

Stroke and transient ischaemic attack in over 16s: diagnosis and initial management (update)

**Consultation on draft guideline - Stakeholder comments table
23 November 2018 – 11 January 2019**

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| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
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| Action on Smoking and Health | Guideline | 6 | General | <p>Please insert each new comment in a new row</p> <p>Smoking is a major cause of stroke and transient ischaemic attack and has significant implications for prognosis following stroke incidence, with smoking cessation significantly improving patient outcomes. Reference to smoking cessation treatment, as outlined in NICE guidance NG92, Stop smoking interventions and services,¹ in guidance relating to the management of stroke and transient ischaemic attack should be considered key, and its omission in the draft guidance rectified. NICE. [NG92] Stop smoking interventions and services. March 2018.</p> <p>Smoking carries significant risk for stroke and ischaemic attack incidence and prognosis:</p> <ul style="list-style-type: none"> • Smoking makes you twice as likely to die if you have a stroke.² • Smoking increases a person's chances of stroke and nearly doubles a person's chances of ischaemic stroke.³ • The risk of stroke increases with the number of cigarettes smoked. Error! Bookmark not defined.⁴ If you smoke 20 cigarettes a day, you are six times more likely to have a stroke compared with a non-smoker.⁵ | <p>Please respond to each comment</p> <p>Thank you for this information which is important in the wider management of stroke. However, this topic was not included in the scope of this guideline update and so we cannot make recommendations about this.</p> <p>We will pass your comment to the NICE surveillance team to consider for future updates of this guideline or update of the Stroke rehabilitation guideline.</p> |

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| | | | | <p>² Stroke Association. State of the nation: stroke statistics. 2009.</p> <p>³ The Stroke Association. Smoking and the risk of stroke. September 2017.</p> <p>⁴ Aldoori M, Rahman SH. Editorial: Smoking and stroke: A causative role. <i>BMJ</i> 1998; 317: 962</p> <p>⁵ Scarborough, P et al. Stroke Statistics 2009. British Heart Foundation, 2009.</p> <p>A number of studies have identified a relationship between smoking and stroke:</p> <ul style="list-style-type: none"> • In 2016, a major international study conducted across 32 different countries found a clear association between current cigarette smoking and experience of strokes. This was consistent across countries, genders and ages. Current cigarette smoking was particularly associated with incidence of ischaemic strokes.⁶ • A Finnish cohort study conducted by the University of Helsinki found that smoking increased risks of subarachnoid haemorrhage, often leading to strokes, in both men and women but this risk was considerably greater for female smokers. Hazard ratios between smoking and strokes differed by sex in all categories studies, with women consistently being at greater risk.⁷ | |
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| | | | | <ul style="list-style-type: none"> In their recent report 'Hiding in Plain Sight: Treating Tobacco Dependency in the NHS',⁸ the Royal College of Physicians (RCP) references a 2013 meta-analysis combining the data from 81 studies relating to smoking risks for stroke in men and women. For current smokers, the study estimated the relative risk of stroke to be 1.57 (95% CI 1.49–1.88) for men and 1.83 (95% CI 1.58–2.12) for women, relative to non-smokers. For former smokers relative to never smokers, the study estimated the relative risk to be 1.08 (95% CI 1.03–1.13) for men and 1.17 (95% CI 1.12–1.22) for women.⁹ <p>⁶ O'Donnell, M. J et al. Global and regional effects of potentially modifiable risk factors associated with acute stroke in 32 countries (INTERSTROKE): a case-control study. <i>The Lancet</i> 2016; 288: (10046) 731-840.</p> <p>⁷ Lindbohm J et al. Sex, smoking, and risk for subarachnoid haemorrhage. <i>Stroke</i> 2016; 47: 1975-1981</p> <p>⁸ Royal College of Physicians. Hiding in Plain Sight: Treating tobacco dependency in the NHS. 2018</p> <p>⁹ Sanne et al. Smoking as a risk factor for stroke in women compared with men: A systematic review and</p> | |
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| | | | <p>meta-analysis of 81 Cohorts, including 3 980 359 Individuals and 42 401 strokes. <i>Stroke</i> 2013; DOI: 10.1161/STROKEAHA.113.002342</p> <p>Furthermore, smoking is recognised as one of the most important preventable risk factors for the development of atherosclerosis,^{10, 11, 12} and atrial fibrillation,^{13,Error! Bookmark not defined.} both of which are major risk factors for stroke.^{14,15}</p> <p>¹⁰ Lee J, Cooke JP. The role of nicotine in the pathogenesis of atherosclerosis. <i>Atherosclerosis</i> 215 (2011) 281-283.</p> <p>¹¹ Dempsey RJ, Moore RW. Amount of smoking independently predicts carotid artery atherosclerosis severity. <i>Stroke</i> 1992;23:693-696.</p> <p>¹² Messner B, Bernhard D. Smoking and cardiovascular disease: Mechanisms of endothelial dysfunction and early atherogenesis. <i>Arteriosclerosis, Thrombosis, and Vascular Biology</i>. 2014;34:509-515</p> <p>¹³ Aune D, Schlesinger S, Norat T, Riboli E. Tobacco smoking and the risk of atrial fibrillation: A systematic review and meta-analysis of prospective studies. <i>Eur J Prev Cardiol</i> 2018 Sep;25(13): 1437-1451. Doi: 10.1177/2047487318780435.</p> | |
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| | | | <p>¹⁴ The Stroke Association. What is stroke, types of stroke, ischaemic stroke. [Accessed January 2019]</p> <p>¹⁵ The Stroke Association. Atrial fibrillation (AF) and stroke. September 2018.</p> <p>Importantly for the proposed guidance, a number of studies have further demonstrated the relationship between smoking and stroke prognosis, finding that smoking cessation dramatically reduces the risk of secondary stroke and death; making smoking cessation a key part of initial management:</p> <ul style="list-style-type: none"> • In a 2017 report, smoking cessation after stroke or transient ischaemic attack reduced the 5-year risk of stroke, myocardial infarction, or death to 15.7% (from 22.6% among those who continued to smoke), the hazard ratio being 0.66 (95%.156 CI 0.48–0.90).¹⁶ • A 12-year study of female nurses found that the elevated risk of stroke in smokers disappeared within 5 years of quitting and that the decline in risk was independent of age, highlighting that it is never too late to quit.¹⁷ • In a large Canadian study, continued smoking after stroke incidence had a negative effect on functional outcome at discharge, mortality at 1 year and length of stay in hospital.¹⁸ A study | |
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| | | | | <p>from Australia similarly found an increased risk of death following stroke among smokers compared to past smokers and never smokers, with the risk maintained for the 10 years of the study.¹⁹</p> <ul style="list-style-type: none"> • Between 5 and 15 years after quitting a person's risk of having a stroke is reduced to the same as a non-smokers²⁰ <p>¹⁶ Epstein KA, Viscoli CM, Spence JD <i>et al.</i> Smoking cessation and outcome after ischemic stroke or TIA. <i>Neurology</i> 2017;89:1723–9.</p> <p>¹⁷ Kawachi, I et al. Smoking cessation and decreased risk of stroke in women. <i>JAMA</i> 1993; 269: 232-236.</p> <p>¹⁸ Edjoc RK, Reid RD, Sharma M, Fang J. Registry of the Canadian Stroke Network. The prognostic effect of cigarette smoking on stroke severity, disability, length of stay in hospital, and mortality in a cohort with cerebrovascular disease. <i>J Stroke Cerebrovasc Disease</i> 2013; doi:10.1016/j.jstrokecerebrovasdis.2013.05.001</p> <p>¹⁹ Kim J, Gall SL, Dewey HM, et al. Baseline smoking status and the long-term risk of death or nonfatal</p> | |
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| | | | <p>vascular event in people with stroke: a 10-year survival analysis. Stroke 2012; 43: 3173-8.</p> <p>²⁰ U.S. Department of Health and Human Services. The Health onsequences of Smoking: what it means to you. U.S. Department of Health and Human Services, Centres for Disease Control and Prevention. National Centre for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.</p> <p>Given the substantial benefits of smoking cessation on prognosis following stroke incidence, including provision of smoking cessation treatment as routine practice in guidance relating to the management of stroke and transient ischaemic attack.</p> <p>Aside from its clinical effectiveness, smoking cessation treatment is also a highly cost-effective intervention. The economic report accompanying NICE guidance NG92 analysed cost-effectiveness for smoking cessation interventions with modelling of six common conditions (lung cancer, stroke, COPD, myocardial infarction, asthma exacerbation and coronary heart disease) caused or exacerbated by smoking. The effectiveness evidence from 30 different interventions, with the costs of interventions ranging from £19 for brief advice to £763 for an extended course of NRT, and</p> | |
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| | | | <p>intervention effectiveness (quitting smoking) ranging from 9% to 47%, found all to be highly cost-effective. A threshold analysis showed that even when the lowest quit rate identified in the effectiveness study (9%) is combined with the most expensive intervention (£763 per person), the intervention is still cost-effective.ⁱ NHS policy²¹ and NICE guidance PH48²² require the identification of smokers and referral for treatment of tobacco dependency. More recently, the NHS Long Term Plan has reinforced and extended this, committing to offer all people admitted to hospital who smoke NHS-funded tobacco treatment services by 2023/24.²³ Smoking cessation treatment following stroke and ischaemic attack delivers significant benefits to both patient outcomes and NHS financial sustainability. For these reasons, including the provision of such treatment, as outlined in NICE guidance NG92,ⁱ in all guidance relating to the management of stroke and ischemic attack is vital, in addition to ensuring that all staff working specifically with patients following stroke incident are trained to either deliver brief advice on smoking and support quit attempts or refer to services which can.</p> <p>²¹ NHS England. Preventing ill health: CQUIN supplementary guidance. 2018.</p> <p>²² NICE. [PH48] Smoking: acute, maternity and mental health services. November 2013</p> | |
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| | | | | ²³ NHS England. The NHS Long Term Plan . January 2019. | |
| British Association of Stroke Physicians | Evidence review A | | - | It is reasonable to propose that people with suspected TIA, who have had full resolution of their symptoms, receive aspirin prior to assessment by a specialist. This is relevant where access to medical assessment might be delayed. However, if very early assessment is likely (i.e. within 24 hours of symptoms) then it is also reasonable to wait for full assessment by a specialist, including neuroimaging as appropriate, before aspirin administration. | Thank you for your comment. The committee discussed this matter in depth and concluded that on balance it was safer to prescribe aspirin early even if the expert assessment in TIA clinic was likely to be within 24 hours. The reasons were that the risk of haemorrhage is very low but there is a possibility of preventing a stroke. There is also a possibility that the assessment may be delayed and aspirin will help protect the patient in the meantime. |
| British Association of Stroke Physicians | Evidence review A | 14 | 32-33 | The committee agreed that once a diagnosis of TIA has been suspected by a healthcare professional, it should be safe to give aspirin without increasing the risk of haemorrhage.” RESPONSE – this is not known; the risks are low, not necessarily negligible. The risk is relatively low, accounting for approximately 5% of minor strokes. 0.5% of those with confirmed ICH have symptom resolution within 24 hours. | Thank you for your comment. We agree that the risk is not zero, and have amended the text to say ‘without significantly increasing the risk of haemorrhage’ to make this clear. |
| British Association of Stroke Physicians | Evidence review A | 14 | 45-46 | The committee were also aware of some retrospective data showing that even when aspirin is given in cases of intracerebral haemorrhage, the clinical condition does not deteriorate”. RESPONSE – this is imprecise. Further, the retrospective data will not have taken into account ultra-acute administration of aspirin, and any potential differences in time-course responses to treatment in terms of ICH risk. Nonetheless, risk of ICH seems very low, | Thank you for your comment and we are glad that you agree with our conclusions. We agree with the limitations to retrospective data that you have highlighted. We have changed the wording to ‘suggesting’ rather than ‘showing’ to highlight the uncertainty in these findings. However, this evidence was only discussed as additional support for the committee’s conclusions rather than the main basis for the recommendation. |

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| | | | | and the benefits likely to outweigh harm with the recommendation given. | |
| British Association of Stroke Physicians | Evidence Review D | 26 | 34-36 | With reference to posterior circulation stroke, it is stated that CT or MRI should be performed to demonstrate that there is 'salvageable' brain tissue and to seek evidence of established injury to functionally critical areas. It should be acknowledged that MRI is superior in this regard, and may be helpful if there is particular concern regarding damage to critical areas. We note also there is not very good evidence to identify what tissue is 'salvageable'. | Thank you for your comment. We agree that MRI is thought to be superior for PCA strokes to assess critical areas of the brain stem and have added some text to the committee discussion section of the evidence review to highlight this. We are not aware of any evidence that CT perfusion is not good enough for assessment of salvageable PCA territory. As we did not review any evidence comparing imaging modalities in this setting we are not able to specify one over the other in the recommendation, and including both CT perfusion and MR-DWI allows clinicians to choose the most appropriate imaging strategy, including in the future if new evidence clarifies the optimal approach. We have also added a note to the committee discussion section of the evidence review to explain that with CT perfusion, blood volume maps may be useful to predict infarction and in DWI MRI, lesions with low apparent diffusion coefficient (ADC) values predict early infarction. |
| British Association of Stroke Physicians | Evidence Review D | 27 | 9-15 | This paragraph on the potential model of service, the implications of transfers and need for responsive repatriation systems is particularly relevant to the successful delivery of thrombectomy. We agree that there is much uncertainty about the best method of delivering thrombectomy in different areas of the country, | Thank you for your comment. The organisation of the service to deliver thrombectomy was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make research recommendations in areas that we have not reviewed. |

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| | | | | and believe the committee should make a research recommendation on this the question. | |
| British Association of Stroke Physicians | Evidence Review D | 30 | | In relation to posterior circulation stroke, this paragraph makes the point that intervention in patients with established infarction of critical structures (eg bilateral pons) risks leaving the person with locked-in syndrome. It would be helpful to state this more explicitly in the actual guideline. The decision to intervene is not just based on demonstration of salvageable brain, but rather whether intervention is likely to confer a useful benefit to the patient. | Thank you for your comment. The committee have discussed this in detail and, as stated in the committee discussion section of the evidence review, they agreed that it is already standard clinical practice to look for established tissue damage in the brain regions affected by the arterial occlusion and in particular the areas of the brain stem. This happens before intervening to avoid where possible patients having severe neurological disability. The committee did not wish to add this detail into the recommendation but emphasised that this is a “consider” recommendation. |
| British Association of Stroke Physicians | Evidence Review D | 30 | 1-24 | This paragraph on the impact of baseline imaging (including advanced imaging), NIHSS and baseline functional status is excellent and supports the need for clinical judgement in making thrombectomy decisions. It would be helpful if this was more explicit in the actual guideline. | Thank you for your comment. The committee have included a recommendation on the factors to take into account when making decisions about thrombectomy. Following stakeholder feedback, we have now emphasised the need to think about the person’s overall clinical status, and specified the mRS and NIHSS scores to be taken into account when determining eligibility and suitability for thrombectomy. The recommendation now reads as follows: Take into account the person’s overall clinical status and the extent of established infarction on initial brain imaging to inform decisions about thrombectomy. Select people who have (in addition to the factors in recommendations 1.4.5 to 1.4.7): |

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| | | | | | <ul style="list-style-type: none"> • a pre-stroke functional status of less than 3 on the modified Rankin scale and • a score of more than 5 on the National Institutes of Health Stroke Scale). [2019] |
| British Association of Stroke Physicians | Evidence review F | 20 | 35-37 | Increased intensity or early start of mobilisation, or both, in AVERT could have been responsible for the worse outcome in the intervention group compared with the comparator (p20, lines 44-46). The intensity of activity was judged to have differed more than the timing between treatment arms (p20, lines 35-37). It is not possible to separate these effects in the study results, and it is certainly possible that the median difference of 4.8 hours between arms had a significant impact at this critical time for cerebral perfusion | Thank you for your comment. We agree and have altered the text accordingly. |
| British Association of Stroke Physicians | Evidence review F | 21 | | The results of AVERT do not support early mobilisation to people with acute stroke who require little or no assistance to mobilise. At least 40% of the participants in both study arms were able to mobilise independently. The study did not report the degree of assistance required to mobilise for the approximately 50% of participants in both groups who required some assistance, but even if only a small minority of these participants (8-10% of the total study participants) required minimal assistance to mobilise, this would mean that the majority of the people included in the overall analysis required either minimal or no assistance to mobilise. Therefore, this study presents no | Thank you for your comment. Our comments in relation to mobilisation when the clinical condition permits are largely based on common sense and expert opinion and are not derived from the AVERT study. Regarding high-intensity mobilisation in the first 24 hours, despite the trial including those able to mobilise independently the committee believed that any harm of the intervention was most relevant to those who need help to sit out of bed, stand or walk, and so the recommendation has been limited to this group. The committee did not want to prevent appropriate early mobilisation in people who are independently mobile after having a stroke. |

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| | | | | evidence that people who are able to mobilise with little or no assistance should be treated differently from people with more severe stroke with regard to very early mobilisation. | |
| British Association of Stroke Physicians | Evidence review H | | | The biggest implications will be establishing the acceptance from neurosurgical colleagues that craniectomy should be offered to all appropriate patients irrespective of age, and using appropriate shared decision making tools. | Thank you for your comment. We agree and we are facilitating this process by producing a decision aid that will help patients and family/carers make informed decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline. |
| British Association of Stroke Physicians | Guideline | 5 | 10 | The resource implications of this recommendation need to be carefully considered, and the effect of negative imaging. There is no clear clinical evidence for the treatment of MR negative transient neurological attacks. Suggest define what TIA syndromes are suitable for imaging, otherwise this might lead to an enormous pressure on pressed radiology departments. It does not seem plausible that the replacement of CT by MR will only have small cost implications, and the clinical benefit is uncertain (and may be harmful). | Thank you for your comment. The recommendation made is not for routine MRI scanning in all patients with suspected TIA but for it to be considered following specialist assessment that will determine whether it is required. The recommendation has been reworded to make this clear. It now reads: After specialist assessment in the TIA clinic, consider MRI (including diffusion-weighted and blood-sensitive sequences) to determine the territory of ischaemia, or to detect haemorrhage or alternative pathologies. If MRI imaging is done, perform it on the same day as the assessment. The decision whether to order an MRI is still a matter of clinical judgement and therefore we do not feel it is appropriate to define suitable TIA syndromes in the recommendations. The evidence for routine MRI scanning was not adequate to make a specific recommendation |

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| | | | | | <p>and so the committee decided to make a research recommendation in this area.</p> <p>Whilst we expect the number to CT scans ordered to drop substantially, the number of MRI scans may only rise a little as many specialists are currently ordering MRIs in additional to CT scans. Further details of the reasoning for this recommendation can be found in the discussion and rationale sections of the evidence review. The net resource impact to the NHS is being considered by the NICE resource impact team.</p> |
| British Association of Stroke Physicians | Guideline | 6 | 5 | Suggest after appropriate discussion of risks and benefits | <p>Thank you for your comment. This was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendation.</p> |
| British Association of Stroke Physicians | Guideline | 8 | 3 | Level 1 care would be regarded as insufficient for unstable patients requiring more detailed observation or intervention including support for a single failing organ system (the CNS) - that is level 2 care and should be recommended as such in this guideline. | <p>Thank you for your comment. This change was made in error and we are very grateful that you brought this to our attention. We have reverted to the levels of care as recommended in the 2008 guideline and we have also reworded the recommendation to clarify that the levels relate to levels of care. It now reads:</p> <p>Administer alteplase only within a well organised stroke service with:</p> <ul style="list-style-type: none"> • staff trained in delivering thrombolysis and in monitoring for any complications associated with thrombolysis • nursing staff trained in acute stroke and thrombolysis to provide level 1 and level 2 care |

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| | | | | | <ul style="list-style-type: none"> • immediate access to imaging and re-imaging, and staff trained to interpret the images. [2008, amended 2019] |
| British Association of Stroke Physicians | Guideline | 8 | 15 | Under point 1.4.5, the guideline essentially implies that thrombectomy should be offered to all patients within 6h of symptom onset who have large vessel occlusion in anterior circulation. Whilst this is reasonable for most patients and is supported by the evidence (eg MR CLEAN trial), it is undoubtedly the case that some patients with very poor collaterals will already have developed a large core of infarction within 6 hours and may not benefit from thrombectomy. In fact this point is well made in Evidence Review D, page 30, lines 1-6. It is acknowledged that point 1.4.8 (Page 9, line 15) states that “the extent of infarction” on baseline imaging should be taken into account when considering thrombectomy. It would be helpful if the information in 1.4.8 could be referenced in 1.4.5 (ie “see 1.4.8 below”), or alternatively the information in 1.4.8 could be moved to the start of the section on thrombectomy. | Thank you for your comment. As suggested, we have now referred to recommendation 1.4.8 in each of recommendations 1.4.5, 1.4.6 and 1.4.7. We have also made recommendation 1.4.8 more specific by stating the mRS and NIHSS scores to be taken into account when determining eligibility and suitability for thrombectomy. This is in order to make implementation of the recommendation possible and to align with the NHS England Clinical Commissioning policy on mechanical thrombectomy for acute ischaemic stroke. We have also emphasised the need to think about the person’s overall clinical status. The recommendation now reads as follows: Take into account the person’s overall clinical status and the extent of established infarction on initial brain imaging to inform decisions about thrombectomy. Select people who have (in addition to the factors in recommendations 1.4.5 to 1.4.7): <ul style="list-style-type: none"> • a pre-stroke functional status of less than 3 on the modified Rankin scale and • a score of more than 5 on the National Institutes of Health Stroke Scale). [2019] |
| British Association of Stroke Physicians | Guideline | 9 | 1 | Point 1.4.6 refers to thrombectomy in 6-24h window. The criterion “if there is potential to salvage brain tissue, as shown by CT and MRI scanning techniques” is obviously important. In | We agree, thank you for your comment. |

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| | | | | practice this decision is likely to involve advanced imaging, correlation with the clinical features and knowledge of the vascular anatomy. | |
| British Association of Stroke Physicians | Guideline | 9 | 9 | Point 1.4.7 refers to thrombectomy in posterior circulation stroke. Again, the criterion “if there is potential to salvage brain tissue, as shown by CT and MRI scanning techniques” is important. In making this decision, there needs to be correlation between the site of occlusion and extent of established infarction, clinical features and determination of what further areas are vulnerable /salvageable. In addition, for posterior circulation stroke in particular, it is important to consider whether functionally critical areas have been irreversibly damaged, which may render thrombectomy futile. This point is well made in Evidence review D, page 31, lines 11-15. MRI may be more useful than CT in this regard. | Thank you for your comment. We agree; this is the intention of our recommendation and is supported as such in our narrative. |
| British Association of Stroke Physicians | Guideline | 9 | 11 | Point 1.4.8 is very important and “tempers” the advice given in the preceding sections (1.4.5, 1.4.6 and 1.4.7). As above, it may be helpful to state “see section 1.4.8” in each of these. In addition, it may be helpful to expand the advice give on determining the extent of established infarction on baseline imaging. Whilst not wishing to be prescriptive, it may be reasonable to make the following points in relation to the extent of baseline infarction: For people with anterior circulation ischaemic stroke, | Thank you for your comments. As suggested, we have now referred to recommendation 1.4.8 in each of recommendations 1.4.5, 1.4.6 and 1.4.7. Following stakeholder feedback we have now specified the mRS and NIHSS scores to be taken into account when determining eligibility and suitability for thrombectomy. This is in order to make implementation of the recommendation possible and to align with the NHS England |

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| | | | | <p>measurement of ASPECTS score on NCCT is suggested. In people with a low ASPECTS score (even within 6 hours), additional imaging with CT perfusion or MRI may be helpful. For people with posterior circulation ischaemic stroke, MRI may be helpful, especially if the clinical features and/or NCCT suggest established infarction of critical areas, for example bilateral pontine infarction.</p> | <p>Clinical Commissioning policy on mechanical thrombectomy for acute ischaemic stroke. We have not included a cut-off for the ASPECTS score because this was not included in the commissioning document, nor was it used as an entry criterion in most of the clinical trials. We have also emphasised the need to think about the person's overall clinical status. The recommendation now reads as follows: Take into account the person's overall clinical status and the extent of established infarction on initial brain imaging to inform decisions about thrombectomy. Select people who have (in addition to the factors in recommendations 1.4.5 to 1.4.7):</p> <ul style="list-style-type: none"> • a pre-stroke functional status of less than 3 on the modified Rankin scale and • a score of more than 5 on the National Institutes of Health Stroke Scale). [2019] <p>Regarding posterior circulation stroke we agree that MRI may be superior to assess critical areas of the brain stem and have added some text to the discussion to highlight this.</p> |
| British Association of Stroke Physicians | Guideline | 10 | 14 | Remove 'include in trial', as far as we are aware none is ongoing. If a second trial is felt to important this should be one of the research recommendations | Thank you for your comment. This section was not reviewed as part of the update but we have amended the recommendation to remove reference to a trial as this is no longer relevant. |
| British Association | Guideline | 11 | 6 | Please comment on reversal of DOACS, (and cost-effectiveness of therapies) perhaps about PCC. | Thank you for your comment. We have amended the wording of this recommendation to read: |

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| of Stroke Physicians | | | | | <p>“Return clotting levels to normal as soon as possible in people with a primary intracerebral haemorrhage who were receiving warfarin before their stroke (and have elevated INR). Do this by reversing the effects of the warfarin using a combination of prothrombin complex concentrate and intravenous vitamin K.”</p> <p>As this section was not reviewed as part of the update we are not able to add any new recommendations about DOAC at this time. We will pass your comments onto the NICE surveillance team who will consider this for the next update of the guideline.</p> |
| British Association of Stroke Physicians | Guideline | 11 | 22 | What is the evidence for harm of immediately starting statins? Suggest that this recommendation is removed, or is converted into a research recommendation | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| British Association of Stroke Physicians | Guideline | 12 | 15 | The committee has recommended (Page 8, line 3) the particular level of nursing intensity appropriate for patients with acute ischaemic stroke, and they should take the same approach for unstable patients with acute intracerebral haemorrhage requiring more detailed observation or intervention including support for a single failing organ system (the CNS) - that is level 2 care and should be recommended as such in this guideline. | Thank you for your comment. Nursing levels of care were not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| British Association | Guideline | 12 | 16 | It is not clearly explained why the blood pressure target of 140 mmHg should be achieved within 2 hours of starting treatment. | Thank you for your comment. We agree and have changed the recommendation accordingly. It now reads as: “Aim for a systolic blood |

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| of Stroke Physicians | | | | The INTERACT2 trial intervention was to lower blood pressure to target within 1 hour of starting treatment. Although this was only achieved in a minority of patients in the intervention group, subsequent secondary analyses of the INTERACT data have more rapid lowering of blood pressure is associated with less haematoma expansion and improved functional outcomes. https://www.ncbi.nlm.nih.gov/pubmed/27143274 ; https://www.ncbi.nlm.nih.gov/pubmed/25801872 . Setting a guideline of 2 hours may encourage slower reduction and we would advocate replacing this with 1 hour. | pressure target of 130 to 140 mmHg within 1 hour of starting treatment and maintain this blood pressure for at least 7 days.” |
| British Association of Stroke Physicians | Guideline | 12 | 16 | The INTERACT2 protocol advised stopping treatment in the intensive arm if systolic blood pressure fell below 130 mmHg and more aggressive lowering in ATACH2 was associated with increased renal adverse events with no additional benefit. We would therefore advocate changing this statement to “aim for a systolic blood pressure target of 130 to 140 mmHg.....”. This will encourage clinicians to avoid significant and sustained drops below 130 mmHg which seem to be harmful from the ATACH II trial findings. | Thank you for your comment. We agree and have changed the recommendation accordingly. It now reads as: “Aim for a systolic blood pressure target of 130 to 140 mmHg within 1 hour of starting treatment and maintain this blood pressure for at least 7 days.” |
| British Association of Stroke Physicians | Guideline | 12 | 16 | The strong recommendations ('offer') for blood pressure lowering in ICH are unusual, given the formally neutral results in 2 large RCTs could be replaced by ('consider'). | Thank you for your comment. We acknowledge the modest size of effect estimates. However, the committee had most confidence in the INTERACT-2 trial, which has been used as the |

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| | | | | | <p>basis for the recommendation parameters. We discussed at length the strength of the recommendation and have detailed our reasons for making a strong recommendation in the discussion section. In summary, this was because:</p> <ul style="list-style-type: none"> • There is good evidence that intensive or rapid systolic blood pressure lowering is safe and has some evidence of effectiveness. This could have been underestimated by including ATACH2 in the meta-analysis, which has a more aggressive regimen in the control arm that is similar to the intervention arm of the other main trial, INTERACT-2 • The mortality rate from intracerebral haemorrhage without intervention is reported to be around 40% at 1 month so any intervention to reduce this is important • Up to 60% of those who survive currently have moderate or severe disability • It will likely standardise care in this condition where much inconsistency is known to exist |
| British Association of Stroke Physicians | Guideline | 12 | 16 | There were some significant exclusions from eligibility for rapid blood pressure lowering in the INTERACT2 trial (eg Glasgow coma scale score, anticipated prognosis) that should be reflected in the guideline, to avoid treatment | Thank you for your comment. We agree and have added the following recommendation. Do not offer rapid blood pressure lowering to people who: |

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| | | | | being offered or considered in patients for whom there is no evidence of benefit and the potential for harm. | <ul style="list-style-type: none"> • have an underlying structural cause (for example tumour, arteriovenous malformation or aneurysm) • have a GCS of below 6 • are going to have early neurosurgery to evacuate the haematoma • have a massive haematoma with a poor expected prognosis. |
| British Association of Stroke Physicians | Guideline | 12 | 19 | In the INTERACT2 trial it was permitted to lower SBP > 220 mmHg with IV antihypertensives to bring it below 220 mmHg and then recruit to the trial. It would this seem reasonable to do the same in clinical practice, rather than treat this group differently. Therefore, we would suggest that this line reads “have a systolic blood pressure greater than 150 mmHg” | <p>Thank you for your comment. We have amended our recommendation to ‘Consider rapid blood pressure lowering for people with acute intracerebral haemorrhage who:</p> <ul style="list-style-type: none"> • present beyond 6 hours of symptom onset, or • have a systolic blood pressure greater than 220 mmHg.’ <p>This cannot be included within the same recommendation as those with a systolic blood pressure of 220 mmHg or less because the strength of recommendation is different. This is because the evidence is weaker for those with SBP >220 mmHg.</p> |
| British Association of Stroke Physicians | Guideline | 12 | 24 | The recommendations use the adjectives ‘rapid’ and ‘controlled’ to describe the suggested speed and magnitude of blood pressure reduction. Whilst ‘rapid’ is based on the intervention tested in INTERACT2 (but noting comments 1&2 above), ‘controlled’ is not further defined in terms of speed but is defined in terms of magnitude (<140 mmHg). This could | <p>Thank you for your comment. After further discussion the committee agree with your suggestion and have changes the recommendation as follows:</p> <p>‘Consider rapid blood pressure lowering for people with acute intracerebral haemorrhage who:</p> |

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| | | | | be interpreted as anything from within 1 h of starting treatment using parenteral drugs or after several days using enteral drugs. As such, this may be unhelpful to clinicians and cause uncertainty. It may be better for the sake of clarity to state that the same intervention as for patients within 6 h of onset could be considered but that evidence is lacking and this is at the discretion of clinicians. | <ul style="list-style-type: none"> • present beyond 6 hours of symptom onset, or • have a systolic blood pressure greater than 220 mmHg. <p>Aim for a systolic blood pressure target of below 130 to 140 mmHg within 1 hour of starting treatment and maintain this blood pressure for at least 7 days.'</p> |
| British Association of Stroke Physicians | Guideline | 12 | 24 | It is surprising to find the committee recommending intensive blood pressure lowering for patients with ICH beyond 6 hours in the complete absence of evidence to support such a recommendation. There are many examples in medicine of treatments being 'extrapolated' beyond the evidence only to subsequently discover such an approach is associated with harm - indeed, the extrapolation of the target for blood pressure lowering seen in ATACH2 beyond what was seen in INTERACT2 is a pertinent example in this situation. The committee should avoid making recommendations for which there is no evidence of benefit and the potential for harm. | Thank you for your comment. Given the lack of evidence in this cohort we have made a weaker recommendation ("consider"). This leaves it at the discretion of clinicians to determine which patients to implement this recommendation for. It was noted that the majority of patients presenting with a systolic blood pressure above 220 mmHg do not have a reading of >230 mmHg. As such it was thought to be sensible to allow clinicians the option to aim for rapid blood pressure lowering in this group as, for example, there is little difference between a reading of 220 and 221 mmHg. Also, in the INTERACT-2 trial people with SBP >220 on initial assessment could be included in the trial if the SBP was brought down to 220 or less within 24 hours. |
| British Association of Stroke Physicians | Guideline | 15 | 22-24 | Statement 1.7.2 appears to suggest that people can be mobilised (sitting, standing walking) actively if their clinical condition permits. This might well be read as stating that as soon as someone can sit, stand or walk they should be actively encouraged to do so, and in particular | Thank you for your comment. Whilst the committee noted the evidence against high-intensity mobilisation they did not believe that patients whose clinical condition allowed them should be discouraged from mobilising in the first 24 hours. |

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| | | | | that people with mild stroke who are able to mobilise independently can be mobilised without restriction. This is not supported by the relevant evidence as stated above. In modern health care services, people are kept in hospital for as short a time as possible, therefore there is a danger that statement 1.7.2 will result in premature mobilisation after acute stroke and worse outcomes. Therefore precede this text with 'after 24 hours' for those with stroke | We have amended the recommendations on mobilisation to make them clearer that those that require help to sit, stand or walk that should not be offered high intensity mobilisation. The recommendations now read : Help people with acute stroke to sit out of bed, stand or walk as soon as their clinical condition permits as part of an active management programme in a specialist stroke unit. [2019] For people with acute stroke who require help to sit out of bed, stand or walk, do not offer high-intensity mobilisation in the first 24 hours after symptom onset. [2019] |
| British Association of Stroke Physicians | Guideline | 15 | 22-26 | The unexpected adverse finding of harm from early mobilisation within 24 hours from the AVERT trial is robust and should be implemented into practice, but applies only to patients who required assistance to mobilise and were expected to remain in hospital at least 3 days, and thus does not apply to mild patients who require little or no assistance to mobilise. Recommendation 1.7.3 should specify that these patients are excluded from the recommendation and should continue to receive 'usual care' i.e. be allowed to mobilise as able immediately after assessment by a competent healthcare professional. | Thank you for your comment. The recommendation has been edited to read: 1.7.3 For people with acute stroke who require help to sit out of bed, stand or walk, do not offer high-intensity mobilisation in the first 24 hours after symptom onset. Although the AVERT trial did include patients who could mobilise independently, the committee agreed that it would be inappropriate and impractical to limit mobilisation in this group. They did not believe that the harms associated with very early, high intensity mobilisation in the AVERT trial would be seen in this group. |
| British Association | Guideline | 15 | 25-26 | Despite the above reservations, statement 1.7.3 appropriately encompasses both timing and intensity of mobilisation after acute stroke. | Thank you for your comment. Due to the many variables included in the AVERT trial mobilisation protocol it is not possible to provide |

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| of Stroke Physicians | | | | However, we have some residual concern that use of the phrase “high intensity” might be taken to imply rehabilitation of particularly high intensity; while the intervention in AVERT III was substantially more intensive than the comparator, this was a median of 31 minutes mobilisation per day, which does not seem exceptionally intensive. We suggest this is changed to 'mobilisation as part of rehabilitation'. | a strict definition in the recommendation itself. However, we have linked to a summary of the trial protocol as an explanation of ‘high intensity’ which should make this clearer. |
| British Association of Stroke Physicians | Guideline | 18 | 1 | Suggest an additional research recommendation is made for UK-specific transfers of care for thrombectomy that covers urban and rural areas, and mixed. | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make any recommendations. |
| British Association of Stroke Physicians | Guideline | 19 | 34 | There is a place for phone screening for TIAs where the story is clearly non TIA e.g. syncope, BPPV, TGA or other. TIA is a historical diagnosis and so lends itself to telephone screening | Thank you for your comment. Service delivery was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| British Association of Stroke Physicians | Guideline | 23 | 13 | Should end either with ‘in patients deemed suitable for thrombectomy’ or ‘with pre stroke m Rankin of 2 and less’. This is to ensure that the tertiary centres are not referred unsuitable patients as it is likely that only a small number of patients will benefit with huge implications on resources. | Thank you for your comment. The text has been updated to include more detail about this. Also, following stakeholder feedback we have now specified the mRS and NIHSS scores to be taken into account when determining eligibility and suitability for thrombectomy within recommendation 1.4.8. This is in order to make implementation of the recommendation possible and to align with the NHS England Clinical Commissioning policy on mechanical thrombectomy for acute ischaemic stroke. The recommendation now reads as follows: |

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| | | | | | Take into account the person's overall clinical status and the extent of established infarction on initial brain imaging to inform decisions about thrombectomy. Select people who have (in addition to the factors in recommendations 1.4.5 to 1.4.7): <ul style="list-style-type: none"> • a pre-stroke functional status of less than 3 on the modified Rankin scale and • a score of more than 5 on the National Institutes of Health Stroke Scale). [2019] |
| British Association of Stroke Physicians | Guideline | 24 | 2 | Perhaps the reason CT has been mentioned is due to the fact that this is considered as the first imaging. however if the guidance wants to emphasize patient selection beyond 6 hours of onset then we should recommend to remove CT and recommend MR based imaging. | Thank you for your comment. We are not aware of any evidence that CT perfusion cannot assess salvageable PCA territory. As we did not review any evidence comparing imaging modalities in this setting we are not able to specify one over the other in the recommendation, and including both CT perfusion and MR-DWI allows clinicians to choose the most appropriate imaging strategy, including in the future if new evidence clarifies the optimal approach. |
| British Association of Stroke Physicians | Guideline | 24 | 11 | Onset should be defined specifically in posterior circulation stroke as a sudden onset or sudden deterioration from initial minor symptoms | Thank you for your comment. We agree and have added a definition of stroke onset for this group to our discussion. We have defined it to be "sudden onset of focal neurological symptoms clinically localised to the PCA circulation or a sudden deterioration from initial minor symptoms". |
| British Association of Stroke Physicians | Guideline | 24 | 30 | If NICE wants to recommend pathways and implications, then it must also recommend where the imaging is done for patients with onset between 6 to 24 hours. This is going to | Thank you for your comment. We have added this suggested method of implementation to our discussion section. |

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| | | | | be the bottleneck for implementation. Most practical way of implementation would be recommend that DGH performs advanced imaging and reporting should be done by the tertiary centre. | |
| British Association of Stroke Physicians | Guideline | 25 | 38 | The population of patients presenting to services > 6 h after onset with SBP > 150 mmHg is not small. In a local audit registry maintained at Salford Royal Hospital, 225 of 922 (24.4%) consecutive patients presenting to the stroke service with ICH fell in to this group. As such, we believe that a research recommendation should be made for this group, rather than the 'consider' recommendation in 1.5.5. | Thank you for your comment. The committee acknowledge that evidence in this area is lacking. However the committee felt that there was too much uncertainty around the potential trial population and feasibility of a trial for a definite research recommendation to be made. |
| British HIV Association | General | General | General | BHIVA recommends that an HIV test should be carried out. | Thank you for your comment. HIV testing was not included in the scope of this guideline update. |
| British Society of Interventional Radiology | Guideline | 8 | 15 | This recommendation will be a challenging deliver in practice because of the out-of-hours Neuro IR service is nationally under developed and the acute IR is stretched so presumably there would be practical measures to build up neurosurgeons training to do these. | Thank you for your response. We recognise that implementation may be challenging in some areas currently. Your comments will be considered by NICE where relevant support activity is being planned. |
| Department of Health and Social Care | General | General | General | Thank you for the opportunity to comment on the draft for the above guideline. I wish to confirm that the Department of Health and Social Care has no substantive comments to make, regarding this consultation. | Thank you for your comment. |
| London North West | Guideline | 19 | 25 | The recommendation of all TIAs being assessed within 24 hours of symptom onset, | Thank you for your comment. We fully recognise and acknowledge throughout this section of the |

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| Healthcare NHS Trust | | | | whilst based on expert clinical opinion as opposed to evidence, is not an achievable standard for the vast majority of hospitals to meet without significant investment on a national level, in regard to staffing as well as provision of diagnostics, especially at weekends. If adopted in the guidance, units will strive and fail to meet this standard, opening themselves to unfair questioning of their service provision at a time when stroke services are already stretched. This could affect staff morale, confidence in services from local populations and referral centres due to inability to meet this standard, let alone the financial impact to acute trusts if best practice tariffs are married to NICE guidance in the future. A less stringent recommendation of referrals being vetted by a specialist and appropriate referrals being seen within 24 hours of referral would be a way of allowing services to strive to see appropriate patients as soon as possible without overloading current systems. | guidance that the provision of a responsive 24 hour TIA clinic will have potentially significant resource implications for many services. Your comments will be considered by NICE where relevant support activity is being planned. |
| National Stroke Nursing Forum | Guidance | General | General | In light of the addition of recommendations on thrombectomy and reduction of blood pressure in intracranial haemorrhage, the NSNF would ask the committee to consider the nursing implications of the associated monitoring of these interventions and recommend that that all acute stroke patients (that will encompass thrombectomy, intracerebral haemorrhage and | Thank you for your comment. We did not review any evidence on levels of nursing care as part of this update so we are unable to make recommendations on this. |

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| | | | | thrombolysis) require level 2 nursing for a minimum of the first 24 hours post stroke. | |
| National Stroke Nursing Forum | Guidance | 4 | 17 | The NSNF believes that stating referral within 24 hours will add unnecessary delays in the system and delay in contact with the specialist. With electronic referrals available, it is feasible to recommend immediate referrals to enable the patient to be seen by the specialist within 24hrs of symptom onset. | Thank you for your comment. We have amended the recommendation to make it clear that the referral is immediate and the patient is seen by a specialist within 24 hours. |
| National Stroke Nursing Forum | Guidance | 5 | 1 | This statement does not reflect the committee's rationale for not stratify risk due to insensitive tools currently available, and therefore the NSNF recommends that the wording is changed to 'do not stratify risk of subsequent stroke e.g. ABCD scores to inform referral process' | Thank you for your comment. This was our intention and we have reworded the recommendation to make this clearer. It now reads "Do not use scoring systems such as ABCD2 to assess risk of subsequent stroke or to inform urgency of referral". |
| National Stroke Nursing Forum | Guidance | 6 | Footnote 2 | The NSNF is concerned about the definition of stroke unit. It seems to imply that stroke beds can be co-located on a medical ward with MDT input, and does not emphasise the need for dedicated nursing team with stroke knowledge and skills. There is emerging observational evidence from SSNAP that appropriate stroke specialist nursing can impact stroke mortality. The NSNF recommends that the stroke nursing contribution is clarified. | Thank you for your comment. This was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make any recommendations. . We will pass your comments to the surveillance team who will consider this for the next update. |
| National Stroke Nursing Forum | Guidance | 8 | 3 | The NSNF welcomes the use of National Critical Care nursing levels to inform the level of staffing for post thrombolysis patients. However it is concerned that the committee removed level 2 nursing from the guidance. | Thank you for your comment. This change was made in error and we are very grateful that you brought this to our attention. We have reverted to the levels of care as recommended in the 2008 guideline and we have also reworded the |

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| | | | | <p>It is the experience of NSNF members who care for these patients on a daily basis that level 1 does not reflect the monitoring required for patients in the first 24 hours post thrombolysis. It is our members' concern that reducing the level to only level 1 as will increase risk to patients due to lack of nursing levels to appropriately monitor these patients.</p> <p>This recommendation will have a larger impact The NSNF recommends that level 2 nursing is required for the first 6 hours post thrombolysis, reducing to level 1 after 6 hours. The NSNF is willing to submit to the committee our experiences of the nursing levels required for this group of patients.</p> | <p>recommendation to clarify that the levels relate to levels of care. It now reads: Administer alteplase only within a well organised stroke service with:</p> <ul style="list-style-type: none"> • staff trained in delivering thrombolysis and in monitoring for any complications associated with thrombolysis • nursing staff trained in acute stroke and thrombolysis to provide level 1 and level 2 care • immediate access to imaging and re-imaging, and staff trained to interpret the images. [2008, amended 2019] |
| NHS England | Guideline | 5 | 5 | <p>There may be issue with capacity and timely availability of imaging services specifically MRI to meet the requirements of this guideline.</p> | <p>Thank you for your comment. The recommendation made is not for routine MRI scanning in all patients with suspected TIA but for it to be considered following specialist assessment that will determine whether it is required. The recommendation has been reworded to make this clear. It now reads: After specialist assessment in the TIA clinic, consider MRI (including diffusion-weighted and blood-sensitive sequences) to determine the territory of ischaemia, or to detect haemorrhage or alternative pathologies. If MRI imaging is done, perform it on the same day as the assessment. The evidence for routine MRI scanning was not adequate to make a specific recommendation</p> |

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| | | | | | <p>stating objective criteria and so the committee decided to make a research recommendation in this area.</p> <p>Whilst we expect the number to CT scans ordered to drop substantially, the number of MRI scans may only rise a little as many specialists are currently ordering MRIs in additional to CT scans. Further details of the reasoning for this recommendation can be found in the discussion and rationale sections of the evidence review. The potential for substantial resource impact to the NHS is being considered by the NICE resource impact team.</p> |
| NHS England | guideline | 14 | 13 | The Office of the CAHPO welcome inclusion of the section on early mobilisation and positioning for people with acute stroke | Thank you for your comment. |
| NHS England/ Intercollegiate Stroke Working Party | Recommendations for Research | General | General | The recommendations for research should be expanded significantly given the implications of recent trials such as AVERT and thrombectomy trials. (KS) | Thank you for your comment. When reviewing the evidence the committee decides if the current evidence base is sufficient to make a recommendation for practice. If not they are able to make a research recommendation. They would not therefore make both a research recommendation and a practice recommendation in the same area. |
| NHS England/ Intercollegiate Stroke | Guideline | 4 | 14 | The guidance should more generally state “Offer antiplatelet...” rather than “Offer aspirin” (KS) | Thank you for your comment. Other antiplatelet agents were outside of the scope and so we did not review evidence in this area and cannot change the recommendation. We will pass your |

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| Working Party | | | | | comments onto the surveillance team at NICE to consider for the next update of the guideline. |
| NHS England/ Intercollegiate Stroke Working Party | Guideline | 4 | 16-17 | The guidance should more explicitly state that people who have had a suspected TIA should be seen and treated within 24h of onset (KS) | Thank you for your comment. We have amended the recommendation to make it clear that the referral is immediate and the patient is seen by a specialist within 24 hours. |
| NHS England/ Intercollegiate Stroke Working Party | Guideline | 8-9 | Sections 1.4.6/1.4.7 | The evidence for mechanical thrombectomy only relates directly to CT Perfusion (used in 4 trials running out to 6/8/16/24 hours respectively and to collateral scoring using multiphase CTA out to 12h in 1 trial) . Therefore, we would strongly assert that the committee state in more detail about the imaging to more clearly reflect the evidence available. e.g. if there is the potential to salvage brain tissue, as shown by proven CT or MRI scanning techniques – <i>namely CT or MR perfusion 6-24h (refs DAWN/DEFUSE 3 & REVASCAT trials) or CTP or collateral scoring on multiphase CTA up to 12h (ref ESCAPE trial)</i> (KS) | Thank you for your comment. We have made the recommendation more specific, as follows: 'if there is the potential to salvage brain tissue, as shown by imaging such as CT perfusion or diffusion-weighted MRI sequences showing limited infarct core volume'. |
| NHS England/ Intercollegiate Stroke Working Party | Guideline | 8-9 | Section 1.4.8 | This section should be clarified, as the evidence base for these recommendations almost exclusively included patients with pre stroke modified Rankin Score of <3 and NIHSS of >5. As the trials are still ongoing for mRS 3 & | Thank you for your comment. Following stakeholder feedback we have now specified the mRS and NIHSS scores to be taken into account when determining eligibility and suitability for thrombectomy. This is in order to make implementation of the recommendation possible |

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| | | | | <p>NIHSS <6, recommendations should not be made to include these patients. Therefore, we would advise qualification around the recommendations in this section, such as:</p> <ul style="list-style-type: none"> • pre stroke functional status (<i>benefit of MT confirmed for those with mRS <3</i>) • clinical severity of stroke (<i>benefit of MT confirmed for those with NIHSS >5</i>) • extent of established infarction on initial brain imaging (<i>benefit of MT confirmed for those with ASPECTS 6-10 proven; caution should be employed regarding MT in those with CT ASPECTS 3-5; MT is relatively contraindicated with CT ASPECTS 0-2</i>) <p>If they omit those clarifications in brackets then it is “open season” to attempt MT when not proven to be safe or efficacious. That has additional hazards to patients & major costs to NHS (KS)</p> | <p>and to align with the NHS England Clinical Commissioning policy on mechanical thrombectomy for acute ischaemic stroke. We have not included a cut-off for the ASPECTS score because this was not included in the commissioning document, nor was it used as an entry criteria in most of the clinical trials. We have also emphasised the need to think about the person’s overall clinical status. The recommendation now reads as follows: Take into account the person’s overall clinical status and the extent of established infarction on initial brain imaging to inform decisions about thrombectomy. Select people who have (in addition to the factors in recommendations 1.4.5 to 1.4.7):</p> <ul style="list-style-type: none"> • a pre-stroke functional status of less than 3 on the modified Rankin scale and • a score of more than 5 on the National Institutes of Health Stroke Scale). [2019] |
| NHS England/ Intercollegiate Stroke Working Party | Guideline | 12 | 20-22 | <p>The wording of this recommendation be clarified to more clearly reflect the evidence from ATACH-2. We recommend that the recommendation be amended to: “Aim for systolic blood pressure target of 14-mmHg within 2 hours of starting treatment and maintain this blood pressure for at least 7 days” (KS)</p> | <p>Thank you for your comment. The committee decided that the blood pressure lowering protocol should be in line with the INTERACT 2 trial to avoid the increased rate of renal adverse events seen with the more aggressive lowering used in ATACH2. Therefore, the recommendation has been changed to: Aim for a systolic blood pressure target of 130 to 140 mmHg within 1 hour of starting treatment and maintain this blood pressure for at least 7 days.</p> |

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| NHS England/ Intercollegiate Stroke Working Party | Guideline | 12 | 24 | We feel that the inclusion of the word “Consider” weakens this recommendation. (KS) | Thank you for your comment. We use the word ‘consider’ to reflect the weaker evidence base in this area. |
| NHS England/ Intercollegiate Stroke Working Party | Guideline | 13 | 1-2 | The wording of this recommendation be amended to more clearly reflect the evidence from INTERACT-2 and ATACH-2. We recommend that the recommendation be amended to: “Aim for systolic blood pressure target of 140mmHg within 2 hours of starting treatment and maintain this blood pressure for at least 7 days” (KS) | Thank you for your comment. The committee decided that the blood pressure lowering protocol should be in line with the INTERACT 2 trial to avoid the increased rate of renal adverse events seen with the more aggressive lowering used in ATACH2. Therefore the recommendation has been changed to: Aim for a systolic blood pressure target of 130 to 140 mmHg within 1 hour of starting treatment and maintain this blood pressure for at least 7 days |
| NHS England/ Intercollegiate Stroke Working Party | Guideline | 15 | 15-18 | We do not believe that this particular recommendation, specifically relating to head position is necessary and therefore nominate that it be omitted or the wording changed so that the recommendation more generally refers to overall positioning rather than only head positioning. (KS) | Thank you for your comment. We reviewed the evidence for optimal head positioning and it did not suggest any difference between lying flat or with the head elevated. We decided that it would helpful to provide a consensus recommendation supportive of continuing current best practice rather than no recommendation or a recommendation for further research. |
| NHS England/ Intercollegiate Stroke Working Party | Guideline | 15 | 23 | The wording “clinical condition permits” is too vague (KS) | Thank you for your comment. However, we believe that clinicians will be able to appropriately interpret this phrase. |

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| NHS England/ Intercollegiate Stroke Working Party | Guideline | 15 | 25 | The clinical implications of the statement “do not offer” are too great unless high intensity mobilisation is more clearly defined, therefore “high intensity mobilisation” must be explicitly defined within the wording of the guidance. Alternatively, we suggest that recommendation read “Patients with difficulty moving early after stroke who are medically stable should be offered frequent, short daily mobilisations (sitting out of bed, standing or walking) by appropriately trained staff with access to appropriate equipment, typically beginning between 24 and 48 hours of stroke onset. Mobilisation within 24 hours of onset should only be for patients who require little or no assistance to mobilise.”, as stated in the 2016 National Clinical Guideline for Stroke. (KS) | Thank you for your comment. Due to the many variables included in the AVERT trial mobilisation protocol it is not possible to provide a strict definition in the recommendation itself. However, we have provided an explanation of what we mean by ‘high intensity’ in the section ‘terms used in this guideline’. The recommendation has been edited to read: 1.7.3 For people with acute stroke who require help to sit out of bed, stand or walk, do not offer high-intensity mobilisation in the first 24 hours after symptom onset. |
| NHS England/ Intercollegiate Stroke Working Party | Guideline | 17 | 16-19 | We disagree with the current wording of this recommendation. The wording of the recommendation should be changed to more accurately reflect the Mental Capacity Act. (KS) | Thank you for your comment. This recommendation is strongly supported by the other recommendation advising discussion of risks and benefits and is in line with the Mental Capacity Act. Most people who are eligible for decompressive hemicraniectomy will not have capacity to make a decision in relation to the operation and it will mostly be family/ carers who are making the decision. We are also producing a decision aid that will help patients and family/carers make informed decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline. |

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| <p>NHS England/ Intercollegiate Stroke Working Party</p> | <p>Guideline 1.1.5 and 1.1.6</p> | <p>19</p> | <p>7-30</p> | <p>The new guidance states that all patients with a suspected TIA should be seen by a specialist within 24 hours and offered 300mg aspirin (unless contraindicated) It is welcomed that all TIA patients are to be treated with the same degree of urgency-the previous guidance was difficult to remember This is significantly different from the 2008 guidance which was at best confusing and required GPs to undertake a 'risk stratification' using the ABCD score. High risk patients were to be seen within 24 hours and low risk within 1 week. This often caused confusion when the patient had left several days before presentation. The new guidance suggests that the risk stratification scoring was not robust in classifying patients at 'low risk'. From a GP perspective this is now much clearer and also likely to have a better impact on patients and public. Patients are now used to recognising stroke and seeking urgent help using the FAST tool but this is also likely to raise awareness that TIA or mini stroke also requires the same degree of urgency. Whilst it is clearer and therefore easier to follow there are implications for capacity. As the public become more aware that a TIA needs urgent attention, this will impact on the number of 'on the day' assessments for primary</p> | <p>Thank you for your comments.</p> <p>The section on recognition of symptoms and FAST was not reviewed as part of this update so we have not made new recommendations or amended the existing recommendations on who the public should seek advice from. We will pass your comments to the surveillance team at NICE for consideration when the guideline is next updated.</p> <p>We have added a sentence to the discussion around the impact of the recommendation to indicate that general practices will need to ensure that they have adequate supplies of aspirin.</p> |
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| | | | | <p>care - in a profession that is already under huge pressure. The public need to have a clear pathway to follow. As in the FAST tool-will they be advised to call 999 or seek GP advice? The former will impact on emergency services but the latter may result in an unnecessary delay. GPs are just going to take a quick history and either refer to the stroke unit/AMU or whatever the acute pathway is or advise patients on a telephone consultation to call 999 or go to A&E. Therefore the initial pathway need to be very clear. Secondly if administration of 300mg aspirin is going to be the gold standard GP practices will need to ensure they have enough available-practice for this is currently unstandardized and often left to the paramedics to administer. Clear advice and funding will need to be established. (AMH)</p> | |
| NHS England/ Intercollegiate Stroke Working Party | Shaded grey areas | | | <p>1.1.3 There is no evidence that the ROSIER enhances the diagnosis of stroke in the emergency room 1.1.7 This contradicts 1.1.4 that specifies giving aspirin immediately 1.2.3 What does the word urgent mean (included a number of times in the guideline – not specific enough?</p> | <p>Thank you for your comment. These comments relate to areas that were not covered within the scope of this guideline. We therefore did not look at any evidence and cannot change the existing recommendations. We have been able to make changes where they do not relate to the evidence review or the old recommendations are incompatible with our new recommendations.</p> |

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| | | | | <p>1.2.4 This would exclude patients are improving as by definition they are not stable</p> <p>1.2.5 we do not believe that there is any need anymore to include both NASCET and ECST criteria – no one uses ECST and potentially a source for confusion</p> <p>1.3.2 Brain scanning should be performed on all suspected stroke within 1 hour</p> <p>1.3.3 What does 'as soon as possible mean'?</p> <p>1.4.2 Don't need to specify level 1 nursing - staff trained in stroke sufficient</p> <p>1.4.11 Specify which antiplatelet drugs – there are lots where there is no evidence at all – so should limit to clopidogrel, aspirin and dipyridamole</p> <p>1.4.7 No evidence for this – patients in AF are not going to have stroke prevented with aspirin and for many patients reasonable to start anticoagulants before the 2 weeks are up</p> <p>1.5.7 blood pressure control before thrombolysis is part of its marketing authorisation – it is not optional</p> <p>1.6.4 should specify not an NG tube within 24 hours of IV thrombolysis</p> <p>1.9.1 Should not be waiting for hydrocephalus to become symptomatic before considering neurosurgery</p> <p>(KS)</p> | <p>We have been able to make the following changes or responses relevant to these comments:</p> <p>1.1.7. refers to aspirin given for secondary prevention by the specialist, whilst 1.1.4 refers to the first contact with a healthcare professional prior to referral to a TIA clinic.</p> <p>1.2.5 We have changed the recommendation and algorithm to refer to NASCET only as ECST is no longer used.</p> <p>1.3.2. We have added the word 'suspected' to the recommendation</p> <p>1.3.3. We have added "within 24hours of symptom onset to the recommendation"</p> <p>1.4.2. We have changed to wording to say "nursing staff trained in acute stroke and thrombolysis to provide level 1 and level 2 care"</p> |
| NHS South Sefton Clinical | Evidence review B | general | general | <p>This is an ideal situation but it may be difficult to implement in primary care. The referral could be made within 24 hours but it may not be</p> | <p>Thank you for your comment. We fully recognise and acknowledge throughout this section of the guidance that the provision of a responsive 24</p> |

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| Commissioning Group | | | | possible to convert this in to an assessment in a designated TIA clinic within 24 hours. This will require serious consideration on how best to Implement TIA clinics 7 days a week. | hour TIA clinic will have potentially significant resource implications for many services. We recognise that implementation may be challenging in some areas currently. However it should also be noted that this strategy is likely to prevent strokes which, as well as being beneficial to patients, would result in cost savings later on. The committee noted the results of an original cost–utility analysis, which was undertaken for this review question in the 2008 version of the stroke guideline (CG68). The analysis concluded that ‘immediate assessment’ had both better health outcomes and lower costs than ‘assessment within a week’ for the entire population of suspected TIA, without the use of a risk stratification tool. Your comments will be considered by NICE where relevant support activity is being planned. |
| NHS South Sefton Clinical Commissioning Group | Evidence review C | general | general | This approach of combining clinical assessment with weighted MRI scans should improve the diagnosis of TIAs as indicated As identified if a DWI MRI scan is required the local pathway is going to be dependent on scanning capacity in the local trust as if there are daily TIA clinics and there is a problem with a scanner for whatever reason then it could have an adverse effect on the whole pathway. | Thank you for your comment. We are glad you agree with the recommendation. We have acknowledged in the guideline the potential impact on services and recognise that implementation may be challenging in some areas currently. Your comments will be considered by NICE where relevant support activity is being planned. |
| NHS South Sefton | Evidence review E | general | general | As part of the recommendations for patients with acute intracerebral haemorrhage it is | Thank you for your comment. This update focuses only on blood pressure management in |

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| Clinical Commissioning Group | | | | suggested that a systolic blood pressure target of below 140 mmHg is achieved and maintained for at least 7 days. Should this link to the NICE Hypertension in Adults Guidelines for on-going treatment advice? | the case of acute intracerebral haemorrhage but a link more generally would be useful. The NICE pathways team will make a link from the stroke guideline to the hypertension guideline, although this guideline relates to hypertension in general. |
| NHS South Sefton Clinical Commissioning Group | Guideline | 4 | 14 | 1.1.4 The guidance included in 1.1.1 does not help with the identification of a posterior circulation stroke or TIA as it fails to increase the awareness of events affecting the posterior circulation. | Thank you for your comment. We acknowledge that this is a difficult issue because there is far greater variability in the presentation of posterior circulation events. However, it was beyond the scope of this guideline update to make recommendations about the identification of posterior circulation stroke. |
| Northern England Clinical Networks | Guideline | 5 | 3 | This recommendation is unclear and is likely to lead to important variation in practice. It is unclear whether aspirin should only be administered after specialist diagnosis. I think it would be reasonable for any sufficiently trained healthcare provider (e.g. general practitioner or paramedic) to administer aspirin to a patient with suspected TIA as soon as possible after the event, and before specialist assessment. Delaying until specialist assessment is likely to increase the number of patients suffering stroke in the interim. | Thank you for your comment. The recommendation to offer aspirin immediately is intended to be on first contact with a healthcare professional, as outlined in the discussion. The recommendation appears before the recommendation to refer to specialist assessment. The secondary prevention recommendation applies after specialist assessment. We have clarified this by amending the recommendation as follows: Offer secondary prevention, in addition to aspirin, as soon as possible after the diagnosis of TIA is confirmed. |
| Northern England Clinical Networks | Guideline | 5 | 16 | It is recommended that carotid imaging be performed “urgently”. This is ambiguous. It would be helpful to specify an objective time scale – e.g. “on the same day as clinical | Thank you for your comment. We have refreshed this recommendation from the 2008 guideline as the previous timescale of 1 week for carotid imaging is out-dated and inconsistent with new |

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| | | | | assessment”, which would match with the adjacent recommendation on the timing of MRI | recommendations for rapid referral and review in the TIA clinic. However, because this area was not within the scope of this update, we were unable to look at any evidence to provide a more detailed timescale. |
| Northern England Clinical Networks | Guideline | 6 | 4 | The word “urgently” is again ambiguous. Please specify an objective measurable time-scale, e.g. on same day. | Thank you for your comment. We have refreshed this recommendation from the 2008 guideline as the previous timescale of 1 week for carotid imaging is out-dated and inconsistent with new recommendations for rapid referral and review in the TIA clinic. However, because this area was not within the scope of this update, we were unable to look at any evidence to provide a more detailed timescale. |
| Northern England Clinical Networks | Guideline | 7 | 2 | The word “immediately” is imprecise. Please specify an objective measurable time-scale e.g. “within one hour” | Thank you for your comment. This is defined in the footnote. |
| Northern England Clinical Networks | Guideline | 7 | 12 | The phrase “as soon as possible” is very imprecise. Please specify an objective measurable time-scale e.g. “within 12 hours” | Thank you for your comment. This was defined in the footnote but we have moved this up into the recommendation itself to make it clearer. |
| Northern England Clinical Networks | Guideline | 8 | 3 | The recommendation that level 1 nursing is appropriate for patients undergoing thrombolysis will have significant effects in reducing nurse staffing of hyperacute stroke units. The current recommended levels for all hyperacute stroke patients are a maximum of 2 patients per qualified nurse – which equates to level 2 care - for all patients within the first 72 hours of stroke. We have been unable to | Thank you for your comment. This change was made in error and we are very grateful that you brought this to our attention. We have reverted to the levels of care as recommended in the 2008 guideline and we have also reworded the recommendation to clarify that the levels relate to levels of care. It now reads: |

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| | | | | sustain an argument for this level of nursing, and have managed to maintain lower ratios of 5-6 patients per qualified nurse on our HASU only by arguing that at least those undergoing thrombolysis are level 2. If the level 1 recommendation is stated as acceptable for patients receiving thrombolysis, who have the highest acuity on stroke units, then it is likely that nursing levels on hyperacute stroke units will be reduced to 10-15 patients per qualified nurse which is current local practice for level 1 patients. | Administer alteplase only within a well organised stroke service with: <ul style="list-style-type: none"> • staff trained in delivering thrombolysis and in monitoring for any complications associated with thrombolysis • nursing staff trained in acute stroke and thrombolysis to provide level 1 and level 2 care • immediate access to imaging and re-imaging, and staff trained to interpret the images. [2008, amended 2019] |
| Northern England Clinical Networks | Guideline | 9 | 3 | The licensed time window for alteplase is 4.5 hours, so to recommend use of thrombolysis in this section, which is about patients presenting between 6 and 24 hours, “as long as it is within licensed time window” is self-contradictory. | Thank you for your comment. This recommendation refers to posterior stroke at any time up to 24 hours after onset, not only between 6 and 24 hours. Therefore this is not self-contradictory. |
| Northern England Clinical Networks | Guideline | 11 | 2 | This recommendation makes sense only for patients anticoagulated with warfarin, and not for the majority of patients who are now treated with Direct Oral Anticoagulants and require different reversal treatments. | Thank you for your comment. We have amended the wording of this recommendation to read: “Return clotting levels to normal as soon as possible in people with a primary intracerebral haemorrhage who were receiving warfarin before their stroke (and have elevated INR). Do this by reversing the effects of the warfarin using a combination of prothrombin complex concentrate and intravenous vitamin K.” |
| Northern England Clinical Networks | Guideline | 11 | 22 | The guidance to not start statins within 48 hours of acute stroke appears to be based on soft evidence that long term statin use may increase long term risk of cerebral | Thank you for your comment. This area is outside of the scope for this update. |

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| | | | | haemorrhage. This was always and remains a dubious interpretation and should be reviewed. | |
| Northern England Clinical Networks | Guideline | 12 | 3 | There is good evidence that providing oxygen to patients with stroke at this level of oxygen saturation may increase disability and mortality. This guidance is out of date and should be reviewed. | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| Northern England Clinical Networks | Guideline | 12 | 18-19, 26-7 | If the recommendation (on line 18) is that patients with systolic greater than 150 mm Hg presenting before 6 hours should have their blood pressure lowered, and (on line 26) that patients presenting after 6 hours with systolics greater than 150 mm Hg should have their blood pressure lowered, then it is superfluous, and confusing, to recommend blood pressure lowering in patients with blood pressure greater than 220 mm Hg (unless the word at the end of line 26 should be “and” rather than “or” as currently). | Thank you for your comment. There was evidence that rapid blood pressure lowering is safe in those presenting within 6 hours and with systolic blood pressure 150-220mmHg and so a strong recommendation has been made for this group. As there was little or no evidence in those presenting beyond 6 hours or those with SBP >220 mmHg a separate, weaker recommendation has been made for these groups. |
| Northern England Clinical Networks | Guideline | 16 | 19-27 | These groups overlap, and between them cover virtually all patients with intracerebral haemorrhage but without hydrocephalus. Would it be more straightforward, and clearer, to say that patients with intracerebral haemorrhage are unlikely to benefit from surgery (or even will not benefit from surgery) unless hydrocephalus is present. | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. . We will pass your comments to the NICE surveillance team who will consider them when they next review the guideline for update. |
| Nutricia Advanced Medical Nutrition | Guideline | 18 | 19 | There is evidence to support the inclusion of the following best practice advice for the care of adults with acute stroke or transient ischaemic attack: | Thank you for your comment. This was not included in the scope of this guideline update. We therefore did not look at any evidence in this |

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| | | | <p>After specialised swallowing assessment a texture modified diet and thickened fluids of a safe texture should be given to patients¹.</p> <p>Increasing viscosity of fluids using thickener is a well-established management strategy for Oropharyngeal Dysphagia (OD)².</p> <p>Patients requiring thickened fluids should be prescribed a gum based fluid thickening product, which does not react with the amylase enzyme found in saliva (which starts the digestion of starch in the mouth), therefore preventing the thickened fluid from ‘thinning’ to ensure a safer swallow by maintaining correct consistency in the mouth³.</p> <p>Sever swallowing difficulties that do not allow sufficient oral intake and are anticipated to persist for more than 1 week require early enteral nutrition via feeding tube (at least within 72 hour)¹.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Wirth et al. Experimental & Translational Stroke Medicine 2013, 5:14. http://www.etsmjournal.com/content/5/1/14 2. Newman R, Vilardell N, Clavé P, Speyer R. Effect of Bolus Viscosity on the Safety and Efficacy of Swallowing and the Kinematics of the Swallow Response in Patients with | <p>area and cannot change the existing recommendations.</p> |
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| | | | | <p>Oropharyngeal Dysphagia: White Paper by the European Society for Swallowing Disorders (ESSD). Dysphagia. 2016;epub:epub.</p> <p>3. Oudhuis L, Vallons K, Sliwinski E. 'Effect of human saliva on the consistency of drinks thickened with a new thickener for dysphagia patients compared to a standard food thickener.' Clinical Nutrition Supplements.2011; 6(1):18(OP043).</p> | |
| Nutricia Advanced Medical Nutrition | Guideline | 19 | 7 | <p>Inclusion of the following prevalence statistics is vital to highlight the enormity of malnutrition and dehydration risk for adults with acute stroke or transient ischaemic attack:</p> <p>Dehydration and malnutrition are common in hospital in-patients with stroke and associated with poor outcomes^{1,2}</p> <p>62% of stroke patients suffer from dehydration at some point during their admission².</p> <p>Up to one quarter of stroke patients become more malnourished in the first weeks following stroke, and the risk of malnutrition increases with increasing hospital stay^{3,4}.</p> <p>A UK study carried out in hyper acute stroke units found that the prevalence of patients at high risk of malnutrition is 29%⁵.</p> | <p>Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. .</p> |

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| | | | <p>This agrees with the proportion of stroke patients at risk of malnutrition reported by Carrión and colleagues of 38.3%⁶.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Foley, N.C., Salter, K.L., Robertson, J., Teasell, R.W. & Woodbury, M.G. (2009) Which reported estimate of the prevalence after stroke is valid? Stroke 40, E66-E74. 2. Rowat A, Graham C & Dennis M, 2012. Dehydration in hospital-admitted stroke patients: detection, frequency, and association. Stroke, 43, 857-9. 3. Davalos A, Ricart W, Gonzalez-Huix F, Soler S, et al, 1996. Effect of malnutrition after acute stroke on clinical outcome. Stroke, 27, 1028-32. 4. Yoo SH, Kim JS, Kwon SU, Yun SC, et al, 2008. Undernutrition as a predictor of poor clinical outcomes in acute ischemic stroke patients. Arch Neurol, 65, 39-43. 5. Gomes F et al. Risk of Malnutrition On Admission Predicts Mortality, Length Of Hospital Stay And Hospitalisation Costs At 6 Months Post Stroke. Stroke, 2014; 45: A63. 6. Carrión et al. Nutritional status of older patients with oropharyngeal dysphagia in a chronic versus an acute clinical situation. Clin Nutr. 2017 Aug;36(4):1110-1116 | |
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| Nutricia Advanced Medical Nutrition | Guideline | 19 | 23 | <p>There is evidence to support the prescription of pre-thickened nutritionally complete oral nutritional supplements (ONS) for this patient group who have dysphagia and require nutritional supplementation.</p> <p>Manual addition of a powder thickener to standard ONS is not recommended, it is extremely difficult to thicken an ONS to a safe, uniform consistency with the manual addition of a powder thickener¹. In practice there is a wide variation in drink consistency when prepared by patients, staff and carers^{2,3,4}.</p> <p>Patient who require nutritional support and have dysphagia should be prescribed a nutritionally complete pre-thickened ONS product, which are aligned with the International Dysphagia Diet Standardisation Initiative (IDDSI).</p> <p>A product available in the lowest volume available may aid compliance^{5,6}. Compliance is significantly better with high energy, low volume ONS vs standard energy, 200ml ONS^{5,6}.</p> <p>References:</p> <p>1. Bedson JV. Are dysphagic patients receiving thickened nutritional supplement drinks? Dietetic recommendations and nursing practice. CN; 9(1): 47-49</p> | <p>Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations.</p> |
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| | | | | <ol style="list-style-type: none"> 2. Garcia J et al. Quality of care issues for dysphagia; modifications involving oral fluids. <i>Journal of Clinical Nursing</i>. Jun;19(11-12):1618-24. 3. Thomas B, Ed. <i>Manual of dietetic practice</i>, 3rd ed, Oxford: Blackwell Scientific Publications 2007 4. Glassburn DL; Deem JF (1998). "Thickener Viscosity in Dysphagia Management: Variability among Speech-Language Pathologists." <i>Dysphagia</i> 13(4): 218-22 5. Hubbard GP, et al. <i>Clin Nutr</i>. 2012;31:293-312 6. Hubbard GP, et al. <i>Proc Nutr Soc</i>. 2010;69(OCE2):E164 | |
| Nutricia Advanced Medical Nutrition | Guideline | 20 | 8 | <p>Inclusion of the following prevalence statistics is vital to highlight the incidence of aspiration and severity of aspiration for adults with acute stroke or transient ischaemic attack:</p> <p>The incidence of aspiration in the acute phase of stroke varies from 16% to 52%. Silent aspiration occurs in 8% to 27% of acute stroke patients. Of identified aspirators, 20% to 67% developed silent aspiration¹.</p> <p>Oropharyngeal dysphagia (OD) is related to the development of severe complications that originate from two main alterations: impaired safety of swallow or the incapability to protect the respiratory airway effectively, this is caused by a</p> | <p>Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations.</p> |

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| | | | | <p>slow neural response associated with delayed laryngeal vestibule closure. Tracheobronchial aspirations cause respiratory complications, including aspiration pneumonia in up to 50% of cases, with an associated mortality of up to 50%².</p> <p>When a decrease in deglutition safety occurs, choking and airway obstruction develop, most commonly as a tracheobronchial aspiration that may result in pneumonia in 50% of cases, with an associated mortality up to 50%³.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Teasell. Dysphagia and aspiration following stroke, EBSR 2018 2. MMI Pilot study Martin, 2018 (https://www.ncbi.nlm.nih.gov/pubmed/29806864) 3. Clave et al. Approaching oropharyngeal dysphagia. Rev Esp Enferm Dig 2004; 96(2): 119-131 | |
| Nutricia Advanced Medical Nutrition | Guideline | 24 | 8 | <p>There is evidence to support the inclusion of the following best practice advice for the care of adults with acute stroke or transient ischaemic attack: Review should be timely and in line with best practice recommendations. Delays in screening for and assessing dysphagia after stroke, are associated with higher risk of stroke-associated pneumonia¹. Since SAP is one of the main</p> | <p>Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations.</p> |

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| | | | | <p>causes of mortality after acute stroke, early dysphagia assessment may contribute to preventing deaths from acute stroke¹.</p> <p>Reference:</p> <p>1. Bray BD, Smith CJ, Cloud GC On behalf of the SSNAP Collaboration, et al. The association between delays in screening for and assessing dysphagia after acute stroke, and the risk of stroke-associated pneumonia. <i>J Neurol Neurosurg Psychiatry</i> 2017;88:25-30.</p> | |
| Royal College of Emergency Medicine | Guideline | General | General | <p>CT angiogram out of hours often requires a doctor to be present for concern of anaphylaxis which could put pressure of ED resources if other safe, less resource intensive options are not explored.</p> | <p>Thank you for your comments. We recognise that implementation may be challenging in some areas currently. Your comments will be considered by NICE where relevant support activity is being planned. We have added information to the committee discussion section of the evidence review to clarify that the CTA should be performed immediately after the plain CT once haemorrhage is excluded to avoid a second visit to the scanner.</p> |
| Royal College of Emergency Medicine | Guideline | General | General | <p>When will the CT angiogram be performed after a routine CT head differentiating Ischaemic vs. Haemorrhagic in the Emergency Department (ED), and if out of hours will this be expected to fall on the stroke service to decide this next step/scan or will ED clinicians be advised to start requesting CTA once a stroke is confirmed?</p> | <p>Thank you for your response. While we cannot specify implementation details within the recommendation we have added information to the committee discussion section of the evidence review to clarify that the CTA should be performed immediately after the plain CT once haemorrhage is excluded to avoid a second visit to the scanner. We anticipate that this would fall within the remit of an ED clinician.</p> |

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| | | | | | We have amended the recommendation to add that; "If a person might be eligible for thrombectomy, imaging with CT contrast angiography should follow. CT perfusion imaging (or MR equivalent) should be added if a person may be eligible for thrombectomy beyond 6 hours of symptom onset" |
| Royal College of Emergency Medicine | Guideline | General | General | If the CTA is expected to follow the CT head once a stroke type has been differentiated, could the CTA be done at the same time with hot reporting from a radiologist to reduce the number of transfers to and from the scanner? Could Higher Speciality Trainees (HST) /Consultant Emergency Doctors or Stroke HST / consultant be considered competent to rule out significant haemorrhage to make these decisions where a Radiologist isn't readily available? As a means of reducing delay in definitive diagnosis required to guide the next management step e.g. thrombectomy in the anterior circulation and to reduce the amount of patient movements which come with risk and resource usage. | <p>Thank you for your response. While we cannot specify implementation details within the recommendation we have added information to the discussion section to clarify that the CTA should be performed immediately after the plain CT once haemorrhage is excluded to avoid a second visit to the scanner. We anticipate that this decision would not always require a radiologist.</p> <p>We have amended the recommendation to add that; "If a person might be eligible for thrombectomy, imaging with CT contrast angiography should follow. CT perfusion imaging (or MR equivalent) should be added if a person may be eligible for thrombectomy beyond 6 hours of symptom onset".</p> |
| Royal College of Emergency Medicine | Guideline | 5 | 10-13 | 1.2 imaging in suspected TIA - Suggests same day MRI imaging from TIA clinic 7 days a week. We suspect this will be challenging for most non-tertiary units where MRI imaging is very limited out-of-hours, and same day scans rarely achievable in hours for anything but suspected cauda equina. | Thank you for your comment. The recommendation made is not for routine MRI scanning in all patients with suspected TIA but for it to be considered following specialist assessment that will determine whether it is required. The evidence for routine MRI scanning was not adequate to make a specific |

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| | | | | | recommendation and so the committee made a research recommendation in this area. Whilst we expect there may be an increase in MRIs requested, there will be a decrease in CTs ordered and a reduction in risk from radiation dose. We note your comments about implementation and agree that this may be challenging in some areas currently. |
| Royal College of Emergency Medicine | Guideline | 8 | 7 | 1.4.3 - 'Appropriate training' needs to be more clearly defined in the final guideline. What is the lowest grade people can be to be considered qualified enough to be trainable to administer alteplase? What is the minimum standard of training to ensure clinicians feel empowered to give it appropriately without needless delay? | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| Royal College of Emergency Medicine | Guideline | 8 | 8-10 | 1.4.3 - Does management within an acute stroke service include the possibility of being transferred to an acute centre within a reasonable timeframe in the event that a stroke patient was taken to a non-hyper-acute stroke service in error by a crew or arrived with own transport. E.g. Clinically and radiologically an ischaemic stroke, NIHSS score significant and indication for thrombolysis present but transfer to acute services will put the patient over this 4.5 hour window for treatment. Does the ED doctor (if appropriately trained), than administer the thrombolysis and transfer out to the acute service for ongoing management / surveillance / imaging? What happens in these less than perfect situations; can a person be transferred | Thank you for your comment. These are all important points in relation to implementation of a Networked Stroke Reperfusion Service but are outside the scope of our guidance. |

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| | | | | after thrombolysis is administered or must they be monitored at that hospital for a period. Or do they transfer the patient immediately to the acute service when triaged as not being at the best hospital for their needs? Guidance on these real but awkward scenarios would be useful in the final guidance. | |
| Royal College of Emergency Medicine | Guideline | 8 | 15 | 1.4.5 - Suggests thrombectomy to be offered within 6 hours of onset symptoms alongside thrombolysis for acute anterior stroke and confirmed occlusion of proximal anterior circulation on CTA or MRA. This will be difficult to achieve as many units unable to offer CTA / MRA out-of-hours and even if performed and condition confirmed a transfer to a unit offering thrombectomy would be required. This would be unachievable if patients present anywhere but a unit able to offer thrombectomy. Would require all HAS to have access to both imaging and thrombectomy services which is not present in many units currently. The time constraints of 6 hours given the need for secondary ambulance transfers would be challenging given the current demands on ambulance services. | Thank you for your response. We agree that the recommendations may be challenging to implement in some areas currently. We have discussed these considerations in the evidence review .Your comments will be considered by NICE where relevant support activity is being planned. |
| Royal College of Emergency Medicine | Guideline | 8 | 22 | 1.4.6 - Extending access for thrombectomy to 24 hours for proximal anterior occlusions will greatly increase numbers of eligible patients and will increase demands for imaging (CTA / MRA) and secondary transfer, unless increased centralisation of stroke services occurs or | Thank you for your comment. We agree that there will need to be some service redesign or expansion in access to implement these recommendations and have discussed this in the evidence review . Your comments will be |

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| | | | | expansion in imaging / thrombectomy access in non-tertiary units occurs. | considered by NICE where relevant support activity is being planned. |
| Royal College of Emergency Medicine | Guideline | 9 | 3 | 1.4.7 - Extending access for thrombectomy to 24 hours for proximal posterior occlusions will greatly increase numbers of eligible patients and will increase demands for imaging (CTA / MRA) and secondary transfer, unless increased centralisation of stroke services occurs or expansion in imaging / thrombectomy access in non-tertiary units occurs. | Thank you for your comment. We agree that there will need to be some service redesign or expansion in access to implement these recommendations and have discussed this in the evidence review . Your comments will be considered by NICE where relevant support activity is being planned. |
| Royal College of Emergency Medicine | Guideline | 12 | 24 | Further definition of 'controlled' blood pressure lowering is required. It is vague and can create indecision amongst care providers – by virtue of 'rapid' being defined as less than 2 hours in the bullet point above it, can controlled be assumed to be anything longer than 2 hours? There appears to be little evidence on this cohort of patients specifically as outlined in the evidence section, but some objective statement of time length leaves less ambiguity. | Thank you for your comment. After further discussion we have amended our recommendation to 'Consider rapid blood pressure lowering for people with acute intracerebral haemorrhage who: <ul style="list-style-type: none"> • present beyond 6 hours of symptom onset, or • have a systolic blood pressure greater than 220 mmHg. Aim for a systolic blood pressure target of below 130 to 140 mmHg within 1 hour of starting treatment and maintain this blood pressure for at least 7 days.' The committee decided that it was reasonable, by extrapolating from the available evidence, to allow clinicians to aim for rapid blood pressure lowering in these patients when they deem it to be appropriate. |
| Royal College of Nursing | General | General | General | The Royal College of Nursing (RCN) welcomes proposals to update the NICE guidelines - | Thank you for your comment. We have responded separately to each of your comments below. |

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| | | | | <p>Stroke and transient ischaemic attack in over 16s: diagnosis and initial management.</p> <p>The RCN invited members who care for people with this condition to review the draft document on its behalf. The comments below reflect the views of our reviewers.</p> | |
| Royal College of Nursing | Guideline | 4 | 17 and 18 | <p>Suggest add the following wordings: 'To be done within 24 hours of onset of symptoms, when appropriate'.</p> <p>This recommendation to always refer to people of suspected TIA for specialist assessment "<i>within 24 hours of onset of symptoms</i>" may not be appropriate if it is decided by the healthcare professional referring. It is important the patient is referred immediately. However, the specialist may decide, in view of the referral, that the patient does not need to be seen within 24 hours because it may not be clinically appropriate.</p> <p>This recommendation might be a challenge to implement in practice if some TIA services do not have the capacity to provide carotid imaging and Computed tomography angiography (CTA) and there are no available staff, for example over the weekend.</p> | <p>Thank you for your comment. We have amended the recommendation to make it clear that the referral is immediate and the patient is seen by a specialist within 24 hours. Clinical judgement is implicit throughout the recommendations and therefore decisions not to see a patient within 24 hours where appropriate are up to the specialist. We recognise that implementation may be challenging in some areas currently. Your comments will be considered by NICE where relevant support activity is being planned.</p> |
| Royal College of Nursing | Guideline | 5 | 1 and 2 | <p>Suggest add the highlighted wordings: Do not use scoring systems, such as ABCD2, to</p> | <p>Thank you for your comment. This was our intended meaning and we have reworded the recommendation to make this clearer. It now</p> |

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| | | | | assess risk of subsequent stroke and decision about referral time. | reads “Do not use scoring systems such as ABCD2 to assess risk of subsequent stroke or to inform urgency of referral”. |
| Royal College of Nursing | Guideline | 5 | 7 | We do not support this recommendation. We consider that a CT brain scan should still be offered if available because not all services will have access to MRI. | Thank you for your comment. We note your comments about implementation and recognise that this may be challenging in some areas currently. The committee thought that many initial CT scans were unnecessary and patients are being exposed to unnecessary ionising radiation dose. Whilst we expect the number of CT scans ordered to drop substantially, the number of MRI scans may only rise a little as many specialists are currently ordering MRIs in addition to CT scans. Further details of the reasoning for this recommendation can be found in the discussion and rationale sections of the evidence review. |
| Royal College of Nursing | Guideline | 5 | 10 | This recommendation will be a challenge to implement in practice because not all services have MRI slots available to cater for a potential increase in the number of patients that will be seen on a daily basis. We would suggest that MRI is considered as the first option and CT brain scanning an alternative if the first option is not available. | Thank you for your comments. The committee noted that MRI should be considered for specific patients to determine the territory of ischaemia, or to detect haemorrhage or alternative pathologies. The committee agreed that CT should only be performed where there is a clinical suspicion of alternative diagnosis that CT could detect. Considering the risks and benefits of CT, including the potential for unnecessary radiation dose, the committee did not want to state that a CT should be done as a second choice. Further details of the reasoning for this recommendation can be found in the |

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| | | | | | discussion and rationale sections of the evidence review. The evidence for routine MRI scanning was not adequate to make a specific recommendation and so the committee decided to make a research recommendation in this area. We note your comments about implementation and agree that this may be challenging in some areas currently. |
| Royal College of Nursing | Guideline | 5 | 17 | We think there needs to be a timeframe definition for what is meant by “urgent” and that it should be on the same day of the specialist assessment. “Urgent” in this context should be in line with Royal College of Physicians’ Stroke guidelines which state that carotid surgery should be “performed as soon as possible and within 1 week of first presentation or deferred for 72 hours in people treated with intravenous thrombolysis”. | Thank you for your comment. We have refreshed this recommendation from the 2008 guideline as the previous timescale of 1 week for carotid imaging is out-dated and inconsistent with new recommendations for rapid referral and review in the TIA clinic. However, because this area was not within the scope of this update, we were unable to look at any evidence to provide a more detailed timescale. |
| Royal College of Nursing | Guideline | 6 | 4 | Patients should be referred on the same day for carotid endarterectomy. | Thank you for your comment. We have refreshed this recommendation from the 2008 guideline as the previous timescale of 1 week for carotid imaging is out-dated and inconsistent with new recommendations for rapid referral and review in the TIA clinic. However, because this area was not within the scope of this update, we were unable to look at any evidence to provide a more detailed timescale. |

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23 November 2018 – 11 January 2019**

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| Royal College of Nursing | Guideline | 6 | 25 | Suggest add the highlighted wording: "Either from the community, from the emergency department or clinic" | Thank you for your comment. We have amended the recommendation to add "outpatient clinics". |
| Royal College of Nursing | Guideline | 7 | General | May want to consider thrombolysis for patients presenting with a wake up stroke, in which advanced brain imaging has demonstrated potential to salvage brain tissue | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make any recommendations. |
| Royal College of Nursing | Guideline | 7 | 2 | Suggest add highlighted word: "With suspected acute stroke" | Thank you for your comment. We have amended the recommendation as suggested to include the word "suspected" as this is more accurate. |
| Royal College of Nursing | Guideline | 7 | 12 | Suggest add highlighted word: "In everyone with suspected acute stroke" | Thank you for your comment. We have amended the recommendation as suggested to include the word "suspected" as this is more accurate. |
| Royal College of Nursing | Guideline | 8 | 3 | The National Stroke Nursing Guideline recommends 'Level 2 nursing staff'. It is probably important to also add a timeframe. Suggest change to the following wordings: "Level 2 nursing staff trained in acute stroke and thrombolysis" | Thank you for your comment. We have reverted to the levels of care as recommended in the 2008 guideline and we have also reworded the recommendation to clarify that the levels relate to levels of care. It now reads: Administer alteplase only within a well organised stroke service with: <ul style="list-style-type: none"> • staff trained in delivering thrombolysis and in monitoring for any complications associated with thrombolysis • nursing staff trained in acute stroke and thrombolysis to provide level 1 and level 2 care • immediate access to imaging and re-imaging, and staff trained to interpret the images. [2008, amended 2019] |

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| | | | | | We are not able to add a timeframe as we did not review any evidence for this topic in the guideline update. |
| Royal College of Nursing | Guideline | 8 | 10 | Suggest add “and competent level 2 nursing staff trained in acute stroke care” | Thank you for your comment. This change was made in error and we are very grateful that you brought this to our attention. We have reverted to the levels as recommended in the 2008 guideline and we have also reworded the recommendation to clarify that the levels relate to levels of care. It now reads: Administer alteplase only within a well organised stroke service with: <ul style="list-style-type: none"> • staff trained in delivering thrombolysis and in monitoring for any complications associated with thrombolysis • nursing staff trained in acute stroke and thrombolysis to provide level 1 and level 2 care • immediate access to imaging and re-imaging, and staff trained to interpret the images. [2008, amended 2019] |
| Royal College of Nursing | Guideline | 9 | 13 | Suggest change to pre-morbid modified Rankin Scale (mRS) | Thank you for your comment. Following stakeholder feedback we have now specified the mRS and NIHSS scores to be taken into account when determining eligibility and suitability for thrombectomy. This is in order to make implementation of the recommendation possible and to align with the NHS England Clinical Commissioning policy on mechanical thrombectomy for acute ischaemic stroke. We have also emphasised the need to think about |

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| | | | | | the person's overall clinical status. The recommendation now reads as follows: Take into account the person's overall clinical status and the extent of established infarction on initial brain imaging to inform decisions about thrombectomy. Select people who have (in addition to the factors in recommendations 1.4.5 to 1.4.7): <ul style="list-style-type: none"> • a pre-stroke functional status of less than 3 on the modified Rankin scale and • a score of more than 5 on the National Institutes of Health Stroke Scale). [2019] |
| Royal College of Nursing | Guideline | 9 | 14 | Clinical severity of stroke should not be taken into consideration. | Thank you for your comment. The committee do think that clinical severity of stroke (i.e. NIHSS score) is an important consideration, and very few people with a low score were included in the trials used to form the recommendations. |
| Royal College of Nursing | Guideline | 11 | General | There needs to be a recommendation for DOACS too for non-valvular Atrial Fibrillation. . | Thank you for your comment. This section of the guideline was not reviewed as part of this update. |
| Royal College of Nursing | Guideline | 11 | 2 to 6 | Not everyone will need vitamin K, especially if they have had an intracerebral haemorrhage (ICH) secondary to a Direct Oral Anticoagulants (DOAC). We consider that this recommendation needs to be revised to cater for patients with ICH on a DOAC. | Thank you for your comment. We have amended the wording of this recommendation to read: "Return clotting levels to normal as soon as possible in people with a primary intracerebral haemorrhage who were receiving warfarin before their stroke (and have elevated INR). Do this by reversing the effects of the warfarin using a combination of prothrombin complex concentrate and intravenous vitamin K." |

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| | | | | | As this section was not reviewed as part of the update we are not able to add any new recommendations about DOAC at this time. We will pass your comments onto the NICE surveillance team who will consider this for the next update of the guideline. |
| Royal College of Nursing | Guideline | 11 | 22 and 23 | We disagree with this recommendation. The current practice and national guideline stroke guidelines, such as the Royal College of Physicians' states that Statin should not be started in patients with ICH. | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| Royal College of Nursing | Guideline | 11 | 22 and 23 | There also needs to be a recommendation here for Atorvastatin, in line with the other NICE guidelines and the Royal College of Physicians (RCP) Stroke guidelines. | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| Royal College of Nursing | Guideline | 12 | 8 and 9 | This seems to be in conflict with current practice and what is recommended in the RCP Stroke guidelines | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| Royal College of Nursing | Guideline | 13 | 21 to 23 | Suggest amend to read: 'Within 4 hours of admission, ensure that people with acute stroke have their swallowing screened by an appropriately trained healthcare professional before being given any oral food, fluid or medication.' | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| Royal College of Nursing | Guideline | 14 | 8 and 9 | Suggest add: 'Except if they have received thrombolysis' | Thank you for your comment. We have amended the recommendation to include the words "unless they have had thrombolysis".. |

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| Royal College of Occupational Therapists | Guideline | General | General | It would be helpful if there were more recommendations included in this document that relate to specific therapy (occupational therapy, physiotherapy or speech and language therapy) interventions. For example Stroke Early Supported Discharge should be offered to those with mild or moderate stroke. | <p>Thank you for your comment. Specific therapies were not identified during scoping as areas that required an update so were not included in our reviews. Service delivery was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make recommendations. .</p> <p>However, the NICE stroke rehabilitation guideline (CG162) specifically covers early supported discharge after stroke in recommendations 1.1.8 to 1.1.17. NICE are proposing to update the stroke rehabilitation guideline shortly, subject to consultation. We will pass your comments to the surveillance team at NICE. We would also encourage you to respond to the consultation.</p> <p>Also, the NICE guideline on Emergency and acute medical care in over 16s: service delivery (NG94) provides recommendations on service delivery for acute care. Recommendation 1.1.6 is particularly relevant for early supported discharge “Provide multidisciplinary intermediate care as an alternative to hospital care to prevent admission and promote earlier discharge. Ensure that the benefits and risks of the various types of intermediate care are discussed with the person and their family or carer”.</p> <p>Additionally, NG94 recommendation 1.2.8 states “Provide access to physiotherapy and</p> |
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| | | | | | occupational therapy 7 days a week for people admitted to hospital with a medical emergency.” |
| Royal College of Occupational Therapists | Guideline | General | General | This may be difficult as unfortunately many therapy interventions in stroke lack a robust evidence base, though there is evidence based on consensus opinions, which is included in other guidelines, for example those from the Royal College of Physicians (available here: https://www.strokeaudit.org/SupportFiles/Documents/Guidelines/2016-National-Clinical-Guideline-for-Stroke-5t-(1).aspx) | Thank you for your comment. We have now referred to this guidance in the context section of the guideline. We have made consensus based recommendations in the absence of evidence for areas that are included in our scope. |
| Royal College of Occupational Therapists | Guideline | General | General | It should be noted that whilst this guideline focuses on the first 48 hours after stroke, many stroke survivors will be discharged home during this time and it would therefore be useful to include recommendations related to transition/discharge from the acute setting to the community. Good acute management should include recommendations regarding thorough and detailed handover to community services for ongoing care/follow up. | Thank you for your comment. It was not part of the scope of this guideline update to review issues of service delivery. However, the NICE stroke rehabilitation guideline CG162 specifically covers early supported discharge after stroke in recommendations 1.1.8 to 1.1.17. NICE are proposing to update the stroke rehabilitation guideline shortly, subject to consultation. We will pass your comments to the surveillance team at NICE. We would also encourage you to respond to the consultation. Also the NICE guideline on Emergency and acute medical care in over 16s: service delivery (NG94) does provide recommendations on service delivery for acute care. Recommendation 1.1.6 is particularly relevant for early supported discharge “Provide multidisciplinary intermediate care as an alternative to hospital care to prevent admission and promote earlier discharge. |

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| | | | | | Ensure that the benefits and risks of the various types of intermediate care are discussed with the person and their family or carer“. |
| Royal College of Occupational Therapists | Guideline | General | General | None of the recommendations related to therapy (Early mobilisation and optimum positioning of people with acute stroke) will have significant cost applications. These recommendations largely reflect what is currently happening in clinical practice. | Thank you for your comment. |
| Royal College of Occupational Therapists | Guideline | 12 | 20-22 | Maintaining a systolic BP target below 140mmHg is a helpful guideline to have for therapists because there is inconsistency amongst stroke doctors in terms of the BP parameters provided to therapists during therapy sessions. The challenge will be in keeping some patients in bed/chair because of their BP when they are desperate to be able to get out of bed and start mobilising. | Thank you for your comment. We agree this may be challenging in some cases, but we hope that mobilisation will take place as described in our recommendations and the clinical status of the patient will be taken into account. |
| Royal College of Physicians | Content | | | The guideline covers interventions up to 2 week. At this stage a number of patients are being cared for at home – perhaps the guideline could include recommendations for early supported discharge? | Thank you for your comment. It was not within the scope of this guideline to review evidence about where the patient would be when they are being treated. The NICE stroke rehabilitation guideline (CG162) specifically covers early supported discharge after stroke in recommendations 1.1.8 to 1.1.17. The gap in timeframes for the 2 pieces of guidance has been recognised and is one of the reasons that NICE are proposing to update the stroke rehabilitation guideline shortly, subject to consultation. We will pass your comments to the |

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| | | | | | <p>surveillance team at NICE. We would also encourage you to respond to the consultation.</p> <p>Also the NICE guideline on Emergency and acute medical care in over 16s: service delivery and organisation (NG94) provides recommendations on service delivery for acute care. Recommendation 1.1.6 is particularly relevant for early supported discharge “Provide multidisciplinary intermediate care as an alternative to hospital care to prevent admission and promote earlier discharge. Ensure that the benefits and risks of the various types of intermediate care are discussed with the person and their family or carer”.</p> |
| Royal College of Physicians | General | General | General | The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our Joint Stroke Medicine Committee and would like to make the following comments. | Thank you for your comment. We have responded separately to each of your comments below. |
| Royal College of Physicians | Guideline | 4 | 16 | The guidance should read that people should be seen for specialist assessment and investigation within 24 hours of onset of symptoms. The current wording is ambiguous and could be read that the referral needs to be done within 24 hours of onset of symptoms rather than that the patient should receive a specialist assessment within this time frame. | Thank you for your comment. We have amended the recommendation to make it clear that the referral is immediate and the patient is seen by a specialist within 24 hours. |
| Royal College of Physicians | Guideline | 5 | 3,4 | This contradicts page 4 line 14 which states that aspirin should be offered once a TIA is | Thank you for your comment. The recommendation to offer aspirin immediately is intended to be on first contact with a healthcare |

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| | | | | suspected. Should this state that when the diagnosis is confirmed by a stroke specialist? | professional, as outlined in the discussion. This is separate from the secondary prevention recommendation which applies after specialist assessment. We have clarified this by amending the recommendation as follows: Offer secondary prevention, in addition to aspirin, as soon as possible after the diagnosis of TIA is confirmed. |
| Royal College of Physicians | Guideline | 5 | 16 | The time frame for carotid imaging should be stated i.e. same day. | Thank you for your comment. We have refreshed this recommendation from the 2008 guideline as the previous timescale of 1 week for carotid imaging is out-dated and inconsistent with new recommendations for rapid referral and review in the TIA clinic. However, because this area was not within the scope of this update, we were unable to look at any evidence to provide a more detailed timescale. |
| Royal College of Physicians | Guideline | 5 | 20 | Is the word stable needed? If a patient is improving they may not be stable but should still be considered for carotid endarterectomy. | Thank you for your comment. This was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing evidence-based recommendation. The word stable in the recommendation was based on evidence that patients with unstable neurological symptoms (stroke in evolution, crescendo TIA) may be harmed by early surgery. In neurologically stable patients, there was no clear difference in the incidence of postoperative neurological deficit after CEA performed at 1–4 weeks after stroke onset. |

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| Royal College of Physicians | Guideline | 6 | 1 | It would be good if a single measure of carotid stenosis could be recommended. | Thank you for your comment. We have amended the recommendation and the algorithm to refer to NASCET and not ECST criteria in line with current practice and to avoid confusion. |
| Royal College of Physicians | Guideline | 6 | 4 | A definition of 'urgently' would be helpful. A timeframe for undertaking CEA should also be given. | Thank you for your comment. We have refreshed this recommendation from the 2008 guideline as the previous timescale of 1 week for carotid imaging is out-dated and inconsistent with new recommendations for rapid referral and review in the TIA clinic. However, because this area was not within the scope of this update, we were unable to look at any evidence to provide a more detailed timescale. |
| Royal College of Physicians | Guideline | 6 | 10 | Suggest remove 'stable'. | Thank you for your comment. This was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendation. The word stable in the recommendation was based on evidence that patients with unstable neurological symptoms (stroke in evolution, crescendo TIA) may be harmed by early surgery. In neurologically stable patients, there was no clear difference in the incidence of postoperative neurological deficit after CEA performed at 1–4 weeks after stroke onset. |
| Royal College of Physicians | Guideline | 6 | 14 | Suggest state 'do not have carotid endarterectomy' rather than 'do not have surgery'. | Thank you for your comment. This was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendation. |

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| Royal College of Physicians | Guideline | 6 | 19 | It would be good if a single measure of carotid stenosis could be recommended. | Thank you for your comment. We have amended the recommendation and the algorithm to refer to NASCET and not ECST criteria in line with current practice and to avoid confusion. |
| Royal College of Physicians | Guideline | 7 | 2 | Could a time frame be specified for immediately? | Thank you for your comment. This is defined in the footnote. |
| Royal College of Physicians | Guideline | 7 | 12 | Could a time frame be specified for as soon as possible? | Thank you for your comment. This was defined in the footnote but we have moved this up into the recommendation itself to make it clearer. |
| Royal College of Physicians | Guideline | 8 | 3 | The recommendation is that patients who are thrombolysed have level 1 nursing. In most units level 2 nurse staffing are provided for these patients. This new recommendation will have a negative impact upon stroke care. | Thank you for your comment. This change was made in error and we are very grateful that you brought this to our attention. We have reverted to the levels of care as recommended in the 2008 guideline and we have also reworded the recommendation to clarify that the levels relate to levels of care. It now reads: Administer alteplase only within a well organised stroke service with: <ul style="list-style-type: none"> • staff trained in delivering thrombolysis and in monitoring for any complications associated with thrombolysis • nursing staff trained in acute stroke and thrombolysis to provide level 1 and level 2 care • immediate access to imaging and re-imaging, and staff trained to interpret the images. [2008, amended 2019]. |
| Royal College of Physicians | Guideline | 9 | 4 | The statement about the thrombolysis licenced time window (4.5 hours) and 24 hour time window seem contradictory. | Thank you for your comment. This recommendation refers to posterior stroke at any time up to 24 hours after onset, not only between |

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| | | | | | 6 and 24 hours. Therefore this is not self-contradictory. |
| Royal College of Physicians | Guideline | 9 | 13,14,15 | Pre-stroke functional status, clinical severity of stroke, extent of established infarct on initial brain imaging are vague. Suggest define. | Thank you for your comment. Following stakeholder feedback we have now specified the mRS and NIHSS scores to be taken into account when determining eligibility and suitability for thrombectomy. This is in order to make implementation of the recommendation possible and to align with the NHS England Clinical Commissioning policy on mechanical thrombectomy for acute ischaemic stroke. We have not included a cut-off for the ASPECTS score because this was not included in the commissioning document, nor was it used as an entry criteria in most of the clinical trials. We have also emphasised the need to think about the person's overall clinical status. The recommendation now reads as follows: Take into account the person's overall clinical status and the extent of established infarction on initial brain imaging to inform decisions about thrombectomy. Select people who have (in addition to the factors in recommendations 1.4.5 to 1.4.7): <ul style="list-style-type: none"> • a pre-stroke functional status of less than 3 on the modified Rankin scale and • a score of more than 5 on the National Institutes of Health Stroke Scale). [2019] |
| Royal College of Physicians | Guideline | 9 | 19 | Suggest specify that aspirin should not be given to patients who have been thrombolysed within the previous 24 hours. | Thank you for your comment. We believe that this is adequately covered in the BNF, which states that the dose should be '300 mg once |

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| | | | | | daily for 14 days, to be initiated 24 hours after thrombolysis or as soon as possible within 48 hours of symptom onset in patients not receiving thrombolysis' |
| Royal College of Physicians | Guideline | 10 | 12 | What is the role of NOACs in the treatment of acute venous stroke? | Thank you for your comment. Treatment with NOACs was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make any recommendations. |
| Royal College of Physicians | Guideline | 10 | 16 | There have been trials of cervical artery dissection published since 2008 e.g. CADISS. | Thank you for your comment. This section was not reviewed as part of the update but we have amended the recommendation to remove reference to a trial as this is no longer relevant. |
| Royal College of Physicians | Guideline | 11 | 1, 8 | The guideline does not mention reversal of NOACs. Should the guideline state that anticoagulants can be started immediately following brain imaging in patients with TIA and non-disabling stroke? | Thank you for your comment. This section of the guideline was not reviewed as part of this update. |
| Royal College of Physicians | Guideline | 11 | 22 | Suggest give a timeline for immediate. The interpretation of the data re early statin for patients with ICH is contentious. | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| Royal College of Physicians | Guideline | 12 | 19, 27 | Patients with BP over 220mmHg should also be offered rapid BP lowering. | Thank you for your comment. We have amended our recommendation to 'Consider rapid blood pressure lowering for people with acute intracerebral haemorrhage who: • present beyond 6 hours of symptom onset, or |

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| | | | | | <ul style="list-style-type: none"> • have a systolic blood pressure greater than 220 mmHg.’ <p>As the evidence was weaker for this cohort, this is a ‘consider’ rather than an ‘offer’ recommendation.</p> |
| Royal College of Physicians | Guideline | 12, 13 | 21,1 | Suggest ‘maintain this blood pressure’ rather than ‘maintain the blood pressure’. Evidence from INTERACT 2 suggests that BP target should be achieved within 1 rather than 2 hours. | <p>Thank you for your suggestions. We have amended the recommendation accordingly in line with the target in INTERACT2, as follows: ‘Consider rapid blood pressure lowering for people with acute intracerebral haemorrhage who:</p> <ul style="list-style-type: none"> • present beyond 6 hours of symptom onset, or • have a systolic blood pressure greater than 220 mmHg. <p>Aim for a systolic blood pressure target of below 130 to 140 mmHg within 1 hour of starting treatment and maintain this blood pressure for at least 7 days.’</p> |
| Royal College of Physicians | Guideline | 13 | 24 | Within a 7 days hyper acute stroke service it is unreasonable for patients are screen as unsafe to swallow to wait for 72 hours for a specialist assessment of swallowing. | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| Royal College of Physicians | Guideline | 14 | 8 | Most stroke physician would avoid placing a nasogastric tube within 24 hours of giving thrombolysis. | Thank you for your comment. We have amended the recommendation to include the words “unless they have had thrombolysis” |
| Royal College of Physicians | Guideline | 15 | 15 | Our experts question the necessity of this paragraph. | Thank you for your comment. We reviewed the evidence for optimal head positioning and it did not suggest any difference between lying flat or |

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| | | | | | with the head elevated. We decided that it would helpful to provide a consensus recommendation supportive of continuing current best practice rather than no recommendation or a recommendation for further research. |
| Royal College of Physicians | Guideline | 15 | 25 | Define high-intensity mobilisation. Does this apply to all patients? Some people will interpret this recommendation that patients should not be mobilised within 48 hours. The AVERT result only apply to patients who needed help to mobilise. | Thank you for your comment. Due to the many variables included in the AVERT trial mobilisation protocol it is not possible to provide a strict definition in the recommendation itself. However, we have linked to a summary of the trial protocol as an explanation of 'high intensity'. Although the AVERT trial did include patients who could mobilise independently, the committee agreed that it would be inappropriate and impractical to limit mobilisation in this group. They did not believe that any of the harms associated with very early, high intensity mobilisation in the AVERT trial would be seen in this group. Therefore, the recommendation has been edited to read: 1.7.3 For people with acute stroke who require help to sit out of bed, stand or walk, do not offer high-intensity mobilisation in the first 24 hours after symptom onset. |
| Royal College of Physicians | Guideline | 16 | 4 | Why is a separate section needed for avoiding aspiration pneumonia – could this be included in assessment of swallowing function? | Thank you for your comment. This section was not reviewed as part of the update to this guideline and therefore has not been changed. |
| Royal College of Physicians | Guideline | 16 | 12 | Where there are long transfer times or potential delays it is prudent to transfer patients with asymptomatic hydrocephalus. | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make recommendations. |

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| Royal College of Physicians | Guideline | 16 | 16 | 1.9.3 is covered within 1.9.1. 1.9.4 should be simplified - most patients with ICH who do not have hydrocephalus do not benefit from surgical intervention. | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. . |
| Royal College of Physicians | Guideline | 17 | 16 | Most people who require a decompression hemicraniectomy will not have the capacity to make a decision re this operation. | Thank you for your comment. We agree and this is why we included discussing with family/carers in the recommendation. We are also producing a decision aid that will help family/carers make informed decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline. |
| Royal College of Physicians | Recommendations for research | 18 | 1 | Further research is needed to identify the optimal models of stroke care provision. | Thank you for your comment. Service models were not included in the review for this update and therefore recommendations for practice or research could not be made. |
| Royal College of Radiologists | Guideline 1.2 | 5-6 | 5-21 | We agree with these recommendations. | Thank you for your comment. |
| Royal College of Radiologists | Guideline 1.4.6 | 8 | | The evidence base for undertaking thrombectomy (MT) in 6-24h window only relates directly to CT Perfusion – used in 4 trials running out to 6/8/16/24h (SWIFT PRIME/REVASCAT/DEFUSE-3 & DAWN respectively) & to collateral scoring using multiphase CTA out to 12h in 1 trial (ESCAPE) We are very concerned that this guideline recommendation as written fails to clarify the advanced brain imaging triage necessary for patients presenting 6-24h. | Thank you for your comment. We have made the recommendation more specific, as follows: if there is the potential to salvage brain tissue, as shown by imaging such as CT perfusion or diffusion-weighted MRI sequences showing limited infarct core volume. |

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| | | | | Current wording indeed suggests that any CT brain imaging in a patient presenting 6-24h is adequate to determine eligible for MT. That lack of detail potentially could lead to considerable patient harm & NHS cost arising from unnecessary transfers & even procedures We would strongly urge that detail needs to be included about the evidence based imaging triage for undertaking thrombectomy in 6-24h window. | |
| Royal College of Radiologists | Guideline 1.4.5 to 1.4.8 | 8-9 | 14-16 | Provision of thrombectomy services will require an expansion in interventional neuroradiology training posts. The expansion of this service will put additional strain on radiology departments due to increased demand for CT and CTA. Other than the comments above, we agree with the thrombectomy recommendations. | Thank you for your comments. We recognise that implementation may be challenging in some areas currently and we have discussed these considerations in the evidence review. Your comments will be considered by NICE where relevant support activity is being planned. |
| Royal College of Radiologists | Guideline 1.4.7 | 9 | | The evidence base for undertaking thrombectomy (MT) in 6-24h window only relates directly to CT Perfusion – used in 4 trials running out to 6/8/16/24h (SWIFT PRIME/REVASCAT/DEFUSE-3 & DAWN respectively) & to collateral scoring using multiphase CTA out to 12h in 1 trial (ESCAPE) We are very concerned that this guideline recommendation as written fails to clarify the advanced brain imaging triage necessary for patients presenting 6-24h. | Thank you for your comment. We have made the recommendation more specific, as follows: • if there is the potential to salvage brain tissue, as shown by imaging such as CT perfusion or diffusion-weighted MRI sequences showing limited infarct core volume. |

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| | | | | <p>Current wording indeed suggests that any CT brain imaging in a patient presenting 6-24h is adequate to determine eligible for MT. That lack of detail potentially could lead to considerable patient harm & NHS cost arising from unnecessary transfers & even procedures We would strongly urge that detail needs to be included about the evidence based imaging triage for undertaking thrombectomy in 6-24h window</p> | |
| Royal College of Radiologists | Guideline 1.4.8 | 9 | | <p>NICE guideline should clarify/recognise that the thrombectomy trials almost exclusively included patients with a pre stroke modified Rankin Score of <3 and NIHSS of >5. The evidence is not there yet (trials are ongoing) for undertaking MT in patients of mRS 3 & NIHSS <6. Such patients should only routinely have MT within the context of such RCTs</p> <p>So we would urge qualification around their statement for 1.4.8 such as the wording added in the parentheses below</p> <ul style="list-style-type: none"> • pre stroke functional status (<i>benefit of MT confirmed for those with mRS <3</i>) • clinical severity of stroke (<i>benefit of MT confirmed for those with NIHSS >5</i>) • extent of established infarction on initial brain imaging (<i>benefit of MT is confirmed for those with ASPECTS 6-</i> | <p>Thank you for your comment. Following stakeholder feedback we have now specified the mRS and NIHSS scores to be taken into account when determining eligibility and suitability for thrombectomy. This is in order to make implementation of the recommendation possible and to align with the NHS England Clinical Commissioning policy on mechanical thrombectomy for acute ischaemic stroke. We have not included a cut-off for the ASPECTS score because this was not included in the commissioning document, nor was it used as an entry criteria in most of the clinical trials. We have also emphasised the need to think about the person's overall clinical status. The recommendation now reads as follows: Take into account the person's overall clinical status and the extent of established infarction on initial brain imaging to inform decisions about thrombectomy. Select people who have (in</p> |

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| | | | | <p><i>10; however caution should be employed regarding MT in those with CT ASPECTS of 0-5,-especially 0-2 as there is evidence from HERMES data that MT is relatively contraindicated with CT ASPECTS 0-2)</i></p> <p>Without such clarification (as in brackets above) then it is “open season” to attempt MT in situations when it is not proven to be either safe or efficacious. That has additional hazards to patients & major costs to NHS.</p> | <p>addition to the factors in recommendations 1.4.5 to 1.4.7):</p> <ul style="list-style-type: none"> • a pre-stroke functional status of less than 3 on the modified Rankin scale and • a score of more than 5 on the National Institutes of Health Stroke Scale). [2019] |
| Royal College of Radiologists | Guideline | 24 | 2 | <p>Again the brain imaging that should be obtained before considering MT is omitted from guideline. – See p24 line 2.</p> <p>Guideline should state what imaging is required – e.g. add wording such that it reads along lines:</p> <p><i>advanced brain imaging (such as MRI with DWI/Perfusion or CT.CTA/CT perfusion) should be performed to demonstrate that there is salvageable brain tissue and to seek evidence of established injury to functionally critical areas of the posterior circulation</i></p> | <p>Thank you for your comment. We have made the recommendation more specific, as follows:</p> <ul style="list-style-type: none"> • if there is the potential to salvage brain tissue, as shown by imaging such as CT perfusion or MRI DWI sequences showing limited infarct core volume. |
| Royal College of Speech and Language Therapists | General | | | <p>Paragraph 1.6 -- nutrition and hydration. We are pleased to see this highlighted and it is important that early attention is given to those with a possible stroke--- it would be important to</p> | <p>Thank you for your comments. Section 1.6 on nutrition and hydration was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations.</p> |

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| | | | | <p>stress that management plan is put in place for those on non-oral feeding discharge home.</p> <p>Paragraph 1.8, and 1.7.1 1.8 refers to the importance of positioning but does not cross refer to the section on avoiding Aspiration Pneumonia (1.7.1) -- whilst assessment is very important and the other guidance is correct there needs reference to positioning which is critical and needs to be mentioned i.e. the patient should not be given food or drink whilst lying down or in a semi-reclined position. There is evidence about the importance of the effect of positioning on the swallowing mechanism.</p> <p>We do not see any reference to mental capacity testing or identification of aphasia and the management of these. Since there is guidance regarding mobility--- perhaps these should be included as well reflecting the RCP guidance.</p> | <p>We also did not update section 1.8 on aspiration pneumonia as it was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. We do not think it is necessary to cross refer to the section on aspiration pneumonia in 1.7 as they closely follow on from each other in the guideline. Recommendation 1.7.1 states that patients should be assessed (including their physical abilities) to determine optimal head position.</p> <p>Mental capacity testing and aphasia were not included in the scope of this guideline update. We therefore did not look at any evidence in this area. However, recommendation 1.7.1 does recommend that cognitive abilities are taken into account.</p> |
| Royal College of Speech and Language Therapists | Guideline | General | General | <p>One third of people following a stroke will have aphasia (communication problems) which affects their ability to understand others and express themselves. Despite this there is no reference in the guideline to supporting communication to allow people to understand and express their wishes and consent to treatment / procedures. Some examples have been provided below however we would encourage the guideline developers to factor</p> | <p>Thank you for your comment. We agree that issues around communication and consent are very important for this group of patients but in principle, they are no different to any other adult patient consent issues, other than the fact that communication may be impaired. It was not within the scope of this guideline update to address this issue because it was not thought to be specific to stroke. As for all NICE guidelines, we include links to information about consent</p> |

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| | | | | <p>this in to all recommendations relating to patient treatment options.</p> | <p>and shared decision making above the recommendations, which apply to people who have had a stroke. Initial and/or emergency interventions (thrombolysis, thrombectomy, blood pressure control, hemicraniectomy) have their own rules / issues with regard to consent / assent.</p> <p>The patient experience for adults guideline (CG138) also provides useful guidance on general issues of patient care.</p> |
| Royal College of Speech and Language Therapists | Guideline | General | General | <p>There is also no mention in the Guideline to shared decision making and how people with aphasia will be supported and what patient decision aids will be needed especially for people with more complex aphasia.</p> | <p>Thank you for your comment. Ongoing support of patients with aphasia was outside the scope of this Guideline update. Shared decision making underlies all NICE guideline recommendations. As for all NICE guidelines, we include links to information about consent and shared decision making above the recommendations, which apply to people who have had a stroke. The patient experience for adults guideline (CG138) also provides useful guidance on general issues of patient care.</p> <p>We are producing a decision aid that will help patients and family/carers make informed decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline.</p> |
| Royal College of Speech and Language Therapists | Guideline | 9 | 11 | <p>Capacity to consent (which may be impaired if communication difficulties are present) should be acknowledged as a factor to be taken into account when considering thrombectomy, therefore we recommend the following addition:</p> | <p>Thank you for your comment.</p> <p>We agree that issues around capacity to consent are very important for this group of patients but in principle, they are no different to any other</p> |

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| | | | | <p>1.4.8 Take into account the following factors when considering thrombectomy (in addition to recommendations 1.4.5 to 1.4.7):</p> <ul style="list-style-type: none"> • Pre-stroke functional status • clinical severity of stroke • extent of established infarction on initial brain imaging. [2019] <p>capacity to consent and required support in understanding/expressing this.</p> | <p>adult patient consent issues, other than the fact that communication may be impaired. It was not within the scope of this guideline update to address this issue because it was not thought to be specific to stroke. As for all NICE guidelines, we include links to information about consent and shared decision making above the recommendations, which apply to people who have had a stroke.</p> <p>The patient experience for adults guideline (CG138) also provides useful guidance on general issues of patient care.</p> |
| Royal College of Speech and Language Therapists | Guideline | 15 | 15 | <p>Ability to understand given information and communicate preferences should be acknowledged as a factor be taken into account when determining optimal head position, therefore we recommend the following addition:</p> <p>1.7.1 Assess the individual clinical needs and personal preferences of people with acute stroke to determine their optimal head position. Take into account factors such as their comfort, physical and cognitive abilities including ability to communicate preferences, and postural control.</p> | <p>Thank you for your comment. It is implicit throughout the guideline that patients' communication needs should be taken into account and so we don't feel it is necessary to add this wording to this recommendation.</p> |
| Royal College of Speech and Language Therapists | Guideline | 17 | 16 | <p>Ability to understand given information about risks/benefits of treatment options and to communicate consent, wishes and preferences to treatments can be confounded by communication difficulties arising after stroke (aphasia). Therefore we recommend the following addition:</p> | <p>Thank you for your comment. Most people who are eligible for decompressive hemicraniectomy will not have capacity to make a decision in relation to the operation and it will mostly be family/ carers who are making the decision. We are producing a decision aid that will help patients and family/carers make informed</p> |

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| | | | | 1.9.6. Discuss the risks and benefits of decompressive hemicraniectomy with people or their family members or carers (as appropriate), taking into account their functional status before the stroke, and their wishes and preferences. [2019]. Particular consideration should be given to those experiencing communication difficulties who may need support in understanding the risks and benefits, and in expressing their preferences, and/or provide consent. | decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline. |
| Salford Royal NHS Foundation Trust | Guideline | 1.4.1 .2 | | We are concerned that the level of nursing care for post thrombolysis and post thrombectomy care has been reduced to level 1 nursing alone. This could challenge effective staffing levels and ability to monitor these patients on the hyperacute stroke unit effectively. Both these patients and PICH patients undergo frequent observation and monitoring for the first 24 hours on the HASU setting or are just stepped down from a HDU environment if this was indicated initially. As such HASUs need to be able to address a blend of level 1 and 2 care often with high patient turnover. Stroke (update): NICE guideline DRAFT (November, 2018) 8 of 38 Administer alteplase only within a well organised stroke service with: <ul style="list-style-type: none"> • staff trained in delivering thrombolysis and in monitoring for any complications associated with thrombolysis | Thank you for your comment. This change was made in error and we are very grateful that you brought this to our attention. We have reverted to the levels of care as recommended in the 2008 guideline and we have also reworded the recommendation to clarify that the term 'level' relates to 'levels of care'. It now reads: Administer alteplase only within a well organised stroke service with: <ul style="list-style-type: none"> • staff trained in delivering thrombolysis and in monitoring for any complications associated with thrombolysis • nursing staff trained in acute stroke and thrombolysis to provide level 1 and level 2 care • immediate access to imaging and re-imaging, and staff trained to interpret the images. [2008, amended 2019] |

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| | | | | <ul style="list-style-type: none"> • level 1 nursing staff trained in acute stroke and thrombolysis • immediate access to imaging and re-imaging, and staff trained to interpret the images. [2008, amended 2019] <p>Here are the levels for critical care nursing: National Codes:</p> <p>Level 0 (Patients whose needs can be met through normal ward care in an acute hospital) Level 1 (PATIENTS at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward with additional advice and support from the critical care team.) Level 2 (PATIENTS requiring more detailed observation or intervention including support for a single failing organ system or post-operative care and those 'stepping down' from higher levels of care.) Level 3 (PATIENTS requiring advanced respiratory support alone or monitoring and support for two or more organ systems. This level includes all complex PATIENTS requiring support for multi-organ failure.)</p> | |
| Society and College of Radiographers | Evidence review C | 7 | 8-10 | <p>The Society and College of Radiographers is concerned that if all patients with suspected TIA are imaged with MRI instead of CT there will be an increased cost and resource burden. We therefore recommend a concurrent revision of</p> | <p>Thank you for your comment. The recommendation made is not for routine MRI scanning in all patients with suspected TIA but for it to be considered following specialist assessment that will determine whether it is required. The recommendation has been</p> |

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| | | | | <p>imaging referral guidelines to reflect the guidance.</p> | <p>reworded to make this clear. It now reads: "After specialist assessment in the TIA clinic, consider MRI (including diffusion-weighted and blood-sensitive sequences) to determine the territory of ischaemia, or to detect haemorrhage or alternative pathologies. If MRI imaging is done, perform it on the same day as the assessment".</p> <p>The evidence for routine MRI scanning was not adequate to make a specific recommendation and so the committee decided to make a research recommendation in this area.</p> <p>Stopping routine CT scanning will reduce costs, although the recommendation regarding MRI scanning may increase use to some extent. The potential for substantial resource impact to the NHS is being considered by the NICE resource impact team.</p> <p>We are not sure which imaging referral guidelines you are referring to. Within this guideline, imaging for acute stroke was not highlighted as an area for update at the start and therefore was outside the scope for this update.</p> |
| Society and College of Radiographers | Guideline | 5 | 7 -13 | <p>The Society and College of Radiographers welcomes guidance that supports appropriate referral for CT and specifically not offering a CT brain scan to people with a suspected TIA unless there is clinical suspicion of an alternative diagnosis that CT could detect. This</p> | <p>Thank you for your comments.</p> <p>We note your comments about implementation and agree that this may be challenging in some areas currently. Your comments will be</p> |

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| | | | | <p>is a positive step towards reduction of the stochastic risks to the population from exposure to ionising radiations. It may also offer some opportunity for CT services to enable faster access to other patients.</p> <p>The Society and College of Radiographers supports the use of same day MRI where appropriate and recognises that this may have an impact on services that do not currently provide rapid access to MRI. There are likely to be resource implications in terms of staffing and access time for other service users.</p> | <p>considered by NICE where relevant support activity is being planned.</p> |
| Society and College of Radiographers | Guideline | 7 | 1 | <p>Although this section is not for comment The Society and College of Radiographers strongly believes that “brain imaging” could be interpreted as non-enhanced CT brain and this might lead to critical missed opportunities and time delays before a cerebral angiogram is performed. This could be particularly detrimental in cases where emergent mechanical thrombectomy is indicated. (see later point 7).</p> | <p>Thank you for your comment. We agree that this is important. We have amended the recommendation to add:</p> <p>If a person might be eligible for thrombectomy, imaging with CT contrast angiography should follow. CT perfusion imaging (or MR equivalent) should be added if a person may be eligible for thrombectomy beyond 6 hours of symptom onset.</p> |
| Society and College of Radiographers | Guideline | 8 | 15 | <p>The Society and College of Radiographers suggests “Offer thrombectomy as soon as possible and within 6 hours of symptom onset”</p> | <p>Thank you for your suggestion. We agree and have edited the recommendation accordingly.</p> |
| Society and College of Radiographers | Guideline | 18 | 4-7 | <p>The Society and College of Radiographers welcomes the research recommendation - Does early MRI brain scanning improve</p> | <p>Thank you for your comment.</p> |

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| | | | | outcome after suspected transient ischaemic 7 attack (TIA)? | |
| Society and College of Radiographers | Guideline | 21 | 20-21 | The Society and College of Radiographers endorses the importance of clinical assessment by an adequately trained specialist working within local referral guidelines in a TIA clinic to identify people who may need MRI to detect ischaemia or alternative pathologies. | Thank you for your comment. |
| Society and College of Radiographers | Guideline | 21-22 | 25-30, 1-6 | The Society and College of Radiographers would like the committee to recognise that the potential increase in MRI requests will not necessarily be offset by the decrease in CT imaging. The skills sets required for these two imaging modalities are quite different and often not transferrable. There may also be additional workforce implications where services that provided 24/7 CT access do not currently provide 24/7 access to MRI. | <p>Thank you for your comment.</p> <p>The recommendation made is not for routine MRI scanning in all patients with suspected TIA but for it to be considered following specialist assessment that will determine whether it is required. The recommendation has been reworded to make this clear. It now reads: After specialist assessment in the TIA clinic, consider MRI (including diffusion-weighted and blood-sensitive sequences) to determine the territory of ischaemia, or to detect haemorrhage or alternative pathologies. If MRI imaging is done, perform it on the same day as the assessment.</p> <p>Whilst we expect the number to CT scans ordered to drop substantially, the number of MRI scans may only rise a little as many specialists are currently ordering MRIs in addition to CT scans. Further details of the reasoning for this recommendation can be found in the discussion and rationale sections of the evidence review. The potential for substantial resource impact to</p> |

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| | | | | | the NHS is being considered by the NICE resource impact team. |
| Society and College of Radiographers | Guideline | 36 | Table 2 | The Society and College of Radiographers believes that 1.3.2.1 Brain imaging should be specified as Non-enhanced CT; CT cerebral angiogram or CT perfusion as appropriate throughout the guidance. Scanning technique and routine practice has evolved considerably since 2008 but this does not appear to be appropriately reflected in the guidance. The Society and College of Radiographers recognises that this guidance is likely to inform local policies and procedures and so it would be helpful to indicate the right test at the right time. Recalling patients for additional imaging can have potentially critical consequences. | Thank you for your comment. We agree that this is important. We have amended the recommendation to add: "If a person might be eligible for thrombectomy, imaging with CT contrast angiography should follow. CT perfusion imaging (or MR equivalent) should be added if a person may be eligible for thrombectomy beyond 6 hours of symptom onset". |
| Society of British Neurological Surgeons | Guideline | 17 | 2-4 | The SBNS is concerned that the evidence is not strong enough to remove the age cut off of 60. This recommendation will increase the number of elderly persons who will survive with severe disability. The earlier recommendation of age 60 was for a specific group of patients with Malignant Middle cerebral stroke. As age advances cerebral atrophy increases and the comparison with the younger cohort is not accurate. Also, the morbidity and mortality of Cranial reconstruction is not negligible and could add to the poor outcome of survivors. | Thank you for your comment. We looked at new evidence separately in those aged over and under 60 years of age and benefits were seen in both groups. Although the committee acknowledge in the discussion section of the evidence review that the benefits are smaller in the over 60s, the effect is still clinically meaningful. Therefore, there was no evidence to suggest that age in itself should be used as a cut off criterion for surgery. We do not think that there will definitely be an increase in the number of elderly people surviving with severe disability because the recommendation is strongly supported by the recommendation advising discussion of risks and benefits. It will also be |

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| | | | | | supported by a decision aid that will help patients and family/carers make informed decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline. |
| Society of British Neurological Surgeons | Guideline | 17 | 16-19 | We agree that involvement of family and carers is very important. Proper advanced directives are rarely available. In practice it is not easy to make a judgement regarding performance status, co-morbidity status and the nuances of patient/family/carer views without a face to face discussion with the neurosurgeon. Some patients may be declined and others found to be unsuitable following admission to neurosurgery. | Thank you for your comment. It is our intention that these decisions are very much supported by face to face discussion. To facilitate this we are producing a decision aid that will help patients and family/carers make informed decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline. |
| Society of British Neurological Surgeons | Guideline | 28 | 15-31 | I think we need to be very cautious about this operation in the elderly and more data is required before giving firm recommendations. I suspect removing the age barrier will lead to an increase in the numbers of operations performed and disability! | Thank you for your comment. We did not have evidence supporting age in itself as a cut off for surgery. The recommendation stresses the importance of discussing the risks and benefits and we are in the process of developing a decision tool. Given this we do not necessarily agree that there will be an increase in the number of operations performed. |
| Society of British Neurological Surgeons | Guideline | 29 | 24-26 | Neurosurgery on call services are already extremely busy and overstretched especially after hours and weekends. The removal of the age cut off will cause a significant increase in referrals to neurosurgery for discussion. The decision will be time consuming to obtain views of family etc. This will have a knock-on effect on | Thank you for your comment. We looked at new evidence separately in those aged over and under 60 years of age and benefits were seen in both groups. Although the committee acknowledge in the discussion section of the evidence review that the benefits are smaller in the over 60s, the effect is still clinically meaningful. Therefore, there was no evidence to |

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| | | | | <p>the other emergency conditions that are being managed. We also believe that the number of operations will increase despite the presumed trade off because of pre-stroke performance status because many aged over 60 are in good medical condition.</p> <p>There is a case to consider modification of the recommendation so that the age above 60 group are operated in a research setting with proper governance arrangements so that we have better evidence.</p> | <p>suggest that age in itself should be used as a cut off criterion for surgery. Decisions around decompressive hemicraniectomy will need time for discussion and we are producing a decision aid that will help patients and family/carers make informed decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline.. There will be separate decision aids for those above and below 60. With consideration of the trade-offs of surgery and the increasing number of people eligible for endovascular therapy, the committee did not consider that there was likely to be a significant rise in the numbers having the operation.</p> |
| The Stroke Association | Guideline | General | General | <p>The Stroke Association welcomes the update of the clinical guideline on the treatment of stroke and the opportunity to provide comments on this final proposed guideline. We also fed back on the draft scope in October 2017.</p> <p>Given the significant improvements and developments in the treatment and care of stroke in the last decade since this guideline was published, and despite appreciating that this is a partial update, we remain disappointed that more areas of the guideline are not being updated.</p> <p>Despite a near 50% reduction in mortality since 2007, stroke is still the 4th largest cause of</p> | <p>Thank you for your comment. The scope for this update was based on areas where significant new research had been published or where practice had changed considerably. We have added reference to the NHS Long term plan and the National Stroke programme into the context section of the guideline. We think that the recommendations provided make a considerable step forward in the provision of care for patients.</p> |

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| | | | | <p>death in the UK and the single biggest cause of disability, with huge associated costs to the health services, social care, informal care and the wider economy through lost productivity. Further, the structure and delivery of many elements of stroke services has changed following the implementation of the 2007 National Stroke Strategy, which ended in December 2017.</p> <p>The Stroke Association has been working in partnership with NHS England and other key arm's length bodies, including a representative from NICE to develop the new National Stroke Programme which is underpinned by the NHSE England Long Term Plan. The programme focuses on where most value can be gained in improving stroke treatment and care, including a strong focus on urgent and emergency care. It is therefore extremely timely that the full clinical guideline be updated to ensure that they reflect new research developments and emerging and established best practice so that the progress already made in treating this devastating condition over the last decade is not lost. That said, the update is a missed opportunity to ensure all relevant arm's length bodies and associated policy and clinical guidance are moving in the same direction, with the same level of ambition to make the much-needed improvements we need to see.</p> | |
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| The Stroke Association | Guideline | General | General | <p>As we mentioned in our submission to the consultation on this guideline's draft scope in October 2017, the Intercollegiate Stroke Working Party updated the Royal College of Physicians Guideline in 2016 which is a ready-made source of key evidence and clinical consensus on areas where more research is needed¹. Crucially, it makes recommendations for commissioners on the ideal structure of stroke services, an area where there is very strong evidence that could be better promoted to commissioners in order to improve patient outcomes. We recommend that the final guideline mentions or links to the RCP guideline.</p> <p>National clinical guideline for stroke. Intercollegiate Stroke Working Party. Fifth Edition 2016. Available at: https://www.strokeaudit.org/SupportFiles/Documents/Guidelines/2016-National-Clinical-Guideline-for-Stroke-5t-(1).aspx</p> | <p>Thank you for your comment. We have added a reference to the Intercollegiate Stroke Working Party Guideline in the context section of the guideline.</p> |
| The Stroke Association | Guideline | General | General | <p>We remain disappointed that the guideline committee membership was made up almost exclusively of professionals working in acute medicine. We of course welcome the presence of lay members and a GP but given that 45% of stroke survivors feel 'abandoned' when they leave hospital, and given the need to improve</p> | <p>Thank you for your comment. As the scope for this update focused on specific issues in the early management of stroke and TIA the committee was recruited to reflect the areas relevant for the reviews we were conducting. The committee did include a physiotherapist and a radiographer.</p> |

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| | | | | transition between hospital and community services, there should have been others representing different parts of the stroke pathway, including allied health professionals. This was a real missed opportunity. | |
| The Stroke Association | Guideline | General | General | Another opportunity was the decision not to review the wider scope of this guideline to include stroke rehabilitation, which currently has its own separate guideline. It is contrary to the rationale behind the establishment of the National Stroke Programme – to join up and share best practice and improve stroke treatment and care across the whole pathway by strengthening national leadership and oversight. NICE continuing to separate its guidance reinforces the perception of stroke rehabilitation and longer term support as less important or urgent which, of course, it is not. It also means there is a gap in the guidelines as this draft stroke/TIA guideline covers acute treatment up to 48 hours and only ‘some interventions up to 2 weeks’. The rehabilitation guideline applies from two weeks meaning that in practice, a whole host of interventions some patients may require are not adequately covered by either guideline. | Thank you for your comment. The gap in timeframes for the 2 pieces of guidance has been recognised and is one of the reasons that NICE are proposing to update the stroke rehabilitation guideline shortly, subject to consultation. We will pass your comments to the surveillance team at NICE. We would also encourage you to respond to the consultation. Of note, the NICE pathways are able to link together different NICE guidelines in an interactive online pathway and we will therefore be able to make the link between the two guidelines. |
| The Stroke Association | Guideline | General | General | We remain disappointed that this guideline does not seek to update guidance around important aspects of the acute pathway such as the need to do a brain scan of a suspected stroke patient within 1 hour. This clear | Thank you for your comment. We did not update the section on imaging for suspected stroke as this was not identified as an area for update at the scoping stage, but we have amended the current recommendation |

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| | | | | <p>recommendation is set out in the 2016 RCP stroke guideline and is measured through SSNAP. The National Stroke Programme, and the service specifications it is seeking to develop, is likely to make recommendations in this area and there is a risk that there could be a conflict in guidance to the system.</p> | <p>1.3.2 to bring it in line with recommendations on thrombectomy to state: “Perform brain imaging immediately with a non-enhanced CT for people with acute stroke if any of the following apply:</p> <ul style="list-style-type: none"> • indications for thrombolysis or thrombectomy • on anticoagulant treatment • a known bleeding tendency • a depressed level of consciousness (Glasgow Coma Score below 13) • unexplained progressive or fluctuating symptoms • papilloedema, neck stiffness or fever • severe headache at onset of stroke symptoms. <p>If a person might be eligible for thrombectomy, imaging with CT contrast angiography should follow. CT perfusion imaging (or MR equivalent) should be added if a person may be eligible for thrombectomy beyond 6 hours of symptom onset.</p> <p>‘Immediately’ is defined in the footnote as ‘ideally the next slot and definitely within 1 hour, whichever is sooner’, in line with the National Stroke Strategy.</p> <p>Also recommendation 1.3.3 Perform scanning as soon as possible in everyone with acute stroke without indications for immediate brain imaging.</p> |
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| | | | | | 'As soon as possible' is defined as 'within a maximum of 24 hours after onset of symptoms'. |
| The Stroke Association | Guideline | General | General | We are disappointed that the guideline has not been updated to include the need to provide clear, accessible information and support to stroke patients and their families, particularly those stroke survivors with communication difficulties. Because stroke can so often have a profound effect on ability to communicate, it can reduce capacity not only to make decisions, but also to convey them. 33% of stroke survivors are affected by communication problems, including receptive aphasia (difficulty understanding what is being said), expressive aphasia (difficulties expressing oneself), or a mix of the two. ² Our 2016 survey of stroke survivors found that 27% of them have either severe or moderate communication difficulties (aphasia), and this percentage is sure to be higher for individuals in the immediate aftermath of their stroke, as aphasia tends to be worst in the first days and weeks following a stroke. ³ Stroke can also affect short-term memory which can make communication slower and more difficult. It is therefore not satisfactory for guidance in this area to be restricted to the separate stroke rehabilitation | Thank you for your comment. The areas covered by this partial update were limited to the specific areas agreed in the initial scope and this area was not prioritised at that stage and we therefore did not review evidence in this area. However, the NICE stroke pathways will link together this guideline and the stroke rehabilitation guideline in an interactive online format. The NICE guideline on “Patient experience in adult NHS services: improving the experience of care for people using adult NHS services (CG138)” also covers general aspects of care which are relevant to stroke patients. |

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| | | | | <p>guideline. We strongly recommend an addition to this guideline to rectify the problem.</p> <p>² Stroke Association, 'State of the Nation', January 2016, https://www.stroke.org.uk/resources/state-nation-stroke-statistics</p> <p>³A <i>New Era for Stroke</i>, conducted by The Stroke Association in March 2016. 1,174 stroke survivors in England, Scotland, Wales and Northern Ireland responded to the survey.</p> | |
| The Stroke Association | Guideline | General | General | <p>There are a number of terms used in the guideline which are either vague or open to various interpretation. Some of our clinical colleagues have also raised this issue, highlighting that terms such as "urgent" are subjective. We would call for as much specificity as is reasonably possible within this guideline and ask that the clinicians' concerns around terminology are addressed in the final version.</p> | <p>Thank you for your comment. We have included definitions wherever possible. However, we have not been able to make changes in the areas not covered by the scope of this update. For example, regarding carotid imaging, we cannot specify what timeframe "urgent" will refer to as we have not reviewed any evidence on this topic.</p> |
| The Stroke Association | Guideline | 4 | Sections 1.1.4 – 1.1.5 | <p>We welcome the new recommendations on aspirin after TIA and swift referral. TIA is often a pre-cursor to a larger stroke and it is vital that all TIAs are quickly and thoroughly investigated, with aspirin offered where appropriate.</p> | <p>Thank you for your comment.</p> |
| The Stroke Association | Guideline | 4 | 16-17 | <p>For example, in this section, the Intercollegiate Stroke Working Party has requested that the guidance should more explicitly state that people who have had a suspected TIA should be seen and treated within 24 hours of onset. Referring patients does not necessarily mean</p> | <p>Thank you for your comment. We have amended the recommendation to make it clear that the referral is immediate and the patient is seen by a specialist within 24 hours.</p> |

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| | | | | being seen by a specialist and treatment commenced. | |
| The Stroke Association | Guideline | 8 | Sections 1.4.5 – 1.4.8 | <p>We strongly welcome the inclusion of mechanical thrombectomy in this guideline. We are clear that while relatively few stroke patients are eligible for the procedure, provision of thrombectomy can and should be a catalyst for services improvements across the acute pathway. Despite NHS England’s decision in April 2017 to routinely commission mechanical thrombectomy, we know progress to develop services has been patchy. While the National Stroke Programme will support the roll-out of thrombectomy more widely in England, the inclusion of the procedure in this guideline is another step along the road to the procedure becoming normalised and hopefully available to a larger number of eligible patients.</p> <p>That said, we are disappointed that the guideline does not include guidance for clinicians around supporting those patients with negative experiences of thrombectomy. A 2015 survey carried out by the Stroke Association found that 24% of respondents described their experience in a neutral or negative way. Some people reported pain or discomfort during their procedure and some struggled to cope psychologically with the rapidity of their recovery from the procedure. This has been reinforced to us anecdotally by specialists in at</p> | <p>Thank you for your comment in relation to recommending thrombectomy.</p> <p>The specific point in relation to psychological support for patients with stroke (either following thrombectomy or otherwise) was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make any recommendations.</p> |

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| | | | | least one major stroke unit. We strongly recommend the guideline is amended to include the need for all thrombectomy patients to have an assessment of the psychological needs soon after the procedure and reviewed thereafter. | |
| The Stroke Association | Guideline | 8 | 15 | Insert “as soon as possible and” (or other appropriate wording to emphasise the urgency) before “within 6 hours”. | Thank you for your suggestion. We agree and have edited the recommendation accordingly. |
| The Stroke Association | Guideline | 8 | Section 1.4.6 | <p>We are pleased that NICE is reflecting the latest evidence such as the DAWN trial⁴, which suggests thrombectomies can be carried out on patients between 6 and 24 hours after symptom onset. A longer treatment window will hopefully mean more eligible patients able to have the procedure and able to realise the significant benefits we know it brings to many patients. We would also caution that there could be a risk that extending the time limit for treatment could lead to some patients having their treatment delayed unnecessarily. We would like the guideline to be clear that as with many stroke clinical interventions, speedy treatment is optimal and this is no different with mechanical thrombectomy, with greatest benefit seen in those treated within 6 hours.</p> <p>⁴ Desai SM, Haussen DC, Aghaebrahim A, <i>et al</i>, Thrombectomy 24 hours after stroke:</p> | Thank you for your suggestion and for acknowledging our inclusion of the latest evidence, such as the DAWN trial. We agree and have changed the recommendation to read: Offer thrombectomy as soon as possible to people who were last known to be well between 6 hours and 24 hours previously. |

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| | | | | beyond DAWN, <i>Journal of NeuroInterventional Surgery</i> 2018; 10 :1039-1042. | |
| The Stroke Association | Guideline | 8-9 | Section 1.4.8 | We are aware that colleagues from the stroke clinical community such as the Inter-Collegiate Stroke Working Party have raised the need for clarification in this and other sections covering mechanical thrombectomy around the evidence base. For example, they raise the point that the evidence NICE has referred to around the procedure only relates directly to CT perfusion scanning. We would ask that these concerns are addressed and the draft guideline amended if necessary. | <p>Thank you for your comment. We have made the recommendation more specific, as follows:</p> <ul style="list-style-type: none"> • if there is the potential to salvage brain tissue, as shown by imaging such as CT perfusion or diffusion-weighted MRI sequences showing limited infarct core volume. |
| The Stroke Association | Guideline | 11 | 8 | <p>Although this section is not being updated, we would highlight that aspirin has been proven to have no effect on reducing the likelihood of stroke in people with atrial fibrillation. As per NICE's AF guidance⁵, this should not be recommended and instead, the guidelines should state that anticoagulation should begin as soon as possible, with patients discharged with effective protection.</p> <p>⁵ NICE Atrial fibrillation: the management of atrial fibrillation (CG180), Do Not Do Recommendation. Available: https://www.nice.org.uk/donotdo/do-not-offer-aspirin-monotherapy-solely-for-stroke-prevention-to-people-withatrial-fibrillation</p> | <p>Thank you for your comment. This area is outside the scope of the update but we will pass you comment to the NICE pathways team who will consider if a link can be made between these guidelines.</p> |

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| The Stroke Association | Guideline | 15 | 25 | <p>We are pleased to see guidance around not offering high-intensity mobilisation in the first 24 hours after symptom onset, although we would request a clear definition of what NICE defines as high-intensity mobilisation. As we mentioned in our submission to the draft scope consultation, the AVERT study in 2015 found that very early mobilisation had a detrimental effect on outcomes and therefore has changed the recommendations around early mobilisation in the RCP 2016 stroke guidelines. The current recommendations around mobilisation in CG68 do not provide sufficient clarity around this and therefore should be updated.</p> <p>Further, a 2016 paper looking at appropriate dosing of mobilisation and rehabilitation in AVERT found that smaller, more frequent bursts of activity has the potential to provide patient benefit⁶. As such, we would like to see guidance around that set out more explicitly in the guideline.</p> <p>⁶ Bernhardt, J., et al, Prespecified dose-response analysis for A Very Early Rehabilitation Trial, Neurology. Published online. February 17 2016. Available at: http://www.neurology.org/content/early/2016/02/17/WNL.000000000002459.full.pdf</p> | <p>Thank you for your comment. Due to the many variables included in the AVERT trial mobilisation protocol it is not possible to provide a strict definition in the recommendation itself. However, we have added a link to a summary of the trial protocol as an explanation of 'high intensity'.</p> <p>We considered the evidence you cite, however as it was lower level evidence from a sub-analysis from a single trial it was not a sufficient basis to inform a recommendation. Detail of this has been added to the discussion of the evidence.</p> |
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| The Stroke Association | Guideline | 17 | Section 1.9.6 | We welcome the guidance to discuss the risks and benefits of decompressive hemicraniectomy with patients and/or family and carers. Any information and support, as long as it is appropriately and accessibly communicated, is beneficial. Decision-making around this procedure is obviously critical and potentially very difficult for patients and/or family and carers. NICE has been in contact with us to ask for insight and support around a potential patient decision aid. When we canvassed a small number of clinicians, there was not consensus on whether a patient decision aid was needed and would advise further engagement work with professionals and people affected by this procedure. We are very happy to support NICE with this work. | Thank you for your comment and support. We are producing a decision aid that will help patients and family/carers make informed decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline. |
| The Stroke Association | Guideline | 24 | 29 | As stated above, we welcome the guideline's inclusion of mechanical thrombectomy. In this section, with mention of resource and practice implications, it would seem appropriate to mention the National Stroke Programme, co-chaired by NHS England and the Stroke Association, which will support local health economies to deliver mechanical thrombectomy to more eligible patients. | Thank you for your comment. We have now mentioned the National Stroke Programme, the NHS Long Term plan and the commissioning policy for mechanical thrombectomy in the context section of the guideline. |
| The Stroke Association | Guideline | 30 | 25 | As per our submission to the draft scope consultation, we would like to see mention given to the disparity in prevalence and age of | Thank you for your comment. The committee did not consider gender to be a factor that would impact the efficacy, safety or cost effectiveness of the interventions considered in this update. |

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| | | | | <p>initial stroke between men and women.⁷ Nearly double the number of working age strokes now occur in men than in women. While we welcome an equality consideration being given to those under the age of 55, we would again urge consideration of gender as a key factor.</p> <p>⁷ Age and gender breakdown. SSNAP 2017. Available: https://www.strokeaudit.org/Documents/National/Clinical/Apr2016Mar2017/Apr2016Mar2017-AgeGenderBreakdown.aspx</p> | |
| The Stroke Association | Guideline | 31 | 5 | <p>Stroke Association research estimates that the cost to the NHS of stroke is considerably more than that set out in the draft guideline context section. Indeed, Stroke Association research suggests that current costs to the NHS are around £3.4bn, estimated to rise by 2035 to over £10bn. Current societal costs UK-wide are around £26bn and could reach over £90bn by 2035⁸ We would like to see this section amended to include these latest figures, building on the economic data from SSNAP we referred to in our submission to the draft scope consultation in 2017.</p> <p>⁸ Patel A, berdunov V, King D, Quayyum Z, Wittenberg R, Knapp M, (2017). Executive</p> | <p>Thank you for your comment. We have updated the context section using the figures for England from your report.</p> |

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| | | | | summary Part 2: Burden of Stroke in the next 20 years and potential returns from increased spending on research. Stroke Association. | |
| The Stroke Association | Guideline | 31 | 8 | Given that the guidelines clearly states it applies to patients above the age of 16, it would seem appropriate, as per our draft scope submission, to refer to the Royal College of Paediatrics and Child Health 2017 guidelines on the treatment of stroke in children, which covers all stroke patients under 18 years old. These were also developed using a NICE accredited process ⁹ . ⁹ Stroke in childhood: clinical guideline for diagnosis, management and rehabilitation. RCPCH May 2017. Available at: https://www.rcpch.ac.uk/stroke-guideline | Thank you for your comment. We have now referred to this guidance in the context section of the guideline. |
| Thrombosis UK | General | General | General | Having reviewed the documentation, we agree with the suggested area being reviewed for update. We have no further comments or observations to add to the draft. | Thank you for your comment. |
| UK Clinical Pharmacy Association | Guideline | General | General | Dosing of aspirin for patients (where clopidogrel not appropriate) >70kg 150mg per day, and patients <70kg 75mg/day ...Rothwell PM et al Lancet 2018;392 (10145) 387-99 | Thank you for your comment. This interesting study relates to secondary prevention further along the management pathway. As our recommendation relates to the initial loading dose of aspirin, 300mg is still appropriate, as per the BNF. |

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| | | | | | Secondary prevention of stroke is covered by recommendations in Lipid modification (NICE clinical guideline 67), Hypertension (NICE clinical guideline 127), Type 2 diabetes (NICE clinical guideline 87) and atrial fibrillation (NICE clinical guideline 36). |
| UK Clinical Pharmacy Association | Guideline | General | General | Comment: 16 year olds are viewed as under paediatric services, and at our Trust, patients >17 have been seen in the stroke unit and treated in the same way as 18 years and older. What recommendation/guidance for stroke units to include 16 and 17 year olds as part of the stroke pathway, thus bypassing paediatric services? | Thank you for your comment. In the guideline we have made no distinction between 16, 17 and 18 year olds; our guidance applies to “over 16s”. Local trusts have different policies in terms of where patients are seen and it is not within our remit to specify how the recommendations should be implemented. |
| UK Clinical Pharmacy Association | Guideline | 5 | general | Confirmed TIA- clopidogrel 300mg stat then clopidogrel 75mg thereafter as per RCP Oct 2016, Stroke guidelines | Thank you for your comment. Clopidogrel was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make any recommendations. . We will pass your comments onto the surveillance team at NICE to consider for the next update of the guideline. |
| UK Clinical Pharmacy Association | Guideline | 14 | 6 | ...add medication after ...to take adequate nutrition, fluids and medication orally... | Thank you for your comment. We have amended the recommendation as suggested. |
| UK Clinical Pharmacy Association | Guideline | 14 | 15 | Add Medication Administration – patients with acute stroke who are unable to adequately swallow oral medication should have their oral medication reviewed for amending the formulation to be administered safely | Thank you for your comment. We have added the following wording to the recommendation. <ul style="list-style-type: none"> • have their oral medication reviewed to either amend the formulation or route of administration. |

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| UK Clinical Pharmacy Association | Guideline | 16 | 4 | Add medication after fluidsGive food, fluids and medication to people with dysphagia... | Thank you for your comment. We have amended the recommendation as you suggest. |
| UK Neurointerventional Group | Evidence Review D | General | General | ...The UKNG welcomes the findings of the evidence review regarding Mechanical Thrombectomy. The findings are based on the best currently available scientific evidence. The Group note that the evidence base around mechanical thrombectomy is fast changing and that clinical practice may need to evolve in line with this before further revisions of these guidelines are produced | Thank you for your comment. |
| University Hospitals of Leicester NHS Trust | Evidence review A | General | General | We agree with the policy to start Aspirin at the time of referral, by the clinician initiating referral to the TIA clinic. This has been our practice for many years now, with no reported adverse occurrences. Referrers don't always adhere to this and make their own judgement, because referrals are often made to "rule-out" TIA, where the likelihood is very small, and the diagnosis unlikely. The rate of intracranial haemorrhage (ICH) in the suspected TIA clinic population is very low in our practice too. The ICH patients usually had ongoing neurological symptoms. Despite ongoing symptoms, patients often get referred to the TIA clinic as their symptoms are minor and not deemed to require ED attendance or thrombolysis. We would suggest a caveat saying something like " <i>in the presence of persistent symptoms</i> " | Thank you for your comment. We do not think a change is needed to the recommendation because if symptoms are persistent then it is not a TIA and the person should be referred to the emergency department or directly to a stroke unit. This is captured in recommendations 1.3.1 to 1.3.3. |

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| | | | | <i>or suspicion of intracranial haemorrhage, ED referral for same day brain imaging should be considered to rule out bleeding before initiating Aspirin”</i> | |
| University Hospitals of Leicester NHS Trust | Evidence review B | General | General | <p>We agree with the recommendation to abandon ABCD2 as a clinical risk triage tool. However, there has been significant utility in terms of managing referrals to the TIA clinic.</p> <p><i>We feel that our TIA clinic services are going to be over-stretched with the new 24 hour target for the whole suspected TIA population, and more investment would be required to deliver the proposed blanket 24 hour target.</i></p> | <p>Thank you for your comment. We fully recognise and acknowledge throughout this section of the guidance that the provision of a responsive 24 hour TIA clinic will have potentially significant resource implications for many services. We recognise that implementation may be challenging in some areas currently. However it should also be noted that this strategy is likely to prevent strokes which, as well as being beneficial to patients, would result in cost savings later on. The committee noted the results of an original cost–utility analysis, which was undertaken for this review question in the 2008 version of the stroke guideline (CG68). The analysis concluded that ‘immediate assessment’ had both better health outcomes and lower costs than ‘assessment within a week’ for the entire population of suspected TIA, without the use of a risk stratification tool.</p> <p>Your comments will be considered by NICE where relevant support activity is being planned.</p> |
| University Hospitals of Leicester NHS Trust | Evidence review C | General | General | <p>The proposal to remove CT imaging is welcome.</p> <p>However, there are significant limitations with MRI provision at our site (and in most Trusts).</p> | <p>Thank you for your comment. The committee agreed that MRI should only be considered after specialist assessment and they expected that fewer brain scans would probably be performed overall. Currently all patients with</p> |

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| | | | | <p>The referrer and patient expectation is often to receive a brain scan, and the criteria for when to do and NOT to do an MRI scan remain subjective.</p> <p><i>In the absence of objective criteria, the use and provision of MR imaging may be limited by financial constraints, with a significant risk of potentially over-riding clinical decision making. Thus, clear objective criteria for when not to image would be very welcome.</i></p> | <p>TIA get a CT in the ED whereas not all patients will receive an MRI following expert assessment. The recommendation has been amended to state that MRI should be considered after specialist assessment in the TIA clinic to “determine the territory of ischaemia, or detect haemorrhage or alternative pathologies”. The committee note that many patients currently receive an MRI with these indications and so would not expect the number of MRIs to increase greatly.</p> <p>The evidence for routine MRI scanning was not adequate to make a specific recommendation and so the committee decided to make a research recommendation in this area.</p> |
| University Hospitals of Leicester NHS Trust | Evidence review D | General | General | <p>Whilst we agree that the clinical evidence is now over-whelming in support of provision of thrombectomy, the clinical implications of providing a comprehensive service are underestimated in the document.</p> <p>Specific issues include:</p> <ol style="list-style-type: none"> 1. Lack of provision of a structured service in many areas 2. Inadequate number of interventional neuroradiologists to provide 24-7 cover (even on a regional / hub & spoke model service) 3. The requirement of CTA will become universal for all non-haemorrhagic stroke, and will have significant implications. Clear | <p>Thank you for your comment.</p> <p>Points 1-2: We agree that there will be an impact on services in relation to implementation of the recommendations and have made our recommendations based on the best available evidence. We recognise that implementation may be challenging in some areas currently and have discussed these points in the evidence review.</p> <p>Point 3: We have added some additional text to recommendation 1.3.2. “If a person might be eligible for thrombectomy, imaging with CT contrast angiography should follow. CT perfusion imaging (or MR equivalent) should be added if a</p> |

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| | | | | <p>objective criteria for undertaking CTA might enable a gradual change in clinical practice to minimise the resource implications.</p> <p>4. We suggest a staged approach whereby the focus should primarily be on intervention <6 hours; then for wake up patients, and subsequently to consider the 6-24 hour window.</p> <p>5. There needs to be further clarification about the “potential to salvage brain tissue” with objective criteria to define the term. The availability of routine urgent reporting for brain perfusion studies is limited to none, and significant Radiology resource would be required if this were to be implemented.</p> | <p>person may be eligible for thrombectomy beyond 6 hours of symptom onset”</p> <p>Point 4: Your comments will be considered by NICE where relevant support activity is being planned.</p> <p>Point 5: We have addressed potentially salvageable brain tissue in the narrative of the guideline based on the findings of further imaging. We have also added more detail into the recommendation about the type of imaging that is needed: ‘if there is the potential to salvage brain tissue, as shown by imaging such as CT perfusion or diffusion-weighted MRI sequences showing limited infarct core volume’. However, detailed consideration of detection of salvageable tissue was beyond the scope of this guideline.</p> |
| University Hospitals of Leicester NHS Trust | Evidence review E | Table 3 1.11.1.3 | | <p>Table 3 shows no significant RR estimates for any of the clinically relevant outcomes. Moreover, there is a significant heterogeneity and only 2 studies included which have differing design and conclusions. Whilst the benefits & harms section (1.11.1.3) refers to QOL benefits, Table 3 reports no difference in the EQ-5D scores.</p> <p>With respect to the mRS 0-2 outcome, Table 3 suggests that the point estimate is 26 more per 1000 people treated, but this is a non-</p> | <p>Thank you for your comment. For EQ-5D, the INTERACT2 trial, which was the most relevant to UK practice, showed a statistically significant benefit. This was not the case when the data were pooled with the PATICH study, performed in China including patients having surgical haematoma evacuation with a target post-operative systolic BP of 120-140 mmHg. It is this pooled data that are reported in Table 3, but the committee considered the finding from the more applicable INTERACT2 study provided the best information for the recommendation. This has</p> |

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| | | | | <p>significant result, where the range includes 4 fewer people with mRS 0-2 per 1000; with moderate risk of bias.</p> <p>The rationale for offering an intervention associated with no clear benefit remains unclear.</p> <p>The general recommendation to “offer” could be reasonable, however will contribute to significant uncertainty and variability in clinical practice. More objectivity is required if this were to be implemented. (for example, BP reduction in ischaemic stroke is indicated when there are hypertensive urgencies like encephalopathy, ACS etc)</p> <p>a) It is not clear when the “offer” should actually translate to implementation. Is the suggestion that the patient is offered the choice?</p> | <p>now been made clear in the benefits and harms section.</p> <p>For mRS 0-2, the committee discussed at length the clinical relevance of this finding of 26 more per 1000 in the context of other outcome data and the clinical scenario. Despite the uncertainty around the estimate the committee considered the likely absolute benefit to be sufficiently clinically meaningful to recommend systolic blood pressure lowering in this population, especially as other management options are lacking and there is an absence of evidence of harm.</p> <p>In NICE guidelines recommendations to ‘offer’ a particular treatment are to be interpreted as a strong recommendation that should be implemented for all people whose condition meets the criteria in the recommendation. The term ‘offer’ reflects the need for patient choice about their treatment.</p> |
| University Hospitals of Leicester NHS Trust | Evidence review H | General | General | <p>In our practice, there remains considerable variation in terms of the response from Neurosurgery with regards to provision of decompressive hemicraniectomy, even when NICE criteria are met.</p> <p>It would be useful to have more data on outcomes following the procedure especially with regards to functional status at 6-12 months, to be able to appropriately counsel</p> | <p>Thank you for your comment. We agree and we are facilitating this process by producing a decision aid that will help patients and family/carers make informed decisions about proceeding with decompressive hemicraniectomy and this will be published alongside the guideline.</p> |

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| | | | | <p>patients / relatives; and to have an educated discussion with Neurosurgical colleagues (often in another hospital / Trust) towards standardised decision making, as opposed to <i>ad hoc</i> decision making.</p> <p>Standard information sheets for patients and relatives would help enable evidence-based discussion.</p> <p>Specific guidance for Neurosurgeons including quality metrics for monitoring is required to implement this aspect of the guideline in full.</p> | |
| University Hospitals of Leicester NHS Trust | General | | | <p>In addition to your comments below on our guideline documents, we would like to hear your views on these questions:</p> <ol style="list-style-type: none"> 1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. We feel there are 3 areas where a major impact will be felt: <ol style="list-style-type: none"> a. Provision of the 24 hour TIA clinic target will be a major challenge, especially at larger centres b. TIA clinic MRI imaging constraints will need to be reviewed c. Thrombectomy provision will remain patchy unless major investment follows (as was done for delivery of intravenous thrombolysis); with inconsistent availability and use of CTA | <p>Thank you for your comment.</p> <ol style="list-style-type: none"> 1. We agree that impact may be felt in the areas that you have identified. We have discussed our considerations of these points in the evidence reviews relating to each of these topics. 2. Thank you for highlighting these areas. We have discussed our views on the cost implications in the relevant section of each evidence review. <ol style="list-style-type: none"> a) and c) The committee also identified 24 hour TIA assessment and thrombectomy (incorporating the additional imaging requirements) as areas that may have significant cost implications to the NHS. There will be challenges in some areas to |

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| | | | | <p>unless this gets mandated and “sticks are added” to ensure routine CTA in non-haemorrhagic stroke</p> <p>2. Would implementation of any of the draft recommendations have significant cost implications?</p> <p>a. 24h TIA clinic target</p> <p>b. MR imaging as a one-stop service in the TIA clinic</p> <p>c. Thrombectomy esp when delivered off-site</p> <p>d. MR / CT Perfusion studies – availability and urgent reporting manpower limitations</p> <p>3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)</p> <p>a. Objective criteria / indications for MR imaging (& when imaging is not required) in the TIA clinic</p> <p>b. Objective criteria / indications for CTA in stroke patients, as a step to thrombectomy</p> <p>c. Objective criteria / indications for decompressive hemicraniectomy; & supporting patient info material about outcomes to make informed decisions</p> | <p>implement these recommendations immediately.</p> <p>b) Regarding MR imaging in the TIA clinic, it was the committee’s opinion that any increase in costs from an increase in MR imaging in the TIA clinic was likely to be offset by the saving from avoiding routine CT scanning. MRIs are currently ordered for similar indications and so they do not believe the increase in scans will be very great. They note that they are not recommending routine MRI for all TIA and a research recommendation was made in this area. They also note that we are not recommending that CT is never used, just not routinely in all patients as is often done in current practice. This discussion is captured in more detail in the relevant evidence reviews.</p> <p>3. Thank you for these suggestions. We were not able to go into the detail of implementation initiatives in the guideline but your comments are helpful and will be considered by NICE where relevant support activity is being planned.</p> <p>a. We have reworded our recommendation on MRI in the TIA clinic to read “After specialist assessment in the TIA clinic, consider</p> |
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| | | | | | <p>MRI (including diffusion-weighted and blood-sensitive sequences) to determine the territory of ischaemia, or detect haemorrhage or alternative pathologies. If MRI is done, perform it on the same day as the assessment.” We believe that this clarifies the criteria and indications for MRI.</p> <p>b. Although we did not review the evidence for the section on ‘Specialist care for people with acute stroke’, we have amended the wording of the recommendation on imaging in line with the new recommendations on thrombectomy. We added the following wording “If a person might be eligible for thrombectomy, imaging with CT contrast angiography should follow. CT perfusion imaging (or MR equivalent) should be added if a person may be eligible for thrombectomy beyond 6 hours of symptom onset.”</p> <p>c. We are producing a decision aid that will help patients and family/carers make informed decisions about decompressive hemicraniectomy and this will be published alongside the guideline.</p> |
| University Hospitals Southampton | Evidence review H | | comment | Evidence form DESTINYII suggests only a small percentage of patients achieve an MRS of 3 and the remainder have an MRS 4-5. ? | Thank you for your comment. This evidence from DESTINYII was included in the meta-analysis that informed the committee discussion. Hence |

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| NHS Foundation Trust | | | | impact on tertiary referral centres on transfer of patients of all ages for malignant MCA watch from peripheral hospitals. Impact on beds with increasing referrals for MT | the study was not considered separately, but it was the pooled effect from the body of evidence together that was assessed. We recognise that implementation may be challenging in some areas currently. Your comments will be considered by NICE where relevant support activity is being planned. |
| University Hospitals Southampton NHS Foundation Trust | Guideline | 5 | 2 | ? NASCET criteria only as most centres do not use ECST criteria | Thank you for your comment. We have amended the recommendation and the algorithm to refer to NASCET and not ECST criteria in line with current practice and to avoid confusion. |
| University Hospitals Southampton NHS Foundation Trust | guideline | 9 | comment | Advice re when to consider dual antiplatelets for TIA/ minor stroke based on current evidence would be helpful (CHANCE and POINT trials) | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot make recommendations. . We will pass your comment to the NICE surveillance team who will consider it when the guideline is due to be updated. |
| University Hospitals Southampton NHS Foundation Trust | Guideline | 12 | 8 | ? evidence behind maintaining BGL 4-11. ? practicalities of managing this acutely and need for variable dose insulin infusions etc | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| University Hospitals Southampton NHS | Guideline | 12 | 18 | ? Evidence for rapid BP lowering in patients with ICH presenting within < 6 hrs. NNT= 40 ? cost effectiveness of intense nursing intervention to maintain BP lowering to this level? | Thank you for your comment. The evidence for rapid blood pressure lowering is presented in the document 'Evidence review E: Blood pressure'. The NNT used in the costing was calculated using the absolute risk difference presented in |

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| Foundation Trust | | | | | Table 3 in the clinical review section. A footnote has now been added with the details. Note that this has also now been revised to “Discussion of nursing costs has also been incorporated. The committee noted that it may be that additional nursing time is required for monitoring, however this is difficult to quantify as people will already be being managed in a high dependency area of an emergency department or hyper acute stroke unit and the additional time required is unclear. “ |
| University Hospitals Southampton NHS Foundation Trust | Guideline appendix algorithm | 1,2 | comment | ? incorporate when to consider Dual antiplatelets for TIA/minor stroke (CHANCE and POINT trials) | Thank you for your comment. This area was not included in the scope of this guideline update. We therefore did not look at any evidence in this area and cannot change the existing recommendations. |
| University of Edinburgh | Evidence review C | 6 and 9 | 20-21 and 5-7 | We do not agree entirely with your statement that the ‘... <i>diagnostic accuracy outcomes would not adequately answer the review question</i> ’ as in order to formulate adequate recommendations you need to establish the accuracy of the different imaging techniques (CT, MRI) in identifying ischemia, haemorrhage or alternative relevant pathologies (mimics). So diagnostic outcomes DO answer your research question and indeed your C1 and C2 recommendations (page 9) imply this. | Thank you for your comment. We are glad that most of our conclusions align with yours based on the NIHR HTA. We acknowledge that diagnostic accuracy outcomes could provide some supporting evidence for this review, but the committee prioritised the more clinically relevant test and treat study design for the review question. We note that the NIHR HTA did not identify any relevant diagnostic accuracy studies. |
| | | 7 and | 3 | ‘No relevant health economic studies were identified’ – the NIHR HTA commissioned an evidence synthesis of MRI in stroke prevention, | We have edited the wording in the economic included studies section to say no studies were ‘included’ rather than ‘identified’. |

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| | | 31 | 6 | <p>which was conducted to higher methodological standards, externally peer reviewed and subsequently published in the NIHR Journals Library in 2014 (your reference 11) as well as in further high impact medical journals, all of which is contradicts your criticism of ‘very serious limitations’. The peer review scores were 8/9, 5/9, 9/9, and 8/9 for scientific quality. A few highlights: <i>“All of the components of the study were carried out to the highest standard, given the limitations of available evidence. The methods are all state of the art, including the methods of systematic review, meta-analysis of observational and diagnostic data, and economic modelling.” “I think this is one of the best HTA reports I have seen. It summarizes important areas of clinical evidence in a wide and confusing area of clinical practice. It identifies very worrying deficits in current clinical recommendations and “de-bunks” many of the ingrained beliefs around clinical scoring systems and imaging of the brain in the management of TIA/ minor stroke.” “Overall the quality and methods of the work is of a very high standard. The applicants have used appropriate methods including guidance on reporting.”</i></p> <p>The table of excluded health economic studies says that the above HTA commissioned work was assessed as directly relevant but ‘with very</p> | <p>In terms of the reasons for exclusion of the HTA cost effectiveness model from the health economic review for the guideline, as you suggest this was due to limitations in the clinical evidence base in TIA which means there are limitations in estimates of key inputs in the model. We appreciate that the reason for exclusion of the cost effectiveness model was not clear in the consultation version of the evidence review and have now added text explaining the rationale. We have also amended the explanation in the excluded studies table. For clarification the rating ‘very serious limitations’ is one of three standard categorisations from the checklist used when assessing economic studies for inclusion from the perspective of the guideline. However, as discussed above this has now been replaced with description of the specific issues to avoid misinterpretation.</p> <p>Regarding the reasons on page 10, lines 23-29 you refer to, these relate to why the HTA systematic review and meta-analysis were excluded from the clinical review of the evidence. This text has been edited to make this clearer. The key reason for exclusion from the clinical review was that the review protocol for the guideline specified test and treat studies comparing MRI and CT and none were identified in the HTA. The comment regarding population has been removed from this section.</p> |
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| | | 10 | 23-29 | <p><i>serious limitations and so was excluded from the health economic review</i>. No reasons for this statement of serious limitations are given. What 'very serious limitations'? The statement implies a methodological flaw, whereas perhaps you mean that the analysis had to use estimates of effects albeit based on the best available evidence at the time (in the absence of relevant randomised evidence), in which case the statement should be replaced with one that is more considered, less open to misinterpretation.</p> <p>The reasons given on p 10, lines 23-29 do not amount to 'very serious limitations' but simply reflect the absence of relevant evidence at the time, as highlighted in the HTA report. It identified that the ABCD and related scores were unreliable, possibly even harmful, and should be avoided, a conclusion with which you concur (draft guideline p 19, line 9-17). Please note that the HTA report distinguished TIA from minor stroke, therefore your comment is incorrect. Furthermore, TIA and minor stroke are on a continuum in terms of risk factors and stroke prevention, therefore it would be artificial to separate them too much in any case.</p> <p>The HTA report (ref 11) is clear that it used all available evidence at the time, on which you appear also to have drawn heavily. The health</p> | <p>Regarding the positive yield of MRI, the committee thought that 30-40% is not negligible and noted it is likely to be significantly better than the yield for CT, which is currently requested routinely with its associated risk from radiation dose. The committee also thought that, as the recommendation for MRI is after expert assessment, the number of MRIs being requested was unlikely to increase significantly as clinicians currently order MRIs at this stage even when the patient has had CT.</p> <p>Thank you for highlighting the point that it is not possible to identify which people are likely to have a CT-detectable lesion clinically. We have edited the recommendation to remove the examples, as follows:</p> <p>1.2.1 Do not offer CT brain scanning to people with a suspected TIA unless there is clinical suspicion of an alternative diagnosis that CT could detect.</p> <p>We have also added text to the discussion to explain that the suspicion may be raised by the presence of 'red flag' symptoms, such as headache or fever, that suggest the cause may not be due to a TIA.</p> <p>NICE guideline development methods allow for expert opinion to be taken into account alongside or in the absence of other evidence identified in</p> |
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Stroke and transient ischaemic attack in over 16s: diagnosis and initial management (update)

**Consultation on draft guideline - Stakeholder comments table
23 November 2018 – 11 January 2019**

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| | | | <p>economic model, build by experts in the Health Economic Research Unit at the University of Aberdeen, was populated by all available clinical and diagnostic data, gathered and meta-analysed specifically for this work - e.g., on rates of MRI DWI positivity in TIA (with sensitivity analyses), subsequently published in Annals of Neurology; on risk prediction of ABCD and related scores, subsequently published in Neurology; on rates of mimics, on costs of imaging, stroke care, etc., all published in the heavily peer-reviewed HTA monograph (see above).</p> <p>Furthermore, the work drew on two previous HTA-commissioned and extensively peer-reviewed health economic analyses of imaging in stroke, also published in the NIHR Journals Library and in further relevant medical journals, including in the Lancet, Stroke, Radiology and Statistics in Medicine to name a few.</p> <p>Indeed, the above HTA commissioned work identified, highlighted and acknowledged the absence of randomised trial or other relevant evidence comparing MRI with conventional care pathways, and concluded (as you do) that reliable randomised or other reliable comparative studies were needed! The HTA report was thus critical of UK stroke guidelines at the time, since they recommended use of ABCD scores and</p> | <p>the systematic review. Our recommendations have been well received by stakeholders and we hope this will lead to an improvement in the care of patients and the best use of resources.</p> |
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| | | | | <p>frequent use of MRI in TIA assessment, an expensive policy for which the HTA report had identified no justification. Subsequently, in light of the HTA report, the Canadian Stroke Guideline removed the recommendation for ABCD scores (as you do), and it is fortunate that NICE are also modifying their current clinical recommendation on ABCD scores and encouraging more research on use of MR in TIA assessment to provide more reliable evidence.</p> <p>Therefore, it is rather improper to imply that the HTA report was unreliable through use of the phrase 'very serious limitations' when all the HTA report did was make best use of the available evidence (by critically assessing and synthesising them) and point out that MRI should NOT be used <i>routinely</i> in TIA diagnosis (as the current expert panel does) without more reliable evidence that included clinically relevant outcomes.</p> | |
| | | 10-11 | 31-44 and 1-22 | <p>You propose that it is possible to identify clinically which TIA patients are likely to have a haemorrhage or mass lesion rather than an ischaemic lesion. While 'expert clinical opinion' is the essential starting point (p12 line 3), unfortunately, it was shown many years ago that distinguishing haemorrhage from tumour, from infarct is not possible clinically. The NIHR</p> | |

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| | | | <p>HTA report (ref 11) includes a chapter on the frequency and types of mimics, and many papers were published in the 1990s (summarised in the HTA review of CT in acute stroke 2004) demonstrating that brain imaging with CT or MRI was the only reliable way of differentiating ICH from ischaemic causes, and in the case of MRI, only if a blood sensitive sequence was included. It is also well-established that it is not possible to differentiate clinically between small parenchymal haemorrhages or subdurals from tumours presenting as TIA or from ischaemic lesions. While some patients may have atypical symptoms pointing to a non-vascular cause of symptoms, in the main, these distinctions are only possible with a scan – and CT will identify most tumours, <5day old parenchymal ICA (more than 5 days old requires MRI), subdurals, AVMS, and some recent small infarcts. Many would agree that a brain scan of any type is not necessary in many TIAs. MRI is not needed to identify tumours (line 13), MS is a rare cause of TIA, and the meta-analysis of the frequency of MRI DWI positive findings in TIA clearly shows that an ischaemic lesion will NOT be seen in 60-70% (ie most) TIAs, meaning that most MRI in TIA is actually non-contributory and unhelpful for diagnosis.</p> | |
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| | | | | There is frequent mention of the committee’s ‘expert opinion’ and its use to inform recommendations e.g., on immediate use of MR soon after TIA, for example. This seems at odds with the underpinnings of NICE, which is to use all available evidence, of which there is much relevant material in the HTA report (ref 11), much of which concurs with the committee’s ‘expert opinion’ despite the wording of the Evidence Review. ‘Expert opinion’ has limited basis for recommending widespread use of limited imaging resources; it is what led to problems in the previous Stroke Guidelines. A more tempered approach would be more likely to have impact. | |
| University of Edinburgh | Guideline | 21 | 2 - 30 | <p>While many TIAs do not require a brain scan, please note that it is not possible to differentiate clinically between tumours, haemorrhages, subdurals and ischaemic lesions presenting as TIA. Please see above. CT is used to exclude the non-ischaemic causes (all of the above or which are visible) leaving ‘presumed ischaemia’ diagnosis (which is the default anyway) in those without an alternative visible cause. There is an extensive literature on this, summarised in the heavily peer reviewed and edited 2004 and 2014 HTA reports.</p> <p>Suggesting immediate MRI instead of CT will not save money, but will further overburden already overloaded MR scanners. You really</p> | <p>Thank you for your comment. The committee agreed that while routine CT scanning for all people with suspected TIA often takes place currently it is not an appropriate strategy as it rarely confirms a diagnosis of TIA yet may expose people to unnecessary radiation and waste resources. It was agreed that a more appropriate strategy is to reserve CT scanning for use when there is clinical suspicion of an alternative diagnosis that CT could detect. We have edited the recommendation to remove the examples, as follows:</p> <p>1.2.1 Do not offer CT brain scanning to people with a suspected TIA unless there is clinical suspicion of an alternative diagnosis that CT could detect.</p> |

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| | | | | <p>need better evidence before making such proposals that are currently only based on 'expert opinion'. MR will NOT confirm ischaemic lesions in most TIAs since ischaemic lesions are only visible in about a third of TIAs (leaving 2/3 of scans as negative) – see meta-analysis in chapter 6 of the HTA report (ref 11) and Annals of Neurology publication – the few subsequent publications concur with these findings. You are advocating for a lot of negative scans at high costs for the NHS, displacing patients with more evidence-based indications from the scanner.</p> | <p>We have also added text to the discussion to explain that the suspicion may be raised by the presence of 'red flag' symptoms, such as headache or fever, that suggest the cause may not be due to a TIA. This committee were confident that stopping routine scanning in all people with suspected TIA would reduce CT scans and therefore costs.</p> <p>Please note that the recommendation made about MRI is not for routine MRI scanning instead of routine CT scanning in all patients with suspected TIA but for MRI to be considered following a specialist assessment that will determine whether it is required. We have amended the recommendation to clarify when this might be. This selective approach is considered to align with common practice in the TIA clinic currently. No evidence was identified regarding routine MRI scanning for all patients and so a research recommendation was made.</p> |
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**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

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