NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1824 Prophylactic or therapeutic use of endoanchoring systems in endovascular aortic aneurysm repair.**

Your information

Name:	Colin Bicknell
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Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	4319889

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. 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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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☒ 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:

N/A

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

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? 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	I am familiar with the technology and am experienced in its use. This technology is used in many centres in the UK. There is an increasing use in the UK. The technology is used by Vascular Surgeons and Interventional Radiologists.

	procedure/technology, please indicate your experience with it.	
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. I have done clinical research on this procedure involving patients or healthy volunteers as part of the International ANCHOR registry. I have been named as this research was published.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The technology is an adjunctive procedure to endovascular aneurysm repair. It is minor/moderate addition to the established procedure. 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?	It is an addition to existing standard care.

Current management

5	Please describe the current standard of care that is used in the NHS.	Aneurysms of the aorta are treated with either open repair or endovascular aortic repair. The subject of a recent NICE report.

		For those that need EVAR, endoanchors can be used. To enhance the fixation of the endograft, or to improve the seal of the endograft because of type 1A endoleak either at the primary procedure or at a secondary procedure. Alternatives would be - No endoanchors and risk of migration (which may be high in diseased aortic necks) - Reballoooning, and Palmaz stent placement for type 1a endoleak during the primary procedure - Proximal extension with a chimney graft or fenestrated graft in the case of a type 1a endoleak if late endoleak occurs. In reality these different procedures are used in different settings and they are not alternatives.
6	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 there are no similar technologies.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	This technology provides a useful adjunct to EVAR which is useful/vital in some circumstances and allows fixation and better sealing of the graft.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with elective or emergency AAA or thoracic aortic aneurysm and diseased aortic necks, young patients that require long term fixation, those who have had an endograft placed and have a type 1a endoleak.
9	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?	It could significantly reduce the number of patients that undergo fenestrated stent grafting which is expensive and time consuming.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	The technology costs more than EVAR alone, however, it is significantly cheaper than FEVAR.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	This depends on the reason for use.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No more clinical facilities needed. They are placed in the hybrid suite and Interventional Radiology suite.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training can be performed on a model/simulator in a few hours. No further training for experienced surgeons/Interventional Radiologists is needed.

Safety and efficacy of the procedure/technology

14	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	There are few if any reported adverse events directly as a result of the technology.
15	Please list the key efficacy outcomes for this procedure/technology?	To enhance the fixation of the endograft, or to improve the seal of the endograft because of type 1A endoleak either at the primary procedure or at a secondary procedure.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The main concern is the long term efficacy and exactly which patients will benefit from this technology over the longer term
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Competing technologies such as FEVAR, which is more expensive but gives a seal of the aneurysm in “normal” aorta higher and so may well give a longer lasting result may provide better value for money long term and avoid reintervention. This is a possibility, and more evidence if needed

18	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.

Abstracts and ongoing studies

19	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.	All available in standard literature searches.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	The ANCHOR registry The PERU registru

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)?	At least 80% of the EVAR population would be suitable, I estimate 30% may benefit.

22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No, except cost is an issue
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	A trial into the use of endoanchors in large or conical necks
25	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. − 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: Freedom from migration and type 1a endoleak, stratified for neck hostility Adverse outcome measures: Infection, aortic rupture

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	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
Direct - financial	Consultancy with Medtronic, paid lecturing for Medtronic on endoanchors, pain for running endoanchor courses, Grant funding for clinical trials not involving endoanchors	**2009**	**current**
Direct - financial	Consultancy with Gore, payments for lecturing, Grant funding for clinical trials	**2012**	**current**
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:	**Colin Bicknell**
Dated:	**30.09.21**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1824 Prophylactic or therapeutic use of endoanchoring systems in endovascular aortic aneurysm repair.

Your information

Name:	Dr David Wells
Job title:	Consultant Interventional Radiologist
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Professional organisation or society membership/affiliation:	GMC / FRCR / BSIR
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	GMC:- 4204286

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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.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am familiar with the technology and have performed 5 cases independently and assisted in others
	Have you used it or are you currently using it?	Yes
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Will used in most vascular hubs in the UK Likely to be used more frequently especially if the indications for use change
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	Yes Vascular Surgery
	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please	No we don't refer to other specialities

	indicate your experience with it.	
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	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It is a novel approach to anchoring a graft in place to avoid graft migration and in some instances treat Type 1a endoleaks Definitely novel and of uncertain 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?	An addition to standard care

Current management

5	Please describe the current standard of care that is used in the NHS.	Endovascular repair of abdominal aortic aneurysms

6	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

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	In patients with complications where there is slip / migration of the graft or to stabilise the graft. There may also be an indication to use the anchors to treat Type 1a end leaks
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with on going aneurysmal neck expansion
9	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?	There is a possibility it could reduce further re intervention after EVAR
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	This is likely to cost much more than standard care
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Until more research is done this should be utilised for specific post procedural re intervention with more emphasis on using the correct graft for the right patient within the IFU (instructions for use)
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No new clinical facilities are needed. Training in the device handling and endoanchor delivery is paramount to patient safety as is volume
13	Is any specific training needed in order to	Yes need specific training on the device and complications from using the device

	use the procedure/technology with respect to efficacy or safety?	

Safety and efficacy of the procedure/technology

14	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	Endo anchoring close to the renal arteries can cause on table hypotension in the patient There is the potential for an endo anchor to be detatched from the delivery system and embolise distally Vascular access complications, the delivery system is large calibre The delivery of the anchors can be time consuming with the x ray gantry at high angles which increases the x ray dose to the patients and operators. There is the potential for skin damage in doses > 1 gray
15	Please list the key efficacy outcomes for this procedure/technology?	No further graft migration after endoanchors or treatment of a documented Type 1a endo leak
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No high level evidence for safety and efficacy High x ray dose to patient and operators
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	It is a very expensive adjunct procedure and there is talk of using endoanchors at the time of the initial EVAR which will double the cost of the procedure, significantly increase the x ray dose to the patient and operators and increase the time under anaesthetic
18	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.

Abstracts and ongoing studies

19	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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

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)?	10 / year
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No apart for cost to the NHS

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	A database of endoanchors within the VASQIP data
25	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. − 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: Documented cessation of graft migration Reduction in neck dilatation Freedom from Type 1a endolaek Adverse outcome measures: Number of re interventions Skin damage / telangiectasia and dose recording Embolisation of endoanchor Vascular access complications

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	None		
Choose an item.			
Choose an item.			

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Print name:	**Dr David wells**
Dated:	**17th Sept 2021**