

National Institute for Health and Care Excellence
IP1026/2 – Mechanical clot retrieval for treating acute ischaemic stroke
Consultation Comments table
IPAC date: Friday 18 December 2015

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				Please respond to all comments
1	Consultee 5 Company	1.1	██████ welcomes the “normal arrangements”™ recommendation by NICE for mechanical clot retrieval for treating acute ischaemic stroke, and the updated recommendations around use of this procedure. We consider this to be reflective of the current evidence base, and the comments received by the Specialist Advisers.	Thank you for your comment. The consultee agrees with the main recommendation.
2	Consultee 3 NHS Professional Consultant Neuroradiologist	1.1	I trained as an interventional neuroradiologist in the center which performed the first endovascular thrombolysis for basilar artery occlusion. I performed my first ia stroke treatment in 1993 and have been involved in stroke imaging and intervention since then. I agree with the statements of the neuroradiological experts: There is now level 1 evidence for the efficacy and safety of a procedure which has been performed for more than 20 years abroad.	Thank you for your comment. The consultee agrees with the main recommendation.
3	Consultee 6 Consultant Neuroradiologist	1.1	We were delighted to see that NICE in their recent consultation has recommended mechanical clot retrieval for treating acute ischaemic stroke on the basis of efficacy and safety.	Thank you for your comment. The consultee agrees with the main recommendation.

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4	Consultee 7 Stroke Association	1.1	Comments on provisional recommendations We welcome and support NICE's recommendation in section 1.1 that the evidence on mechanical clot retrieval is adequate to support it being made available on the NHS subject to normal arrangements regarding clinical governance, consent and audit for the treatment of ischaemic stroke. This is particularly welcome due to the limited available treatments for acute stroke, which provide poorer outcomes for those with larger clots, who have been shown to benefit most from thrombectomy in clinical trials. We also understand that there are now new mandatory questions on thrombectomy in the Sentential Stroke National Audit Programme, which we hope will be used to help further the evidence base on this innovative new treatment.	Please respond to all comments Thank you for your comment. The consultee agrees with the main recommendation.
5	Consultee 3 NHS Professional Consultant Neuroradiologist	1.1	The joint recommendation of ESO/ESMINT/ESNR should be the basis for high quality service delivery in the UK.	Thank you for your comment. The joint recommendation of ESO/ESMINT/ESNR is described in the overview under 'Existing assessments of this procedure'.

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6	Consultee 14 Company	1	<p>AHA/ASA revised recommendations (Oct 2015) state there is Class I, Level of Evidence A that patients should receive endovascular therapy with a stent retriever if they: have prestroke mRS 0-1, have AIS and received IV r-tPA within 4.5 hours of onset, the causative occlusion is in the ICA or proximal MCA, are age 18 or older, have an NIHSS score of 6 or greater, have an ASPECTS score of 6 or greater, and treatment can be initiated (groin puncture) within 6 hours of symptom onset.</p> <p>Observing patients after IV r-tPA to assess for clinical response before pursuing endovascular therapy is not required to achieve beneficial outcomes and is not recommended (Class III, Level of Evidence B-R)</p> <p>Use of stent-retrievers is indicated in preference to the MERCI device (Class I; Level of Evidence A)</p>	<p>Thank you for your comment.</p> <p>The AHA/ASA revised recommendations are described in the overview under 'Existing assessments of this procedure'.</p>
7	Consultee 14 Company	5	<p>6ESO/ESMINT/ESNR Consensus Statement</p> <p>7AHA/ASA Recommendations, Stroke 2015; 46: 3020-3035.</p> <p>8SNIS Recommendations, Jayaraman et al., J NeuroIntervent Surg 2015; 7 (5): 316.</p>	<p>Thank you for your comment.</p> <p>The joint recommendation of ESO/ESMINT/ESNR and the AHA/ASA recommendations are described in the overview under 'Existing assessments of this procedure'.</p> <p>Jayaraman (2015) is included in appendix A of the overview.</p>

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8	Consultee 14 Company	4	<p>The data from these 5 trials, even though some were halted early due to loss of equipoise, has been categorized as compelling by numerous experts, including leading neurologists*. The American Heart Association / American Stroke Association revised its stroke treatment recommendations citing Class 1, Level A evidence in support of endovascular therapy with a stent-retriever in specific patients.</p> <p>“AHA/ASA revised recommendations state there is Class I, Level of Evidence A that patients should receive endovascular therapy with a stent retriever if they: have prestroke mRS 0-1, have AIS and received IV r-tPA within 4.5 hours of onset, the causative occlusion is in the ICA or proximal MCA, are age 18 or older, have an NIHSS score of 6 or greater, have an ASPECTS score of 6 or greater, and treatment can be initiated (groin puncture) within 6 hours of symptom onset.</p> <p>....Use of stent-retrievers is indicated in preference to the MERCI device (Class I; Level of Evidence A)”</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The joint recommendation of ESO/ESMINT/ESNR and the AHA/ASA recommendations are described in the overview under ‘Existing assessments of this procedure’.</p>

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9	Consultee 14 Company	1	<p>*Grotta & Hacke, Stroke 2015; 46: 1447-1452 - “The main take home points for neurologists from the body of evidence contained in the 5 trials are (1) IAT is a potentially effective treatment and should be offered to patients who have documented occlusion in the distal ICA or M1 arteries, have a relatively normal NCCT, significant neurological deficit, and can have recanalization within 6 hours of LSN; (2) benefits refer to patients receiving r-tPA before IAT; r-tPA should not be withheld if the patient meets criteria, and benefit in patients who do not receive r-tPA or have r-tPA exclusions requires further study; (3) favorable results occur when IAT is performed at an endovascular stroke center by a coordinated multidisciplinary team that extends from the prehospital stage to the endovascular suite, minimizes time to recanalization, uses stent-retriever devices, and avoids general anesthesia (GA).” (Grotta & Hacke)</p> <p>(Pierot & Derdeyn, Stroke 2015; 46: 1440-1446 – “EVT with stent-retrievers is now proven effective and is dramatically so, for a well-defined subset of patients with acute ischemic stroke. Current practice needs to incorporate the lessons from the recent trials: careful patient selection and optimizing time to reperfusion and reperfusion rate are critical to providing any benefit to our patients.”)</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Grotta JC (2015) was identified in the original literature search but it was not included in the overview because it is a review.</p> <p>Pierot L (2015) was identified in the original literature search but it was not included in the overview because it is a review.</p>

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10	Consultee 11 Company	General	<p>Please find attached references of clinical evidence in support of the comments above, and we wish to further thank NICE for considering this evidence and our comments.</p> <p>REFERENCES:</p> <p>1- Hacke W. The results of the recent thrombectomy trials may influence stroke care delivery: are you ready? Vol 10, July 2015, 646-650. 2015 World Stroke Organization DOI: 10.1111/ijis.12541</p> <p>2- James C. Grotta: Stroke Neurologist's Perspective on the New Endovascular Trials, MD Stroke. 2015;46:00-00. DOI: 10.1161/STROKEAHA.115.008384</p> <p>3 - Consensus statement on mechanical thrombectomy in acute ischemic stroke " ESO/Karolinska Stroke Update February 2015 in collaboration with ESMINT and ESNR.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Hacke W (2015) is an editorial and so does not meet the criteria for inclusion in the overview.</p> <p>Grotta JC (2015) was identified in the original literature search but it was not included in the overview because it is a review.</p> <p>The consensus statement from the ESO/ESMINT/ESNR is described in the overview under 'Existing assessments of this procedure'.</p>

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11	Consultee 6 Consultant Neuroradiologist	1	<p>I wanted to take this opportunity to highlight research recently carried out by our group and that has been published in September 2015 in the high impact journal Stroke (please see link below).</p> <p>http://stroke.ahajournals.org/content/46/9/2591.full</p> <p>It is the first and only study to date, to perform a model based cost-utility analysis for mechanical thrombectomy in the UK. The model shows that, compared to intra venous tissue - type plasminogen activator alone, the ICER (incremental cost-effectiveness ratio) of mechanic thrombectomy was £7061 per QALY (quality adjusted life year) gained from a UK NHS and personal social services perspective. The ICER was based on incremental costs of £7431 per patient and a gain of 1.05 QALYs per patient accrued over a 20 year period. A sensitivity analysis demonstrated the robustness of these results.</p> <p>Inclusion of this work would allow recommendation of this procedure to be made on cost-effectiveness grounds in addition to efficacy and safety, which would be very much aligned with the NHS 5 Year Forward View. This would certainly facilitate implementation and commissioning of this procedure through discussions with local Clinical Commissioning Groups. Kind regards,</p> <p>██████</p>	<p>Please respond to all comments</p> <p>Thank you for your comment</p> <p>The cited reference is: Ganesalingam J, Pizzo E, Morris S et al. (2015) Cost-Utility Analysis of Mechanical Thrombectomy Using Stent Retrievers in Acute Ischemic Stroke. Stroke 46:2591-2598</p> <p>The NICE Interventional Procedures programme does not consider cost-effectiveness.</p>

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12	Consultee 13 Royal College of Radiologists and the British Society of Neuroradiologists	General	The guidance does not include a section on resources. In addition to the major resources required to deliver the thrombectomy service there is a need to provide a minimum of high quality CT brain and CT angiographic imaging at all centres where these patients present. This requires the rapid availability of scanners, radiographers trained to perform more than a basic CT head scan and expert interpreters, all on a 24/7 basis.	Thank you for your comment. Interventional Procedure Guidance considers whether a procedure is safe and efficacious. It is not within the remit of the programme to consider resources or cost effectiveness.
13	Consultee 2/4 UK Neurointerventional Group	1.2	<p>From the UK Neurointerventional Group</p> <p>- this is a recognised NICE stakeholder & a Special Interest Group of the Royal College of Radiologists</p> <p>We are pleased to see the updated provisional guidance on this topic from NICE IPP. However, we do have some major concerns over the wording of a key recommendation.</p> <p>Re: Recommendation 1.2</p> <ul style="list-style-type: none"> It would be appropriate to clarify what brain imaging is meant here. It is not just the intracranial circulation that needs to be assessed. Advanced brain imaging is critical to the proper patient selection for a procedure that is beneficial (in expert hands) but has significant risks. Our suggested wording would be: “...interpretation of imaging of the brain (including ASPECTS & collateral CTA scoring or CT Perfusion or MRI) and the extra and intracranial circulations by CT/MR angiography.” <p>The suggested wording makes it clear that advanced brain imaging is required but as the optimum imaging strategy remains uncertain it doesn't mandate any particular approach.</p>	<p>Thank you for your comment.</p> <p>Section 1.2 of the guidance has been changed.</p> <p>Section 6.3 of the guidance notes that there is uncertainty about the best type of imaging to guide patient selection.</p>

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14	Consultee 8 British Society of Neuroradiologists	1.2	<p>Comments from The British Society of Neuroradiologists (BSNR) Thank you for the opportunity to review and consider this draft guidance. We would like to comment on the following section Provisional recommendations 1.2 Selection of patients for mechanical clot retrieval for treating acute ischaemic stroke should be done by clinicians experienced in the use of thrombolysis for stroke and in interpretation of imaging of the brain and intracranial circulation. The procedure should only be carried out by specialists with regular experience in intracranial endovascular interventions, with appropriate facilities and support.</p> <ul style="list-style-type: none"> The required imaging should include the brain and the craniocervical circulation, not just the intracranial circulation. While the exact imaging used may vary from centre to centre and in all likelihood will evolve as new evidence emerges, some clarification of the imaging required would be helpful. A suggestion would be “....interpretation of imaging of the brain (including ASPECTS & collateral CTA scoring or CT Perfusion or MRI) and the extra and intracranial circulations by CT/MR angiography.” The terms used in the second sentence are vague and could be interpreted very differently by different individuals and organisations. Could the guidance be more specific in defining these important parameters? 	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Section 1.2 of the guidance has been changed.</p> <p>Section 6.3 of the guidance notes that there is uncertainty about the best type of imaging to guide patient selection.</p>

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15	Consultee 13 Royal College of Radiologists and the British Society of Neuroradiologists	1.2	<p>Provisional recommendations</p> <p>1.2 Selection of patients for mechanical clot retrieval for treating acute ischaemic stroke should be done by clinicians experienced in the use of thrombolysis for stroke and in interpretation of imaging of the brain and intracranial circulation. The procedure should only be carried out by specialists with regular experience in intracranial endovascular interventions, with appropriate facilities and support.</p> <p>• The required imaging should include the brain and the craniocervical circulation, not just the intracranial circulation. While the exact imaging used may vary from centre to centre and in all likelihood will evolve as new evidence emerges, some clarification of the imaging required would be helpful. A suggestion would be 'interpretation of imaging of the brain (including ASPECTS & collateral CTA scoring or CT Perfusion or MRI) and the extra and intracranial circulations by CT/MR angiography.'</p>	<p>Thank you for your comment.</p> <p>Section 1.2 of the guidance has been changed.</p> <p>Section 6.3 of the guidance notes that there is uncertainty about the best type of imaging to guide patient selection.</p>
16	Consultee 7 Stroke Association	1.2	<p>Section 1.2 states that the selection of patients for thrombectomy should only be done by clinicians with experience in, 'interpretation of imaging of the brain and intracranial circulation. The procedure should only be carried out by specialists with regular experience in intracranial endovascular interventions, with appropriate facilities and support' but the guidance does not set out what type of imaging should be used or what 'regular experience' and 'appropriate facilities and support' would look like.</p>	<p>Thank you for your comment.</p> <p>The Committee may wish to consider changing the wording of section 1.2 of the guidance to:</p> <p>Section 1.2 of the guidance has been changed.</p> <p>Section 6.3 of the guidance notes that there is uncertainty about the best type of imaging to guide patient selection.</p>

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17	Consultee 2/4 UK Neurointerventional Group	1.2	All of the level 1 evidence to date supporting mechanical clot retrieval is based on the procedure being carried out by experienced neurointerventionists (of various specialist backgrounds) in neuroscience units with neurosurgical and neurocritical care support immediately available. On patient safety grounds this fact should be explicit in the amended guidance. Our suggested wording would be: "The procedure should be carried out by trained neurointerventional specialists with regular experience in intracranial endovascular interventions, with appropriate facilities and neuroscience support"	Thank you for your comment. Section 1.2 of the guidance has been changed.
18	Consultee 2/4 UK Neurointerventional Group	1.2	This is about protecting patients. A neurointerventionist may be an interventional neuroradiologist but they also come from a number of other specialties by initial specialist training (internationally radiological, neurosurgical or neurological provide the majority). However it is their subsequent neuroimaging and neurointerventional training that is key to undertaking this cerebral mechanical clot retrieval procedure both safely and effectively. There is no evidence that non neurointerventionists can undertake the procedure safely & effectively. Stating that operators are "trained neurointerventionists" would give a clear expectation & reassurance that patients would be able to rely upon. Defining specialists would assist commissioners.	Thank you for your comment. Section 1.2 of the guidance has been changed.

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19	Consultee 3 NHS Professional Consultant Neuroradiologist	1.2	<p>It may be beneficial in small clots as the time to reperfusion may be shorter. This is currently not equally evidence based.</p> <p>The procedure is highly time critical.</p> <p>Evidence is entirely based on the procedure being performed by interventional neuroradiologists with expertise in stroke.</p> <p>The procedure requires a different skill set from cardiac or general body vascular intervention and should be performed or taught in dedicated centres by practitioner experienced in intracranial intervention.</p>	<p>Thank you for your comment.</p> <p>Section 1.2 of the guidance has been changed.</p>
20	Consultee 13 Royal College of Radiologists and the British Society of Neuroradiologists	1.2	<p>â€¢ The terms used in the second sentence are vague and could be interpreted very differently by different individuals and organisations. Could the guidance be more specific in defining these important parameters?</p> <p>o In the 7 recent randomised control trials demonstrating the benefit of mechanical clot retrieval, the operators were all experienced neurointerventionists performing the procedure in neuroscience centres. Currently in the UK, intracranial endovascular procedures are performed almost entirely by radiologists fully trained in interventional neuroradiology (INR). There is one exception, a neurosurgeon who has had full training in INR equivalent to the higher training undergone by a radiologist. Any future practitioner of mechanical thrombectomy should receive equivalent specialist training in INR whichever their primary specialty.</p>	<p>Thank you for your comment.</p> <p>Section 1.2 of the guidance has been changed.</p>

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21	Consultee 8 British Society of Neuroradiologists	1.2	<p>o In the 7 recent randomised control trials demonstrating the benefit of mechanical clot retrieval, the operators were all experienced neurointerventionists performing the procedure in neuroscience centres. Currently in the UK, intracranial endovascular procedures are performed almost entirely by radiologists fully trained in interventional neuroradiology (INR). There is one exception, a neurosurgeon who has had full training in INR equivalent to the higher training undergone by a radiologist. Any future practitioner of mechanical thrombectomy should receive equivalent specialist training in INR whichever their primary specialty.</p>	<p>Thank you for your comment.</p> <p>Section 1.2 of the guidance has been changed.</p>
22	Consultee 7 Stroke Association	1.2	<p>Given the specialist nature of this procedure, and the fact that the evidence was largely developed in specialist centres with highly skilled and experienced staff, with specialist expertise, highly efficient systems and using the right equipment, we think that this guidance should provide more specific recommendations on these issues in order to ensure that every patient receives high quality care regardless of where they are treated. We are also aware that in order to fully implement thrombectomy, the NHS will need to expand the number of interventional neuroradiologists as well as training additional clinicians in order to meet the likely demand for this treatment. The training will need to include: neurosciences, image interpretation, case selection, operative techniques and supporting clinical trials.</p>	<p>Thank you for your comment.</p> <p>Section 1.2 of the guidance has been changed.</p>

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23	Consultee 10 NHS Professional Consultant Stroke Physician	1.2	There will be a need for other speciality involvement eg. Cardiologists(as they already perform cardiac angioplasty so will be easier and quicker to train) to provide 7 days a week 24 hour service thrombectomy cover as there are few interventional neuro radiologists in some places . If we only involve interventional neuro radiologists, providing thrombectomy cover round the clock will be challenging ,there will be inequity in providing quality care to all stroke patients throughout UK.	Please respond to all comments Thank you for your comment. Section 1.2 of the guidance has been changed.
24	Consultee 12 British Cardiovascular Intervention Society	1.2	Most cardiologists are not trained in these neuro-interventions and would require neurointerventionalists to train them. Such a process is feasible, as has been demonstrated in parallel ground-breaking catheter-based interventional fields, such as that of transcatheter aortic valve implantation. BCIS look forward to contributing to discussions on how future training programmes could be developed for those BCIS members who are willing and able to be effectively trained in these techniques, to increase the pool of catheter specialists able to provide a 24/7 stroke service. While we dont wish to change the wording of this recommendation we suggest that it should be assumed to include cardiovascular interventionists with appropriate training.	Thank you for your comment. Section 1.2 of the guidance has been changed.

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25	Consultee 12 British Cardiovascular Intervention Society	1.2	<p>Re: The procedure should only be carried out by specialists with regular experience in intracranial endovascular interventions, with appropriate facilities and support.</p> <p>Section 1.2</p> <p>We agree with this recommendation but we believe there are only approximately 90 interventional neuroradiologists in the UK who are trained in these techniques. This may not be enough to deliver 24/7 programmes to all stroke patients in the UK. The UK's 705 interventional cardiologists are high volume, catheter-directed, vascular interventional specialists with a broad range of skills, delivering 24/7 hyperacute heart attack interventions on over 23,000 acutely unwell patients per year. If it is felt that there is a need for other UK catheter specialists in the field of cardiovascular medicine to assist in stroke thrombectomy programmes, BCIS would be able to provide advice and assistance.</p>	<p>Thank you for your comment.</p> <p>Section 1.2 of the guidance has been changed.</p>
26	Consultee 13 Royal College of Radiologists and the British Society of Neuroradiologists	1.2	<p>The view of the BSNR is that in order to maintain skills at an optimum level, a practitioner should be undertaking as a minimum approximately 50 intracranial procedures per year, some of which will be mechanical thrombectomy.</p>	<p>Thank you for your comment.</p> <p>NICE Interventional Procedure guidance does not usually stipulate the minimum treatment numbers that should be done by a particular practitioner.</p>

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27	Consultee 8 British Society of Neuroradiologists	1.2	The view of the BSNR is that in order to maintain skills at an optimum level, a practitioner should be undertaking as a minimum approximately 50 intracranial procedures per year, some of which will be mechanical thrombectomy.	Please respond to all comments Thank you for your comment. NICE Interventional Procedure guidance does not usually stipulate the minimum treatment numbers that should be done by a particular practitioner.
28	Consultee 3 NHS Professional Consultant Neuroradiologist	1.2	Minimum treatment numbers should be adopted of at least 25 better 50 per year per centre.	Thank you for your comment. NICE Interventional Procedure guidance does not usually stipulate the minimum treatment numbers that should be done in a particular centre.
29	Consultee 9 Royal College of Physicians	1.2	<p>Dear all</p> <p>The RCP is grateful for the opportunity to respond to the above consultation.</p> <p>We have liaised with experts in stroke medicine and would like to make the following comment:</p> <p>Provisional recommendation 1.2 should stress the importance of the involved clinicians keeping up to date with the emerging evidence around the characteristics of which patients are most likely to benefit from the intervention.</p> <p>I would be grateful if you could confirm receipt.</p> <p>Best wishes</p> <p>██████ ██████</p>	<p>Thank you for your comment.</p> <p>This would be expected to happen as part of usual practice and revalidation.</p> <p>Section 6 of the guidance notes that the technique is evolving and lists some of the current uncertainties.</p>

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30	Consultee 2/4 UK Neurointerventional Group	1.2	It should also be made clear that selection of patients is done by both stroke physicians and neurointerventionists in concert and not by one alone	Thank you for your comment. Section 1.2 of the guidance states that 'Selection of patients for mechanical clot retrieval for treating acute ischaemic stroke should be done by clinicians experienced in the use of thrombolysis for stroke and in interpretation of relevant imaging.'
31	Consultee 3 NHS Professional Consultant Neuroradiologist	1.2	Clot extraction should be performed in patients with low chance of recanalisation after iv thrombolysis, i.e. large clot volume or contraindications to thrombolysis.	Thank you for your comment. Section 1.2 of the guidance states that 'Selection of patients for mechanical clot retrieval for treating acute ischaemic stroke should be done by clinicians experienced in the use of thrombolysis for stroke and in interpretation of relevant imaging.'
32	Consultee 13 Royal College of Radiologists and the British Society of Neuroradiologists	1.2	<ul style="list-style-type: none"> o Facilities and support include angiographic equipment and specialist radiographic and nursing staff together with anaesthetic and specialist stroke clinicians. The availability of support from neurosurgery and dedicated neuro critical care is also important. o Angiographic equipment should ideally comprise a biplanar system with digital subtraction (DSA) and be optimised for neuroangiography. A single plane system may suffice as a backup. Some angiographic systems, notably those typically used for cardiac interventions, are not suitable for intracranial endovascular procedures without considerable modification. 	Thank you for your comment. The Committee may wish to consider changing the wording of section 1.2 of the guidance to: Section 1.2 of the guidance has been changed.

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
33	Consultee 8 British Society of Neuroradiologists	1.2	<ul style="list-style-type: none"> o Facilities and support include angiographic equipment and specialist radiographic and nursing staff together with anaesthetic and specialist stroke clinicians. The availability of support from neurosurgery and dedicated neuro critical care is also important. o Angiographic equipment should ideally comprise a biplanar system with digital subtraction (DSA) and be optimised for neuroangiography. A single plane system may suffice as a backup. Some angiographic systems, notably those typically used for cardiac interventions, are not suitable for intracranial endovascular procedures without considerable modification. 	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee may wish to consider changing the wording of section 1.2 of the guidance to:</p> <p>Section 1.2 of the guidance has been changed,</p>
34	Consultee 14 Company	2.1	<p>Section 2.1</p> <p>Acute ischemic stroke is typically caused by arterial thrombosis or embolism. However, cerebral venous thrombosis is a rarer cause of acute ischemic stroke with similar symptoms to arterial ischemia. It's epidemiology is not well established, but hints of somewhere around 1:62.2 to 1:8.5 causes of stroke are due to this. Typically, doctors tend to quote 1% to 2% of all strokes are due to this cause.</p> <p>http://stroke.ahajournals.org/content/26/7/1193.full</p> <p>The reason this is important is because mechanical thrombectomy has been performed for cerebral venous thrombosis with success.</p> <p>http://stroke.ahajournals.org/content/early/2015/04/21/STROKEAHA.114.007465</p> <p>http://www.ncbi.nlm.nih.gov/pubmed/23313983</p>	<p>Thank you for your comment.</p> <p>Section 2.1 of the guidance has been changed.</p> <p>This guidance only relates to the use of mechanical thrombectomy for treating patients with acute ischaemic stroke.</p>

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35	Consultee 14 Company	3.1	Section 3.1 Similar to notes for 2.1, mechanical clot retrieval has also been performed for cerebral venous thrombosis	Thank you for your comment. This guidance only relates to the use of mechanical thrombectomy for treating patients with acute ischaemic stroke.
36	Consultee 14 Company	2.3	Section 2.3: The target population for mechanical thrombectomy is patients experiencing an acute ischemic stroke due to a proximal or large neurovascular vessel occlusion. Patients with an occlusion of a major intracranial artery, such as the internal carotid artery (ICA), middle cerebral artery (MCA), or basilar artery(BA) have a very poor prognosis if the occlusion is not opened. (Jayaraman MV, Hussain MS, Abruzzo T, et al. Embolectomy for stroke with Emergent Large Vessel Occlusion (ELVO): Report of the Standards and Guidelines committee of the Society of NeuroInterventional Surgery. J NeuroIntervent Surg 2015;7:316-21: “The natural history of patients with acute ischemic stroke and occlusion of a major intracranial vessel such as the internal carotid artery (ICA), middle cerebral artery (MCA), or basilar artery is dismal, with high rates of mortality and low rates of disability-free survival... Among acute ischemic stroke, ELVO accounts for the greatest proportion of patients with long-term disability.”)	Thank you for your comment. The cited article is included in appendix A of the overview. Section 6.3 of the guidance states that there is uncertainty about the ‘selection of patients with strokes in different parts of the brain (specifically anterior and posterior circulation areas)’.

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37	Consultee 7 Stroke Association	3.1	Section 3.1 outlines the procedure for mechanical clot retrieval seen in clinical trials, setting out that patients have scans, followed by a thrombectomy. However, the wording here is slightly misleading as the published literature shows that the vast majority of patients in studies had thrombolysis first before having a mechanical clot retrieval. The way this is worded makes the reverse seem true. Further, the consensus statement published in February 2015 by the European Stroke Organisation states that, 'mechanical thrombectomy should not prevent the initiation of intravenous thrombolysis where this is indicated, and intravenous thrombolysis should not delay mechanical thrombectomy.'	Thank you for your comment. Section 3.1 of the guidance has been changed.
38	Consultee 7 Stroke Association	3.1	Section 3.1 also states 'the procedure is done with patients under sedation but general anaesthesia is sometimes used,' but does not provide guidance that may help clinicians decide whether sedation or general anaesthesia is most appropriate for their patients. We think a recommendation on this should be included here.	Thank you for your comment. This is not within the remit of the guidance.

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
39	Consultee 7 Stroke Association	3.2	<p>Section 3.2 notes that trials have used different types of device and different techniques. However, it is clear from published literature that ‘second generation’ devices provide significantly improved clinical outcomes, and therefore we feel a stronger recommendation on the type of device which should be used would be helpful.</p> <p>Section 3.3 should state that the vast majority of patients in the trials had thrombectomy within 4.5 hours rather than stating only it should be delivered ‘as soon as possible.’</p>	<p>Thank you for your comment.</p> <p>Section 3 of the guidance is intended to be a brief summary of the way the procedure is typically done.</p> <p>Section 6.1 of the guidance states: ‘The Committee noted that the technology used in mechanical clot retrieval for treating acute ischaemic stroke is evolving and that outcomes may vary between different types of retrieval device. Most of the evidence considered by the Committee was based on the use of stent retrievers.’</p> <p>Section 6.3 of the guidance notes that there is still uncertainty about the precise relationship between the interval from the onset of symptoms to treatment and clinical outcomes</p> <p>Most of the trials described in table 2 of the overview aimed to treat patients 6 to 8 hours after the onset of stroke symptoms.</p>
40	Consultee 7 Stroke Association	6.1	<p>Again, section 6.1 should make reference to new research which sets out that the second generation devices offer improved clinical outcomes over the devices used in earlier trials.</p>	<p>Thank you for your comment.</p> <p>The Committee considered this comment but decided not to change the guidance.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
41	Consultee 14 Company	6.3	<p>Section 6.3:</p> <p>The most recent trials that demonstrated statistically significant benefit to endovascular therapy as compared to IV t-PA alone were conducted using more advanced technology – stent-retrievers. The evidence shows that use of stent-retrievers led to high rates of rapid recanalization and the associated good clinical outcomes. The recanalization rates were higher not only than the IV t-PA only arm, but also in comparison to the earlier trials where first-generation retrievers like the Merci, and first-generation aspiration devices like Penumbra, were utilized. Thus, the data strongly supports the use of the stent-retriever category of devices.</p> <p>(Pierot & Derdeyn, Stroke 2015; 46: 1440-1446 – “The data from these trials demonstrate the dramatic technological improvement using Stentriever”)</p> <p>(ESO/ESMINT/ESNR Consensus – “there is very good evidence for early thrombectomy with stent retrievers. There is good evidence to favour stent retrievers over the MERCI™ device. At this moment only limited data on other types of recanalization devices such as the Penumbra™ system are available”)</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee considered this comment but decided not to change the guidance.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
42	Consultee 11 Company	General	While we acknowledge it is not the role of the IP programme to consider fully the comparative effectiveness of competing technologies, in this particular evidence summary the majority of the clinical (inc RCT) evidence was undertaken using the stent retrieval technique. Importantly for readers of this guidance document, it should be clearer that there is little clinical evidence that the results of the stent retrieval trials would apply to other clot retrieval techniques and sequencing of these techniques during the procedure [ref 1, 2, 3)].	Please respond to all comments Thank you for your comment. Section 6.1 of the guidance states ‘The Committee noted that the technology used in mechanical clot retrieval for treating acute ischaemic stroke is evolving and that outcomes may vary between different types of retrieval device. Most of the evidence considered by the Committee was based on the use of stent retrievers.’
43	Consultee 7 Stroke Association	4 and 5	In sections 4 and 5, which review the evidence from the clinical trials on the safety and efficacy of mechanical clot retrieval, it would be helpful to include references, and top line information on the device used as well as patient selection criteria and clinical pathway. This will help ensure the guidance is as practical as possible to help support local decision making in areas that wish to offer this procedure, as some local areas are already developing services and it makes sense to ensure they are the best possible and that others can learn from what they are doing.	Thank you for your comment. Further details of the evidence described in the guidance are provided in the overview for the procedure, which is published on the NICE website to accompany the guidance. This includes the full references, details of patient selection criteria and the specific devices used.

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
44	Consultee 14 Company	4	<p>Section 4:</p> <p>Five recent RCTs (MR CLEAN, ESCAPE, Extend IA, SWIFT PRIME and REVASCAT) demonstrated that mechanical thrombectomy administered within 6 to12 hours after stroke onset is effective and safe and delivered statistically significant improvements in clinical outcomes in patients with large vessel occlusions as compared to IV t-PA alone. Intra-arterial therapy was consistently favored vs. the control arm with a number needed to treat for one additional good outcome of ~4.</p> <p>(Grotta & Hacke, Stroke 2015; 46: 1447-1452 – “despite differences in the timing and amount of recanalization achieved, there was a consistent difference across all studies in good outcome between the interventional and control arms favoring IAT of 14% to 31% (number needed to treat for one additional good outcome, ≈4;Figure). Variability in benefit between studies probably reflects differences in the patients selected irrespective of IAT treatment.... The consistency and logic of the results can make neurologists confident that they should refer similar acute stroke patients as evaluated in these IAT trials.....”)</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The 5 RCTs named by the consultee are included in table 2 of the overview.</p> <p>Grotta JC (2015) was identified in the original literature search but it was not included in the overview because it is a review.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
45	Consultee 14 Company	4	<p>(Campbell et al, Endovascular stent thrombectomy: the new standard of care for large vessel ischaemic stroke.Lancet Neurology 2015 Aug;14(8):846-54 :</p> <p>, Despite differences in the details of eligibility requirements, all these trials required proof of major vessel occlusion on non-invasive imaging and most used some imaging technique to exclude patients with a large area of irreversibly injured brain tissue. The results indicate that modern thrombectomy devices achieve faster and more complete reperfusion than do older devices, leading to improved clinical outcomes compared with intravenous alteplase alone. The number needed to treat to achieve one additional patient with independent functional outcome was in the range of 3.2–7.1 and, in most patients, was in addition to the substantial efficacy of intravenous alteplase. No major safety concerns were noted, with low rates of procedural complications and no increase in symptomatic intracerebral haemorrhage.... On the basis of available trial data, intravenous alteplase remains the initial treatment for all eligible patients within 4.5 h of stroke symptom onset. Those patients with major vessel occlusion should, in parallel, proceed to endovascular thrombectomy immediately rather than waiting for an assessment of response to alteplase, because minimising time to reperfusion is the ultimate aim of treatment”)</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Campbell et al. (2015) was identified in the updated literature search but it will not be included in the overview because it is a review.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
46	Consultee 14 Company	4	(Pierot & Derdeyn, Stroke 2015; 46: 1440-1446 - "These data confirm the benefit of early mechanical reperfusion for selected patients with large vessel occlusion and recent ischemic stroke. The strongest evidence is for patients treated with intravenous tPA" " In the most recent trials (MR CLEAN, ESCAPE, EXTEND-IA, and SWIFT PRIME), clinical outcome at 3 months was better in EVT group. .. The 2 main differences between the positive and negative trials were (1) the mandatory use of CTA or MRA for the demonstration of a large vessel occlusion by CTA or MRA...and) and (2) the use of latest generation devices (stent-retrievers) mandatory in EXTEND-IA, SWIFT PRIME, recommended (ESCAPE) and widely used in MR CLEAN. In ESCAPE and MR CLEAN EVT stent-retrievers were used in 86.1% and 97.4% cases, respectively.)	Please respond to all comments Thank you for your comment. Pierot L (2015) was identified in the original literature search but it was not included in the overview because it is a review.

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
47	Consultee 14 Company	4	<p>*Grotta & Hacke, Stroke 2015; 46: 1447-1452 - “The main take home points for neurologists from the body of evidence contained in the 5 trials are (1) IAT is a potentially effective treatment and should be offered to patients who have documented occlusion in the distal ICA or M1 arteries, have a relatively normal NCCT, significant neurological deficit, and can have recanalization within 6 hours of LSN; (2) benefits refer to patients receiving r-tPA before IAT; r-tPA should not be withheld if the patient meets criteria, and benefit in patients who do not receive r-tPA or have r-tPA exclusions requires further study; (3) favorable results occur when IAT is performed at an endovascular stroke center by a coordinated multidisciplinary team that extends from the prehospital stage to the endovascular suite, minimizes time to recanalization, uses stent-retriever devices, and avoids general anesthesia (GA).” (Grotta & Hacke)</p> <p>(Pierot & Derdeyn, Stroke 2015; 46: 1440-1446 – “EVT with stent-retrievers is now proven effective and is dramatically so, for a well-defined subset of patients with acute ischemic stroke. Current practice needs to incorporate the lessons from the recent trials: careful patient selection and optimizing time to reperfusion and reperfusion rate are critical to providing any benefit to our patients.”)</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The 2 cited papers are not included in the overview because they are reviews.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
48	Consultee 14 Company	5	<p>Section 5.0:</p> <p>. The evidence suggests that mechanical thrombectomy is safe – with regard to all-cause mortality at 90 days, SICH and recurrent stroke - when compared with standard medical care alone, in selected patients. There remains insufficient evidence, however, to determine the significance or otherwise of device- and/or procedure-related complications which may be associated with this intervention. It appears that the results of the five trials published most recently have acted as a ‘watershed’ for mechanical thrombectomy, with a number of other trials having halted and an apparent sea- change in attitude when compared with that which followed publication of the first three trials in 2013. As a result, numerous professional societies have come together to advocate for the immediate practice of rapid assessment and addition of mechanical thrombectomy as a treatment for patients with large proximal vessel occlusions due to the compelling evidence of clinical benefit, with minimal additional risk, as compared to treatment with IV t-PA alone-6-8. Additional studies will be helpful in further delineating subpopulations and techniques that will further enhance the delivery of optimal care for this devastating disease.</p>	Thank you for your comment.

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
49	Consultee 7 Stroke Association	6.2	Section 6.2 should also set out that while the published evidence shows that some mechanical clot retrievals were carried out after 7 to 8 hours elapsed from stroke symptom onset, the vast majority of procedures were undertaken within 4.5 hours, which is the same time frame currently set out in clinical guidelines for the administration of thrombolysis.	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Most of the trials described in table 2 of the overview aimed to treat patients 6 to 8 hours after the onset of stroke symptoms.</p> <p>Section 3.3 states that ‘The aim is to perform the procedure as soon as possible after the onset of stroke symptoms.’</p>
50	Consultee 7 Stroke Association	6.3	We agree with the committee’s areas of uncertainty outlined in section 6.3. Additional areas where we feel more evidence is needed, that should be noted in this section, include: the best system or care pathway for delivering thrombectomy in a timely and safe manner – for example using ‘drip and ship’ or other models, and the professional competencies and training required in order to offer the best possible patient outcomes.	<p>Thank you for your comment.</p> <p>Section 6.3 of the guidance currently lists the following uncertainties:</p> <ul style="list-style-type: none"> • the precise relationship between the interval from the onset of symptoms to treatment and clinical outcomes • the best type of imaging to guide patient selection • the best kind of retrieval device • whether to use clot retrieval plus thrombolysis or clot retrieval alone • selection of patients with strokes in different parts of the brain (specifically anterior and posterior circulation areas). <p>The NICE Interventional Procedures programme assesses the safety and efficacy of new interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
51	Consultee 8 British Society of Neuroradiologists	General	<p>Additional Comments</p> <p>This may be outside the intended scope of the guidance but there is no mention of the fact that the initial assessment and diagnostic imaging will in many cases be at a different centre from where the thrombectomy will be carried out. Guidance will be needed for referral protocols between the referring centre and the centre carrying out the intervention and also for physical transfer of the patient ie the “drip and ship” model.</p> <p>The guidance does not include a section on resources. In addition to the major resources required to deliver the thrombectomy service there is a need to provide a minimum of high quality CT brain and CT angiographic imaging at all centres where these patients present. This requires the rapid availability of scanners, radiographers trained to perform more than a basic CT head scan and expert interpreters, all on a 24/7 basis.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The NICE Interventional Procedures programme assesses the safety and efficacy of new interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition.</p> <p>Cost-effectiveness is not part of the remit of the NICE Interventional Procedures Programme.</p>
52	Consultee 13 Royal College of Radiologists and the British Society of Neuroradiologists	General	<p>Additional Comments</p> <p>This may be outside the intended scope of the guidance but there is no mention of the fact that the initial assessment and diagnostic imaging will in many cases be at a different centre from where the thrombectomy will be carried out. Guidance will be needed for referral protocols between the referring centre and the centre carrying out the intervention and also for physical transfer of the patient ie the “drip and ship” model.</p>	<p>Thank you for your comment.</p> <p>This is not within the remit of IP guidance.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
53	Consultee 1 Healthcare Improvement Scotland	General	<p>Dear Colleague</p> <p>I am not able to comment on this consultation but would wish to highlight the EUnetHTA rapid assessment report which will be published towards the end of 2015.</p> <p>http://www.eunetha.eu/news/closed-public-consultation-draft-project-plan-endovascular-therapy-using-mechanical-thrombectomy</p> <p>warm wishes</p> <p>■</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The linked document is a project description and planning paper for 'Endovascular therapy using mechanical thrombectomy devices for acute ischaemic stroke'.</p>
54	Consultee 7 Stroke Association	General	<p>Equalities considerations</p> <p>There are equality considerations that the committee should make reference to in this guidance. The incidence of stroke rises with age. Black people are twice as likely to have a stroke compared to white people and Black and South Asian people have strokes at a younger age compared to white people. Therefore treatments to prevent mortality and serious disability resulting from stroke, if widely available, could reduce the impact of stroke on these groups and therefore potentially help reduce health inequality. Although it is not protected under the Equality Act, people from the most economically deprived areas of the UK are also around twice as likely to have a stroke than those from the least deprived areas. We therefore think this should also be noted in the guidance so that socioeconomic depravity can be considered to help reduce health inequality.</p>	<p>Thank you for your comment.</p> <p>The Committee are made aware of equality considerations before a procedure is discussed.</p> <p>An equality impact assessment is published on the NICE website at the same time as the guidance is published.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
55	Consultee 7 Stroke Association	General	<p>Patient perspective</p> <p>To develop our response to this consultation, the Stroke Associate conducted a short online survey, which included a lay friendly summary of the key evidence on mechanical clot retrieval. It was sent to members of our Supporters' Network, a group of stroke survivors and their friends and family. Responses were collected between 10 and 16 November 2015. Despite the short window for consultation, we were pleased to receive 282 responses, including 39 from people with either direct experience of thrombectomy, or experience via a close family member or friend.</p> <p>Of the respondents who had experience of mechanical clot retrieval, 51% had a stroke themselves, 31% were a family member or friend, 10% were the partner or carer of someone who had a stroke and 8% were health professionals. The vast majority (85%) had received thrombolysis prior to undergoing a mechanical clot retrieval. Ten per cent did not and a further 5 per cent were unsure or could not remember if they had received thrombolysis.</p> <p>Sixteen per cent of people received a mechanical clot retrieval as part of a clinical trial, 67 per cent did not and a further 16 per cent were unsure or did not remember.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
56	Consultee 7 Stroke Association	General	<p>We asked respondents to describe their experience of mechanical clot retrieval. Just over half (55%) of those who had a mechanical clot retrieval described their experience of treatment in a positive way. Of the remainder, some didn't remember that period of time and felt unable to comment on the experience of the treatment (14%), others described the experience of receiving treatment in a neutral or negative way (24%), and a few described their experience of another aspect of their treatment (7%).</p> <p>The most common comments about experiences of mechanical clot retrieval were:</p> <ul style="list-style-type: none"> • Their recovery was quick (28%) • Thrombolysis drugs did not work on them (21%) • They feel the treatment saved their life (17%) • They are left with minimal or no disability (17%) • They are able to live their life in the way they want following their stroke (7%) 	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
57	Consultee 7 Stroke Association	General	<p>Of the three respondents who reported a negative experience of mechanical clot retrieval, the reasons cited were:</p> <ul style="list-style-type: none"> • The treatment caused a cardiovascular accident • The treatment caused a bleed • The procedure was performed incorrectly and was therefore ineffective <p>When asked about the benefits of mechanical clot retrieval, only one person who had the procedure told us they felt it did not provide any benefit. All of the others felt the main benefits were:</p> <ul style="list-style-type: none"> • They avoided severe disability (50%) • They are alive (43%) • They made a quick recovery (33%) • They are able to live their life how they want to following their stroke (13%) • Thrombolysis drugs did not work for them (10%) 	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
58	Consultee 7 Stroke Association	General	<p>When asked what the negative aspects of mechanical clot retrieval were, 56% of respondents who had experience of the procedure felt that there were none. Those who felt there were downsides to the treatment cited a range of negative aspects, including:</p> <ul style="list-style-type: none"> • Pain or discomfort during the procedure (7%) • The risks of the procedure including bleeding (7%) • Being unsure if their disability was caused by the stroke or the treatment (7%) • Not knowing what was happening (4%) • Their mental health suffered as they recovered so well and were discharged early (4%) • Their artery blocked again (4%) <ul style="list-style-type: none"> • A mistake was made with their treatment (4%) 	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
59	Consultee 7 Stroke Association	General	<p>All 282 respondents were asked whether they thought mechanical clot retrieval should be available on the NHS. 94 per cent of respondents felt that mechanical clot retrieval either definitely (80%) or probably (14%) should be available on the NHS.</p> <p>The most common reason given for why they felt thrombectomy should be available was that anything that helps people recover from stroke should be available (38%). A lot of these comments went on to say that thrombectomy would “give people a chance”, as well as highlighting the current lack of treatment options available for stroke. Preventing disability was a high priority for respondents throughout our survey.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
60	Consultee 7 Stroke Association	General	<p>Other respondents said that this treatment should be available because:</p> <ul style="list-style-type: none"> • This is an important new treatment with a good evidence base (14%) • It saves lives (9%) • Preventing disability saves money in the long run (6%) • A stroke affects not just the individual, but the whole family (5%) • Thrombolysis doesn't always work and other treatments should be available (3%) • Stroke is an overlooked condition and more treatments should be researched and made available (2%) <p>Five per cent of respondents did not have an opinion on whether mechanical clot retrieval should be available or not, mainly because they felt they did not know enough to have an opinion. Some felt that there needs to be more evidence before it is made available (2%), others felt that it would only be worth implementing if stroke services are improved generally (2%). A couple of people mentioned that this treatment was not useful for haemorrhagic stroke.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
61	Consultee 7 Stroke Association	General	<p>Only one per cent of people felt it should not be made available, this was because they felt more research was needed into the benefits verses the risks of the procedure.</p> <p>Every respondent who had mechanical clot retrieval felt that it should definitely be made available on the NHS.</p> <p>Patient quotes from survey</p> <ul style="list-style-type: none"> • It proved to be the best form of treatment for myself and therefore help to speed up my recovery. I would recommend it to anyone. • Immediately after I regained the use of my affected side. I was walking within a week. Talking immediately after and basically was able to manage my own rehab. • Overall, I had a very positive experience (FYI - I'm a 33 year old male, fit and healthy). The team of doctors around me were constantly communicating with me, which kept me at ease. I experienced some sharp pain in my brain, but this was well worth it, as I have made virtually a full recovery. As soon as the procedure was finished, virtually all of the symptoms I was experiencing during my stroke had disappeared (during my stroke I had slurred speech, dropped left face, intermittent inability to use left arm, and dizziness). The doctor who led the procedure seemed amazed at the turnaround pre vs post procedure. 	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
62	Consultee 7 Stroke Association	General	<ul style="list-style-type: none"> • My friend was completely disabled and only able to move the eyes. Medication did not work. Mechanical clot retrieval was performed immediately in the local hospital and NIHSS was 1 the next day and 0 a day later. My friend is living with her family and her dogs and has no deficits from her stroke. My friend's story is documented on ITV news. • Difficult to stay [what my experience was]. My body was jerking itself, did not numb the incision are enough. Got a fuzzy burning sensation in head whilst happening and also felt as though eyeball was being pushed out. • I have made an amazing recovery and so grateful that I was offered this procedure at [REDACTED] in [REDACTED]. I had a stroke on 26/8/2015 and was discharged on 8/9/15. Within 3 weeks of discharge I was walking, running, swimming, driving and cooking and caring for myself at home. I am eternally grateful for having received this treatment. • He coped really well and recovered very quickly - far faster because of this as the drugs did not work for him. 	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
63	Consultee 7 Stroke Association	General	<ul style="list-style-type: none"> I was unaware of the stroke when it happened, I collapsed at Kings Cross Station in London on the way back home to Edinburgh, on the 28th of April this year, and my partner made the decision to put me on the trial when I was unconscious. Without the clot retrieval and the stent inserted, I fully believe my recovery time would have been much longer. I regained basic speech within a few days (although had follow ups with a speech therapist for a few months after), I was paralysed down my right side but regained movement also within a few days, and was walking within a week (although not for long distances). I left the hospital in London after only 10 days and was transferred up to Scotland, where I was back home only a day later. 	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>
64	Consultee 7 Stroke Association	General	<p>My husband suffered a stroke in November 2012. The clot busting drugs showed no signs of working so he was rushed to another hospital and underwent a mechanical clot retrieval. As he was rushed into the operating room the surgeon simply told me that if they did not attempt this my husband would not survive. The procedure was 100% successful in removing the blood clot. The only down side is that due to the elapse of time before the procedure could take place my husband has suffered some permanent brain injury which affects his speech, and ability to read and write. However he is now able to lead a relatively normal life. He is now back at work part time as our village sub postmaster and is an active Scout Cub leader and member of our village fete committee. We will always be grateful to the surgeon who carried out this procedure</p>	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
65	Consultee 7 Stroke Association	General	<ul style="list-style-type: none"> • It left me with an accidental bleed in my brain & total spasticity in left arm & a dropped left foot & unable to stand & walk before mechanical surgery both left arm would move & I could stand in entrance to lift in Intensive care on Left & right leg. • I was extremely lucky that I had a surgeon who did this for me as the thrombosis treatments made the stroke worse. • I have been told by numerous health professionals that without this procedure, I would be either dead or bed bound. • The only negative I had was when they did it the second time without anaesthetic. There was some slight pain to my head. 	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have undergone this procedure.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
66	Consultee 11 Company	General	<p>It was pleasing to hear at the committee meeting the committee's supportive comments of the clinical evidence available for consideration and that is reflected in the positive recommendation to normal arrangements.</p> <p>We note in section 6.3 the committee's uncertainties with regard to the "best kind of retrieval device" we believe there should be more detailed commentary to this point. The rationale for this comment is owing to the fact the term "Mechanical Clot retrieval" as we understand it's use in this IPC document as a generic all-encompassing term for the different techniques used for the goal of clot retrieval which implies a class effect. This quite rightly leads the committee to the question as to which is the "best" technique. In such circumstance's we believe the clinical evidence summary contained with the consultation document should be more explicit in relation to the various techniques, for example stent retrieval, suction, rotation ablation or mechanical manipulation.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The overview, which is published on the NICE website at the same time as the guidance, provides more details about individual studies. This includes the specific devices used.</p>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
67	Consultee 7 Stroke Association	General	<p>Stroke Association response to NICE's interventional procedure consultation document on mechanical clot retrieval for treating acute ischaemic stroke</p> <p>The Stroke Association welcomes the opportunity to comment on this draft interventional procedure guidance. The Stroke Association is the leading charity working to support stroke survivors in the UK. In England, approximately 110,000 people have a stroke each year. It's the fourth single largest cause of death and is the largest cause of complex disability, so any new treatments that reduce mortality and disability resulting from stroke are very much welcomed.</p>	Thank you for your comment.
68	Consultee 7 Stroke Association	General	<p>The Stroke Association would like to see robust guidance on mechanical clot retrieval that is consistently implemented. This will ensure equity of access to this treatment and prevent an increase in the variation in care that already exists across the country in treating acute stroke. It is also important to be mindful that the total number of patients included in the trials on thrombectomy were relatively low, so ensuring robust data is captured and shared on the implementation of mechanical clot retrieval as well as clinical outcomes is essential in adding to the evidence base.</p>	Thank you for your comment.
69	Consultee 2/4 UK Neurointerventional Group	NOTE	<p>I am the Co CI of 2 randomised trials in the field - PISTE (stopped recruitment & writing up) & STABILISE - a device trial part industry funded & recruitment is ongoing - institutional funding. However, my comments are not personal but on behalf of UK Neurointerventional Group</p>	Thank you for your comment.

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