United Kingdom of Great Britain & Northern Ireland triggered Article 50 of the Lisbon Treaty, formally starting the two-year period for talks with the European Union (EU) in which to reach a withdrawal agreement, and thus conclude the process commonly referred to as Brexit. With less than seven months to go now before the UK formally departs from the EU, there is still much uncertainty about where the negotiations are heading and whether a deal with the EU will be agreed or not.

Many large and small businesses operating within the UK that rely upon free trade with the EU have recently provided warnings about the impact that ‘No Deal’ will have upon their operations and employment. Although both the UK and EU want to reach a deal, there has recently been increasing talk from both sides about ‘No Deal’ being an eventual outcome given the state of the negotiations, and preparations are now being undertaken for this. The impact of Brexit upon the field of urology in the UK has not been examined formally in the medical literature, but there are many aspects of ‘No Deal’ that could impact on how urologists practise, and how patients are cared for. Some of the key areas are explored here.

Staffing

The freedom of movement of people and services across borders are two of the four freedoms of the EU’s Single Market, and this extends to professional qualifications. Directive 2005/36/EC provides automatic recognition of medical degrees and allows for the right to exercise a profession in a Member State other than the one in which the qualification was obtained. It is estimated that approximately 10,000 doctors working in the UK qualified in countries from the European Economic Area (EEA), which also comprises Norway, Iceland and Liechtenstein, accounting for 9.1% of those on the General Medical Council (GMC) register, and 19.2% of all surgeons. The British Medical Association (BMA) in 2017 surveyed 1720 such doctors, and found that not only were 45% considering leaving the UK in the aftermath of the EU Referendum, 19% had already made plans to leave; in a separate GMC survey that same year, a higher proportion of doctors (60.8%) said they were considering leaving the UK at some point in the future. In both surveys, the main reasons for considering leaving were uncertainties over immigration and residency status, the emotional impact of negative attitudes towards EU citizens in the aftermath of the referendum, and feeling unwanted in the UK.

The loss of mutual recognition of professional qualifications between the UK and EEA may lead to EEA-qualified doctors having to sit similar licensing tests that current non-EU doctors undertake, which at the moment exist in the form of the Professional and Linguistics Assessments Board. The GMC noted that such a situation could be a positive move for UK patients in allowing them to assess the professional skills of doctors from across the EEA, especially given the differences in training structures across Europe. This has been welcomed by the Royal College of Surgeons in their position paper *Making the Best of Brexit for the NHS*.

The issue of staffing does not affect just doctors. Seven percent of nurses in the UK are EU nationals, according to a Briefing Paper from the House of Commons published in February 2018. It was well publicised that in the year after the referendum in 2016, there was a 96% fall in the number of nurses from the EU registering to work in the UK, although the introduction of a new English language test for EU nurses may also have contributed, and between 2017 and 2018 a record number of nurses from EEA countries left the Nursing and Midwifery Council (NMC) register, numbering 3962 compared to 1311 in the period from 2013 to 2014. Only 805 EU nurses registered with the NMC last year, the lowest level ever, and in a similar survey to that of their EEA medical counterparts, this time carried out by the NMC in a series of interviews, 47% of respondent nurses stated that Brexit had encouraged them to consider working outside the UK, with 59% having already left or made plans to leave.

It is not known what proportion of the urological medical workforce in the UK have primary citizenship from EEA countries, but the potential departure of these doctors and nurses, in the short-term would exacerbate further the gaps many departments experience at all levels of staffing from junior doctors to consultants, further stretching the workforce to cover both elective and emergency work. This may even be despite the Home Office publishing details of how EU citizens currently living in the UK can apply for “settled status” after March 2019.

These problems in the longer term may be addressed by the expansion in the number of UK medical school places from 6000 to 7500 a year from 2018, along with the creation of five new medical schools. If ‘No Deal’ happens though, and EEA nationals leave the UK medical workforce as feared, then the NHS may have to look from outside the EU to developing nations, particularly those with previous colonial links to the UK, to recruit both medical and nursing staff as has been the case historically. However, this group of doctors may not choose to come to the UK due to problems perceived such as absence / lack of career progression and the improved job satisfaction in their own home country.

European Working Time Directive (EWTD)

The EWTD has been a controversial EU Directive amongst the surgical community in the UK, ever since its extension to cover junior doctors’ work contracts in 2004. It reduces the average working week to 48 hours and provides other protections, such as a period of 11 hours continuous rest per day. Whilst it has been credited for improving work-life balance and adequate rest, it has been lamented for its impact on surgical training, with a perceived reduction in training time and rota inflexibilities. It has been argued by the Royal College of Surgeons that non-participation in the EWTD, especially in the case of ‘No Deal’

where the UK is no longer subject to the European Court of Justice (ECJ), will allow the NHS to address the way in which junior doctor rotas are designed so as to permit good quality training time. The current junior doctors' contract though, implemented in 2016, does have the recommended rest times from the EWTD written into it separately, and so a 'No Deal' Brexit would not have immediate effects on the provision of this.

Current urology trainees, the majority of whom participate in non-resident on-call rotas and benefit from a day off the next day after a 24 hour on-call, may oppose the removal of these legislated rest periods, although the opportunity then does arise to designate this as protected training time within the job free from service commitments.

Euratom

The Prime Minister in July 2017 announced that the UK will withdraw from the European Atomic Agency Community (Euratom), which is not an EU institution but is under the jurisdiction of the ECJ. Euratom establishes a single market in trade of nuclear materials and technology, and provides a regulatory framework for these materials including isotopes for medical use. The UK currently does not have reactors capable of producing these and sources them mostly from France, Germany and the Netherlands as these are geographically closer. Membership of the EU Customs Union allows these materials to pass through the UK border quickly without any checks so that they do not decay and reach hospitals in time for use.

One such isotope is molybdenum-99, which has a half-life of 66 hours and therefore relies on quick transit across borders. Once it starts decaying, a generator can be used to extract technetium-99m, the most commonly used isotope in diagnostic imaging, and for urology this is a vital intravenous administration for nuclear medicine bone scans used for the detection of metastases from urological malignancies, and renograms to determine differential renal function and drainage.

Concerns have also been raised regarding access to radioisotopes used for radiation therapy; one of these being strontium-89 which is administered to patients with bone metastases from prostate cancer. In the event of a 'No Deal' where no agreement is reached on Euratom membership and customs, the UK risks difficulties in guaranteeing the supply of these materials, and whilst it is possible to source them from outside the EU through reactors in Canada and South Africa, talks with these countries are unlikely to open until the UK formally departs the EU next year. An associate agreement with Euratom can only be reached once the UK establishes a State System of Accountancy and Control for Nuclear Material, in order to satisfy the obligations to the International Atomic Energy Agency. However, even if an associate agreement is reached, the potential lack of a customs agreement may lead to delays in rapidly transporting such material across the UK border, hence leading to significant decay by the time it reaches hospitals. Such materials cannot also be stockpiled before the UK's formal withdrawal due to the likelihood of decay. This would undoubtedly impact the diagnostic work for prostate cancer where bone scans are regularly performed to stage tumours.

A glimpse to these potential problems occurred in 2009 when there was a global shortage of molybendum-99 due to the temporary shutdown of two reactors, leading to bone scans being reserved for the most urgent patients. Such a scenario could be faced again in the near future by UK urologists.

Medicines and medical devices

The European Medicines Agency (EMA) provides centralised regulation for the approval, authorisation and testing of new medications, to name a few of its functions. It ensures that all new products are held to the same high standards and efficacy throughout EU countries before being released onto the market. The UK's withdrawal from the EMA though has forced many pharmaceutical and medical devices companies to invest specific time and effort into their operations after Brexit, particularly for the possibility of 'No Deal', for example in the duplication of facilities.

Reports have emerged of the potential impact of 'No Deal' upon the supply of medicines in the UK, with Matt Hancock, the recently appointed Secretary of State for Health, confirming to the House of Commons Exiting the European Union Committee that the NHS was preparing to stockpile medicines and blood products in the event of 'No Deal'. No comprehensive list of medicines and medical devices that would be affected by 'No Deal' have been made, although the Government in response to recommendations from the Commons Health and Social Care Committee confirmed that teams were "progressing work to assess the impact on the supply chains of all medicines and medical devices used in the NHS". Some pharmaceutical and medical device companies have announced plans to stockpile their own supplies of medicines in both the UK and EU, including AstraZeneca, although one of its products, Zoladex, commonly used by urologists and oncologists to treat prostate cancer, is produced at its plant in the UK and is therefore unlikely to be stockpiled for the UK market.

The UK's current status as an EU Member State and member of the EMA allows for its participation in the complex Europe-wide supply chains involved in manufacturing a medicine, which can cross multiple borders before becoming the finished product. Disruptions at the border with no new customs agreement is the biggest issue for pharmaceutical companies due to cost, as well as the delay in getting the medicine completed. UK urologists in the event of 'No Deal' could also find themselves with delayed access to new medications released, as the UK forms only 2.3% of the global pharmaceutical market compared to the 22% from the EU; pharmaceutical companies may therefore find it more attractive and lucrative to launch their products in the EU instead.

Talk around stockpiling of medical devices has arisen too. Again, the UK Government has not released a comprehensive detailed list of such devices it is looking at, but many such devices are important in urology. No statements on the impact of Brexit have yet been made by Karl Storz-Endoskope and Olympus, whose endoscopic instruments are widely used by many UK urologists, although both companies have manufacturing locations based in the UK. There has been no analysis of specific medical devices widely used in urology, such as urinary catheters. It is interesting to note that the companies whose catheters are used the most in UK hospitals have manufacturing locations outside the UK, including in the EU. 'No Deal' could therefore have the same impact as on medicines with delays and payment of import duties being levied on these products.

Such talk around medicines has led to criticism of the UK Government for its preparations. There were encouraging signs though for the continued supply of medicines to the UK when the House of Commons voted in favour of Amendment NC17 to the Trade Bill this month, which made it a negotiating objective for the UK Government to seek continued participation in the European regulatory medicines network. Whether this will be achieved is yet to be seen in the autumn.

Continental collaboration

Only six days after the referendum result, the European Association of Urology (EAU) issued a statement that the support for the UK to leave to EU was "an extremely

retrograde step", especially because of collaborative practice across the continent and cross-border research. One such reason for this statement is likely to have been European Reference Networks (ERNs) which were established in 2017, their development encouraged by the EU's Cross-Border Healthcare Directive where EU citizens have the right to access healthcare in any EU country and be reimbursed for that care by their home country. The vast majority of these are dedicated to rare diseases, including the ERN on Rare Urogenital Disease (EUROGEN) which is led by the Sheffield Teaching Hospitals NHS Trust. These allow for collaboration in knowledge and research between clinicians across the EU, and improved access for patients with rare urological diseases to treatments which may not be available in their own country. With the UK no longer participating in the Healthcare Directive if 'No Deal' occurs, UK patients with rare urological diseases would no longer have the benefits of such collaborative work, to have the right to be referred for treatment in other EU Member States. They may also be disadvantaged by the potential loss of access UK clinicians and scientists may experience to new and ongoing research.

What will happen?

The UK's relationship with the EU with regards to healthcare provision, collaboration and research is very close and complex, and such an association is undoubtedly a key part of the current UK-EU links that the Government would like to preserve.

There are many more aspects of these ties not covered above which will be impacted, such as participation in clinical trials, the exodus of EU researchers from British universities, or even the extra financial pressures the NHS would face, the effects of which would be felt in urology. All of the areas examined though will directly affect urology practice in the UK should 'No Deal' happen. The precise detail is sadly lacking and may only become fully evident as the time gets ever closer to the UK's exit. Many UK urologists are therefore sure to follow the conclusion of the Article 50 talks closely to gauge how they will be able to provide the best care possible for their patients once the final outcomes are known.

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