NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1840 Tunnelled peritoneal drainage catheter insertion for treatment-resistant, recurrent ascites due to cirrhosis**

Your information

Name:	DANIEL CONROY
Job title:	CONSULTANT RADIOLOGIST
Organisation:	BELFAST HEALTH AND SOCIAL CARE TRUST
Email address:	d.conroy17@gmail.com
Professional organisation or society membership/affiliation:	BRITISH SOCIETY OF INTERVENTIONAL RADIOLOGY
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 6103489

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

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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 procedure/technology, please indicate your experience with it.	I have personally placed approximately 50 of these catheters in my career. They are widely used for a variety of indications including cirrhosis and malignant ascites. They can also be used to treat recurrent pleural effusions. In my institution, tunnelled catheters are not placed outside the setting of radiology. All referrals are sent from other clinical specialties.

2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have not been involved 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):	Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It is already standard care for the treatment of recurrent ascites in my institution

Current management

5	Please describe the current standard of care that is used in the NHS.	Initial management would include placement of a temporary, non-tunnelled drainage device. Recurrent ascites requiring frequent drainage would usually require long term tunnelled drainage catheter placement.

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?	There are likely to be different versions of the same catheter with minimal variation in design and applicability.

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?	Long-term drainage option for patients. Reduced risk of infection leading to peritonitis.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Any patient with recurrent ascites of any cause, not just cirrhosis.
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?	Tunnelled catheters are usually placed to prevent recurrent drainage procedures, e.g. every two weeks for patients. They reduce the risk of infection. They allow intermittent drainage to be performed in the community.
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)	Initial outlay higher, but overall, the lack of recurrent attendance at hospital leads to reduced costs.
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)?	Tunnelled catheters usually performed in a more specialised setting, e.g. sterile procedure room or in radiology departments
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	As box above.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	More training needed, but this is a widely used method already therefore there are plenty of trained operators available.

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	Injury to subcutaneous arteries leading to haemorrhage. Peritoneal infection. Overall, these complication rates would be similar to placement of a non-tunnelled version.
15	Please list the key efficacy outcomes for this procedure/technology?	
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Nil
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Nil
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	500 – 1000 across the UK
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Very simple procedure. Easy to maintain post procedure
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?	None.

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	None
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: Reduction in hospital attendances Adverse outcome measures: Haemorrhage Infection

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	This is a widely practiced procedure for recurrent ascites, both from cirrhosis and malignancy. It is not new (in use for 10-15 years). It is a low risk procedure. It has minimal costs associated with it.

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Declarations of interests

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

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

☒ 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:	**DANIEL CONROY**
Dated:	**30TH NOVEMBER 2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1840 Tunnelled peritoneal drainage catheter insertion for treatment-resistant, recurrent ascites due to cirrhosis

Your information

Name:	Joanne McDonagh
Job title:	Clinical Nurse Specialist Hepatology
Organisation:	University Hospitals Birmingham The Queen Elizabeth Hospital
Email address:	Joanne.mcdonagh@uhb.nhs.uk
Professional organisation or society membership/affiliation:	NMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	97I2921E

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have been involved with managing patients with liver disease and ascites for 6 years. During this time I have cared for patients with long term ascitic drains LTAD. I have not seen the drain insertion performed I have drained the fluid via the LTAD on patients in the hospital setting
	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 procedure/technology, please	This is used widely for malignant ascites and on a small amount of carefully selected and counselled patients in their last months of life when they are palliative and advanced care planning highlighted that repeated hospital visits for regular drains is not their wish in their last months of life. Yes Oncology and cardiology Patient selection via an MDT consultant and wider hepatology team. The LTAD's can be inserted in radiology by a radiologist trained to in insert the drain.

	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) I have been part of published retrospective data analysis.
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 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 go alongside attending hospital for day case paracentesis.

Current management

5	Please describe the current standard of care that is used in the NHS.	Day case paracentesis 9 hours length of stay from weekly drains to adhoc drains depending on patient and aetiology
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?	
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	
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?	
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)	
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)?	
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	
13	Is any specific training needed in order to	

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

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
15	Please list the key efficacy outcomes for this procedure/technology?	
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	
22	Are there any issues with the usability or practical aspects of the procedure/technology?	
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?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Adverse outcome measures:

Further comments

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

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Choose an item.			

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Dated:	**Click here to enter text.**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1840 Tunnelled peritoneal drainage catheter insertion for treatment-resistant, recurrent ascites due to cirrhosis

Your information

Name:	Katharine Caddick
Job title:	Hepatology Clinical Nurse Specialist
Organisation:	North Bristol NHS Trust , Southmead Hospital Bristol
Email address:	Katharine.caddick@nbt.nhs.uk
Professional organisation or society membership/affiliation:	MNC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	92I5645E

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I regular advocate, and refer for patients to have tunnelled peritoneal drainage catheter insertion for treatment-resistant, recurrent ascites due to cirrhosis. NBT outpatient paracentesis service manages on average 45 patients a year. Comprising of an average of 229 paracentesis. Of these patients 8.3% require a tunnelled peritoneal drainage catheter at end of life. The insertion is undertaken by Interventional radiology in discussion with the hepatology team. t. my role I identify the patients that are not managing out patient paracentesis at end of life and those that would benefit from this catheter. These patients are always referred to palliative care – either at the same time or would be previously known to them. They are only used when the patient is palliative to increase the quality of life when there is no more to be gained from the regular outpatient drainage. I am regularly called by inpatient teams in the hospital and district nurse teams to help trouble shoot and advise on the management of these abdominal catheters. They are planned to remain in situ until the patient dies.

	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 procedure/technology, please indicate your experience with it.	The use of the catheters also requires patients to have regular visits by district nurse colleagues- this gives a dual benefit as they will be regular reviewed and supported whilst in the community . The uptake of tunnelled peritoneal drainage catheter within the hepatology in this hospital for abdominal drainage is small and has been consistent over the past 4 years. Patients are selected carefully, and it is used at the end of life to help with palliation in the community. This is more widely used by the pleural team in the hospital as a short-term procedure – rather than as an aid to palliation and quality of life in the community. If patients are not already known to the palliative care team when this catheter is being considered the Hepatology team will refer to Palliative care at that point.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	

	Which of the following best describes the procedure (please choose one):	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?	This should be used alongside planned regular large volume paracentesis for the majority of patients; as an addition to existing standard care This should only be used when the patient is end stage – the last 6 -12 months of life – when there is no more to be gained from regular paracentesis.

Current management

5	Please describe the current standard of care that is used in the NHS.	We follow the BSG Guidelines on the management of ascites in cirrhosis 2020 Large volume paracentesis (LVP) is the standard of care for managing large volume ascites both in conjunction with diuresis to relieve symptoms of a tense abdomen, as well as in the management of refractory ascites, when diuretics become ineffective or the side effects preclude their continued use. Development of refractory ascites is of prognostic significance, therefore, at its onset, suitability of liver transplantation should be considered and assessed as a priority. TIPSS should be considered in patients with refractory ascites. Patients with refractory ascites who are not undergoing evaluation for liver transplant should be offered a palliative care referral. Besides repeated LVP, alternative palliative interventions

		for refractory ascites should also be considered.
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?	NIL

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?	Patients with cirrhosis and refractory ascites often report a poor quality of life, requiring multiple hospital admissions for paracentesis.it is an independent predictor of 12-month Considering the tunnelled catheter in a select group of patients of patients with advanced cirrhosis receive timely palliative care. Patients are able to have symptom-guided drainage and avoid repeated hospitalisations. they can be managed in the community
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes patients with refractory ascites end stage liver cirrhosis who require regular paracentesis.. patients who are not suitable for other treatment types such as TPPS or transplant and have 6-12 month prognosis.
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 currently being used within this trust prevent hospital admissions and invasive treatment – to improve quality of life. The patients prognosis will remain the same and the outcomes will not change but the palliation and quality of life will be improved
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)	We are already using this process to prevent hospital admissions – and this will reduce the cost. As a whoe the cost of the tunnelled catheer is likely to be similar to that of a large volume paracentesis. However it will cost less than a hospital admission.
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,	about same-in terms of staff, equipment, and care setting

	or about same-in terms of staff, equipment, and care setting)?	
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	nil
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes the community team will require training to use the drains. This can be provided by the manufacturer. And support for the District nurses and hospital staff can be given by existing hepatology CNS

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	Infection through the entry site to the skin / Sub acute bacterial peritonitis Risk at insertion – bowel perforation / Significant bleeding (this would be no more than paracentesis) Leakage from the entry site cellulitis Tunnel catheter being pulled out and causing traina to the tissue Leakage around the entry causing excoriation to skin **https://www.bsg.org.uk/wp-content/uploads/2020/10/gutjnl-2020-321790.full_.pdf** Results from a recent feasibility RCT comparing palliative LTAD with LVP in refractory ascites due to cirrhosis have just been published (REDUCe study). In this 3-month study, 36 patients were randomised, 19 to LVP and 17 to LTAD. All

		patients received prophylactic antibiotics for the study duration. Following randomisation, the median number (IQR) of hospital ascitic drains for LTAD versus LVP groups were 0 (0, 1) versus 4 (3, 7), respectively. Only two patients allocated to LTAD required hospital admissions specifically for ascites drainage. Self-limiting cellulitis/leakage occurred in 41% (7/17) in the LTAD vs 11% (2/19) in the LVP group; peritonitis incidence being 6% (1/17) vs 11% (2/19), respectively. Median (IQR) fortnightly community/ hospital/social care ascites-related costs were lower in the LTAD group than in the LVP group, £329 (253, 580) versus £843 (603, 1060), respectively. Qualitative data (currently only published as a summary) indicate that LTAD could transform the care pathway. The REDUCe study --- Macken L, Bremner S, Gage H, et al. Randomised clinical trial: palliative long-term abdominal drains vs large-volume paracentesis in refractory ascites due to cirrhosis. Aliment Pharmacol Ther 2020;52:107–22.
15	Please list the key efficacy outcomes for this procedure/technology?	
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	

18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. .

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	https://www.bsg.org.uk/wp-content/uploads/2020/10/gutjnl-2020-321790.full_.pdf
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Within our outpatient paracentesis service manages on average 45 patients a year. Comprising of an average of 229 paracentesis. Of these patients 8.3% require a tunnelled peritoneal drainage catheter at end of life.

22	Are there any issues with the usability or practical aspects of the procedure/technology?	The tunnelled drains and the drainage bottles need to match as they don't always fit different suppliers. The drain bottles are not universal. Community teams require support in the form of training and close contact with the hepatology team and palliative care teams when patients have these tunnelled catheters as the patients have end stage disease. Patients should be known to the palliative care team in the community.
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?	
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.	Beneficial outcome measures: **over the last 12 mths of life** Life expectancy with / without pleurX at the same stage of liver disease. Quality of life markers throughout the last 12 mths of life admissions to the hospital; in the last 12 months of life. Childs Pugh score Rockwood frailty score WHO performance state markers with/ without pleurX for the last year of life. Patients comfort /

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: **over the last 12 mths of life** How many hospital admissions with complications Number of episodes with Sub acute Bacterial Peritonitis Number of episodes with Leakage around the site Number of episodes with Cellulitis How any drains fall out / need replacing Whether the patients need other intervention such as continued paracentesis throughout the last 12 mths of life

Further comments

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

Declarations of interests

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Choose an item.			
Choose an item.			
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Print name:	**Katharine Caddick**
Dated:	**25/11/21**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1840 Tunnelled peritoneal drainage catheter insertion for treatment-resistant, recurrent ascites due to cirrhosis**

Your information

Name:	Sumita Verma
Job title:	Professor of Hepatology and Hon Consultant Hepatologist
Organisation:	Brighton and Sussex Medical School and University Hospitals Sussex NHS Foundation Trust
Email address:	s.verma@bsms.ac.uk
Professional organisation or society membership/affiliation:	Fellow of Royal College of Physicians Edinburgh, Member of American Association for Study of Liver Disease/ European Association for Study of Liver/British Association for Study of Liver
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 42502018

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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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?	Palliative care, including palliative interventions remain suboptimal in advanced cirrhosis. Refractory ascites has a median transplant free survival of 6 months Most patients with refractory ascites (>70%) will not be candidates for liver transplantation/transjugular portosystemic intrahepatic shunt due to comorbidity, psychosocial issues, frailty and donor shortages. (Macken L, et al. Gut. 2017;66:A161; Moreau R, et al. Liver Int. 2004;24:457-64; Medici V, et al. Liver Transpl. 2008;14:1100-1106). Even if such patients are listed for transplantation, due to their low prognostic scores (as ascites is not given priority in MELD/UKELD scores), they might die on transplant wait list. For most patients with refractory ascites, the most common intervention is recurrent hospitalisation every 7-10 days for drainage (palliative large volume paracentesis – LVP). Not unsurprisingly about 75% with refractory ascites due to cirrhosis die in hospital. Tunnelled long-term abdominal drains (LTAD) allow symptom guided drainage in the community and are routinely used in refractory malignant ascites. While there are similarities in refractory ascites due to cancer and cirrhosis (limited life expectancy), two important differences preclude routine LTAD use in cirrhosis. Firstly, those with cirrhosis can have complicated social issues like addiction, making community care difficult. Secondly, unlike those with cancer, patients with cirrhosis are at higher risk of ascitic fluid infection (peritonitis) due to increased bacterial translocation, gut dysbiosis and immune dysfunction. The concern is whether LTADs could further increase this infection risk. We inserted our first LTAD for refractory ascites due to cirrhosis in 2011. Since then we have developed increasing expertise and experience in their use. I was the Chief Investigator for the only published feasibility randomised controlled trial (RCT) comparing LTAD vs. LVP in refractory

		ascites due to cirrhosis (REDUCe Study). This was funded by the NIHR (RfPB PB-PG-0214-33068). The REDUCe study demonstrates feasibility with preliminary evidence of LTAD acceptability/effectiveness/safety and reduction in health resource utilisation. (Macken L, et al. Aliment Pharmacol Ther. 2020; 52:107-122). However, there is still a need for a definitive trial to provide conclusive evidence. We have just been successful in obtaining funding from the NIHR (HTA 133889) (Feb 2020) for a definitive national trial assessing LTAD in refractory ascites due to cirrhosis (REDUCe 2 Study).
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	During the conduct of our feasibility trial and following its publication, national interest in LTAD have increased. However, unlike refractory ascites due to malignancy, LTAD are not standard of care in cirrhosis, the main concern being risk of infection (peritonitis). However, others and we are inserting LTAD drains on a case-by-case basis as a palliative intervention in those who are not candidates for liver transplantation. Risks and benefits are clearly discussed with patients and they are informed that current evidence is from a small trial only. Once a definitive trails provides conclusive evidence and if this is favourable then we would expect uptake to be quick
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	LTAD are routinely used in refractory ascites due to malignancy and this has undergone NICE appraisal (White J et al, Appl Health Econ Health Policy 2012;10:299-308).
	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	As above
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	**I have done clinical research on this procedure involving patients or healthy volunteers.** I was the Chief Investigator for the only RCT comparing LTAD Vs. LVP that has been published (see below in list of publications).

		I was also invited by the British Society of Gastroenterology to write the recently published national ascites guidelines (senior author) (see below in list of publications). These are the first British, European or American ascites guidelines to include palliative management. One of the recommendations of the guidelines was further trails assessing LTAD as a palliative intervention in refractory ascites due to cirrhosis. In view of the increasing national interest in LTAD following on from our study at the request of British Society of Gastroenterology and British Association for Study of the Liver we are producing a LTAD guidance manuscript which is to be submitted for publication to Frontline Gastroenterology by 18th Mar 2022 **I have published this research.** 1. Aithal GP, Palaniyappan N, China L, Harmala S, Macken L, Ryan J, Wilkes E, Moore K, Leithead J, Hayes P, O'Brien A, **Verma S**. British Society of Gastroenterology. Guidelines on the management of ascites in cirrhosis. Gut. 2021;70:9-29. 2. Cooper M, Pollard A, Pandey A, Bremner S, Macken L, Evans C, Austin M, Parnell N, Steer S, Thomson S, Hashim A, Mason L, **Verma S**. Palliative Long-term Abdominal Drains Versus Large Volume Paracentesis in Refractory Ascites due to Cirrhosis (REDUCe Study): Qualitative Outcomes. J Pain Symptom Manage.2021;62:312-325. 3. Macken L, Bremner S, Gage H, Touray M, Williams P, Crook D, Mason L, Lambert D, Evans CJ, Cooper M, Timeyin J, Steer S, Austin M, Parnell N, Thomson SJ, Sheridan D, Wright M, Isaacs P, Hashim A, **Verma S**. Randomised Clinical Trial: Palliative Long-term Abdominal Drains Versus Large Volume Paracentesis In Refractory Ascites Due to Cirrhosis. Aliment Pharmacol Ther. 2020;52:107-122. 4. Macken L, Bremner S, Sheridan D, **Verma S**. Editorial: palliative long-term abdominal drains in refractory ascites – a step in the right direction, but not the complete solution. Authors' reply. Aliment Pharmacol Ther. 2020;52:723-724. 5. Macken L, Bremner S, Sheridan D, **Verma S**. Letter: long-term abdominal drains in refractory ascites - evolving concept of palliative care in decompensated cirrhosis. Authors' reply. Aliment Pharmacol Ther. 2020;52:1268-1269. 6. Macken L, Hashim A, Mason L, **Verma S.** Permanent indwelling peritoneal catheters for palliation of refractory ascites in end-stage liver disease: a systematic review. Liv Int. 2019; 39:1594-1607. 7. Macken L, Mason L, Evans C, Gage H, Jordan J, Austin M, Parnell N, Cooper M, Steer S, Boles J, Bremner S, Lambert D, Crook D, Earl G, Timeyn J, **Verma S**. Palliative long-term

abdominal drains versus repeated drainage in individuals with untreatable ascites due to advanced cirrhosis: study protocol for a feasibility randomised controlled trial. Trials. 2018;19:488**.**

8. Macken L, Joshi D, Messenger J, Austin M, Mason L, **Verma S.** Palliative long-term abdominal drains in refractory ascites due to end stage liver disease: a case series. Palliat Med. 2017;31:671-675.

Conference proceedings

1. Abbot J, **Verma S**, Saxsena A. Long term Abdominal Drain for Palliation in Advanced Liver Cirrhosis: a survey of risks& barriers. Poster ID 43. Gut.2020;69:A7.
2. Macken L, Mason L, Evans C, Steer S, Bremner S, Crook D, Thomson S, Sheridan D, Isaacs P, Wright M, Hashim A, **Verma S**. REDUCe study: multi-centre feasibility RCT in cirrhosis-related palliative refractory ascites. Participant reported outcomes. Gut. 2019;68 (Suppl 2): A121.
3. Macken L, Mason L, Gage H, Jordan J, Touray M, Evans E, Austin M, Parnell N, Cooper M, Steer S, Boles J, Bremner S, Lambert D, Crook D, Earl G, Timeyin J, Thomson S, Sheridan D, Isaacs P, Wright M , Hashim A, **Verma S**. Long-term palliative abdominal drains vs large-volume paracentesis in cirrhosis-related refractory ascites: multi-centre feasibility RCT (REDUCe). Gut.2019;68 (Suppl 2):A122.
4. Macken L, Mason L, Bremner S, Gage H, Touray M, Evans C, Cooper M, Timeyin J, Steer S, Lambert D, Crook D, Austin M, Parnell N, Thomson S, Sheridan D, Wright M, Isaacs P, Hashim A, **Verma S**. Long term palliative abdominal drains versus large volume paracentesis in refractory ascites due to cirrhosis: a multi-centre feasibility randomised controlled trial (the REDUCe Study).J Hepatol 2019; Suppl 70:e660.
5. Gelmon L, Macken L, Mason S, **Verma S**. Exploring consultant physicians' attitudes and beliefs towards barriers to advance care planning and palliative care in end stage liver disease. Gut. 2017;66 (Suppl 2):A93-A94.
6. Macken L, Hashim A, Potts J, **Verma S**. Care of patients with end stage liver disease and refractory ascites remains suboptimal: need for earlier input from palliative care. Gut. 2017; 66 (Suppl 2):A161.

Invited Talks

Verma S. Refractory ascites. Keynote speaker at British Association for Study of Liver End of Life Special Interest Group Annual Meeting Oct 2021.

		Verma S. Update on REDUCe Study. Keynote speaker at the British Association for Study of Liver End of Life Special Interest Group Annual Meeting Oct 2021. **Verma S**. REDUCe study and other trials into long-term abdominal drains. Key note speaker at British Association for Study of Liver End of Life Special Interest Group Annual Meeting Oct 2020 **Verma S**. Long-Term Drainage of Refractory Ascites in the Patient With End-Stage Liver Disease What Is The Case Of Need And What Is The Evidence? Presented at British Association for Study of Liver Sept 2020.
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?	LTAD have the potential to revolutionise the palliative management of refractory ascites due to cirrhosis. Additionally they will lead to integrated working between hepatology, community nursing and community palliative care teams. This will lead to development of structured palliative care pathways, which remains an important unmet need in patients with cirrhosis. Compared to current standard of care (repeated palliative hospitalisation for drainage – LVP), LTAD result in symptom-guided drainage with potential for improvement in symptoms and quality of life. They also allow transfer of care to the community with death occurring in preferred place of residence. . LTAD could also potentially be cost effective to the NHS. During our extensive Patient and Public Involvement over the last 10 year, patients and caregivers have described repeated hospital drainage (LVP) as “unbearably painful”, “traumatic”, “dehumanising” and “logistically difficult and expensive”. Patients felt like a “burden” worsening their “shame” and “anxiety”. Avoiding hospitalisation including the hospital journey was seen as the overarching goal. Patients and caregivers stated that ascites management with LTAD would “empower” them; that they would be comfortable with drainage in the community and that tense ascites affected body image more than having a LTAD inserted
	Which of the following best describes the procedure (please choose one):	Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure’s safety and efficacy.

		X Definitely novel and of uncertain safety and efficacy: while it is standard of care in refractory malignant ascites there is only preliminary safety and efficacy data in cirrhosis and there is need for evidence from a definitive trial 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?	This technology has the potential to replace current standard care for most patients with refractory ascites, the only absolute contraindication being loculated ascites

Current management

5	Please describe the current standard of care that is used in the NHS.	The current standard of care for refractory ascites is repeated hospitalisation for drainage every 7-10 days (LVP) and receiving intravenous human albumin solution
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?	Other potential options include the ALFA ascites pump (Sequena Medical). It is not routinely available in the UK and costs > 30K. It is an invasive procedure and does have potential for adverse events. It has been evaluated by NICE “This procedure should only be used with special arrangements for clinical governance, consent, and audit or research” (NICE Guidance IPG631) LTAD is a much less invasive procedure, does not require general anaesthesia and based on our feasibility study data (Macken Aliment Pharmacol Ther 2020;52:107-122), risk of adverse events, especially peritonitis seem no higher than that seen with standard of care (LVP) (5%-10%). With the ALFA pump pooled estimates of peritonitis is 27% (Lepida A, Aliment Pharmacol Ther. 2019; 50:978-987). Finally, the ALFA pump is more expensive >30K vs.1K for LTAD (assuming a 3 month drainage).

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?	By reducing the needed for repeated drainage it will eliminate the need for repeated insertion of a temporary drain which is painful and uncomfortable Improved symptom control Improved health related quality of life Transfer of care to community with avoidance of repeated hospitalisation Death in preferred place of residence, an important part of UK Govt Strategy (https://www.gov.uk/government/publications/end-of-life-care-strategy-promoting-high-quality-carefor-adults-at-the-end-of-their-life) By reducing risk of crisis hospital admission, it will also benefit caregivers Integrated working between hospitals and community thereby developed a structured palliative care pathway for patients with cirrhosis
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with refractory ascites due to advanced cirrhosis who are not candidates for liver transplantation/transjugular intrahepatic portosystemic shunt.
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. LTAD can reduce hospitalisation as shown in our feasibility study, as only 13% of patients randomised to LTAD needed further hospitalisation specifically for ascites (Macken L, et al. Aliment Pharmacol Ther. 2020; 52:107-122). LTADs will also bring shared learning between hospital specialist and community teams with increased confidence for community practitioners on how to best meet complex needs in advanced cirrhosis. This will improve palliative care pathways and raise the profile of this disenfranchised cohort thus promoting equality in end of life research. The NHS will benefit, as moving services from the hospital to the community is likely to be a cost-effective strategy, as shown in our feasibility study (Macken L, et al. Aliment Pharmacol Ther 2020;52:107-122).
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	Based on our feasibility study likely to cost less than current standard of care (Macken L, et al. Aliment Pharmacol Ther 2020;52:107-122)

	about the same? (in terms of staff, equipment, care setting etc)	
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)?	As above
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Most interventional radiologists are already trained in inserting LTAD as this is standard of care in refractory malignant ascites. If LTAD become standard of care in cirrhosis, this could increase community-nursing workload. Working with family caregivers to help with drainage will be key to delivering LTAD as was successfully achieved during our feasibility Study (Macken L, et al. Aliment Pharmacol Ther. 2020;52:107-122). During our meetings with our PPI group, most were supporting of caregivers being involved in ascites drainage. Emphasis will be on working with family caregivers to enable day-to-day management of drainage, with nursing time and resource focused on holistic person-centred end of life care. The priority for patients and their families is for the person to receive care in their usual residence – at home. Delivering care to patients with advanced disease near the end of life is a priority patient group in the community. The management of LTADs is a component of nursing care that will be incorporated in the provision of end of life care for this patient group. If LTAD become widely adopted, Commissioning should move relevant monies from hospital to community nursing.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	LTAD are inserted in hospital by interventional radiologists who are familiar with the procedure as it is routinely used in refractory malignant ascites. So no additional training will be needed to use the procedure. Community nurses are also familiar with the procedure though not in patients with cirrhosis and will training in this.

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

Based on our feasibility study adverse events as follows (Macken L, et al. Aliment Pharmacol Ther. 2020;52:107-122).

Complication	**Recommended management**	**Incidence observed in the REDUCe trial (LTAD vs. LVP)**
Leakage/cellulitis	Leakage usually self-limiting, if persists may need an extra suture. Cellulitis Usually results due to leakage and is again self-limiting. If persist may need a short course of antibiotics. Very rarely LTAD needs to be removed and can be resited	Leakage/cellulitis 41% vs 11%
Suspected peritonitis	Do a diagnostic tap for cell count and culture from peritoneum as well as taking sample from LTAD. Treat as per usual peritonitis guidelines. Decision to remove LTAD must be made on a case by case basis after discussion with patient/caregiver Routine sampling of ascitic fluid from LTAD and or routine blood tests in asymptomatic patients is not recommended.	6% vs. 11%
Elevation in serum creatinine	Manage as clinically indicated	Baseline and week 12 serum creatinine (µmol/L) (median, IQR) LTAD vs. LVP groups: 109 (79-141) vs. 113.5 (89-134) and 104.5 (81- 115.5) vs 127 (63-158) respectively.
LTAD blockage	Admit to hospital and discuss need for replacement	0%
LTAD displacement	Admit to hospital if necessary and discuss need for replacement	6%
Bleeding	Usually self-limiting	0% vs. 5%

		<table><tr><td>Unable to manage ascites symptoms despite draining 1-2L three times a week from LTAD</td><td>Will need LVP in hospital - drain ascitic fluid via LTAD using adaptor with human albumin solution as per standard LVP protocols</td><td>13%</td></tr><tr><td></td><td></td><td></td></tr></table> LTAD long-term abdominal drain LVP large volume paracentesis These adverse events are similar to that reported by us in an earlier systematic review (Macken L, et al. Liver Int. 2019;39:1594-1607) and a recent case series from Birmingham (Corrigan M, et al. Frontline Gastroenterol. 2020; 12:108-112).
15	Please list the key efficacy outcomes for this procedure/technology?	Health related quality of life and symptom burden, peritonitis incidence, need for hospital based LVP, caregiver work load, cost-effectiveness, acceptability by patients/caregivers/healthcare professionals
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	A feasibility study provides preliminary evidence on acceptability, safety, efficacy and cost effectiveness (Macken L, et al. Aliment Pharmacol Ther. 2020; 52:107-122), but this needs to be confirmed by a definitive trial. Two main concerns are 1. Those with cirrhosis can have complicated social issues like addiction, which may make transfer of care to the community difficult. 2. Unlike those with cancer, patients with cirrhosis are at higher risk of ascitic fluid infection (peritonitis) due to increased bacterial translocation, gut dysbiosis and immune dysfunction. The concern is whether LTADs could further increase this infection risk
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The procedure is routinely used in refractory malignant ascites so no concerns. The issue is using LTAD in a new clinical condition (cirrhosis). Though our feasibility study data is encouraging (Macken L, et al. Aliment Pharmacol Ther. 2020;52:107-122), this needs to be confirmed by a definitive trial
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	**XX 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.	Abbot J, **Verma S**, Saxsena A. Long term Abdominal Drain for Palliation in Advanced Liver Cirrhosis: a survey of risks& barriers. Poster ID 43. Gut.2020;69:A7
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	We have just received funding from the NIHR (HTA133889) (Feb 2022) to conduct a definitive national study (REDUCe 2 study). This 5-yr study will recruit about 300 patients across 35 sites in England and Scotland. Recruitment will commence end of this year. We are also working to develop a national registry of all patients who have undergone or undergoing LTAD insertion for refractory ascites due to cirrhosis Safety and Efficacy of Small Frequent Paracentesis Using an Indwelling Catheter Compared With Repeated Large Volume Paracentesis in Cirrhotic Patients With Refractory Ascites - A Randomized Controlled Trial (I-CARE) ClinicalTrials.gov Identifier: NCT04406298 Study ongoing and been conducted in New Delhi India

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)?	Based on an earlier study (Hudson B, et al. Lancet Gastroenterol.2018; 3: 95–103), between Jan 1, 2013, and Dec 31, 2015, 13 818 people in England died from liver disease and had LVP within their last year of life. They could have been potentially suitable for a LTAD.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	It is a relatively uncomplicated intervention. Most community nursing teams are already familiar with it as routinely used in refractory malignant ascites. Its use has also increased in Hepatology following on from the publication of our feasibility study ((Macken L, et al. Aliment Pharmacol Ther 2020;52:107-122).
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 major issues though increased community workload will need to be addressed
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	A definitive RCT comparing LVP vs. LTAD in refractory ascites due to cirrhosis
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	Outcome measures (to be assessed at 3 months) **Primary outcome.** Health related quality of life assessed by the Short Form Liver Disease Quality of Life questionnaire, the only validated liver specific tool in advanced cirrhosis **Secondary outcomes** 1. Cumulative peritonitis incidence 2. Symptom burden 3. Informal caregiver impact in LTAD 4. Health resource utilisation and cost-utility analysis based on QALYs

	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:	5. Patient, caregiver and health care professional perceptions/perspectives using qualitative methods **Adverse outcomes:** Peritonitis incidence Acute kidney injury incidence Need for LTAD removal (%) Cellulitis/leakage incidence Need for hospital-based LVP Place of death (hospital vs. community)

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	This intervention has the potential to revolutionise palliative management of refractory ascites in cirrhosis. Following preliminary evidence of acceptability, safety, efficacy and cost effectiveness, we await the results of our definitive national trial.

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
Indirect	Rocket Medical provided the LTAD free of cost for our feasibility study and will also be providing them free of cost for the definitive RCT. We used Rocket Medical rather than PleurX LTADs as that was standard of care at our trust. We are not advocating one LTAD over another and there is no evidence to indicate that Rocket Medical LTADs are superior to PleurX LTAD and vice versa. Rocket Medical were not and will not be involved in study design, data collection or manuscript write up and will not claim any Intellectual Property based on the trial.	**From 2013 – current**	
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:	**Sumita Verma**
Dated:	**06.02.2022**