NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1857 Percutaneous thoracic duct embolization for persistent chyle leak

Your information

Name:	Adrian Marchbank
Job title:	Consultant Cardiothoracic Surgeon
Organisation:	University of Plymouth Hospitals NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Society for Cardiothoracic Surgery in UK and Ireland (SCTS)
Nominated/ratified by (if applicable):	SCTS
Registration number (e.g. GMC, NMC, HCPC)	GMC 3296709

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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.

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 a consultant cardiothoracic surgeon, appointed in 2000. I have experience in all aspects of general cardiothoracic surgery, excluding paediatrics and transplantation. My specialist interests are minimal access thoracic surgery including robotics, chest trauma, and advanced lung cancer. I am familiar with the procedure, but I do not practice it, as I have made referrals to interventional radiology who perform the procedure for chyle leak. Historically, I have managed patients with chylothorax medically and occasionally surgically. I have experience of a few patients who have undergone the procedure, and my anecdotal experience is that it has been successful. I am unaware of how widely it is performed, but given my personal experience, I suspect the speed of uptake will be considerable. The procedure is performed by clinicians from a different speciality (Interventional Radiology) in my experience I have made referrals for the procedure. I am aware that Upper GI Surgeons have also referred patients for this procedure

	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. *Y* I have done research on this procedure in laboratory settings (e.g. device-related research). *N* I have done clinical research on this procedure involving patients or healthy volunteers. *N* I have published this research. N I have had no involvement in research on this procedure.*N* Other (please comment): Invited Book chapter 'Ch 28 Chylothorax' pp 695 – 706 in 'Key Questions in Thoracic Surgery' Eds Moorjani et al, tfm Publishing Ltd (2016)
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):	Minor variation of longstanding technique involving established techniques and technology Established practice and no longer new. N A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Y Definitely novel and of uncertain safety and efficacy.N The first in a new class of procedure.N
4	Does this procedure/technology have the potential to replace current standard care or	Yes. Likely to reduce prolonged morbidity and requirement for surgical procedure

	would it be used as an addition to existing standard care?	

Current management

5	Please describe the current standard of care that is used in the NHS.	Available on named patient basis in my organisation depending upon clinical requirements.
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?	Reduced morbidity from prolonged low fat diet, length of stay, requirement for TPN, requirement for surgical mass ligation
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patient with chyle leak or chylothorax: Traumatic (usually post surgery: cervical, thoracic, oesophageal, cardiac, abdominal). Trauma Non traumatic: Malignancy, especially lymphoma, post RT, infection, infiltrative conditions, such as sarcoidosis, amyloidosis Idiopathic
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?	Yes, as mentioned in 7
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)	Likely to be clinically effective and cost effective
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)?	Likely to have cost implications in Interventional Radiology, but cost-effective across the NHS

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Specific to Interventional Radiology
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Specific to Interventional Radiology

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	Specific to Interventional Radiology
15	Please list the key efficacy outcomes for this procedure/technology?	Specific to Interventional Radiology
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Specific to Interventional Radiology
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Specific to Interventional Radiology

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.N A minority of hospitals, but at least 10 in the UK.Y Fewer than 10 specialist centres in the UK.N Cannot predict at present.

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

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an	All patients with chyle leak or chylothorax might be considered for the procedure. The target population is c10 000 patients per year undergoing surgery and at risk, with ,1% developing chyle leak, so maybe 100

	estimated number, or a proportion of the target population)?	
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Specific to Interventional Radiology
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?	Clinical effectiveness
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Is there a registry?
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: Duration of chyle leak (measured by duration of intercostal drainage (days), requirement for dietary modification (days)). LOS (days). Reduction in surgical procedures for chylothorax (numerator and denominator compared with historical controls) Adverse outcome measures: Procedural failure (%), complications (define in advance, %), as above

26	Is there any other data (published or otherwise) that you would like to share with the committee?	unaware

Further comments

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

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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.	None		
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:	**Adrian Marchbank**
Dated:	**1/6/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1857 Percutaneous thoracic duct embolization for persistent chyle leak

Your information

Name:	Colin Nice
Job title:	Consultant Interventional Radiologist
Organisation:	The Newcastle Upon Tyne NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Society of Interventional Radiology (BSIR), Cardiovascular and Interventional Radiology Society of Europe (CIRSE)
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	GMC 3558726

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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 experienced (Consultant IR for 20 years) in the use of the equipment and constituent techniques required for this procedure (ultrasound and fluoroscopic guided puncture and access), the use of microcatheters and the use of microcoils and N-Butyl Cyanoacrylate (NBCA) glue for embolisation. I introduced this technique into our trust (NUTH) in June 2020 after thoroughly researching it and gaining approval from the trust's New Interventional Procedures Committee and have used this technique to treat 6 patients since then (with the use of intranodal lymphangiography-step 1 of the procedure in a further 2 patients-to perform diagnostic imaging CT lymphangiography or Dynamic contrast enhanced MR lymphangiography).
	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	The technique is used in the UK, largely in tertiary centres with cardiothoracic surgery, ENT surgery or paediatric cardiothoracic centres. I would estimate that approximately 10 centres are regularly performing this in the UK. It is unlikely that there will be rapid uptake in other centres as these problems are relatively infrequent (although undoubtedly undertreated at present). These procedures are only performed by Interventional Radiology teams in the UK (although as part of a wider multidisciplinary team involving thoracic Surgeons) and sometimes surgical ligation of thoracic duct will be performed by them as part of the range of treatments. Patients are referred into IR by surgical teams (to treat post-surgical ductal injuries and leaks) and occasionally for non-traumatic chylothorax. We filter referrals (to ensure that only high volume, persistent leaks, or high risk leaks are treated) and would advise simple dietary and medical measures if these had not already been instituted at the time of referral. All of our referrals thus far have been appropriate. We have had discussions with paediatric cardiothoracic surgery regarding treating chyle leaks (chylothorax, chylous ascites, plastic bronchitis, protein losing enteropathy in

	procedure/technology, please indicate your experience with it.	Fontan circulation or following congenital heart defect repair) but the aetiology of chyle leaks in this group is far more complex and there is a risk of cerebral lipiodol toxicity in children with right to left cardiac shunts). **It is very important that any guidance clearly recognises the additional complexity and risks that exist within this patient group**. Locally we have opted not to offer these treatments until we have gained more experience with the simpler persistent chyle leaks.
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. No I have done research on this procedure in laboratory settings (e.g. device-related research). No I have done clinical research on this procedure involving patients or healthy volunteers. No I have published this research. N/A I have had no involvement in research on this procedure. I reviewed the literature prior to submitting a New Interventional procedure application to our trust but did not undertake any formal bibliographic research. Other (please comment)
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):	This has become the standard of care in the US and Western Europe. The historical gold standard was surgical thoracic duct ligation but this sometimes fails. Thoracic duct anatomy is variable and sometimes cannot be identified surgically. Thoracic surgery is more morbid and often these procedures are re-operations (following initial lobectomy, oesophagectomy etc). This a novel technique but it was first reported in 2002 *(Cope C, Kaiser LR. Management of unremitting chylothorax by percutaneous embolization and blockage of retroperitoneal lymphatic vessels in 42 patients. J Vasc Interv Radiol.2002;13:1139–48)*. Because of the technical complexity and relatively small numbers of patients requiring this treatment uptake has been slow but there has been increasing interest and new centres in the last 5 years. The technique is also increasingly discussed in the IR literature and at meetings.

		Established practice and no longer new. **Yes** 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.
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?	Yes it is likely to be the dominant treatment modality in centres (or networks) where it can be performed although there will still be a role for thoracic surgical interventions in selected cases.

Current management

5	Please describe the current standard of care that is used in the NHS.	Very dependent upon whether this treatment is provided within a centre or region. If provided, then thoracic duct embolisation is likely to be the main treatment. When this is not available then surgical thoracic duct ligation (or possibly a pleuroperitoneal shunt) is likely to be offered.
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?	Lower morbidity than surgical re-exploration. Faster recovery time and earlier hospital discharge. May also succeed in cases where surgical re-exploration has failed.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with persistent high volume chyle leaks following cervical or thoracic surgery.
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?	Yes, lower morbidity and less invasive than surgical re-exploration. Faster recovery time and earlier hospital discharge.
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 staffing and equipment already exist in large interventional radiology departments. The procedures are however time-consuming, realistically 4 hours for low volume centres (most centres). There is a substantial reduction in post-procedure hospital stay which is likely to make these procedures cost saving overall (although I haven't seen any health economic studies on this).
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)?	Cost saving overall but moving the costs from inpatient ward stay costs to interventional radiology staffing and consumable equipment costs.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	High quality ultrasound machine (for groin lymph node puncture). High quality interventional radiology fluoroscopic suite or theatre. Nearly all large IR departments already have these.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Both the nodal puncture and puncturing of the cisterna chyli are not done routinely by UK IR Consultants. The nodal puncture is fairly straightforward and low risk and is quickly learnt but there are still a few pitfalls to be aware of and use of ancillary equipment such as pneumatic calf compression and infusion pumps is important. Puncture and catheterisation of the cisterna chyli is technically very challenging, even for experienced IR consultants and is a critical step, without which embolisation is not possible. Support from an experienced operator would help, however there are very few of these and the clinical urgency of these cases (aiming for treatment within a week of referral) means that it may be very difficult for a proctor to attend. We did our first cases in 2020 without a proctor as dual operators-2 IR consultants, both with >20 years, having thoroughly reviewed the literature and online learning resources (the CIRSE library and Children's Hospital of Philadelphia were both very good). Discussion with IR colleagues in Bournemouth and sharing of protocols was also very helpful.

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	Failure-30% in experienced centres (usually a failure to cannulate the cisterna and access the thoracic duct). Puncture related abdominal wall complications (bleeding and bruising) -10% but most will be minor and not require further treatment. The technique involves passing a small calibre needle across the abomen to puncture the cisterna chyli (and the same track is then used to introduce the microcatheter). Important structures are inevitably punctured and crossed and this is unavoidable. Injury to bowel, gallbladder, bile duct or blood vessels may require surgery but this is infrequent.

Organ	How often traversed
Liver	24/29 (83%)
Blood vessels	15/29 (52%) (portal vein n=10, Inferior vena cava n=5, hepatic vein n=1, hepatic artery n=1, renal vein n=1, aortic wall n=1)
Pancreas	9/29 (31%)

		<table><tr><td>Bowel</td><td>8/29 (28%) (Small bowel n=4, Colon n=2, gastric sleeve n=2)</td></tr><tr><td>Pleura</td><td>2/29 (7%)</td></tr><tr><td>Gallbladder or bile duct</td><td>Each 1/29 (3,5%)</td></tr><tr><td>Pericardium</td><td>1/29 (3,5%)</td></tr></table> Claus C. Pieper, Hans H. Schild Transabdominal thoracic duct embolization – which anatomic structures do we actually cross in transabdominal puncture? CIRSE Meeting 2018 Contrast allergy-either minor (self limiting) or moderate (requiring drug treatment) may occur. Anaphylaxis is a possible risk but likely to be very rare. Pulmonary embolus is a documented complication but these have been asymptomatic in the cases reported. A single US publication (1) suggests that there may also be a low incidence of lower limb swelling and chronic diarrhoea following thoracic duct embolisation. Lipiodol neurotoxicity with serious neurological deficit (even potentially fatal) has been reported in children with congenital heart disease or congenital lymphatic abnormalities undergoing lymphatic interventions to treat life-threatening lymphatic pathologies (plastic bronchitis and protein losing enteropathy). This is thought to occur through right to left cardiac shunts or lympho-venous reflux. *1 David Laslett, MS, Scott O. Trerotola, MD, Maxim Itkin, MD. Delayed Complications following Technically Successful Thoracic Duct Embolization Published:November 23, 2011DOI:https://doi.org/10.1016/j.jvir.2011.10.008*
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction / cessation of chyle leakage. Re-intervention rates. Mortality (this will probably be determined by the underlying condition and pre-existing surgery). Nutritional status.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	A single US publication (1-see above) suggests that there may also be a low incidence of lower limb swelling and chronic diarrhoea following thoracic duct embolisation. I think this was a patient reported questionnaire

17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No major technical differences or controversies.
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. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Probably about 10 (but ideally there should be access for all cardiothoracic, upper GI surgical and ENT surgical units so ultimately more will be required, or a networked approach). Cannot predict at present.

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.	Claus C. Pieper, Hans H. Schild Transabdominal thoracic duct embolization – which anatomic structures do we actually cross in transabdominal puncture? CIRSE Meeting 2018 Published case series; Mallick A. Br J Anaesth. 2003;91(2):265-272. Schild HH. Dtsch Ärztebl 2013;110(48):819-26. Schild HH. Röfo 2015;187(7):584-8. Dugue I. Br J Surg 1998;85:1147-9. Cerfolio RJ. Cardiovasc Surg 1996; 112:1361-6 Pieper CC, Schild HH. CVIR 2015;38(4):1050-4. Pieper CC, Schild HH. JVIR 2015;26(9):1405-8. Itkin M , J Thorac Cardiovasc Surg 2010;139(3):584-89
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I do not think there are any.

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)?	5-10 per year for large tertiary centre. I would estimate 200-300/year in the UK (if only adult post surgical cases are included). If paediatric congenital heart disease cases were added too this may add 50-100 cases per year.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Technical complexity and training of operators.
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
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	More long term outcomes to resolve the question regarding possible long term lower limb swelling and diarrhoea (but the underlying condition of persistent chyle leak is life-threatening).
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	Beneficial outcome measures: Short term (in hospital); Persistent chyle leak volume-daily until drains removed. Patient weight, Need for supplementary nutrition, Quality of life questionnaire (nutrition, pain, wellbeing). Adverse outcome measures: Death (within 30 days),

	complications. Please state the post procedure timescales over which these should be measured:	Need for re-intervention (at any time).
26	Is there any other data (published or otherwise) that you would like to share with the committee?	No

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Our first case is a fairly typical example; Day 16 post mediastinal tumour resection with a large volume chyle leak, nutritional deterioration requiring TPN and still draining >1000mls per day. Detailed informed consent discussion, including that this was the first time the procedure was to be performed within the trust and that there may be an unquantifiable additional risk because of this. Procedural time 3 hours 40 minutes (well within the accepted range). Post embolisation only drained a further 10mls and was discharged home at 48hrs. No complications observed. Both the patient and the referring surgical team were delighted with this outcome.

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	Cardiovascular and Interventional Radiology Society of Interventional Radiology (European Board of Interventional Radiology-deputy Chairperson)	**1st September 2019**	**Ongoing**
Direct - financial	Boston Scientific- research funding relating to treatment of peripheral vascular disease (EMINENT trial)-unrelated to lymphatic interventions.	**7th November 2017**	**Ongoing**
Direct - financial	**Public Health England Professional and Clinical Advisor (Screening Quality Assurance Service)**	**January 2016**	**Ongoing**

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Print name:	**Colin Nice**
Dated:	**29/04/2022**