Standards for providing safe acute ischaemic stroke thrombectomy services (September 2015)

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These groups are recognised Special Interest Groups of their respective Royal Colleges and the short life working party was operating under the oversight of the Intercollegiate Stroke Working Party

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Introduction

Stroke is the third leading cause of death and the leading cause of disability in Europe. The management of acute ischaemic stroke is a major healthcare challenge but improving outcomes for acute stroke patients offers major benefits to patients, healthcare systems and society as a whole.

The immediate aim of treatment of acute ischaemic stroke is to recanalise an occluded vessel as quickly, safely and effectively as possible so as to restore reperfusion to the ischaemic brain region. Currently the standard treatment for acute ischaemic stroke for patients presenting up to 4.5 hours after onset is intravenous thrombolysis using tissue plasminogen activator (IVT) [1]. This treatment results in a recanalisation rate of only 50% of patients with distal vessel occlusions. However, recanalisation rates of large proximal vessel occlusion are disappointing at 24 hours after IVT treatment, with rates of 14% for internal carotid arteries and 35% for middle cerebral arteries being reported [2]. Over one third of patients with anterior circulatory ischaemic stroke will have large vessel occlusion.

The prognosis for patients with clinically severe stroke secondary to proximal occlusion is poor with the NINDS trial demonstrating that only 10% of patients with an NIHSS score of 20 or more achieved independence at three months [2]. Previous randomised controlled studies reported in 2013 (IMS III, MR RESCUE, SYNTHESIS Expansion) evaluating endovascular approaches in acute ischaemic stroke caused by large vessel occlusive stroke showed no additional benefit to endovascular approaches [3, 4, 5], however despite this in many locations outside the UK these procedures have been incorporated into usual clinical practice [6, 7].

Reasons for the neutral results include use of older, less effective recanalisation devices, longer time window from onset to intervention and the inability to effectively identify patients with large vessel occlusion with appropriate angiographic imaging in a timely fashion. The rationale to deploy endovascular therapies for ischaemic stroke is to potentially improve outcomes by facilitating early recanalisation of an occluded large artery as quickly as possible. Data from the IMS III study confirmed that time window for treatment is a crucial factor and subgroup analysis from this study suggested that improved outcomes (although not statistically significant) were observed in patients who received endovascular therapy within 90 minutes of IVT if thrombolysis treatment was commenced within 2 hours of stroke onset.

Following this, NICE (2013) [8] made the following recommendations stipulating that patients who are suitable for thrombolysis and satisfy the criteria for a research study (e.g. Pragmatic Ischaemic Stroke Thrombectomy Evaluation-PISTE) [9] should be considered for enrolment into a randomised controlled trial and finally patients for whom thrombolysis has failed or is unsuitable due to contraindications can be considered for thrombectomy if not eligible for a trial. This statement was supported by the NHS Improvement Stroke Working Party document in 2012 [10].

However since this recommendation, there have been five published randomised controlled trials [11-15] evaluating the effects of interventional thrombectomy in addition to IVT compared with standard treatment (i.e. IVT alone delivered within 4.5 hours). These all demonstrated significantly improved outcomes with endovascular therapy. These studies were heterogeneous in terms of patient selection, imaging triaging criteria used for large vessel occlusion and salvageable brain tissue (CT Angiography, CT or MR Perfusion), rescue therapy in failed IVT or contraindication to IVT, onset to treatment of endovascular therapy (within 6,8 or 12 hours). This creates issues around generalisability. The consistent theme of improved functional independence (Rankin Score 0-2)

from these studies was driven by improved patient selection by neuro-imaging with rapid demonstration of large vessel occlusion, enrolment of patients with moderate to severe stroke (NIHSS of 17), change in technology with stent retriever devices as well as an improved heightened response of door to intervention time (stroke onset to groin puncture < 4.5 hours). The numbers needed to be treated by thrombectomy to prevent one case of functional dependency or death ranged from 3 to 7. Only some trials reported a positive effect on mortality. The summary of the trials are described below:

MR CLEAN (N= 500) [11] confirmed that endovascular therapy as rescue therapy in failed IVT delivered within 6 hours of ischaemic stroke resulted in a 13.5% absolute increase in functional independence with no difference in symptomatic haemorrhage or mortality. Patients underwent CT imaging and CT angiography to identify large vessel occlusion prior to randomisation but there is uncertainty whether alternative imaging modalities were used to select patients further.

ESCAPE (N=316) [12] confirmed that a policy of using complex imaging assessment (Multiphase CT angiography) to identify patients with large vessel occlusion suitable for treatment with endovascular therapy within 12 hours of onset (15% randomised beyond 6 hours) was beneficial and resulted in 24% absolute increase in functional outcome. Of interest, patients who could not receive IVT also appeared to benefit, although this needs to be confirmed in future studies.

EXTEND IA (N=70) [13] again used complex neuro-imaging to identify potentially salvageable brain tissue with treatment completed within 8 hours, however although there were significant differences favouring endovascular therapy (31% absolute increase in functional independence), the patients were highly selected and the results not generalisable.

SWIFT PRIME (N=196) [14] confirmed that using a complex imaging strategy of CT/CT Angiography and CT/MR Perfusion imaging to identify patients treated within 6 hours of onset resulted in 25% absolute increase in favourable outcome. Of note, the median time of arrival in the emergency department to groin puncture was 90 minutes.

REVASCAT (N=206) [15] demonstrated that in patients who failed to revascularise after 30 minutes of IVT and with evidence of large vessel occlusion and large ischaemic core (Perfusion Imaging), delivery of endovascular therapy within 8 hours of onset resulted in a 15% absolute increase in functional outcome.

An important pragmatic question to answer is whether there is strong evidence for early adjunctive endovascular therapy using a strategy of CT imaging and CT angiography alone rather than deploying complex neuro-imaging to further triage patients to identify those where thrombectomy may well result in futile recanalisation. The former policy has the potential to be delivered quicker within the current NHS structure. This strategy was deployed in the THRACE study [16]. THRACE (N=414) evaluated endovascular therapy in patients where there was no or minor neurological improvement (< 5 points of NIHSS) after IVT who had evidence of large vessel occlusion evaluated by CT angiography. Interventional treatment had to commence within 5 hours of stroke onset and be completed within 6 hours. Although not yet published (*Presented European Stroke Organisation, April 2015*), intermediate results at 90 days suggest a 12.1% absolute difference in functional outcome, consistent with the growing evidence for endovascular therapy.

In the presence of current data, it can be argued that equipoise no longer exists for selected patients with moderate to severe stroke with large vessel occlusion. However future research is required to evaluate the cost benefits [25] of delivering this complex intervention across the stroke pathway as well as ensuring we have a pragmatic paradigm in delivering such a process which is generalisable within the NHS. Estimating the percentage of patients who may benefit from endovascular therapy also needs to be recognised in the context of resources required to evolve the hyper-acute stroke infrastructure. The published trials to date are not generalisable and the numbers recruited were small in total but there is suggestion that 5 to 10% of the ischaemic stroke population may now be eligible for such treatment [17]. That % would rise if time windows for IAT are extended by on going trials and proposed studies into IAT in stroke of unknown time onset using advanced imaging triage were also positive. NICE will be required to update its review and technology appraisal on these interventions thus providing guidance, quality standards and cost effectiveness data for these processes and will provide a platform for specialist commissioning arrangements in the future.

In light of the prevailing evidence, the ESO Karolinska Consensus Stroke Update Consensus statement (2015) [18] has made a number of recommendations:

1) Mechanical thrombectomy, in addition to intravenous thrombolysis when eligible is provided to patients with large artery occlusions in the anterior circulation up to 6 hours after symptom onset (Grade A, Level 1a).
2) If IVT is contraindicated (warfarin with therapeutic INR), thrombectomy is recommended as first line of treatment for patients with large vessel occlusion (Grade A, Level 1a).
3) Regarding patient selection, intracranial vessel occlusion must be diagnosed with non-invasive imaging prior to consideration of thrombectomy (Grade A, Level 1a), perfusion imaging determining penumbral size may be used for further selection (Grade B, Level 1b) and high age is alone is not a reason to withhold thrombectomy (Grade 1, Level 1a).

The consensus supports the continued collection of patient data systematically into an established national programme audit (SSNAP or SITS TBY) or the Scottish Stroke Care Audit Programme embedded within special arrangements for clinical governance, audit and quality improvement. The recent results from the published randomised controlled trials could potentially impact on recruitment to ongoing trials (PISTE has been temporarily halted by its steering committee) but it is important that patients are considered for enrolment into trials where there is on going uncertainty.

In the advent of increasing evidence supporting endovascular therapy albeit for only a modest percentage of the stroke population, it is important to produce a consensus on the minimum standards of care, reflecting the methodology used in the trials, required to support such a service in terms of specialist staffing/skill mix and organisation of services. It is recommended that such interventions should only be undertaken within specialist stroke centres that fulfil agreed standards of care for both staff and process and meet any additional requirements of a RCT or Registry. Every trust where such procedures are undertaken has a duty to ensure that safe arrangements are in place [19]. This document has been developed to aid this process by describing the key requirements for an endovascular acute ischaemic stroke therapy service, including the minimum service support requirements and basic performance standards that should be met.

Recommendations for Endovascular Therapy for Acute Ischaemic Stroke

Organisation of Care

Sites

If endovascular therapy is being considered for the treatment of acute ischaemic stroke this should be confined to neuroscience centres incorporating hyperacute stroke units (HASU) embedded within a high quality comprehensive stroke service with access to neurosurgical, neurocritical care and specialist in and out-patient stroke services. The findings from the trials are generalisable to only those centres that have access to advanced brain imaging facilities and appropriate [neuro]endovascular expertise with efficient in-hospital hyper-acute pathways.

The key features of what a HASU should incorporate include:

- 24 hour availability of an experienced consultant stroke physician [20]
- Immediate access to brain imaging including CT Angiography/Perfusion & MRI as required [21]
- Direct admission to HASU from A&E < one hour
- Continuous physiological monitoring (ECG, oximetry, blood pressure)
- Specialist stroke physician ward rounds 7 days per week
- Acute stroke protocols/guidelines
- Nurses trained in swallowing screening, stroke neurological assessment (including the NIHSS assessment), eligibility assessment for thrombolysis and administering thrombolysis treatment

Endovascular stroke therapy should only be carried out in the context of high quality hyperacute stroke services with the appropriate experience in delivering such interventions. Evidence suggest that hospitals with an annual thrombolysis volume ≥ 50 cases per annum achieve significantly better onset to needle, door to needle and door to imaging time than thrombolysis volumes < 50 cases [22] and this may enhance endovascular delivery times. Sites participating in randomised controlled trials for neuro-endovascular therapy were from comprehensive stroke centres performing between 40 and 60 procedures annually.

Skill Mix

The decision to undertake endovascular stroke therapy should be made jointly by a multidisciplinary team compromising a consultant stroke physician, [neuro]interventionist (with the necessary experience and skills) and an anaesthetist (preferably experienced in neurological care).

The stroke physician undertaking the decision to consider endovascular therapy must satisfy the criteria the BASP criteria for a stroke specialist including:

- Completion of specialist training or recognised expertise (existing specialists)
- Ongoing active involvement in stroke management (at least 5PA of which 3 PA is direct clinical care)
- Annual attendance of at least one specific training event
- Evidence of continued professional development in the field of stroke medicine
- Participation in national stroke related audit
- Basic research skills (participation or facilitation of stroke research)

The stroke physician should be trained in delivering thrombolysis and in the monitoring of any complications associated with thrombolysis and endovascular therapy.

This must be underpinned by regular quality and audit meetings within a quality improvement group incorporating stroke physicians, neurointerventionists, neuroradiologists, intensivists ± emergency medicine physicians [6].

There should be provision of 24/7 consultant cover provided by at least 6 BASP thrombolysis trained consultants on a rota able to make thrombolysis and hyper acute treatment decisions (1). BASP have recommended that for a hyper-acute service admitting 600 new admissions annually, 10.5 direct clinical care PA would be required to support such a service [23].

Pre-Hospital:

Emergency Medical Services (EMS) play a vital role in hyper-acute stroke care and local protocols and algorithms should be in place for dispatch, assessment, pre-notification and transport strategies

All potentially eligible patients for intravenous thrombolysis initially should be transferred immediately to a centre with hyper-acute stroke services with early notification of the specialist stroke team. There is currently no existing literature on training EMS in identifying potential patients eligible for endovascular therapy. There is no evidence that EMS should directly transfer patients outside the intravenous thrombolysis window directly to centres with endovascular capability.

Inter Hospital Transfer:

Transfer from a primary hospital to a centre providing endovascular therapy can potentially result in considerable delays in administrating treatment which may impact on outcome. This needs to be considered in the decision whether to transfer or not. However data from SWIFT PRIME suggested that although patients who were treated with IVT from an outside hospital had less favourable outcome overall, they still benefited from treatment regardless of which site IVT was provided [14]. Regardless of this, it is important that provision of intravenous thrombolysis is not delayed under any circumstances.

'Hub and Spoke' models have been used regionally to deliver IVT successfully however, regional strategies with a Network approach for endovascular therapy will need to be considered in light of level 1 evidence for this procedure.

If algorithms are to be developed for secondary transfer of patients eligible for endovascular therapy, then local protocols for transferring and accepting patients need to be clearly outlined.

Process of Care

Endovascular Therapy Recommendations and Quality Benchmarks:

Eligibility for mechanical thrombectomy should not delay the initiation of IVT where this is indicated.

Consider endovascular stroke therapy in the following patients:

> A)- Those with proximal intracranial large vessel occlusion in a symptomatic territory leading to a disabling neurological deficit (NIHSS ≥6) of known onset and <5 hours ago* (< 4 hours if considering inter-hospital transfer)

B) Those with contraindications to intravenous thrombolysis therapy (e.g. recent surgery, warfarin treatment with therapeutic INR)

C) Those failing to respond to intravenous thrombolysis *(However the time window defining failed IV tPA has not been established and further trials may be required to define the criteria for failed IV. THRACE defined this as no improvement or minor neurological improvement of < 5 points on the NIHSS and REVASCAT defined this as failure of revascularisation after 30 minutes of IVT)*

D) Those suitable for entry into randomised controlled trial where there is clinical uncertainty

**If the major vessel occlusion is in posterior circulation, time window may be up to 12-24h depending on clinical status of patient*

Thrombolysis should not delay initiation of the thromebectomy pathway. To be able to meet the door to groin target of less than 90 minutes, thrombectomy needs to be considered in patients who meet the criterion A and are considered fit for the intervention. If thrombolysis is given and the patient responds (Criterion C NOT fulfilled), preparations for thrombectomy can be halted.

The metric of 'arrival to start of treatment' should be within 90 minutes wherever possible, unless the indication for intervention only developed after arrival (e.g. deterioration in NIHSS after thrombolysis).

Door to Imaging:
All patients with an acute stroke being evaluated for endovascular therapy should be imaged immediately (ideally the next imaging slot).

Use of CT angiography or MR imaging/angiography should not unduly delay therapy with intravenous thrombolysis or delay door to arterial puncture. *In practice hospitals that undertake CTA routinely in acute stroke achieve this by review of plain CT occurring whilst CTA is performed and then not waiting for CTA report before instituting IVT (where indicated).*

General Anaesthesia:
If general anaesthesia is used due to clear indications and patient safety concerns during the procedure, then ongoing physiological monitoring including airway management should be undertaken in the appropriate setting until stable. This should occur either within high dependency or intensive care settings, where necessary with specialist stroke support.

The following outcomes should be measured from the SITS TBY data collection set:

- Revascularisation achieved- with a TICI grade 2b or 3 in ≥60% of patients
- Rankin 0-2 at 3 months achieved in ≥33% of cases
- Symptomatic Intracranial Haemorrhage using SITS definition (parenchymatous Haemorrhage type 2 combined with deterioration of NIHSS score≥ 4 points at 22-36 hours (in no more than 12% SICH should be expected)
- Early deaths (within 72 hours)

Recommendations for individual trusts

Neuroradiology departments

1. Recognition that existing interventional neuroradiology services should be supported to develop/expand ability to provide stroke endovascular therapy within the NHS subject to NICE guidance update.

- Whether this is currently (June 2015) confined to normal working hours or extended hours will depend upon local circumstances & funding
- [Urgent] regional planning for future delivery of extended hours services should be undertaken

2. There should be clarity within the trust and among referring clinicians and service commissioners about what endovascular stroke services are available, when they are available and what happens when the service is not available

- Local patient pathways should exist, be clear and widely available
- Local protocols and SOPs for each step of the pathway should be accessible
- The trust's clinical governance committee and relevant referring clinicians need to be aware of the situation
- Delivery of intra-arterial interventions in acute stroke should only be in the context of established, high quality stroke services, where all patients have timely access to specialist stroke units
- Consideration for intra-arterial interventions in acute stroke should not compromise the timely delivery of intravenous thrombolysis in eligible patients

3. Service provision must be subject to a formal rota

- It is not safe or sustainable to rely on ad hoc arrangements as such arrangements do not ensure that all eligible patients are treated [24]
- Nor is it acceptable to assume another centre will be willing or able to provide the service without official and agreed service level agreements (A mechanism should be in place for informing clinical teams about when service is available

4. There should be recognition of the resource implication on Interventional Neuroradiologists (INR) consultants of supporting even a limited hours stroke endovascular service and also of the knock on impact on diagnostic neuroimaging services

- Appropriate diagnostic neuroimaging support and protocols should be in place
- A whole support team of staff is required to deliver endovascular stroke therapy and this needs to be IMMEDIATELY available
- Anaesthetic staff with appropriate training/experience in neurocritical care plus ODP support
- Angio suite staffing – nursing and radiographic
- After care is a critical requirement – neuro-critical care facility should be immediately available post procedure

5. Services should have regular clinical-radiological MDT meetings where endovascular stroke patients can be reviewed/discussed. As well as enrolment into RCT/Registry, appropriate local audit processes should be in place

- Quality improvement processes for IAT should be in place
    - quality improvement group could include a combination of interventionists, neurologists, stroke physicians, intensivists & diagnostic neuroradiologists. Additional members might include representative(s) from quality assurance/improvement or risk management teams

6. IA intervention should be delivered in specialist stroke centres that fulfil the following attributes

- adherence to defined standards (as section above)
- consultant-led & delivered services with adequate volumes of activity
- formal commissioning arrangements in place
- demonstrable research capability and activity where clinical activity extends beyond core evidence from the randomised trials underpinning NICE guidance

- **Recommendations for individual endovascular operators**

1. All doctors are bound to adhere to GMC guidance and comply with principles and values set out in Good Medical Practice

2. Operators should not normally carry out procedures with which they are unfamiliar (in the UK at present this, to all intents and purposes, essentially limits provision of endovascular intracranial stroke therapy to consultant interventional neuroradiologists)
    - If a procedure is required on a reasonably regular basis then individual operators must maintain the necessary skills
    - There will inevitably be a risk benefit assessment to be made in any individual case and patients and presentations do vary considerably. The risk of any patient transfer, presence or absence of alternative therapies and INR experience will all need to be taken into account.
    - This risk benefit analysis should be reflected in the consent/assent obtained and documented.

3. Operators should recognise that ad-hoc rotas are not in the best interest of patients [RCR ref 24]
    - This form of service provision may conceal lack of safe, reliable service provision
    - There must be a safe environment for performing the procedure and close liaison with the appropriate clinical team(s)

4. Operators should participate in multidisciplinary case review

5. It is the duty of the operator to report any risk management concerns to the trust's clinical governance committee

Implementation of standards and quality benchmarks

Departmental leads should ensure the following:

- Local agreement is reached amongst INRs about what service is provided
- Process for maintenance of skills is in place (this may include updating practical skills by spending time in other departments)
- Mechanism for information to be available to clinicians on regular basis about when service is available
- Formal contracts exist with referring trusts
- Agreed local protocols should be evidenced based (within limits of evidence)
- National guidelines are adhered to
- Appropriate case review and quality improvement processes are in place

Quality Benchmarks for Endovascular stroke therapy

1. Local protocol specifies reasonable indications for the procedure to be undertaken:

- Proximal large artery occlusion in symptomatic territory plus symptom onset known and <5 hrs ago
- Time window may be extended within local protocol if:
    - Fails to respond to IVT/IVT CAI and imaging favourable (cf ESCAPE trial)
        - *Time window greater if vertebrobasilar occlusion (specify in local protocol)*

- Account is taken in indication protocol of NIHSS and patient factors – co-morbidity
    - *At least 95% of patients treated with IA therapy should meet the institutional selection criteria*
    - *100% of patients have the required process and outcomes data entered into a trial or registry*

2. TIMINGS

- Lysis to groin puncture time of <90 minutes
- Puncture time to start of revascularisation: <45 minutes in at least 65%
- Puncture time to end of revascularisation: median ≤60 minutes

3. OUTCOMES

- Revascularisation achieved: at least 60% should have TICI grade 2b or better
- Clinical outcome: at least 33% of patients with strokes treated by endovascular methods should have a mRS score of 0–2 at 90 days.
    - *Large artery occlusive stroke treated with IVT alone results in good outcome in trials in range 19-42%*
- SICH: rate should be <12% and all cases with symptomatic ICH should be reviewed
- All deaths within 72h of procedure are reviewed

Anaesthetic management of endovascular treatment of acute ischaemic stroke

1. Recommendations for provision of care

- The anaesthetic care of these patients should be supervised by Neuroanaesthetists with skilled assistance. It should be consultant led.
- If a patient is sedated the responsible anaesthetist must be present in the procedure suite.

2. Recommendations for pre assessment

These patients present as time critical emergencies, akin to evacuation of an extradural haematoma or category 1 Caesarian section. Delays have detrimental effects on patient outcome. Time to groin puncture after IVT thrombolysis should be **<90 mins.** Pre assessment of the patient must be done as quickly as possible to avoid delay.

3. Recommendations for anaesthetic management

- The choice of anaesthetic should be tailored to the individual patient based on neurological status, airway control and treatment plan in close communication with the INR.
- Local anaesthesia should be aimed for, if feasible, in patients who are cooperative and can protect their airway.
- General anaesthesia is recommended in patients with a reduced level of consciousness, uncooperative or agitated patients, those who cannot protect their airway or those already intubated.
- Patients receiving local anaesthesia with sedation should be monitored and provision made to enable rapid conversion to a general anaesthetic if necessary.

4. Recommendations for airway management

- Tracheal intubation is recommended for those patients with reduced level of consciousness, signs of brain stem dysfunction, those unable to protect their airway, with active nausea and vomiting before intervention and patients who become hypoxic or develop airway obstruction under sedation.
- Supplemental oxygen administration is recommended during sedation.
- All patients should be monitored with pulse oximetry and capnography.
- FiO_2 should be titrated to maintain SpO_2 > 94%. Ventilation should be adjusted to maintain normocapnia under anaesthesia. Hypercapnia should be avoided in patients undergoing sedation.

5. Recommendations for haemodynamic management

- Haemodynamic monitoring should include ECG and continuous blood pressure or, if non-invasively, measured at least once every 3 minutes.
- Continuous invasive arterial monitoring is recommended for all interventional procedures as long as arterial cannulation will not delay intervention. The femoral artery cannulated by the neurointerventionist may sometimes be used to provide continuous arterial monitoring if necessary.
- In patients having general anaesthesia systolic blood pressure should be maintained within 10% baseline with fluids and / or vasopressors. Suggested targets are >140mmHg but < 220mmHg (< 180mmHg in patients who have received IV tPA).
- These blood pressure targets may need adjustment in communication with the stroke physician/INR.

6. Recommendations for Postoperative Care

- Critical care should be contacted to establish the availability of level 2/3 facilities for postoperative care. However this should not delay the start of intervention. If necessary, alternative facilities can be sought whilst the procedure is performed.
- Patients who have received GA should be managed on NICU or High dependency care / stroke unit postoperatively to continue physiological monitoring and neurological monitoring.

7. Protocols

Irrespective of anaesthetic technique the two most important anaesthetic goals are minimising any time delay and haemodynamic control. Institutional protocols can assist in the safe and timely delivery of care. These protocols should address:

- Choice of anaesthetic agents
- Timeliness of induction
- Blood pressure parameters
- Postoperative care

7. Audit

Institutions should audit their practice including type of anaesthetic, monitoring, timing, anaesthetic agents used and complications.

Models of safe endovascular stroke provision

1. **Individual neuroscience centres** provide safe endovascular stroke service for patients admitted via their local ED/hyperacute acute stroke unit (HASU)
    a. ADVANTAGES: more readily deliverable and fairly limited additional resource requirement
    b. DISADVANTAGES: relatively few NHS stroke patients potentially eligible are able to receive endovascular therapy

2. **Hub and spoke arrangement** with acute stroke patients accepted by neuroscience linked HASUs for thrombectomy from outside hospitals and where practicable development of the "London model" of ambulance bypass to take suspected stroke patients to a comprehensive HASU rather than simply the nearest ED.
    a. ADVANTAGES:
        i. far more NHS stroke patients able to receive endovascular therapy
        ii. deliverable by existing services with additional resource requirement & pathway reconfiguration
        iii. need for robust transfer arrangements and close monitoring of times taken will be a driver for service improvement to all stroke patients – as per IVT model
        iv. synergy/quality improvement gains of building up existing neuroscience & stroke services rather than starting from scratch to develop a service
        v. Enables INRs to work with other practitioners to expand service provision & training whilst mentoring & supporting safe thrombectomy practice
    b. DISADVANTAGES:
        i. more formalised and complex service and governance arrangements needed (but that in fact may well be a good outcome)
        ii. additional resource requirement as existing INR & diagnostic neuroradiology services require expansion

3. **Local provision** of IA thrombectomy **by any "qualified" provider**
    a. ADVANTAGES: most eligible NHS stroke patients able to receive endovascular therapy
    b. DISADVANTAGES
        i. Lack support services on site for safe IAT – Neurocritical care, INR & neurosurgery
        ii. No robust trial evidence that non INR services can/will attain excellent technical, clinical and safety outcomes required for IAT to be SAFE & cost effective
        iii. Multiple small volume centres with relatively inexperienced operators are extremely unlikely to achieve the same quality of outcomes as fewer high volume centres with experienced operators
        iv. Current services are all INR based so nobody else presently "qualified"
        v. Long lead time for non INR staff to attain skills i.e. become "qualified"
        vi. Inadequate IAT numbers in most cases to maintain the skills of a whole team whose only Neurointerventional work is stroke thrombectomy (~40 cases per operator per annum & minimum team for 24/7 cover of 5 operators)
        vii. Staff, equipment, consumable & imaging infrastructure costs for multiple small centres operating rotas are all greater than for centralised high volume services

Routes to service delivery

Networking

In view of Grade Level 1a evidence, networking of centres to deliver a regional or supraregional 24/7 service may be one approach, however in the short term, extended hours 7 days per week may be the initial stepwise approach to accommodate such service reconfiguration.

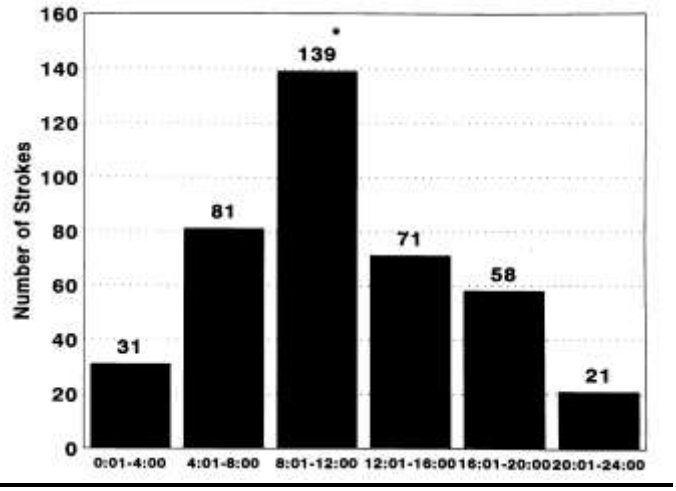
There is currently insufficient stroke workload at present to attain/maintain skills unless operators are active INR practitioners utilising the same skillset in the treatment of other intracranial neurovascular conditions on a very regular (weekly) basis. One consideration may be to align both neuro-interventional services for thrombectomy and for coiling (SAH) in a regional collaboration but this will depend on local circumstances.

The urgency of the need for stroke intervention militates somewhat against supra regional INR centre networking – though this might be feasible in London and potentially most of the other 6 metropolitan areas in England (e.g. where units are ≤1h ambulance transfer apart)

Hours

~90% of all strokes occur 0430-2300 & so could be managed by a thrombectomy service operating 0700-2400 (see figure below)

- However, of those strokes occurring 2300-0430, many/most will be "wake up" stroke & so a far higher proportion will be stroke of unknown time onset (SUTO) than is the case in strokes occurring 0700-2300. Currently no intervention is proven to be effective in SUTO.
- So actually >95% of strokes eligible for thrombectomy under current scientific evidence would be covered by a 0700-2300 hours service
- There is thus a clear sensible rationale for gradual extension of IAT cover towards 24/7 rather than attempting to go from "no service" to "24/7" immediately



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Abbreviations

CS = Conscious sedation
ED = Emergency Department
GA = General anaesthesia
GMC = General Medical Council
IA = Intra-arterial
IAT = Intra-arterial thrombectomy
IMS 3 = Third interventional management of stroke trial
INR = Interventional Neuroradiologist
IV = Intravenous
IVT = Intravenous thrombolysis
mRS = modified Rankin score
NICE = National Institute for Health & Clinical Excellence
NIHSS = National Institutes for Health stroke scale
RCT= randomised controlled trial
SICH = symptomatic intracerebral haemorrhage
SITS = Safe implementation of treatments in stroke
tPA = tissue plasminogen activator