NICE National Institute for Health and Care Excellence

# Professional Expert Questionnaire

**Technology/Procedure name & indication: IP881/2 Carotid artery stent placement for asymptomatic extracranial carotid stenosis**

**Your information**

| | |
|---|---|
| **Name:** | Anna Podlasek |
| **Job title:** | GP in training |
| **Organisation:** | Health Education East Midlands |
| **Email address:** | [redacted] |
| **Professional organisation or society membership/affiliation:** | Associate in Training of Royal College of General Practitioners |
| **Nominated/ratified by (if applicable):** | BSIR |
| **Registration number (e.g. GMC, NMC, HCPC)** | 7686818 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

yes ☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

**yes** ☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

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## Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

| | | |
|---|---|---|
| 1 | Please describe your level of experience with the procedure/technology, for example:<br>Are you familiar with the procedure/technology?<br>Have you used it or are you currently using it?<br><br>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? | I have an experience in the simulation training of carotid stenting, and I have taught the technique to many Consultants worldwide as a Lead for High Fidelity Simulation at Tayside Innovation Medtech Ecosystem (TIME) at the University of Dundee, UK. I regularly attend continuing medical education meetings on the topic and am up-to-date with the current devices and their development. I do support international research and co-author manuscripts on carotid disease pathology.<br>I have limited experience performing the procedure on patients, but I have assisted in a total of <20 carotid stenting procedures. Currently, I am in GP training, and on a daily basis, I am not involved with patient selection or referral to another speciality for this procedure.<br><br>**Carotid stenting (CAS)** is not widely used in the NHS, as its open-surgery alternative **(carotid endarterectomy, CEA,** NHS patient info on CEA**)** is more often utilised.<br>CAS in the UK is considered an alternative to the CEA in circumstances when surgery is at a higher risk of complications. Such times include:<br>- previous surgery has been performed, either for the same problem (which has recurred) or other neck surgery. |

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| | | - when surgery on the other side has resulted in nerve damage, which would be problematic should that be repeated on the side in question.<br>- when the carotid artery branches high in the neck, which makes it difficult to reach surgically.<br>- When the patient has had radiotherapy (X-ray treatment) to the neck in the past.<br>- Other diseases, like problematic heart disease or patients who need heart surgery that<br>- Other disease that would be at increased risk by general anaesthesia can be done under local anaesthesia/conscious sedation. |
| | − Is this procedure/technology performed/used by clinicians in specialities other than your own? | In the UK, most of the procedures are done by interventional neuroradiologists. In Poland and other parts of Europe, interventional cardiologists or interventional radiologists with adequate skills perform CAS. This is variable depending on region and staff expertise. |
| | − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. | N/A |
| **2** | − Please indicate your research experience relating to this procedure (please choose one or more if relevant): | **I have done bibliographic research on this procedure.**<br>**I have done research on this procedure in laboratory settings (e.g. device-related research).**<br>~~I have done clinical research on this procedure involving patients or healthy volunteers.~~<br>**I have published this research.**<br>~~I have had no involvement in research on this procedure.~~<br>~~Other (please comment)~~ |

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| **3** | Does the title adequately reflect the procedure?<br><br>Is the proposed indication appropriate? If not, please explain.<br><br>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?<br><br>Which of the following best describes the procedure (please choose one): | Yes, the title adequately reflects the procedure.<br><br>Yes, the proposed indication is appropriate. In a community-based cohort of patients with asymptomatic severe carotid stenosis who did not undergo surgical intervention, the estimated rate of ipsilateral carotid-related acute ischemic stroke was 4.7% over 5 years Incidence of Ischemic Stroke in Patients With Asymptomatic Severe Carotid Stenosis Without Surgical Intervention . Performing CAS among asymptomatic patients would help to mitigate these risks.<br><br>In the current standard of care, usually, the best medical therapy is used (antiplatelets/statin) or CEA. Unfortunately, this is sometimes insufficient for adequate protection or poses periprocedurl risks. However, the lack of universal/targeted screening causes a lack of detection of potential candidates for any preventative intervention. The CAS procedure is well established, but the devices are continuously improved.<br><br>**Established practice and no longer new.**<br><br>~~A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.~~<br><br>~~Definitely novel and of uncertain safety and efficacy.~~<br><br>~~The first in a new class of procedure.~~ |
| **4** | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? | The procedure should be used in addition to the current standard best medical therapy (antiplatelets and statins)<br><br>The individualised patient risk factors should guide MDT-based decision of interventional vs surgical intervention.<br><br>. |

| | | |
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| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?<br><br>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance? | Yes, there is a rapid development of new generation of carotid stents. The newest changes is a dual-layer stent Dual-Layered Stents: The New Standard for Carotid Stenting? There are also many new distal/proximal protection devices. Optimising Brain Protection During Carotid Stenting: How Much Is Enough?; Carotid Artery Stenting: JACC State-of-the-Art Review ,<br><br>In recent years, a modification of the procedure was done with stenting via direct carotid access (TCAR): Transcarotid artery revascularisation (TCAR) stenting or angioplasty for intracranial carotid artery stenosis: Case series and novel application., Transcarotid artery revascularisation (TCAR): a technical video. In addition to the classic femoral access, radial access is also trialled Procedural success with radial access for carotid artery stenting: systematic review and meta-analysis<br><br>Yes, it has changed. Modern studies report a <1% complication rate of CAS, which is lower than the commonly quoted randomised controlled trials from 10-20 years ago. |

## Current management

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| **6** | Please describe the current standard of care that is used in the NHS. | The current standard of care is the best medical therapy (clopidogrel/statins) or CEA. However, many cases stay undetected or remain undertreated without widerspread detection via general/targeted screening and antiplatelet resistance testing. |
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br><br>If so, how do these differ from the procedure/technology described in the briefing? | no |

Potential patient benefits and impact on the health system

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| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | - decreased risk of ischemic events<br>- improved cognitive function<br>- no need for general anasthesia |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | - patients with multimorbidity<br>- patients with incomplete circle of Willis |
| **10** | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | yes, it could lead to<br>- less invasive treatment<br>- improved outcomes<br>- fewer hospital visits |
| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | The procedure can ben done in the existing interventional radiology theatres and no new infrastructure needs to be created for this purpose.<br>It would be worthwhile to introduce targeted screening with widely available ultrasounds (for example during AAA screen) |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | Yes, every operator has a learning curve for the procedure (literature suggests 40 cases The effect of increasing operator experience on procedure-related characteristics in patients undergoing carotid artery stenting ). The training can ben done with the help of high-fidelity simulator, or with the help of Theil cadaveric model, or during proctored real-life cases. |

## Safety and efficacy of the procedure/technology

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| **13** | What are the potential harms of the procedure/technology? | CAS as every medical procedure has risk of complications, such as infection, bleeding, access complication (pseudoaneurysm, groin hematoma), in stent stenosis, bradycardia, hypotensions, vessel perforation, ipsilateral ischemic event, myocardial infarction, or death. |

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| | Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:<br>Adverse events reported in the literature (if possible, please cite literature)<br>Anecdotal adverse events (known from experience)<br>Theoretical adverse events | In the Asymptomatic Carotid Trial I (ACT -1) the primary composite 30-day endpoint rate was 3.8% with first-generation CAS and 3.4% with CEA (p = 0.01 for noninferiority).<br>In the second asymptomatic carotid surgery trial (ACST-2) that randomly allocated 3,625 patients to CAS (n=1811) or CEA (n= 1814) with a mean follow-up of 5 years, more major procedural strokes occurred with CEA (0.99% vs. 0.82%), while CAS was associated with more non-disabling strokes (2.65% vs 1.60%). The there was no statistically significant difference in the incidence of any peri-procedural stroke (3.6% vs 2.4% , p= 0.06) and long-term effects of both procedures was comparable.<br>Further reduction in peri-procedural stroke rate <1% by 30 days using micronet-covered stents and coupled with their long-term treatment durability suggest that a more effective endovascular plaque sealing than that achieved in ACST-2 (with mostly firstgeneration stents), has the potential to achieve outcomes superior to open surgery. Brott et al |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | Morbidity and mortality |
| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | Efficacy and safetyof CAS have been widely proven. |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | Yes, there is ongoing discussion comparing it to CEA, However, the data forming this discussion was acquired 10-20 years ago, and the technology and risk/benefits ratio has changed significantly, |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | **Most or all district general hospitals.**<br>A minority of hospitals, but at least 10 in the UK.<br>Fewer than 10 specialist centres in the UK.<br>Cannot predict at present. |

## Abstracts and ongoing studies

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| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).<br><br>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. | What Is the Role of Transcarotid Artery Revascularization in the Treatment of Carotid Stenosis? |
| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | Endarterectomy Combined With Optimal Medical Therapy (OMT) vs OMT Alone in Patients With Asymptomatic Severe Atherosclerotic Carotid Artery Stenosis at Higher-than-average Risk of Ipsilateral Stroke (ACTRIS)<br><br>Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial (CREST-2)<br><br>A Randomised Trial of Clinical Decision Making in Asymptomatic Carotid Stenosis<br><br>Carotid Revascularization Versus Best Medical Treatment for Asymptomatic Carotid Stenosis<br><br>Endarterectomy vs Stenting in Chinese Asymptomatic Carotid Stenosis Patients (ESCALATE)<br><br>Safety and Efficacy of the CGuard™ Carotid Stent System in Carotid Artery Stenting (C-Guardians)<br><br>Evaluation of the 3-in-1 Neuroguard IEP System for Carotid Artery Stenosis (PERFORMANCE) |
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | Rationale for screening selected patients for asymptomatic carotid artery stenosis<br><br>The evolution from an "average" study patient to patient-specific characteristics to guide interventions in vascular medicine<br><br>Carotid Stenosis and Stroke: Medicines, Stents, Surgery - "Wait-and-See" or Protect? |

## Other considerations

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| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | de Weerd et al performed meta analysis of 23706 participants that revealed the prevalence of severe asymptomatic carotid stenosis in the general population ranges from 0% to 3.1 Results: Prevalence of moderate asymptomatic carotid stenosis ranged from 0.2% (95% CI, 0.0% to 0.4%) in men aged <50 years to 7.5% (5.2% to 10.5%) in men aged > or =80 years. For women, this prevalence increased from 0% (0% to 0.2%) to 5.0% (3.1% to 7.5%). Prevalence of severe asymptomatic carotid stenosis ranged from 0.1% (0.0% to 0.3%) in men aged <50 years to 3.1% (1.7% to 5.3%) in men aged > or =80. For women, this prevalence increased from 0% (0.0% to 0.2%) to 0.9% (0.3% to 2.4%).<br><br>At least 1/3 of ischemic strokes are caused by carotid artery disease. |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br>− Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.<br>− Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: | Beneficial outcome measures:<br>- morbidity and mortality<br><br>Adverse outcome measures:<br>- periprocedural stroke (24h)<br>- in-stent stenosis (24h)<br>- stroke/TIA/amaurosis fugax at 30d or 90d<br>- death at 30d or 90d |

## Further comments

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| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | N/A |

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## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| Choose an item. | | | |
| Choose an item. | | | |
| Choose an item. | | | |

yes ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

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| **Print name:** | **Anna Podlasek** |
| **Dated:** | **01/02/2023** |

View results

Respondent

2 Anonymous

30:23
Time to complete

## Your information

1. Name: *

Mr Dominic Howard

2. Job title: *

Academic Vascular and Endovascular Surgeon

3. Organisation: *

Oxford University Hospitals NHS Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

GMC and RCS (England)

6. Nominated/ratified by (if applicable):

7. Registration number (e.g. GMC, NMC, HCPC) *

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## How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice**

8. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

## The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

9. Please describe your level of experience with the procedure/technology, for example:

   Are you familiar with the procedure/technology?

   I am actively involved in treating patients with asymptomatic carotid disease (both surgery and stenting). I am the PI (Oxford) for the ACST2 trial which randomised asymptomatic patients with carotid disease for either stenting or surgery. I have published extensively on the topic including several recent Lancet publications.

10. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

    - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

    Most carotid stents are performed by a neuroradiologist in the UK. However the decision to perform the procedure, including estimation of risks and benefits for an individual patient, review of anatomy and feasibility for stent placement and access, and management of the patient pre and post intervention are carried out by vascular surgeons with a specialist interest in the area, such as myself.

11. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

13. Is the proposed indication appropriate? If not, please explain

14. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is comparable in terms of risks and benefits to the current standard of care (medical therapy and/or carotid endarterectomy), however it is a novel approach requiring specialist skill-set and only major vascular centres should be performing this. There is now trial evidence supporting its use in appropriate patients. It is a novel approach, but carotid stenting has now been refined and performed safely for over a decade across the globe.

15. Which of the following best describes the procedure:

- ○ Established practice and no longer new.
- ○ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ◉ Definitely novel and of uncertain safety and efficacy.
- ○ The first in a new class of procedure.

16. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Good question. For now, it is an excellent option for patients who are high risk for existing standard of care or who cannot have standard of care due to technical reasons. In the future it may replace standard of care if outcomes continue to improve, which is quite possible.

17. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

Over the last decade, access options and technical improvement in deploying carotid stents safety have resulted in better outcomes for patients. This process will continue.

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes. The ACST2 trial results are a key piece of evidence published recently.

## Current management

19. Please describe the current standard of care that is used in the NHS.

Medical therapy +/- carotid surgery (endarterectomy) in selected cases

20. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

TCAR is a version of carotid stenting that should be included in this appraisal has it may have lower risks than standard carotid stenting

## Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using this procedure/technology?

Small reduction in stroke risk due to carotid disease over a 5-10year period post intervention (5-10%)

22. Are there any groups of patients who would particularly benefit from using this procedure/technology?

High grade asymptomatic carotid disease in patients with features that would place them at higher risk of stroke on medical therapy alone

23. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Yes. Local anaesthetic procedure that is minimally invasive and can potentially be performed as a day-case or 24 hour stay.

24. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    Major vascular centres only with 24/7 interventional neuroradiology specialist support.

25. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Yes. Operators need high volume (more than 50 cases) to achieve excellent results for patients.

## Safety and efficacy of the procedure/technology

26. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    2-3% risk of stroke and/or death
    Access complications (bleeding, limb ischaemia)
    Coronary complications

27. Please list the key efficacy outcomes for this procedure/technology?

30-day and 1-year stroke and / or death rate
Myocardial infarction
Access complications
Stent patency at 30 days and 1 year

28. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Long term stroke risk reduction compared to medical therapy and surgical intervention

29. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Is it non-inferior to surgery or not.

30. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

## Abstracts and ongoing studies

31. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    ASCT2 trial
    Howard et al. Degree of stenosis and stroke risk in asymptomatic patients (Lancet 2021)

32. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    ASCT2
    CREST2

33. Please list any other data (published and/or unpublished) that you would like to share.

## Other considerations

34. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    500

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    **Beneficial outcome measures.**

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Prospective national registry of demographics, intervention details, and core outcomes would be best

36. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    **Adverse outcome measures.**

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    30-day and 1year adverse events. 5-year outcomes (stroke, stent patency, death) would also be excellent.

## Further comments

37. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

    N/A

## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

38. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

39. Description of interests, including relevant dates of when the interest arose and ceased. *

N/A

40. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.** *

- (●) I agree
- ( ) I disagree

## Signature

41. Name: *

Mr Dominic Howard

42. Date: *

20/02/2023

NICE National Institute for Health and Care Excellence

# Professional Expert Questionnaire

**Technology/Procedure name & indication: IP881/2 Carotid artery stent placement for asymptomatic extracranial carotid stenosis**

## Your information

| | |
|---|---|
| **Name:** | Dr Fatemeh Sakhinia |
| **Job title:** | Consultant Interventional Radiologist |
| **Organisation:** | University Hospitals of North Midlands NHS Trust |
| **Email address:** | [redacted] |
| **Professional organisation or society membership/affiliation:** | Royal College of Radiologists and British Society of Interventional Radiology |
| **Nominated/ratified by (if applicable):** | British Society of Interventional Radiology |
| **Registration number (e.g. GMC, NMC, HCPC)** | GMC 6146783 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

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## Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

| | | |
|---|---|---|
| 1 | Please describe your level of experience with the procedure/technology, for example:<br><br>Are you familiar with the procedure/technology? | I am familiar with carotid artery stenting and have performed the procedure both during my Interventional Radiology training and currently as a consultant. My experience is predominantly in the symptomatic patients with internal carotid artery stenosis. However, I have also performed a small number in the asymptomatic patients. |
| | Have you used it or are you currently using it?<br>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?<br>– Is this procedure/technology performed/used by clinicians in specialities other than your own?<br>– If your specialty is involved in patient selection or referral to another specialty for this | I am currently performing carotid artery stenting, but not for asymptomatic patients. So I am familiar with the procedure and the technique.<br>- Carotid artery stenting is performed at a number of trusts but not in large numbers currently. It is however, a procedure that is rising in demand and is of benefit to a group of patients who would benefit from it.<br>- There are some neuro-interventional radiologists who also perform this procedure but not in the elective setting. They perform “drive-by” carotid stenting in the acute setting with patients being treated for acute stroke during a stroke thrombectomy procedure.<br>- My specialty (IR) is involved in patient selection as part of an MDT with referring vascular surgeons and stroke physicians. We normally discuss the referrals in the MDT with our surgical colleagues and make a decision on whether stenting is beneficial when compared to carotid endarterectomy for that particular patient. We also provide diagnostic cross |

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| | procedure/technology, please indicate your experience with it. | sectional imaging for patients with carotid artery disease with CT and MR Angiography. |
| **2** | – Please indicate your research experience relating to this procedure (please choose one or more if relevant): | I have had no involvement in research on this procedure. |
| **3** | Does the title adequately reflect the procedure?<br><br>Is the proposed indication appropriate? If not, please explain.<br><br>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?<br><br>Which of the following best describes the procedure (please choose one): | Yes it does.<br><br>Carotid stenting is not widely performed for asymptomatic patients in the UK. Asymptomatic carotid disease is preferentially treated with medical management in the UK. The benefits for surgery or stenting for asymptomatic disease are less than for symptomatic patients and current commissioning polices restrict offering surgery or stenting to patients with asymptomatic disease. Furthermore there is the perception that procedural risks often outweigh the benefits in terms of stroke prevention<br><br>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. |
| **4** | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? | Likely an addition to existing standard of care. |

| | | |
|---|---|---|
| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?<br><br>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance? | There have been new stents available with novel design for stenting the carotid artery. An example of this is “C Guard” –<br><br>With stenting of the carotid artery it is customary to use cerebral embolic protection devices – akin to a fishing net to catch debris to prevent it from escaping into the circulation of the brain causing stroke. There have been no recent modifications to this technology.<br><br>An entirely new technique of carotid stenting with flow reversal called “TCAR” is available in the USA marketed by a company Silk Road Medical. So far this device and technique are unavailable in the UK or Europe. The approach is trans carotid rather than transfemoral.<br><br>Two trials reported upon recently are worth a mention<br><br>ACST 2 (Lancet 2021) suggested that when patients were treated with surgery or stenting for asymptomatic disease – the results were similar with both procedures having comparable benefits.<br><br>SPACE 2 – (EJVES 2016) tried to answer a more fundamental question – whether surgery or stenting afforded better protection compared to medical therapy alone but failed in its objective as it was unable to recruit enough number of patients to the medical arm.<br><br>The 5 year results recently reported (Lancet Neurology 2022) suggested that surgery or stenting with appropriate medical therapy were not superior to medical therapy alone for asymptomatic disease but the results were guarded because of the small sample size. |

## Current management

| | | |
|---|---|---|
| **6** | Please describe the current standard of care that is used in the NHS. | Current standard of care in the NHS for Asymptomatic carotid disease is best medical management with multi-modal drug therapy and addressing risk factors such as smoking, hypertension, hyperlipidaemia and diabetes mellitus. |

| | | |
|---|---|---|
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br><br>If so, how do these differ from the procedure/technology described in the briefing? | Other than conventional surgery – carotid endarterectomy, no there is nothing else |

## Potential patient benefits and impact on the health system

| | | |
|---|---|---|
| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | Carotid stenting is minimally invasive as compared to surgery. Can be performed under local anaesthesia rather than general anaesthesia, (although carotid surgery can also be performed under LA), which has many benefits and avoids some of the major risks associated with surgery and GA. Reduced hospital stay. Earlier mobilisation.<br>Stenting has been reported to have lower rates of myocardial infarction and cranial injury compared to surgery |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | Patients requiring coronary artery bypass grafting (CABG) with cardiac bypass during the operation, who have significant carotid artery disease may benefit from this procedure, to prevent peri or postoperative stroke risks. |
| **10** | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | Yes – it is recognised from previous trials on asymptomatic carotid disease there are patients in particular younger men who benefit from intervention the most in terms of long term reduction in stroke risk. |
| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | Interventional radiology angiography suite/Hybrid theatre |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | Yes. Vascular interventional radiologists are the predominant specialists who can perform this procedure and training is required even for these specialists to attain the necessary skills to perform the procedure safely with zero to minimal procedural related complications. |

## Safety and efficacy of the procedure/technology

| | | |
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| **13** | What are the potential harms of the procedure/technology? | Stroke (3%) |

| | | |
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| | Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:<br>Adverse events reported in the literature (if possible, please cite literature)<br>Anecdotal adverse events (known from experience)<br>Theoretical adverse events | TIA (1-2%)<br>Vascular injury<br>Occlusion of the carotid artery<br>In-stent stenosis<br>Arterial access complications such as pseudoaneurysm or bleeding requiring surgery<br>Failure to complete the procedure<br>Death |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | Stroke at 30 days - < 3%<br>Death at 30 days - < 3%<br>Complications including MACE – (major adverse cardiac events), bleeding. |
| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | Peri-procedural stroke risk<br>Failure of stenting |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | Yes there is equipoise about the safety and efficacy of carotid stenting (CAS) compared to carotid endarterectomy (CEA) in the literature.<br>Meta-analyses of four large RCTs showed that the 30-day death/stroke rate was 2.19% for CEA vs 3.08% for CAS. But CAS is associated with lower rates of Myocardial Infarction. |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | A minority of hospitals, but at least 10 in the UK. – large arterial networks |

## Abstracts and ongoing studies

| | | |
|---|---|---|
| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your | Recently presented and published comprehensive 2022 European Society Guidelines on management of carotid artery disease (https://esvs.org/wp-content/uploads/2022/10/2023-CPG-on-the-Management-of-Atherosclerotic-Carotid-and-Vertebral-Artery-Disease.pdf) |

| | | |
|---|---|---|
| | own work).<br>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. | |
| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | ACST-2 (Lancet 2021) https://doi.org/10.1016/S0140-6736(21)01910-3<br>SPACE – 2 (Lancet Neurology 2022) https://doi.org/10.1016/S1474-4422(22)00290-3 |
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | One other area of consideration is the causal role of asymptomatic carotid disease in cognitive decline.A recent systemic review had failed to an association (EJVES 2021 https://doi.org/10.1016/j.ejvs.2021.03.024) benefit, however this remains an area of interest and future research in particular if CAS reduces cognitive decline. |

## Other considerations

| | | |
|---|---|---|
| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | The number needed to treat from various trials to prevent one stroke range from 17 to 42 for ipsilateral stroke and 19-63 patients for any stroke. |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br>– Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life | Beneficial outcome measures:<br>No future minor or major stroke – at 30 days and 1 year<br>No cognitive impairment |

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| | measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.<br><br>– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: | Adverse outcome measures:<br>Stroke<br>Death<br>MACE<br>Bleeding |

## Further comments

| | | |
|---|---|---|
| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | Carotid artery stenting in asymptomatic patients to prevent cognitive impairment is a potential area for future research. |

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## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| Choose an item. | | | |
| Choose an item. | | | |
| Choose an item. | | | |

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

| | |
|---|---|
| **Print name:** | **Fatemeh Sakhinia** |
| **Dated:** | **30/01/23** |

NICE National Institute for Health and Care Excellence

## Professional Expert Questionnaire

**Technology/Procedure name & indication:** **IP881/2 Carotid artery stent placement for asymptomatic extracranial carotid stenosis**

**Your information**

| | |
|---|---|
| **Name:** | Click here to enter text. Grunwald |
| **Job title:** | Click here to enter text. Consultant |
| **Organisation:** | Click here to enter text. NHS Tayside |
| **Email address:** | Click here to enter text. [redacted] |
| **Professional organisation or society membership/affiliation:** | Click here to enter text. UKNG, WIST, |
| **Nominated/ratified by (if applicable):** | Click here to enter text. BSIR |
| **Registration number (e.g. GMC, NMC, HCPC)** | Click here to enter text. 6148672 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

☒ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

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| Click here to enter text. |

**Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.**

| | | |
|---|---|---|
| 1 | Please describe your level of experience with the procedure/technology, for example:<br>Are you familiar with the procedure/technology? | As Co-Director of one of the largest Neuroradiology Departments in Germany, I personally conducted >500 carotid stents in symptomatic and asymptomatic patients. Over the last 20 years I have been closely involved in the development of the technique, material and devices, evolvements in imaging and other criteria for patient selection, plaque morphology, IVUS imaging, meta-analyses, proctoring of CAS procedures, research into cognitive changes after CAS in asymptomatic patients and developing international consensus statements on the treatment of asymptomatic carotid stenosis. |
| | Have you used it or are you currently using it?<br>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? | The procedure is currently not widely used. There are only few centres that perform CAS on a regular basis. This has impacted enrolment in recent CAS trials so that inclusion criteria needed to me modified. It also has implications for Endovascular Stroke Treatment- as many tandem lesions (meaning occlusion of the carotid and middle cerebral artery) are currently not treated due to the lack of experience of interventionalists and perceived uncertainty about recommendations.<br>The speed of uptake is increasing relatively fast due to the rising number of Thrombectomies and increasing evidence on the benefits of the procedure with recognition on patient selection based on other criteria than just degree of stenosis. |
| | – Is this procedure/technology performed/used by clinicians in specialities other than your own? | Next to my speciality, the procedure is also performed by a few UK Cardiologists and Radiologist. In most of Europe the procedure is predominantly performed by Cardiologists and Neuroradiologists. There is a new protection system and technique “TCAR” transcarotid artery revascularization procedure (carotid stenting through a small incision at the base of the neck and direct carotid artery) which is often performed jointly with vascular surgeons. |

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| | – If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. | Yes, my speciality (Neuroradiology) is predominantly involved in patient selection as we are usually the 1st to detect the lesion (Doppler/Duplex, CTA/MRA), analyse plaque morphology, vascular lesion load, measure degree of stenosis, presence of a dissection …and suitability for intervention. The patient is then ideally jointly discussed with stroke neurology (putting clinical history, compliance to take medication, previous symptoms etc into context) and vascular surgery (except in acute stroke where operation is not a viable option). This allows optimised choice of treatment option for the patient (precision medicine). |
| **2** | – Please indicate your research experience relating to this procedure (please choose one or more if relevant): | I have done bibliographic research on this procedure.<br><br>I have done research on this procedure in laboratory settings (e.g. device-related research).<br><br>I have done clinical research on this procedure involving patients or healthy volunteers.<br><br>I have published this research in >30 peer reviewed CAS papers.<br><br>I have also designed teaching modules for training doctors and staff to safely perform CAS using high-fidelity simulators and, more recently, developed a novel perfused human cadaveric model to safely teach the procedure and use of devices.<br>Other symptomatic and asymptomatic CAS related research topics include current evidence, lesion load in asymptomatic patients, carotid disease in special cases such as moyamoya disease, anticoagulation regimes, animal studies on stent material and design, carotid artery stenting for acute stroke, hyperperfusion syndrome after CAS in symptomatic and asymptomatic patients, CAS versus surgery, controversies around carotid stenting, comparison of stent free cell area and cerebral lesions in asymptomatic patients, complications during carotid artery stenting, evaluation of proximal protection devices. |
| **3** | Does the title adequately reflect the procedure?<br><br>Is the proposed indication appropriate? If not, please explain. | Yes.<br><br>Yes, but there should be an understanding of “asymptomatic”. Previously “asymptomatic” related only to clinical symptoms. However, many strokes do not cause measurable symptoms and thus remain unnoticed. MR imaging (with the right protocol) can detect small DWI lesions (small fresh strokes). These patients are nowadays considered as “symptomatic” despite the absence of |

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| | | measurable symptoms. Also, the controversial question remains after what time a symptomatic lesion becomes an “asymptomatic” lesion. |
| | How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? | The procedure is not innovative and is well established. The technology of both stents and delivery systems as well as protection devices has however made significant advances resulting in the speedy uptake of this procedure in many countries.<br>CAS in general and in asymptomatic carotid stenosis is an established practice in many countries. With modern high-fidelity simulators it has been well demonstrated that the learning curve of an operator can be accelerated so that I would classify a potentially more widespread introduction of CAS in asymptomatic carotid stenosis in the UK as a minor variation. However, the learning curve of >50 cases is crucial, and the lack of operator experience has previously been a main point of criticism in some randomized studies. |
| | Which of the following best describes the procedure (please choose one): | Both: Established practice and no longer new.<br><br>A minor variation on an existing procedure, which is unlikely to alter the procedure’s safety and efficacy. |
| **4** | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? | In the UK, the current standard of care in asymptomatic stenosis in most centres is “best medical treatment”. The procedure/technology will likely be used as an addition to existing standard care (best medical treatment). In addition endarterectomy will be an option and this needs, in my opinion, to be discussed on an individual basis. |
| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? | Absolutely. There has been significant improvement in the devices, stents, protection systems and a better understanding of antiplatelet regimes. 1/3 of patients are low or non-responders to Aspirin or Clopidogrel which are important drugs to prevent strokes during or after the procedure. This can now be tested for and medication adapted. Devices are smaller and have better deliverability. Proximal protection systems allow protection before passing the lesion. Dual layer stents offer tight plaque coverage. |
| | Has the evidence base on the efficacy and safety of this procedure changed | I am not aware of a NICE guidance after 2011. The evidence has substantially changed since then, especially with results from 2021. Today, there is increasing evidence on new stent types, protection systems, medication and that the carotid plaque (along with the “vulnerable blood” |

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| | substantially since publication of the guidance? | properties) itself plays an important, mechanistic part in transforming a lesion from asymptomatic to symptomatic. |

## Current management

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| **6** | Please describe the current standard of care that is used in the NHS. | “best medical management” in many centres<br>CAS or Op in some centres. |
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br>If so, how do these differ from the procedure/technology described in the briefing? | Other than endarterectomy, a potential alternative is “TCAR” transcarotid artery revascularization procedure (carotid stenting through a small incision at the base of the neck and direct carotid artery)- a joint surgical and interventional procedure. |

## Potential patient benefits and impact on the health system

| | | |
|---|---|---|
| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | Significant reduction of severe strokes (1/3 of our Thrombectomy cases are due to an underlying calcified carotid stenosis/occlusion) and could have been preventable.<br>Avoidance of plaque rupture and/or erosion which can lead to focal thrombus formation and stroke related to haemodynamic compromise.<br>Avoidance of athero-thromboembolism to the brain, resulting in occlusion of an intracranial vessel. |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | Epidemiologic data indicate that the presence of Asymptomatic carotid disease may increase the risk of stroke by more than 50%<br>There are additional concerns raised on the impact of heamodynamically significant carotid<br>atherosclerotic disease in patients with an incompetent circle of Willis and cognitive decline<br>potentially related to hemodynamic insufficiency and subclinical embolism from the lesion.<br>Patients where maximised medical therapy may have potential adverse effects, such as an increase in bleeding with antiplatelet therapy and the residual stroke risk while on medications.<br>Patients with the following features: contralateral transient ischaemic attack or stroke, ipsilateral silent cerebral infarction, stenosis progression, echolucent plaque, intraplaque haemorrhage or large necrotic core. |
| **10** | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | Undoubtedly. Atherosclerotic carotid disease is responsible for a much greater proportion of strokes than just those presenting with tandem occlusion of the intra- and extracranial vessels (approximately 20%). It is also the underlying cause for hemodynamic strokes due to a high-grade carotid stenosis. In addition, showers of emboli from a “hot” carotid plaque can cause severe strokes, even in the absence of large vessel occlusion.<br>Data suggests an overall proportion of carotid stenosis related strokes at the level of at least 30%.<br>A recent population-based study in 65 year old Swedish men showed a five-year cumulative neurological event rate of 6.5% with carotid stenosis of 50-79% (annual rate 1.3%) and 42% with stenosis of 80-99% (annual rate 18.4%). Although the stroke risk may be lower in younger individuals with asymptomatic carotid artery stenosis, given that the risk (similar to the stroke risk in AFib23) is cumulative over time, it remains very relevant. |

| | | |
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| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | The facilities are already widely available in Cardiology, Radiology, Neuroradiology.<br>Detection of ACAS by ultrasound does not causes harm nor necessitates an invasive intervention and is broadly available.<br>For operator training, hands-on training courses on high fidelity simulators (i.e. Angiomentor) that mimic the procedure and provide haptic feedback (that is basically identical to a real case) already exist - and it is possible to put real cases from CT-angiography data on the simulator to train operators and teams.<br>NHS Tayside Dundee have also managed to create a unique perfused human cadaveric model where interventional procedures such as CAS or complication management are being taught in the currently most “life-like” human model and cathlab setting available. |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | The learning curve for interventionalists is considered between 50 and 80 cases. Simulator training in CAS has been shown to allow acquisition of skills.<br>The perfused human cadaveric model in Dundee is the most realistic training model available so far and operator and team training can be performed with the real devices. |

## Safety and efficacy of the procedure/technology

| | | |
|---|---|---|
| **13** | What are the potential harms of the procedure/technology?<br>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:<br>Adverse events reported in the literature (if possible, please cite literature)<br>Anecdotal adverse events (known from experience)<br>Theoretical adverse events | While undertaken to prevent subsequent stroke, an important consideration is that both surgical and endovascular routes of carotid revascularization are themselves associated with the risk of symptomatic and asymptomatic cerebral embolism. Reperfusion bleed, contrast reaction, stent restenosis/ thrombosis, bleed or aneurysm at access site, dissection, bradycardia, hypotension due to vasovagal stimulation.<br>Vasospasm, protection device complications, |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | Morbidity and mortality. |

| | | |
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| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | Efficacy and safety of this procedure has been widely demonstrated. |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | This limitation of Maximised Medical Treatment (MMT)is clearly demonstrated within the symptomatic patient's cohort enrolled into recent clinical studies, a significant proportion of whom suffered a stroke despite MMT. |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | A minority of hospitals, but at least **20** in the UK.<br>At least in all centres performing Thrombectomy. |

## Abstracts and ongoing studies

| | | |
|---|---|---|
| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).<br>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. | |
| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | CREST 2, ACTRIS, ESCALATE, C-Guardians, Performance, |
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | Recent evidence indicates that less 20 unselected patients with a significant carotid stenosis need to be revascularized (NNR) to prevent 1 stroke. NNR is likely to be significantly lower in patients with increased lesion-level and/or clinical risk features |

## Other considerations

| | | |
|---|---|---|
| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | Clinically “significant” atherosclerotic carotid artery disease is usually defined as ≥50% reduction in diameter at is present in 2% to 16% of the general population (similar to atrial fibrillation). Carotid stenosis is more prevalent in diabetes, coronary artery disease, and peripheral artery disease. Contemporary clinical data show a yearly stroke rate of ≈2.5% in real-life cohorts, including patients on maximal (by today’s criteria) medical therapy. This exceeds the annual stroke risk of 2.1% associated with paroxysmal AFib. |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br>− Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.<br>− Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: | Beneficial outcome measures:<br>Morbidity and Mortality at 90 days<br>Adverse outcome measures:<br>Morbidity and Mortality at 90 days |

## Further comments

| | | |
|---|---|---|
| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | Plaque morphology,<br>Impact of CAS on cognitive function and avoidance of Dementia |

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**Declarations of interests**

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| Choose an item. | NA | | |
| Choose an item. | | | |
| Choose an item. | | | |

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

| | |
|---|---|
| **Print name:** | **Click here to enter text. GRUNWALD** |
| **Dated:** | **Click here to enter text. 1.2.23** |

View results

Respondent

1 Anonymous

88:45

Time to complete

## Your information

1. Name: *

Richard Bulbulia

2. Job title: *

Consultant Vascular Surgeon and Senior Clinical Research Fellow

3. Organisation: *

University of Oxford and Gloucestershire Hospitals NHS Foundation

Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

Vascular Society of GB&I; European Society of Vascular Surgery

6. Nominated/ratified by (if applicable):

VS

7. Registration number (e.g. GMC, NMC, HCPC) *

GMC 4100148

## How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice**

8. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

## The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

9. Please describe your level of experience with the procedure/technology, for example:

   Are you familiar with the procedure/technology?

   Yes. With Alison Halliday, I lead the largest-ever trial comparing carotid surgery vs carotid stenting in asymptomatic patients (ACST-2). This RCT randomised 3600 patients and, with a median follow-up of around 5 years has shown that, following a successful procedure, both surgery and stenting offer similar durable protection against stroke.

10. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

    - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

    I am a surgeon, and do not perform carotid stenting, but I do refer selected patients for this procedure, which can be done by interventional radiology / interventional neuro-radiology / cardiology / endovascular surgeons (IR and Interventional Neuro-Radiology most common in UK).
    Asymptomatic carotid intervention is infrequently performed in the UK, despite clear (and recent) authoritative societal guidelines (ESC, ESVS, ESO) which endorse selective intervention in those patients considered to be at an increased risk of stroke. But several hundred thousand carotid stents and endartectomies are performed worldwide each year. Rates of intervention may increase in the UK (as they did following ACST-1's results), if the ongoing CREST-2 study (2400 asymptomatic patients randomised to CEA/CAS versus Medical Therapy alone) confirms the current Level 1 evidence that successful carotid intervention in asymptomatic patients halves long-term stroke risk (but this is speculative).

11. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) Other

13. Is the proposed indication appropriate? If not, please explain

Considering asymptomatic intervention separately from symptomatic intervention is overly simplistic. In the UK, intervention on truly asymptomatic patients is infrequent. Many will have had a prior ipsilateral carotid event (>6 months), a contra-lateral event etc. In reality, carotid intervention captures a spectrum of acuity, from hyper-acute (ie, stenting culprit lesions identified at thrombectomy) to entirely asymptomatic (eg, elective intervention on a screen-detected asymptomatic stenosis). Given low rates of asymptomatic carotid intervention in UK (currently), it is likely that any expansion of CAS will be largely in symptomatic patients.

14. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

CAS has been around for several decades. But it is certainly innovative compared to open surgery and has several potential advantages (shorter length of stay, no scar, reduced bleeding risk, no cranial nerve damage, lower risk of procedural MI). Randomised trials clearly show that the long-term durability of CEA and CAS are similar out to around 5 years post-procedure. But, CAS is associated with an increased risk of procedural stroke (1-2%), largely non-disabling, and the 'challenge' for CAS is to match the low procedural risks seen with CEA.
In response, there have been several recent advances in CAS, most of which were not reflected in previous RCTs. These include: advances in stent design (dual layer mesh covered stents); safer access (radial / carotid [TCAR]) to avoid the aortic arch; better cerebral protection (flow reversal); better case selection and, perhaps most importantly, greater operator experience. Additionally, the increasing use of endovascular treatments for acute stroke has led to interest in stenting culprit carotid lesions identified during stroke thrombectomy. Registry data suggest that (in expert hands) these improvements are associated with better procedural outcomes.

15. Which of the following best describes the procedure:

- (●) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

16. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

CAS may replace some CEA procedures, if procedural risks in an individual patient are considered comparable, or CAS clearly safer (eg, hostile neck / increased cardiac risk).

17. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

Yes. See Q14. Briefly: Dual layer mesh covered stents; Access (radial/carotid [TCAR}; Cerebral Protection (flow-reversal); Case Selection; Operator Expertise

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes. Procedural risks in contemporary registries (a better assessment of procedural risk than trials) appear lower with these technical advances. Additionally, a tabular meta-analysis of all CEA v CAS trials including ACST-2 suggest CEA and CAS are broadly comparable at 5 years following a successful carotid procedure. Lancet 2021, 398. 1065-1073).

## Current management

19. Please describe the current standard of care that is used in the NHS.

Medical therapy alone for most asymptomatic carotid stenosis patients. Selective intervention (mostly with CEA) for those considered high risk for stroke and 'young enough' to derive benefit from intervention.

20. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

No

## Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using this procedure/technology?

Compared to surgery: For asymptomatic patients, CAS is assocaited with a shorter in-patient stay, avoidance of some procedural morbidity (surgical wound, procedural MI, cranial nerve damage). But CAS is associated with an increased risk (1-2%) of procedural stroke, mostly minor (mRS 0&1).

Compared to medical therapy alone, CAS (and CEA) will HALVE the long-term residual risk of stroke, and this protection is durable. Unlike medical therapy, compliance with surgery / stenting is 100%!

22. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Yes. Hostile neck (previous radiotherapy / neck surgery / prior carotid endarterectomy). Increased cardiac risk.

23. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

CAS is less invasive than CEA.

24. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Can be safely performed in any IR / Endovascular facility

25. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Trans-femoral / trans-radial CAS is highly operator dependent, with a steep learning curve, and a competence threshold of >70 cases. In contrast, trans-carotid CAS [TCAR} appears significantly easier to learn. It is now becoming the dominant mode of carotid intervention in the US (replacing trans-femoral CAS and encroaching CEA). If / when it becomes available in UK, it may prove similarly popular (again, speculative).

# Safety and efficacy of the procedure/technology

26. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Stroke (mostly minor mRS 0&1).
    Increased risk of new white matter lesions on brain DWMRI, of uncertain clinical consequence.

27. Please list the key efficacy outcomes for this procedure/technology?

    Procedural risks (composite of death, stroke, MI) at 30 days.
    And separately, long-term stroke onset rates following successful CAS.

28. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    The durability of CAS >5 years post implantation is almost entirely unknown. The 'price' for any endovascular intervention when compared to open surgical repair is commonly poorer long-term durability. We hope to follow-up the 3600 ACST-2 patients (RCT of CEA v CAS) until 2026 (median follow-up of 10 years) to provide reliable information on this important question of long-term durability.

29. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    The role of any asymptomatic carotid intervention, given improvements in medical therapy, is highly controversial. The mode of carotid artery repair in patients in whom some intervention is considered necessary is an entirely different question, and should be considered separately.

30. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) Most or all district general hospitals.
- (•) A minority of hospitals, but at least 10 in the UK.
- ( ) Fewer than 10 specialist centres in the UK.
- ( ) Cannot predict at present.

## Abstracts and ongoing studies

31. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

32. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    We hope to continue following up the ACST-2 cohort until 2026, thereby providing a direct randomised comparison of CEA v CAS at a median follow-up of 10 years.

    CREST-2 (CEA/CAS vs Medical Therapy) should finish recruitment in 2023/24, and report a few years later. NB: this trial does not directly compare CEA with CAS, rather any carotid intervention vs medical therapy alone.

33. Please list any other data (published and/or unpublished) that you would like to share.

ACST-2 report in Lancet 2021 (398) 1065-1073, with a particular emphasis on Figure 4. This tabular meta-analysis of all the CEA vs CAS trials shows that, for both symptomatic and asymptomatic patients, the long-term durability of CEA vs CAS out to 5 years is broadly comparable.

## Other considerations

34. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

After ACST-1 5-year report, around 1000 asymptomatic carotid procedures were performed each year in UK. This has now fallen to around 400 (COVID-19 impact makes recent data unreliable). If the ongoing CREST-2 trial reconfirms the benefits of asymptomatic carotid intervention, numbers could rise again, and, indeed, an endovascular treatment option might allow more people to benefit from the durable protection against stroke associated with successful carotid intervention (again, speculative). Around 5000 symptomatic carotid procedures are performed in UK each year, and CAS may replace CEA in some of these cases (but beyond scope of current appraisal).

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

**Beneficial outcome measures.**

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Short-term: Procedural complications (Death, stroke, MI) at 30-days.
Long-term: Any stroke & Ipsilateral Carotid territory stroke >30 days
NB: Most considered procedural risk and long-term efficacy separately (though both are obviously important).

36. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

**Adverse outcome measures.**

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

As above. Procedural risks at 30 days = safety
>30 day stroke onset rates = efficacy

## Further comments

37. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

The long-term follow-up of ACST-2 is a unique opportunity to directly and reliably compare the durability of CEA vs CAS between 5-10 years post implant. This should be supported / endorsed by NICE.
Trials comparing the current CAS technologies (stent design, access, protection) with CEA in symptomatic patients needed.
Trials comparing acute CAS during endovascular thrombectomy for large vessel anterior circulation stroke are underway in Europe, and UK involvement should be encouraged.

## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

38. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [x] Indirect
- [x] No interests to declare

39. Description of interests, including relevant dates of when the interest arose and ceased. *

PI ACST-2

40. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.** *

- (●) I agree
- ( ) I disagree

## Signature

41. Name: *

Richard Bulbulia

42. Date: *

16/02/2023

NICE National Institute for Health and Care Excellence

# Professional Expert Questionnaire

**Technology/Procedure name & indication: IP881/2 Carotid artery stent placement for asymptomatic extracranial carotid stenosis**

## Your information

| | |
|---|---|
| **Name:** | Stephen D'Souza |
| **Job title:** | Consultant Interventional Radiologist |
| **Organisation:** | Lancashire Teaching Hospitals NHS Foundation Tust |
| **Email address:** | [redacted] |
| **Professional organisation or society membership/affiliation:** | British Society of Interventional Radiologists |
| **Nominated/ratified by (if applicable):** | Click here to enter text. |
| **Registration number (e.g. GMC, NMC, HCPC)** | 3262711 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

X Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

X I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

| |
|---|
| Click here to enter text. |

## Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

| | | |
|---|---|---|
| 1 | Please describe your level of experience with the procedure/technology, for example:<br>Are you familiar with the procedure/technology? | I have been performing carotid artery stenting for more than 10 years and have completed over 150 of these pocedures |
| | Have you used it or are you currently using it? | I am still performing this procedure. |
| | − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? | Only a few (<10 centres in the UK perform this procedure) |
| | − Is this procedure/technology performed/used by clinicians in specialities other than your own? | Both vascular and neurovascular radiologists perform this procedure |

| | | |
|---|---|---|
| | − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. | No re-referral |
| **2** | − Please indicate your research experience relating to this procedure (please choose one or more if relevant): | I have done bibliographic research on this procedure and kept up to date with latest evidence and trials<br><br>~~I have done research on this procedure in laboratory settings (e.g. device-related research).~~<br><br>~~I have done clinical research on this procedure involving patients or healthy volunteers.~~<br><br>~~I have published this research.~~<br><br>I have had no involvement in research on this procedure.<br><br>Other (please comment) |
| **3** | Does the title adequately reflect the procedure?<br><br>Is the proposed indication appropriate? If not, please explain.<br><br>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?<br><br>Which of the following best describes the procedure (please choose one): | Yes<br><br>Yes<br><br>Although an established procedure only about 10-15% of all carotid stenosis treatment in symptomatic and asymptomatic patients, is by Carotid artery stent placement with the remainder performed as carotid endarterectomy.<br><br>There are still variations in the way the procedure is performed related to access, use of protection device and which type and type of stent.<br><br>Established practice and no longer new. |

| | | |
|---|---|---|
| | | |
| **4** | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? | This is likely to remain an additional option if the standard (CEA) is not possible |
| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?<br><br>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance? | There has been changes to the types of stent and cerebral protection devices used.<br>Trials have not required or dictated how CAS procedure performed.<br><br>Evidence suggests that CAS is as safe as CEA in symptomatic and asymptomatic patients using the same end points. |

## Current management

| | | |
|---|---|---|
| **6** | Please describe the current standard of care that is used in the NHS. | Although an established procedure only about 10-15% of all carotid stenosis treatment in symptomatic and asymptomatic patients, is by Carotid artery stent placement with the remainder performed as carotid endarterectomy.<br>All patients managed with BMT |
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br>If so, how do these differ from the procedure/technology described in the briefing? | Carotid endarterectomy is the alternative and current “gold standard”<br><br>No new alternative to stenting itself but there are variations in access (radial, brachial and direct common carotid approach and embolic protection devices (filter, proximal and Moma device) |

## Potential patient benefits and impact on the health system

| | | |
|---|---|---|
| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | Reduced risk of stroke over the long term<br>Equivalence to CEA<br>Reduced cardiac risk |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | Treating recurrent stenosis after CEA<br>Pts with carotid disease and access site issues which preclude CEA<br>Pts with cardiovascular disease, tandem lesions and severe contralateral disease |
| **10** | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | Treating asymptomatic patient will have a benefit but this can be with CEA or CAS |
| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | Full vascular IR suite |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | Yes |

## Safety and efficacy of the procedure/technology

| | | |
|---|---|---|
| **13** | What are the potential harms of the procedure/technology?<br>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: | Stroke 1-3%<br>Bleeding<br>Puncture site complication |

| | | |
|---|---|---|
| | Adverse events reported in the literature (if possible, please cite literature)<br>Anecdotal adverse events (known from experience)<br>Theoretical adverse events | Management of neuro complications of CAS Wholey et al J endovascular Therapy june 25 2016<br>Issues with stent deployment, filter wire insertion and removal, hypotension and bradycardia (stimulus on carotid sinus) and complications of drugs |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | Overall stroke reduction Vs CEA Vs BMT<br>All cause death, stroke and MI |
| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | Benefits of different types of stent, approach and protection devices |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | Higher stroke rate and lower MI rate with CAS but all cause similar |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | Should be performed a regional or superregional vascular centres |

## Abstracts and ongoing studies

| | | |
|---|---|---|
| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).<br>Please note that NICE will do a comprehensive literature search; we are | |

| | | |
|---|---|---|
| | only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. | |
| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | |
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | |

## Other considerations

| | | |
|---|---|---|
| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | Thousand but nationally currently not coping with symptomatic patient treatment whether CAS or CEA |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br>− Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.<br>− Adverse outcome measures. These should include early and late | Beneficial outcome measures:<br>Stroke reduction Long term<br>Stroke rates, procedural, within 30 days and long term<br>Puncture site complications (as on dual anti platelets and given heparin in procedure) 30 days<br><br>Adverse outcome measures: |

| | | |
|---|---|---|
| | complications. Please state the post procedure timescales over which these should be measured: | As above |

## Further comments

| | | |
|---|---|---|
| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | Lot of info related to symptomatic CAS rather than pure asymptomatic cases. |

NICE National Institute for Health and Care Excellence

## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| Choose an item. | | | |
| Choose an item. | | | |
| Choose an item. | | | |

X I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

| | |
|---|---|
| **Print name:** | **Stephen D'Souza** |
| **Dated:** | **03/02/2023** |