

REPORT

AGENDA ITEM: 8.1

To:	Board of Directors	Date:	30 January 2019
Subject:	Brexit Update		
Presented by:	Chief Operating Officer	Purpose:	Information

Executive summary

Since the vote to leave the EU and subsequent triggering of Article 50 NHS England, Government departments and other relevant bodies have been making preparations, largely based on the assumption that there would be an agreed deal and therefore an orderly exit with a transition period allowing for new legislation and agreements to be made before final withdrawal. In recent weeks it has become more likely that the UK will leave the EU with no deal with immediate departure and therefore no or limited opportunity for a smooth transition. As a result NHS organisations are now being asked to identify their own risks and confirm that all necessary actions are being taken.

This paper sets out the risks identified and the actions taken to date and those that will continue over the coming weeks and months. This is a fast moving agenda and it may be that there have been significant developments since this paper was written however the Board is asked to note the contents and further updates will be provided as and when relevant

Risks associated with this report

A risk assessment has been completed (scoring 9) – this is based primarily on the two most significant risks as noted in the paper (workforce and supply chain)

Link(s) to The WWL Way 4wards

<input checked="" type="checkbox"/>	 Patients	<input checked="" type="checkbox"/>	 Performance
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Introduction

Following the UK's decision to leave the EU and subsequent triggering of Article 50 work has been on-going to identify the impact on the NHS. In October 2018 the Greater Manchester Resilience Team convened a teleconference to share the risks identified by NHSE and the Department of Health and Social Care (DHSC) and the work ongoing to address these. NHS Providers were asked to consider these, identify which risks were relevant and satisfy themselves that appropriate action was in place. At that stage no central reporting (other than those linked to some of the specific workstreams, in particular medicines and procurement more broadly) was required. Subsequent to this and with the rise in likelihood of a "no deal Brexit" the DHSC has circulated further guidance with specific action for providers and commissioners. The remainder of this paper will set out

Risk Overview

The initial work identified a list of 9 areas of impact and full information on these is shown at Appendix 1. They were split into 3 risk categories by NHSE and these are shown below

Category 1: potential high risk, cross-org responsibilities

- **Workforce:** risks to future supply, divergence on future regulations
- **Supply chain:** risks to disruption in supply chain, cost pressures and border delays
- **Research and innovation:** risks to reduced collaboration with EU (inc. clinical trials), divergence on regulations, access to innovative treatments and income (inc funding for clinical research staff)

Category 2: potential medium risk, single policy issues

- **Reciprocal healthcare:** risks to more complicated cost recovery processes, and UK citizens returning to the UK (increasing demand and cost)
- **Operations:** system readiness and access to services across borders
- **EPRR and pandemic planning:** risks to information sharing and systems across borders
- **Procurement & competition:** risk to disruption to new contracts

Category 3: potential low / medium risk, limited NHSE responsibility

- **Data and IG:** risks to longer term alignment and implications for services across borders
- **Medicines & devices regulation:** risks to disruption and delays in access to new products in the UK
- **Public health:** maintaining public health standards in UK legislation

An analysis confirmed that the risks most relevant to the Trust were workforce and supply chain and a meeting was convened, chaired by Mary Fleming, to review the readiness of the Trust in each of these areas. Finance, HR and pharmacy all confirmed that they had received separate requests for information and processes via their own specialist leads. On this basis at that stage it was agreed that each of the leads (Associate Director of Finance, Deputy Director of HR and Chief Pharmacist) would continue to respond to requests through their own channels and would utilise their own governance routes rather than establishing a separate workstream

DHSC EU Exit and Operational Readiness Guidance

The above work continued but just before Christmas, following the increase in uncertainty, the DHSC issued “Operational Readiness Guidance” which included a number of specific actions for Providers and Commissioners. There is an expectation that this is taken on by resilience leads and is being managed by the Greater Manchester LHRP with NHSE. The Provider Action Card is provided in full at Appendix 2 but a summary of the requirements and current status is shown below

Risk Area	Status	Lead	Risk Rating
Risk assessment and business continuity planning	Complete / Ongoing	Helen Salvini	
Communications and Escalation	Complete / Ongoing	Mary Fleming Helen Salvini External Comms	
Reporting, assurance and information	Complete / Ongoing	Helen Salvini	
Supply of Medicines and Vaccines	Complete / Ongoing	Mike Parks	
Supply of Medical Devices and Consumables	Complete / Ongoing	Procurement	
Supply of non-clinical consumables, goods and services	Complete / Ongoing	Procurement	
Workforce	Complete / Ongoing	HR	
Professional Regulation		HR	
Reciprocal Healthcare	Complete / Ongoing	Mark Almond	
Research and clinical trials – EU research and innovation scheme	Complete	Finance / R&D	
Clinical trials and clinical investigations	Ongoing	Procurement / R&D	
Data sharing, processing and accessing	Ongoing	Information Governance	
Finance	Ongoing	Helen Salvini / Finance	

Of course it should be noted that whilst at present all areas are considered to be low risk to the Trust even in the event of a “no deal” Brexit the political situation is evolving quickly so the risks will continue to be evaluated on a regular basis. It is this uncertainty which is more of a risk in itself. The Wigan Borough Resilience Forum discussed the Brexit risks on January 17th and confirmed that no organisation believes there are any high risk areas

based on the current information. The leads from each organisation will continue to share plans

Conclusions and Recommendations

The Board is asked to note the contents of the report which provides assurance that at present the risk to the Trust is considered to be low. Regular updates will be provided as and when the situation evolves and it is recommended that at this stage the specific risks continue to be managed through the previously identified governance routes. An overarching risk assessment has been completed on Datix (currently scoring a 9) and this will be updated as more information becomes available and any increase in the risk will be escalated as appropriate.

The NHS England European Transition Work Programme : Nine Areas of Potential Impact

Workforce

- ~62,000 (5%) of NHS workforce, not including primary care
- ~95,000 (7%) in social care workforce
- Regulations, including language testing, professional registration and shared databases on fitness to practice, education and training

Reciprocal Healthcare

- UK residents in the EU: 27m EHICs issued, 900k residents. £650m spent in 2015.
- EU residents in the UK: 3.2m residents, 25m visits. £305m income in 2015.
- 1,014 approved applications for UK residents to access healthcare in EU in 2016, £1.1m reimbursed.
- EU reciprocal beds for specialist capacity

Medicines & Devices Regulation

- MHRA regulates medicines, medical devices and blood components for transfusions, including marketing authorisation and pharmacovigilance
- Centralised assessment process, of which MHRA provided one of the highest levels of support to the EMA

Supply Chain

- ~83% of medical products (medical devices, clinical consumables, medical capital equipment and medicines) are imported into the UK from, or through, other EU countries
- 45% of medicines used in the UK are imported from the EU
- Tariffs, trade changes, FX impacts and customs delays could all affect supply

Research & Innovation

- EU funding direct and indirect into the NHS, including Horizon2020, European Regional Development Fund (ERDF), and other health programmes
- Collaborations, e.g. European Reference Networks for rare and complex diseases
- Clinical Trials regulation, single point of entry and cross-border trials

Procurement & Competition

- NHS Procurement, Patient Choice regulations in addition to EU legislation.
- Healthcare contracts with a lifetime value above £589,148 must be advertised in OJEU. Most NHS-funded contracts are within scope

EPRR, Health Protection & Public Health

- European Centre for Disease Prevention and Control (ECDC) – shared intelligence, early warning system, and access to WHO databases.
- Emergency response (e.g. Channel Tunnel)
- EU legislation, e.g. food safety and nutrition, alcohol, tobacco, waste, and air pollution

Data & IG

- EU databases (e.g. medical revalidation and appraisal)
- EU regulation – GDPR, collaboration on harmonising clinical coding

Operations

- Health services contracted with EU providers (e.g. T&O capacity in France, MRI scans reviewed by doctors in EU)
- Potential for Le Touquet agreement to be renegotiated post-Brexit, with the potential to cause an increase of migrants to the UK

Appendix 2 : DHSC Provider Action Card

Risk	Current Status (January 2019)	Further Action Required	Action Owner
Risk assessment and business continuity planning			
<ul style="list-style-type: none"> • Undertake an assessment of risks associated with EU Exit by the end of January 2019, covering, but not limited to: <ul style="list-style-type: none"> ○ The seven key areas identified nationally and detailed below. ○ Potential increases in demand associated with wider impacts of a 'no deal' exit. ○ Locally specific risks resulting from EU Exit. 	Complete	Regular review of risk assessment as political situation develops	Helen Salvini
<ul style="list-style-type: none"> • Continue business continuity planning in line with your legal requirements under the Health and Social Care Act 2012, taking into account this guidance and working with wider system partners to ensure plans across the health and care system are robust. These organisational and system-wide plans should be completed at the latest by the end of January 2019. 	On-going	Plans being discussed at Wigan Borough Resilience Forum 17 th January	Helen Salvini
<ul style="list-style-type: none"> • Test existing business continuity and incident management plans against EU Exit risk assessment scenarios by the end of February to ensure these are fit for purpose. 	On-going	Awaiting official risk scenarios but business continuity plans fully updated December 2018	Helen Salvini
Communications and escalation			
<ul style="list-style-type: none"> • Ensure your board is sighted on EU Exit preparation and take steps to raise awareness amongst staff. 	On-going	Board paper January 2019 To be included in February Team Brief	Helen Salvini Rachel Holden
<ul style="list-style-type: none"> • Ensure Local Health Resilience Partnerships, Local Resilience Forums and Local A&E Delivery Boards are sighted on EU Exit preparation in your local health economy. 	On-going	Regular updates to LHRP Board paper to be shared after meeting	Helen Salvini
<ul style="list-style-type: none"> • Review capacity and activity plans, as well as annual leave, on call and command and control arrangements around the 29 March 2019, but at this point there is no ask to reduce capacity or activity around this time. 	Complete	Will be reviewed if situation changes	Helen Salvini
<ul style="list-style-type: none"> • Be ready for further operational guidance from NHS England and Improvement as contingency planning work progresses. 	On-going	N/A	Helen Salvini
<ul style="list-style-type: none"> • Confirm escalation routes for different types of issues potentially arising from or affected by EU Exit into the regional NHS EU Exit teams listed in this document 	Complete	N/A	Helen Salvini
<ul style="list-style-type: none"> • Note your nominated regional NHS lead for EU Exit and their contact details (included in the overview on page 5). 	Complete	N/A	Helen Salvini
<ul style="list-style-type: none"> • Escalate any issues you have identified as having a 	On-going	Risks to be escalated as necessary	Helen Salvini

Risk	Current Status (January 2019)	Further Action Required	Action Owner
potentially widespread impact immediately to your regional EU Exit team.			
<ul style="list-style-type: none"> Confirm your organisation's Senior Responsible Officer for EU Exit preparation and identify them to your regional EU Exit team as soon as possible. This role should be held by a board level member and will entail providing information returns to NHS England and Improvement, reporting emerging EU Exit-related problems, and ensuring your organisation has updated its business continuity plan to factor in all potential 'no deal' exit impacts. Organisations should also identify named staff to work in a team with the Senior Responsible Officer to support EU Exit preparation, implementation and incident response. 	Complete (SRO is Mary Fleming)	N/A	Mary Fleming / Helen Salvini
Reporting, assurance and information			
<ul style="list-style-type: none"> Be aware that if additional reporting is required, NHS England and Improvement will provide further guidance on requirements. However, existing reporting from NHS organisations will be used to develop a baseline assessment of the EU Exit impact on the health and care system. 	Complete	N/A	Helen Salvini
<ul style="list-style-type: none"> Note that regional NHS EU Exit teams will be in contact shortly to confirm your progress on these actions. 	Complete	N/A	Helen Salvini
<ul style="list-style-type: none"> For queries relating to specific topic areas in this guidance, please contact the relevant departmental mailboxes. Any immediate risks or concerns about provision of NHS service continuity should be escalated to the relevant regional NHS EU Exit mailbox 	On-going	N/A	Helen Salvini
Supply of Medicines and Vaccines			
<ul style="list-style-type: none"> Follow the Secretary of State's message not to stockpile additional medicines beyond their business as usual stock levels. No clinician should write longer prescriptions for patients. The Department's UK-wide contingency plan for the continued supply of medicines and vaccines from the moment we leave the EU is being developed alongside pharmaceutical companies and other government departments. 	On-going	N/A	Mike Parks
<ul style="list-style-type: none"> Note that there is no need to contact suppliers of medicines directly. 	Complete	N/A	Mike Parks
<ul style="list-style-type: none"> Direct staff to promote messages of continuity and reassurance to people who use health and care services, including that they 	On-going	To be completed in February Team Brief	Rachel Holden

Risk	Current Status (January 2019)	Further Action Required	Action Owner
should not store additional medicines at home.			
<ul style="list-style-type: none"> Note that Chief and Responsible Pharmacists are responsible for ensuring their organisation does not stockpile medicines unnecessarily. Any incidences involving the over-ordering of medicines will be investigated and followed up with the relevant Chief or Responsible Pharmacist directly. 	Complete	N/A	Mike Parks
<ul style="list-style-type: none"> Note that the Department and NHS England and Improvement are developing arrangements to allow local and regional monitoring of stock levels of medicines. 	Complete	N/A	Mike Parks
<ul style="list-style-type: none"> Be aware that UK-wide contingency plans for medicines supply are kept under review, and the Department will communicate further guidance as and when necessary. 	Complete	N/A	Mike Parks
<ul style="list-style-type: none"> Continue to report current shortage issues and escalate queries for medicine supply issues unrelated to current shortages through existing regional communication channels. 	On-going	N/A	Mike Parks
<ul style="list-style-type: none"> Meet at a local level to discuss and agree local contingency and collaboration arrangements. The Chief Pharmaceutical Officer will hold a meeting with the chairs of regional hospital and CCG Chief Pharmacist networks (and representatives of private hospital Chief Pharmacists) in January 2019 to help inform local plans. 	On-going	Pharmacy following national guidance	Mike Parks
Supply of medical devices and clinical consumables			
<ul style="list-style-type: none"> Note that there is no need for health and adult social care providers to stockpile additional medical devices and clinical consumables beyond business as usual stock levels. Officials in the Department will continually monitor the situation and if the situation changes, will provide further guidance by the end of January 2019. 	Complete	N/A	Procurement
<ul style="list-style-type: none"> Send queries about medical devices and clinical consumables provided by NHS Supply Chain to your usual contact. If you receive medical devices and clinical consumables from other suppliers, you should contact them directly with any queries as you would normally do. 	Complete	N/A	Procurement
<ul style="list-style-type: none"> Be aware that the contingency plan is kept under review, and the Department will communicate further guidance as and when necessary. 	On-going	N/A	Procurement

Risk	Current Status (January 2019)	Further Action Required	Action Owner
Supply of non-clinical consumables, goods and services			
<ul style="list-style-type: none"> Be aware that NHS Trust and Foundation Trust procurement leads have been asked to undertake internal reviews of purchased goods and services to understand any risks to operations if there is disruption in supply. This excludes goods and services that are being reviewed centrally, such as food, on which the Department has written to procurement leads previously. 	On-going	N/A	Procurement
<ul style="list-style-type: none"> Continue commercial preparation for EU Exit as part of your usual resilience planning, addressing any risks and issues identified through your own risk assessments that need to be managed locally. 	Complete	N.A	Procurement
<ul style="list-style-type: none"> Continue to update local business continuity plans to ensure continuity of supply in a 'no deal' scenario. Where appropriate, these plans should be developed in conjunction with your Local Health Resilience Partnership. All health organisations should be engaged in their relevant Local Health Resilience Partnership, which should inform Local Resilience Forum(s) of local EU Exit plans for health and care. 	On-going	N/A	Helen Salvini
<ul style="list-style-type: none"> Await further advice from the Department on what actions should be taken locally. 	On-going	N/A	Procurement
<ul style="list-style-type: none"> Submit the results of their self-assessment on non-clinical consumables, goods and services to contractreview@dhsc.gov.uk, if not done so already. 	Complete	N/A	Procurement
<ul style="list-style-type: none"> Act upon further guidance to be issued by the Department in January 2019. This will be based on analysis of NHS Trusts and Foundation Trusts' self-assessments. 	On-going	N/A	Procurement
Workforce			
<ul style="list-style-type: none"> Assess whether your organisation has incurred a reduction in the number of EU nationals in your workforce before the UK leaves the EU. 	Complete	N/A	HR
<ul style="list-style-type: none"> Publicise the EU Settlement Scheme to your health and care staff who are EU citizens. The scheme will open fully by March 2019 and remain open until 31 December 2020 in a 'no deal' scenario, so there will be plenty of time for EU staff to register. 	Complete	N/A	HR
<ul style="list-style-type: none"> Monitor the impact of EU Exit on your workforce regularly and 	On-going	Paper to Workforce Committee December	HR

Risk	Current Status (January 2019)	Further Action Required	Action Owner
<p>develop contingency plans to mitigate a shortfall of EU nationals in your organisation, in addition to existing plans to mitigate workforce shortages. These plans should be developed with your Local Health Resilience Partnership, feed into your Local Resilience Forum(s) and be shared with your local commissioner(s). Consider the implications of further staff shortages caused by EU Exit across the health and care system, such as in adult social care, and the impact that would have on your organisation.</p>		2018	
<ul style="list-style-type: none"> Undertake local risk assessments to identify any staff groups or services that may be vulnerable or unsustainable if there is a shortfall of EU nationals. 	Complete	To be reviewed as political situation evolves	HR
<ul style="list-style-type: none"> Ensure your board has approved business continuity plans that include EU Exit workforce planning, including the supply of staff needed to deliver services. 	Complete	At this stage no significant risks anticipated but as political situation evolves this will be reviewed	HR
<ul style="list-style-type: none"> Notify your local commissioner and regional NHS EU Exit Team at the earliest opportunity if there is a risk to the delivery of your contracted services. 	On-going	Not anticipated at this stage but will be reviewed as political situation evolves	HR
Professional regulation (recognition of professional qualifications)			
<ul style="list-style-type: none"> Inform your staff that health and care professionals (including UK citizens), whose qualification has been recognised and who are registered in the UK before 23:00 on 29 March 2019, will continue to be registered after this point. 	On-going		HR
<ul style="list-style-type: none"> Inform your staff that health and care professionals (including UK citizens), who apply to have their qualification recognised in the UK before 23:00 on 29 March 2019, will have their application concluded under current arrangements. 	On-going		HR
<ul style="list-style-type: none"> Await further information from the Government on the future arrangements for health and care professionals (including UK citizens) with an EU/EEA or Swiss qualification, who apply to have their qualification recognised in the UK from 23:00 on 29 March 2019. 	On-going		HR
Reciprocal Healthcare			
<ul style="list-style-type: none"> Note that, in a no deal scenario, the current arrangements for reciprocal healthcare and for overseas visitors and migrant cost recovery will continue to operate until 29 March 2019, 	Complete	N/A	Mark Almond

Risk	Current Status (January 2019)	Further Action Required	Action Owner
depending on the reciprocal agreements that are concluded.			
<ul style="list-style-type: none"> Continue to support individuals who apply for NHS authorised treatment or maternity care in another member state (the S2 and cross-border healthcare processes). 	Ongoing	N/A	Mark Almond
<ul style="list-style-type: none"> Note that the Department will provide updates and further information on reciprocal healthcare arrangements prior to 29 March 2019. 	Complete	N/A	Mark Almond
<ul style="list-style-type: none"> Maintain a strong focus on correctly charging those who should be charged directly for NHS care. Information on implementing the current charging regulations can be viewed on the webpage here 	Ongoing	N/A	Mark Almond
<ul style="list-style-type: none"> Ensure there is capacity available for any further training that may be required if there are changes to the reciprocal healthcare arrangements. This should be undertaken by the Overseas Visitor Management team, and guidance and support materials will be made available to support this training. 	Ongoing	N/A	Mark Almond
<ul style="list-style-type: none"> Note that the Department will provide updates and further information in due course. This information will cover migrant cost recovery charging after 29 March 2019 to enable NHS Trusts and Foundation Trusts to amend processes and train staff if reciprocal healthcare arrangements change. 	Complete	N/A	Mark Almond
Research and clinical trials - EU research and innovation funding schemes			
<ul style="list-style-type: none"> Note that the Government has guaranteed funding committed to UK organisations for certain EU funded projects in the event of a 'no deal' scenario. This includes the payment of awards where UK organisations successfully bid directly to the EU while we remain in the EU, and the payment of awards where UK organisations are able to successfully bid to participate as a third country after exit, until the end of 2020. 	Complete		David Hughes
<ul style="list-style-type: none"> Provide information about your Horizon 2020 grant here. This should be actioned as soon as possible. Further guidance can be found here and all queries should be sent to EUGrantsFunding@ukri.org. 	N/A		David Hughes
<ul style="list-style-type: none"> Contact officials at EU-Health-Programme@dhsc.gov.uk with information regarding your Third Health Programme grant, and 	N/A		David Hughes

Risk	Current Status (January 2019)	Further Action Required	Action Owner
any queries that you have, as soon as possible.			
Clinical trials and clinical investigations			
<ul style="list-style-type: none"> Follow the Government's guidance on the supply of investigational medicinal products (IMPs) for clinical trials in a 'no deal' scenario, if you sponsor or lead clinical trials or clinical investigations in the UK. 	N/A		R&D
<ul style="list-style-type: none"> Consider your supply chains for those IMPs, medical devices, in vitro diagnostic devices, advanced therapy medicinal products, radioisotopes and other clinical consumables, used in clinical trials and investigations, which originate from, or travel through, the EU and EEA as soon as possible if you sponsor or lead clinical trials or investigations in the UK 	On-going		Procurement / R&D
<ul style="list-style-type: none"> Liaise with trial and study Sponsors to understand their arrangements to ensure that clinical trials and investigations using IMPs, medical devices, IVDs, advanced therapy medicinal products, radioisotopes and other clinical consumables which come from, or via, the EU or EEA, are guaranteed in the event of any possible border delays. If multiple sites are involved within the UK, then co-ordinate with the lead site or Chief Investigator in the UK, or organisation managing the clinical trial/investigation, e.g. Clinical Research Organisation, to ensure a single approach to the Sponsor 	On-going		Procurement / R&D
<ul style="list-style-type: none"> Respond to any enquires to support the Department's comprehensive assessment of the expected impact of a 'no deal' exit on clinical trials and investigations. The Department is working closely with the NHS to gain a greater understanding of who might be affected by supply issues. 	On-going		Procurement / R&D
<ul style="list-style-type: none"> Continue participating in and/or recruiting patients to clinical trials and investigations up to and from 29 March 2019. This should occur unless you receive information to the contrary from a trial Sponsor, organisation managing the trial or clinical investigation, or from formal communications that a clinical trial or clinical investigation is being impacted due to trial supplies. 	On-going		R&D
Data sharing, processing and access			
<ul style="list-style-type: none"> Investigate your organisation's reliance on transfers of personal 	On-going		Information

Risk	Current Status (January 2019)	Further Action Required	Action Owner
<p>data from the EU/EEA to the UK, especially those that are critical to patient care and/or would have a serious impact upon the system if they were disrupted.</p>			Governance
<ul style="list-style-type: none"> Note that many organisations tend not to disaggregate personal and non-personal data. As such, please be aware that restrictions on personal data may have knock-on effects on data more generally. 	Complete		Information Governance
<ul style="list-style-type: none"> Follow the advice from The Department for Digital, Culture, Media and Sport and the ICO on data protection in a 'no deal' scenario, which can be viewed on gov.uk and on the ICO website, in particular to determine where to use and how to implement standard contractual clauses. 	On-going		Information Governance
<ul style="list-style-type: none"> Ensure that your data and digital assets are adequately protected by completing your annual Data Security and Protection Toolkit assessment. This self-audit of compliance with the 10 Data Security Standards is mandatory to complete by the end of March 2019, but completing it early will enable health and adult social care providers to more quickly identify and address any vulnerabilities. 	On-going		Information Governance
Finance			
<ul style="list-style-type: none"> Record costs (both revenue and capital) incurred in complying with this guidance. Costs with a direct financial impact should be recorded separately to opportunity costs. Providers should discuss these costs with their regional NHS EU Exit support team. Feedback from providers will inform decisions on whether further guidance on cost collection is required. 	On-going	Any costs to be noted and reported as necessary	Helen Salvini / David Hughes