NPB 2019-31

Meeting date: 23rd August 2019

Paper: 2019-31

Title:	**Thrombectomy Advisory Group (TAG)– Update to NPB**

Key Issues:	*A well-established evidence base exists which describes the benefits which could be derived from the development of a thrombectomy service for the treatment of acute ischaemic stroke in Scotland.* *The TAG has been working for a year to prepare a proposal which could deliver a 24/7 thrombectomy service for Scotland.* *In May, the NPB agreed that the work of the TAG would be shared with all Board Chief Executives (BCEs)and that planning work would continue across national, tertiary and local dimensions towards a full business case being completed* *BCEs at their meeting in June 2019 agreed all NHS Boards would engage with this planning work.*

Action Required:	NPB is asked to: 1. Note the agreement of Board Chief Executives that all NHS Boards will participate in the preparation of a business case for the provision of a 24/7 thrombectomy service; 2. Note the current work ongoing at national, regional and local level to identify the means to implement the five key elements of a thrombectomy service; 3. Agree that a request for in-year funding will be made to SGH&SCD by TAG; and 4. Agree to receive further reports from TAG.

Prepared by: *Dr Angus Cameron* *Chair of the TAG* *Colin Lauder* *Directors of Planning Group*	**Date: 16th August 2019.**

23rd August 2019
(Paper Number)

Thrombectomy Advisory Group (TAG) – Update to NPB

1 Purpose of the Report

This paper has been prepared by the TAG core group to provide an update to the NPB on the continuing work in preparation of a proposal for the provision of a 24/7 thrombectomy service for Scotland. The paper describes the key elements what will become a composite business case for thrombectomy, and the status of each of these elements.

The current membership of TAG is shown in appendix 1.

2 Background

Stroke is the third commonest cause of death in Scotland and the most common cause of severe disability amongst adults. Around 8,000 people each year in Scotland have a stroke severe enough to require emergency admission to hospital. These patients account for 7% of NHS beds and 5% of the entire NHS budget. Stroke has been a clinical priority for NHS Scotland for over 15 years and stroke care in Scotland is underpinned by a national strategy, the Better Heart Disease and Stroke Care Action Plan, a Stroke Improvement Plan, Scottish Stroke Care Standards, Scottish Stroke Care Audit and SIGN Guidelines.

Thrombectomy supplements the effects of clot dissolving medications (thrombolysis) and is a minimally invasive neuro radiological procedure performed by interventional neuroradiologists (INRs) with the patients' before and after care provided by the stroke team. The process of mechanical clot retrieval aims to rapidly remove the obstructing blood clot or other material from arteries in the brain to prevent or limit damage caused by the stroke. Currently treatment for ischaemic stroke is thrombolysis given as soon as possible after the stroke to dissolve the blood clot. However, this must be given within 4.5 hours of the start of the stroke, only benefits around 1 in 7 people treated and can cause severe bleeding which may be fatal. It cannot be given to patients on anticoagulants or with recent trauma or operations. Across Europe and North America thrombectomy is widely available on a 24/7 basis.

In April 2017 NHS England advised Clinical Commissioning Groups to set aside funding for a national implementation plan which will build on the existing services provided by 26-30 thrombectomy centres, providing mechanical thrombectomy (MT) for an estimated 92% of the English population within a 6 hours optimal window when fully rolled-out. The Commissioners were advised that an indicative cost would be around £100m. Currently 22 hospitals provide some level of thrombectomy cover in England and last year 781 thrombectomies were performed in England. This will increase further in the current year when 8 centres plan to provide a 24/7

thrombectomy service and with plans for non-neurosciences centres to provide services in future.

The Republic of Ireland is also implementing a national thrombectomy service based on 2 centres: Dublin is 24/7 and carries out 85% of these, and Cork is 9-5 and carries out 15%. NHS Northern Ireland currently delivers a national thrombectomy service on a 9am – 5pm basis.

A thrombectomy service had been delivered on an ad hoc basis in one neuroscience centre in Scotland; the Department of Clinical Neurosciences, Western General Hospital, NHS Lothian. In this time 13 patients from 6 NHS Boards received the service performed by two INRs. This service was suspended in the summer of 2018 due to resource constraints and clinical governance concerns.

Thrombectomy is not currently being carried out in Scotland.

4 Evidence Assessment

A summary of the evidence for the effectiveness of thrombectomy as an intervention in episodes of ischaemic stroke was included in earlier papers to NPB (January and May 2019).

5 Options

The Service Planning Submission – as considered by NPB 25th January 2019- made the following planning assumptions based on best available evidence:

- For a dispersed population out with the urgent care catchment for Royal Infirmary Edinburgh (RIE) and QEUH, local assessment followed by transfer to the specialist centres is the only feasible patient pathway;

- For the Scottish population, travel distances, and necessary caseload to sustain clinical competence, indicate a three specialist centre service model is optimal; and

- There may be specific benefits/disadvantages to the location of the North Region centre and an options appraisal should be conducted for that element of the service model.

  Subsequently, the options appraisal process for the North component of the new service concluded that Ninewells Hospital would provide the best option for provision of a thrombectomy service within a reasonably short timescale. A more dispersed model for the North was considered and may form part of a future service model.

6 Implementation Issues

As described in earlier papers**, Five** essential components must **all** be provided for any given catchment population to receive a full thrombectomy service.

These essential components are:

1. The training and/or recruitment of sufficient numbers of interventional neuroradiologists or others credentialed as competent to conduct thrombectomy;
2. Provision of bi-planar angiography suites with sufficient staffing and capacity for the number of cases being referred;
3. Ability to capture and report CT angiography in local emergency hospitals to allow the rapid identification of ischaemic stroke patients who meet the clinical criteria for mechanical thrombectomy;
4. Rapid and efficient transfer of patient from local emergency hospitals (LEHs) to the nearest of the three thrombectomy centres by Scottish Ambulance Service;
5. Provision of recurring and non-recurring funds for the above, both revenue and capital.

The implementation plan for a new Scottish service will therefore be complex, and will only succeed with the close support of local, regional and national NHS bodies, third sector and SGH&SCD.

The current position of planning for this service is described below.

6.1 Planning Across Scotland

Activity and transfer times modelling: Exeter University has been engaged by TAG to build a model which describes the impact on the time-to-thrombectomy arising from the individual components in the patient pathway. This includes, but is not limited to, time-to-thrombolysis, time-to-CTA, transfer time to a thrombectomy centre and time-to-intervention. Exeter University have carried out such work in England to inform the roll-out of their 26 thrombectomy centres. The output of this work will underpin the ongoing development of the pathways across Scotland, including best use of SAS resources.

Scottish Ambulance Service: the SAS planning team have prepared an initial assessment of the work which will be required to complete their section of the overarching business case.

Stroke Nurse Training: with the Scottish Stroke Nurses Forum we have reviewed the London competency framework and establish the areas that will be relevant to the Scottish workforce. This will form the basis of the education programme which will be

developed to up skill staff already trained in thrombolysis to develop the competencies required to support Thrombectomy patients.
Chest Heart and Stroke Scotland (CHSS) have lead on the delivery of Stroke and TIA Assessment Training over the past 9 years and plan to augment this training with a programme on thrombectomy and roll this out using the STAT methodology across Scotland.
We have also asked CHSS to cost the development of a Thrombectomy STARS online module to reinforce this training as an addition to the suite of stroke training tools utilised by all disciplines working in stroke.
Work has started on the national pathway documents for initial assessment at the spoke hospital, and a transfer document and SOP which are available in draft format.

Credentialing: the Council of the General Medical Council confirmed approval to develop a framework to support credentialing when they met in May 2019. They highlighted that training and credentialing in thrombectomy was essential for UK service development. Credentialing would be available to consultants who already had vascular catheter skills (in effect meaning interventional radiologists and interventional cardiologists) and to those without pre-existing catheter skills (ie neurosurgeons, stroke physicians). It is expected that the description of the training and supervising arrangements will be negotiated with the Royal College of Radiologists, and be finalised in 2020.

Dundee has developed a training programme for interventional radiologists based on the use of commercially available mechanical simulators and Dundee's cadaveric simulation system. In parallel, oversight has been agreed from an experienced group of interventional neuroradiologists from Germany (World Federation of Interventional Stroke Treatment) who will certify both the interventional radiologists and their centre. It is anticipated that this programme will satisfy the GMC requirements for credentialing to allow them to undertake thrombectomies in 2020.

CT Angiography (CTA) reporting: it is anticipated that 3000 CTAs will be acquired each year to support the patient pathway. The recent gap-analysis reported that a number of LEHs do not have the ability or capacity to acquire and/or report CTAs over the 24 hour period. There are two emergent options to fill this gap: provision of a central reporting function and/or up-skilling of local stroke physicians with the support of artificial intelligence reporting software. Both of these solutions are being considered in discussion with the imaging and stroke clinical communities.

Business case development and costing: an overarching cost model is being constructed based on national, tertiary and local cost elements, supported by NSS project management and finance functions.

Stakeholder Communications: the spread of this work across all health board areas during the summer months has generated a need for consistent and timeous communications. NHS Lanarkshire will provide comms support to TAG, working closely with SGH&SCD comms. TAG hosted a workshop for clinical stakeholder in

Stirling on 24th June which was well attended from the multi-disciplinary teams across Scotland. Further workshops and communications events will be held through 2019 and 2020.

6.2 Planning for Thrombectomy Centres

The initial planning activity model for three centres assumed:

- West service 24/7 (shared on-call with East) 345 thrombectomies per annum
- East service 24/7 (shared on-call with West) 330 thrombectomies per annum (inc Fife)
- North service 5-day 8-8 service 90 thrombectomies per annum.

The time from onset to thrombectomy is inversely proportional to the subsequent morbidity of a stroke patient. The provision of a service at Ninewells may represent a better option for Fife patients rather that sending all cases to RIE, and this is under consideration. Such a shift would also improve the caseload of the individual operators at Ninewells and improve outcomes.

North Service Provision

Following the recent round of stakeholder meetings and options appraisal, the key planning assumptions for the North service are:

- Thrombectomy will be delivered by credentialed clinicians, interventional radiologists in the first phase;
- The service will be implemented in two phases, dependent on rate of credentialing of the clinical team;
- The numbers of patients being treated in the North is lower than in either of the central belt facilities. Therefore, the capital requirements will focus on the upgrade of an existing IR facility to bi-planar angiography rather than a newbuild as proposed in QEUH and RIE.
- The thrombectomy service will be delivered in Ninewells.
- As a result of the service being hosted by NHS Tayside and located at Ninewells, the Fife will be included in the North catchment population along with Grampian, Highland (exc. Argyll & Bute), Orkney and Shetland.

The North regional service will be implemented in two phases over 2020 as soon as the workforce is trained and can come on-line, assuming GMC approval is given relatively quickly.

East Service Provision

NHS Lothian continue to develop their business case for the provision of thrombectomy at the Royal Infirmary Edinburgh, within the new neurosciences centre.

The service for the East region (Borders, Lothian and Forth Valley with Fife under discussion) would be developed over four distinct phases.

NHS Lothian has developed a planning framework which will oversee the implementation and delivery of a Thrombectomy service in Edinburgh. This comprises a clinically led Thrombectomy Delivery Group (TDG) which oversees 2 emerging workstreams – Part 1 pathway (onset to decision to refer) and Thrombectomy Centre delivery.
Whilst the planning framework is in development and awaiting Acute Services senior management team approval, it is anticipated the TDG will scope and plan for a phased implementation across 4 main phases.

In overview these phases are currently identified as:

Phase 1: preparatory phase. Will include key elements such as extending Stroke outreach to ED 24/7; education of Stroke physicians in assessing patients for Thrombectomy; scoping additional requirements for CT angiography; commencing recruitment to enable phase 2 & 3 of delivery.

Phase 2: delivery of service 8am to 5pm Monday to Friday within Department of Clinical Neurosciences*.

Phase 3: delivery of extended day service Monday to Friday.
The business case for the second angio suite at DCN required to deliver a 24/7 service will be progressed throughout the planning for and delivery of the first 3 phases.

*It is not currently known whether the delay in opening of the new DCN will impact on the approval / acquisition of a second angio suite.

Phase 4: delivery of 24/7 service across the East region.

The timing of these phases cannot be agreed at this stage. It will be contingent, at a minimum, on stability within the national haemorrhagic stroke service and approval of additional resources to support increased staffing across the multi-disciplinary team.

<u>West Service Provision</u>

The initial planning assumption remains that the west thrombectomy centre will receive stroke patients referred from LEHs in Argyll & Bute, Greater Glasgow & Clyde, Dumfries & Galloway, Lanarkshire and Ayrshire & Arran.

NHS Greater Glasgow & Clyde's (NHSGGC) Stroke Improvement Steering Group are overseeing the implementation of the local strategy to improve services for people at risk or who have had a stroke. Clinical teams are leading work to deliver improved pathways which will facilitate a phased implementation of the strategy

where the longer term ambition is to deliver a single hyperacute pathway within NHSGGC.

The remit of the Group has been extended to include the development of plans for the introduction of a West of Scotland Thrombectomy service including rapid access to CTA and thrombolysis where clinically appropriate. Current planning assumption is that thrombectomy would be delivered at a major centre with an on-site hyper acute stroke unit and neurosciences, therefore the West of Scotland service would be delivered from the Queen Elizabeth University Hospital Campus.

In order to progress this development, work has begun to identify a physical location to establish a centre for thrombectomy. This will include consideration of interim options alongside the development of the longer term solution.

Discussions have commenced with NHS Lothian to develop a joint workforce plan to stabilise the current INR service across the central belt and support recruitment. This may allow both East and West centres to progress plans to develop a sustainable INR and thrombectomy service across the two regions.

A high level plan with timescales will be developed for the next TAG meeting in September.

6.3 Local Service Provision

The three-centre model will see a hub and spoke clinical pathway developed between each local emergency hospital (i.e. a unit where thrombolysis is administered and a CTA can be acquired) and the respective regional thrombectomy centre. Currently there is variation in the ability of local emergency hospitals to meet the standards for time to thrombolysis: a renewed effort to achieve the standard in all local emergency hospitals will be appropriate

TAG has been engaging will all territorial boards to begin the planning process for part 1 of that pathway: from stroke onset through to decision to refer for thrombectomy.

Each board has designated a planning lead to gain an initial understanding of where there are gaps in their ability to deliver the patient pathway, with a main focus on CTA. Initial analysis was received by TAG during week of 12th August, and TAG members are now supporting the designated leads in the production of business plans, including resourcing and timescale for implementation.

Table: Hubs and Spokes for Thrombectomy Referrals

Local Emergency Hospital	Thrombectomy Centre	Throbolysis episodes p.a.*
ARI	North	129
Ayr	West	2

Balfour	North	6
Belford	North	8
Borders	East	20
Caithness	North	5
Crosshouse	West	75
Dr Grays	North	15
DGRI	West	30
FVRH	East	42
Gilbert Bain	North	5
GRI	West	19
Hairmyres	West	30
L&I	West	2
Monklands	West	49
Ninewells	North	50
PRI	North	20
QUEH	West	222
Raigmore	North	32
RIE	East	126
SJH	East	24
VHK	To be agreed	77
Western Isles	To be agreed	9
Wishaw	West	42
WGH	East	10

* **Scottish Stroke Care Audit 2018/19**

6.4 Business Case and Funding

Following the BCEs meeting in June, SGH&SCD has agreed that some nonrecurring funding will be made available, through TAG, to support the development of business cases and any other planning required to progress the thrombectomy proposals.

At the time of writing proposals have been submitted for a range of measures which include:

- Training for stroke care nurses to support the patient pathway (all Boards)
- Scottish Ambulance Service modelling and planning
- Academic support to the pathway planning process
- Project management support to TAG
- AI support for reporting of CTAs (all Boards)
- Thrombectomy training for interventional radiologists (North)

The minority of territorial boards have identified areas where some local funding would support the ongoing process.

This non-recurring funding bid is currently being collated and will be passed to SG&HSCD for consideration in September.

With respect to recurring funding for the key service elements for MT provision across Scotland, it is anticipated that a composite business case will be drafted by the beginning of October for consideration as part of the proposals for the SG Health budget beyond April 2020.

7 Key Risks

The most significant risks identified so far are:

- Variation in the quality of the thrombolysis pathway across Scotland, which would undermine the effectiveness of thrombectomy;
- Limitations on the ability to deliver CTAs in local emergency hospitals;
- Limits on the ability to train/recruit retain specialists in interventional neuro radiology;
- Limited bi-planar angiography capacity;
- Requirement for a credentialing programme being agreed at a UK level;
- Potential for post-MT bed blocking in thrombectomy centres if patients cannot be repatriated to their local Stroke centre after the initial 36-48hr treatment process.
- Available HDU capacity within the 3 Thrombectomy centres; and
- Financial pressures (capital and revenue) limiting NHS Scotland's ability to develop the new clinical service.

8 Resource Implications

A "top-down" overall cost model was reported to the January NPB. The composite business case (as per 6.4, above) will describe the "bottom-up" costing work which will include service elements to be provided once for Scotland, development of the three thrombectomy centres, and the necessary service improvements with LEHs to deliver part 1 of the patient pathway.

9 Stakeholder Engagement

A stakeholder group has been formed on the basis of the original, larger, TAG membership list prepared by the Directors of Planning Group in early 2018. This group met in December 2018 and received a briefing on the planning assumptions and emergent conclusions being reached by TAG core group. Feedback from this meeting was used to inform the preparation of the January Submission.

North Regional Planning Group hosted a stakeholder engagement session in Perth recently, and further engagement will take place through options appraisal for that service element.

NHS Lanarkshire has kindly provided some communications management support to TAG, and communications and engagement plan is under review by TAG.

10 Recommendations to NPB

NPB is asked to:

1. **Note** the agreement of Board Chief Executives that all NHS Boards will participate in the preparation of a business case for the provision of a 24/7 thrombectomy service;
2. **Note** the current work ongoing at national, regional and local level to identify the means to implement the five key elements of a thrombectomy service;
3. **Agree** that a request for in-year funding will be made to SGH&SCD by TAG; and
4. **Agree** to receive further reports from TAG.

Dr Angus Cameron — Chair, TAG

Colin Lauder — Directors of Planning Group

16th August 2019

Appendix 1 – TAG Core membership

[Redacted: exemption 38(1)(b) (personal information)]

PfG 2019/20 Commitment	Risks	Additional Information	2019/20 Milestones	2019				2020								
				Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
"ensure that a national planning framework is in place for a high quality and clinically safe thrombectomy service"	SG sit as representatives on the NPB therefore limited control in relation to timescales and progress.	This work is being undertaken by the Thrombectomy Advisory Group and the National Planning Board. Work has been underway for over a year.	Possible first thrombectomy service in Lothian/Dunde													
			NP framework development													