NHS Rotherham CCG Governing Body – January 2019

CHIEF OFFICER'S REPORT

Lead Director:	**Chris Edwards**	Lead Officer:	n/a
Job Title:	**CCG Chief Officer**	Job Title:	n/a

Purpose
This report informs the Governing Body about national/local developments in the past month.

NHSE Gateway Letter: CCG Administration Resources

In November we received a letter from NHS England, setting out the expectation on CCG's to deliver a targeted reduction of our administration costs limit of 20% by 2020/21.

The full letter is attached as appendix 1.

Social Prescribing Service; Provider Procurement Update.

The contract for the provision of social prescribing was tendered in line with OJEU requirements as the current contract could not be extended any further. The PIN was advertised in September and following procurement process the preferred service provider is Voluntary Action Rotherham (VAR). The contract is for 3 years with a possible 2 year extension.

ACTION: GB is asked to ratify the contract award to VAR.

Update from the Data Protection Officer (DPO)

As noted in my December report our DPO, Barry Jackson, has provided an update which is attached as appendix 2. This report includes:

- IG implications of a "no deal" Brexit.
- Update from the courts – Wm Morrison Supermarkets PLC v Various Claimants
- Completion of Data Protection Impact Assessments (DPIAs)

EU Exit update – Letters from Department of Health and Social Care

As part of the Governments ongoing preparations for a March 2019 'no deal' Brexit scenario, we have received copies of three letters sent from the Rt Hon Matt Hancock MP, Secretary of State for Health and Social Care to industry (pharmaceutical companies, suppliers of medical devices and clinical consumables), updating as to the current progress made and updates as to the Government planning assumptions. These letters are attached as appendices 3a, 3b & 3c.

Further to this, in late December we received an update from Sir Chris Wormald the Permanent Secretary, informing NHS organisations of the set-up of a national Operational Response Centre. This will lead on responding to any disruption to the delivery of health and care services in England that may be caused or affected by EU Exit. The Operational Response Centre will co-ordinate EU Exit-related information flows and reporting across the health and care system. We have also been given the EU Exit Operational Readiness Guidance for the health and care system, both are attached as appendices 3d & 3e.

Brexit Preparations

As a result of the current lack of detail on the terms, and the resultant impact, of the withdrawal of the UK from the EU, there is a potential for increased risk to the business continuity provision of the NHS during, and after, the Brexit transition period.

Work has commenced to identify the impacts which may affect the NHS, in order that arrangements may be put in place to prepare for the consequences of differing scenarios (including a no deal outcome).

NHS England has established a European Transition Unit (NHS ETU) to examine risks relating to Brexit nationally.

It has identified nine key areas of risk:
1. Workforce
2. Supply chain
3. EPRR health protection and public health
4. Reciprocal healthcare
5. Research and innovation
6. Data and Information Governance
7. Medicines and Device Regulations
8. Procurement and competition
9. Operations (things contracted and delivered by European partners)

NHS Rotherham CCG has set up a dedicated email address for communications around the Eu Exit and has identified lead officers. We have also started to undertake business continuity planning around the 9 areas highlighted by NHSE above.

SYB ICS Chief Executive's Monthly Update and Performance Scorecard

As I promised last month, please find attached (appendix 4a, 4b & 4c) the latest update from Sir Andrew Cash on the ICS. This month's update covers:

- The key performance scorecards against the other First Wave ICS'
- The Key performance scorecard against the North ICS'
- None of our bids for capital funding from the Department of Health and Social care received funding.
- A number of appointments have been made to the new joint NHSE/I Executive group, a full list of Executives are shown within the report.

Further to this a letter has been received from NHSE/I with the full list of appointments – this is attached as appendix 4d.

NHSI/NHSE Letter 2019/20 Planning

I have received a letter setting out the required content of the submission to be made on the 14th January as "a regional checkpoint to assess progress against the demand, capacity and efficiency objectives set out in the planning letter" from last summer. The full letter is attached as appendix 5.

Letter From Ian Dalton NHSI re support for Winter.

Early December I received a letter (attached as appendix 6) from the NHSI Chief Executive, Ian Dalton, thanking us for our winter preparations and outlining his support to NHS organisations over winter with difficult decisions.

Teledermatology Service

The CCG are proceeding with procuring a teledermatology service in the new calendar year. A number of CCGs in South Yorkshire and Bassetlaw have already introduced teledermatology to reduce pressure on stretched dermatology secondary care services. Practices will continue to refer suspected cancer on the 2ww pathway but as the conversion is very low, for those lesions they are not considering to be cancer, they will also have equipment to enable an image to be uploaded via the clinical system to a provider for specialist review with a report turnaround of 2 days. This system has significantly reduced referrals in other CCGs and enabled limited dermatology capacity to be utilised for treatment.

Communications Update

- News of the successful 'Trailblazer bid' to provide additional mental health support in schools was recently reported by the Rotherham Advertiser as part of their class into Action campaign. A quote from provided on behalf of the Rotherham Integrated Health and Care Board.

- A comprehensive winter communications campaign is currently taking place, with activity increased throughout December in the run up to Christmas. Social media, promotional materials, health wellbeing feature in the Rotherham Advertiser and advertising have been key elements of the campaign.

- Communications materials were launched, with Connected Healthcare Rotherham, in December to promote the Primary Care Extended Access being provided at hubs across Rotherham in the evenings and at weekends. These materials have been shared with Rotherham partners, including the chamber of commerce and fire service, aimed at local people who are unable to visit their GP practice during the week due to work commitments.

Governing Body Development Session

There will be a Governing Body development session from 11:00 to 12:30 prior to the Governing Body meeting on the 6th February. The session is titled "19/20 Business Rules and Allocations".

Appendix 1

NHS England
Skipton House
80 London Rd
SE1 6LH

23 November 2018

Publications Gateway reference: 08648

Sent to CCG Accountable Officers and Chief Financial Officers

Administration Resources

Dear Colleague,

As we approach the publication of the long term plan for the NHS, it is important that we continue to maximise the amount of funding available for direct patient care, which means challenging ourselves to ensure that management and administration functions are delivered in as efficient a way as possible.

NHS England and NHS Improvement, as part of the joint working initiative, have committed to a further targeted reduction of our administration costs limit of 20% by 2020/21.

We are now asking CCGs to deliver the same level of reduction - 20% - by 2020/21. Combined with national level action, this will free up a total of more than £320 million a year compared to 2017/18, to be reinvested in improving patient care and supporting transformation of services as part of the long term plan.

Details of expected running cost reductions at individual CCG level, in the form of resource allocation changes, will be contained within the annual planning guidance, which will be issued in December.

Local actions to deliver running cost savings

CCGs will have the flexibility to determine locally how these efficiencies can be delivered. However, we would suggest that efficiency opportunities exist in the following areas:

- By working more closely with other organisations, as systems across local health economies, to improve efficiency, reduce duplication and remove some bureaucratic and expensive contracting processes. We will support this nationally through our review of payment systems and streamlining of other business processes. In addition, we will support rapid dissemination of the benefits delivered in leading Integrated Care Systems (ICS) and other health systems.
- Working with Commissioning Support Units (CSUs) and other support organisations to ensure efficiency and effectiveness in shared activity is maximised. CSUs, along with all other commissioning organisations, are expected to deliver a 20% reduction in administration costs. CSUs' achievement of this will be dependent on CCGs reducing the Payment by Results tariff burden carried by CSUs through simplified arrangements, including moving to more standardised approaches in what CSUs provide to each CCG.
- Reviewing discretionary expenditure, including continuing the significant reductions in spend on external consultancy support achieved last year.
- Exploring mergers and/or joint working arrangements within local health economies. NHS England will adopt a more flexible approach to those CCGs who wish to apply for a formal merger, by considering applications during the year, instead of on an annual basis. We will particularly support approaches which align a single CCG area with a single ICS.

- Our new regional operating model will support the development of ICS/STPs and ensure support resources are focussed on those areas that need it the most. We will also look to align commissioning resources to local systems wherever possible, for example in primary care.

Timeline

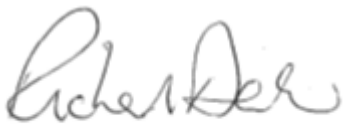
To ensure that full, recurrent savings can be made from the beginning of 2020/21, all CCGs must ensure they are planning for and taking actions to achieve these reductions during 2019/20. Where CCGs believe that they may require help to deliver these reductions, they should discuss any requirements with NHS England.

NHS England will support CCGs who want to work collaboratively with their local system or with each other to make fast progress on improving our collective efficiency and effectiveness, including through NHS Clinical Commissioners. We would like to hear from CCGs who want to pilot new approaches or have already achieved efficiencies that they think could be adopted more broadly across England.

2019/20 administration limits will be issued as part of CCG allocations in December.

Yours sincerely,

Matthew Swindells
Deputy Chief Executive
NHS England



Richard Barker
Regional Director (North)

Appendix 2

DPO Notification – 25th October 2018

This is an adhoc bulletin to notify you of something that your Data Protection Officer believes you should be aware of.

This is just one the many briefings from the government on planning for the potential of a no deal Brexit which has just been issued:
https://www.gov.uk/government/publications/data-protection-if-theres-no-brexit-deal/data-protection-if-theres-no-brexit-deal

the following points from the briefing are to note:

> *If the UK leaves the EU in March 2019 with no agreement in place regarding future arrangements for data protection, there would be no immediate change in the UK's own data protection standards. This is because the Data Protection Act 2018 would remain in place and the EU Withdrawal Act would incorporate the GDPR into UK law to sit alongside it.*
>
> *You would continue to be able to send personal data from the UK to the EU. In recognition of the unprecedented degree of alignment between the UK and EU's data protection regimes, the UK would at the point of exit continue to allow the free flow of personal data from the UK to the EU.*
>
> *The European Commission has stated that if it deems the UK's level of personal data protection essentially equivalent to that of the EU, it would make an adequacy decision allowing the transfer of personal data to the UK without restrictions.*

DPO assessment

So nothing changes for Data Protection immediately after Brexit.
This would then be the position until the EU carries out an adequacy assessment which we believe could happen if they update GDPR and the UK don't adopt the update, or if the UK relax any of the current DPA controls.

The only suggested action required for CCGs now is a review of any data flows between UK and EU.

DPO contact details:

Caroline Million 07989 345121 caroline.million@nhs.net
Barry Jackson 07980697150 barry.jackson@nhs.net

Helpdesk: Embed.gdpr@nhs.net

Kind Regards
Helen Thomis
IG/Primary Care Specialist
Email: helen.thomis@nhs.net
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Kier Property I Design and Business Services
3rd Floor, Scorex House, 1 Commercial Street, Bradford, BD1 4AS

DPO Notification – 26th October 2018

This is an adhoc bulletin to notify you of something that your Data Protection Officer believes you should be aware of.

Wm Morrison Supermarkets PLC v Various Claimants

This case is currently going through the UK courts system and this relates to the most recent decision in the Appeal Court, although it is understood that it may well be subject to an appeal to the Supreme Court. It is highlighted at this stage due to the press coverage it is getting and the potential impact the case could have on organisations processing personal data.

Details of the case:

The employee, a payroll auditor, held a grudge against Morrisons following an earlier disciplinary issue, and decided to take revenge by stealing close to 100,000 colleagues' payroll details and offering them for sale on the Dark Web. He was caught and subsequently prosecuted. Although Morrisons invested significant resources in trying to put right the situation, over 5,000 members of staff subsequently commenced group litigation against the supermarket. The Court of Appeal confirmed that even though Morrisons itself was not directly responsible for the breach; it was vicariously liable for the malicious actions of its rogue employee.

Implications of Appeal Court ruling:

The case is the first major application to data protection of principles well-established in other torts – for instance, responsibility for sexual abuse or violence committed by staff (bizarrely, the current leading case on vicarious liability, Mohamud, also involved the supermarket chain, where they were held responsible after a member of staff seriously assaulted a customer at a petrol station). The difficulty for organisations is that the potential number of claimants arising from a single data protection incident is often going to be much higher than those arising from a fight in a car-park. Furthermore, the amount of damages which claimants are routinely seeking for data protection related claims is increasing.

The Court of Appeal suggested that insurance could be part of the solution. However, care needs to be taken to ensure that any cover is appropriate – for instance in terms of the scope of cover and excess arrangements.

DPO Assessment:

Information only, no actions required at this stage. Keep case under review if it goes to Supreme Court and review guidance coming from NHS Digital or NHS England.

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Caroline Million 07989 345121 caroline.million@nhs.net

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Our values are enthusiastic, collaborative and forward-thinking

DATA PROTECTION OFFICER REPORT

AUTUMN 2018

Barry Jackson/Caroline Million

November 2018

Introduction

This report has been prepared to set out the work of the Data Protection Officer (DPO) within NHS Rotherham Clinical Commissioning Group (the CCG) and to highlight a number of specific areas of work being looked at as well as a strategic view of the future of Data Protection within the United Kingdom legislative framework and the evolution of the NHS.

Background

With the incorporation of the General Data Protection Regulations (GDPR) into UK law with the Data Protection Act 2018 a range of specific organisations, including NHS CCGs were required to appoint a person to the role of DPO. The Information Commissioners Office defines the role as:

- The GDPR introduces a duty for you to appoint a data protection officer (DPO) if you are a public authority or body, or if you carry out certain types of processing activities.

- DPOs assist you to monitor internal compliance, inform and advise on your data protection obligations, provide advice regarding Data Protection Impact Assessments (DPIAs) and act as a contact point for data subjects and the supervisory authority.

- The DPO must be independent, an expert in data protection, adequately resourced, and report to the highest management level.

- A DPO can be an existing employee or externally appointed.

- DPOs can help you demonstrate compliance and are part of the enhanced focus on accountability.

Data Protection Act 2018 and General Data Protection Regulation

Whilst there was understandably a lot of attention given to the GDPR at times it almost took on a life of its own separate to the DPA. In some areas we still hear people talk about the GDPR as if it is a standalone item. The attention on GDPR

during the start of the year promoted a wide awareness of it and the issues surrounding the lawful use of personal information. However, much of this was then lost as the discussion became focused on email and the opt out or opt in marketing that many companies looked to adopt in order to comply with the new legislation. The real danger now is that staff simply assume GDPR was just about marketing emails and move on from it without considering the wider implications of the incorporation of GDPR within the Data Protection Act 2018. Whilst noting that the Data Protection Act 1998 was repealed with the introduction of the new one we should all now concentrate on just referring to the Data Protection Act 2018.

Consent

One of the most significant changes with the introduction of the Data Protection Act 2018 is the change to consent. Under the previous legislation consent was one of a number of legal basis that could be used for the processing of personal data, all of which had the same consequences. However under DPA 2018 the processing of personal data using consent as the legal basis gives the data subject some additional rights, and some of these are likely to be difficult to facilitate in the healthcare environment. An obvious example being the right to erasure, also referred to as the right to be forgotten. It is difficult to see how that could be used in a healthcare setting where audit trails are required not just for patient records but for use of drugs and confidentiality. Organisations need to ensure that staff are aware of the need to reduce reliance on consent and move towards the provision of healthcare as the primary legal basis for processing patient data.

Data Privacy By Design

In order to ensure that the lawful use of personal data is considered at all stages of its use, the concept of Privacy by Design means that you have to integrate data protection into your processing activities and business practices, not only at the beginning or a project but throughout the lifecycle of any system, service, product or process. This approach helps you to comply with your data protection obligations and is now a legal requirement.

Data Protection Notices

A collated list of the DPO notices that have been published during the reporting period is at Annex A.

Strategic Forward View - Brexit

The UK exit from the EU (Brexit) remains a very significant issue that will affect many areas of the healthcare environment. As noted in a recent DPO notice a no deal Brexit would have potentially little immediate impact on the healthcare sector in relation to the processing of personal data. This is based on the judgement that existing laws between the UK and the EU are broadly in line and as such the EU will regard the UK as having an appropriate level of equivalence. Should the EU introduce new controls or amendments to the GDPR that the UK don't adopt or should the UK reduce any of its existing controls then the EU could conduct an assessment to see if the UK still meet the appropriate level of equivalence they require.

Incidents

All breaches of confidentiality are reported to the DPO as a matter of course and the DPO would be the point of contact should the ICO wish to take any further action on an incident. The biggest areas of risk are those where patient data is held such as Continuing Health Care or Individual Funding Requests. It is vital that you ensure that all staff working in these areas are fully trained before they are given access to patient data and are then kept up to date with training.

Data Protection Impact Assessments (DPIAs)

Completed DPIAs are sent to the DPO for final approval. All CCGs must ensure that the process for completing DPIAs is embedded within the organisation and that all staff who may be involved in new processes, services or systems are aware of the process. Wherever data is being, or could be used and may affect the rights and freedoms of individuals it is mandated by law that DPIAs should be carried out.

ANNEX A

DPO Notification – 29th June 2018

Your Data Protection Officer details have now been registered with the Information Commissioners Office.

DPO Notification – 20th August 2018

VOLUNTARY SECTOR AND SOCIAL ENTERPRISES

It has come to our attention that in some cases CCGs hold contracts with these types of organisations even though they are not compliant with either the Information Governance Toolkit or the new Data Protection and Security Toolkit. The NHS Standard Contract terms and conditions mandate that all providers must be compliant.

Action for CCGs: Check that all organisations that you contract with are toolkit compliant

DPO Notification – 4th September 2018

Data Protection Impact Assessments (DPIAs)

Completion of these should now be happening in your CCG as they are mandated by law with all managers, project managers and commissioners of services being fully aware of the process.

Once completed and approved these should be uploaded to your Freedom of Information Publication Scheme. Any sensitive areas such as IT information or staff details can be removed before publication if justified. Uploading of DPIAs ensures compliance but also ensures that you are keeping a comprehensive record of all DPIAs which can be accessed at any time.

DPO Notification – 25th October 2018

This is just one the many briefings from the government on planning for the potential of a no deal Brexit which has just been issued:
https://www.gov.uk/government/publications/data-protection-if-theres-no-brexit-deal/data-protection-if-theres-no-brexit-deal

The following points from the briefing are to note:

If the UK leaves the EU in March 2019 with no agreement in place regarding future arrangements for data protection, there would be no immediate change in the UK's own data protection standards. This is because the Data Protection Act 2018 would remain in place and the EU Withdrawal Act would incorporate the GDPR into UK law to sit alongside it.

You would continue to be able to send personal data from the UK to the EU. In recognition of the unprecedented degree of alignment between the UK and EU's data protection regimes, the UK would at the point of exit continue to allow the free flow of personal data from the UK to the EU.

The European Commission has stated that if it deems the UK's level of personal data protection essentially equivalent to that of the EU, it would make an adequacy decision allowing the transfer of personal data to the UK without restrictions.

DPO assessment
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This would then be the position until the EU carries out an adequacy assessment which we believe could happen if they update GDPR and the UK don't adopt the update, or if the UK relax any of the current DPA controls.

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Details of the case:
The employee, a payroll auditor, held a grudge against Morrisons following an earlier disciplinary issue, and decided to take revenge by stealing close to 100,000 colleagues' payroll details and offering them for sale on the Dark Web. He was caught and subsequently prosecuted. Although Morrisons invested significant resources in trying to put right the situation, over 5,000 members of staff subsequently commenced group litigation against the supermarket. The Court of Appeal confirmed that even though Morrisons itself was not directly responsible for the breach; it was vicariously liable for the malicious actions of its rogue employee.

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The Court of Appeal suggested that insurance could be part of the solution. However, care needs to be taken to ensure that any cover is appropriate – for instance in terms of the scope of cover and excess arrangements.

DPO Assessment:
Information only, no actions required at this stage. Keep case under review if it goes to Supreme Court and review guidance coming from NHS Digital or NHS England.

Appendix 3a

Department of Health & Social Care

From the Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care

39 Victoria Street
London
SW1H 0EU

020 7210 4850

07 December 2018

EU Exit – Human medicines supply in a March 2019 'no deal' scenario: An update

On 23 August 2018, I wrote to all pharmaceutical companies that supply prescription only medicines and pharmacy medicines to the UK that come from, or via, the European Union (EU) or European Economic Area asking you to ensure you have a minimum of six weeks additional supply in the UK, over and above existing business-as-usual buffer stocks, by 29 March 2019.

I am now writing to update you on the progress made to date and some updates to the Government planning assumptions.

As you will be aware, the Government and the EU have now agreed the basis upon which the UK will leave the EU in March 2019. This represents a significant step towards the UK's objective of securing an orderly exit from the EU. Nevertheless, as a responsible Government it is only right that we should continue to plan for all scenarios.

Progress to date

To address the potential border delays should we leave without a deal, the Department established the Medicines Supply Contingency Planning Programme. The Programme has been working with industry to support stockpiling activities of prescription only and pharmacy medicines, and to engage with companies that supply short shelf-life products in order to work through air-freight arrangements.

I want to thank the industry for the positive engagement with the Programme to date – I fully recognise the substantial amount of effort undertaken. I know that you are just as concerned as I am to fulfil your responsibilities and maintain the continuity of medicines supply to UK patients in the event of a 'no deal' scenario and I am grateful for industry support. Any company that has not yet responded should contact the Programme as soon as possible by emailing medicinescontingencyplanning@dhsc.gsi.gov.uk.

We recognise that manufacturers may need to make additional arrangements and we are considering how Government may support this.

In October, the Department invited wholesalers and pre-wholesalers of pharmaceutical warehouse space to bid for government funding to secure the additional capacity needed for stockpiled medicines. I'm pleased to report that we had a good response to that invitation and funding for selected organisations has now been agreed.

Update to cross-Government planning assumptions

In my previous letter I advised that the cross-Government planning assumption about potential border delays would be subject to revision in light of future developments. Government departments have been working to design customs and other control arrangements at the UK border in a way which ensures goods can continue to flow into the country, and won't be delayed by additional controls and checks. On the UK side this work is proceeding well, and we have been clear we will not impose additional controls and checks.

However, the UK Government does not have control over the checks which member states impose at the EU border. The European Commission has made it clear that, in the event of a 'no deal' scenario, it will impose full third country controls on people and goods entering the EU from the UK. Whether this happens or not is in their hands, not ours.

Although we cannot know exactly what each member state will do with respect to checks on the EU border, the cross-Government planning assumptions have been revised so we can prepare for the potential impacts that the imposition of third country controls by member states could have. These impacts are likely to be felt mostly on the short straits crossings into Dover and Folkestone, where the frequent and closed loop nature of these mean that both exports and imports would be affected.

The revised cross-Government planning assumptions show that there will be significantly reduced access across the short straits, for up to six months.

This is very much a worst-case scenario. In a 'no deal' exit from the EU we would, of course, be pressing member states hard to introduce pragmatic arrangements to ensure the continued full flow of goods which would be to their benefit as well as ours. Nevertheless, as a responsible Government, we have a duty to plan for all scenarios. And in areas where we cannot tolerate significant risk to the flow of goods, such as with medicines and medical products, we need to have contingency plans in place for this worst-case planning assumption.

This means that whilst the six-week stockpiling activities remain a critical part of our contingency plans, this now needs to be supplemented with additional actions. The

Government recognises the vital importance of medicines and medical products and is working to ensure that there is sufficient roll-on, roll-off freight capacity to enable these vital products to continue to move freely in to the UK. The Government has also agreed that medicines and medical products will be prioritised on these alternative routes to ensure that the flow of all these products will continue unimpeded after 29 March 2019.

We are well aware that you will need adequate notice and guidance to put arrangements in place to reroute your supplies and my officials running the Medicines Supply Contingency Planning Programme will follow up with you very shortly. A corresponding letter is being sent out today to suppliers of medical devices and clinical consumables.

Thank you for your continued support with this important programme. We are confident that, with adequate preparation and your support, we can together safeguard patient care in the unlikely event of a disorderly 'no deal' exit from the EU.

Yours ever,

MATT HANCOCK

Appendix 3b

Department of Health & Social Care

From the Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care

39 Victoria Street
London
SW1H 0EU

020 7210 4850

07 December 2018

EU Exit – Medical Devices and Clinical Consumables supply in a March 2019 'no deal' scenario: An update

On 23 August 2018, I wrote to suppliers of medical devices and clinical consumables regarding our contingency planning approach. As you are already aware, one of the contingency measures we are taking is to increase stock holding at national level and our NHS Supply Chain colleagues have been contacting those suppliers that routinely import products from European Union (EU) countries to establish the measures necessary to achieve this.

In parallel with this, we also asked all suppliers of medical devices and clinical consumables that source products from EU countries to review their supply chains and determine what steps they need to take so that they can continue to provide products in the unlikely event the UK leaves the EU without a deal.

I am now writing to update you on the progress made to date and some updates to the Government planning assumptions.

As you will be aware, the Government and the EU have now agreed the basis upon which the UK will leave the EU in March 2019. This represents a significant step towards the UK's objective of securing an orderly exit from the EU. Nevertheless, as a responsible Government it is only right that we should continue to plan for all scenarios.

Progress to date

To address potential border delays should we leave without a deal, the Department established a range of contingency measures to maintain continuity of supply of medical devices and clinical consumables. This includes increasing stock holding capacity and starting to stockpile through our national logistics and procurement operations and the development of measures to allow continued movement of products into the UK from the EU at short notice.

The Department has been working with industry in implementing these contingency arrangements and I want to thank suppliers for the engagement with the Programme to date - I fully recognise the substantial amount of effort undertaken. I know that you

are just as concerned as I am to fulfil your responsibilities and maintain the continuity of medical supplies to UK patients in the event of a 'no deal' scenario and I am grateful for industry support. Any company that routinely imports products from other EU countries and has not yet engaged should contact the Department as soon as possible by emailing mdcc-contingencyplanning@dhsc.gov.uk.

Update on cross-Government planning assumptions

In my previous letter I advised that the cross-Government planning assumption about potential border delays would be subject to revision in light of future developments. Government departments have been working to design customs and other control arrangements at the UK border in a way which ensures goods can continue to flow into the country, and won't be delayed by additional controls and checks. On the UK side this work is proceeding well, and we have been clear we will not impose additional controls and checks.

However, the UK Government does not have control over the checks which member states impose at the EU border. The European Commission has made it clear that, in the event of a 'no deal' scenario, it will impose full third country controls on people and goods entering the EU from the UK. Whether this happens or not is in their hands, not ours.

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The revised cross-Government planning assumptions show that there will be significantly reduced access across the short straits, for up to six months.

This is very much a worst-case scenario. In a 'no deal' exit from the EU we would, of course, be pressing member states hard to introduce pragmatic arrangements to ensure the continued full flow of goods which would be to their benefit as well as ours. Nevertheless, as a responsible Government, we have a duty to plan for all scenarios. And in areas where we cannot tolerate significant risk to the flow of goods, such as with medicines and medical products, we need to have contingency plans in place for this worst-case planning assumption.

The Government recognises the vital importance of medicines and medical products and is working to ensure that there is sufficient roll-on, roll-off freight capacity to enable these vital products to continue to move freely in to the UK. The Government has also agreed that medicines and medical products will be prioritised on these

alternative routes to ensure that the flow of all these products will continue unimpeded after 29 March 2019.

We are well aware that you will need adequate notice and guidance to put arrangements in place to reroute your supplies and my officials running the Medical Devices and Clinical Consumables Supply Contingency Planning Programme will follow up with you very shortly. A corresponding letter is being sent out today to suppliers of medicines.

Thank you for your continued support with this important programme. We are confident that, with adequate preparation and your support, we can together safeguard patient care in the unlikely event of a disorderly 'no deal' exit from the EU.

Yours ever,

MATT HANCOCK

Appendix 3c

Department of Health & Social Care

From the Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care

39 Victoria Street
London
SW1H 0EU

020 7210 4850

07 December 2018

Medicines supply contingency plans for a no-deal Brexit scenario

I am writing as part of the Government's ongoing preparations for a March 2019 'no deal' Brexit scenario and the potential impact on the supply of medicines.

On 23 August 2018, I wrote to all pharmaceutical companies that supply prescription only medicines and pharmacy medicines to the UK from, or via, the European Union or European Economic Area asking them to ensure they have a minimum of six weeks additional supply in the UK, over and above existing business-as-usual buffer stocks, by 29 March 2019.

I am writing to update you on the progress made to date and some updates to the Government planning assumptions, which may now affect you even if you do not supply prescription only or pharmacy medicines from or via the EU/EEA into the UK.

As you will be aware, the Government and the EU have now agreed the basis upon which the UK will leave the EU in March 2019. This represents a significant step towards the UK's objective of securing an orderly exit from the EU. Nevertheless, as a responsible Government we have to plan for all scenarios.

Update to cross-Government planning assumptions

In August I advised that the cross-Government planning assumption about potential border delays would be subject to revision in light of future developments.

Government departments have been working to design customs and other control arrangements at the UK border in a way which ensures goods can continue to flow into the country, and won't be delayed by additional controls and checks. On the UK side this work is proceeding well, and we have been clear we will not impose additional controls and checks. However, the UK Government does not have control over the checks which member states impose at the EU border. The European

Commission has made it clear that, in the event of a 'no deal' scenario, it will impose full third country controls on people and goods entering the EU from the UK. Whether this happens or not is in their hands, not ours.

Although we cannot know exactly what each member state will do with respect to checks on the EU border, the cross-Government planning assumptions have been revised so we can prepare for the potential impacts that the imposition of third country controls by member states could have. These impacts are likely to be felt mostly on the short straits crossings into Dover and Folkestone, where the frequent and closed loop nature of these mean that both exports and imports would be affected.

The revised cross-Government planning assumptions show that there will be significantly reduced access across the short straits, for up to six months.

This is very much a worst-case scenario. In a 'no deal' exit from the EU we would, of course, be pressing member states hard to introduce pragmatic arrangements to ensure the continued full flow of goods which would be to their benefit as well as ours. Nevertheless, as a responsible Government, we have a duty to plan for all scenarios. And in areas where we cannot tolerate significant risk to the flow of goods, such as with medicines and medical products, we need to have contingency plans in place for this worst-case planning assumption.

This means that whilst the six-week stockpiling activities remain a critical part of our contingency plans, this now needs to be supplemented with additional actions.

The Government recognises the vital importance of medicines and medical products and is working to ensure that there is sufficient roll-on, roll-off freight capacity to enable these vital products to continue to move freely in to the UK. The Government has also agreed that medicines and medical products will be prioritised on these alternative routes to ensure that the flow of all these products will continue unimpeded after 29 March 2019.

Our data shows that you currently do not manufacture, batch test or release your products in the EU before marketing them in the UK. However, if this has changed I would ask you to contact our Medicines Supply Contingency Planning Programme at medicinescontingencyplanning@dhsc.gov.uk

I am confident that, with adequate preparation and your support, we can together safeguard patient care in the unlikely event of a disorderly ‘no deal’ exit from the EU. My officials running the Medicines Supply Contingency Planning Programme will follow up with you shortly.

Yours ever,

MATT HANCOCK

Appendix 3d

From the Permanent Secretary
Sir Chris Wormald

Department of Health & Social Care

39 Victoria Street
London
SW1H 0EU
permanent.secretary@dh.gsi.gov.uk

21 December 2018

To: All Providers and Commissioners of NHS Services

Dear Colleagues,

EU Exit Operational Readiness Guidance for the health and care system

Earlier this month, the Secretary of State for Health and Social Care issued information on the Government's revised border planning assumptions to industry and the health and care system. These letters focused on supply chain implications in the event that the United Kingdom (UK) leaves the European Union (EU) without a ratified agreement on 29 March 2019 – a 'no deal' exit.

As you will be aware, the Government and the EU have now agreed the basis upon which the UK will leave the EU in March 2019. 'No deal' exit is not the Government's policy, but it is our duty to prepare for all scenarios. Since the Secretary of State's letter in August, and with the assistance of our arm's-length bodies and industry, the Department for Health and Social Care has strengthened its national contingency plans for 'no deal'. With just over three months remaining until exit day, we have now reached the point where we need to ramp up 'no deal' preparations. This means the Department, alongside all other government departments, will now enact the remaining elements of our 'no deal' plans.

Delivering the deal remains the Government's top priority and is the best 'no deal' mitigation. But in line with the Government's principal operational focus on national 'no deal' planning, actions must now be taken locally to manage the risks of a 'no deal' exit.

To inform preparations, I have included the EU Exit Operational Readiness Guidance alongside this letter, which has been developed and agreed with NHS England and Improvement. This guidance sets out the local actions that providers and commissioners of health and adult social care services in England should take to prepare for EU Exit. The guidance will also be shared with colleagues in the devolved

Department of Health & Social Care

administrations to assist them with their preparations as part of UK-wide contingency plans.

This guidance will be sent to all health and care providers, including adult social care providers. I recognise that, while health and social care face similar issues, there is some variation. I am therefore sending a letter in parallel to local authorities and adult social care providers.

The Department, with the support of NHS England and Improvement, and Public Health England, has set up a national Operational Response Centre. This will lead on responding to any disruption to the delivery of health and care services in England, that may be caused or affected by EU Exit. The Operational Response Centre will co-ordinate EU Exit-related information flows and reporting across the health and care system.

The Operational Response Centre will also work closely with all of the devolved administrations to ensure a co-ordinated approach across the UK. The Operational Response Centre will not bypass existing regional reporting structures; providers and commissioners of NHS services should continue to operate through their usual reporting and escalation mechanisms.

NHS England and Improvement will also establish local, regional and national teams to enable rapid support on emerging local incidents and escalation of issues into the Operational Response Centre as required.

NHS providers and commissioners will be supported by NHS England and Improvement local teams to resolve issues caused or affected by EU Exit as close to the frontline as possible. These issues will be escalated to regional level, as required. Where issues are impacting across the health and care system at a national level, the Operational Response Centre will co-ordinate information flows and responses.

In addition to operational support, I recognise the uncertainty that you face, and the Government will therefore continue to update you, as necessary, to inform your preparations for EU Exit.

I encourage you to view the relevant gov.uk page which contains all the relevant information published by the Department, as well as other government departments. This page will be updated regularly so that everyone is aware of developments and actions to take.

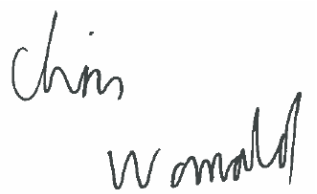
Finally, I would like to thank you and your teams for your continued hard work and for the efforts that lie ahead. I would also like to thank the many national organisations who are contributing to the Department's EU Exit work. Your dedication to

From the Permanent Secretary
Sir Chris Wormald

Department of Health & Social Care

implementing readiness plans for EU Exit and maintaining a world-leading health and care service are greatly appreciated.

Yours sincerely,



SIR CHRIS WORMALD
PERMANENT SECRETARY

Appendix 3e

Department of Health & Social Care

EU Exit Operational Readiness Guidance

Actions the health and care system in England should take to prepare for a 'no deal' scenario.

Published on 21 December 2018

Contents

Purpose

The EU Exit Operational Readiness Guidance, developed and agreed with NHS England and Improvement, lists the actions that providers and commissioners of health and care services in England should take if the UK leaves the EU without a ratified deal – a 'no deal' exit. This will ensure organisations are prepared for, and can manage, the risks in such a scenario.

This guidance has been sent to all health and care providers, including adult social care providers, to ensure the health and care system as a whole is prepared. Adult social care providers are advised to use this guidance as a prompt to test their own contingency plans. A further letter has also been sent in parallel to local authorities and adult social care providers to address specific adult social care issues.

Overview

The EU Exit Operational Readiness Guidance summarises the Government's contingency plans and covers actions that all health and adult social care organisations should take in preparation for EU Exit.

All organisations receiving this guidance are advised to undertake local EU Exit readiness planning, local risk assessments and plan for wider potential impacts. In addition, the actions in this guidance cover seven areas of activity in the health and care system that the Department of Health and Social Care is focussing on in its 'no deal' exit contingency planning:

- supply of medicines and vaccines;
- supply of medical devices and clinical consumables;
- supply of non-clinical consumables, goods and services;
- workforce;
- reciprocal healthcare;
- research and clinical trials; and
- data sharing, processing and access.

The impact of a 'no deal' exit on the health and adult social care sector is not limited to these areas, and the Department is also developing contingency plans to mitigate risks in other areas. For example, the Department is working closely with NHS Blood and Transplant to co-ordinate 'no deal' planning for blood, blood components, organs, tissues and cells (as detailed in the two technical notices on blood and organs, tissues and cells and the recent letter to the health and care system sent by the Secretary of State for Health and Social Care on 7 December 2018).

The actions in this guidance factor in the Government's revised border planning assumptions which were detailed in the Cabinet Office's guidance on 7 December 2018.

In preparation for a 'no deal' exit, the Department, with the support of NHS England and Improvement, and Public Health England, has set up a national Operational Response Centre. This will lead on responding to any disruption to the delivery of health and care services in England, that may be caused or affected by EU Exit. The Operational Response Centre will co-ordinate EU Exit-related information flows and reporting across the health and care system. The Operational Response Centre will also work with the devolved administrations to respond to UK-wide incidents.

The Operational Response Centre has been established to support the health and care system to respond to any disruption, and will not bypass existing local and regional reporting structures.

Working closely with the Operational Response Centre, NHS England and Improvement will also establish an Operational Support Structure for EU Exit. This will operate at national, regional and local levels to enable rapid support on emerging local incidents and escalation of issues into the Operational Response Centre as required. Contact details for the regional EU Exit leads are below:

Region	Contact details for regional EU Exit lead
North East	England.euexitnortheast@nhs.net
North West	England.euexitnorthwest@nhs.net
Midlands	England.mids-euexit@nhs.net
East of England	England.eoe-euexit@nhs.net
London	England.london-euexit@nhs.net
South East	England.se-euexit@nhs.net
South West	England.sw-euexit@nhs.net

NHS providers and commissioners will be supported by local NHS teams to resolve issues caused or affected by EU Exit as close to the frontline as possible. These issues will be escalated to regional level, as required. Where issues are impacting across the health and care system at a national level, the Operational Response Centre will co-ordinate information flows and responses.

This guidance and the planning assumptions within it represent the most up to date information available. Further operational guidance will be issued and updated to support the health and care system to prepare for the UK leaving the EU prior to 29 March 2019.

Summary

This section summarises seven areas where the government is focussing ‘no deal’ exit contingency planning in the health and care system, and where local action is required. Detailed actions for providers, commissioners and NHS England and Improvement regional teams are listed in Annex A (pages 15 to 33). Please read the summary and the action card that is applicable to your organisation.

Common to all of the groups of medical products listed below, it should be noted that government departments have also been working to design customs and other control arrangements at the UK border to ensure goods, including medical supplies, can continue to flow into the UK without being delayed by additional controls and checks.

However, the EU Commission has made clear that, in a ‘no deal’ exit, it will impose full third country controls on people and goods entering the EU from the UK. The cross-government planning assumption has therefore been revised to prepare for the potential impacts that the imposition of third country controls by member states could have. The revised assumption shows that there will be significantly reduced access across the short straits, for up to six months.

Supply of medicines and vaccines

- The Government recognises the vital importance of medicines and vaccines, and has developed a UK-wide contingency plan to ensure the flow of these products into the UK in a ‘no deal’ scenario.

- The plan covers medicines used by patients and service users in all four nations of the UK, as well as the UK Crown Dependencies. The Department is working very closely with the devolved administrations, the Crown Dependencies and other government departments to explore specific issues related to the various supply chains for medicines in the UK, as well as potential mitigations. The plan covers medicines used by all types of providers, including private providers.

- Earlier this year, the Department undertook an analysis using Medicines and Healthcare Products Regulatory Agency and European Medicines Agency data, on the supply chain for all medicines (including vaccines and medical radioisotopes). This identified those products that have a manufacturing touch point in the EU or wider EEA countries.

- In August 2018, the Department for Health and Social Care wrote to pharmaceutical companies that supply the UK with prescription-only and pharmacy medicines from, or via, the EU or European Economic Area (EEA) to prepare for a no deal scenario.

Companies were asked to ensure they have a minimum of six weeks' additional supply in the UK, over and above their business as usual operational buffer stocks, by 29 March 2019. Companies were also asked to make arrangements to air freight medicines with a short shelf life, such as medical radioisotopes.

- Since then, there has been very good engagement from industry to ensure the supply of medicines is maintained in a 'no deal' exit.

- The Department will support manufacturers taking part in the contingency planning and is already providing funding for the provision of additional capacity for the storage of medicines.

- In October, the Department invited wholesalers and pre-wholesalers of pharmaceutical warehouse space to bid for government funding to secure the additional capacity needed for stockpiled medicines, and funding for selected organisations has now been agreed.

- On 7 December 2018, the Department wrote to UK manufacturers of medicines currently using the short straits crossings of Dover and Folkestone as they will want to review supply arrangements in light of the Government's updated planning assumptions.

- Whilst the six-week medicines stockpiling activity remains a critical part of the Department's UK-wide contingency plan, it is now being supplemented by additional national actions.

- The Government is working to ensure there is sufficient roll-on, roll-off freight capacity to enable medicines and medical products to continue to move freely into the UK.

- The Government has agreed that medicines and medical products will be prioritised on these alternative routes to ensure the flow of all these products will continue unimpeded after 29 March 2019. This includes all medicines, including general sales list medicines.

- In the event of delays caused by increased checks at EU ports, the Department will continue to develop the UK-wide contingency plan for medicines and vaccines with pharmaceutical companies and other government departments.

- UK health providers – including hospitals, care homes, GPs and community pharmacies – should not stockpile additional medicines beyond their business as usual stock levels. There is also no need for clinicians to write longer NHS prescriptions and the public should be discouraged from stockpiling.

- 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.

- The Department and NHS England and Improvement are developing arrangements to allow local and regional monitoring of stock levels of medicines; arrangements are also likely to be put in place to monitor the unnecessary export of medicines.

- The Department is putting in place a “Serious Shortage Protocol”. This will involve changes to medicines legislation that will allow flexibility in primary care dispensing of medicines. Robust safeguards will be put in place to ensure this is operationalised safely, including making authoritative clinical advice available.

- Public Health England (PHE) is leading a separate UK-wide programme ensuring the continuity of supply for centrally-procured vaccines and other products that are distributed to the NHS for the UK National Immunisation Programme or used for urgent public health use. In addition to the national stockpiles that PHE has in place to ensure continued supply to the NHS, PHE continues to work alongside contracted suppliers on their contingency plans to ensure that the flow of these products will continue unimpeded in to the UK after exit day.

Supply of medical devices and clinical consumables

- On 23 October 2018, the Secretary of State for Health and Social Care wrote to all suppliers of medical devices and clinical consumables updating them on the contingency measures the Department is taking to ensure the continuity of product supply.

- One of these measures is to increase stock levels of these products at a national level in England.

- The Department is working with the devolved nations and Crown Dependencies to ensure that national contingency arrangements are aligned and able to support specific preparedness measures necessary to meet the needs of their health and care systems.

- The Department is also developing contingency plans to ensure the continued movement of medical devices and clinical consumables that are supplied from the EU directly to organisations delivering NHS services in England.

- The Department has asked all suppliers that regularly source products from EU countries to review their supply chains and determine what measures they need to take to ensure the health and care system has access to the products it needs.

- NHS Supply Chain officials are also contacting suppliers who routinely import products from the EU to establish what measures are required to ensure they can continue to provide products in a ‘no deal’ scenario. Products are already being ordered.

- The Government is working to ensure there is sufficient roll-on/roll-off freight capacity to enable medicines and medical products to continue to move freely into the UK. This will help facilitate the flow of products to both NHS and private care providers.

- The Government has agreed that medicines and medical products will be prioritised on these alternative routes to ensure the flow of these products will continue unimpeded after 29 March 2019.

- 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.

- The Department continues to engage directly with industry suppliers, trade associations, NHS providers and other government departments to develop its contingency planning approach and ensure the continued supply of medical devices and clinical consumables into the UK.

Supply of non-clinical consumables, goods and services

- The Department has identified categories of national suppliers for non-clinical consumables, goods and services that it is reviewing and managing at a national level. Examples of relevant categories include food and laundry services.

- For these categories, the Department is engaging with suppliers and industry experts to identify and plan for any supply disruption. Where necessary, there will be cross-government work to implement arrangements at the point of EU Exit to ensure continued supply.

- On food, for example, the Department is engaging with both suppliers and health experts to identify and plan for any food items that might suffer supply disruption in the event of a ‘no deal’. Standard guidelines will be developed for health and adult social care providers on suitable substitution arrangements for any food items identified as being at risk.

- The Department is also conducting supply chain reviews across the health and social care system to assess commercial risks. This includes reviews for high-risk non-clinical consumables, goods and services, and a self-assessment tool for NHS Trusts and Foundation Trusts. The results of these self-assessments were received at the end of November, and the Department is conducting analysis of the data, that will be used to provide additional guidance to Trusts and Foundation Trusts in January 2019.

Workforce

- The current expectation is that there will not be a significant degree of health and care staff leaving around exit day. Organisations can escalate concerns through existing reporting mechanisms to ensure there is regional and national oversight.

EU Settlement Scheme

- Through the EU Settlement Scheme, EU citizens will be able to register for settled status in the UK if they have been here for five years, or pre-settled status if they have been here for less than five years. This will ensure the rights of EU citizens are protected in the UK after EU Exit, and guarantee their status and right to work.

- Some EU citizens working in the health and care system would have been able to register for EU settled status under the pilot scheme that was open between the 3rd and 21st December 2018. People that did not register under the pilot scheme do not need to worry as the scheme will be fully open 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.

- More information, including where to register, can be found on this website.

Professional regulation (recognition of professional qualifications)

- 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.

- 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.

- 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 will be subject to future arrangements.

Reciprocal healthcare

- These plans are without prejudice to the rights and privileges available to Irish citizens in the UK, and UK citizens in Ireland, under the Common Travel Area arrangements.

- In a 'no deal' scenario, UK nationals resident in the EU, EEA and Switzerland may experience limitations to their access to healthcare services. The Government is therefore seeking to protect current reciprocal healthcare rights through transitional bilateral agreements with other member states.

- The Government has recently introduced the Healthcare (International Arrangements) Bill to ensure we have the legal powers to enter into such agreements in a 'no deal' scenario. The Bill could support a broad continuance of the existing reciprocal healthcare rights under current EU regulations (such as the European Health Insurance Card).

- The Government will issue advice via www.gov.uk and www.nhs.uk to UK nationals living in the EU, to UK residents travelling to the EU and to EU nationals living in the UK. It will explain how the UK is working to maintain reciprocal healthcare arrangements, but this will depend on decisions by member states. It will set out what options people might have to access healthcare under local laws in the member state they live in if we do not have bilateral agreements in place, and what people can do to prepare. These pages will be updated as more information becomes available.

- As is currently the case, if UK nationals living in the EU face changes in how they can access healthcare, and if they return permanently to the UK and take up ordinary residence here, they will be entitled to NHS-funded healthcare on the same basis as UK nationals already living here.

- It is not possible to quantify how many people might return due to changes in reciprocal healthcare, and it is important to note that people might return to the UK for many other reasons such as changes in legal status or costs of living.

Research and clinical trials

EU research and innovation funding schemes

- 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 EU Exit, until the end of 2020.

- This means that successful bids for EU programme funding until the end of 2020 will receive their full financial allocation for the lifetime of the project.

Clinical networks

- In a ‘no deal’ scenario, UK clinicians would be required to leave European Reference Networks (ERNs) on 29 March 2019. However, the UK will seek to strengthen and build new bilateral and multilateral relationships – including with the EU – to ensure clinical expertise is maintained in the UK.

- The Department and NHS England are in contact with the ERNs and no action is required at this stage. Further information will be communicated to the NHS and professional bodies in due course.

Clinical trials and clinical investigations

- The Government has issued guidance on the supply of investigational medicinal products (IMPs) for clinical trials in a ‘no deal’ scenario.

- The Department continues to engage with the life sciences industry regarding contract research and clinical trials of IMPs and medical devices. The Department is working closely with the NHS and is undertaking a comprehensive assessment of the potential impact of ‘no deal’ exit on clinical trials and investigations, to gain a greater understanding of those which might be affected by supply issues. This includes examining supply chains for 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. This assessment aims to conclude in January 2019 and, if necessary, further guidance will be issued thereafter.

- All organisations participating in and/or recruiting patients to clinical trials or clinical investigations in the UK should contact their relevant trial sponsors for confirmation of plans for supply chains for IMPs and medical devices as soon as possible.

- The Department has communicated with Sponsors of trials to emphasise their responsibility for ensuring the continuity of IMP supplies for their trials. The Government will monitor for any clinical trials or clinical investigations impacted due to disruptions to clinical trial supplies. Organisations should therefore continue to participate in and/or recruit patients to clinical trials and clinical investigations from 29 March 2019, unless they receive information to the contrary from a trial sponsor, organisation managing the trial or investigation, or from formal communications.

Clinical Trial Regulation

- For EU-wide trials, the new EU Clinical Trial Regulation (CTR) will not be in force in the EU on 29 March 2019 and so will not be incorporated into UK law.

- However, the Government has stated the UK will align where possible with the CTR without delay when it does come into force in the EU, subject to usual parliamentary approvals. This will provide certainty for organisations conducting trials in the UK.

- Those organisations carrying out clinical trials should follow the normal process for seeking regulatory approval.

Data sharing, processing and access

- It is imperative that personal data continues to flow between the UK, EU and EEA member states, following our departure from the EU. The Department for Digital, Culture, Media and Sport and the Information Commissioner's Office (ICO) have released guidance on data protection in a 'no deal' scenario, which can be viewed on gov.uk and the ICO website.

- The European Commission is unlikely to have made a data protection adequacy decision regarding the UK before EU Exit. An adequacy decision is where the European Commission is satisfied that a transfer of personal data from the EU/EEA to a country outside the EU/EEA would be adequately protected.

- Transfers of personal data from the UK to the EU/EEA should not be affected in a 'no deal' scenario. This is because it would continue to be lawful under domestic legislation for health and adult social care organisations to transfer personal data to the EU/EEA and adequate third countries in the same way we do currently.

- At the point of exit, EU/EEA organisations will consider the UK a third country. This will mean the transfer of personal data from the EU/EEA to the UK will be restricted unless appropriate safeguards are put in place.

- In order to ensure that personal data can continue to be transferred from organisations in the EU/EEA to the UK in the event there is no adequacy decision, alternative mechanisms for transfer may need to be put in place. This is the case even if organisations are currently compliant with the GDPR.

- One solution you could consider, which the ICO states that most businesses find to be a convenient safeguard, particularly when dealing with non-public organisations, is to use one of the standard contractual clauses (SCCs) approved by the EU Commission. Guidance on these SCCs can be found in the links to gov.uk and the ICO website

above. Further information will be issued in due course. For now, health and adult social care organisations should follow the instructions detailed in Annex A to identify data flows that may be at risk in a ‘no deal’ exit.

ANNEX A – Action cards

Card 1 – Action card for providers

Role

All providers of NHS services – including NHS Trusts and Foundation Trusts, primary care organisations and independent sector organisations who provide NHS services – must consider and plan for the risks that may arise due to a ‘no deal’ exit.

All providers should continue with their business continuity planning, taking into account the instructions in this national guidance, incorporating local risk assessments, and escalating any points of concern on specific issues to regional NHS EU Exit or departmental mailboxes listed in this guidance. Officials monitor these mailboxes and will respond to queries. Contact details for the regional NHS EU Exit Teams are included in the overview on page 5.

Clinical Commissioning Groups and NHS England should agree the handling of communications with general practice in line with existing delegation arrangements.

Actions for providers

Local EU Exit readiness preparations

Risk assessment and business continuity planning

- Undertake an assessment of risks associated with EU Exit by the end of January 2019, covering, but not limited to:
    - 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.
- 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.
- 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.

Communications and escalation

All providers to:

- Ensure your board is sighted on EU Exit preparation and take steps to raise awareness amongst staff.
- 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.
- 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.
- Be ready for further operational guidance from NHS England and Improvement as contingency planning work progresses.

NHS providers to:

- 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.
- Note your nominated regional NHS lead for EU Exit and their contact details (included in the overview on page 5).
- Escalate any issues you have identified as having a potentially widespread impact immediately to your regional EU Exit team.
- 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.

Reporting, assurance and information

NHS providers to:

- 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.

- Note that regional NHS EU Exit teams will be in contact shortly to confirm your progress on these actions.

- 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

Supply of medicines and vaccines

All health and adult social care providers to:

- 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.

- Note that there is no need to contact suppliers of medicines directly.

- Direct staff to promote messages of continuity and reassurance to people who use health and care services, including that they should not store additional medicines at home.

- 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.

- Note that the Department and NHS England and Improvement are developing arrangements to allow local and regional monitoring of stock levels of medicines.

- 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.

- Continue to report current shortage issues and escalate queries for medicine supply issues unrelated to current shortages through existing regional communication channels.

Regional pharmacists and emergency planning staff to:

- 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.

Supply of medical devices and clinical consumables

- 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.

- 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.

- Be aware that the contingency plan is kept under review, and the Department will communicate further guidance as and when necessary.

- Send queries regarding medical devices and clinical consumables to mdcc-contingencyplanning@dhsc.gov.uk.

Supply of non-clinical consumables, goods and services

All providers to:

- 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.

- 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.

- 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.

- Be aware that the Department is conducting supply chain reviews across the health and care system, and work is in progress to identify risk areas specific to primary care.

- Await further advice from the Department on what actions should be taken locally.

NHS Trusts and Foundation Trusts to:

- Submit the results of their self-assessment on non-clinical consumables, goods and services to contractreview@dhsc.gov.uk, if not done so already.

- 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.

Workforce

- Assess whether your organisation has incurred a reduction in the number of EU nationals in your workforce before the UK leaves the EU.

- 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. Further information can be viewed here.

- Monitor the impact of EU Exit on your workforce regularly and 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.

- 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.

- Ensure your board has approved business continuity plans that include EU Exit workforce planning, including the supply of staff needed to deliver services.

- 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.

- Escalate concerns through existing reporting mechanisms.
- Send queries on workforce to WorkforceEUExit@dhsc.gov.uk.

Professional regulation (recognition of professional qualifications)

- 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.
- 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.
- 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.

Reciprocal healthcare

All providers to:

- 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, depending on the reciprocal agreements that are concluded.
- Continue to support individuals who apply for NHS authorised treatment or maternity care in another member state (the S2 and cross-border healthcare processes).
- Note that the Department will provide updates and further information on reciprocal healthcare arrangements prior to 29 March 2019.

NHS Trusts and Foundation Trusts to:

- 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.
- 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.

- 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.

GP practices to:

- Promote completion of the supplementary questions section of the GMS1 form, and then, as appropriate, send the form to NHS Digital (NHSDigital-EHIC@nhs.net) or the Department for Work and Pensions' Overseas Healthcare Team (overseas.healthcare@dwp.gsi.gov.uk). The response on a person's non-UK EHIC/S1 helps the Department seek reimbursements from EU member states for those who are covered by the reciprocal healthcare arrangements. More information on the GMS1 form can be found here. Further information for primary care staff on providing healthcare for overseas visitors from the EU/EEA can be found here.

Research and clinical trials

EU research and innovation funding schemes

- 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.

- 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.

- Contact officials at EU-Health-Programme@dhsc.gov.uk with information regarding your Third Health Programme grant, and any queries that you have, as soon as possible.

Clinical trials and clinical investigations

- 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.

- 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.

- 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.

- 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.

- 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.

- Send queries concerning IMPs or medical devices to imp@dhsc.gov.uk

Data sharing, processing and access

- Investigate your organisation’s reliance on transfers of personal 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.

- 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.

- 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.

- 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.

- Await further guidance, which will be issued to health and care providers in due course. Assistance will also be available through webinars in early 2019.

Finance

- 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.

Queries

For queries relating to specific topics areas, providers should contact the departmental mailboxes listed in this guidance:

- Medicine shortage queries should be raised by business as usual routes
- Medical devices and clinical consumables to mdcc-contingencyplanning@dhsc.gov.uk.
- NHS Trusts and Foundation Trusts' self-assessment on non-clinical consumables, goods and services to contractreview@dhsc.gov.uk.
- Workforce to WorkforceEUExit@dhsc.gov.uk.
- Third Health Programme grants to EU-Health-Programme@dhsc.gov.uk.
- Horizon 2020 grants to EUGrantsFunding@ukri.org
- IMPs or clinical devices to imp@dhsc.gov.uk.

Any immediate risks or concerns relating to continuity of NHS service provision should be escalated to the relevant regional NHS EU Exit mailbox.

Card 2 – Action card for commissioners

Role

In addition to current responsibilities, commissioners – including Clinical Commissioning Groups, Primary Care Commissioning and specialised commissioning – should ensure that their contracted health and care services are ready to manage the risks arising in a ‘no deal’ exit.

Commissioners should continue with their business continuity planning, taking into account the instructions in this national guidance, incorporating local risk assessments and escalating any points of concern on specific issues to the relevant mailboxes.

Commissioners should also liaise with providers of services that they commission, to ensure they are taking account of the actions for providers outlined in this guidance. EU Exit and its implications on health and care services should be discussed at commissioner board level on a regular basis to ensure sufficient oversight.

Actions for commissioners

Local EU Exit readiness preparations

Risk assessment and business continuity planning

- Undertake an assessment of risks associated with EU Exit by the end of January 2019, covering, but not limited to:
    - The seven key areas identified nationally and detailed below.
    - Potential increases in demand associated with the wider impacts of a ‘no deal’ exit.
    - Locally specific risks resulting from EU Exit.
- Continue business continuity planning in line with your legal requirements under the Health and Social Care Act 2012, including 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.
- Support providers to 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.

Communications and escalation

All commissioners to:

- Ensure your board is sighted on EU Exit preparation and take steps to raise awareness amongst staff.
- 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.
- Be ready for further operational guidance from NHS England and Improvement as contingency planning work progresses.
- Review capacity and activity plans, as well as annual leave, on call and command and control arrangements around the 29 March 2019.

NHS commissioners to:

- 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.
- Note your nominated regional NHS lead for EU Exit and their contact details (included in the overview at page 5).
- Escalate any issues you have identified as having a potentially widespread impact immediately to your regional EU Exit team.
- 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.

Reporting, assurance and information

NHS commissioners to:

- 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.

- Note that regional NHS EU Exit teams will be in contact shortly to confirm your progress on these actions.

- For queries relating to specific topics 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.

Supply of medicines and vaccines

- Promote the Secretary of State's message: healthcare providers should not stockpile medicines beyond their business as usual stock levels, and no clinician should write longer prescriptions for patients. The Department's UK-wide contingency plan for the supply of medicines and vaccines is being developed alongside pharmaceutical companies and other government departments.

- Advise providers that there is no need to contact suppliers of medicines directly.

- Ensure providers are encouraging staff to reassure patients that they should not store additional medicines at home as the Government is working with industry to ensure a continued supply of medicines from the moment we leave the EU.

- Inform providers 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.

- Inform providers that the Department and NHS England and Improvement are developing arrangements to allow local and regional monitoring of stock levels of medicines.

- Be aware that the UK-wide contingency plan for medicines and vaccines is kept under review, and the Department will communicate further guidance as and when necessary.

- Share letters from the Department aimed at an NHS and wider health and care provider audience (such as the third sector, private sector and home care).

- Note that the Department has engaged directly with specialist commissioning leaders about prisons and defence. This is to address their specific needs and concerns relating to medicine supply.

- Continue to report current shortage issues and escalate queries for medicine supply issues unrelated to current shortages through existing regional communication channels.

Regional pharmacists and emergency planning staff to:

- 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.

Supply of medical devices and clinical consumables

- 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, we will provide further guidance by the end of January 2019.

- 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.

- Be aware that the contingency plan is kept under review, and the Department will communicate further guidance as and when necessary.

- Send queries regarding medical devices and clinical consumables to mdcc-contingencyplanning@dhsc.gov.uk.

Supply of non-clinical consumables, goods and services

- Be aware that the Department is conducting supply chain reviews across the health and care system, and work is in progress to identify risk areas specific to primary care, adult social care and public health services.

- 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.

- Check your providers continue to update their local business continuity plans to ensure continuity of supply in a 'no deal' scenario.

- Await further advice from the Department on where actions should be taken locally by commissioners and providers of NHS-commissioned services.

Workforce

- Ensure healthcare providers that deliver your commissioned services publicise the EU Settlement Scheme to their health and care staff who are EU citizens, and support them to apply for the scheme.

- Monitor the workforce impacts of EU Exit in your primary and secondary care providers' business continuity plans and highlight risks to WorkforceEUExit@dhsc.gov.uk.

- Ensure your providers' board-approved business continuity plans include workforce planning.

- Assess whether your organisation has incurred a reduction in the number of EU nationals in your workforce before the UK leaves the EU.

- Publicise the EU Settlement Scheme to your staff who are EU nationals and actively support them to apply for the scheme when it opens in March 2019. Further information can be viewed here.

- Monitor the impact of EU Exit on your own workforce regularly, and update your local business continuity plans as necessary.

- Send workforce queries to WorkforceEUExit@dhsc.gov.uk

Professional regulation (recognition of professional qualifications)

- Inform your staff and healthcare providers 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.

- Inform your staff and healthcare providers 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.

- 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.

Reciprocal healthcare

- 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, depending on the reciprocal agreements that are concluded.

- Inform NHS Trusts and Foundation Trusts that they should continue to maintain a strong focus on correctly charging those who should be charged directly for NHS care.

- 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.

Research and clinical trials

- 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.

- Ensure your providers who receive Horizon 2020 grants input basic information about their awards into a portal, which can be accessed here, as soon as possible. Further guidance can be found here and all queries should be sent to EUGrantsFunding@ukri.org.

- Ensure your providers who receive Third Health Programme grants contact officials at EU-Health-Programme@dhsc.gov.uk with information regarding their awards and any queries that they have, as soon as possible.

Clinical trials and clinical investigations

- Support your providers to respond to 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.

- Support your providers who run clinical trials or investigations in the UK to consider their supply chains for those IMPs, medical devices, in vitro diagnostic devices, advanced therapy medicinal products, radioisotopes and other clinical consumables which come from, or via, the EU or EEA as soon as possible. Providers should contact relevant trial Sponsors, and 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.

- Support your providers to participate in and/or recruit to clinical trials and investigations up to and from 29 March 2019. This should occur unless providers receive information to the contrary from a trial Sponsor, organisation managing the clinical trial or investigation, or from formal communications that a clinical trial or clinical investigation is being impacted due to trial supplies.

- Send queries concerning IMPs or medical devices to imp@dhsc.gov.uk.

Data sharing, processing and access

- Investigate your organisation’s reliance on transfers of personal 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.

- 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.

- 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.

- 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 be completed by end March

2019, but early completion will enable health and adult social care organisations more time to identify and quickly address any vulnerabilities.

- Await further guidance, which will be issued to health and care providers in due course. Assistance will also be available through webinars in early 2019.

Finance

- 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. Commissioners should discuss these costs with their regional NHS EU Exit support team. Feedback from commissioners will inform decisions on whether further guidance on cost collection is required.

Queries

For queries relating to specific topics areas, commissioners should contact the departmental mailboxes listed in this guidance:

- Medicine shortage queries should be raised by business as usual routes
- Medical devices and clinical consumables to mdcc-contingencyplanning@dhsc.gov.uk.
- NHS Trusts and Foundation Trusts' self-assessment on non-clinical consumables, goods and services to contractreview@dhsc.gov.uk.
- Workforce to WorkforceEUExit@dhsc.gov.uk.
- Third Health Programme grants to EU-Health-Programme@dhsc.gov.uk.
- Horizon 2020 grants to EUGrantsFunding@ukri.org
- IMPs or clinical devices to imp@dhsc.gov.uk.

Any immediate risks or concerns relating to continuity of NHS service provision should be escalated to the relevant regional NHS EU Exit mailbox.

Card 3 – Action card for NHS England and Improvement regional teams

Role

In addition to current responsibilities, NHS regional teams will be required to provide regional system oversight in a ‘no deal’ scenario. The forthcoming NHS EU Exit Operational Support Structure will operate at a national and regional level, and support existing regional teams. Its functions will include monitoring local preparations, responding to the escalation of issues, and co-ordinating assurance and reporting arrangements at regional level.

NHS regional teams should communicate the necessary actions to providers and commissioners, and ensure that these instructions are being followed. This assurance should be gained through reporting on resilience and business continuity plans, and through existing meetings with providers and commissioners in your area. Once the dedicated NHS EU Exit regional teams are established, they will undertake assurance of local business continuity plans in relation to EU Exit.

Regional NHS leads and mailboxes for EU Exit have been established. Further details of the structure and function of the regional operational support teams will be communicated as the functions are implemented.

Published to GOV.UK in pdf format only.

Global and Public Health Directorate / EU and International Health / EU Exit Preparedness

www.gov.uk/dhsc

How are we doing? An overview

Key performance report: November 2018 (September data)

Appendix 4a

	A&E (95%)	RTT (92%)	Diagnostics 6 weeks	2ww (93%)	2ww breast (93%)	31 day (96%)	62 day (85%)	EIP (50%)	IAPT Access 4.75% Q4)	IAPT Recovery (50%)
South Yorkshire and Bassetlaw	91.6	91.7	0.5	93.2	90.3	95.1	80.1	82.8	4.8	52.6
Greater Manchester										
Bucks, Oxfordshire and Berkshire West										
Frimley Health										
Dorset										
Nottinghamshire										
Blackpool & Fyde - Lancashire and S.Cumbria										
Milton Keynes, Bedfordshire & Luton										
Gloucestershire										

The ICS financial position is reporting a year to date favourable variance against plan of £1.6m excluding PSF; all organisations are currently forecasting break even against plan before PSF. Some organisations have agreed favourable changes to their control totals with regulators in order to access incentive payments. This will provide benefit to the ICS system improvement plan value.

How are we doing? An overview

Appendix 4b

Key performance report: November 2018 (September data)

North

	A&E (95%)	RTT (92%)	Diagnostics 6 weeks	2ww (93%)	2ww breast (93%)	31 day (96%)	62 day (85%)	EIP (50%)	IAPT Access 4.75% Q4)	IAPT Recovery (50%)
South Yorkshire and Bassetlaw	91.6	91.7	0.5	93.2	90.3	95.1	80.1	82.8	4.8	52.6
Greater Manchester										
Cheshire and Merseyside										
Cumbria and North East										
Humber, Coast and Vale										
Lancashire and South Cumbria										
West Yorkshire										

The ICS financial position is reporting a year to date favourable variance against plan of £1.6m excluding PSF; all organisations are currently forecasting break even against plan before PSF. Some organisations have agreed favourable changes to their control totals with regulators in order to access incentive payments. This will provide benefit to the ICS system improvement plan value.

Appendix 4c

ICS CEO Report

SOUTH YORKSHIRE AND BASSETLAW
INTEGRATED CARE SYSTEM

December 2018

Author(s)	**Andrew Cash, Chief Executive, SYB ICS**
Sponsor	

Is your report for Approval / Consideration / Noting

For noting and discussion

Links to the STP (please tick)

☑ **Reduce inequalities**	☑ **Join up health and care**	☑ **Invest and grow primary and community care**	☑ **Treat the whole person, mental and physical**
☑ **Standardise acute hospital care**	☑ **Simplify urgent and emergency care**	☑ **Develop our workforce**	☑ **Use the best technology**
☑ **Create financial sustainability**	☑ **Work with patients and the public to do this**		

Are there any resource implications (including Financial, Staffing etc)?

N/A

Summary of key issues

This monthly paper from the ICS CEO provides an:

- Update on the work of the ICS CEO over the last month

Recommendations

The Collaborative Partnership Board partners are asked to note and share the update.

Integrated Care System CEO Report

SOUTH YORKSHIRE AND BASSETLAW
SHADOW INTEGRATED CARE SYSTEM

December 2018

1. Purpose

This monthly paper from the ICS CEO provides an:

- Update on the work of the ICS CEO over the last month

2. Report – December 2018

2.1 ICS Place Conversations

The place-based conversations to understand the good practice happening in Place and explore issues or areas where additional support would be helpful are now underway. The first conversation took place in Doncaster last month. The conversation, which was focused on understanding the key issues and aspirations at a local level, was positive and has helped to inform the process for future discussions with the other local areas in South Yorkshire and Bassetlaw.

All the Place conversations focus on building on what is working well and bringing about improvements through local support and mutual accountability.

2.2 Performance Scorecard

The attached scorecards show our collective position at September 2018 (October for A&E data) as compared with other areas in the North of England and also the other ICSs. Although we are still performing well on our NHS Constitution commitments to our populations, our collective A&E performance remains below 95% and our 31 day cancer standard and 62 day cancer standard remain red. Our position on diagnostics within 6 weeks, however, has moved from red to green but we are also now red for two week wait for breast cancer. Partners are working extremely hard to align our collective position, with remedial actions in place.

The ICS financial position is reporting a year to date favourable variance against plan of £1.6m excluding PSF; all organisations are currently forecasting break even against plan before PSF. Some organisations have agreed favourable changes to their control totals with regulators in order to access incentive payments. This will provide benefit to the ICS system improvement plan value.

2.2 Capital Bids

The Department of Health and Social Care announced the expected £1 billion funding for capital projects.

Unfortunately, none of our bids received funding and SYB ICS will therefore not be receiving any additional national monies in this round. This was disappointing news as we had some excellent bids that connected care and services across our partnership and the opportunity to bring further benefits for our patients and population has been missed. Nonetheless, it is also a good time to remember that our populations are already starting to

benefit from our collective bidding success last year when we were awarded almost £20 million for projects across the region. As a quick reminder, our successful bids were:

- The additional CT scanner at Doncaster and Bassetlaw Hospitals (£4.8m)
- The new hub for Yorkshire Ambulance Services in Doncaster (£7m)
- The co-location of the children's emergency department and assessment unit at Barnsley Hospital (£2.5m)
- Improvements to the configuration of hyper acute stroke unit at Sheffield Teaching Hospitals (£4.6m)

In this context, it is perhaps not a surprise that we have not benefited from more funding from this current bidding. As we are not expecting any further rounds of allocations now until 2020/21, partners will be discussing the next steps on our ambitions that were connected to the bids when we meet again at the Executive Steering Group on Tuesday 18 December.

2.3 ICS Leads meeting - December

ICS Leads from across the country met this month in Manchester and as well as a national update on the Long Term Plan, it was a showcase for some of the work underway in Greater Manchester (GM). It was an opportunity to understand more about GM's work in developing a primary care advisory board and the connectivity between partners at place and the system.

2.4 NHS Long Term Plan

The national NHS team is working to present its Long Term Plan to the government with the timing dependent on the debates on the EU Withdrawal Agreement.

Local NHS organisations will also receive their budgets for the next five years this month, and guidance on planning services for 2019/20. The national team is holding events with local health and care leaders to discuss the content of the plan and how it should affect their planning and engagement over the coming months.

We will be working with all our partners to collectively build our South Yorkshire and Bassetlaw response to the Plan. We will also be working closely with staff, patients, the public and other stakeholders to determine what the NHS Long Term Plan means for their area, and how services need to adapt and improve.

Local Healthwatches are being supported with significant investment, via Healthwatch England, to work with local health organisations in ensuring that the views of patients and the public are heard.

The Voluntary Community and Social Enterprise (VCSE) Health and Wellbeing Alliance is also being supported to facilitate further engagement at a regional level between local health organisations and people from groups with particular health needs, and whose voices are not often heard.

2.5 NHS England and NHS Improvement joint directors announced

A number of appointments have been made to the new joint NHS Executive Group. They are:

- Julian Kelly, who has been director general within the Ministry of Defence's nuclear division since May 2017, and is due to take up the joint chief financial officer post by April 2019
- Professor Stephen Powis will be medical director, having been in this role for NHSE since the start of 2018
- Ruth May will be chief nursing officer, having been executive director of nursing at NHSI since 2016
- Emily Lawson will be director for transformation and corporate development, having both performed these roles for NHSE.

They join the following appointments that have already been announced:

- Matthew Swindells, NHSE's director of operations and information since 2016, will be deputy chief executive
- Pauline Philip will be director of emergency and elective care, having been jointly employed in a similar role since 2015.
- Ian Dodge will be director for strategy and innovation

The joint directors of the new regional teams have also been confirmed. They are:

- South West – Elizabeth O'Mahony, currently NHSI's chief financial officer.
- South East – Anne Eden, already joint NHSE and I regional director for the South East.
- Midlands – Dale Bywater, currently NHSI's regional director for the Midlands and East.
- East of England – Ann Radmore, currently Kingston Hospital Foundation Trust chief executive.
- North West – Bill McCarthy, currently deputy vice chancellor at Bradford University and chair of Bradford Teaching Hospital Foundation Trust and a former NHS England and Department of Health executive director.
- North East and Yorkshire – Richard Barker, currently NHSE's director for the North of England.
- London – Sir David Sloman, currently Royal Free London Foundation Trust.

3. Recommendation

The Collaborative Partnership Board partners are asked to note the update and Chief Executives and Accountable Officers are asked to share the paper with their individual Boards, Governing Bodies and Committees.

Date 11 December 2018

Appendix 4d

To:

Provider CEOs
CCG AOs
STP leads
Integrated care system leads

NHS Improvement and NHS England
Wellington House
133-155 Waterloo Road
London SE1 8UG

020 3747 0000

www.england.nhs.uk
www.improvement.nhs.uk

11 December 2018

Dear colleague

Our new NHS Executive Group

We are writing to share with you a number of the appointments to our new senior leadership team, the NHS Executive Group. This is a major milestone in bringing the work of NHS England and NHS Improvement together and transforming how we support the NHS. The NHS Executive Group will provide leadership across our organisations so together we can do more for the NHS and patients.

As we finalise the NHS Long Term Plan we are delighted to have secured strong leaders to head up our seven regional teams, integrating NHS England and NHS Improvement. They will play a major leadership role in their geographies, making decisions on how best to assure performance and support improvements, as well as supporting local system transformation.

The regional directors will support the development and identity of sustainability and transformation partnerships and integrated care systems, and will be responsible for proactively sharing learning from local areas across the national health and care system.

The seven regional director appointments we are announcing today are:

- Richard Barker – NHS North East and Yorkshire Regional Director
- Dale Bywater – NHS Midlands Regional Director
- Anne Eden – NHS South East Regional Director
- Bill McCarthy – NHS North West Regional Director
- Elizabeth O'Mahony – NHS South West Regional Director
- Ann Radmore – NHS East of England Regional Director
- Sir David Sloman – NHS London Regional Director

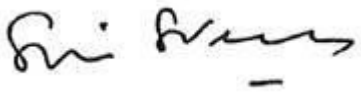
Further information on these appointments can be found on our website.

These individuals bring a wealth of knowledge and experience from previous roles within and outside the NHS, and we are delighted that our organisations will benefit from everything they will offer.

The new regional directors are expected to formally lead their teams from April 2019. Please continue in the meantime to work with your current regional director.

We will continue to keep you updated and work with you to shape our new operating model.

Yours sincerely



Simon Stevens
Chief Executive
NHS England

Ian Dalton
Chief Executive
NHS Improvement

Appendix 5

7 December 2018

By email:

To: CCG Accountable Officers
Provider Chief Executives
STP/ICS Leaders

Dear colleague,

2019/20 Planning: Content of 14th January Submission

Background

In the joint planning approach letter issued by Simon Stevens and Ian Dalton on 16th October 2018 there was a request that commissioners and providers should work together through STP/ICSs during the autumn on aligned, profiled demand and capacity planning and make rapid progress on detailed, quality impact-assessed efficiency plans. To gauge progress on these early actions an "initial plan submission in mid-January that will be focused on activity and efficiency… planning with headlines collected for other areas" was requested.

The recently announced window for publication of the Long-Term Plan from 12 to 21 December has clarified our expectations of the process and data collection items for the 14 January plan collection. We will use the 14 January as a regional checkpoint to assess progress against the demand, capacity and efficiency objectives set out in the planning letter. To support this checkpoint commissioners and providers will be asked to complete activity planning templates for submission and review by the regional team. Financial planning returns will not be required for the 14 January and therefore the demand and capacity plans should be based on the capacity, both staffing and beds, that is already in place.

STP/ICSs should convene local leaders as early as possible to agree collective priorities and parameters for organisational planning. We expect systems to agree shared capacity and activity assumptions from the outset to enable the development of a single, system-wide framework for the organisational activity plans. Once collectively agreed, the shared assumptions should drive the development of provider and commissioner activity plans. These plans need to be demonstrably aligned across providers and commissioners. System-level planning should take full account of the significant contribution of specialist services, with STPs/ICSs and NHSE regional hubs expected to work together to ensure alignment of plans.

This early work to agree collective capacity and activity assumptions should help simplify the process and reduce the adversarial back-and-forth that some areas have previously experienced. Shared plans that drive collective action will be an important marker of which systems are ready to develop into ICSs, with the additional freedoms and flexibilities this entails.

The regional team will work with the collective leadership of NHS bodies in a system to undertake both an assurance and support role with the aim of ensuring high quality draft plans, which are aligned across providers and commissioners as well as to system priorities. These draft plans will be submitted on 12 February.
This paper provides technical details on the 14 January activity plan submission. Activity planning templates and associated technical guidance will be released to organisations on 13 December.

Data items for collection
Activity and capacity plans will be requested for the following lines:

- Activity:
    - Referrals – GP, Other
    - Outpatients – First and Follow Up attendances, and outpatient procedures
    - Elective Admissions – Day Case and Ordinary
    - Non-elective Admissions – Zero and 1+ Length of Stay
    - A&E attendances – Type 1 and Other
- Providers will also be asked for plans for bed numbers
- It should be noted that plans will not be requested for any performance trajectories, or for RTT activity lines
- Providers can view the current version of the activity template on the provider information network – please contact NHSI.returns@nhs.net to request access.

For all activity lines we will provide provisional 18/19 FOT data, and require organisations to supply the following:

- Any adjustments to the 18/19 FOT
- A total 19/20 plan figure

This is the minimum information required to allow the calculation of planned growth percentages for 19/20. Careful consideration has been given to the intended use of these initial plans, the state of play of contract negotiations and the resultant burden on the NHS; we have therefore limited the submission to three further elements:

Monthly activity profiles

- Organisations to provide planned activity figures for each month of the year, rather than just the year as a whole.

- This will allow initial assurance of the profile of activity over the year, to ensure plans take account of seasonal demand and capacity and that progress can be better tracked in-year.

Waterfall

- Organisations to break down planned activity by components of change – for example the amount of additional activity they expect to provide due to demographic change, or any change in activity which is a result of counting and coding changes.
- This will provide further information to support the assurance of planned activity, in particular to enable the calculation of 'real' growth rates.

Alignment data

- Commissioners to attribute the proportion of activity assigned to each of their main providers – as well as identifying the proportion of activity they expect to commission from non-acute NHS providers, and from the independent Sector.
- Providers to be asked to perform a similar exercise to attribute activity across commissioners, including identifying the proportion of activity expected to come from specialised commissioning and other commissioning.
- Collecting this information in the January submission will allow early insight into the extent to which plans are aligned between commissioners and providers.

Each of the above elements will be applied to the January submission and **Annex A** contains examples of how each of these will be collected in the commissioner and provider planning templates.

We are aware of the need for regional colleagues to be able to access an early view of data to allow local support for the planning process. We will facilitate this where possible and are exploring options which will allow sight of the data during the collection window.

<u>Note regarding Forecast Outturn and Commissioner Assignment</u>
All the above elements require the generation of Forecast Outturns (FOTs) as a basis for commissioner and provider plans. A number of changes are due to be made over the coming period to the Identification Rules (IR) tool that is used as part of the process for attributing activity between commissioners. We are working closely with Specialised Commissioning analysts to understand and estimate the effect of these changes at individual commissioner level in time to populate the template for the January submission (i.e. by December). However, the timetable is a challenging one and the changes to the tool will not be finalised until after the start of 19/20. Therefore, the commissioner FOTs which will be produced for the January collection will be provisional (and will be clearly marked as such in the templates and other guidance accompanying the submission) and there is a risk that they will

deviate from the final position as a result of the estimation process. The FOTs will be refreshed for the February submission template. We will be applying the learning gained from the similar exercise that was needed during the 17/18 planning round.

Yours sincerely

Lyn Simpson
Executive Regional Managing Director (North)
NHS Improvement

Richard Barker
Regional Director (North)
NHS England

Annex A

Monthly Activity Profile example

Code	Activity Line	CCG Adjusted 18/19 FOT	2019/20 Activity												2019 Tot
			April	May	June	July	August	September	October	November	December	January	February	March	
E.M.7	Total Referrals (General and Acute)	42,140	-	-	-	-	-	-	-	-	-	-	-	-	-
E.M.7a	Total GP Referrals (General and Acute)	28,186													-
E.M.7b	Total Other Referrals (General and Acute)	13,954													-
E.M.XX	Total Consultant Led Outpatient Attendances	76,166	-	-	-	-	-	-	-	-	-	-	-	-	
E.M.8	Consultant Led First Outpatient Attendances	21,951													-
E.M.9	Consultant Led Follow-Up Outpatient Attendances	54,215													-

Waterfall Example

			Enter as a + or - figure to add or subtract activity from the 17/18 FOT to get to the 17/18 plan. Absolute values to be entered here and not percentages. For Sheet Validation 3 above - Please ensure that the 18/19 Annual Plans = Sum of the 17/18 FOT + FOT difference + Counting and Coding + Underlying Trend + Transformational Change + Policy Changes for each activity line.							
			To capture any difference between the centrally-supplied outturn for 2017/18 and the local view of activity in 2017/18**. The local view should use the same 'currency' and definitions as those used centrally; and should not include differences in activity figures associated with central and local production of the numbers.	To capture the CCG Adjusted FOT once any differences to the centrally supplied figure have been applied	To capture the effect of, for example, changing definitions, boundaries, reporting standards.	To capture any change in the volume of actual activity in 19/20 compared to 18/19 which is being carried out as part of a one off exercise, for example measures to reduce the waiting list	To capture any additional activity as a result of changes in population and underlying changes in trend.	Apply the impact of transformation/ allocative efficiency. To include, for example, NCMs, UEC, Rightcare, Prevention, Self care and procedures of limited clinical value.	To capture the impact of new policies, for example, Hospital 7 day services, Primary Care access, Cancer, Mental Health	
	Centrally-Supplied 18/19 Forecast Outturn		CCG FOT Difference	CCG Adjusted FOT	Counting and Coding Changes	Other Non Recurrent Activity	Underlying Trend and Demographic Growth	Transformational Change	Policy Changes	19/20 Annual Plan
	NHS Acute Activity									
Total Referrals (General and Acute) - E.M.7	41,326	FOT Detail	0	42,140	0	0	0	0	0	0
Total GP Referrals (General and Acute) - E.M.7a	28,186	FOT Detail		28,186						0
Total Other Referrals (General and Acute) - E.M.7b	13,954	FOT Detail		13,954						0
Total Consultant Led Outpatient Attendances - E.M.XX	76,166		0	76,166	0	0	0	0	0	0
Consultant Led First Outpatient Attendances - E.M.8	21,951	FOT Detail		21,951						0
Consultant Led Follow-Up Outpatient Attendances - E.M.9	54,215	FOT Detail		54,215						0

Alignment example

First Outpatient

Provider Code	Provider Name	Expected share of CCG Activity	Revised share of CCG Activity	Comments
-	NHS Acute Providers	90.4%		
-	Other NHS providers	0.0%		
	Independent Sector Providers	0.0%		
NHS Acute Providers: Further Detail				
RAE	BRADFORD TEACHING HOSPIT	91.2%		
RR8	LEEDS TEACHING HOSPITALS I	4.6%		
RWY	CALDERDALE AND HUDDERSFI	1.6%		

Additional NHS Acute Providers: First Outpatient

Please provide details of any providers not listed above which are expected to provide over X% of First Outpatient attendances for the coming year.

Provider Code	Provider Name	Expected Share of CCG Activity

Waterfall Example

			i	i									i		i	i		
Planning line	FOT Methodology	Centrally-Supplied 18/19 Forecast Outturn	To capture any difference between the centrally-supplied outturn for 2018/19 and the local view of activity in 2018/19**. The local view should use the same 'currency' and definitions as those used centrally; and should not include differences in activity figures associated with central and local production of the numbers.	To capture the trust Adjusted FOT once any differences to the centrally supplied figure have been applied	Please provide below an explanation for any FOT difference provided in the waterfall	To capture the effect of, for example, changing definitions, boundaries, reporting standards.	To capture any change in the volume of actual activity in 19/20 compared to 18/19 which is being carried out as part of a one off exercise, for example measures to reduce the waiting list	To capture any additional activity as a result of changes in population and underlying changes in trend.	Apply the impact of transformation/ allocative efficiency. To include, for example, NCMs, UEC, Flightcare, Prevention, Self care and procedures of limited clinical value.	To capture the impact of new policies, for example, Hospital 7 day services, Primary Care access, Cancer, Mental Health			Please provide below an explanation for any growth variances over 5% provided in the waterfall	OPTIONAL: Activity included in local contracts (eg SLAM) but excluded from the SUS plan	OPTIONAL: Activity excluded from local contracts (eg SLAM) but included within the SUS plan	OPTIONAL: Activity included in local contracts	OPTIONAL: Please provide below an explanation for variations between SUS activity figures and local contract activity figures
		Provider FOT NHSI Derived	Provider FOT Difference	Provider Adjusted FOT	FOT Difference: Comments	Counting and Coding Changes	Other Non Recurrent Activity	Underlying Trend and Demographic Growth	Transformational Change	Policy Changes	19/20 Annual Plan	19/20 Annual Plan Growth	Growth: Comments	SUS Exclusions	SUS Inclusions	Local Activity Total	Local Activity Comments
GP Referrals (General and Acute)	FOT Detail																	
Other Referrals (General and Acute)	FOT Detail																	
Total Referrals (General and Acute)	FOT Detail																	
Consultant Led First Outpatient Attendances	FOT Detail																	
Consultant Led Follow-Up Outpatient Attendances	FOT Detail																	
Total Consultant Led Outpatient Attendances	FOT Detail																	
Total Outpatient Appointments with Procedures	FOT Detail																	
Total Elective Admissions - Day care	FOT Detail																	
Total Elective Admissions - Ordinary	FOT Detail																	
Total Elective Admissions	FOT Detail																	
Total Non-Elective Admissions - 0 LoS	FOT Detail																	
Total Non-Elective Admissions - +1 LoS	FOT Detail																	
Total Non-Elective Admissions	FOT Detail																	
Total A&E Attendances excluding Planned Follow Ups	FOT Detail																	
Type 1 A&E Attendances excluding Planned Follow Ups	FOT Detail																	

Monthly Activity Profile example

	Assesment Link (Click for detail)	FOT 18/19 Forecast Out-turn 31/03/2019 Year Ending	Y1 M01 Plan 30/04/2019 Month 1	Y1 M02 Plan 31/05/2019 Month 2	Y1 M03 Plan 30/06/2019 Month 3	Y1 M04 Plan 31/07/2019 Month 4	Y1 M05 Plan 31/08/2019 Month 5	Y1 M06 Plan 30/09/2019 Month 6	Y1 M07 Plan 31/10/2019 Month 7	Y1 M08 Plan 30/11/2019 Month 8	Y1 M09 Plan 31/12/2019 Month 9	Y1 M10 Plan 31/01/2020 Month 10	Y1 M11 Plan 28/02/2020 Month 11	Y1 M12 Plan 31/03/2020 Month 12	*i* FY 19/20 Plan 31/03/2020 Year Ending	% Growth Plan 31/03/2020 Year Ending	Comments Plan 31/03/2020 Year Ending
2018/19 GP Referrals (General and Acute)																	
GP Referrals (General and Acute)																	
2018/19 Other Referrals (General and Acute)																	
Other Referrals (General and Acute)																	
2018/19 Total Referrals (General and Acute)																	
Total Referrals (General and Acute)																	
2018/19 Consultant Led First Outpatient Attendances																	
Consultant Led First Outpatient Attendances																	
2018/19 Consultant Led Follow-Up Outpatient Attendances																	
Consultant Led Follow-Up Outpatient Attendances																	
2018/19 Total Consultant Led Outpatient Attendances																	
Total Consultant Led Outpatient Attendances																	
2018/19 Total Outpatient Appointments with Procedures																	
Total Outpatient Appointments with Procedures																	
2018/19 Total Elective Admissions - Day case																	
Total Elective Admissions - Day case																	
2018/19 Total Elective Admissions - Ordinary																	
Total Elective Admissions - Ordinary																	
2018/19 Total Elective Admissions																	
Total Elective Admissions																	
2018/19 Total Non-Elective Admissions - 0 LoS																	
Total Non-Elective Admissions - 0 LoS																	
2018/19 Total Non-Elective Admissions - +1 LoS																	

Alignment example

ACTIVITY BY COMMISSIONER Consultant led First Outpatient attendances (Specific Acute)	Commissioner Name Plan 31/03/2020	Commissioner Code Plan 31/03/2020	Commissioner Percentage Plan 31/03/2020	Commissioner Total Plan 31/03/2020
First Outpatients CCG Line 1				0
First Outpatients CCG Line 2				0
First Outpatients CCG Line 3				0
First Outpatients CCG Line 4				0
First Outpatients CCG Line 5				0
First Outpatients CCG Line 6				0
First Outpatients Other CCG	Other CCG (individually less than 3%)	CCG-other		0
First Outpatients Specialist commissioning	Specialist Commissioning	CCG-Speccom		0
First Outpatients Other commissioning	Other Commissioning	Othercom		0
Total activity split by CCG patient care activities			0.0%	**0**

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ACTIVITY BY COMMISSIONER: CCGs Consultant led follow up outpatient attendances (Specific Acute)	Commissioner Name Plan 31/03/2020	Commissioner Code Plan 31/03/2020	Commissioner Percentage Plan 31/03/2020	Commissioner Total Plan 31/03/2020
FU Outpatients CCG Line 1				0
FU Outpatients CCG Line 2				0
FU Outpatients CCG Line 3				0
FU Outpatients CCG Line 4				0
FU Outpatients CCG Line 5				0
FU Outpatients CCG Line 6				0
First Outpatients Other CCG	Other CCG (individually less than 3%)	CCG-other		0
FU Outpatients Specialist commissioning	Specialist Commissioning	CCG-Speccom		0
FU Outpatients Other	Other Commissioning	Othercom		0
Total activity split by CCG patient care activities			0.0%	**0**

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Signage	Blank cells
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ACTIVITY BY COMMISSIONER: CCGs Elective admissions spells (day cases) (Specific Acute)	Commissioner Name Plan 31/03/2020	Commissioner Code Plan 31/03/2020	Commissioner Percentage Plan 31/03/2020	Commissioner Total Plan 31/03/2020
Day case CCG Line 1				0
Day case CCG Line 2				0
Day case CCG Line 3				0
Day case CCG Line 4				0
Day case CCG Line 5				0

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Appendix 6

NHS Improvement
Chief Executive and Chair's Office
Wellington House
133-155 Waterloo Road
London SE1 8UG

Tel: 020 3747 0000

BY EMAIL

5 December 2018

To: NHS provider chief executives, medical directors and directors of nursing, ICS / STP leads

Dear colleagues

Winter preparation, safety and learning

First of all, I want to thank you for all the work you and your teams are doing. We know that NHS services are planning for sustained pressures over the next few months and we also know the NHS has experienced record demand throughout the summer and treated more patients than ever before.

Clinical decision-making

It is important during these busy periods that you and your staff know you have our support when making critical clinical decisions about how best to deploy teams across different areas of your organisation and wider system. All of our patients deserve high quality, safe care, including those patients attending emergency departments arriving by ambulance, or receiving care in an escalation area. We recognise that you will need to take the right staffing decisions to manage the totality of risk across your organisations and the wider system. No one would want rigid adherence to guidelines to get in the way of sound clinical judgements about how best to care for patients.

It is important that such decisions are guided by robust governance and operating procedures. Our 'Developing Workforce Safeguards' document collects together evidence about the best approaches to safe staffing decisions. If you need, we can support you to make these decisions, either through our regional teams or the Safe Staffing Support Team, who can provide support with acuity assessment, risk and impact assessment, board reporting and monitoring. Your Regional Director will work with you to agree the best support, should you need it.

Capacity

Bed occupancy was relatively high over the summer period and has remained so as we enter winter. We know that having sufficient headroom is critical to providing safe effective emergency care and it is important that any potential additional emergency capacity is realised ahead of winter. Financial considerations must not be a barrier to opening bed capacity that you will need during busy periods and all the evidence shows that by planning as early as possible you should be able to open additional capacity in the most cost-effective way. I would ask that you continue working with your Regional Director and their teams to refine your capacity plans and take important capacity-related decisions as soon as you can.

Ownership of emergency flow

As we all know, flow issues that manifest in the emergency department are not solved by taking action in the emergency department alone. Organisations perform best when all staff – from those on

the ‘front door’ to the board, and everyone in between – feel ownership of the emergency care pathway. I know you will already be working with your teams on this, but please consider whether there is anything more you can do to ensure that teams outside of your emergency department fully understand the contribution they are expected to make over the next few months. Demand surges this winter will at times affect patients in community, mental health, ambulance and acute settings; and in care homes. All organisations have a shared responsibility to help solve these problems and I know you will already be working with all your local partners, including social care on these matters.

Safety and learning

There has been some discussion over the past few weeks about steps that national bodies may take in extreme and very rare circumstances, for example where there has been deliberate or wilful neglect. As you will know, in serious circumstances, we or the Care Quality Commission would expect to take strong action to protect patient safety. But the vast bulk of individuals and organisations do not behave this way and this should never be our starting point. I know from conversations with the Chief Executive of the Care Quality Commission that he shares this view.

Our starting point is that transparency, learning and improvement should be highly-prized assets in all of our organisations, and I want to keep building a culture where these flourish as a more effective way to drive change. Blame, and fear of punishment, create a vicious cycle and make it more likely that problems are hidden. Decades of safety research tells us that hidden problems are not addressed; and that a blame culture means that staff are scared to speak up for fear that it will damage their organisation or the individuals they work with.

During challenging periods, it is particularly important that we collectively build and maintain a culture where teams can transparently raise concerns, talk about problems with care delivery, expose risks and confront head on the very real challenges of managing and delivering healthcare when resources are tight and demand is continuously increasing.

I recognise that you and your staff are all working flat out for patients and that the summer was busier than usual, so your staff will be entering the winter period without having had a period of relative quiet. I know you will be doing everything you can to look after them.

Thank you for all of your hard work and please let me know if there’s anything more we can do to help.

Yours sincerely

Ian Dalton CBE
Chief Executive, NHS Improvement

cc Ian Trenholm, Chief Executive, Care Quality Commission
Dr Kathy McLean, Executive Medical Director and Chief Operating Officer, NHS Improvement
Ruth May, Executive Director of Nursing, NHS Improvement
Dale Bywater, Anne Eden, Jennifer Howells, Steve Russell, Lyn Simpson, Executive Regional Managing Directors, NHS Improvement
Dr Aidan Fowler, National Director of Patient Safety, NHS Improvement