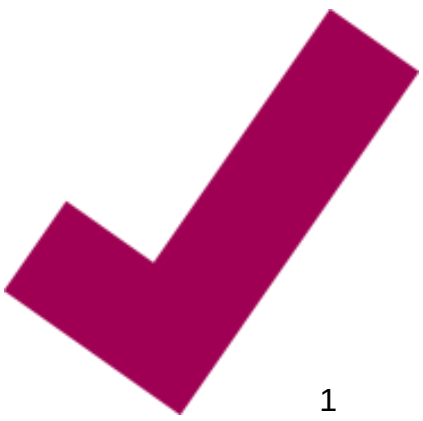
NHS England

Clinical Commissioning Policy Proposition: Mechanical thrombectomy for acute ischaemic stroke



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1 Executive Summary

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

Ischaemic stroke secondary to proximal anterior circulation occlusion

Ischaemic stroke is the most common type of stroke. It happens when an artery (blood vessel) is blocked by a blood clot, cutting off blood flow to part of the brain. Without a blood supply, brain cells can be damaged or destroyed because they may not receive enough oxygen. Symptoms may include numbness or weakness on one side of the body and problems with balance, speech and swallowing. Symptoms may range from mild and resolve, through to severe stokes that can lead to coma and death.

About current treatments

Interventional treatment in about 15% of patients involves drug treatment as soon as possible after the stroke to dissolve the blood clot (thrombolysis). Effective stroke care also includes specialist care and rehabilitation.

About the new treatment

Mechanical clot retrieval aims to restore normal blood flow to the brain, using a device to remove the blood clot blocking the artery. The patient first has cerebral angiography (a procedure using Computerised Tomography (CT) or Magnetic Resonance Imaging (MRI) scanning that shows blood flow through the arteries in the neck and brain) to see where the blood clot is.

The clot removal procedure is usually done under sedation, but sometimes general anaesthetic is used. A thin tube called a catheter is inserted into an artery, usually in the groin, and fed to the site of the clot. The clot retrieval device is inserted through the catheter, catches the clot, and is then pulled out through the catheter.

This treatment - mechanical clot retrieval for treating acute ischaemic stroke - aims to remove the clot blocking the artery within the brain, restoring blood flow and minimising brain tissue damage. When used with other medical treatments such as clot-busting drugs, and care on a specialist stroke unit/rehabilitation, mechanical thrombectomy can significantly reduce the severity of disability caused by a stroke.

What we have decided

NHS England has carefully reviewed the evidence to treat ischaemic stroke caused by a (proximal) large arterial occlusion of the internal carotid or middle cerebral arteries in the head with mechanical thrombectomy. We have concluded that there is enough evidence to consider making the treatment available.

2 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission Mechanical Thrombectomy for acute ischaemic stroke.

This document also describes the proposed criteria for commissioning, proposed governance arrangements and proposed funding mechanisms.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether mechanical thrombectomy for acute ischaemic stroke will be routinely commissioned is planned to be made by NHS England by XXXXX 2017 following a recommendation from the Clinical Priorities Advisory Group.

3 Proposed Intervention and Clinical Indication

Stroke is a devastating disease for the patient and family and is estimated to cost the NHS around £3bn per year, with additional cost to the economy of a further £4bn in lost productivity, disability and informal care (National Audit Office 2005). About 20% of patients die within the first year (and the majority of these patients die within the first 3 months) and over 50% of survivors are left with long-term disability. A disproportionately high share of the disability burden arises within the 30-50% of patients with proximal large artery occlusive stroke. Many of these patients will have a mixture of cognitive, mood and physical function problems.

85% of strokes are ischaemic, resulting from a blood vessel becoming blocked. Brain tissue is then damaged from a lack of oxygen and nutrients. Up to 20% of people with ischaemic strokes are suitable for, and respond to intravenous thrombolysis. However, many of those treated will not benefit because the blood clot is too large and does not completely dissolve. In addition, some patients cannot receive the treatment due to contraindications such as recent surgery or being on anticoagulant (blood-thinning) drugs. For some of these patients, the evidence suggests that mechanical thrombectomy performed within six hours of the onset of

symptoms is an effective treatment that can reduce brain damage and prevent or limit long term disability. Evidence suggests that the quicker this intervention is delivered the greater the benefits. Other than established intravenous thrombolysis, there are no other acute interventions that have been shown to reduce the area of infarcted brain despite efforts to develop new and more effective thrombolytic agents or neuroprotective drugs.

The group of patients that are likely to benefit from mechanical thrombectomy are those with proximal occlusion of the internal carotid or middle cerebral arteries who present early after the stroke before there is irreversible ischaemic damage to the brain. These patients, often with extensive thrombus, are much less likely to respond to the conventional intravenous thrombolysis and more likely to experience severe disability. Around 40% of ischaemic strokes are caused by a large artery occlusion (LAO).

For patients who do not respond to intravenous thrombolysis there has previously been no active intervention available to prevent brain damage. Treatment in these patients is limited to rehabilitation and high quality nursing care.

The Intervention:
A specially-designed clot removal device is inserted through a catheter into the blocked artery to remove the clot. The catheter is usually inserted into the femoral artery in the groin and advanced up to the location of the blockage. The clot removal device is then inserted through the catheter to remove the clot (thrombus) blocking the artery. In addition to introducing this procedure, the intervention will require a new model of care which builds on existing acute stroke networks.

4 Definitions

Ischaemic Stroke: a stroke caused by a blood vessel to the brain becoming blocked leading to death of brain cells

Mechanical Thrombectomy: the technique of removing a blood clot from the artery through a catheter

Thrombolytic agents: drugs that dissolve blood clots

Neuroprotective drugs: drugs that reduce the likelihood of brain cells dying when

they are deprived of nutrition and oxygen

Intravenous thrombolysis: giving a thrombolytic agent into a vein

Neurointerventionist: a clinician who undertakes procedures such as thrombectomy

5 Aims and Objectives

This policy proposition considered the current stroke pathway, immediate treatment, criteria, practices and the impact of the full implementation of Mechanical Thrombectomy as part of this pathway for those patients who comply with the criteria.

This policy proposition aims to define NHS England's commissioning position on Mechanical Thrombectomy as part of the treatment pathway for adults undergoing treatment for severe ischemic stroke where this is the responsibility of NHS England specialised commissioning teams.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for adults and improve access to the procedure as soon as possible after the onset of stroke symptoms.

6 Epidemiology and Needs Assessment

There are approximately 80,000 stroke admissions in England per year. Currently, around 12% of all stroke patients receive intravenous thrombolysis and the majority of patients suitable for thrombectomy will come from this group, with the remainder made up of those for whom intravenous thrombolysis is contraindicated; for example as a result of recent surgery or the patient taking anticoagulants.

It is estimated that up to 8,000 patients per year are eligible for treatment in England. Commissioning services able to deliver this intervention will need to be carefully planned to ensure that quality and accessibility are optimised.

7 Evidence Base

An extensive search of the international research literature was undertaken to

establish the effectiveness of mechanical thrombectomy. Sixteen relevant research studies; seven trials, and a further nine systematic literature reviews and meta-analyses (two of which use secondary analyses of pooled trial data) were identified as relevant, and were examined in detail.

All seven trials examined the effects of mechanical thrombectomy on patients who were functioning independently prior to their stroke. All reported strongly positive findings, with the proportion of people who could function independently at 90 days following stroke increasing by between 19-35%. All trials also examined the safety of the mechanical thrombectomy, usually by monitoring total mortality and the probability of an intracranial haemorrhage. None of the trials showed a significant excess of either of these outcomes compared with best medical treatment.

The facilities, personnel and equipment required to undertake thrombectomy take time to coordinate. These studies provide valuable insights into the time this takes, measured by time from arrival in a health care facility to arterial puncture. For most patients admitted direct to the thrombectomy hospital site arterial puncture was achieved within an hour and a half of admission (median 81 minutes) and in just under two hours (median 116 minutes) for those requiring transfer to the thrombectomy centre (Goyal et al., 2016).

The trials differed in aspects of their design, including the interventions allowed as best medical therapy. However many examined the effects of adding mechanical thrombectomy to a best medical therapy protocol that included intravenous thrombolysis (which has to be administered within 4.5 hours of stroke onset), with prompt initiation of further therapy (aiming for clot retrieval within 6 hours). This suggests that these trials can be used to build on established protocols for acute stroke management in England, where prompt access to thrombolysis is a mainstay of best medical treatment.

Five systematic literature reviews synthesised the results of the same/similar pool of studies, and reached similar conclusions. The absolute chance of patients being able to function independently at 90 days after stroke were improved by around 20% (19-22%) among those undergoing mechanical thrombectomy compared with controls (Bush et al., 2016, Marmagkiolis et al., 2015, Lambrinos et al., 2016, Touma et al., 2016, Anonymous, 2016). This suggests that for every 4 to 6 patients

undergoing thrombectomy following stroke, one more will be able to function independently at 90 days, compared to those that receive thrombolysis alone.

The studies that pooled individual level data gave similar findings. The larger of these calculated median disability scores at 90 days, and concluded that the median score on the Modified Rankin (mR) scale for those who received best medical therapy was 4 i.e. that patients were moderately severely disabled. In contrast, the median score at this time for patients who had also undergone mechanical thrombectomy was 2 i.e. they were able to function independently. Further, using a "differences in differences" approach mechanical thrombectomy increases the odds of being in a less disabled category at 90 days (one point different on the mR scale) by more than two fold (Odds ratio 2.26 p<0.0001) (Goyal et al., 2016).

Pooled analysis allowed other factors to be explored, particularly the significance of time from symptom onset to key events in the treatment pathway, such as decision to treat (randomisation), start of procedure, and restoration of cerebral blood flow. The HERMES study (Saver et al. 2016) identified that the absolute chance of being functionally independent 90 days after thrombectomy diminish by 3.4% with each hour's delay to starting the procedure (arterial puncture), and the probability of a beneficial reduction in decline in disability (one point on the mR scale at 90 days) fell by 5.3% for each hour's delay. Whilst treatment benefits fell, the outcomes for those undergoing thrombectomy were better than those receiving best medical therapy for up to 7 hours from stroke onset (i.e. where arterial puncture could be achieved within this time).

In summary, For every 4 to 6 people with an acute ischaemic stroke who present with an identifiable occlusion in the anterior cerebral circulation who undergo mechanical thrombectomy, one more person will be functioning independently at three months compared with if they had received intravenous thrombolysis alone.

Rapid treatment is important, as the benefit from mechanical thrombectomy falls by 5.3% for every hour of delay. However, the percentage that can be expected to be independent declines from 50% for thrombectomy within 3 hours to 45% at 4.5 hours, to 40% at 6 hours and to 33% by 8 hours, even with a favourable advanced brain imaging profile in the patients treated beyond 6 hour. Some patients where advanced brain imaging indicates the continuing presence of salvageable brain

tissue may still have better outcomes from thrombectomy than best medical treatment alone, even if thrombectomy occurs up to 12 hours after onset. There is no evidence to support later treatment in the absence of a favourable advanced brain imaging profile.

Symptomatic intracranial haemorrhage is no more common among people who had thrombectomy (4.4%) than best medical therapy (4.3%). Death rates at 3 months appear lower for those undergoing thrombectomy (15.3%) than for those receiving best medical therapy (18.9%), though these differences were not statistically significant.

Specifically, to ensure that those with the most to gain achieve important benefits, a decision should be made on both thrombolysis and on referral for thrombectomy within 4.5 hours of stroke onset, ideally achieving arterial puncture within 6 hours.

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of Mechanical Thrombectomy for acute ischaemic stroke.

8 Proposed Criteria for Commissioning

Inclusion Criteria:

Mechanical Thrombectomy will be routinely commissioned for patients, of all ages with proximal occlusion of the internal carotid or middle cerebral arteries who present early after the stroke before there is irreversible ischaemic damage to the brain.

The criteria that would need to be met for treatment are:

1) Thrombectomy (clot retrieval) can be achieved within 6 hours of the onset of symptoms, unless advanced brain imaging (perfusion or multiphase computed tomography angiography (CTA)) indicates substantial salvageable brain tissue is still present up to 12 hours after the onset of symptoms.

AND either:

a) Where there has been an inadequate response to intravenous thrombolysis by the time of groin puncture OR

b) for patients who are unable to receive intravenous thrombolysis because they

are on anticoagulants or have had recent surgery

AND

2) Where a proximal occlusion (intracranial carotid; and/or, M1 or proximal M2 segments of middle cerebral artery) in the anterior cerebral circulation is demonstrated on vascular imaging

AND

3) Where there are no major ischaemic changes on plain computed tomography (CT) or MRI brain scan

AND

4) With significant new disability with a score of >5 on the National Institute of Health Stroke Score (NIHSS)

AND

6) Previously independent in activities of daily living (Modified Rankin score less than 3).

The National Institutes of Health Stroke scale (NIHSS)

The NIHSS is used to measure the severity of a stroke. It scores areas such as level of consciousness, vision, sensation, movement, speech and language with a maximum of 42 points representing the most severe symptoms.

The levels of stroke severity on the NIHSS are categorised as:

0: no stroke
5–15: moderate stroke
16–20: moderate/severe stroke
21–42: severe stroke.

Modified Rankin scale (mRS)

This is a functional assessment scale that measures the degree of disability or dependence of people who have suffered a stroke.

The scale runs from perfect health without symptoms to death:

0: No symptoms.
1: No significant disability. Able to carry out all usual activities, despite some symptoms.
2: Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities.
3: Moderate disability. Requires some help, but able to walk unassisted.
4: Moderately severe disability. Unable to attend to own bodily needs without assistance, and unable to walk unassisted.
5: Severe disability. Requires constant nursing care and attention, bedridden, incontinent.
6: Death

Exclusion Criteria:

1) No proximal intracranial large artery occlusion
2) No appropriate vascular access or contraindications to arterial puncture

9 Proposed Patient Pathway

The model of care includes; the admission of patients to the nearest hyperacute stroke unit (HASU); undertake the initial investigations including CT or magnetic resonance (MR) angiography; start treatment with intravenous thrombolysis as appropriate; and then transfer urgently those who might benefit from thrombectomy and fulfil the criteria in section 8, to the nearest neuroscience centre that fulfils the criteria and is commissioned against this policy to provide thrombectomy services, (A full list of neuroscience centres is attached in appendix 1)

10 Proposed Governance Arrangements

All centres performing mechanical thrombectomy must be recognised by NHS England as one of their listed centres for thrombectomy and specifically in accordance with both:

D04 Neurosciences Specialised Neurology - Service Specification

and

D04 Interventional Neuroradiology for Haemorrhagic and Ischaemic Stroke - Service Specification Insert

Also, have regard to the 'Standards for providing safe acute ischaemic stroke thrombectomy services - British Association of Stroke Physicians (BASP September 2015).

All centres must enter patients admitted with stroke on the Sentinel Stroke National Audit Programme (SSNAP) database, which is used to monitor and audit stroke treatment and outcomes.

11 Proposed Mechanism for Funding

Funding and commissioning of mechanical thrombectomy will be managed through

the relevant local NHS England specialised commissioning team.

Reimbursement for treatment will be dependent on activity being reported via SUS as detailed within this document (appendix 2) and is dependent on the completion of the Sentinel Stroke National Audit Programme (SSNAP) database as outlined in section 10 of this policy proposition.

12 Proposed Audit Requirements

Outcome Measures

- Treatment related Mortality
- 30 day mortality post treatment
- Disability at 6 months
- Disease/Procedure-related complications such as symptomatic intracranial haemorrhage
- Disease-associated complications (e.g. lower respiratory tract infections, urinary infections, from SSNAP)
- Time from onset to thrombectomy
- Time from onset to arrival at thrombectomy centre
- Time from arrival to arterial puncture
- Time from arterial puncture to thrombectomy

All patients with stroke admitted to hospital in England are included on the Sentinel Stroke National Audit Programme (SSNAP) database, which is used to monitor and audit stroke treatment and outcomes.

13 Documents That Have Informed This Policy Proposition

1. NICE- Mechanical clot retrieval for treating acute ischaemic stroke - Interventional procedures guidance [IPG548] Published date: February 2016

2. Standards for providing safe acute ischaemic stroke thrombectomy services PM White , A Bhalla, J Dinsmore, M James, N McConachie, C Roffe *, G Young (British Association of Stoke Physicians (BASP) September 2015)

14 Date of Review

This document will be reviewed annually and will lapse upon publication by NHS England of any updated clinical commissioning policy for the proposed intervention.

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APPENDIX 1

Neuroscience Centres

1	RF4	BARKING, HAVERING AND REDBRIDGE UNIVERSITY HOSPITALS NHS TRUST	S
2	RNJ	BARTS AND THE LONDON NHS TRUST	L
3	RXH	BRIGHTON AND SUSSEX UNIVERSITY HOSPITALS NHS TRUST	S
4	RGT	CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	ME
5	RWA	HULL AND EAST YORKSHIRE HOSPITALS NHS TRUST	N
6	RYJ	IMPERIAL COLLEGE HEALTHCARE NHS TRUST	L
7	RJZ	KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST	L
8	RXN	LANCASHIRE TEACHING HOSPITALS NHS FOUNDATION TRUST	N
9	RR8	LEEDS TEACHING HOSPITALS NHS TRUST	N
10	RVJ	NORTH BRISTOL NHS TRUST	S
11	RX1	NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST	ME
12	RTH	OXFORD RADCLIFFE HOSPITALS NHS TRUST	S
13	RK9	PLYMOUTH HOSPITALS NHS TRUST	S
14	RM3	SALFORD ROYAL NHS FOUNDATION TRUST	N
15	RHQ	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST	N
16	RTR	SOUTH TEES HOSPITALS NHS FOUNDATION TRUST	N
17	RHM	SOUTHAMPTON UNIVERSITY HOSPITALS NHS TRUST	S
18	RJ7	ST GEORGE'S HEALTHCARE NHS TRUST	L
19	RTD	THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST	N
20	RET	THE WALTON CENTRE NHS FOUNDATION TRUST	N
21	RRV	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST	L
22	RRK	UNIVERSITY HOSPITAL BIRMINGHAM NHS FOUNDATION TRUST	ME
23	RJE	UNIVERSITY HOSPITAL OF NORTH STAFFORDSHIRE NHS TRUST	ME
24	RKB	UNIVERSITY HOSPITALS COVENTRY AND WARWICKSHIRE NHS TRUST	ME

APPENDIX 2

Coding and reporting for Mechanical Thrombectomy

Coding for the intervention is as follows:

Treatment function code 400 (Neuro)

The revenue cost per patient is based on HRG YA12Z. The cost of the device is included in the tariff. (As detailed in the NICE IPC548 which describes the appropriate coding of mechanical clot retrieval.)

As per HSCIC – Clinical Classifications Service issued on the 26 November 2016, the OPCS-4 codes for Mechanical clot retrieval for treating acute ischaemic stroke are:

L71.2 Percutaneous transluminal embolectomy of artery
Includes: Percutaneous transluminal thrombectomy of artery:

Y53.- Approach to organ under image control

Z35. Cerebral artery or O28.1 Basilar artery

ICD-10 of I63.9 Cerebral infarction, unspecified