NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1929 Percutaneous thrombectomy for massive pulmonary embolus**

Your information

Name:	Dare Seriki
Job title:	Consultant Vascular Radiologist
Organisation:	Manchester University NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Society of Interventional Radiology, Royal College of Physicians, Royal College of Physicians
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4204073

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

☒ 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?	I am a consultant vascular radiologist. I have been a consultant since September 2004. I have dealt with pulmonary artery disease as a registrar and as a consultant at both Lancashire Teaching Hospitals NHS Trust and also at Manchester University NHS Foundation Hospitals. I have extensive expertise in pulmonary artery embolization for AVMs. Wythenshawe is the Regional HHT centre. I also have experience in mechanical thrombectomy for pulmonary emboli and helped introduced the service into Wythenshawe using the Angiojet and Penumbra devices.
	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 technology is not widely used. Only a small number of Trusts in the UK. (<10) In general only used by Vascular Interventional Radiologists. Some cardiologists have expressed an interest, however the technology should only be used by those clinicians who regularly perform pulmonary angiographpy. My speciality is involved in patient selection and intervention. We currently use this technology. The number of cases performed are small 2-3 every 12 months in our Trust. However the number of referrals are 20-30 per 12 months. Procedures are only performed on one site Monday-Friday 0900-1700 by 3 Vascular 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. 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):	The technology is used in other vessels (arteries and veins), however this cohort of patients are extremely unwell and there is a significant risk of morbidity and mortality from patients who do or do not undergo intervention. This is an established in the major centres, however the patient care and management is extremely complex, multidisciplinary and time consuming. Not many centres provide this service. There is now a lot of evidence of the 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?	It will be an adjunct to correct practice (IV thrombolysis). This treatment (in particular the ClotTriever) It has the potential to increase options available to patients with submassive PE due to its safety profile, and efficacy in patients who cannot be thrombolysed.

Current management

5	Please describe the current standard of care that is used in the NHS.	Suspected massive PE. (BP < 90 mmHg for > 15 mins, other causes excluded)

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?	Urgent CTPA and ECHO If evidence of right heart strain then consider IV thrombolysis as per standard protocols Contact PERT (Pulmonary Emobolus Response Team – Respiratory Physician, Intensivist, Vascular Radiologist +/- Cardiothoracic Surgeon) if thrombolysis contraindicated or patient continues to be unstable post thombolysis

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?	Increased survival. Reduced time in hospital and ICU
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with massive and submassive PE
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?	As above. Increased survival. Reduced hospital stay. Reduced ICU stay. Reduced use of ECMO. Reduced bleeding complications from thrombolysis Reduced morbidity as number of patients with chronic PE will reduce Lots of health inequalities at present. Service is not widely available throughout UK or even in cities with have the service due to the complex nature of the procedure and expertise.
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)	Costs will be equivalent or less than current pathways for each patient. However the number of patients treated will increase significantly over time as the procedure becomes more widespread A lot of patients do not gain access to this treatment.
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)?	Reduced use of ICU and ECMO should produce savings. Patients should be discharged home quicker as improvement is more dramatic. However there is a cost of the device(s) £1000- £10,000 per procedure. There are also resource implications around staffing, ICU, Respiratory and Vascular Radiology.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Access to ICU Access to an interventional radiology suite with anaesthetic facilities

		Access to anaesthetic support who have experience of cardiothoracic anaesthesia and can place dual lumen ET tubes.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training on the use of the device(s) from the medical device companies.

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	• Death • Major haemorrhage • Cardiac arrhythmias • Pulmonary artery damage • Cardiac complications; tamponade, myocardial infarction, valvular dysfunction • Puncture site complications; haematoma, haemorrhage, pseudo aneurysm • Iodine anaphylaxis, contrast nephropathy
15	Please list the key efficacy outcomes for this procedure/technology?	• Elevation of systolic blood pressure over 100mmHg • Significant improvement in respiratory function – oxygenation, tachypnoea
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No concerns at present
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No

18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	10 or less specialist centres 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.	2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society European Heart Journal (2020) 41, 543603 ESC GUIDELINES doi:10.1093/eurheartj/ehz4 Percutaneous mechanical thrombectomy in a real-world pulmonary embolism population: Interim results of the FLASH registry Tu T Toma et al Catheter Cardiovasc Interv . 2022 Mar;99(4):1345-1355. doi: 10.1002/ccd.30091. Epub 2022 Feb 3. A Prospective, Single-Arm, Multicenter Trial of Catheter-Directed Mechanical Thrombectomy for Intermediate-Risk Acute Pulmonary Embolism: The FLARE Study. Tu T, Toma C, et al FLARE Investigators.JACC Cardiovasc Interv. 2019 May 13;12(9):859-869. doi: 10.1016/j.jcin.2018.12.022. Mangi M A, Rehman H, Bansal V, et al. (July 19, 2017) Ultrasound Assisted Catheter-Directed Thrombolysis of Acute Pulmonary Embolism: A Review of Current Literature. Cureus 9(7): e1492. DOI 10.7759/cureus.1492 Safety and efficacy of ultrasound-accelerated catheter-directed lytic therapy in acute pulmonary embolism with and without hemodynamic instability Nykamp et al, Journal of Vascular Surgery: Venous and Lymphatic Disorders July 2015 P251 A Randomized Trial of the Optimum Duration of Acoustic Pulse Thrombolysis Procedure in Acute Intermediate-Risk Pulmonary Embolism. The Optalyse PE Trial. JACC: Cardiovascular Interventions Vo 11 No 14 2018
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	As Above The FLASH Registry The FLARE Registry

		The Seattle II Study The Ultima Trial

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)?	
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No. Just need appropriate trained staff, vascular radiologists, Interventional Radiology (IR) nursing and radiographic staff and appropriate anaesthetic and ITU support.
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?	A UK 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.	Beneficial outcome measures: • Elevation of systolic blood pressure over 100mmHg • Significant improvement in respiratory function – oxygenation, tachypnoea • RV size and function • Length of stay • Length of stay in ICU • Functional respiratory reserve post procedure •

	- Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures:
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,	This is an interesting and highly effective technique. It offers a major advantage in the treatment of massive and submassive PE. The main issues relate to postcode lottery and 24/7 availability of this life saving procedure.

NICE National Institute for Health and Care Excellence

Declarations of interests

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

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

☒ 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:	**Dare Seriki**
Dated:	**17/11/22**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1929 Percutaneous thrombectomy for massive pulmonary embolus**

Your information

Name:	David Thompson
Job title:	Consultant Vascular Radiologist
Organisation:	Manchester University NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Radiologists/ British Society of Interventional Radiologists
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 3549108

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.

☐ 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:

Consent given

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 full time Vascular Interventional Radiologist with 17 years as a consultant working at Teaching Hospitals with a Cardiothoracic Unit. I have particular interests in Vascular Intervention in the chest, personally regularly performing Pulmonary arteriovenous malformation embolisation, Bronchial artery embolisation procedures and regularly assisting cardiologists with large bore arterial access for TAVI procedures. I have been involved with our hospitals fledgling PERT team (Pulmonary Embolism Response Team) for the last three years and although we have only performed 2 or 3 thrombectomy procedures a year I am often actively involved in discussions regarding PE treatment. I also work closely with our Cardiothoracic Anaesthetists as part of the regional Ventilation support and ECMO service. I am familiar with the use of USS assisted thrombolysis (EKOS) and have used the Penumbra Indigo aspiration system in PE treatment. I am trained in the use of the Inari Flowtreiver system which is currently going through governance approval in our trust This is a fairly niche service currently offered by selective teaching hospitals largely with cardiothoracic units and is likely to be slow to be taken up by hospitals in the short term and is currently not suitable to roll out across less specialised units . To my knowledge, in the UK it is performed either by Vascular radiologists or Cardiologist Other specialities involved in patient selection, discussion and treatment include respiratory medicine, Cardiothoracic anaesthetics and surgery , haematology and cardiology and other clinicians with an interest in PE

	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 given presentations locally and regionally on Intervention in PE
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 use of large Bore (14 to 24Fr) aspiration devices is relatively new advance in the treatment of PE. Their use is not proven to be advantageous in the long term although they look very promising in the short term. Current standard of care in the UK is conservative treatment or IV thrombolysis for massive PE. Local thrombolysis is not widely used. Elsewhere in the US and some European countries the standard of care is for more aggressive intervention I would describe the use of large bore thrombectomy devices in the UK as novel and of uncertain safety and efficacy Widespread rollout of their use in Massive and intermediate high risk PE patients would be regarded as a novel approach to PE treatment in the UK The use of small bore devices and EKOS is a variation of current treatment
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?	BOTH It could either be viewed as an alternative to thrombolysis or could largely replace systemic thrombolysis/ EKOS in certain centres

Current management

5	Please describe the current standard of care that is used in the NHS.	Assuming that we are only discussing the 5% of PE patients with high risk PE's then current treatment is conservative anticoagulation or thrombolysis
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?	Penumbra Indigo system Inari Flowtreiver EKOS uss assisted thrombolysis Angiovac (not widely applicable) Bard Angiojet (USS black box warning and not realistically applicable now)

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 mortality in Massive/Int high risk patients, reduced ICU/hospital stay, less use of rescue ECMO, reduce risk of long term sequelae (CTEPH/CTED etc)
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Massive PE and Int high risk patients who have a historical 30 day mortality of 10 to 30% Patients high risk/contraindicated for thrombolysis
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?	Again for high risk patients, less mortality, less sequelae of PE, shorter stay in hospital and less risk of CVA The use of large bore devices is certainly more invasive but the major adverse event rate would appear to be similar or less than the stroke rate if they were to be thrombolysed.
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)	Again, this procedure is probably only applicable to 5% of PE patients. Treatment costs of the IR procedure would be in the region of £4000 to 8000 which is much higher than thrombolysis but hopefully this would be offset by shorter stay in hospital, less use of ICU (and ECMO) reduced stroke rate and more productive patients long term with fewer long term sequelae of PE
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)?	Difficult to assess long term. High short term costs hopefully recouped by better survival and outcomes or the patients. I am not aware of long term cost modelling
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Interventionalists happy performing large bore procedures in the lungs. Interventional Suite, back up from intensivists and ultimately an ECMO service. The service should also have a working PERT team

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Specific device training required and probably need to perform approx. 10 procedures a year to maintain competence

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	Death , vein damage and catastrophic haemorrhage, arrythmia, cardiac valve injury, pulmonary artery injury, haemothorax, tamponade, failure to clear clot, allergy, stroke for clot in transit through a patent foramen ovale All should be less than 2% in a high risk patient with a background mortality of 10 to 30% Extract-PE trial for Penumbra Flash 800 registry for Inari
15	Please list the key efficacy outcomes for this procedure/technology?	30 day mortality, hospital stay, long term outcomes at 6months and beyond
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Mainly long term outcomes and applicability to more widespread rollout
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Perceived as a high risk procedure however thrombolysis is relatively high risk as well and all this needs to be borne in mind with the mortality risk of the patients that we would be treating (?5% of PE patients)
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present. Likely to be suitable to be rolled out in large hospitals with a large cardiology unit and or cardiothoracic surgery unit ie up to 30 units

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.	The data from the first 800 patients of the FLASH registry (INARI) was recently presented at TCT meeting in September 2022 Penumbra/EKOS data not as new
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Flash Registry (INARI)

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)?	Probably less than 5% of PE patients as a total but units will need to be performing at least one procedure a month to maintain competence
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Training and maintaining skills Need the backup of a PERT team for patient selection A National registry should be considered
23	Are you aware of any issues which would prevent (or have prevented) this	Short term cost to the radiology unit. Lack of suitable training. Lack of knowledge of new devices and evidence. General poor treatment of PE throughout the NHS

	procedure/technology being adopted in your organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Long term data/registries
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: Improvement in biomarkers, echo appearance and PA pressures, hospital stay. Long term review with QUALY and cardiopulmonary testing and echo at 3 to 6 months out to 2 years Adverse outcome measures: Major procedural adverse events up to 48 hours, in hospital mortality, need for adjuvant therapy/repeat therapy. Length of stay
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Need to realise that potentially treating less than 5% of PE patients with this device. For some centres, the standard of care may already be USS assisted thrombolysis

NICE National Institute for Health and Care Excellence

Declarations of interests

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

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

☒ 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:	**David Thompson**
Dated:	**15/11/22**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1929 Percutaneous thrombectomy for massive pulmonary embolus**

Your information

Name:	Miss Emma Wilton
Job title:	Consultant Vascular Surgeon
Organisation:	Oxford University Hospitals NHS Foundation Trust
Email address:	
Professional organisation or society membership/affiliation:	British Society of Endovascular Therapy, Vascular society of Great Britain and Ireland, Royal college of Surgeons of England
Nominated/ratified by (if applicable):	British society of Endovascular Therapy
Registration number (e.g. GMC, NMC, HCPC)	GMC No.: 4766261

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 familiar with the procedure but do not perform this myself. I have seen my Interventional Radiology colleagues perform the procedure. I do, however, use some of the same devices in the treatment of acute deep venous thrombosis in the lower limbs. I believe the procedure is currently not that widely used but I suspect that will increase dramatically if centres have approval to use it. The procedure is performed in my institution by my Interventional Radiology colleagues. My specialty, Vascular surgery, is not directly involved in these cases. However, I do use the same/ similar technology and procedures for treating acute lower limb deep vein thrombosis. We are one of the biggest centres already using percutaneous mechanical thrombectomy to treat acute deep vein thrombosis in the lower limbs.

	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.
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 standard treatment for massive pulmonary embolus includes systemic or catheter-directed thrombolysis. This new technique reduces the need for thrombolytic agents reducing the bleeding risk. It also achieves rapid clot removal and quick restoration of pulmonary circulation. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It is an addition to standard care in appropriately selected cases.

Current management

5	Please describe the current standard of care that is used in the NHS.	For massive pulmonary embolus the current standard of care is anticoagulation, cardiopulmonary support and pulmonary artery reperfusion by either open surgery, systemic thrombolysis or catheter-directed thrombolysis.

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?	The fact that thrombolytic infusions will not be required thereby reducing the bleeding risk to the patient. A quicker resolution of symptoms may also be achieved.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those in whom thrombolysis is contraindicated due to a significant bleeding risk
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?	Hopefully it would lead to improved outcomes, reduced length of stay on an intensive care/ HDU potentially reducing total length of hospital stay. It is still an invasive procedure.
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)	Possibly less overall. Equipment/ device costs more but hopefully will have less number of ITU/HDU bed days.
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)?	Possibly less overall. Equipment/ device costs more but hopefully will have less number of ITU/HDU bed days.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No additional facilities would be required

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training would be needed on the various percutaneous thrombectomy devices if the clinician is not already familiar with them.

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	Access site complications (bleeding, nerve injury, damage to other structures e garter) DVT Infection Major bleeding Cardiac injury Pulmonary injury
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in the RV/LV ratio Improved/ normalisation of systemic blood pressure and pulmonary artery pressure
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	nil
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not that I am aware
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. 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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	FLARE: Mechanical Thrombectomy for intermediate risk PE FLowTriever for Acute Massive Pulmonary Embolism (FLAME) PEERLESS RCT

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)?	

22	Are there any issues with the usability or practical aspects of the procedure/technology?	No. Standard learning curve only
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?	No just monitoring clinical results and patient outcomes
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: Adverse outcome measures:
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I have delivered workshops to both Vascular Surgeons and Interventional Radiologists on a particular device used for percutaneous mechanical thrombectomy to treat massive pulmonary embolus

NICE National Institute for Health and Care Excellence

Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Consulting agreement with Inari Medical	**2021**	
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:	**Miss Emma Wilton**
Dated:	**03/10/2022**