NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Intrasaccular blood-flow disruption device insertion for intracranial aneurysm**
Name of Specialist Advisor:	Hiren Patel
Specialist Society:	Society of British Neurological Surgeons

1 Do you have adequate knowledge of this procedure to provide advice?

* Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

* Yes.

☐ No. If no, please enter any other titles below.

Comments:

The intra-saccular device on the market is better known as the WEB (Woven EndoBridge)

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

* Yes.

* Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

It is accepted as a device for treatment of broad necked aneurysms. The controversy is of its use applies when alternatives such as micro-neurosurgical clipping or even simple coiling of aneurysms- better understood methods of treatment) are not considered as treatment options in favour of the intra-saccular device. There is also a controversy when this device is used for aneurysms that do not have a broad neck that could be treated by conventional means (simple coiling). There is no evidence about the long term efficacy of these devices. The role of this device for ruptured aneurysms is not clear

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

* I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

I have carried out this procedure on a handful of occasions and it is not what I would consider is part of my routine practice. I regularly provide an opinion on the appropriateness of this procedure in my role as a member of a well functioning neurovascular MDT.

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

* I take part in patient selection or refer patients for this procedure regularly.

Comments:

See above.

2.3 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).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

I have had no involvement in research on this procedure.

* Other (please comment)

Comments:

I have not done any laboratory or clinical research on this device. I am a co-applicant on a research proposal looking at whether it is feasible to perform a comprehensive study comparing safety of non-surgical treatment of brain aneurysms with either the Woven EndoBridge (WEB) or with best alternative treatment, but this has not been funded. I have read some of the literature as part of continuing medical education, and as part of the research team, but this is not in a systematic manner.

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

* 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.

Comments:

This procedure in my opinion is widely used in the United Kingdom. The number of cases performed by each unit, as well as the indications for its use vary between units. The device is considered safe for use in complex aneurysms when balanced against the risks of 'conventional treatments' although this has not been tested formally.

3.2 What would be the comparator (standard practice) to this procedure?

For anterior circulation aneurysms, simple coiling, balloon assisted coiling, stent assisted coiling, or craniotomy and clipping. For most posterior circulation aneurysms coiling, stent assisted coiling.

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

* 10% to 50% of specialists engaged in this area of work.

☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

There are no neurosurgeons that regularly do this procedure as most neurosurgeons do not perform endovascular procedures. I would estimate that between 10-50% of neuro-interventionalists perform this procedure.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

The main risks of the procedure reported from prospective studies are those of thrombo-embolic complications and there is reported rate of approximately 15%. The symptomatic rate of complications is about 5%, with a similar morbidity. There is a risk of intra-procedural rupture of an intracranial aneurysm (1.8%). The overall failure rate is low in prospective studies but these devices for the prospective registries are being deployed by 'experts'.

2. Anecdotal adverse events (known from experience)

Poor case selection leads to use of more 'rescue' therapy such that there is need for an additional intra-vascular device such as a stent. Groin haematoma from utilisation of a larger femoral access sheath than routine

3. Theoretical adverse events

Risks from use of anti-platelet therapy. Delay in time to treatment if treatment is for an ruptured aneurysm.

4.2 What are the key efficacy outcomes for this procedure?

The key efficacy outcomes for this procedure are those of morbidity from this procedure which is reported above. This seems to be similar overall to the treatment of intracranial aneurysms in general. There is also the outcome of aneurysm closure and it appears that 50% of aneurysms are not completely occluded by this technique

with a retreatment rate (over a short time period) of 7%. It is argued that 80% of aneurysms are well occluded.

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

The long term results and stability of aneurysm closure are the main concern.

4.4 What training and facilities are needed to do this procedure safely?

These devices are placed by trained neuro-interventionalists. In my opinion, prior to use of these devices, the treatment options should be discussed at an MDT considering other alternatives. For operators that have not deployed this device a suitable proctor should be available. Simulation training would help with sizing of the device, and allow a better understanding of how the device would sit in the aneurysm being targeted for treatment.

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

There are no major trials that I know of. There are registries from France and Europe (WEBCAST, French observatory), but I am unsure about the level of case ascertainment for these studies.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

No

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

No, beyond concerns about risk of complications in low volume providers

5 Audit Criteria
Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

Radiological aneurysm occlusion rate at 6 months and 2 year recurrence rates, Modified Rankin Scale at discharge and at 6 months.

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Procedural complications (intraprocedural rupture, thromboembolic complications, symptomatic complications, groin complications), MRS >3, need for retreatment, delayed haemorrhage related to the aneurysm.

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

This device is in use already. I think that there will be a steady increase in units where there is no balanced MDT (surgeons and interventionists) as there is increased experience.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ 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.

Comments:

This procedure will be done in the approximate 30 neurosciences centres in the UK, and I suspect that at least one procedure has been done already per centre.

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☐ Moderate.

* Minor.

Comments:
The disease is uncommon, is treated in low volume in specialised centres and although the device is expensive, the overall impact to the NHS is likely negligible.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

nil

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☑ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional * **YES**

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

payments in cash or kind		**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	*	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	*	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	*	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	*	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	*	**YES**
	☐	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	*	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	*	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

I am a director of a concussion clinic which is the name of the company that I do my private practice through.

I am the audit director of the British Neurovascular group.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

June 2018

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 Personal family interest

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 Personal non-pecuniary interests

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as **'specific,'** or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as **'non-specific'**. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Intrasaccular blood-flow disruption device insertion for intracranial aneurysm**
Name of Specialist Advisor:	Paul Maliakal
Specialist Society:	UK Neurointerventional Group

1 Do you have adequate knowledge of this procedure to provide advice?

☒ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☐ Yes.

☒ No. If no, please enter any other titles below.

Comments:

May I recommend ' Endovascular insertion of intra saccular blood flow disruption device for cerebral aneurysm' to specify that this is an interventional procedure rather a neurosurgical procedure.

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☒ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

☒ I do this procedure regularly.

Comments:

I have performed around 125 of these procedures since 2013.

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☒ I take part in patient selection or refer patients for this procedure regularly.

Comments:

I work closely with my neurosurgical colleagues as part of the neurovascular MDT in identifying the patients suitable for the procedure and in seeing the patients with un ruptured aneurysms in the neurovascular clinic prior to the procedure. Decision to use the device in suitable patients with ruptured aneurysms is taken after an urgent discussion with the neurosurgical team.

2.3 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).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☒ Other (please comment)

Comments:

I have contributed anonymised patient data from patients with ruptured aneurysms treated with these devices to the United Kingdom device registry. I have contributed anonymised data to published work.

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☒ 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.

Comments:

Many UK tertiary neurosciences centres use this device but the degree of experience varies and is operator dependent.

3.2 What would be the comparator (standard practice) to this procedure?

Coil embolization of cerebral aneurysm

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☒ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

Generic risks of an endovascular procedure such as;

1. General anaesthetic related risks

2. Vascular access related risks such as groin haematoma, pseudo aneurysm that may require surgical repair, retro peritoneal haemorrhage or risks related to closure devices.

3. Cerebral arterial access related risks such as guide catheter associated spasm, dissection, occlusion or rupture resulting in neurological sequelae.

4. Rupture of the aneurysm during catherisation.

Device related risks;

1.Protrusion of the device into the parent arterial lumen that may disrupt blood flow; often this can be corrected with redeployment of the device; using a different sized device; intra luminal stent to move the device protrusion away from the arterial lumen and restore blood flow

2. Anecdotal adverse events (known from experience)

Personal experience of displacement of a deployed device from the aneurysm sac into the lumen of the parent artery. I was able retrieve the device and avert neurological sequelae.

Published report of leading edge of the device rupturing the dome of an aneurysm. This was rectified with deployment of the device.

3. Theoretical adverse events

4.2 What are the key efficacy outcomes for this procedure?

1. Significantly improved safety profile in the treatment of wide necked aneurysms due to reduced requirement for luminal stents with their associated risks; reduced use of anti-platelet medication; reduced procedural time; reduced use of contrast medium; reduced radiation dose and avoidance of anti-coagulation with Heparin in acutely ruptured aneurysms (centre specific practice).
2. Reduced rates of aneurysm recanalization when compared with coil embolization.

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

Use of this device in large (>10 mm) / partly thrombosed aneurysms and in re-canalised aneurysms may not effect a satisfactory outcome as there is a risk of recanalization. This may be averted with use of adjuvant devices such as coils or flow diverting stents.

Newly available low profile 17 system is softer than the larger devices and encounters issues during deployment in aneurysms that are off centred from the midline. This improves if a 21 microcatheter is used to deploy the device. Visibility on fluoroscopy is also less than that of the larger devices.

On late follow up, there is evidence of clot retraction with in the device deforming the device and making the recess more prominent. I do not think this finding increases risk of haemorrhage.

4.4 What training and facilities are needed to do this procedure safely?

Initial training on Silicon models, phantoms provided in recognised courses and animal labs is recommended prior to deployment in patients, proctored by an expert. 5-10 procedures may be a minimum requirement but this is depended on the level of previous experience of the relevant clinician.

Training should be obtained with different sizes of the device as they behave differently during deployment.

Procedure should only be performed in comprehensive neurosciences centres with neurosurgical / stroke services back up.

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

WEBCAST, WEBCAST 2, CLARYS, WEB-IT

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

The New Low-Profile WEB 17 System for Treatment of Intracranial Aneurysms: First Clinical Experiences
S.B.T. van Rooij, J.P. Peluso, M. Sluzewski, H.G. Kortman, and W.J. van Rooij

Safety and efficacy of aneurysm treatment with WEB
in the cumulative population of three prospective,
multicenter series
Laurent Pierot,1 Jacques Moret,2 Xavier Barreau,3 Istvan Szikora,4 Denis Herbreteau,5
Francis Turjman,6 Markus Holtmannspötter,7 Anne-Christine Januel,8 Vincent Costalat,9
Jens Fiehler,10 Joachim Klisch,11 Jean-Yves Gauvrit,12 Werner Weber,13 Hubert Desal,14
Stéphane Velasco,15 Thomas Liebig,16 Luc Stockx,17 Joachim Berkefeld,18 Andrew Molyneux,19 James Byrne,19 Laurent Spelle2

WEB Treatment of Ruptured Intracranial Aneurysms:
A Single-Center Cohort of 100 Patients
S.B.T. van Rooij, W.J. van Rooij, J.P. Peluso, M. Sluzewski, R.S. Bechan, H.G. Kortman, G.N. Beute,
B. van der Pol, and C.B. Majoie

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

None that I am aware of

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

Device implantation success rate
Use of adjuvant devices
mRS at 1 month and 1 year especially for patients with ruptured aneurysms
Aneurysm occlusion rates at angiographic follow up at 3 months and 2 years. WEBCAST used grades 1-4 for defining occlusion rates based on follow up catheter angiography and this seems widely accepted. Many centres perform MRA follow up rather than catheter angiogram follow up. These centres still use WEBCAST criteria modified for MRA.

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Early:

Intra-procedural rupture of aneurysm during device deployment;
Thrombo-embolic complications up to 1 month post procedure

Late: Aneurysm recanalization and re bleed rates

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Moderately as a high level of technical ability is required

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ 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.

Comments:

Only in tertiary neurosciences centres

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☐ Moderate.

☒ Minor.

Comments:
I estimate it to be between 10-25 devices per annum in the neurosciences centres. This may increase to 25-50 if UK follows the examples of European centres that now use these devices as a primary tool in treating ruptured cerebral aneurysms

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

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Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐ **YES** ☒ **NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐ **YES** ☒ **NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐ **YES** ☒ **NO**

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	☒	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	☒	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	☒	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	☒	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☒	**YES**
	☐	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

2 Single event consultancy agreements with industry in the last 12 months for lectures given in national and international meetings – Honorarium, travel and accommodation. These were not with the manufacturers of the device in question.

Industry sponsors an Interventional Neuroradiology Course that I organise. Industry sponsors the Northern regional M&M meeting that I organise. These were not with the manufacturers of the device in question.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

June 2018

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

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1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

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2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

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4 **Personal non-pecuniary interests**

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

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- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Intrasaccular blood-flow disruption device insertion for intracranial aneurysm**
Name of Specialist Advisor:	Phil White
Specialist Society:	UK Neurointerventional Group

1 Do you have adequate knowledge of this procedure to provide advice?

X Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

X Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

Not really much controversy other than as with any new device, longer term results uncertain. Medium term results now clearer and good with very good safety profile

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

X I do this procedure regularly.

Comments:

Have been deploying such devices since 2013 – several per annum

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

X I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 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).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

Have done local audit & been involved in national audit – though not an author on that

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

X 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.

Comments:

With >6y of regular use in many UK centres I would no longer regard this as new but as established

3.2 What would be the comparator (standard practice) to this procedure?

Stent assisted coiling (SAC) or neurosurgical clipping depending on anatomy

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

X 10% to 50% of specialists engaged in this area of work.

☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

At least 20/26 (currently active) UK INR units have used devices like this & regularly so in >10 of them

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

See Pierot L et al J Neurointerv Surg 2017;10:556-562

2. Anecdotal adverse events (known from experience)

Technical failure, Clot formation, aneurysm rupture (this is less common than coiling)

3. Theoretical adverse events

See paper referenced above for more detial

4.2 What are the key efficacy outcomes for this procedure?

a) Adequate aneurysm occlusion at 1y or longer – seems to be >80%, which for comparator aneurysm group is better than endovasucalr alternatives
b) Retreatment rate – again seems a bit lower than EVT alternatives

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

5y+ long term results inevitably uncertain

4.4 What training and facilities are needed to do this procedure safely?

For established neurointerventional aneurysm operators limited - some exposure to simulator training (half day or so more than adequate) + proctor for first 3-5 cases
Biplane 3D Angio suite optimised for neuro use is essential thoug th accurately size the device. This is crucial

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

See ref above for most of these. No RCT as yet only prospective registries

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

No

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

No

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

This is always very difficult in a low volume procedure where the case mix is also quite variable. Not less than 20 but really far more to narrow confidence intervals

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

Angiographic outcomes

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Perioperative rupture, bleed or stroke

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Modest expansion unless positive RCT when it would pick up appreciably

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ Most or all district general hospitals.

X A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

Can only safely be carried out by trained neurointerventionist in a Neuroscience centre with biplane 3D Neuroangio suite, functional neurovascular MDT (for case selection) & immediate NSurg support

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☐ Moderate.

X Minor.

Comments:
Although >5000 endovascular aneurysm treatments per annum in UK, this procedure is not relevant in >80% either due to aneurysm size, morphology or site
As device probably already accounts for ~5% of total, the additional % increase over several years & small difference in cost between SAC and WEB in most aneurysms mean minor impact likely

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Not really except safety profile in published studies looks very good

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☐ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	X	**YES**
	☐	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	X	**NO**
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Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	X	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	X	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	X	**YES**
	☐	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:
I am Co-CI of STABILISE trial into mechanical thrombectomy in stroke. This is 50% funded by an institutional grant form Microvention Terumo

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Codman & Covidien who also make products for EVT of aneurysm part supported the PISTE trial via institutional grants to Glasgow Uni (<30%). I was coCI of PISTE

I undertake educational consultancy work for Microvention Terumo. In the past 1-2y I have also undertaken consultancy work on aneurysms for Stryker as a member of a global advisory board and >2y ago have previously undertaken consultancy work for Codman, Boston and BALT.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

June 2018

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