NHS Improvement

# Advice to the Competition and Markets Authority: Proposed merger of Central Manchester University Hospitals NHS Foundation Trust and University Hospital of South Manchester NHS Foundation Trust

## Appendix: Advice on the improvements likely to arise from the parties' proposals

June 2017

NHS Improvement

Delivering better healthcare by inspiring and supporting everyone we work with, and challenging ourselves and others to help improve outcomes for all.

# Contents

# Introduction

This appendix sets out our analysis of the proposals included in the parties' patient benefits case which, in our view, are likely to lead to improvements for patients. The proposals are examples of the wider opportunities created by the proposed merger.

As set out in the main advice report, we have assessed the proposals put forward by the parties in their benefits case against the Competition and Markets Authority (CMA) framework. This appendix focuses on the first element of that framework: whether the proposed change represents a real improvement in quality, choice or innovation of services for patients or in value for money for commissioners.

The other elements (whether the proposed change is likely to be realised within a reasonable period as a result of the merger and whether the proposed change is unlikely to accrue without the merger or a similar lessening of competition) are addressed in the main advice report.

This appendix is set out as follows:

# Acute coronary syndrome

Acute coronary syndrome (ACS) is an umbrella term referring to patients experiencing a medical emergency in which the blood supply to the heart has suddenly become blocked. This includes unstable angina (unexpected or irregular severe chest pain) and two forms of myocardial infarction, commonly known as a heart attack: ST elevation myocardial infarction (STEMI) in which the coronary artery is fully blocked, and non-ST elevation myocardial infarction (NSTEMI) in which the coronary artery may only be partially blocked.

The parties' acute coronary syndrome proposals focus on NSTEMI patients. NSTEMI patients require urgent diagnosis and treatment, although in most cases patients do not require immediate treatment as a patient with a fully blocked artery would. Once a patient has been diagnosed with NSTEMI, they are likely to receive coronary angiography. This is a further diagnostic procedure that involves using a dye injection and x-rays to confirm whether a blockage or narrowing has occurred in the coronary arteries and, if so, to identify the exact location. This test helps a cardiology team determine the most appropriate treatment for a patient. Treatment for NSTEMI patients may involve coronary angioplasty (inserting a balloon and possibly a stent to open up the artery), cardiac surgery (such as coronary artery bypass grafts) or medication alone.

From the parties' submissions, we identified four main proposals for NSTEMI patients:

- seven-day access to ACS specialist consultants and diagnostics (angiography)
- improved access to multi-disciplinary team (MDT) decision making – they propose to initiate daily meetings of a cardiothoracic MDT to discuss treatments for complex patients, including complex NSTEMI patients
- creating a consolidated ACS service on a single site – they propose to continue to provide ACS services from Manchester Royal Infirmary (MRI) and Wythenshawe Hospital during the first one or two years following the merger, and then to centralise their services onto a single ACS unit on one of the hospital sites (not yet determined)
- establishing standardised pathways and protocols for patients referred from local hospitals.

**In our view, the parties' proposals would be likely to result in improvements for some NSTEMI patients through reduced time to diagnosis and treatment.**

**Our assessment below sets out which patients we would expect to benefit from the parties' proposals and the impact we would expect the proposals to have on those affected.**

## Current service arrangements

NSTEMI patients in Greater Manchester typically follow one of the following pathways:

- Patients experiencing chest pain or other symptoms of heart attack present or arrive by ambulance at Central Manchester or South Manchester. Having been diagnosed with NSTEMI, we understand that they will be reviewed by an ACS specialist consultant (once available) and where appropriate placed on a waiting list for coronary angiography and treatment.
- Patients present or arrive by ambulance at one of the 10 regional hospitals other than Central Manchester or South Manchester. Patients diagnosed with NSTEMI are admitted to the local hospital and reviewed by a consultant cardiologist.[1] Where appropriate the cardiologist will then refer the patient to Central Manchester, South Manchester, Bolton NHS Foundation Trust or Wrightington, Wigan and Leigh NHS Foundation Trust for review by an ACS consultant, coronary angiography and treatment. Patients requiring cardiac surgery will be referred only to Central Manchester or South Manchester.

Our understanding is that there are six consultants at Central Manchester and five consultants at South Manchester who specialise in the diagnosis and treatment of ACS. At both trusts, access to an ACS consultant is generally available for NSTEMI patients during normal working hours (8am to 5pm), Monday through Friday. With respect to out-of-hours (including weekends), we understand that ACS consultants are on the general cardiology on-call rota. As such, the ACS consultants are available to review NSTEMI patients outside of normal working hours only if it is their turn to work on the on-call general cardiology rota. This means out-of-hours access to an ACS specialist is limited.

Both South Manchester and Central Manchester currently deliver angiography services to NSTEMI patients between 9am and 5pm, Monday to Friday. If a patient is deemed to require more urgent angiography outside of these times, they will be treated via an emergency ad hoc list.

[1] STEMI patients are immediately transferred to Central Manchester, South Manchester , Bolton NHS Foundation Trust or Wrightington, Wigan and Leigh NHS Foundation Trust, depending on their location, capacity of the hospital, time of day and complexity of the patient's condition. Generally more complex patients are directed to Central Manchester or South Manchester.

The parties told us that under the current arrangements, not all NSTEMI patients are receiving an angiography within the timeframes recommended by NICE guidelines. NICE guidelines recommend that patients determined to be at an intermediate or higher risk of further cardiovascular complications or death receive angiography (with follow-up angioplasty if indicated) within 72 hours of first admission to the hospital and within 24 hours if their symptoms cannot be stabilised.[2]

The parties told us that Greater Manchester audit data shows that between October and December 2016 approximately 50% of all NSTEMI referrals were treated within 72 hours. Data specific to Central Manchester and South Manchester was not available, and it is unclear what proportion of those patients who were not treated within 72 hours, were intermediate or higher risk (the category of patients which NICE guidelines say should be treated within 72 hours). We also note that the parties have said that they use ad hoc arrangements to manage high or intermediate risk patient on weekends. Therefore, many of the highest risk patients may already be treated within NICE guidelines.

The parties told us that patients admitted directly to either trust waited an average of 4.1 to 5.8 days from admission to angiography, depending on the day of the week that patients were admitted to the hospital. The parties submitted evidence showing that average wait times were longer for patients admitted on a Friday or Saturday. Patients admitted on other days of the week may also have their wait extended because of the lack of weekend provision causing a backlog.

Patients initially admitted to a local hospital and then transferred to one of the trusts waited an average of 4.9 to 7.4 days from initial admission at their local hospital to angiography, including an average waiting time of 2.2 to 3.4 days at their local hospital before referral to Central Manchester or South Manchester. This does not include time taken to transfer patients between hospitals.

The parties submitted that NSTEMI patients are waiting longer for angiography than recommended because:

- There is a lack of out-of-hours and weekend availability of specialist ACS consultants and cath labs (where angiography is carried out).
- The number of patients needing angiography or surgical beds can periodically exceed capacity at either trust and there is not currently an arrangement to make use of any spare capacity that may exist at the other trust, resulting in patients sometimes waiting longer than would be the case if the trusts co-ordinated their cath lab activity and bed capacity.

[2] NICE Quality Standard QS68: Acute coronary syndromes in adults. Published September 2014. Available at: www.nice.org.uk/guidance/qs68

- Patients sometimes have to wait to see a cardiology consultant at local hospitals to refer them to Central Manchester or South Manchester.

The parties also said there can be delays between diagnosis and treatment because if a patient's condition is complex they may be discussed at an MDT meeting before the most appropriate course of treatment is chosen. Currently, for each trust, these meetings occur once a week, so some complex patients may wait up to a week for decisions about treatments.

## The parties' ACS proposals and NHS Improvement's views on whether they represent improvements for patients

The parties submit that their proposed changes to NSTEMI services will reduce the time that patients wait from admission at Central Manchester or South Manchester to diagnosis and treatment. They also submit that the proposals will reduce the time that patients wait from admission at local hospitals to a referral by a cardiologist to Central Manchester or South Manchester.[3] They say these changes will result in improved clinical outcomes and patient experience because more intermediate and higher risk patients will be treated within 72 hours as recommended by NICE. They say that low risk patients will also experience reduced wait times which will bring better outcomes (although to a lesser extent than higher risk patients).

### Seven-day access to ACS specialist consultants and diagnostics

The parties propose to provide NSTEMI patients with access to specialist ACS consultants, as well as access to diagnostic tests and treatments, seven days a week. They plan to establish an ACS on-call rota to ensure a specialist is available out-of-hours and during weekends to review NSTEMI patients.[4] They would deliver weekend diagnostics for NSTEMI patients by running an NSTEMI angiography list on alternate weekend days. For example, patients may receive angiography at South Manchester on a Saturday or at Central Manchester on a Sunday.

In our view, the increased availability of ACS consultants and diagnostic services would likely result in a reduction in the time that some NSTEMI patients wait for angiography and treatment. We expect that a significant proportion of the 4,039 NSTEMI patients treated at Central Manchester or South Manchester would experience these reduced waiting times, although it was unclear exactly how many

[3] The parties also submitted that the proposals will reduce the wait time from post-procedure to discharge, however, we did not receive enough information to consider how the proposals might affect post-procedure wait times.
[4] Our understanding is that these consultants would be released from their existing general cardiology on-call duties to facilitate the new sub-specialist rota. The parties have said that under the proposed arrangements there will be four cardiology consultants on-call at any time: one ACS consultant covering NSTEMI patients, one ACS consultant covering STEMI patients, one heart rhythm management consultant and one general cardiology consultant.

patients would benefit in this way. We would expect that the 1,700 patients admitted to the Central Manchester or South Manchester on a Thursday, Friday or Saturday would experience the greatest improvement.

We considered how the proposals might impact two categories of patients who the parties say will experience reduced wait times:

- Patients with intermediate or higher risk of death or complications: as noted, the parties did not precisely identify how many of these patients are currently not receiving angiography within NICE guidelines.[5] We expect that many of the highest risk patients are already within the 72 hour guideline because they are added to ad hoc weekend emergency lists, but that following implementation of the proposal more patients (including those for whom the level of risk is only determined following angiogram) would receive care within this timeframe. We would expect those currently treated within the NICE guidelines through the use of these ad hoc arrangements would benefit from being able to access a dedicated NSTEMI list in a more systematic way following introduction of the proposed arrangements.

- Low risk patients deemed to require angiography: we expect that wait times to angiography would be reduced for some of these patients as well because the weekend lists would provide greater access. We note that these reductions in waiting times would be likely to result in more NSTEMI patients being treated within European guidelines[6], which recommend that all patients requiring angiography receive this within 72 hours, rather than just those at an intermediate or higher risk of further cardiovascular complications or death.[7]

In our view, any reduction in time to angiography would lead to improvements through:

- more patients receiving treatment in line with national and European guidance; in terms of the significance of the improvements for these patients, we note that the guidance is aimed at preventing recurrent ischaemia (insufficient blood supply to the heart which can cause severe chest pain and

[5] While the parties submitted that approximately 50% of referrals between October and December 2016 were treated within 72 hours, NICE guidelines specifically refer to patients determined to be at an intermediate or higher risk of further cardiovascular complications or death receiving angiography (with follow-up angioplasty if indicated) within 72 hours of first admission, rather than all patients.
[6] Roffi et al. 2015 European Society of Cardiology Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. European Heart Journal (2016) 37 (3): 267-315. Available at: https://academic.oup.com/eurheartj/article/37/3/267/2466099/2015-ESC-Guidelines-for-the-management-of-acute
[7] These guidelines also recommend that people at a high risk of future cardiovascular complications receive angiography within 24 hours and those at a very high risk, within 2 hours.

ACS) and alleviating pain and anxiety but also note that some ad hoc arrangements exist for those at the highest risk of adverse complications (including recurrent ischaemia).

- reduced anxiety experienced by NSTEMI patients and their families while waiting for diagnosis.

**Improved access to MDT decision-making**

The parties propose to increase the frequency of cardiothoracic MDT meetings from once weekly at each site to daily for the combined ACS services. They said that currently they cannot hold MDT meetings more than once a week because cardiac surgeons who participate have other duties that make them unavailable for more frequent MDT meetings. By combining their cardiac teams, the parties said that they can introduce new work patterns that would allow one cardiac surgeon per week to be released from normal duties to focus on providing prompt opinion on inpatients, supporting ACS specialists and others to make timely treatment decisions.

In our view, holding daily cardiothoracic MDT meetings would be likely to benefit patients through reducing wait times for an appropriately convened MDT to make decisions about care. This improvement would affect patients for whom the optimal treatment is unclear and who experience delays under the current arrangements because they are waiting for the MDT team to convene. The parties did not precisely identify how many patients are currently experiencing such delays so we were unable to determine how many patients this would affect.

**Creating a consolidated ACS service on a single site**

The parties have submitted that demand for angiography and surgical beds can periodically exceed capacity at either trust. They said this can result in patients waiting longer than would be the case if the parties combined their cath lab activity and bed capacity. The parties expect that through the merger, they would be able to consolidate their ACS service on a single site, allowing them to better manage capacity.

In our view, consolidating the ACS service onto a single site would allow the parties to more easily flex their capacity to meet and balance their demand in a way that the parties could not easily manage as separate entities or as a single service run across multiple sites. We would expect this to contribute to the reduced waiting times that would result from the implementation of the parties' proposals.

### Standardised pathways and protocols

The parties propose to work with other local hospitals to establish standardised pathways and protocols across Greater Manchester to reduce variation in referral rates and timeliness of referrals. The parties also propose to have a specialist consultant available to provide patient management advice to referring hospitals to help patients at those local hospitals get prompt access to the correct treatment pathways.

In our view, these proposals would be likely to result in improvements for some patients being transferred to Central Manchester or South Manchester from other local hospitals in the form of reduced waiting times from admission at local hospitals to referral. These standardised protocols and pathways and the availability of an on-call ACS specialist to provide telephone advice and remote review could reduce the need for cardiology consultant input at other local hospitals, which would mean that a lack of availability of consultants at such hospitals would not result in delays in patient referral. In our view, reductions in time to referral would be likely to have an impact on the number of patients able to be treated in line with national and European guidance although we are unable to determine, based on the information made available to us, how many patients would be affected or the extent of the reduction in waiting time they may experience.

## Conclusion

**In our view, the parties' proposals would be likely to result in improvements for some NSTEMI patients through reduced time to diagnosis and treatment. While it is unclear how many patients would have reduced waiting times or the extent that their wait times would be reduced, the reduction in waiting times would likely lead to more patients receiving treatment in line with national and European guidance (aimed at improving patient outcomes) and reduced anxiety for NSTEMI patients and their families while waiting for diagnosis.**

# Heart rhythm abnormalities

An arrhythmia is a problem with the rate or rhythm of the heartbeat. The main types of arrhythmia are:

- atrial fibrillation (where the heart beats irregularly and faster than normal)
- supraventricular tachycardia (episodes of abnormally fast heart rate at rest)
- bradycardia (where the heart beats more slowly than normal)
- heart block (where the heart beats more slowly and irregularly than normal and can cause people to collapse)
- ventricular fibrillation (a rare, rapid and disorganised rhythm of heartbeats that rapidly leads to loss of consciousness and sudden death if not treated immediately).[8]

According to NHS Choices, arrhythmias are experienced by more than two million people a year in the UK and while they can affect all age groups, atrial fibrillation is more common in older people. Most people with an abnormal heart rhythm can lead a normal life if it is properly diagnosed and treated.

Treatments for arrhythmia will depend on the type, cause and severity of the arrhythmia and may include:

- a pacemaker – a small device that is implanted in the patient's chest (on either a planned or emergency basis) under local anaesthetic which produces electrical signals to help the patient's heart beat at a normal regular rate
- implantable cardioverter defibrillator (ICD) – a device similar to a pacemaker that monitors a person's heart rhythm and shocks their heart back into a normal rhythm whenever this is needed.

The parties' heart rhythm proposals focus on patients requiring the implantation of a pacemaker on a non-elective basis and those patients who have received a shock from their ICD and need their device analysed on a non-elective basis.[9]

[8] NHS Choices, Arrhythmia, July 2015. Available at: www.nhs.uk/conditions/arrhythmia/Pages/arrhythmia.aspx

[9] Sometimes the device will deliver a shock inappropriately due to misinterpretation of the heart rhythm or other technical malfunction. According to the parties, patients who experience a shock from their ICD will usually present to their local emergency department and be admitted for specialist

From the parties' submissions, we identified three main proposals for cardiac rhythm management (CRM) patients:

- improved access to specialist cardiology CRM consultants for non-elective pacemaker implantation – the parties propose to combine their CRM consultants to develop a seven day service, including a comprehensive on-call rota for out-of-hours and weekends
- improved access to specialist cardiology CRM consultants and cardiac physiologists for non-elective ICD analysis – the parties propose to combine their specialist CRM consultants and specialist CRM cardiac physiologists to develop a seven day service, including a comprehensive on-call rota for out-of-hours and weekends[10]
- standardised pathways and protocols in conjunction with other local hospitals and local ambulance services.

**As set out below, in our view, the parties' proposals would be likely to result in improvements for some non-elective patients in the form of reduced time to implantation of pacemakers or reduced time to ICD analysis. Our assessment below sets out which patients we would expect to benefit from the parties' proposals and the impact we would expect the proposals to have on those affected.**

## Current service arrangements

Central Manchester and South Manchester, as well as other acute trusts in Greater Manchester, treat patients suffering from heart rhythm abnormalities. Central Manchester and South Manchester provide specialist services in the implantation and maintenance of pacemakers and ICDs for patients in Greater Manchester with heart arrhythmias. We understand from the parties that as cardiac centres, Central Manchester and South Manchester both offer services for patients with heart rhythm abnormalities that are not available at other acute trusts in Greater Manchester, including emergency pacemaker implantation and complex ICD troubleshooting. Patients requiring non-elective pacemaker implantation or ICD analysis may present directly to Central Manchester or South Manchester or arrive by ambulance. Patients may also be transferred from other local hospitals for both pacemaker implantation and ICD analysis.[11]

analysis and treatment. This analysis will identify whether the ICD has delivered a shock inappropriately or whether the patient requires treatment.

[10] We note that the same proposed seven day CRM service will cover both non-elective pacemaker implantation and ICD analysis.

[11] We understand from the parties that the criteria for transferring patients from local hospitals to South Manchester or Central Manchester relate to the complexity of the patient and the need for

Our understanding is that there are five consultant cardiologists specialising in CRM at Central Manchester and eight at South Manchester. At both trusts, access to a CRM consultant is generally available for CRM patients during normal working hours (8am to 5pm) Monday through Friday. With respect to out-of-hours (including weekends), we understand that CRM consultants are on the general cardiology on-call rota, which provides cover for patients who require cardiology input out-of-hours or at weekends. As such, the CRM consultants are available to review CRM patients outside of normal working hours only if it is their turn to work on the on-call general cardiology rota. This means out-of-hour access to a CRM consultant is limited.[12]

In addition, we understand that the trusts each have five senior cardiac physiologists who are trained in cardiac device management.[13] The CRM cardiac physiologists participate in the general cath lab on-call rota and will therefore only be available to assess ICDs outside of normal working hours if it is their turn to work on the on-call general cath lab rota. We understand from the parties that experienced cardiac physiologists can deal independently with some technical ICD issues but would seek advice from a consultant on medication issues and whether any form of interventional therapy may be appropriate.

We understand from the parties' submissions that about 600 pacemakers are implanted at Central Manchester and South Manchester per year and approximately one third of those are implanted on a non-elective basis. In addition, there are approximately 450 instances each year of a patient's ICD device being analysed on an urgent or emergency basis. The parties estimate that about two thirds of this demand will occur out-of-hours or at the weekend.[14]

The parties say the lack of comprehensive out-of-hours and weekend cover for CRM services can lead to delays in patient treatment and suboptimal treatment. This includes delays for patients who have been admitted to other hospitals in Greater Manchester where local clinicians have been unable to immediately access expert opinion from a relevant specialist at Central Manchester or South Manchester. We understand from the parties that patients requiring pacemaker implants on a non-elective basis who are admitted at the weekend wait

time critical intervention. For example, the parties said that while some local hospitals are able to implant pacemakers they only run lists once or twice per week.

[12] For example, the parties state that in 2015 there was a CRM specialist consultant consistently available at UHSM throughout the week (including out-of-hours and on the weekend) for only slightly more than one third of all weeks. The parties state that the level of coverage would be even less at Central Manchester.

[13] Cardiac physiologists carry out cardiac tests and may also work in the cath laboratory assisting with pacemaker/ICD implantation.

[14] This estimate is based on approximately two thirds of the hours during the week being outside normal working hours and assuming an even distribution of patients requiring urgent or emergency attention.

approximately 1.3 days longer than those admitted during the week.[15] The parties have not provided data on how long patients requiring their existing ICD device to be analysed are waiting.

In their submission the parties referenced British Heart Rhythm Society position statements and clinical standards that state:

- All patients requiring emergency pacing should have access to appropriate specialist care at all times – patients presenting to the ambulance service with arrhythmia emergencies should be directed to a hospital where such patients can be safely and appropriately managed (including having the facilities and staff to insert temporary pacing wires on a 24/7 basis and to offer permanent pacemaker implantation within 24 hours if indicated).[16]
- There must be a 24 hour service available to deal with patients admitted with ICD device related issues.[17]

The parties have not set out how many of their non-elective patients required pacemaker implantation within 24 hours in line with the above guidance, or how many did not receive this under the current arrangements.

For patients requiring non-elective implantation of a pacemaker, the parties submit that additional time prior to treatment can cause considerable discomfort for the patient and anxiety for both the patient and their family. A longer wait prior to treatment can also result in longer recovery times. The parties also say that for some patients, delays in being transferred to Central Manchester or South Manchester from other local hospitals may mean that a temporary pacing wire, which can be associated with significant risk of morbidity and mortality, is inserted to stabilise the patient.

## The parties' heart rhythm proposals and NHS Improvement's views on whether they represent improvements for patients

The parties submit that their proposed changes to CRM services will help reduce time to treatment and length of stay for CRM patients (including by reducing the time that some patients wait from admission at local hospitals to being transferred

[15] The parties submitted that patients admitted at the weekend wait an average of 4.5 days from admission (either at one of the trusts or at another local hospital before being transferred to one of the trusts) to discharge. Patients admitted during the week waited an average of 3.2 days.
[16] British Heart Rhythm Society, Position statement on the out-of-hours management of Bradyarrhythmia emergencies. Nick Linker and Mark Earley on behalf of BHRS Council, January 2016. Available at: www.bhrs.com/files/files/Guidelines/160216-BHRS%20Position%20Statement%20%2C%20Bradyarrhythmia%20emergencies.pdf
[17] British Heart Rhythm Society, Standards for implantation and follow up of cardiac rhythm management devices in adults. January 2015. Available at: www.bhrs.com/files/files/Clinical%20Service%20Standards/150106-Standards-Standards%20for%20CRM%20Devices%202015.pdf

to Central Manchester or South Manchester), reduce risks arising from stabilisation measures that may be used in local hospitals prior to treatment, and reduce risks of complications.

**Improved access to specialist cardiology CRM consultants for non-elective pacemaker implantation**

Under the proposed arrangements the parties will combine their clinical resources to offer a combined CRM service which includes comprehensive on-call out-of-hours and weekend cover. The parties propose to implement the joint CRM rota within the first year after the merger and then later to consolidate their services onto a single site (not yet determined). The parties have also said that through the merger they will design the single service to ensure there are daily pacemaker implantation slots which are modelled on activity. This may involve one slot in the morning for any patient who has been admitted overnight and one slot at the end of the day. Further modelling work is being undertaken and the parties say they will need to have the ability to flex their capacity to meet demand.

In our view, the increased availability of CRM specialist consultants would be likely to reduce the time that some patients would wait for non-elective implantation of a pacemaker, particularly patients presenting out-of-hours or at weekends. From the information provided we would expect that this would benefit a significant proportion of the approximately 133 patients[18] requiring non-elective pacemaker implantation out-of-hours or at the weekend. It is unclear how much waiting times for pacemaker implantation are likely to reduce as a result of the proposals or how many patients presenting in normal working hours would benefit. However, in our view, any reduction in time to treatment would result in:

- reduced patient anxiety experienced while awaiting the procedure
- reduced risk of complications due to prolonged immobilisation, especially as most patients are elderly.[19]

For those patients who require implantation of a pacemaker within 24 hours, the likely reduced time to treatment may lead to additional clinical improvements

[18] The parties submit that this figure of 133 patients is based on 200 patients presentations per year and the assumption that if patients present evenly across the week, approximately two thirds of patients will present out-of-hours. We have not tested the assumption that patients requiring specialist CRM input present evenly across the week.
[19] We understand that most of the patients who require an urgent pacemaker implant are elderly and that (in all patients, but particularly the elderly) there is a progressive loss of physical strength and functional capacity with each day of bed rest.

associated with receiving care delivered in line with best practice guidance published by British Heart Rhythm Society.[20]

**Improved access to specialist cardiology CRM consultants and cardiac physiologists for non-elective ICD analysis**

Under the proposed arrangements the parties will combine their clinical resources to offer a combined CRM service which includes comprehensive on-call out-of-hours and weekend cover of both CRM consultants and CRM cardiac physiologists.

In our view, the increased availability of CRM specialists (consultants and cardiac physiologists) would be likely to reduce the time that some patients presenting out-of-hours or on weekends would wait for urgent or emergency analysis of their existing ICD device. It is unclear how many patients would benefit in this way[21] or the impact that this improved access would have on patients. We expect that at a minimum, some patients would experience reduced anxiety while waiting to find out why a shock was delivered and reduced time to treatment if treatment is required.

**Standardised pathways and protocols in conjunction with other local hospitals and local ambulance services**

The parties propose to reduce waiting times for patients being taken to Central Manchester or South Manchester through:

- direct ambulance transfers (that remove the need for patients to be admitted to other local hospitals)
- the establishment of standardised protocols and pathways that would help ensure medical teams at other local hospitals are able to access specialist phone advice and support from the parties so that patients get the best management, and ensure patients are more transferred more quickly from local hospitals to the merged trust.

We note that successful implementation of standardised pathways and protocols with local hospitals will require engagement and an education process. The parties also recognised that consultation with local ambulance services would be needed before they could further consider implementation of direct ambulance transfers.

[20] British Heart Rhythm Society, Position statement on the out-of-hours management of Bradyarrhythmia emergencies. Nick Linker and Mark Earley on behalf of BHRS Council, January 2016. Available at: /www.bhrs.com/files/files/Guidelines/160216-BHRS%20Position%20Statement%20%2C%20Bradyarrhythmia%20emergencies.pdf

[21] While the parties have provided information relating to the out-of-hours availability of specialty consultants at South Manchester (and estimated the availability at Central Manchester), they have not provided such information in relation to cardiac physiologists or information on how many patients have had increased waiting times due to unavailability of a relevant CRM clinician.

In our view, such reductions in times to transfer or treatment would be likely to reduce patient anxiety experienced while awaiting the procedure and reduce the risk of complications due to prolonged immobilisation, especially as most patients are elderly. They would also be likely to have an impact on the number of patients able to have their pacemaker implanted on a non-elective basis within 24 hours (where indicated) in accordance with the British Heart Rhythm Society's position statement. The proposals would also be likely to reduce the risks of patients deteriorating while they await transfer and treatment. Improved pathways and the specialist advice and support would also be likely to help reduce the risks arising from the insertion of temporary pacing wires at other hospitals. By transferring patients to the merged trust more quickly, we expect the use of temporary pacing wires could be avoided altogether for some patients. For those patients who continue to require a temporary wire, we expect the more timely transfer would increase the likelihood of the wire being inserted at Central Manchester or South Manchester following, rather than prior to transfer. This would reduce the risk of the wire being inserted by someone other than a cardiology consultant.[22]

## Conclusion

**In our view, the parties' heart rhythm proposals are likely to result in improvements for patients requiring non-elective implantation of pacemakers or non-elective ICD analysis in the form of reduced time to treatment or reduced time to ICD analysis. While it is unclear how many patients will experience this improvement or the extent to which waiting times would be reduced, for those that are affected, the reduced waiting time would be likely to lead to reduced anxiety and reduced risk of complications due to prolonged immobilisation.**

**We also find that the proposals are likely to result in improvements for non-elective patients through reduced time from admission to other local hospitals to transfer to the merged trust, and this would be likely to result in the use of temporary pacing wires being avoided for some patients. Where a temporary pacing wire is still needed, the proposals would result in a higher chance of the wire being inserted after transfer, which reduces the risk of it being inserted by someone other than a cardiology consultant.**

[22] We understand from the parties that at Central Manchester and South Manchester temporary pacing wire insertion is always performed by a cardiologist whereas at other local hospitals this procedure may be done by general medical registrars.

# Acute aortic surgery

Acute aortic surgery refers to surgical procedures to repair the aorta, the main artery in the body which carries oxygenated blood away from the heart to the rest of the body. The parties' submission focusses on surgery to repair one of the most critical forms of aortic damage, a Type A aortic dissection.[23]

An aortic dissection is a tear in the inner lining of the aorta which allows blood to flow through the walls of the aorta. In Type A dissection, the tear begins in the part of the aorta closest to the heart, referred to as the ascending aorta. When a patient presents with symptoms that are due to a tear causing bleeding through the walls of the aorta, urgent life-saving surgery to repair this is imperative. Type A dissection of the aorta is therefore a critical, life threatening condition which requires emergency aortic surgery. Failure to treat this condition is highly likely to be fatal and delays in diagnosis and treatment considerably reduce the chances of survival.

From the parties' submissions, we identified four main proposals for patients with Type A aortic dissection:

- improved access to aortic surgeons and cardiac surgeons with an interest in aortic surgery to reduce time to emergency surgery for patients currently transferred to other centres
- improved access to aortic surgeons and cardiac surgeons with an interest in aortic surgery, thereby avoiding the need for non-specialists to perform the surgery
- increased patient volumes on a single site
- developing pathways and protocols to ensure patients with Type A aortic dissection that present to other local hospitals in Greater Manchester are correctly diagnosed and promptly transferred to the merged trust.

**As set out below, in our view, the parties' proposals would be likely to result in improvements for patients with Type A aortic dissection. Our assessment below sets out which patients we would expect to benefit from the parties' proposals and the impact we would expect the proposals to have on those affected.**

[23] Other forms of aortic damage requiring non-elective surgery are: Complicated Type B Dissection, thoracoabdominal emergencies and intramural haematoma.

## Current service arrangements

We understand from the parties that there are currently no agreed guidelines for referring patients requiring acute aortic surgery across Greater Manchester to a specialist centre. Our understanding is that patients access emergency surgery via one of two routes:

- They will present to or be taken via ambulance to an A&E department in Greater Manchester other than Central Manchester or South Manchester. If they are correctly diagnosed with Type A aortic dissection (or a related condition) clinicians at the local hospital will attempt to identify a cardiac surgical centre able to admit the patient and undertake emergency surgery. Central Manchester and South Manchester are the cardiac surgical centres in Greater Manchester. The parties told us that the first centre of choice for the local hospital will vary according to the preference of the referring clinician. If neither trust is able to accept the patient (for example if a specialist surgeon is not available or if they do not have an intensive care bed available) the A&E team at the local hospital will need to identify another cardiac surgical centre that is able to accept the patient. Greater Manchester patients may therefore be transferred to Liverpool, Blackpool or Stoke for their emergency surgery.
- They will present to or be taken via ambulance to Central Manchester or South Manchester. Following diagnoses and if a specialist surgeon and an intensive care bed is available, they will receive emergency surgery at that hospital. If a patient arrives when an intensive care bed is not available the trusts will look at ways to operationally flex their intensive care unit capacity to avoid the patient travelling to another provider. If this is not possible the trust would have to call other cardiac surgical centres (such as Liverpool Heart and Chest Hospital NHS Foundation Trust (Liverpool Heart and Chest Hospital)) to see which other trust the patient could be transferred to. If no specialist surgeon is available when a patient arrives at Central Manchester or South Manchester the patient may be operated on by a non-specialist surgeon or, if that surgeon declines to operate due to clinical risk, the trust will look to other cardiac surgical centres and seek to transfer the patient.

We understand from the parties that:

- At Central Manchester there are currently five cardiac surgeons (including two aortic surgeons and two cardiac surgeons with an interest in acute aortic surgery) and one general cardiac surgery rota.
- At South Manchester there are currently seven cardiac surgeons (including two aortic surgeons) and two cardiac surgery rotas (one general cardiac surgery rota and one cardiac transplant rota).

The parties say that in 2015-16, 27 patients with a Type A aortic dissection were operated on at Central Manchester and South Manchester. From the information provided by the parties we do not know when or how often a specialist surgeon is unavailable at either trust and the parties told us they do not hold data on how often they are unable to accept a patient due to the lack of available surgeon or an intensive care bed. However, on the basis of the information provided, we understand that between 12 and 17 of the 27 Type A dissection repair emergency procedures carried out by the parties in 2015-16 were performed by cardiac surgeons who were not specialists in aortic surgery. The parties also told us that in 2014-15, 14 patients registered with a GP in Greater Manchester were operated on at Liverpool Heart and Chest NHS Foundation Trust. The parties believe this is a reasonable estimate of the number of times per year the two trusts are unable to accept a patient for acute aortic surgery from a local hospital.[24]

The parties told us that the process of identifying a cardiac surgical centre able to accept a patient and then transferring the patient to that centre can cause dangerous delays, as the mortality rate for these patients worsens with every hour of delay before definitive treatment.

The parties told us that specialist scanning equipment required to diagnose a Type A dissection is not available at all times in all A&E departments in Greater Manchester. As such some people may not be correctly diagnosed and may not receive the surgery they need.

## The parties' acute aortic surgery proposals and NHS Improvement's views on whether they represent improvements for patients

The parties submit that their proposed changes to acute aortic surgery services will improve outcomes for patients, including by reducing mortality.

### Improved access to specialists resulting in reduced time to emergency surgery for patients currently transferred to other centres

The parties propose to offer a single service for aortic surgery patients by combining their aortic surgeon workforce, which means they can provide comprehensive on-call out-of-hours and weekend cover for emergency services. The proposed rota will be a low intensity but high frequency 1 in 4 rota. The parties

[24] We note that travel times between some Greater Manchester hospitals and Liverpool Heart and Chest Hospital are such that in some of these cases Liverpool Heart and Chest Hospital may have been the first choice for referring clinicians.

say that this new rota will ensure that an appropriate surgeon is always available at the merged trust. The parties anticipate that this will allow the approximately 14 patients per year who are currently being transferred out of area (primarily to Liverpool Heart and Chest Hospital) to be treated at the merged trust, resulting in a reduction in time to treatment.

In our view, this reduced time to treatment may contribute to improved outcomes for patients. The parties have provided evidence that timely diagnosis and rapid surgical management of acute Type A aortic dissection are considered to be of paramount importance for better outcomes and survival, with an estimated mortality rate of more than 1% each hour after onset of symptoms.[25, 26] However, we note that factors other than time to surgery are also highly relevant, such as institutional and surgeon volume and surgical techniques.[27,28] We also note that the parties have not provided us with their current mortality rates as they say the volume is too small to be statistically relevant. As such, it is unclear whether or how much patient mortality might improve as a result of the reduced time to treatment and we note evidence that Liverpool Heart and Chest Hospital (where most patients that cannot be treated by the parties are currently transferred for surgery) provides a service with low mortality rates.[29]

**Improved access to specialists resulting in reduced risk of surgery by non-specialists**

The parties told us that non-specialist surgeons typically decline to operate on acute aortic dissection patients. Therefore, when a specialist surgeon is not available the referring doctor will have to try another referral route. The parties told us that in 2015-16 there were 27 patients with a Type A aortic dissection operated on at the trusts. They also told us that, of these patients, five Central Manchester patients and between five and ten South Manchester patients were operated on by a surgeon with a specialisation in aortic surgery. We therefore understand that

[25] Basir et al. Repair of type A dissection-benefits of dissection rota. *Annals of Cardiothoracisc Surgery*. 2016, 5(3): 209-215.
[26] Ramanath et al. Acute Aortic Syndromes and Thoracic Aortic Aneurysm. *Mayo Clinic Proceedings*. 2009, 84: 465-481.
[27] Basir et al. Repair of Type A dissection-benefits of dissection rota. *Annals of Cardiothoracisc Surgery.* 2016, 5(3): 209-215.
[28] Chikwe et al - National Outcomes in Acute Aortic Dissection: Influence of Surgeon and Institutonal Volume on Operative Mortality. *Annals of Thoracic Surgery*. 2013;95:1563–9.
[29] Liverpool is a leading aortic centre carrying out a high volume of procedures per year (in the region of 150). Data published in 2016 on a cohort of patients receiving surgery at Liverpool between 2007 and 2015 demonstrated a mortality rate of 11.7% - 13.3%. A UK wide registry published in 2008 reported a 23% mortality rate for patients undergoing urgent or emergency surgery for aortic dissection, which they reported to be in line with published international registries. Bridgewater B, Keogh B. Society for Cardiothoracic Surgery in Great Britain and Ireland, sixth adult cardiac surgical database report 2008*, Demonstrating quality*. Oxfordshire: Dendrite clinical systems Ltd. 2009. Available online: www.scts.org/_userfiles/resources/SixthNACSDreport2008withcovers.pdf

between 12 and 17 Type A aortic dissection patients may have been operated on by a non-specialist surgeon.

As noted, the parties propose to offer a single service for aortic surgery patients by combining their aortic surgeon workforce, which means an appropriate surgeon is always available at the merged trust. While it is difficult to be conclusive (given the parties told us that non-specialist surgeons at the trusts typically refuse to operate on acute aortic dissection patients) in our view, the proposals may reduce the risk of patients being operated on by a non-specialist surgeon. If, as a result of the proposals, patients are operated on by a specialist surgeon when under the current arrangements they would have been operated on by a non-specialist, based on the evidence provided we would expect that this would contribute to improved patient outcomes. [30]

**Increased patient volumes on a single site**

Through the merger the parties propose to treat more patients with Type A aortic dissection than either trust currently treats individually.

The parties provided evidence suggesting that although there is currently no guidance on minimum volumes of aortic surgery to be undertaken per surgeon or trust, there is a strong inverse relationship between operative mortality and both institutional and surgeon volume. Patients undergoing emergency repair of acute aortic dissection by lower-volume surgeons and centres have approximately double the risk-adjusted mortality of patients undergoing repair by higher-volume care providers.[31]

Consolidating services onto a single site through the merger (and treating patients in Greater Manchester who under the current arrangements are transferred out of area) would mean that the merged trust would perform a higher number of Type A aortic dissections operations than the individual trusts currently perform which, in our view, would contribute to improved outcomes for the approximately 27 patients currently treated by the trusts per year. It is unclear how much of an improvement is

[30] We note evidence submitted by the parties of improved outcomes, including reduced mortality, following implementation of a specialist aortic rota at Liverpool Heart and Chest NHS Foundation Trust (see footnote 26). The authors of this study recognised that a number of variables could have resulted in the decreased mortality rate observed, but concluded that the development of standardized surgical techniques and the regular performance of these on a weekly basis as well as the increased number of cases per surgeon are among the predominant contributing factors to the benefits demonstrated.

[31] As well as the expertise of the individual surgeon, clinical outcomes from complex procedures can also be driven by expertise that exists across the entire multidisciplinary team and the efficiencies an expert team can deliver across the complete operative care pathway. As such volume outcome relationships can exist at both the level of the surgeon and the institution. Studies suggest that both relationships exist for acute aortic dissection repair. See Chikwe et al National Outcomes in Acute Aortic Dissection: Influence of Surgeon and Institutional Volume on Operative Mortality, *Annals of Thoracic Surgery*. 2013;95:1563–9.

likely to result from the higher institutional volumes or how much surgeon volumes (which has also been found to impact mortality outcomes) might improve under the proposed arrangements.

**Improved diagnosis at other local hospitals**

The parties propose to reduce the number of patients not being correctly diagnosed at other hospitals by developing protocols and a pathway for the management of patients with suspected aortic dissection. This pathway would involve rapid access to appropriate CT scanning (which we understand from the parties is not available in all hospitals in Greater Manchester), specialist reporting and then the aortic surgical team at the merged trust deciding on the best option for transferring and managing the patient. The parties acknowledge that implementation of this plan will require engagement and an education process for the A&E and acute medicine teams around Greater Manchester.

We think that these proposals would be likely to result in improvements for patients presenting to other hospitals in Greater Manchester that are not currently being correctly diagnosed with Type A aortic dissection or not accessing treatment sufficiently quickly. While it unclear how many patients would experience this improvement we note that, as this condition is highly likely to be fatal if le untreated, improved diagnosis has the potential to be lifesaving.

## Conclusion

**In our view, the parties' proposals to improve acute aortic surgery services would be likely to result in improvements for the approximately 27 patients per year with Type A aortic dissection currently being treated by Central Manchester or South Manchester through improved quality of care as a result of increased patient volumes and through reducing the risk of being operated on by a non-specialist surgeon.**

**The proposals are also likely to result in improvements in the form of reduced time to surgery for the approximately 14 patients per year currently being transferred to other centres.**

**Finally, if pathways and protocols are developed and implemented between local hospitals and the merged organisation, this would likely result in improved diagnosis and reduced time to surgery for patients initially presenting at other hospitals in Manchester. For those patients affected, these proposals would be likely to lead to improved clinical outcomes, including reduced mortality, though we are unable to quantify the extent of such an improvement.**

# Vascular surgery

Patients with vascular disease have disorders of the arteries, veins and lymphatic vessels. This may include inflammation or weakness of the blood vessels or build-up of fatty deposits. Vascular disorders can affect the flow of blood to and from major organs and limbs. If not treated, vascular disorders can lead to serious conditions such as stroke, rupture of an artery, or amputation due to blood not circulating adequately through the limbs.

There are a number of options for treating patients with vascular disease. These include lifestyle changes and medication, interventional procedures such as carotid endarterectomy (a surgical procedure to unblock the carotid artery), angioplasty (inserting a balloon or stent to open up the vessel), and surgery. The type of treatment will depend on the seriousness of a patient's vascular disease and other conditions that the patient may have.

In recent years, hospitals in the NHS have moved towards providing vascular services in a networked way. This is in response to evidence showing improved outcomes for patients when vascular surgery is provided in hospitals with high caseloads.[32] The vascular networks typically feature groups of hospitals working together in a hub and spoke model. The hub hospital provides a full range of vascular services and is the singular provider of arterial surgery and complex interventional procedures for all patients who are referred to hospitals within the network. Spoke hospitals that are part of the network provide non-surgical services (such as diagnostics, day case procedures and treatment for less complex vascular conditions such as varicose veins, and outpatient appointments at vascular clinics) but they refer patients to the hub for arterial surgery and complex procedures. Network models aim to create hubs that achieve better outcomes for patients by doing high numbers of surgical and interventional procedures.

Three common types of arterial surgery are performed at hub centres:

- carotid endarterectomy – a surgery to remove build-up from the carotid artery, the main blood vessel supplying the head and neck
- abdominal aortic aneurysm (AAA) repair – a surgery to treat swelling of the aorta
- lower limb revascularisation procedures or major amputation for lower limb peripheral arterial.

[32] *National vascular registry annual report 2016*.

Both trusts currently have vascular hubs. They propose to consolidate their hubs to create one larger vascular hub at Central Manchester 's MRI hospital which would provide arterial surgery and complex interventional procedures for patients across Greater Manchester.

**As set out below, in our view, the parties' proposals would be likely to result in improvements for vascular surgery patients through the merged trust treating higher volumes of patients. Our assessment below sets out which patients we would expect to benefit from the parties' proposals and the impact we would expect the proposals to have on those affected.**

## Current and proposed arrangements

In Greater Manchester, there are three hub and spoke vascular networks:

- Central Manchester, at MRI, is the hub providing elective and non-elective arterial surgery and complex interventional procedures to patients referred from Trafford Hospital, Salford Royal NHS Foundation Trust and Bolton NHS Foundation Trust (the spoke hospitals).[33]
- South Manchester, at Wythenshawe Hospital, is the hub providing elective and non-elective arterial surgery and complex interventional procedures to patients referred from Tameside and Glossup Integrated Care NHS Foundation Trust, Stockport NHS Foundation Trust, Macclesfield District General Hospital and The Christie NHS Foundation Trust (the spoke hospitals).
- Pennine Acute Hospitals NHS Trust, at Royal Oldham Hospital, is the hub providing arterial surgery and complex interventional procedures to patients referred from North Manchester General Hospital, Fairfield General Hospital and Rochdale Infirmary (the spoke hospitals).

The parties told us that there were a total of 3,288 patients admitted for treatment at Central Manchester and South Manchester for vascular services in 2015-16, including day-case, inpatient elective and non-elective patients. There were a total of 9,147 first outpatient appointments at the two trusts.[34]

[33] In addition, Central Manchester has been designated as the centre for complex endovascular surgery (a surgical procedure in which a catheter containing medications or miniature instruments is inserted through the skin into a blood vessel for the treatment of vascular disease), working with the Royal Liverpool to provide complex endovascular services.
[34] Figures for each trust separately and for the spoke hospitals within the trust's networks (other than Trafford) were not provided.

**Requirements for an arterial surgical hub**

In 2013-14, NHS England began commissioning specialised vascular services. NHS England required all trusts providing vascular services to belong to a vascular network, and it set out requirements for vascular networks. The aim was to consolidate arterial surgery in higher volume sites and improve access and outcomes for patients. NHS England said that arterial surgery hubs should:

- have a vascular team with a minimum of six vascular surgeons and six vascular interventional radiologists to ensure comprehensive on-call emergency cover out-of-hours and at weekends for vascular patients; NHS England said a 24/7 interventional radiology rota may need to be organised on a network-wide basis to ensure that interventional radiology services for other specialties are not destabilised in spoke hospitals
- ensure that each surgeon will do, at a minimum, about ten emergency and elective surgeries per year in each of the three types of common surgeries described above; with each centre doing at least 60 AAA and lower limb procedures, and 50 carotid procedures[35]
- have a catchment area to generate sufficient case volume; NHS England said a minimum population of 800,000 would be appropriate "but for a world class service a larger catchment area will be required."

Our examination of evidence submitted by the parties indicates that Central Manchester is meeting and South Manchester appears to be meeting the national requirements for an arterial surgical hub:

- Central Manchester has six vascular surgeons and five vascular interventional radiologists with, we understand, additional input provided by an interventional radiologist from a local trust. South Manchester has six vascular surgeons and four vascular interventional radiologists. Each trust provides 24/7 out-of-hours cover for vascular surgery and vascular interventional radiology. The latter is provided through a 1:9 shared out-of-hours rota between Central Manchester and South Manchester.
- We examined how many elective and non-elective AAA, lower limb revascularisation, and carotid procedures each trust does.[36] We found that for each trust, and for each procedure, surgeons are on average exceeding the current standard for minimum number of surgeries per year.

[35] NHSE said at the time that the standards for AAA and carotid endarterectomy were indicators but would become minimum requirements as services are reconfigured.
[36] The caseload number for these vascular procedures for South Manchester, Central Manchester and other NHS trusts are published in the National Vascular Registry 2016 Annual Report, available at: www.vsqip.org.uk/content/uploads/2016/12/National-Vascular-Registry-2016-Annual-Report.pdf.

- The hub site of each trust is serving the minimum population of 800,000.

We recognise that South Manchester has fewer than six vascular interventional radiologists and appears to be compliant with a 24/7 on-call vascular interventional radiology rota only because of the joint rota with Central Manchester.

The parties also told us that under current arrangements, patients at one hub may not be able to access sub-specialist services that are available at the other hub. They gave examples of a lack of inpatient renal medicine provision, interventional radiology support for complex cardiology, endovascular aortic aneurysm repair and distal revascularisation (which can prevent amputation) at South Manchester, as well as a lack of emergency interventional radiologist and vascular on-call cover for major trauma at Central Manchester.

**Commissioners' intentions for vascular services**

Commissioners in Greater Manchester have said they intend to further consolidate vascular services in Greater Manchester to a single hub, rather than having three. All other hospitals in Greater Manchester would be spoke hospitals networked with the new single hub.

Commissioners have said the reconfiguration is intended to improve compliance with national standards[37] and help to sustain the workforce, by addressing shortages in vascular surgeons, vascular interventional radiologists, vascular anaesthetists and radiology nurses in the existing networks. They expect the reconfiguration to further improve outcomes for patients, including mortality rates and complication rates.

Commissioners' plans to reconfigure the service appear to be at an early stage. It is not clear how commissioners will determine where the single hub sits or which provider will operate it. Commissioners have said, however, that they will build on existing arrangements, in particular sub-specialised services that are provided only at MRI, and that the "proposed single hospital for Manchester should permit the unification of the vascular surgical workforce of Central Manchester and South Manchester in the future."[38] Our assessment is based on the parties' proposal to consolidate into one vascular hub.

[37] Commissioners have said Central Manchester meets the standards but not all services providers do - is it not clear whether this refers to South Manchester or Pennine.
[38] Vascular Project Initiation Document, Greater Manchester Combined Authority and NHS in Greater Manchester, Oct. 24, 2016.

## The parties' vascular proposals and NHS Improvement's views on whether they represent improvements for patients

The parties submit that their proposed changes to vascular surgery services will improve outcomes for patients, including mortality.

### Creating a single vascular surgery hub

The parties propose to consolidate their existing hubs at MRI, which will provide elective and non-elective arterial surgery and complex interventional procedures to patients currently served by the trusts. MRI would provide all out-of-hours and weekend emergency cover for Greater Manchester. Wythenshawe would continue to provide non-arterial day case surgery and day case vascular interventional radiology.

In our view, the increased number of patients served at one hub would be likely to result in improvements in mortality rates. There is good evidence to support the link between higher volumes of vascular surgery and improved patient outcomes.[39] The proposal would result in an increased caseload for the combined hub. In our view, this would be likely to result in an overall increase in the number of surgeries that each surgeon performs. This will depend on how surgeries are distributed among surgeons and the number of surgeries that each surgeon currently does per year, however it appears possible to us, based on our examination of the current average numbers of surgeries per surgeons, that more surgeons may meet or exceed the 10-surgery standard.

We accept that these improvements would be likely to result in reduced mortality rates, although we note that outcomes data submitted by the parties shows that they each already have low mortality rates relative to other surgical centres.

We are less convinced that combining services into a single hub will result in reductions in length of stay, complication rates following admission and tissue loss and limb amputations for diabetic foot patients. The parties acknowledge that evidence to support these improvements is undeveloped. We acknowledge that, as the parties said, frequency of senior medical review can influence length of stay or complication rates; however, it is not clear to us how the proposal increases the frequency of senior medical review.

While the parties also submitted that through the merger they could improve access to sub-specialised services that currently may be available at only one of the two hubs, in our view, the trusts should already be making all possible efforts to ensure that patients receive the services they need in a timely way at a provider where the service is available. We would expect that, where having access to such sub-

[39] See eg, *The reconfiguration of clinical services*, The Kings Fund, November 2014, p. 70-71.

specialist services is in the best interest of a patient, the trust that does not provide the service should arrange an appropriate way for the patient to access the service provided by another trust. Where a hub is designated to provide a particular sub-specialist treatment or procedure (such as for complex endovascular surgery at Central Manchester ) we would expect this to be offered to a wider population than just the network this hub centre supports. If this is not currently happening in a way that works for patients, this is a matter for commissioners and providers to resolve now.

## Conclusion

**In our view, the parties' proposals to improve vascular surgery services would be likely to result in improved mortality rates as a result of the increased caseload of the combined vascular hub.**

# Transient ischaemic attack (mini-stroke)

Transient ischaemic attack (TIA), also known as a mini stroke, is a condition in which a disruption in blood supply results in a lack of oxygen to the brain. TIA can cause sudden symptoms similar to a stroke but the effects often only last for a few minutes or hours and fully resolve within 24 hours. However, they can be a precursor to a full stroke, which has a risk of death and debilitating effects. While the symptoms of TIA resolve quickly, patients require urgent medical assessment and treatment to receive an accurate diagnosis and to help prevent another TIA or a full stroke happening in the future. Treatment can include medication to treat the underlying cause of the TIA or, in some cases, surgery to unblock the carotid arteries which are the main blood vessels that supply the brain.

Typically patients will present at their nearest A&E or other emergency service having experienced stroke like symptoms that have resolved.[40] At their local A&E, or emergency service, patients are assessed and their history taken to ascertain whether they have had a suspected TIA and what their risk is of a subsequent stroke. This is done using validated clinical scoring systems. As per NICE guidance, the assessing clinician will start the patient on initial medication therapy (usually aspirin therapy) regardless of what their risk score is of a subsequent stroke. The level of risk the patient has of a subsequent stroke, assessed and scored by the initial clinician, determines how soon a patient is seen by a specialist for further assessment, investigations and treatment. This is within 24 hours for high risk patients and within one week for low risk patients. If clinically appropriate, and patients do not need to be admitted, they will be referred to a specialist TIA or stroke clinic[41] before being discharged from the A&E or other emergency service.

The parties propose to increase access to TIA services, initially by offering an additional clinic at one of the sites on either Saturday or Sunday[42] (within the first year of the merger) and later by offering a seven-day service between the sites. The parties will be able to offer this service by combining the clinical resources of the two trusts (though some additional recruitment may be required[43]) and

[40] We note that there is a lot of public information to encourage people to seek immediate emergency help if they experience any stroke-like symptoms, even if they resolve after only a few minutes.
[41] As per the 2008 NICE guidance described below.
[42] The parties note that this will likely be co-located with the vascular surgical service and will require access to diagnostic services.
[43] We understand from the parties that it has been agreed that additional funding to support recruitment of additional consultants will be provided if this recruitment is required.

harmonising the current activity to ensure there is TIA clinic availability on at least one site.

**As set out below, in our view, the parties' proposals would be likely to result in improvements for some TIA patients in the form of reduced time to assessment. Our assessment below sets out which patients we would expect to benefit from the parties' proposals and the impact we would expect the proposals to have on those affected.**

## Current service arrangements

Both Central Manchester and South Manchester provide TIA services. Referrals to both Central Manchester's and South Manchester's TIA services can be made from A&E and GPs.[44]

- Central Manchester provides TIA services at MRI and Trafford Hospital: Central Manchester sees approximately 296 TIA patients per year at MRI. MRI runs a TIA clinic in the outpatient department once per week on Tuesdays. We understand that this clinic is covered on a rota basis by two consultant stroke physicians, one associate specialist[45] and one advanced nurse practitioner. On other weekdays new patients at MRI are seen on an ad hoc basis on the stroke ward. We understand from the parties that sometimes these TIA patients will be admitted to the ward and sometimes they will be assessed on the ward without being admitted. Ten new patients can be seen each week at the Tuesday TIA clinic and two new patients can be seen each day on the stroke ward.

  Central Manchester also sees approximately 360 TIA patients per year at Trafford Hospital. At Trafford new TIA patients are seen four days per week by an associate specialist.

- South Manchester sees approximately 720 TIA patients per year. South Manchester holds daily TIA clinics from Monday to Friday. From information provided by the parties we understand that three consultants cover these clinics with two advanced nurse practitioners. Four new patients can be seen at each daily clinic.

We understand from the parties that the consultants covering the TIA clinics have a range of other inpatient duties. For example, a number of these consultants are also on the general medical on-call rota. This means that increasing their availability to cover additional stroke clinics would be difficult.

[44] The parties have told us that very few patients arrive at the parties via ambulance as under the guidelines for the stroke network ambulances take appropriate patients to the hyper acute units at Salford or Stepping Hill.
[45] An associate specialist is a non-training role where the doctor has at least four years of postgraduate training, two of those being in a relevant specialty.

Neither Central Manchester nor South Manchester provides TIA clinics on the weekends. If a patient suffers from a suspected TIA late on a Friday or over the weekend they will not be assessed in a TIA clinic until Monday at the earliest, unless a stroke consultant is rostered to be on-call.[46]

NICE guidance[47] from 2008 states that patients presenting with suspected mini-stroke who are high risk patients should be assessed within 24 hours and low risk patients should be assessed within seven days. For high risk patients, additional guidance states that, where needed, certain investigative tests (eg blood tests, electrocardiogram, brain scan and carotid imaging) should be completed within 24 hours and certain treatments (eg aspirin, statin, control of blood pressure) should be started within 24 hours.[48] NICE reviewed its guidance in January 2017 and is currently in the process of updating its recommendations, including sections on rapid recognition of symptoms and diagnosis.

In 2016 the Royal College of Physicians released new guidance[49] recommending that all patients with suspected TIA should be assessed urgently within 24 hours by a specialist physician in a neurovascular clinic (also known as a TIA clinic) or an acute stroke unit. This guidance also says that TIA patients who are considered candidates for carotid surgical intervention should have carotid imaging performed urgently within 24 hours.[50] The Royal College of Physicians guidance is based on more recent clinical evidence than the 2008 NICE guidance.

The parties told us that under the current arrangements, while they are mostly compliant with the NICE Guidelines, not all TIA patients are being assessed within 24 hours as is now recommended by the Royal College of Physicians. Based on the evidence provided by the parties, we estimate that Central Manchester 's MRI saw approximately 37% of TIA patients within 24 hours and South Manchester saw approximately 41% within 24 hours. The parties did not provide data on how many TIA patients were treated by Central Manchester 's Trafford Hospital within 24 hours. Not being assessed in line with the Royal College of Physicians' guidelines may increase a patient's risk of subsequent larger stroke.[51]

[46] At Central Manchester FT there are no direct admissions to the stroke ward on the weekend as there is no specialist consultant presence. At South Manchester FT a patient may be admitted to the stroke ward on the weekend (as geriatricians undertake daily rounds on the weekend and are able to make that decision) however they would not be seen assessed by a stroke specialist until Monday at the earliest.
[47] NICE Clinical Guidance CG68. *Stroke and transient ischaemic attack in over 16s: diagnosis and initial management*. 2008. Available at: www.nice.org.uk/guidance/cg68
[48] Stroke Integrated Performance Measure Return (IMPR)
[49] *National Clinical Guideline for Stroke*. Fifth Edition 2016. Royal College of Physicians. Available at: www.strokeaudit.org/Guideline/Full-Guideline.aspx
[50] The 2016 Royal College guidance followed a review by the National Institute of Health Research Technology, which found that the common way of predicting risk (using what is called an ABCD2 score based on the clinical characteristics of the patient and their symptoms) does not always accurately predict subsequent stroke risk if used as a triage for TIA clinic review.
[51] The Royal College of Physician's guideline references a study which looked at the risk of stroke within seven days of confirmed TIA (Giles MF & Rothwell PM, 2007. Risk of stroke early after

## The parties' proposals for mini-stroke patients and NHS Improvement's views on whether they represent improvements for patients

The parties submit that their proposed changes to TIA services will reduce the time that TIA patients wait for assessment. They say that this will result in more patients being assessed within 24 hours as recommended by the Royal College of Physicians and a reduction in the morbidity and mortality risks associated with subsequent strokes.

In our view, combining the services would result in the ability to develop new work plans for existing staff that would be likely to result in additional capacity to assess TIA patients, particularly at the weekend. This would be likely to reduce the time that patients wait to be assessed. It is unclear exactly how many TIA patients would benefit from reduced waiting times or the extent to which their waiting times would reduce. We expect that patients admitted late on a Friday, on a Saturday, or early on a Sunday could experience the greatest improvement[52]. The reductions in waiting times would be likely to result in more TIA patients being treated within 24 hours. In terms of the significance of the improvements for those patients affected, we note that the Royal College of Physicians' guidance in relation to TIA patients is aimed at reducing the risk of subsequent larger stroke and associated mortality and morbidity outcomes.

## Conclusion

**In our view, the parties' proposals to increase access to TIA services (initially by offering six-day services and then later by offering seven-day services between the sites) would likely lead to a reduction in time that some TIA patients wait for assessment. While some patients would benefit from the introduction of a weekend TIA clinic at one of the sites, more patients are likely to benefit once seven-day services between the sites are introduced. We note that it is unclear how many additional patients will be assessed within the 24 hours recommended by the Royal College of Physicians as a result of the proposed arrangements. However, for those patients who are, the reduced time to assessment would be likely to lead to reduced risk of subsequent larger stroke.**

transient ischaemic attack: a systematic review and meta-analysis. *Lancet Neurol*, 6, 1063-72). It showed a risk of stroke at two days of between 2.0 and 4.1%, and at 7 days of between 3.9 and 6.5%. It also showed the risk of completed stroke was much lower in studies of emergency treatment in specialist stroke services compared to non-urgent settings (0.9% v. 11.0%).

[52] During the first stage where a new weekend TIA clinic is offered on one of the days, the days on which patients will experience the most benefit will depend on whether Saturday or Sunday is chosen.

# Urgent gynaecology surgery

Patients may need urgent gynaecology surgery for a range of conditions relating to the female reproductive system. We understand from the parties that there are three main urgent gynaecology surgical procedures:

- Surgical management of miscarriage: some women who have had a miscarriage will require surgical management to conclude the miscarriage in a timely and predictable manner.
- Marsupialisation of Bartholin's abscess: the Bartholin's gland is situated on the lower part of the opening of the vagina. A Bartholin's abscess (a painful collection of pus) develops when the gland is infected. Marsupialisation is a surgical procedure used to drain the abscess to relieve symptoms.
- Laparoscopic salpingectomy for women diagnosed with an ectopic pregnancy: laparoscopic salpingectomy is keyhole surgery during which the entire fallopian tube containing the pregnancy is removed. Due to the risks associated with ectopic pregnancies these women remain in hospital while they wait for their procedure.

The parties say that these procedures are generally urgent in that from a medical point of view the aim is to carry out surgery as soon as possible, but these are distinct from emergency life threatening cases where there is an immediate clinical medical need for the procedure to be performed.

The parties propose to improve access for patients requiring urgent gynaecology surgery by creating an additional dedicated urgent gynaecology surgery list and pooling their patient lists so that women can access three scheduled lists each week.

**As set out below, in our view, the parties' proposals would be likely to deliver improvements for some patients requiring urgent gynaecology surgery in the form of reduced time to surgery. Our assessment below sets out which patients we would expect to benefit from the parties' proposals and the impact we would expect the proposals to have on those affected.**

## Current service arrangements

Central Manchester and South Manchester both provide general gynaecology services, including gynaecology surgery. Central Manchester is a provider of specialised services in women's health for Greater Manchester and the North-West region, including cancer services, uro-gynaecology, reproductive medicine and fetal medicine.

Central Manchester provided urgent gynaecology surgery services for 292 women in 2015-16, including:

- 247 surgical management of miscarriage procedures
- 18 marsupialisation of Bartholin's abscess procedures
- 14 laparoscopic salpingectomy procedures
- 13 other urgent gynaecology surgery procedures.

Central Manchester has two theatre sessions where patients requiring urgent gynaecology surgery can be managed. These theatre sessions are on Monday and Friday afternoon and up to six cases can be performed in each session. More urgent cases are sometimes added to emergency theatre lists but the parties say that these cases are often delayed so that life threatening emergencies can be prioritised.

South Manchester provided urgent gynaecology surgery services for 127 women in 2015-16, including:

- 104 surgical management of miscarriage procedures
- 7 marsupialisation of Bartholin's abscess procedures
- 16 laparoscopic salpingectomy procedures.

South Manchester has no planned theatre times for patients requiring urgent gynaecology surgery. Instead, patients are managed in one of two ways:

- Patients can be added to the Trust-wide emergency theatre list. As described above for Central Manchester, we understand that gynaecology patients on the emergency list are often delayed due to the need to prioritise patients with life threatening emergencies.
- Patients can be added onto elective gynaecology surgical theatre lists as an extra. According to the parties, the shorter time to surgery for urgent patients means that elective patients' operations can be cancelled or the theatre

session can overrun its allocated time having a knock-on effect for the next list that is due to take place.

We understand that there is no guidance recommending how quickly women should have the urgent gynaecology surgical procedures described earlier. However, the parties state that the present arrangements result in delays and cancellations for women requiring this surgery causing poor patient experience (including for some conditions an extended period of pain) and increased risk of clinical deterioration. According to the parties, the average wait time for women requiring urgent gynaecology surgery was 3.3 days at South Manchester and three days at Central Manchester. At South Manchester, in 90% of cases the women waited over two days for surgery. The proportion of Central Manchester patients who waited longer than two days was broken down by procedures as below:

- 53.44% of women who received surgical management of miscarriage
- 33.33% of women who had marsupialisation of Bartholin's abscess
- 21.43% of women who received laparoscopic salpingectomy
- 30.77% or women who received other urgent gynaecology surgery.

## The parties' urgent gynaecology proposals and NHS Improvement's views on whether they represent improvements for patients

The parties submit that their proposed changes to urgent gynaecology surgery services will reduce the time women wait for these urgent procedures. The parties expect that the proposals will result in the maximum wait for urgent gynaecology surgery being two days. The parties submit that their proposed changes will enable improved patient experience, and reduce the risk of a patient's condition deteriorating into an emergency.

From the parties' submissions, we identified three groups of urgent gynaecology patients that could potentially experience reduced time to surgery through the proposals:

- patients requiring urgent surgical management of miscarriage
- patients requiring urgent marsupialisation of Bartholin's abscess
- patients requiring urgent laparoscopic salpingectomy surgery.

**Improved access for patients requiring urgent surgical management of miscarriage**

The parties propose to introduce a new dedicated urgent gynaecology surgical theatre session at South Manchester on a Wednesday and to pool their patient lists so that women from either site can access the next available scheduled theatre list. The three dedicated theatre sessions would take place at Central Manchester on Monday and Friday and South Manchester on Wednesday. Central Manchester patients will therefore have access to an additional list each week and South Manchester patients will now have access to three scheduled lists per week (whereas under the current arrangements there are no scheduled lists).

In our view, the increased access to planned urgent gynaecology surgery theatre time would be likely to lead to modest reductions in the time that some women will wait for urgent surgical management of miscarriage. On the basis of the information provided by the parties we estimate that as many as half of Central Manchester patients and the majority of South Manchester patients could experience this reduced time to surgery though it is unclear how much waiting times are likely to reduce.[53] From the data provided we would expect the reduction in waiting times to be modest but we agree that any reduction in time to surgery for these women would be likely to lead to a reduction in psychological distress. The parties said that delays in this surgery can also increase the risk of spontaneous miscarriage and haemorrhage.

We note that for some patients a reduced wait for surgery would be dependent on them choosing to be operated on at a different site to the one where the decision for surgery was made. We also note that patients who under current arrangements receive same day or next day surgery via an emergency or elective surgical list may receive less timely (albeit more certain) surgery under the proposal. However, the parties told us that where capacity exists on the emergency or elective lists it will still be possible to receive care via these lists.

**Improved access for patients requiring urgent marsupialisation of Bartholin's abscess**

In our view, the increased access to planned urgent gynaecology surgery theatre time would be likely to reduce the time that some women will wait for urgent marsupialisation of Bartholin's abscess. On the basis of the information provided by the parties we estimate that as many as one third of Central Manchester patients and the majority of South Manchester patients could experience this reduced time

[53] This is based on just over half of Central Manchester FT patients requiring urgent surgical management of miscarriage currently waiting more than two days for surgery and more than 90% of South Manchester FT's urgent gynaecology patients waiting longer than two days for surgery and that the assumptions that urgent surgical lists will not be capacity constrained.

to surgery though it is unclear how much waiting times are likely to reduce.[54] From the data provided we would expect the reduction in waiting times to be modest but we agree that any reduction in time to surgery for these women would likely lead to clinical and patient experience benefits, including reduced physical pain, reduced distress and reduced risk of recurrence. We also understand from the parties that these patients are often immobile and delays in treatment can impact women's wellbeing and daily life.

Again, we note that for some patients a reduced wait would be dependent on them choosing to be operated on at a different site and that some patients may receive less timely surgery by being operated on a planned urgent list.

**Improved access for patients requiring urgent laparoscopic salpingectomy surgery**

In our view, increased access to planned urgent gynaecology surgery theatre time would be likely to reduce the time that some women would wait for urgent laparoscopic salpingectomy surgery. We note that the parties have said that some women would continue to be managed on the next available emergency or elective theatre list at both hospital sites due to greater clinical risk that waiting for surgery presents to these women. However, some women will be managed using the planned urgent gynaecological surgery theatre lists on Mondays, Wednesdays and Fridays. As these women are in hospital while they wait for their surgery this may require them to be transferred between the hospital sites (if deemed to be clinically appropriate) in order to access the next available urgent gynaecological surgery theatre list.

On the basis of the information provided by the parties it is unclear how many of the approximately 30 women receiving laparoscopic salpingectomy per year at the trusts may experience this improvement. We note that both trusts currently aim to perform this surgery within 24 hours and that both estimate that half of the women do not currently receive surgery within this timeframe.

In our view, a reduction in time to treatment would benefit women requiring urgent laparoscopic salpingectomy through reduced risk of their condition deteriorating prior to their surgery, reduced psychological distress associated with waiting for treatment and increased certainty of when their surgery will take place. We understand from the parties that delayed surgery can increase the risk of morbidity and mortality from a rupture resulting in internal haemorrhage. We note that the parties provided evidence of six incidents at Central Manchester between January

[54] This calculation is based on a third of Central Manchester patients requiring urgent marsupialisation of Bartolin's abscess currently waiting for more than two days for surgery and more than 90% of South Manchester 's urgent gynaecology patients waiting longer than two days for surgery.

and October 2016 of clinicians formally reporting a delay in laparoscopic salpingectomy which appear to be related to issues with theatre capacity and scheduling. The parties also told us they have evidence of four cases at Central Manchester in 2016 of urgent gynaecology patients being escalated to an emergency status[55] and that South Manchester expects that its figures for emergency escalation would be similar.

## Conclusion

**In our view, the parties' proposals to create a dedicated urgent gynaecology surgery list at South Manchester in addition to the existing two dedicated lists at Central Manchester, and pool their patient lists would be likely to lead to modest reductions in the time that some women wait for surgery. While it is unclear how many patients would experience this improvement, for those that do, the reduced time to surgery would be likely to lead to reduced psychological distress, pain, risk of recurrence and risk of a patient's condition deteriorating to an emergency status (depending on the condition for which the woman requires surgery).**

[55] The parties did not say which urgent gynaecological condition these women had so not all of these four women may have been waiting for laparoscopic salpingectomy.

# Kidney stone removal

Kidney stones form when salt or minerals normally found in urine become solid crystals (crystallise) inside the kidney. Small kidney stones may go undetected and be passed out painlessly in the urine. However, they can build up inside the kidney and form much larger stones which may block part of the urinary system causing intense pain and discomfort in the abdomen or groin.

Depending on their size and location, kidney stones can be treated in several ways. The most common hospital-based treatment is extracorporeal shock wave lithotripsy (lithotripsy). Lithotripsy involves locating the kidney stone using x-ray imaging or ultrasound scanning and then sending targeted shock waves to the kidney stone to break it up into small pieces. This allows the kidney stone to pass naturally from the body. Lithotripsy is usually performed by a technician or other individual with specialised training and is usually a day case procedure, without the need for general anaesthetic.

There are a number of other methods of treatment available to patients, including ureteroscopy, which all require general anaesthetic necessitating admission to the hospital and longer recovery times. The most appropriate method of treatment depends on a number of elements including the stone's characteristics, location of the stone and other factors particular to the patient.

From the parties' submissions, we identified three main proposals for kidney stone patients:

- improved access to lithotripsy – the parties propose to consolidate their specialist nurses (one from South Manchester and one from Central Manchester ) and centralise their lithotripsy services at Wythenshawe Hospital where they will increase the operating hours of the lithotripsy unit
- increased choice of day and time of treatment
- increased choice of treatment.

**As set out below, in our view, the parties' proposals would be likely to deliver improvements for some kidney stone patients in the form of reduced time to treatment, increased choice of treatment and increased choice of day and time of treatment. Our assessment below sets out which patients we would expect to benefit from the parties' proposals and the impact we would expect the proposals to have on those affected.**

## Current service arrangements

South Manchester currently provides lithotripsy 3.5 days a week at its dedicated Lithotripsy Unit at Wythenshawe Hospital. The unit is staffed by a specialist nurse and has a dedicated radiographer. We understand from the parties that the unit receives referrals from across Greater Manchester and the Isle of Man. Once a referral is received a letter is sent out to the patient asking them to call the unit to book a day and time that is most suitable for them (within available appointments). The average time to treatment is 3-4 weeks, although patients who need to be seen quicker are prioritised and an appointment is provided within two weeks. We note from data provided by the parties that South Manchester 's patients currently have a shorter time to treatment for this service than the mean in England.[56] The capacity of the unit is currently five appointments on each of the 3.5 days per week that the unit operates, or around 800 appointments a year. The parties told us that the unit is one of the 20 busiest in the country (out of 105 Trusts that provide this service). The Lithotripsy Unit at South Manchester closes when staff are absent as there is no cover. The parties reported that 145 patients received lithotripsy services at South Manchester in 2015/16.

Central Manchester currently provides lithotripsy services at a mobile unit once a fortnight. Central Manchester has a contract with Focus Medical[57] who supplies Central Manchester with a mobile unit which Central Manchester staffs. The services are currently provided under the supervision of a consultant urologist but following recent recruitment, this will soon be undertaken by a specialist nurse. Central Manchester currently has seven slots once a fortnight, with the option to add an afternoon session accommodating a further five patients if a significant waiting list develops. The parties reported that 61 patients received lithotripsy services at Central Manchester in 2015/16.

The average waiting time for this service at Central Manchester is approximately 4-6 weeks. The parties told us that given the infrequency of the mobile unit at Central Manchester, patients who require treatment urgently generally receive an alternative treatment (such as a more invasive ureteroscopy).

## The parties' proposals for kidney stones patients and NHS Improvement's view on whether they represent improvements for patients

The parties submit that their proposed changes to lithotripsy services would result in a number of improvements for patients. They anticipate there would be a reduction in time to treatment for Central Manchester patients and a greater choice

[56] Data cited by the parties as GIRFT, HES analysis 2012 – 2014.
[57] Focus Medical is a private provider of mobile Lithotripsy and Shock-Wave Therapy to hospitals throughout the UK and Republic of Ireland.

of the time and day of treatment for all patients. The parties state the reduced waiting times would result in improved quality of life for patients[58] and a reduction in the number of emergency readmissions.[59] The parties also say that Central Manchester patients who require urgent treatment would now have the choice of lithotripsy (where clinically appropriate) where they would not previously have had it due to relatively infrequent availability of the lithotripsy machine. They expect this expanded choice of treatment would lead to reduced stays in hospital and reduced risk of complications following the treatment.

**Improved access to a lithotripsy service**

The parties propose to bring together the specialist nurse from Central Manchester together with the specialist nurse from South Manchester to offer a single lithotripsy service at South Manchester 's Wythenshawe Hospital. We understand from the parties that South Manchester has sufficient radiographers to run an extended lithotripsy service with the specialist nurses. Central Manchester would also stop using the mobile lithotripsy unit. Under the proposed changes to the lithotripsy service, the parties would increase their operating hours for lithotripsy from the Wythenshawe Hospital to five days a week 8am to 5pm (as opposed to 3.5 days a week or once a fortnightly at Central Manchester as is the current arrangement).[60] This would lead to 7 appointments a day (so 35 appointments a week being available).

In our view, the proposals would be likely to deliver improvements to a subset of Central Manchester patients who require treatment for kidney stones in the form of reduced time to treatment.[61] From the information provided it is unclear exactly how many patients will be affected or the precise extent to which wait times will improve. However, in our view, it is unlikely that the time patients wait for non-urgent lithotripsy treatment would improve beyond the 3-4 weeks patients are currently waiting at South Manchester. This is because the parties propose to use the current booked admission process that South Manchester has in place. This process appears to take 3-4 weeks from referral to treatment since the parties told us that there is currently no waiting list at South Manchester. It therefore appears that the 3-4 week wait experienced by patients results from the booking process in place.

[58] Through less pain and less risk of sepsis or renal impairment.
[59] The parties submit that there is a clinical presumption that a patient will have a higher chance of re-presenting to emergency services with further pain or sepsis the longer that a stone is present in a patient's ureter and the bigger the stone is.
[60] The parties have told us that the exact operating hours of the lithotripsy service will be reviewed as part of the implementation and rota planning and an assessment will be made of patient requirements to ascertain whether evening or weekend slots might better accommodate patient demand.
[61] 61 patients received lithotripsy treatment at Central Manchester in 2015/2016 based on the parties' submissions.

While we anticipate that the reduced time to treatment for current Central Manchester patients may be modest (ie from an average of 4-6 weeks to 3-4 weeks), in our opinion any reduction in wait times would be likely to be an improvement for lithotripsy patients. We note that kidney stones can be extremely painful and can result in absence from work and difficulties in carrying out everyday tasks. The parties also told us that reduced time to treatment leads to reduced risk of sepsis or renal impairment as well as reduced rates of emergency readmission.

Currently, the Lithotripsy Unit at South Manchester must close when staff are absent. Consolidating the services and staff of both parties on one site would mean that once the changes are implemented the unit would have access to two specialist nurses and would not necessarily have to close when staff take leave. This would increase the availability of the lithotripsy service. This could represent an improvement in the service received by those South Manchester patients who would have had to wait for the unit to reopen to receive their treatment under the current arrangements (potentially waiting longer than the 3-4 week average time to treatment).

**Increased choice of day and time of treatment**

Under the proposed changes the parties will offer lithotripsy services five days a week from 8am to 5 pm.[62] The parties will have a shared listing system for lithotripsy with a single booked admission process. The proposed operating hours of the lithotripsy unit represent an increase in the day and time of treatment offered. The proposed arrangements will therefore represent an improvement through increased choice of day and time of treatment for both South Manchester and Central Manchester patients, although the improvement is likely to be most significant for Central Manchester patients. We note however that the nature of the condition means that most patients would be expected to opt for the earliest available appointment for treatment.

**Increased choice of treatment**

Under the proposed arrangements Central Manchester patients who require urgent treatment and would otherwise have had to have alternative treatments such as ureteroscopy due to lack of timely access to lithotripsy, will now have the option of lithotripsy if that is deemed clinically appropriate.

In our view, the proposed changes would be likely to deliver improvements to Central Manchester patients who require treatment for kidney stones and who, under the current arrangements, are not able to access lithotripsy treatment within

[62] The parties told us that the exact operating hours of the lithotripsy service will be reviewed as part of the implementation and rota planning and an assessment will be made of patient requirements to ascertain whether evening or weekend slots might better accommodate patient demand.

the timeframe needed (due to the fact that this service is only offered once a fortnight). These patients currently receive alternative treatments under general anaesthetic, such as ureteroscopy. Under the proposed arrangements, these patients would be able to receive lithotripsy treatment if that treatment is decided to be clinically appropriate. The parties told us that Central Manchester treat approximately 140 emergency patients per year. Based on the information provided, it is unclear how many of the approximately 140 kidney stone patients treated at Central Manchester per year received ureteroscopy when lithotripsy would have been the preferred treatment option.

It is also unclear how much of an impact this would have on patients as there are positive and negative factors associated with both approaches and the treatment offered will depend on clinical factors and be a clinically led decision. However, we understand from the parties that ureteroscopy involves general anaesthetic and is associated with a higher complication rate and longer hospital stay than lithotripsy treatment but has a higher stone free rate in some circumstances. In our view, the proposed change would lead to clinical improvement for patients who, under the current arrangements, are not able to access lithotripsy treatment where this has been deemed to be the most clinically appropriate treatment option.

## Conclusion

**In our view, the parties' proposal to centralise lithotripsy services at Wythenshawe Hospitals and extend the opening hours of that unit would be likely to lead to reduced time to lithotripsy for some patients currently treated at Central Manchester. While we expect the reduced time to treatment may be modest, in our view, any reduced waiting time would be an improvement for patients. We also expect the proposal would lead to improved choice of day and time of treatment for patients currently treated at both Central Manchester and South Manchester and improved choice of treatment for some emergency patients currently treated at Central Manchester.**

# Urology cancer surgical services

Urological cancers include a range of tumours with different presentations which affect the prostate, bladder or kidney.

Cancer services are delivered across population based networks using a hub and spoke model, organised by commissioners. One hospital trust is designated as a specialist cancer centre (the hub). The hub provides specialist cancer treatments and surgery for its own patients[63] and for patients from several local hospitals identified as being within their network (the spokes). These local hospitals within the network will each offer a range of local cancer services such as diagnostics and follow up treatments. In addition, there are supra-network cancer centres, which provide very highly specialised and complex treatments for rare cancers as well as specialist cancer treatments and surgery. Patients are initially referred by their GP to their local hospital service for outpatients and diagnostic procedures. Patients would then follow agreed pathways within their designated network into and out of the specialist cancer centre for surgery or specialist treatment.

Each network has MDTs and regular meetings for each cancer and tumour type where a patient's case is discussed and a treatment plan agreed. The specialist teams from the specialist cancer centre will also work jointly with the local hospitals within their network, such as providing locally based outpatient clinics.

The parties propose to implement the planned commissioner led reconfiguration of specialised urology cancer surgery services in Greater Manchester, which will consolidate specialised urology cancer surgery services at two high volume specialised urology cancer surgical centres in Greater Manchester (one will provide kidney and bladder resection surgery and the other prostate robotic surgery). Commissioners have run a procurement to select the providers of these services (see discussion below).

**The commissioners expect the planned reconfiguration to result in improvements including lower mortality rates, reduced post-operative complications, reduced length of stay and improved long term outcomes. In our view, these improvements are likely to happen even in the absence of the merger.**

[63] The hub will also provide all other cancer care and services.

## Current service arrangements and the commissioner led reconfiguration

South Manchester (Wythenshawe Hospital) and Central Manchester (MRI) are two of four specialist urology cancer surgery centres (hubs) serving the population of Greater Manchester, Cheshire and High Peak[64] and delivering specialist urological surgery and care for prostate, bladder and kidney cancer patients. Members of the South Manchester team also work in the supra-network team at the Christie.

Both South Manchester and Central Manchester operate specialist MDTs for urology cancer surgery and services which include clinicians specialised in surgery, oncology, pathology and radiology as well as nursing and dietetics.

Urology cancer surgery is commissioned by NHS England and the current NHS England national specification[65] states that the specialist urological cancer MDT should:

- cover a population of more than one million
- undertake a combined total of at least 50 radical prostatectomies (prostate) and/or total cystectomies (removal of the bladder) per year.

The population and surgical volumes set out in the NHS England specification reflect key recommendations from NICE's Improving Outcomes Guidance (IOG).[66]

Since August 2015 there has been ongoing work by commissioners in Greater Manchester to redesign all specialised cancer services to ensure that they are fit for the future. A number of providers who deliver specialised urology cancer surgery services within Greater Manchester do not comply with current national standards and guidance, including South Manchester.[67] Furthermore, the commissioners feel that even more challenging standards are required, in line with research evidence, to ensure world-class outcomes are achieved in this area.[68]

Following a process of clinical and patient engagement work over the last 20 months, commissioners have decided that specialised urology cancer surgery services should be delivered from two high volume specialised urology cancer

[64] The other trusts designated as specialist cancer centres for urology cancer services are Salford Royal NHS Foundation Trust, Stockport NHS Foundation Trust.
[65] NHS England, B14/S/a 2013/14 NHS standard contract for cancer: Specialised Kidney, Bladder and Prostate Cancer Services (adult), 2013.Available at: www.england.nhs.uk/wp-content/uploads/2013/06/b14-cancr-kidney-blad-pros.pdf
[66] NICE Guidance on Cancer Services (CSG2) *Improving Outcomes in Urological Cancers*, 2002. Available at www.nice.org.uk/guidance/csg2
[67] South Manchester only covers a population of around 400,000 and does not perform the requisite number of specialist operations to allow clinicians to maintain skills and achieve the best outcomes for patients.
[68] Specialised Services Commissioning in Greater Manchester (2016) *The Case for Change for Oesophago-gastric (OG) Cancer Surgery, and Urological Cancer Surgery Services*, February 2016.

surgical centres in Greater Manchester.[69] This will allow providers to achieve compliance with the standards expressed in the NICE IOG (and a more challenging set of quality standards) and achieve the best outcomes for patients.[70] In the commissioners' view, organising urology cancer surgical services in Greater Manchester in this way will ensure that patients have access to the same high quality care irrespective of where they live.

Commissioners commenced a procurement exercise in January 2016 with the contract award expected in 2017. Following their review,[71] commissioners have decided on a detailed specification which requires kidney and bladder resection surgery to be delivered at one specialist urology cancer surgery centre and specialist prostate cancer robotic surgery to be delivered from a different specialist urology cancer surgery centre. The parties have been told that the process of selecting the two specialist urology cancer surgical centres is proceeding and the decision is due to be made soon. The parties believe that either Central Manchester or South Manchester will be the trust that delivers kidney and bladder resection surgery.

## NHS Improvement's views on the proposals

The commissioners' Case for Change sets out the improvements that are likely to result from the proposed reconfiguration, including improvements associated with all urology cancer surgery providers meeting minimum population and surgical volume standards set out in IOG such as lower mortality rates, reduced post-operative complications, reduced length of stay and improved long term outcomes.[72]

As the procurement exercise is already under way, in our view, the commissioner led redesign of urology cancer surgery services in Greater Manchester would likely be implemented and deliver the expected improvements to patients even in the absence of a merger. (See 4.3.3 of the main section of our advice).

[69] Our understanding is that commissioners' reconfiguration plans do not include any changes to urology cancer services provided by the local hospitals who act as spokes within each network. However, where these local hospitals refer patients for their specialist urology cancer surgery and treatment will change as a result of the commissioners' plans.
[70] The correlation between surgical volumes and improved outcomes in this area is well documented. See, eg, Quoc-Dien Trinh et al, A Systematic Review of the Volume–Outcome Relationship for Radical Prostatectomy European Urology, Volume 64 Issue 5, November 2013, Pages 786-798.
[71] Overview of the Transformation Process for the Commissioning of Specialised OG and Urology Cancer in Greater Manchester, July 2016.
[72] Specialised Services Commissioning in Greater Manchester – The Case for Change for Oesophago-gastric (OG) Cancer Surgery, and Urological Cancer Surgery Services, February 2016.

# General surgery

General surgery is an extensive area of elective and non-elective surgery which incorporates several sub-specialist fields. These sub-specialties are generally divided into colorectal surgery (which covers diseases of the colon, rectum and anal canal) and gastrointestinal surgery (which covers diseases affecting the liver, oesophagus and stomach). Much of the surgery performed electively is for the treatment of cancer, in particular colorectal surgery. The non-elective service covers the care and treatment of surgical emergencies affecting the abdomen, some of which are life-threatening for the patient.

The parties propose to implement the commissioner-led Healthier Together Programme, which designates MRI as one of four 'hub' hospitals (along with Royal Oldham Hospital, Salford Royal Hospital, and Stepping Hill Hospital) to provide emergency general surgery and high risk general surgery services in four sectors covering General Manchester.

**The improvements expected to result from the commissioners' reconfiguration include improved clinical outcomes and improved access to sub-specialist care. Although these improvements are likely to happen even in the absence of the merger, in our view, the opportunities created by the merger would be likely to allow the parties to deliver the improvements of the programme more quickly and with less cost.**

## Current service arrangements and commissioner-led reconfiguration

The parties told us that South Manchester (Wythenshawe Hospital) and Central Manchester (MRI) both currently provide emergency general surgery for patients requiring non-elective surgery who have presented as an emergency, either via ambulance or some other route.

At Central Manchester there are 11 general surgeons, including seven specialising in colorectal surgery, three in upper gastrointestinal surgery and two in general surgery.[73] In 2015-2016, at Central Manchester there were 9,129 first outpatient appointments and 5,058 inpatient admissions (including day-case surgery, elective and non-elective inpatient admissions). The parties also submit that of their admissions, there were around 2,800 non-elective general surgery patients treated at Central Manchester.

[73] The parties told us that in addition to these 11 surgeons there is one part time surgeon who is not part of the on-call rota and predominantly does day-case surgery at Trafford Hospital.

At South Manchester there are ten general surgeons, including seven specialising in colorectal surgery, two in upper gastrointestinal surgery and one in emergency surgery. At South Manchester, for the same year, there were 6,546 first outpatient appointments and 4,356 inpatient admissions (including day case surgery, elective and non-elective inpatient admissions). The parties also submit that of their admissions, there were around 1,900 non-elective general surgery patients treated at South Manchester.

The parties told us that in common with other trusts they are experiencing pressures with bed availability for these patients, but that in comparison to some other providers in Greater Manchester a lack of general consultant surgeon cover for on-call and emergency general surgery is less of an issue for them.

As part of the Healthier Together programme, a wider programme for health and social care reform across Greater Manchester, commissioners have done extensive work to look at how to improve emergency surgical care for the patients of Greater Manchester. This work had clinical leadership and relied on gathering an evidence base to enable commissioners to select an option for reconfiguring services.

For emergency general surgery, the Healthier Together programme found that, across Greater Manchester, the right consultant surgeon was not always present and a critical care bed was not always available for post-operative care. They found this led to inconsistent quality of care and poorer patient outcomes.[74]

Further, a Healthier Together programme review of standardised mortality rates for general emergency surgery found that, when compared nationally, three of Greater Manchester's providers fell within the 30 trusts with the highest relative risk of mortality, but conversely three Greater Manchester trusts fell within the 30 trusts with the lowest relative risk of mortality (two of these three being Central Manchester and South Manchester ).[75]

The aim of the programme therefore is to reduce this variation by bringing the standards of all Greater Manchester hospitals performing emergency general surgery up to the best and reducing mortality to that of the lowest, and then beyond that to the lowest centile nationally.

MRI was designated as one of four 'hub' hospitals (along with Royal Oldham Hospital, Salford Royal Hospital, and Stepping Hill Hospital) to provide emergency general surgery and high risk general surgery services in four sectors covering General Manchester. South Manchester did not receive this designation, as South

[74] Association of Greater Manchester Authorities, *Healthier Together: The Greater Manchester Case for Change,* September 2012, pg 33. Available at: www.pat.nhs.uk/about-us/service-changes-and-developments/Healthier%20Together%20GM%20CaseforChange.pdf
[75] National Emergency Laparotomy Audit, *The Second Patient Report of the National Emergency Laparotomy Audit (NELA), December 2014 to November 2015,* July 16. Available from: www.nela.org.uk/reports

Manchester hospitals and Central Manchester hospitals are in the same sector covering Manchester and Trafford. As a result of the reconfiguration, emergency and high risk general surgery patients currently presenting at each South Manchester hospital site will in future be directly transported to Central Manchester 's Manchester Royal Infirmary. The change is expected to be fully implemented in August 2018.

## NHS Improvement's views on the proposals

The Healthier Together Pre-Consultation Business Case sets out the improvements that are expected for patients requiring emergency general surgery across Greater Manchester as a result of consolidating general surgery services as planned under the programme.[76] These expected improvements include improved clinical outcomes and improved access to sub-specialist care. It is unclear how many of the 4,700 emergency general surgery patients per year across Central Manchester and South Manchester will experience the improvements identified by the Healthier Together Programme or what the impact of these improvements will be on the patients affected.

The Healthier Together Programme is already in the process of being implemented across Greater Manchester and, in our view, the benefits of the programme would be delivered even without the merger. We understand from the parties that to implement the planned changes for emergency general surgery patients in the absence of the merger would cost approximately £19.4 million. However, the parties believe that through the merger they will be able to implement the changes for approximately £10.3 million. The parties believe that they can achieve these savings through better utilisation of the merged trust's estates which would allow the parties to create capacity to accommodate patients moving out of the MRI site to allow for the additional emergency general surgery and colorectal patients from South Manchester.

While the parties have further planning to do in order to find the additional capacity required to implement the programme and the implementation costs are therefore not final, in our view, the parties are likely to be able to deliver the improvements of the programme more quickly and with less cost through opportunities created by the merger than without it.

[76] Association of Greater Manchester Clinical Commissioning Groups, *Healthier Together Pre-Consultations Business Case for Greater Manchester Health and Social Care Reform, Part 1 of 2, Final,* April 2014. Available at: https://healthiertogethergm.nhs.uk/files/4814/4535/6556/Appendix_1_Pre-consultation_Business_Case_Part_1.pdf

# Elective orthopaedics

Elective orthopaedic surgery refers to planned surgical procedures to treat injuries and conditions that affect the musculoskeletal system (the bones, joints, ligaments, tendons, muscles and nerves). Common elective orthopaedic procedures include hip and knee replacement surgery.

From the parties' submission, we identified two main proposals for elective orthopaedic patients:

- ring fencing elective care services – the parties propose to transfer existing elective orthopaedic surgical activity from South Manchester to Central Manchester 's Trafford Hospital site
- improved access to complex procedures and innovative treatments.

The parties submit that through consolidating their services onto one site they will also be able to:

- develop sub-specialist teams able to conduct more complex procedures (reducing travel time for some patients in Greater Manchester requiring these procedures who are currently travelling to Wrightington Hospital, part of Wrightington, Wigan and Leigh NHS Foundation Trust, for surgery)
- provide more specialist orthopaedic care, reducing length of stay, post-operative wound infection rates and MRSA infection rates, readmission rates and surgical revisions[77]
- develop specialist physiotherapists, occupational therapists and nurses
- place significant focus on education, research and innovation
- standardise patient pathways and protocols
- deliver financial improvements through reduced length of stay and reduced reliance on expensive loaned equipment.

**As set out below, in our view, the parties' proposals would be likely to deliver improvements for some elective orthopaedic patients in the form of improved access, outcomes and patient experience. Our assessment below sets out which patients we would expect to benefit from the parties' proposals and the impact we would expect the proposals to have on those affected.**

[77] A surgical revision is surgery performed to replace or compensate for a failed implant (for example a failed hip replacement) or to correct undesirable effects of previous surgery.

## Current service arrangements

The parties told us that orthopaedics is one of the largest specialties by patient numbers and revenue at both trusts. Our understanding is that both trusts deliver non-complex elective orthopaedic procedures, with more complex procedures being nationally commissioned from other providers by NHS England.

Central Manchester primarily delivers its routine non-complex elective orthopaedic services from Trafford Hospital. Complex elective orthopaedic patients, namely those who may need access to other services during their inpatient stay (such as intensive care), are treated at MRI. Non-elective (emergency) orthopaedic services are also delivered from MRI. Patients at Trafford Hospital therefore have access to a standalone elective service. Under this arrangement, the trust's ability to provide timely surgery for their elective orthopaedic patients is not impacted by non-elective activity. This form of separation between non-elective and elective orthopaedic patients is often called ring fencing and is considered best practice. Central Manchester has seven orthopaedic surgeons who specialise in lower limb surgery, four who specialise in upper limb surgery, three foot and ankle specialists, one full time and one part time sarcoma specialists and one so tissue knee surgery specialist.

South Manchester delivers both elective and non-elective orthopaedic services from Wythenshawe Hospital. They have 12 orthopaedic consultants, including four who specialise in hip and knee surgery, three who specialise in foot and ankle surgery, two who specialise in upper limb hand and wrist surgery and three in upper limb shoulder surgery.

The parties told us that a lack of surgical theatre and bed capacity at Wythenshawe Hospital, along with the co-location of elective and non-elective orthopaedics services, results in competing pressures between these two elements of the orthopaedic surgical service. The parties told us that in order to manage these competing pressures South Manchester employs a number of sub-optimal strategies, including:

- admitting elective patients to a day case bed in the hope that an inpatient bed will become available later in the day; if an inpatient bed cannot be secured the patient has to stay overnight in a day case bed
- admitting non-elective patients onto non-orthopaedic surgical wards (ie away from the specialist care provided on an orthopaedic ward)

- placing non-elective patients on elective orthopaedic theatre lists and / or in elective care beds, resulting in cancellations of elective operations.

The parties told us that between April 2015 and March 2017 South Manchester cancelled 222 operations on the day of operation either as a direct or indirect result of bed availability. They told us that since April 2016 they have consistently failed to meet the national target of 92% of patients receiving treatment within 18 weeks of referral (the RTT target). In February 2017, only 76.3% of patients were receiving treatment within this timeframe (against the national average of 85.4%). The Care Quality Commission raised these issues in their latest report on Wythenshawe Hospital. [78] The report noted that the lack of surgical bed capacity was resulting in higher than average cancelled operations, failure to rearrange cancelled operations in a timely manner and an overall failure to meet the RTT target for planned surgical procedures.[79]

The parties told us that cancellations result in a poor patient experience and delays to surgical treatments that will alleviate pain. Cancellations also cause a knock on effect to other patients whose procedures need to be rescheduled to accommodate the cancelled patient. They told us that admitting patients to a day case bed or non-orthopaedic ward results in patients being cared for in an inappropriate environment (for example staying overnight in a day base bed away from the specialist orthopaedic care provided on an orthopaedic inpatient ward) and often leads to patients being transferred between wards multiple times, both of which can result in a longer length of stay.[80]

In addition to the current problems at South Manchester, the parties told us that both trusts are experiencing challenges related to the high degree of consultant sub-specialisation within the orthopaedic surgical teams. They told us that as certain expertise is focused around a smaller number of consultants this can decrease the resilience of the service, with unexpected leave and / or retention problems leading to cancelled operations and treatment delays.

[78] University Hospital of South Manchester NHS Foundation Trust: Wythenshawe Hospital Quality Report. Care Quality Commission. June 2016. Available at: www.cqc.org.uk/location/RM202
[79] Where patients have been waiting more than eighteen weeks to commence treatment, we would expect providers to inform their commissioners and for commissioners to offer those patients a choice of suitable alternative provider.
[80] Research Report: Improving length of stay: what can hospitals do? Nuffield Trust. September 2015. Available at: www.nuffieldtrust.org.uk/research/improving-length-of-stay-what-can-hospitals-do

In addition, the parties told us they both have low patient volumes compared to other large cities in England with a single orthopaedic elective surgical unit.

The parties told us the low volumes of patients at each trust means:

- They are unable to perform highly complex procedures (for example, ankle replacements) where a higher patient volume is required, and as a result patients have to travel to Wrightington Hospital (part of Wrightington, Wigan and Leigh NHS Foundation Trust) to receive complex care.
- They cannot justify the purchase of equipment for certain procedures and so have to loan this equipment when needed.
- Their research activities are limited.

## The parties' proposals for elective orthopaedic patients and NHS Improvement's views on whether they represent improvements for patients

The parties submit that their proposed changes to elective orthopaedic services will lead to a number of improvements, including improved patient care, reduced elective cancellations and time to treatment, reduced length of stay and reduced travel time.

### Ring fencing elective care services

The parties propose to move approximately 90% of patients currently receiving elective surgery at South Manchester 's Wythenshawe Hospital to Central Manchester 's Trafford Hospital, consolidating their elective orthopaedic surgical activity onto the one site. In doing so these patients would be ring fenced away from the current pressures created by non-elective orthopaedic patients presenting at South Manchester. Patients with more complex care needs[81] will continue to receive surgery at MRI or Wythenshawe Hospital. Related outpatient, diagnostic and follow-up services for patients currently treated at South Manchester will continue to be delivered locally in Wythenshawe Hospital.

In our view, the proposal would be likely to lead to improved patient experience for some patients who currently choose to be treated at South Manchester through

[81] Patients classified under the American Society of Anaesthesiologists Physical Status Classification System as a 'Level 4' (A patient with severe systemic disease that is a constant threat to life) or higher will continue to be treated at MRI or Whythenshawe.

reduced cancellations and time waiting for treatment. We note that reduced waiting times are likely to be associated with a reduced period of pain and inactivity and improved health related quality of life for some patients. It is unclear exactly how many patients will experience reduced time to treatment or the extent to which waiting times might be reduced. We also note these patients are currently choosing to receive treatment at South Manchester and that the loss of this choice of treatment location created by the proposal may be a disadvantage to some patients.

The clinical advantages of having ring fenced elective orthopaedic units are well known: these include fewer cancellations (with the associated clinical benefits described above), shorter lengths of stay and reduced infection rates.[82] The parties told us that since Central Manchester 's acquisition of Trafford Hospital and the introduction of ring fenced elective orthopaedic surgery on that site, Central Manchester improved its theatre utilisation from 70% in 2015-16 to 87% in 2016-17 and reduced its orthopaedic surgery cancellation rate from 9.7% to 5.7%.

In addition to the general advantages of ring fencing described above, we think length of stay and patient experience will be improved for some patients as the suboptimal strategies currently employed by South Manchester to manage their capacity will no longer be used. We note that the parties provided evidence demonstrating that orthopaedic patients experiencing multiple moves between inpatient wards during their inpatient stay or not being cared for on a dedicated orthopaedic ward can increase their length of stay.

**Improved access to complex procedures and innovative treatments**

The parties propose to create larger sub-specialty teams of orthopaedic surgeons. They submit that, with access to the combined patient populations of both trusts, the sub-specialist surgical teams could perform highly complex elective orthopaedic surgery.

We recognise there is need for a good geographical spread of provision for elective orthopaedic surgical procedures to ensure patients can access these services as

[82] *A National Review of Adult Elective Orthopaedic Services in England*. Getting It Right First Time. British Orthopaedic Association. March 2015. Available at: www.boa.ac.uk/wp-content/uploads/2015/03/GIRFT-National-Report-MarN.pdf

close to their home as possible. However, as noted in the GIRFT report,[83] for the most complex orthopaedic surgical cases some concentration of patient activity is required to gain 'critical mass' and enhance quality of care. We understand that Manchester patients are currently able to access complex orthopaedic surgery at Wrightington Hospital (27 miles from Trafford Hospital). The parties have said that combining their elective work will bring the volumes of patients that would justify offering complex surgeries that patients now access at Wrightington Hospital.

While the combined elective orthopaedic service may be able to offer complex surgery, it is not clear that the patient population could sustain two complex surgery centres (one at the Wrightington Hospital and one at the merged trust) or that provision of complex surgery within Manchester would necessarily represent an improvement for patients. We note that if the merged trust were to provide this service, it may diminish the number of complex patients receiving surgery at Wrightington Hospital which could impact the quality of care at that centre. We also note that it is not clear that the parties could offer this service without a careful review by commissioners.

## Conclusion

**In our view, the parties' proposals to transfer and ring fence South Manchester 's elective care services on Trafford Hospital would represent an improvement to some patients in the form of improved access, outcomes and patient experience. We would expect that current South Manchester patients would experience the greatest improvement.**

[83] *A National Review of Adult Elective Orthopaedic Services in England*. Getting It Right First Time. British Orthopaedic Association. March 2015. Available at: www.boa.ac.uk/wp-content/uploads/2015/03/GIRFT-National-Report-MarN.pdf

# Head and neck cancer surgery

Head and neck cancers include a range of tumours affecting the mouth, nose, sinuses, throat, larynx (voice box), neck and thyroid gland. Patients tend to present with symptoms ranging from persistent hoarseness to lumps in the neck or suspicious sores inside the mouth which are sometimes identified during dental check-ups. Patients are referred by their GP under the 2-week suspected cancer referral pathway or can attend via A&E with compromising symptoms.

Treatment options will depend on the type and area affected by the tumour. Surgery for these types of tumours is often highly complex and life changing (such as total laryngectomy which results in a permanent tracheostomy and loss of voice). Patients can require highly skilled microvascular reconstruction and free flap surgery[84] and prosthetics.[85]

Head and neck cancer surgery is performed by ear, nose and throat (ENT) surgeons[86] and oral maxillofacial (OMF) surgeons.[87] There will be some patients who require both types of skilled expertise (ENT and OMF) for their particular surgery and therefore these surgeons will perform joint operations.

Due to the complexity and invasive nature of some of this type of cancer surgery the care and follow up of these patients requires highly skilled MDT input, such as tracheostomy nursing care, specialised dietician and speech and language therapy. Further treatments such as radiotherapy and chemotherapy are often required as well as long term follow up and rehabilitation.

Services for treating head and neck cancers are organised around networks in a similar way to other cancers. Please see our assessment of the urology cancer proposals for how cancer networks are organised generally.

From the parties' submissions, we identified four main proposals for head and neck cancer surgery patients:

[84] Free flap surgery is the transfer of tissue with an artery and vein from one part of the body to another. This procedure is now widely used for the reconstruction of defects following cancer ablation in the head and neck.
[85] An artificial substitute or replacement for a missing part of the body, such as eye, limb, heart, joint, facial bone or palate.
[86] ENT surgeons tend to concentrate on surgery of the throat, larynx, nose, sinuses and thyroid.
[87] OMF surgeons who tend to concentrate on surgery involving the mouth and oral cavity, the upper and lower jaw and any requiring micro revascularisation.

- increased patient volumes from consolidating head and neck cancer surgery services onto a single site
- more robust microvascular surgery rota
- improved access to specialist head and neck cancer surgeons
- reduced travel time for patients requiring osseo-integration (prosthetics).

**As set out below, in our view, the parties' proposals would be likely to result in improvements for head and neck cancer patients in the form of improved outcomes, improved access and improved patient experience. Our assessment below sets out which patients we would expect to benefit from the parties' proposals and the impact we would expect the proposals to have on those affected.**

## Current service arrangements

Both South Manchester and Central Manchester (the hubs) provide specialist head and neck cancer surgery within Greater Manchester. This specialist cancer care is commissioned by NHS England.

South Manchester currently deals with 150 new head and neck cancer cases each year. Those patients are referred to South Manchester from local GPs or diagnostic centres at other local hospitals (the spokes). Head and neck cancer patients are treated at Wythenshawe hospital on a 19 bed ward, together with other general OMF and ENT patients (non-cancer surgical patients). The parties told us that in 2014-2015 these patients had an average length of stay of 11.7 days.

South Manchester has a specialist MDT to deal with head and neck cancer cases. South Manchester has five surgeons who specialise in head and neck cancer surgery. Of those five surgeons, three are ENT surgeons and two are OMF surgeons (who also perform highly skilled microvascular work, including reconstruction and free flap surgery). Head and neck cancer patients at South Manchester are cared for by nurses who have the necessary skills relating to complex airway management (such as for tracheostomy patients). The trust is developing a competency based training assessment for these nurses and expects all nurses caring for patients with head and neck cancer to have been assessed within 12 months.

Current on-call arrangements at South Manchester mean that non-cancer ENT and OMF surgeons are on-call for head and neck cancer patients.

Central Manchester currently handles approximately 250 new head and neck cancer cases per year. Those patients are either referred directly from GPs or from diagnostic centres at other local hospitals (the spokes). Head and neck cancer

patients are treated at MRI. There are 20 head and neck cancer beds on a ward shared with vascular services. The parties told us that in 2014-2015, these patients had an average length of stay of 8.4 days.

Central Manchester has a specialist MDT to deal with head and neck cancer patients. Central Manchester has six surgeons (as well as one vacant post) who specialise in head and neck cancer surgery. Four of these surgeons are ENT surgeons who specialise in head and neck cancer surgery and two are OMF surgeons (who also perform the microvascular work). There is currently a vacant specialist OMF surgeon post. Head and neck cancer patients are cared for by specially trained and competency assessed nurses.

Current on-call arrangements at Central Manchester mean that non-cancer ENT and OMF surgeons are on-call for head and neck cancer patients.

The parties submit that, under the current arrangements, they are facing a number of challenges with their head and neck cancer services, for example:

- While both trusts meet the NICE guidance on improving outcomes on head and neck cancers[88] South Manchester does not meet the more recently published recommendations[89] increased minimum volumes per centre to 250 new cases per year.
- Specialist head and neck cancer surgeons are not always available out-of-hours and at weekends to treat emergencies which means that patients sometimes receive emergency treatment or surgery from a surgeon working outside of their expertise.
- The trusts currently rely on a goodwill ad hoc 1:2 rota[90] for their microvascular surgeons out-of-hours and at weekends which is not robust and does not meet the NICE guidance.
- Difficulties in recruiting and retaining specialist trained nurses are contributing to nurse staffing incidents.[91]
- Lack of co-ordination between the parties and local referring hospitals is leading to delays for patients and makes it difficult for clinical nurse specialists to attend MDT meetings for all their patients.

[88] NICE Guidance on Cancer Services – Improving Outcomes in Head and Neck Cancers, 2004. Available at: www.nice.org.uk/guidance/csg6
[89] Head and Neck Cancer United Kingdom National Multidisciplinary Guidelines, March 2016. Available at: http://bahno.org.uk/wp-content/uploads/2014/03/UK-Head-and-Cancer-Guidelines-2016.pdf
[90] We understand from the parties that this is not a formal rota and only operates because the consultants themselves organise it.
[91] We understand the nurse staffing incidents referred to are workforce incidents subject to mandatory reporting, eg where a lack of suitably qualified or trained staff or a lack of staff numbers are reported as part of the daily safety and risk assessment a trust performs.

- Head and neck cancer patients at Central Manchester and South Manchester do not currently have access to the full range of specialist treatments available (as some treatments are only provided by one trust) and patients have to travel to Liverpool to access an osseo-integration (prosthetics) service.

## The parties' proposals for head and neck cancer surgery patients and NHS Improvement's views on whether they represent improvements for patients

The parties submit that their proposed changes to head and neck cancer services to consolidate head and neck cancer services onto a single centre will lead to better co-ordination and management of services, improved length of stay for inpatients, and improved health outcomes and experience for patients.

### Increased patient volumes from consolidating head and neck cancer surgery services onto a single site

The parties propose to consolidate their head and neck cancer surgery, MDT meetings, and outpatient clinic services onto a single site (yet to be determined). The other site (and the local spoke hospitals) will continue to provide some services such as diagnostics and follow up care. In addition, day case and non-complex elective surgery for non-cancer ENT and OMF patients will continue to be provided from both hospital sites.

In our view, the increased number of patients served at the combined specialist head and neck cancer MDT and consolidated single centre is likely to result in improvements in patient outcomes. We recognise the evidence which supports the relationship between higher volumes and improved outcomes[92] and would therefore expect all patients currently treated by South Manchester and Central Manchester to experience this improvement, although it is unclear how much outcomes would improve as a result of the merger.

In addition, in our view, patients currently seen at South Manchester would benefit from improved patient outcomes, including mortality rates, through being treated in line with recent recommendations regarding minimum volumes for head and neck cancer MDTs. While both trusts meet the minimum volumes set out in current NICE

[92] Evidence provided by the parties suggests that centres with 75 new cases per year have a ten year overall survivor rate of 20%, but centres with 500 new cases per year have an overall survivor rate of 40%, Volume-Outcome Relationships for Head and Neck Cancer Surgery in a Universal Health Care System, by A. Eskander et al *The Laryngoscope*, 2014.

guidance on improving outcomes in head and neck cancers (which recommends each specialist MDT should see at least 100 new cases a year in order to maintain their competencies and skills[93]), only Central Manchester currently meets a more recently published guideline which recommends 250 cases per year.[94]

**More robust microvascular surgeon rota**

As part of consolidating their head and neck cancer centres, the parties propose to combine their cohorts of microvascular surgeons, and recruit into a vacant post at Central Manchester. This means that the merged trust will have a total of five microvascular surgeons. The parties will provide a 1:5 on-call rota for out-of-hours and weekend emergency surgery for surgical flap rescue.[95]

In our view, the proposals are likely to benefit patients through the introduction of a more formal out-of-hours and weekend consultant rota for microvascular surgeons. While both trusts currently provide ad hoc, goodwill 1:2 rotas, in our view, the proposed 1:5 rota will be more stable than the current ad hoc high frequency rota that the surgeons cover in addition to their general out-of-hours on-call rota for OMF patients. We also note that the contract for consultants recommends employing organisations take practicable steps to reduce high frequency rotas. It is unclear how many patients would benefit from this improvement or the impact it would have on those affected.

**Improved access to specialist head and neck cancer surgeons**

The parties propose to combine their respective ENT and OMF surgeons specialising in head and neck cancer. This combined cohort of 12 specialist surgeons (seven ENT surgeons, including the vacant post, and five OMF surgeons) would form part of the merged trust's general ENT and OMF out-of-hours on-call rotas. This will increase the likelihood that a head and neck cancer patient needing out-of-hours care would see an ENT or OMF head and neck cancer specialist consultant rather than a non-cancer ENT or OMF consultant. The merged trust would also provide twice daily consultant ward rounds and week day cover will be available daily between 8am to 8pm.

[93] NICE Guidance on Cancer Services, *Improving Outcomes in Head and Neck Cancers*, 2004. Available at: www.nice.org.uk/guidance/csg6
[94] *Head and Neck Cancer United Kingdom National Multidisciplinary Guidelines*, March 2016. Available at: http://bahno.org.uk/wp-content/uploads/2014/03/UK-Head-and-Cancer-Guidelines-2016.pdf
[95] Upon suspicion of vascular compromise, a salvage operation of free flaps is considered. An operation is intended to rescue the original flap.

In our view, the increased access to specialist head and neck cancer surgeons would be likely to deliver improvements to some patients in the form of reduced risk of being operated on by a surgeon working outside of their expertise out-of-hours or at the weekends. This is likely to affect a subset of the approximately 12 patients per year that are currently operated on out-of-hours by a non-MDT surgeon.[96] We note that under the proposed arrangements it is not certain that a specialist surgeon will always be available on-call as the 12 specialist surgeons will be part of the general ENT and OMF out-of-hours on-call rota. Therefore, some patients requiring urgent or emergency surgery or treatment for post-operative complications out-of-hours or at weekends may still be operated on by a non-specialist surgeon. We note that NICE IOG recommends that all head and neck cancer surgery should be performed by surgeons who are members of the specialist head and neck cancer MDT and those guidelines are aimed at improving patient outcomes, including mortality.

The parties also explained that at times access to a head and neck cancer surgeon during a working day can be a problem as the designated surgeon can be undertaking certain duties (such as outreach clinics) at one of their spoke hospital sites. The parties explained that cover of a suitable head and neck cancer surgeon at each specialist centre site at the end of a working day is variable, ranging from 12.30pm to 7pm on different week days at Central Manchester.

Following the consolidation, the parties submit that access to 12 head and neck cancer surgeons would allow them to provide twice daily consultant ward rounds and that week day cover will be available daily between 8am to 8pm. We accept that improved access to specialist head and neck cancer surgeons for inpatients at the end of the day and by twice daily ward rounds will lead to more timely decisions and treatments, although it is unclear how many patients will experience this improvement or what the extent of the impact on patients would be, such as a reduced length of stay.

**Reduced travel time for patients requiring osseo-integration (prosthetics)**

The parties propose to develop a new osseo-integration (prosthetics) service.

[96] We understand from the parties that it is rare that a patient is operated on out-of-hours by a non-MDT surgeons but it does happen in emergency situation: the parties estimate this happens approximately once a month at South Manchester.

In our view, offering a prosthetics service in Manchester would represent a benefit in the form of reduced travel time for patients that currently have to travel out of area to access this service. We note that the prosthetic can require multiple fittings meaning that patients may have to repeatedly travel to Liverpool under the current arrangements. We would expect this to impact the approximately 10 patients per year in the Greater Manchester area who currently travel to Liverpool to access this service, though we note that some patients might continue to choose to access this service at Liverpool after the Manchester service is developed. We also note that not having a local service means surgery is not planned around an osseo-integrated prosthetic as the service is not represented at the MDT meetings.

## Conclusion

**In our view, the parties' proposals to improve head and neck cancer surgery services would be likely to result in improved patient outcomes as a result of the increased caseload of the combined hub and combined specialist MDT. The proposals would also be likely to benefit patients through the establishment of a more formal out-of-hours rota for microvascular surgeons. In addition, the improved access to specialist ENT and OMF head and neck cancer surgeons, in our view, would be likely to reduce the risk of being operated on by a surgeon working outside of their experience out-of-hours or at weekends and also lead to more timely decision making during these times. Finally, the approximately 10 patients per year in Greater Manchester who currently travel to Liverpool to access osseo-integration (prosthetics) services would be likely to experience improvements from the proposals in the form of reduced travel time.**

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 Publication code: CG 31/17