NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1887 Middle Meningeal Embolisation for Chronic Subdural Haematomas (CSDH)

Your information

Name:	Adel Helmy
Job title:	Associate Professor, Honorary Consultant Neurosurgeon
Organisation:	University of Cambridge, Cambridge University Hospitals NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	General Medical Council; Society of British Neurological Surgeons; British Neurovascular Group, European Association of Neurological Surgeons
Nominated/ratified by (if applicable):	Society of British Neurological Surgeons
Registration number (e.g. GMC, NMC, HCPC)	GMC: 6065675

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

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 neurosurgeon with a specialist interest in both vascular neurosurgery and trauma. I am part of a formal 1 in 4 rota in neurovascular neurosurgery and work closely with interventional neuroradiologists (INR) on a regular basis. Vascular cases undertaking INR procedures are reviewed in my clinic, admitted under my care and followed up by me. I also have a special interest in neurotrauma clinically and academically. I manage the full spectrum of neurotrauma from mild to severe and from age 16 to the elderly, including Chronic Subdural Haematoma. I am an Associate Professor of Neurosurgery and have a wide publication portfolio in both neurotrauma and neurovascular conditions, [Scopus June 22, Publications: 91; h-index 32]. I am a serving member on the current NICE guideline update for 'Early Management of Head Injury' and therefore have a good understanding of the process for generating evidence based data and synthesising this into NICE guidance.

	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 not carried out any direct research into this technique and I have no conflict of interest.
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):	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?	No, this cannot replace the existing techniques, as current practice targets patients with mass effect and symptoms from CSDH. This technique does not address mass effect acutely. It can therefore only be used as an adjunct, or in a patient group that is not currently selected for treatment.

Current management

5	Please describe the current standard of care that is used in the NHS.	CSDH is a common condition and commonly identified on CT scans done for other reasons. The indications for surgery currently are: a) Neurology compatible with compression of the brain either lateralised to the side of the chronic subdural or global symptoms (such as confusion, reduced conscious state) for bilateral chronic subdurals.

		b) Marked mass effect at risk of deterioration The standard treatment for CSDH is surgical evacuation as the primary problem is one of mass effect (pressure on the brain). A number of techniques are described including: a) Burr hole drainage b) Mini-craniotomy c) Standard craniotomy Burr hole drainage is a very simple and short procedure that can be done under local anaesthetic. Drainage is often supplemented by soft drain insertion for 48 hours following an RCT which showed a ~50% reduction in recurrence.
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?	The standard treatment is safe, effective, cheap and can be done with modest amount of training. Burr holes do not require any specialist equipment and it is the commonest training procedure for very junior neurosurgical specialty trainees. MMA embolization is of uncertain safety, does not treat mass effect, expensive by requiring time in the specialist neuro-angio suite (competing with thrombectomy and aneurysm treatment) and requires subspecialist INR time.

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?	MMA embolization has been promoted in 'patient payer-funded' settings as a way of preventing progression of small CSDH before they become symptomatic and require surgery. It is not yet clear from the literature whether the natural history of CSDH is benign anyway, and whether prophylactic treatment leads to improved patient outcomes.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	This is yet to be established. MMA embolisation requires a general anaesthetic which carries risks in the elderly and frail patient population susceptible to CSDH. In patients who are not symptomatic from mass effect (and therefore have a hard indication for surgical evacuation of the haematoma), it is not clear whether any treatment is required at all.
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?	This is not yet known for two reasons: a) MMA embolization is being promoted as a treatment in a pre-symptomatic phase of the clinical pathway b) We don't know what the natural history of small CSDH without mass effect is There is a risk of over-treating large numbers of patients who would never have ordinarily required any intervention in any circumstance.
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)	It is likely to cost much more as: a) It requires specialist knowledge and skills b) It is targeting a much larger cohort of patients who would ordinarily not have required any 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)?	Currently, there is a large challenge to hospital systems in implementing thrombectomy services which are already proven to be efficacious and cost effective. The same INR staff and neuro-angio suites are required for MMA embolization. There is an opportunity cost in diverting these resources from a proven treatment to an experimental one.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	A massive expansion in INR staff and neuro-angio suites would be required. CSDH is the commonest emergency procedure carried out as part of neurosurgical on-call services. With an ageing population, this is only likely to increase. If patients without mass effect are treated this will lead to a large expansion in the patient population being offered treatment.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	There is a national shortage of INR consultants such that thrombectomy services are struggling to be established 24/7, despite the robust evidence base and national prioritisation of these services.

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	This is a low risk procedure overall. With instrumentation of the external carotid circulation the risks of intracranial stroke are reduced compared with other INR procedures. There is always a small risk of causing thrombo-embolic stroke with any INR procedure. In a frail and elderly population who commonly have CSDH, the greater risks are of general anaesthesia, and admission to hospital.
15	Please list the key efficacy outcomes for this procedure/technology?	This depends on the indications. Currently, this procedure is being used in asymptomatic patients. If this is the case, a large natural history study is required to determine what: a) Proportion of patients require subsequent surgery or intervention b) Functional outcomes are present at 6 months or 1 year following intervention (can be eGOS or mRS) c) Complications of the procedure with a focus on those that occur in the frail population following surgery such as DVT/PE and hospital acquired pneumonia. d) Procedural complications such as stroke/vascular dissection/thromboembolism, failure to embolise both branches of MMA e) Length of stay, number of readmissions (any complication)

16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The procedure appears *radiologically* efficacious. The key question is whether the risks and costs of intervention have an impact on patient functional outcomes.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above, in highly selected patients, it can reduce the size of CSDH radiologically. The uncertainty is whether: a) these patients required intervention in the first place, as compared with the natural history of the disease. b) Burr hole drainage is more cost-effective in the subset who go onto require subsequent intervention
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.	Cardiff SBNS, Aberdeen experience presented.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	https://ichgcp.net/clinical-trials-registry/NCT04372147

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)?	Tens of thousands.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	-
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?	There is a lack of the staff and infrastructure nationally to deliver this service.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	As above, I would like to see natural history and efficacy studies before the widespread adoption of this technique. Without this there is a large risk of diverting scarce resource to an unproven and expensive treatment, for a condition which already has a cheap and simple intervention.
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:	**As per paragraph 15 above**. Beneficial outcome measures: -long term clinical outcomes compared with those that don't have treatment (this is being used as a prophylactic treatment) Adverse outcome measures: -complications of anaesthesia in a frail population are key.

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,	As above, there is a large risk to resource limited NHS services in changing standard care from a cheap, widely available, efficacious treatment to one which is expensive and requires specialist intervention. The second risk is treating a very large group of asymptomatic patients without a robust understanding of the natural history. From our experience in neurosurgical on-call services, small chronic subdural haematomas have a benign natural history and the majority will not require any treatment at all. In the first instance, I would favour that units who carry out this work do so under the guise of a nationally established registry or research study which prospectively collects efficacy and outcome data. Ultimately, an RCT will be required should initial data be promising. I would suggest that these procedures are not adopted in clinical services at the current time but an 'only within ethically approved research' recommendation is made.

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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 AstraZeneca study ANNEXA-I	Dec 21	ongoing
Direct - financial	Pressura Neuro- clinical trial design/implementation and consultancy	2017	Ongoing
Direct - financial	Medico-legal expert in neurosurgery	2018	ongoing

☒ 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:	**Adel Helmy**
Dated:	**20th June 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1887 Middle Meningeal Embolisation for Chronic Subdural Haematomas (CSDH)

Your information

Name:	Ayman Qureshi
Job title:	Diagnostic & Interventional Neuroradiologist
Organisation:	National Hospital for Neurology & Neurosurgery, UCLH NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Radiologists
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC: 7505609

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

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 and its indications. I have performed this procedure in the past (this was carried out in Toronto, Canada during a fellowship training period). The procedure is available at my current institution (having been approved by our local Clinical Effectiveness Steering Group). The experience with this procedure is early in the UK, however I am aware of a few centers performing this. In the UK the procedure would be performed by an Interventional Neuroradiologist. We are involved in patient selection together with the Neurosurgical teams who the patient is admitted under. I have performed this procedure in the past.

	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 research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. I have had no involvement in 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 current standard of care for chronic subdural hamatomas (CSDH) is either surgical evacuation (through burr holes drilled into the skull). Some patients are managed conservatively. MMA embolization is a novel approach which targets the cause of the CSDH - allowing haematoma resorbtion and preventing recurrence. Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Definitely novel and of uncertain safety and efficacy. The first in a new class of procedure.

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 would be used as an adjunct to current care. Some patients with CSDH would continue to require burr hole drainage (e.g those with significant mass effect that need urgent decompression). In these patients MMA embolization may still be used to prevent recurrence after surgery. In smaller CSDH or patients with contraindication to surgery, this procedure has the potential to replace surgery altogether.

Current management

5	Please describe the current standard of care that is used in the NHS.	Drainage of CSDH through burr holes / minicraniotomies, or conservative management in select patients.
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?	Minimising hospital stay and repeat procedures / readmissions.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients on anticoagulation, elderly patients who cannot tolerate 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. Potential to improve outcomes, reduce hospital visits and admission times and is a less invasive treatment.
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)	Less
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)?	About the same, or more if embolization is required as an adjunct to surgery
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Interventional Neuroradiologist, trained nurses, radiographers. Angiography equipment and catheters/microwires/embolic material (already present in performing centers)

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	No. The principles of treatment mirror those that are routinely performed in Interventional Neuroradiology

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	Stroke (approx. 1 – 3%) Access site bleed/complication (0.5 – 1%) Contrast reactions (rare) Radiation related risk (theoretical) Headache
15	Please list the key efficacy outcomes for this procedure/technology?	CSDH resolution/reduction in size on FU scans Recurrence rates on follow up
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long term recurrence of CSDH (whether this is prevented or not)
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):	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.	Ban SP, Hwang G, Byoun HS, Kim T, Lee SU, Bang JS, Han JH, Kim CY, Kwon OK, Oh CW. Middle Meningeal Artery Embolization for Chronic Subdural Hematoma. Radiology. 2018 Mar;286(3):992-999. doi: 10.1148/radiol.2017170053. Epub 2017 Oct 10. PMID: 29019449. Ng S, Derraz I, Boetto J, et al Middle meningeal artery embolization as an adjuvant treatment to surgery for symptomatic chronic subdural hematoma: a pilot study assessing hematoma volume resorption Journal of NeuroInterventional Surgery 2020;12:695-699. Catapano JS, Ducruet AF, Nguyen CL, et al Middle meningeal artery embolization for chronic subdural hematoma: an institutional technical analysis Journal of NeuroInterventional Surgery Published Online First: 19 October 2020. doi: 10.1136/neurintsurg-2020-016552 Fiorella D, Arthur AS. Middle meningeal artery embolization for the management of chronic subdural hematoma. J Neurointerv Surg. 2019 Sep;11(9):912-915. doi: 10.1136/neurintsurg-2019-014730. Epub 2019 Feb 23. PMID: 30798265. Rinaldo L, Cloft H, Brinjikji W E-113 Middle meningeal artery embolization for treatment of chronic subdural hematoma: A prospective institutional case series Journal of NeuroInterventional Surgery 2020;12:A90. Di Cristofori A, Remida P, Patassini M, Piergallini L, Buonanno R, Bruno R, Carrabba G, Pavesi G, Iaccarino C, Giussani CG. Middle meningeal artery embolization for chronic subdural hematomas. A systematic review of the literature focused on indications, technical aspects, and future possible perspectives. Surg Neurol Int. 2022 Mar 18;13:94. doi: 10.25259/SNI_911_2021. PMID: 35399896;
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	• Kellner C, Al-Mufti F, Gupta R, *et al* 75 A prospective, multi-center, randomized controlled pivotal study to evaluate the safety and effectiveness of trufill® NBCA embolization of the middle meningeal artery for the treatment of subdural hematoma – The membrane study

		Journal of NeuroInterventional Surgery 2021;**13:**A104-A105. • **Embolization of Middle Meningeal Artery in Chronic Subdural Hematoma. Improving the Outcome of Chronic Subdural Hematoma by Embolization of Middle Meningeal Artery (ELIMINATE)** • NCT04750200: **Management of CSDH With or Without EMMA- a Randomized Control Trial** • NCT04511572: **Embolization of Middle Meningeal Artery in Chronic Subdural Hematoma** • NCT04923984: **Embolization of Middle Meningeal Artery for Subdural Hematoma in Canada (EMMA Can)** • NCT04270955: **Dartmouth Middle Meningeal Embolization Trial (DaMMET)** • NCT04065113: Middle Meningeal Artery Embolization for Chronic Subdural Hematoma.

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)?	Approx. 2000
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

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	No
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: Clinical outcome: NIHSS score, mRS score, Imaging outcome Adverse outcome measures: Stroke, cranial nerve palsy, access site complications
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,	

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Declarations of interests

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

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

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Print name:	**Ayman Qureshi**
Dated:	**17/07/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1887 Middle Meningeal Embolisation for Chronic Subdural Haematomas (CSDH)

Your information

Name:	Ian Coulter
Job title:	Consultant Neurosurgeon
Organisation:	Royal Victoria Infirmary, Newcastle upon Tyne.
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Society of British Neurological Surgeons (SBNS)
Nominated/ratified by (if applicable):	Prof Peter Hutchinson
Registration number (e.g. GMC, NMC, HCPC)	6166807

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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?	As a consultant neurosurgeon, I do not perform middle meningeal artery embolisation (MMAE), the procedure is typically undertaken by an interventional neuroradiologist (INR). I am nevertheless familiar with the technicalities of the procedure as I understand that it represents an emerging treatment which may be appropriate for some of my future patients. I have not used the treatment, though I understand that it has been undertaken at least once at our centre. I am aware that it has been utilised more often at some other centres in the United Kingdom, though it remains an emerging treatment modality for patients with CSDH.
	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?	There is mounting enthusiasm and hope that this procedure will serve as an efficacious treatment option for the management of some patients with chronic subdural haematoma (CSDH), though I think widespread implementation has been halted by the paucity of higher quality clinical evidence. If pending/ongoing trials report benefits of the procedure in the next few years, there is likely to be a relatively further uptake of the procedure across the NHS.
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	Neurosurgeons are principally responsible for patient selection and will refer to INR colleagues for the treatment and thereafter manage the patient following treatment.
	− If your specialty is involved in patient selection or referral to another specialty for this	Other than INR specialists, it is unlikely that any other specialist clinicians would perform or utilise MMAE for their patients.

	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 in order to facilitate discussion at our departmental consultant meeting as to whether the procedure should be utilised at our centre.
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):	**Definitely novel and of uncertain safety and efficacy.** Although neuro-endovascular procedures are widespread and performed frequently in the NHS, the endovascular treatment of CSDH is still a novel phenomenon, though more centres are offering the procedure (albeit without the support of high-quality evidence).
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	The procedure may replace surgical treatment for a proportion of patients, though MMAE is more likely to utilised as an addition to the existing standard of care, which is surgical decompression of the haematoma.

Current management

5	Please describe the current standard of care that is used in the NHS.	Patients with symptomatic CSDH are often referred to neurosurgeons for surgical decompression of the haematoma. Patients who are asymptomatic or experience minor symptoms are typically managed conservatively as it is possible that spontaneous resolution of the haematoma will occur.

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?	There is potential for some patients with CSDH to undergo MMAE and then avoid surgical treatment and its attendant complications thereafter (primary treatment). There also exists the possibility that MMAE could serve as an adjunctive measure to surgery for some patients in whom the risk of recurrence requiring additional surgery, is deemed to be high (secondary treatment).
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	The procedure, if administered via a local anaesthetic, may be tolerated by some groups of elderly patients and those with a significant co-morbidity burden, potentially easier than a surgical procedure under general anaesthetic – though we don't know if this theoretical advantage will transpire in clinical practice. Some patients (possible the majority), will still require general anaesthesia.
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?	MMAE does represent a relatively less invasive treatment and has the potential to reduce the number of surgical procedures required to manage patients with CSDH. In addition, initial reports suggest the complication rate is low, therefore there also exists the possibility that lengths of hospital stay will reduce. The procedure may be delivered as a day-case procedure for some patients. Reducing the length of stay for some patients will hopefully lead to reduced morbidity and mortality related to hospitalisation. Such potential benefits are perhaps even more pertinent when we consider that with an ageing population, this disease (CSDH) is gradually becoming more common. However, patients undergoing MMAE will still require follow-up, clinical assessments and CT scans to monitor CSDH resolution, so it remains to be seen as to whether fewer hospital visits will occur.
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)	I suspect that the introduction of MMAE treatment is likely to cost more than the current standard of care, as it is foreseeable that we would offer the treatment in addition to surgery in some cases. There also exists the possibility that some patients with mild or no symptoms, would be offered the treatment, but may not have required it, as their haematoma was going to resolve spontaneously anyway. Despite the condition's prevalence we do not have a good understanding of the natural history of conservatively managed CSDHs. Potential cost benefits may occur if MMAE leads to fewer surgical procedures being performed (as suggested by: Catapano JS et al. Total 1-year hospital cost of middle meningeal artery

		embolization compared to surgery for chronic subdural hematomas: a propensity-adjusted analysis. J Neurointerv Surg. 2021 Dec 8:neurintsurg-2021-018327. doi: 10.1136/neurintsurg-2021-018327. Epub ahead of print. PMID: 34880075.)
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)?	I think the resource impact is likely to cost more than the standard of care as the expertise and resources of the INR team and their specialist theatres are required to provide the treatment. Undertaking the procedure will increase the workload of the INR teams, so workflow would need to be assessed in each unit to assess potential impact and manage resources accordingly.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	MMAE would need to be undertaken in an INR theatre with appropriate imaging facilities. If offered to patients with mild or no symptoms (typically patients that would not normally be admitted to a neurosurgical centre), there also exists a need to consider inpatient bed availability and staffing at neurosurgical centres as the number of inpatients may potentially increase (though it is hoped the procedure can be done as a day-case procedure in some instances).
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	MMAE will be undertaken by neuro-interventional radiologists in most centres. Not all consultants will have experience performing the procedure, though the technical expertise required is likely to be less than undertaking other interventional procedures, such as coiling aneurysms.

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	Potential risks of procedure: CSDH re-collection/treatment failure (such that 'surgical rescue' is required) a large recent systematic review identified this overall risk at 5.5%, though has been reported at 9% for those undergoing MMAE as the primary treatment (Di Cristofori A, Remida P, Patassini M, Piergallini L, Buonanno R, Bruno R, Carrabba G, Pavesi G, Iaccarino C, Giussani CG. Middle meningeal artery embolization for chronic subdural hematomas. A systematic review of the literature focused on indications, technical aspects, and future possible perspectives. Surg Neurol Int. 2022 Mar 18;13:94. doi: 10.25259/SNI_911_2021. PMID: 35399896; PMCID: PMC8986643.). The above systematic review suggested that other complications occurred in 6 out of 746 patients, which represents a rate of 0.8%. These complications included: cerebral infarction,

		seizure, intermittent aphasia, one cerebrovascular complication, one cerebrovascular infarction and one acute worsening of the CSDH. Other rare reported complications: Intracranial pseudoaneurysm formation. (Wilseck ZM, Khan AA, Chaudhary N, Gemmete JJ. Iatrogenic pseudoaneurysm of the middle meningeal artery during embolization of bilateral chronic subdural hematomas. Interv Neuroradiol. 2022 Jun 7:15910199221107250. doi: 10.1177/15910199221107250. Epub ahead of print. PMID: 35673708.) Theoretical adverse events: The target patient group is typically elderly, therefore they are more likely to have arteriosclerotic tortuous arterial system, which may be harder to navigate with a vascular catheter and potentially more susceptible to injury and ischaemic complications. Anastomoses of the MMA with ophthalmic artery may lead to inadvertent occlusion of the ophthalmic artery and consequently, visual impairment including blindness. The observation of such anastomoses would typically exclude a patient from MMAE treatment (Fantoni M, Eliezer M, Serrano F, Civelli V, Labeyrie MA, Saint-Maurice JP, Houdart E. High frequency of ophthalmic origin of the middle meningeal artery in chronic subdural hematoma. Neuroradiology. 2020 May;62(5):639-644. doi: 10.1007/s00234-020-02363-6. Epub 2020 Jan 21. PMID: 31965212.) The petrous branch of the MMA is a significant supplier to the facial nerve. Injury to the nerve may cause debilitating neurological and cosmetic complications.
15	Please list the key efficacy outcomes for this procedure/technology?	Resolution of any patient symptoms and avoidance of surgical intervention.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The current evidence available in the medical literature includes case series which may be influenced by selection bias, so as yet, we do not have a good understanding of the optimum criteria for the procedure to be maximally efficacious.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above - we do not really understand which group of patients will derive benefit from the procedure, nor do we understand if it will be a cost-effective procedure to implement.

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. Neurosurgical units with interventional neuroradiology service (10-20 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.	Middle meningeal artery (MMA) embolization for chronic subdural haematoma: A prospective UK study Mohamed, S.; Villabona, A.; Kennion, O.; Padmanabhan, R.; Siddiqui, A.; Prasad, M.; Mukerji, N.. *British Journal of Neurosurgery ; 35(4):509-510, 2021.* Carole Turner (2021) Proceedings of the 2021 Society of British Neurological Surgeons Autumn Meeting, British Journal of Neurosurgery, 35:4, 498-524, DOI: 10.1080/02688697.2021.1994751

20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	https://www.clinicaltrials.gov/ct2/results?cond=Middle+meningeal+artery+embolization&term=&cntry=&state=&city=&dist= 14 international studies are reportedly actively recruiting patients.

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)?	Of an estimated 2500 patients per year identified around the UK with a CSDH, it is possible that 25-50% may be eligible for MMAE as a primary treatment or as an adjunct to surgery.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The optimum agent to embolise the target vessel has yet to be determined, though the safety of various agents have been reported. Administration of Onyx (an embolic agent) into the MMA is painful and likely to require general anaesthesia for elderly patients. Embolic agents have the potential to migrate into smaller vessels, therefore knowledge of the blood supply to cranial nerves is imperative, including being aware of potentially hazardous anastomoses that can exists, such as that which can occur between the MMA and ophthalmic artery. Typically, an observed anastomosis between the MMA and ophthalmic artery would prohibit treatment in most case series reported.
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?	Lack of high-quality evidence supporting efficacy at the present time.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Results from ongoing clinical trials should yield higher value evidence in the near future.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe:	Beneficial outcome measures:

	− 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:	Avoidance of surgical rescue treatment (in those undergoing MMAE as primary treatment) within 6 months. Avoidance of repeat surgery in those receiving MMAE as an adjunctive procedure to surgery within 6 months. Patient reported resolution of symptoms within 3 and 6 months. Radiological: Resolution of CSDH on follow-up CT scan at 6 months Adverse outcome measures: Morbidity experienced as a consequence of the procedure within 6 months (including failure of treatment – which necessitates surgical rescue) Mortality rate within 30 days of procedure and 6 months following procedure.
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,	

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Declarations of interests

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

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

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:	**Ian Coulter**
Dated:	**08/07/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1887 Middle Meningeal Embolisation for Chronic Subdural Haematomas (CSDH)

Your information

Name:	Pragnesh Bhatt
Job title:	Consultant Neurosurgeon
Organisation:	Aberdeen Royal Infirmary
Email address:	[redacted]
Professional organisation or society membership/affiliation:	SBNS
Nominated/ratified by (if applicable):	Prof. Nihal Gurusinghe
Registration number (e.g. GMC, NMC, HCPC)	3473722

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 however haven't carried out myself as there are normally carried out by our Interventional Neuroradiology Colleagues.

	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 s I was asked to give a presentation on the subject at the last SBNS conference in March 2022.
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):	Established practice in many other parts of the world and relatively new in the UK.
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?	Currently, used by few however indications are likely to expand.

Current management

5	Please describe the current standard of care that is used in the NHS.	Surgical evacuation either through the burr-holes or mini-craniotomy

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?	Current standard practice of surgical evacuation is more invasive and the Trial of Dexamethasone in Chronic Subdural Haematoma (Trial of Dexamethasone for Chronic Subdural Hematoma | NEJM) didn't shift our practice trend.

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?	Minimally invasive
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those on antiplatelet/ anticoagulant medication and those who have high risk of anaesthesia/ 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.
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)	Unable to comment with confidence.
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)?	Unable to comment with confidence.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Interventional neuroradiology set up and neurology/ neurosurgery department

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Endovascular/ Interventional neuroradiology

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	Radiation exposure All those related to endovascular procedures
15	Please list the key efficacy outcomes for this procedure/technology?	Clinical and radiological outcome
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Cost effectiveness
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Which is the best embolising material?
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.	As per my presentation.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	As per my presentation.

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)?	10-20% of the case load however this could increase with time/ experience.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Staff availability
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?	Availability of resources

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Awaiting few trial results.
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: As the literature Adverse outcome measures: As the literature
26	Is there any other data (published or otherwise) that you would like to share with the committee?	Already shared with Prof. Gurusinghe however happy to re-attach with mail.

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
Non-financial professional	Invited presentation at the SBNS meeting in Cardiff in March 2022	**30.03.2022**	**01.04.2022**
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:	**Pragnesh Bhatt**
Dated:	**07.07.2022**