

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1865 Transvenous obliteration for oesophageal for gastric varices

Your information

Name:	David Patch
Job title:	Consultant Hepatologist
Organisation:	Royal Free Hospital
Email address:	[REDACTED]
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	3202434

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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	indicate your experience with it.	
2	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have published this research.</p> <p>Other (please comment)</p>
3	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>Minor variation</p> <p>Established practice and no longer new.</p>
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?	In addition

Current management

5	Please describe the current standard of care that is used in the NHS.	TRansvenous variceal obliteration of varices is carried out when endoscopic therapy has been unsuccessful, and may occur at the time of TIPS procedure, or when there is encephalopathy and leaving a TIPS is not desired, or when there is portal vein thrombosis. It is done in
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		interventional radiology suites
6	<p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p>	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?	An additional technique to manage variceal bleeding
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with hard to control variceal bleeding
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?	Not really
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)	No change-we have been doing this for some years and it is not a new technique
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)?	No change
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	A well equipped interventional radiology suite
13	Is any specific training needed in order to	Yes the interventional radiologist needs to be familiar with, and experience of, the procedure

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

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>Embolization of varices may lead to thrombosis of the splanchnic circulation, and if some embolization materials may travel to other organs-(histoacryl glue), or may become displaced (coils)</p> <p>If a trans-organ approach is used (trans hepatic, or transplenic) capsular bleeding may occur</p>
15	Please list the key efficacy outcomes for this procedure/technology?	Cessation of bleeding, survival
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The algorithm of care of patients with variceal bleeding is quite well established-and would be endoscopic first, and interventional radiology if re-bleeding occurs or if high risk for re-bleeding
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The position in relation to TIPs is unclear if seen as a separate procedure
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	<p>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).</p> <p>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.</p>	
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	

Other considerations

21	<p>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)?</p>	<p>At the Royal Free we probably do one procedure a month</p>
22	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	<p>no</p>
23	<p>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?</p>	<p>none</p>

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	The first question is to ensure we are talking about the same procedure Then it's a question of agreeing its indication
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - 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: 	<p>Beneficial outcome measures:</p> <p>Cessation of bleeding</p> <p>Survival</p> <p>Recurrence of bleeding</p> <p>Adverse outcome measures:</p> <p>Encephalopathy</p> <p>Ascites</p> <p>Bleeding from other sites</p> <p>Complications of the procedure</p>

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
<i>Direct - financial</i>	Speaker fees for Gore Inc	Sept 2021	
<i>Direct - financial</i>	Speaker fee-for Cook Medical	July 2021	
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:	David Patch
Dated:	04/03/2022

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Dr Ralph Jackson"/>
Job title:	<input type="text" value="Consultant Vascular and Interventional Radiologist"/>
Organisation:	<input type="text" value="Newcastle-upon-Tyne NHS Foundation Trust"/>
Email address:	<input type="text" value="REDACTED"/>
Professional organisation or society membership/affiliation:	<input type="text" value="British Society of Interventional Radiologists, Royal College of Radiologists"/>
Nominated/ratified by (if applicable):	<input type="text" value="Click here to enter text."/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="3470781"/>

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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:

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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.

<p>1 Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"> - 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 	<p>I first started exploring BRTO for gastric variceal bleeding over 10 years ago and have done roughly 5-6 cases since then. My experience is largely self-taught as no one else in the UK appeared to be doing it. I had discussed with colleagues in liver centres elsewhere in the UK but there appeared to be little belief or interest in it.</p> <p>In the last few years, I have adapted my TIPS technique to take incorporate aspects of BRTO into TIPS for isolated gastric varices.</p> <p>My learning has come from the literature largely from Japan and Korea and more recently from the USA.</p> <p>In the last 2 years or so I am aware of more interest in the major UK liver centres. I have given two talks about BRTO at the BSIR AGM, 2021 and 2016.</p> <p>I don't think that any other specialties either are or are likely to.</p> <p>The technology uses standard equipment and techniques widely used in other IR procedures. There are specifically adapted balloon catheters available in the Far East but as far as I know not in Europe.</p>
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	procedure/technology, please indicate your experience with it.	
2	<p>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have done bibliographic research on this procedure.</p> <p>Other (please comment): As above, presentations about BRTO at the BSIR AGMs</p>
3	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>Established practice and no longer new. Well established in the Far East and increasingly in North America</p>
4	<p>Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?</p>	<p>BRTO could/should replace TIPS for bleeding gastric varices. Should complement endoscopic treatment.</p>

Current management

5	<p>Please describe the current standard of care that is used in the NHS.</p>	<p>Gastric varices are typically managed by Endoscopic techniques (glue/thrombin injection) and subsequent TIPS to reduce future bleeds or as rescue when endoscopy alone has failed.</p>
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<p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p>	<p>No</p>
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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?	Higher success rate than TIPS or endoscopy in stopping recurrent variceal bleeding in patients with isolated gastric varices.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with bleeding IGV. Has been used in the Far East to reduce hepatic encephalopathy but this is a different patient group
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, reduced hospital length of stay, better long term mortality.
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)	Probably less as the equipment already exists in IR depts and relatively inexpensive
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)?	Should cost less
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Should be possible in all centres which manage variceal haemorrhage and have an IR department.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, familiarity with the indications and techniques would be important as with most new procedures. It is, however, an extension of common IR skills and techniques already in clinical practice.
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Safety and efficacy of the procedure/technology

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>Failure to prevent variceal bleeding due to procedural failure. There is a risk of worsening ascites and oesophageal variceal bleeding. Both of these have established and successful treatment options and TIPS remains an option for most.</p> <p>Rarely, portal vein thrombosis can occur.</p> <p>In the Far East, traditionally ethonolamine was used as the sclerosant. There are risks of haemolysis and renal failure. However, commonly used sclerosants eg polidocanol, STS are now used with low risk profiles.</p>
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in recurrent variceal bleeding, 3 day and 1 year mortality
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Unclear how easily this can be rolled out. God quality randomised trials versus TIPS in a western population are lacking
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above. Historical scepticism in the West where TIPS has reigned.
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. Probably. But I am aware that TIPS centres may be reviewed and reduced.

Abstracts and ongoing studies

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

Other considerations

21	<p>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)?</p>	<p>I suspect no more than 50 a year</p>
22	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	<p>Little UK experience at the moment</p>
23	<p>Are you aware of any issues which would prevent (or have prevented) this</p>	<p>No</p>

Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
<i>Direct - financial</i>	I have received a payment from Becton Dickinson for a presentation at a national meeting not related to this IP.	2021	
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:	<input type="text" value="DR RALPH JACKSON"/>
Dated:	<input type="text" value="07/03/22"/>

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Teik Choon SEE"/>
Job title:	<input type="text" value="Consultant Interventional Radiologist"/>
Organisation:	<input type="text" value="Cambridge University Hospitals NHS Foundation Trust"/>
Email address:	<input type="text" value="REDACTED"/>
Professional organisation or society membership/affiliation:	<input type="text" value="Royal college of Radiologist, British Society of Interventional Radiology"/>
Nominated/ratified by (if applicable):	<input type="text" value="British Society of Interventional Radiology"/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="GMC 4591247"/>

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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.

<p>1</p>	<p>Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"> - 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 	<p>This procedure is well recognised although it is not very commonly performed in the UK. It's usually performed by interventional radiologists although in other countries this may also be performed by a surgeon or a liver doctor.</p> <p>It is important to recognise that transvenous obliteration (embolization) of varices could be performed antegradely, retrogradely or a combination of both.</p> <p>The antegrade approach means embolisation is performed via the feeding vein of the varix. This is usually part of the procedure when performing Transjugular Intrahepatic Porto-Systemic Shunt (TIPSS). The embolic materials are usually coils or plugs.</p> <p>The retrograde approach means embolisation is performed via the draining vein of the shunt. This is usually the approach when dealing with a large gastroduodenal shunt This can be performed during the same procedure as TIPSS (although access site may differ), as a separate procedure if the patient does not improve following TIPSS +/- antegrade embolization, or as a single entity without TIPSS.</p> <p>If the procedure is performed retrogradely, it involves a femoral or jugular vein access followed by cannulation of the left renal vein and subsequently the gastroduodenal shunt and varices. Embolisation is then performed using liquid or other solid embolic agents assisted by balloon occlusion to prevent non-target embolization. This is called balloon-occluded retrograde transvenous obliteration (BRTO).</p> <p>There are variations of the BRTO including:</p> <ul style="list-style-type: none"> - vascular plug-assisted retrograde transvenous obliteration (PARTO) - coil-assisted retrograde transvenous obliteration (CARTO) - balloon-occluded antegrade transvenous obliteration (BATO)
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	<p>procedure/technology, please indicate your experience with it.</p>	<p>My current practice involves TIPSS and antegrade embolisation. For antegrade embolization I would prefer to use plugs if feasible. The other option is coils. For retrograde embolisation of a gastroduodenal shunt, I would prefer PARTO as this procedure is less time consuming and in my opinion less likely to result in adverse events compared to BRTO.</p> <p>I have performed complex TIPSS in patients with portal vein thrombosis in association with variceal haemorrhage or bowel ischaemia. Commonly this will also require antegrade embolisation of the afferent supply to the varices. In some cases PARTO are also indicated.</p> <p>Patients with massive refractory variceal haemorrhage are usually transferred to specialist centres and usually a transplant centre where facilities with more complex endoscopic and endovascular interventions are available. This procedure is therefore limited to small number of specialist liver centres the UK.</p> <p>Part of the reasons that BRTO or its variants are not widely performed is because it has not been formally integrated in the pathway for variceal haemorrhage in the UK, and also the lack of awareness regarding the existence of the procedure. I expect there will be more uptake if this is formally incorporated into the patient pathway.</p> <p>In the UK I would expect the procedure will be almost exclusively performed by the interventional radiologists, with a few exceptions for those non-radiologists that have been trained in this area.</p> <p>The decision to proceed is made via a multidisciplinary team and the team may consist of gastroenterologists/hepatologists, interventional radiologists, liver surgeons +/- transplant team. My involvement will include imaging review and assessment of suitability of the procedure. The team will also discuss if a TIPSS is required as this will be indicated in patients with portal hypertension with refractory gastro-oesophageal haemorrhage.</p>
2	<p>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have done bibliographic research on this procedure.</p> <p>My relevant publications:</p> <ul style="list-style-type: none"> • See here! Locating the source of upper GI bleeding. Hawken J, Upponi S, Corbett G, See TC, Leithead JA. Frontline Gastroenterol. 2020 Aug 21;12(6):539-540. • A stepwise thrombolysis regimen in the management of acute portal vein thrombosis in patients with evidence of intestinal ischaemia. Benmassaoud A, AlRubaiy L, Yu D, Chowdary P, Sekhar M, Parikh P, Finkel J, See TC, O'Beirne J, Leithead JA, Patch D. Aliment Pharmacol Ther. 2019 Nov;50(9)

<p>3</p>	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>Gastric varices are less frequent than esophageal varices but gastric variceal haemorrhage is more severe and with worse prognosis.</p> <p>The current standard of care for variceal haemorrhage will consist of active conservative management and endoscopic intervention including band ligation, sclerotherapy, and glue injection. If endoscopic management fails, TIPSS should be considered. TIPSS is only offered in specialist centres, mainly in liver transplant units. The role of early TIPSS in the management of oesophageal varices are well recognised. A combination of TIPSS and antegrade embolisation of the afferent supply to the varices can be performed during the same setting. Literature from retrospective studies would support this approach offers better outcomes. However, in a patient with large gastric varices and with a large gastroduodenal shunt, BRTO or its variants may be required to stop or prevent future haemorrhage, with or without TIPSS and antegrade embolization. The technique is well described and has been used in many other centres outside UK. The concept is novel, and the technique will be a variation of practice. The impact to patient outcome could be significant.</p> <p>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.</p> <p>-I would not consider this a 'minor' variation as technically BRTO or its variant may not be straightforward. Also there is no RCTs available to formally assess outcomes.</p>
<p>4</p>	<p>Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?</p>	<p>As an addition to existing standard care</p>

Current management

<p>5</p>	<p>Please describe the current standard of care that is used in the NHS.</p>	<p>https://www.bsg.org.uk/wp-content/uploads/2019/12/UK-guidelines-on-the-</p>
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		management-of-variceal-haemorrhage-in-cirrhotic-patients.pdf UK guidelines on the management of variceal haemorrhage in cirrhotic patients Dhiraj Tripathi et al.
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, apart from what I described above.

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?	<ul style="list-style-type: none"> • Better haemorrhage control • Potential survival benefits • The new variants of BRTO offer quicker and safer approaches
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	<ul style="list-style-type: none"> • Refractory variceal haemorrhage with large gastroduodenal shunts
9	<p>Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?</p> <p>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?</p>	<ul style="list-style-type: none"> • Literature is fairly consistent in terms of haemorrhage control. This will result in cost savings on intensive beds and other investigations/interventions. • Potential survival advantage although this will require further review.
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)	<p>Transvenous obliteration/embolisation will be an additional procedure. If TIPSS is being performed, antegrade embolisation can be done during the same setting, under general anaesthesia.</p> <p>For retrograde embolisation, it is usually done on a separate setting. This can be done under local anaesthesia +/- conscious sedation.</p> <p>The procedure will have additional cost in terms of the equipment. However, the overall care pathway is likely to cost less due to savings in intensive care, repeated interventions, repeated investigations, and admissions.</p>
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)?	<p>The procedure will have additional cost in terms of the equipment. However, the overall care pathway is likely to cost less due to savings in intensive care, repeated interventions, repeated investigations, and admissions.</p>

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No change in existing facilities are required.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Interventional Radiologists that are familiar with TIPSS and other endovascular embolization procedures will be able to transfer the skills accordingly. Further understanding and awareness is required in terms of flow dynamics, assessment of suitability and approach, and selection of equipment.

Safety and efficacy of the procedure/technology

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>The main adverse event relates to non-target embolization. This is largely due to the flow dynamics, selection of embolic materials.</p> <p>The traditional BRTO technique uses balloon assisted ethanolamine oleate injection. Balloon rupture may occur. Potential adverse events of using this technique include fever, chest pain, gastrointestinal symptoms, haemoglobinuria, ascites, pleural effusion, renal dysfunction, pulmonary oedema, cardiogenic shock, disseminated intravascular coagulation and anaphylactic reaction.</p> <p>BRTO variants e.g. PARTO is less invasive and technically less complex and therefore has significantly improved safety profile.</p> <ul style="list-style-type: none"> • <i>Radiology. 2013 Jul;268(1):281-7. doi: 10.1148/radiol.13122102. Epub 2013 Mar 12. Gastric varices and hepatic encephalopathy: treatment with vascular plug and gelatin sponge-assisted retrograde transvenous obliteration--a primary report. Dong Il Gwon et al.</i> • <i>Korean J Radiol. 2016 Mar-Apr; 17(2): 230–238. Plug-Assisted Retrograde Transvenous Obliteration for the Treatment of Gastric Variceal Hemorrhage. Min-Yung Chang et al.</i> • <i>Yonsei Med J. 2016 Jul 1; 57(4): 973–979. Vascular Plug Assisted Retrograde Transvenous Obliteration (PARTO) for Gastric Varix Bleeding Patients in the Emergent Clinical Setting Taehwan Kim et al.</i> • <i>Vascular and Interventional Radiology. Gastric Varices and Hepatic Encephalopathy: Treatment with Vascular Plug and Gelatin Sponge–assisted Retrograde Transvenous Obliteration—A Primary Report. Dong Il Gwon et al.</i> <p>PARTO has the advantages of no balloon occlusion is required, usually a one off procedure, and quicker to perform compared to BRTO.</p>
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15	Please list the key efficacy outcomes for this procedure/technology?	<ul style="list-style-type: none"> • Variceal haemorrhage control • Reduction of transfusion requirement and other interventions • Reduction of hepatic encephalopathy • Reduction of adverse events with BRTO variants
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	BRTO or variant may increase the portal pressure as result of occlusion of a large gastroduodenal shunt. This may potentially lead to worsening portal hypertension, new collateral vessels and new varices
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Variation of BRTO techniques and the type of embolic materials used.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK. It's not just about the procedure itself, but the overall management of massive refractory variceal haemorrhage which will require other expertise.

Abstracts and ongoing studies

19	<p>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).</p> <p>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</p>	<p>Initial article and probably most cited:</p> <ul style="list-style-type: none"> • Radiology. 1999 May;211(2):349-56. Retrograde transvenous obliteration of gastric varices. S Hirota et al. <p>I am not aware of any new RCT or impactful publications apart from those listed on Pubmed or other standard searches.</p> <p>The following articles may provide further understanding: Hepatology. 2021 Oct;74(4):2074-2084. Endoscopic Cyanoacrylate Injection Versus Balloon-Occluded Retrograde Transvenous Obliteration for Prevention of Gastric Variceal Bleeding: A Randomized Controlled Trial. Xuefeng Luo et al.</p>
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	<p>us if you list any that you think are particularly important.</p>	<p>Can J Gastroenterol Hepatol. 2020 Feb 11;2020:5143013. Comparison of the Effects of TIPS versus BRTO on Bleeding Gastric Varices: A Meta-Analysis. Zi Wen Wang et al.</p> <p>J Gastroenterol Hepatol. 2016 Apr;31(4):727-33. Balloon-occluded retrograde transvenous obliteration versus transjugular intrahepatic portosystemic shunt for treatment of gastric varices due to portal hypertension: A meta-analysis. Yun-Bing Wang et al</p> <p>J Clin Gastroenterol. 2020 Aug;54(7):655-660. Balloon-Occluded Retrograde Transvenous Obliteration (BRTO) Versus Transjugular Intrahepatic Portosystemic Shunt (TIPS) for Treatment of Gastric Varices Because of Portal Hypertension: A Systematic Review and Meta-Analysis. Swathi Paleti et al.</p> <p>Gut Liver. 2018 Nov 15;12(6):704-713. doi: 10.5009/gnl17515. Balloon-Occluded Retrograde Transvenous Obliteration versus Transjugular Intrahepatic Portosystemic Shunt for the Management of Gastric Variceal Bleeding Geunwu Gimm et al.</p> <p>J Clin Exp Hepatol. 2020 Sep-Oct;10(5):421-428. Salvage Balloon Occluded Retrograde Transvenous Obliteration for Gastric Variceal Bleed in Cirrhotic Patients With Endoscopic Failure to Control Bleed/Very Early Rebleed: Long-term Outcomes. Mukund A. et al.</p>
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	<p>Not I am aware of currently</p>

Other considerations

21	<p>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)?</p>	<p>https://www.bsq.org.uk/wp-content/uploads/2019/12/UK-guidelines-on-the-management-of-variceal-haemorrhage-in-cirrhotic-patients.pdf</p> <p>Dig Liver Dis. 2014 May;46(5):419-26. Acute variceal haemorrhage in the United Kingdom: patient characteristics, management and outcomes in a nationwide audit Vipul Jairath et al.</p>
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22	Are there any issues with the usability or practical aspects of the procedure/technology?	The current technology using a variation of PARTO is considered safe and technically not too difficult to do.
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?	Awareness and referral pathway. A lot of centres in the UK do not have out of hour' interventional radiology provision and there is also lack of a formal network.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	I think the technology is robust for haemorrhage control. Further evaluation on patient selection, timing and survival would be very useful. It would be beneficial to commence a registry on acute variceal haemorrhage refractory to endoscopic interventions.
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: <ul style="list-style-type: none"> • Haemorrhage control – the amount of transfusion required • Haemorrhage associated complications including coagulopathy • Requirement for Sengstaken-Blakemore tube or equivalent • ITU stay • Complications relating to the procedure • Other invasive interventions including repeat endoscopy or endovascular interventions • Length of stay • Survival • QALY Adverse outcome measures: <ul style="list-style-type: none"> • Early and late complications relate to uncontrolled haemorrhage and non-target embolization. This should be measured within 24hrs, 7 days and 30 days of the procedure

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I am a Consultant Interventional Radiologist with 16 years' experience in Interventional Radiology. My special interest is in Hepatobiliary interventions, Interventional oncology and Transplant interventions including a particular interest in the management of acute variceal haemorrhage refractory to endoscopic interventions.
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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.			

√ 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:	<input type="text" value="Teik Choon SEE"/>
Dated:	<input type="text" value="8/3/22"/>

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1865 Transvenous obliteration for oesophageal for gastric varices

Your information

Name:	Dr Jayne Dillon
Job title:	Consultant Hepatologist
Organisation:	Leeds Teaching Hospitals Trust
Email address:	[REDACTED]
Professional organisation or society membership/affiliation:	British Association for the Study of the Liver
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4741224

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.

<p>1 Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none">- 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 procedure/technology, please	<p>I am familiar with this procedure, which is undertaken by trained Interventional Radiologists (IR). I don't think this procedure is widely used in the NHS due to the expertise required and access to such. We perform a reasonable number of IR procedures on patients with varices and our IR colleagues use this technique in the minority. I have been involved in patient selection and referral to IR Colleagues and have managed patients who have undergone this procedure.</p>
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	indicate your experience with it.	
2	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	I have done bibliographic research on this procedure.
3	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	An addition to existing standard of care for a select cohort of patients.

Current management

5	Please describe the current standard of care that is used in the NHS.	<p>Standard of care for management of oesophageal and gastric varices is as per current national guidance.</p> <p><i>In the case of bleeding varices:</i></p> <p>Medical management with resuscitation, transfusion, antibiotics, vasoactive drugs and NSBB.</p> <p>Endoscopic management with band ligation for oesophageal and gastro-oesophageal varices</p>
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		<p>and glue/thrombin injection for gastric varices.</p> <p>Balloon tamponade/self-expanding metal stents as a bridge to further definitive treatment if haemostasis not achieved endoscopically.</p> <p>TIPSS, in suitable patients, if there is failure to achieve haemostasis at initial endoscopy or recurrent bleeding despite the above treatment and in gastric variceal bleeding.</p> <p>Current recommendations are that BRTO can be considered if TIPSS is not possible e.g. due to portal vein thrombosis.</p> <p>TIPSS and BRTO are not currently recommended for primary prophylaxis of either oesophageal or gastric varices.</p>
6	<p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p>	<p>TIPSS is more widely used for variceal bleeding, not controlled endoscopically. This is usually carried out by an interventional radiologist, under x-ray guidance via the RIJ. A tract is created between the hepatic vein (systemic circulation) and the portal vein (portal circulation) reducing the portal pressure gradient. This not only reduces the risk of bleeding from both oesophageal and gastric varices, but other potential complications of portal hypertension such as ascites. Adjuvant embolization of gastric varices can be carried out to further reduce the risk of bleeding and eliminate shunts to improve blood flow through the TIPSS, reducing risk of TIPSS dysfunction. There are a number of potential complications with this procedure including hepatic encephalopathy and deterioration in synthetic function.</p> <p>EUS guided assessment and embolization of gastric varices with cyanoacrylate glue +/- coils.</p>

Potential patient benefits and impact on the health system

7	<p>What do you consider to be the potential benefits to patients from using this</p>	<p>Obliteration of gastric varices leading to reduction in re-bleeding rates and reduction in mortality for those patients who have failed endoscopic therapy and in whom TIPSS is not an</p>
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	procedure/technology?	option.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients who have had a gastric variceal bleed in whom TIPSS placement is not technically possible e.g. those with occluded portal vein, or patients deemed unsuitable for TIPSS.
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?	Currently I don't think this would change the overall pathway for the management of variceal bleeds, however it could improve outcomes for select patients by reducing their risk of recurrent bleeding, leading to a reduction in hospital admissions, endoscopies and mortality.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Likely to be the same as all the resources for current standard of care would need to be in place, including a specialist interventional radiological service capable of TIPSS provision.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	This procedure is already being performed in specialist centres, for uptake to increase significantly then the logistics of referral and admission to those centres would need to improve with additional cost.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	An interventional radiology theatre team experienced in managing variceal bleeding, Gastroenterologists/Hepatologists involved in patient selection, and the ability to transfer patients from centres without this expertise.
13	Is any specific training needed in order to use the procedure/technology with respect	Education and training regarding the indications, patient selection, potential complications and performance of this technique.

	to efficacy or safety?	
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Safety and efficacy of the procedure/technology

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>Adverse events reported in the literature:</p> <p>Inadvertent embolization of the portal vein and splenic vein</p> <p>Increase in portal pressure with bleeding from oesophageal varices, development of ascites and hepatic hydrothorax.</p>
15	<p>Please list the key efficacy outcomes for this procedure/technology?</p>	<p>Re-bleeding rates, serious adverse events, need for alternative treatment modalities and patient survival</p>
16	<p>Please list any uncertainties or concerns about the efficacy and safety of this procedure/?</p>	<p>Risk of increasing portal pressure and therefore risk of oesophageal variceal bleeding and development of ascites.</p>
17	<p>Is there controversy, or important uncertainty, about any aspect of the procedure/technology?</p>	<p>Benefits over current standard of care for the majority of patients.</p>
18	<p>If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):</p>	<p>A minority of hospitals, but at least 10 in the UK</p>

Abstracts and ongoing studies

19	<p>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).</p> <p>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.</p>	<p>Henry Z, Patel K, Patton H and Saad W. AGA Clinical Practice Update on Management of Bleeding Gastric Varices: Expert Review. Clinical Gastroenterology and Hepatology, 2021-06-01, Volume 19, Issue 6, Pages 1098-1107</p>
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	<p>Not that I know of</p>

Other considerations

21	<p>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)?</p>	<p>In our tertiary centre we perform about 20-30 TIPSS per annum, approximately a third for variceal bleeding. Numbers for this procedure are unlikely to be higher.</p>
22	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	<p>Timely access to the expertise required to perform this procedure.</p>
23	<p>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?</p>	<p>Lack of experience in this procedure both on behalf of physicians and interventional radiologists. TIPSS being the favoured procedure due to wider reaching benefits, when patients are candidates for this.</p> <p>Access to the expertise/centres to perform this procedure.</p>

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	RCT's on the longer term benefits v current SOC
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - 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: 	<p>Beneficial outcome measures:</p> <ul style="list-style-type: none"> Obliteration of varices with no further bleeding Reduced length of hospital stay Reduced re-admission rates Survival <p>Adverse outcome measures:</p> <ul style="list-style-type: none"> Early and late re-bleeding Venous thrombosis Oesophageal variceal bleed Development/worsening of ascites or hepatic hydrothorax - in the first couple of weeks Deterioration of synthetic function (although reportedly less likely than with TIPSS) Mortality

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.			

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:	Dr Jayne Dillon
Dated:	10.3.22