

Thames Valley Thrombectomy Referral Pathway

Approval

Approval Group	Job Title, Chair of Committee	Date
Thrombectomy Innovation and Transformation Network	Dr Guy Rooney, Chair	06/10/2020

Change History

Version	Date	Authors	Reason
Version 1.0	June 20	K Nagaratnam, M Burn, G Harston, V Young	New Pathway
Version 1.1	March 21	K Nagaratnam	Service availability update, spelling correction and addition of appendix 2

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1.0 Introduction

Around 85,000 people a year are admitted to hospital with a stroke, and there are over 1 million stroke survivors in England, more than half of whom have a disability resulting from their stroke. Mechanical thrombectomy is an effective evidence-based treatment for patients with acute ischaemic stroke caused by large vessel occlusion. One in every 10 stroke patients is eligible for this life saving treatment. For every 3 patients treated with mechanical thrombectomy one additional patient will be functioning more independently at 90 days compared to the treatment with intravenous thrombolysis alone (Goyal et al. 2016). However, this treatment effect is time dependent. In order to achieve the full benefit of the treatment the patients should receive mechanical thrombectomy as soon as possible following symptom onset.

Currently mechanical thrombectomy is provided by tertiary neuroscience centres in the region (John Radcliffe Hospital, Oxford, Charing Cross Hospital, London & Southmead Hospital, Bristol). Eligible ischaemic stroke patients who arrive at the primary stroke centres are transferred to either one of these centres after receiving intravenous thrombolysis. This service model is called 'drip and ship' model. The model where all the stroke patients are taken by the ambulance directly to the tertiary neuroscience centres is called 'mother ship' model. In order for the 'drip and ship model' to be as effective as the 'mother ship model' the patients should leave for the tertiary centre within 60 minutes of their arrival at the primary stroke centre (Holodinsky et al. 2017). The evidence shows (Saver et al., 2016) the probability of the benefit of treatment fell by 5.3% for each hour's delay.

Hence an efficient and well-coordinated pathway is essential to eliminate any unnecessary time delays and to ensure optimal patient benefit.

2.0 Scope of the pathway

This pathway covers the primary stroke centres (PSC) in the Thames Valley region and neighbouring hospitals that refer ischaemic stroke patients with Large Vessel Occlusion (LVO) to John Radcliffe Hospital (JRH) for mechanical thrombectomy (MT).

The PSCs may also have arrangements with other neuroscience centres for referring acute stroke patients with LVO.

The PSCs referring to JRH are:

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- Milton Keynes University Hospital (MKUH)
- Royal Berkshire Hospital (RBH)
- Wycombe General Hospital (WGH)
- Great Western Hospital (GWH)
- Northampton General Hospital (NHG)

It is the responsibility of the PSCs to provide adequate resources and to have pathways in place to identify, refer and to enable safe transfer of acute stroke patients with LVO. This includes adequate access to CT brain and angiogram imaging, and clinical staff. This pathway will not cover the local acute stroke pathways.

The ambulance transfer protocol is covered elsewhere and is not covered by this pathway. Please refer to the appendix for the ambulance transfer protocol.

3.0 Availability of mechanical thrombectomy service

The MT service for the Thames Valley region is currently provided by the John Radcliffe Hospital (JRH) from Monday to Sunday between 08:00 and 20:00. The referrals from PSCs are accepted between 08:00 and 17:45. This is to allow for the patients to arrive in time at the JRH for MT to complete before 20:00. However, patients presenting to the PSCs before 8am can still be discussed with JRH on-call stroke consultant.

The stroke centres should consider having arrangements with alternative neuroscience centres for out-of-hour service provision or to minimise treatment delays when there is lack of capacity in OUH.

Future aim:

The existing service will continue to evolve and develop with the aim of providing 24/7 service.

4.0 Eligibility

4.1 Eligibility for referral for thrombectomy (NG128)

- Age \geq 18
- Pre-morbid modified Rankin Score $<$ 3
- National Institute of Health Stroke Scale (NIHSS) $>$ 5

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- CT brain imaging
 - No evidence of haemorrhage
 - CT ASPECTS score ≥ 6
- CT angiogram of the carotid and circle of Willis confirms proximal LVO (distal internal carotid or M1 segment of the middle cerebral artery (MCA))
- Able to arrive at JRH within 6 hours of symptom onset

4.2 Additional considerations

Occasionally it might be appropriate to consider mechanical thrombectomy in patients not meeting these criteria. Such decisions would be discretionary and made on a case-by-case basis following discussion with the on-call stroke consultant at JRH.

- Posterior circulation stroke/vertebro-basilar occlusion
- Occlusion of the M2 segment of the MCA
- Life limiting co-morbidity and functional dependence

Future aim:

Advanced brain imaging (CT/MR perfusion imaging) could be considered to identify suitable patients who are eligible for mechanical thrombectomy presenting with a last known well time of beyond 6 hours and up to 24 hours.

5.0 Imaging requirements

1. Unenhanced CT head from skull base to vertex
2. CT angiogram from aortic arch to vertex

The coverage is designed to allow a decision to be made as to:

- whether there is a tandem occlusion
- assess what the access to the cerebral circulation is like to ensure the appropriate equipment is selected and minimise the time to reperfusion
- allow parenchymal assessment on the angiography data to highlight established infarcts/hypoperfusion and get an idea about the collateral flow.

The exact imaging protocol (scanner parameters etc) can be whatever is normally used in each institution as the vendor of scanner varies, but the coverage and availability of the

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source data for review are the important factors in order to facilitate decision making regarding transfer of a patient for potential thrombectomy.

6.0 Referral for mechanical thrombectomy from PSCs

6.1 Identification of eligible patients

- a. All acute stroke patients should be assessed by an appropriately trained clinician in the emergency department (or at an equivalent unit) in the PSC on arrival in line with the national standards.
- b. The PSCs should have an agreed pathway between the local ambulance service, emergency department and the stroke team to facilitate pre-alert of the arrival of patients by the emergency services and rapid assessment of the patient by the stroke team. This can be achieved by either face to face assessment or via telemedicine.
- c. The patients should have 24/7 access to urgent non-contrast CT brain imaging and CT angiogram of the carotid and circle of Willis vessels on arrival. The next available scanning slot should be offered to the acute stroke patients. In the event where CTA is not available to all stroke patients due to limited resources all eligible stroke patients for mechanical thrombectomy must have CTA. This should be acquired at the same session as the initial non-contrast CT brain for the patients eligible for MT. (Please refer to the imaging criteria above for further details)
- d. All eligible patients should receive intravenous thrombolysis without delay. The primary stroke centres should aim to achieve door to needle time of < 30 minutes.
- e. The PSCs must have an arrangement for interpreting CTA images and identifying LVO. This can be achieved by
 - o Training the stroke physicians/neurologist to rapidly identify LVO
 - o Immediate reporting by in-house radiologist/outsourcing radiology reporting
 - o Additional support for non-radiologist clinicians using decision support software for identifying LVO (Please refer to the regional AI decision aid quality improvement project below)

N.B: Although formal reporting by a qualified radiologist is required for any imaging the referral for MT should not wait for formal reporting.

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6.2 Image transfer

The images should be transferred to JRH PACS server immediately via linked PACS system from MKUH, RBH and WGH and via 'Blue Light' mode on the Image Exchange Portal (IEP) from GWH and NGH.

For GWH the responsible stroke physician will contact the radiology secretary to image link the CTA and non-contrast CT brain via IEP to JRH. Out of hours, the physician will ask the on call radiographer to do that instead.

The images can also be sent via a cloud link from the e-Stroke Suite mobile app if configured to facilitate rapid decision making.

6.3 Referral to JRH

- a. If an LVO is identified in an eligible patient the referring clinician should contact the oncall stroke physician at the JRH via the phone **(01865 226086)** to discuss the transfer.
- b. The patient and the next of kin should be informed of the referral and be provided with information regarding what to expect in JRH.
- c. If the decision-maker (for IVT and also now for MT) at PSC is non-resident, and/or decision-making processes are reliant on non-specialists such as medical or ED registrars/consultants the PSCs should ensure they have tele-medicine facility to facilitate timely decision making or use AI decision aid software to facilitate rapid decision making.

6.4 Patient transfer

- a. As soon as the decision to transfer is agreed with JRH oncall stroke consultant the referring team should call for the ambulance (SCAS) for **'Inter-Facility Transfer (IFT) category 2'**

For SWAS responsible stroke physician in GWH will ring 999 to call for "emergency time critical transfer/Interfacility transfer Category 2". The escalation number is 0300 369 0076 if there is any delay in ambulance arriving in ED to transfer the patient.

- b. It is the responsibility of the PSC to arrange and deliver transfer of the patient in a safe manner to JRH working in conjunction with the local ambulance service. The overall care of the patient will remain the responsibility of the referring clinician at the

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PSC until the patient arrives at JRH and is taken over by the stroke specialist at JRH. However, clinicians at both ends should work together to ensure the transfer of the patient is undertaken in a safe and timely manner.

- c. The alteplase infusion (thrombolysis treatment), if still running, should not be discontinued for transfer and the transfer should not be delayed until the infusion is completed.
- d. Ambulance clinicians are not currently trained to supervise thrombolytic infusions or provide emergency management of hypertension during acute stroke. An appropriately trained healthcare professional (doctor or nurse) from the PSC will be required to accompany a patient receiving alteplase infusion during ambulance transfer to supervise clinical management.
- e. An anaesthetic transfer may occasionally be needed if clinical deterioration requiring advanced airway management skills is expected by the assessing clinician at the PSC. It is recommended that basilar artery stroke patients are intubated prior to transfer and are accompanied by critical care team/anaesthetist. In this scenario the accepting stroke specialist in JRH should be informed before transfer is agreed and it is the responsibility of the JRH stroke specialist to contact the local critical care team in JRH to receive the patient in their Emergency Department.
- f. The transfer/handover document should accompany the patient to enable safe and efficient handover to the receiving team in JRH. (see appendix)
- g. It is also recommended that the transferred patients have at least 2 intravenous accesses and the transfer nurse/clinician has access to all the medications required for the management of emergencies. Hence it is advised that the transfer clinician carries a 'transfer bag' with all the required medications and adjuncts.

N.B: an escort may not be needed during the transfer if

- Stable stroke patients who have not received intravenous thrombolysis
- Stable stroke patients who have completed IV thrombolysis at the discretion of the referring stroke consultant

6.5 The responsibility of the transfer nurse

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- a. Possess adequate competency and skills to manage potential complications and hypertension during the transfer according to agreed protocols (Please refer to the appendix for the competency and protocols)
- b. Undertake regular observations including BP, pulse, Oxygen saturation, respiratory rate, GCS and any puncture sites for bleeding every 10 minutes during the transfer
- c. Communicate with the paramedics and the responsible consultant in PSC if the need arises or advice needed to manage any complications during the transfer

Future aims

- Acute stroke patients to have direct access to CT scanners on arrival in PSCs
- The primary transfer crew waiting in the PSC for secondary transfer in order to reduce the time wasted in arranging secondary transfer
- Online referral system to replace paper transfer forms
- Use of AI as an integral part of the referral process within the region encompassing image interpretation, image transfer, patient handover and communication

7 Training and education

- a. The stroke specialist clinicians are expected to receive regular training to review and interpret CTA images and to identify LVO. The network could provide support where appropriate. This can be delivered either face to face or via e-learning. Further learning should be encouraged through regular multi-disciplinary meetings to facilitate peer to peer learning within the network.
- b. It is recommended the nursing staff involved in the care of thrombectomy patients including the transfer nurses and HASU nurses receive regular training on the management of thrombectomy patient and the transfer nurses, in addition, receive a 'transfer training' to ensure they achieve and maintain the required competency and skills to manage post thrombolysis emergencies such as oro-lingual oedema, bleeding and hypertension. Please refer to the appendix 2 for the list of competencies (the competencies are derived from National Competency Framework for Registered Practitioners: Level 1 and National Competency Framework for Registered Nurses in Adult Critical Care: Step 1

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8 Repatriation

- a. Patients will be repatriated the day after the thrombectomy unless the clinical condition is unsuitable for a safe transfer.
- b. The team at the JRH will contact the PSC after the post-take ward round to advise on the patient's condition and whether repatriation is clinically appropriate. Contact details are in appendix. If a brain scan is needed in order to make the decision then this should be stated along with the time of scan, if known.
- c. The JRH should ensure that the relatives have been informed of the decision to repatriate and the likely timescale.
- d. The PSC will receive the patient back the same day that repatriation has been confirmed as appropriate. In most cases it will not be possible to keep a "free bed" for this purpose, but the team at the PSC will ensure that a bed is made available in anticipation.
- e. Patients should not be kept at the JRH for more than 2 days unless they are unstable for transfer, or their clinical needs cannot be met at the HASU of the PSC.
- f. Delays to repatriation will be monitored and reviewed as part of clinical governance arrangements.
- g. If patients are discharged directly from the JRH then the PSC should be informed so that local out-patient follow up can be arranged. Local Early Supported Discharge and community stroke support services should also be arranged. Contact details are in appendix

9 Artificial Intelligent Decision Aid Software (Brainomix)

As part of the TITaN project Brainomix, an Oxford-based technology company, is supporting the initiative with zero cost licences for its software for participating hospitals. The Brainomix software, the e-Stroke Suite, has regulatory clearance for prospective clinical use (CE -marked) as a medical device, and helps physicians with identifying and triaging patients for mechanical thrombectomy by supporting interpretation of acute stroke imaging in real time.

The e-Stroke Suite is an innovative intervention to help support the early identification of patients for consideration of mechanical thrombectomy within the TITAN collaboration.

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9.1 Non-contrast CT

Within the e-Stroke Suite, the non-contrast CT module is called e-ASPECTS. e-ASPECTS automatically processes the non-contrast CT head scan to calculate an ASPECT score.

e-ASPECTS generates an output that can be used to facilitate image interpretation by a clinician, in the context of the clinical history, examination and their own image interpretation. Users should be familiar with the e-Stroke Suite user guide, which can be accessed directly on the user interface of the hospital. e-ASPECTS is validated extensively in international studies, was used in the RESILIENT randomised controlled trial, and is being used in ongoing randomised clinical trials.⁴⁻¹⁰

In addition to generating an ASPECT score, e-ASPECTS outputs an estimated ischaemic core volume that has been shown to provide similar results to ischaemic core estimation using advanced imaging.¹¹ This feature is displayed as a red “heat map” (probability map) overlaid on the e-ASPECTS output, which clinicians can use to aid their interpretation of the extent of infarction.

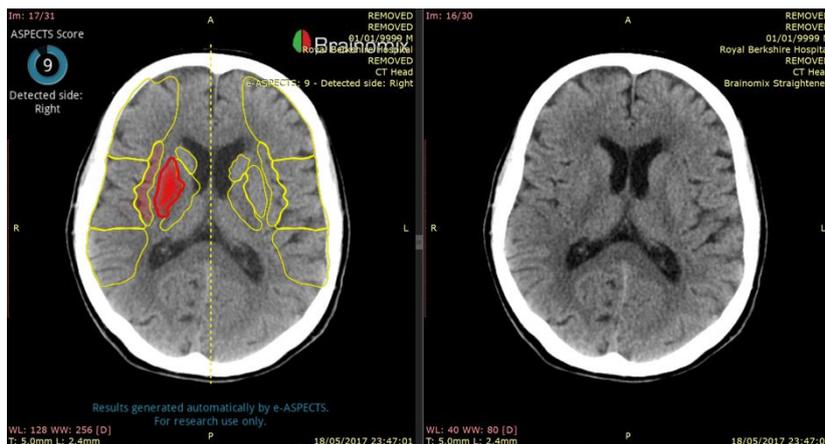


Figure 1: An example of an e-ASPECTS output on a PACS viewer

9.2 CT angiography

e-CTA is the module of the e-Stroke Suite used for aiding interpretation of CT angiography. e-CTA localises large vessel occlusion in the distal internal carotid and middle cerebral arteries, reflecting the patients selected for the successful mechanical thrombectomy trials. The display of e-CTA also provides a selection of maximum intensity projection (MIP) reconstructions to aid LVO detection even if the automated algorithms have not detected this. Additionally, e-CTA quantifies the extent of collateral vessel density on the CTA, quantified as the CTA collateral score (CTA-CS, also known as Tan score)¹² and a percentage of the MCA territory with good vessel density.¹³ The Tan score is a scale from

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0 to 3, in which 2 or 3 represents good collateral vessel density (over 50%) and 0 to 1 is poor.

As with all components of the e-Stroke Suite the user must be familiar with the user guide. The imaging tools are designed to support physicians interpreting scans in real time in the context of the patient’s clinical context. e-CTA supports physicians highlighting the presence of LVO and quantifying the extent of collateral blood vessels using the Tan score.

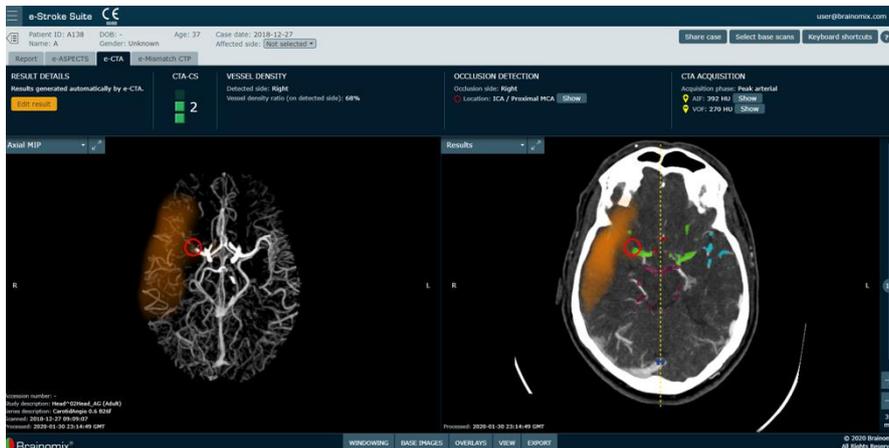


Figure 2: An example of e-CTA output on the web user interface, highlighting the presence of a large vessel occlusion and quantifying the extent of collateral blood vessels.

9.3 Viewing results

The results of the e-Stroke Suite are accessible in multiple formats within 2 minutes of scanning. In parallel to the standard imaging workflow sending images from the CT scanner to PACS, images are sent directly to the e-Stroke Suite server within the hospital network. The images are processed on this server and the results are then viewable on multiple platforms.

- Via the hospital PACS which can be viewed alongside the original image reconstructions of the CT scan already sent to PACS,
- Through the web user interface, which can be accessed within the hospital network,
- Through the viewing of an email output, if configured.
- Using the e-Stroke Suite cloud and smartphone application, if configured.

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10. Clinical standards, targets and audit

The Thrombectomy Innovation and Transformation Network (TITaN) should work in close collaboration with the appropriate Integrated Stroke Delivery Network (SDN) and Oxford Academic Health Science Network (OAHSN) to ensure the agreed clinical standards and targets are achieved through the pathway.

The following clinical standards, targets and audit/outcome measures are indicative. These can be modified and expanded in accordance with the agreement between TITaN, ISDN and AHSN where appropriate.

10.1 Clinical standards

1. 24/7 access to non-contrast CT brain and CT angiogram in all the referring PSCs
2. Availability of trained staff to support the unstable patients and any infusions during transfer
3. 24/7 access to Mechanical Thrombectomy in JRH
4. The patients should be transferred back to PSCs on the same day the repatriation has been confirmed as appropriate

P.S: Where these standards cannot be achieved the relevant organisation should have plans to achieve this in the future.

10.2 Clinical targets

1. Door to needle time (DTN) for intravenous thrombolysis < 30 minutes
2. Door in door out time (DIDO) for mechanical thrombectomy transfers < 60 minutes
3. Event to groin puncture time < 300 minutes
4. Door to groin < 30 minutes for external transfer

10.3 Key audit and outcome measures

1. Treatment-related mortality
2. 6 months mortality
3. Disability at 90 days months (mRS)
4. Disease/procedure-related complications, such as sICH
5. Door to needle time in PSC
6. Door in door out time in PSC

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7. Time from onset to MT
8. Time from onset to arrival at MT centre
9. Time from arrival to arterial puncture
10. Time from arterial puncture to MT
11. Pre-post NIHSS

Reference

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5. https://www.cc3n.org.uk/uploads/9/8/4/2/98425184/01_new_step_1_final_1_.pdf
6. <https://www.norf.org.uk/Competencies-Framework-Level-1>

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Appendix 1 - Thrombectomy Referral Pathway

Referral Criteria

1. Age \geq 18
2. Pre-morbid mRS 0-2
3. NIHSS $>$ 6
4. CT brain
 - a. No evidence of bleeding
 - b. ASPECTS \geq 6
5. CTA – proximal vessel occlusion
6. Able to arrive at neuroscience centre $<$ 6 hours of symptom onset

(Occasionally it might be appropriate to consider for thrombectomy up to 24 hours, in particular if there was a sudden major deterioration after initial mild symptoms, this might occur particularly with basilar occlusions)

Administer IV thrombolysis without delay if indicated.
(Do Not wait for clinical response)

Perform CT angiogram of aortic arch to vertex
with the initial non-contrast CT brain scan

REGFERRAL

Monday to Sunday: 08:00-20:00

Contact Oncall Stroke Physician in Oxford – Tel: 01865 226086

IMAGE TRANSFER

- Via PACS from MKGH, RBH and WGH
- Via IEP (Blue Light) from GWH and NGH
- Via e-Stroke Suite cloud and smartphone application, if configured

BRAINOMIX – Use the AI software as a decision aid tool to identify large vessel occlusion

- Arrange '**Inter-Facility Transfer (IFT) category 2**' to the Emergency Department at JRH following agreement by the stroke consultant on-call at the OUH
- All the patients who are transferred with IV t-PA infusion will need escort

Patients should be transferred awake if clinically safe. If intubation is required, inform the accepting teams before transfer is agreed.

- **Please send the 'nursing transfer document' with the patient** with any relevant clinical documentation, medication lists, blood results etc.
- Pre-alert OUH ED 15 minutes prior to the arrival
- If possible, it would be desirable for a patient's next of kin or legal representative to be transferred with the patient. Contact phone numbers of a patient's relatives, carers and GP would be useful.
- **Please keep a record of the times required for the audit**

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Appendix 2 - Curriculum of Transfer Nurse Competency

ACUTE STROKE			
Acute Neurological Care	<ol style="list-style-type: none"> 1. Demonstrates the ability to perform a full set of neurological observations appropriate for stroke patients 2. Understands and can describe the signs and symptoms of acute neurological deterioration in stroke patients 3. Demonstrates the ability to recognise neurological deterioration and consistently increases the frequency of neurological observations accordingly 4. Demonstrates awareness of who to alert when a stroke patient deteriorates according to local policy 5. Demonstrates a sound knowledge of stroke physiology and can apply this to support patients and relatives 6. Understands and can explain the treatment and management of haemorrhagic strokes 7. Understands and can discuss when to commence anti-platelet therapy 8. Demonstrates the ability to alert medical staff of any complications of intravenous recombinant tissue plasminogen activator (rt-PA) 9. Understands and can discuss the rationale for avoidance of invasive procedures for 24 hours following thrombolysis 10. Demonstrates the ability to accurately and contemporaneously evaluate care and effectiveness of interventions using the Trust approved documentation 		
Inter Hospital Transfer	<ol style="list-style-type: none"> 1. Understands and can describe the following: <ol style="list-style-type: none"> a. Indications for transfer from Resus or HASU b. Importance and implications of time critical transfers 2. Demonstrates an understanding of the process for preparing to transfer the critically ill patient: <ol style="list-style-type: none"> a. Contents of the local emergency/transfer bag and identify the situations in which it may be required b. Monitoring equipment c. Infusion devices/syringe pumps including battery life d. Pharmacology requirements of the patient being transferred e. Pre preparation considerations required for drug administration during transfer f. knowledge of how to calculate oxygen required for duration of transfer and how to open/close cylinders g. Process and sequence of communication required prior to, during and following transfer 		

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	<p>including nursing and medical documentation</p> <ul style="list-style-type: none"> h. Safe moving and handling of the individual and equipment being transferred i. Needs of family for information about transfer <p>3. Demonstrates knowledge of what treatment might be temporarily discontinued for the duration of the transfer e.g. use of feed pumps</p> <p>4. Demonstrates knowledge of local procedure to follow if patient deteriorates during transfer and how to/who to call for help</p> <p>5. Demonstrates the ability to complete transfer documentation and/ or observations during the transfer according to local Trust policy</p> <p>6. Demonstrates the ability to handover the patient clearly and safely to another department/ ward if not returning patient back to same ward after a procedure</p>		
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