NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1912 Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis

Your information

Name:	John Samuel Leeds
Job title:	Consultant Pancreaticobiliary Physician and Endoscopist
Organisation:	Newcastle Upon Tyne Hospitals NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Society of Gastroenterology, Royal College of Physicians, Pancreatic Society of Great Britain and Ireland
Nominated/ratified by (if applicable):	British Society of Gastroenterology endoscopy committee
Registration number (e.g. GMC, NMC, HCPC)	4545136 (GMC number)

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

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

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	I am a highly experienced endoscopist with expertise in endoscopic ultrasound and ERCP. I work in the largest service for these procedures in the UK (>2500 per annum) and personally perform around 450-500 endoscopic ultrasounds per year. We have a large therapeutic practice which includes endoscopic ultrasound guided drainage procedures and I am personally very familiar with this technology. I have performed this procedure many times as it is employed in our routine practice. I have also published several papers on advanced endoscopic techniques and completed an evidence synthesis project funded by the NIHR on biliary radiofrequency ablation. I am a member of the British Society of Gastroenterology Endoscopy committee and the Pancreatic Society of Great Britain and Ireland both of which are competitively elected. This technique is gaining traction in providers as it appears to offer a good alternative to surgery and percutaneous drainage for patients where this is unsuitable. It could be relatively rapidly upskilled throughout the NHS for providers of endoscopic ultrasound. The most common specialities that perform this procedure as gastroenterologists like myself, some surgeons and some radiologists if trained in endoscopic ultrasound. Selection for this procedure is usually via consultation with a multidisciplinary team. Such patients are usually admitted under surgical teams as the gold standard of care is surgical removal of the gallbladder. There are increasing numbers of patients who are not suitable for surgery and therefore this technique has arisen as a viable alternative. Direct discussion of such patients between the surgical and endoscopy team would be the usual method of assessment and case selection.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). **I have done clinical research on this procedure involving patients or healthy volunteers.** I have published this research. I have had no involvement in research on this procedure. Other (please comment) We have also published several papers using the technology for other indications. We are currently participating in a UK wide registry which would include these type of procedures.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The procedure and concept has been around for many years. The standard of care is surgical removal of the gallbladder. In patients where this is not appropriate the most common alternative is a percutaneous drain but this carries significant issues and morbidity and so this has arisen as an alternative. Current uptake is very patchy around the UK and often confined to specialist centres. 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?	Yes. Percutaneous drainage is reasonably straight forward but has significant issues. Current data would suggest that endoscopic ultrasound guided drainage might be superior.

Current management

5	Please describe the current standard of care that is used in the NHS.	For the majority of patients with acute cholecystitis the standard of care is surgical removal of the gallbladder. In patients unsuitable for this the options are conservative management, percutaneous drainage or endoscopic drainage.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	There are 2 main patient groups that would need consideration; acute cholecystitis when unfit for surgical removal and those with underlying malignancy that develop acute cholecystitis. Percutaneous drainage leaves the patient with a tube hanging out of their right hand side likely for the rest of their natural life. For some this may not be very long if they have underlying serious medical conditions but for many this could be months to years. Endoscopic ultrasound guided drainage is all internal and therefore patients do not have an external drain and this is likely to be much better for symptoms and quality of life.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes. Patients unsuitable for surgical gallbladder removal who are likely to live more than a few weeks.
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. Currently many centres are performing percutaneous drainage and this definitely has a role. These tubes often block and cause considerable morbidity. Switching to endoscopic ultrasound guided drainage has the potential to improve outcomes, quality of life and possibly readmission rates for this condition.
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)	Difficult to know exactly. The cost of endoscopic ultrasound and the stent that is used is not inconsiderable however symptoms and quality of life are likely to be better therefore QUALYS might be more efficient.
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)?	Overall this is likely to cost less in the long run. The cost of the stents could be reduced and the time spent in hospital is likely to be less which is clearly cost effective.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Mainly access to providers of endoscopic ultrasound who can deliver this procedure. There would also need to be a culture shift/education for many that this is a viable alternative option.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. Providers would need to be performing endoscopic ultrasound at high quality and good volumes. Previous use of this technology in other indications especially pancreatic fluid collection drainage would be optimal.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	This procedure is associated with several complications which can be broken down into those related to endoscopy and those specific to the intervention. Endoscopy has risks related to sedation as well as bleeding and perforation (roughly 1 in 1000). The drainage intervention is further associated with a risk of bleeding and perforation (about 0.5%). There are also late adverse events. A recent meta-analysis shows an overall adverse event rate of 14.8% with stent malfunction being the most common (3.5%) and a procedure related mortality of 1%. Increasing centre experience (>10/yr) was associated with increased technical and clinical success rates. Use of anti-migration devices also increased the clinical success and reduced adverse events. Reference: Determinants of outcomes of transmural EUS-guided gallbladder drainage: systematic review with proportion meta-analysis and meta-regression. Fabbri C, Binda C, Sbrancia M, Dajti E, Coluccio C, Ercolani G, Anderloni A, Cucchetti A. Surg Endosc. 2022 Jun 2. doi: 10.1007/s00464-022-09339-y. One theoretical adverse event is around eventual progression to surgery. This technique has been used to “bridge” an unfit patient to surgery but the effect of these stents on eventual surgery is not clear.
15	Please list the key efficacy outcomes for this procedure/technology?	Technical success, clinical success, adverse event rates (immediate, short and long term), quality of life, readmission rates, reintervention rates, change in symptoms.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The main issues currently are around access and volume. The meta-analysis above clearly shows a centre volume effect and therefore centres not providing this service are likely to suggest the percutaneous route as they can deliver this. Also it is uncertain whether routine recalling to remove stones from the gallbladder reduces adverse events. This is especially important in patients with a poor prognosis.

17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes. The selection for this procedure over the current standards of care need to be fully elucidated. When and where these procedures are performed and by whom. Medium to long term outcomes. Proper economic analysis versus other potential treatments/procedures.
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. Currently only done in specialist centres but this would need to be evaluated.

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.	1. Chan SM, Chong MKC, Chiu PWY, Ng EKW, Wong MCS, Teoh AYB. Impact of endoscopic ultrasound-guided gallbladder drainage on reducing costs of reintervention and unplanned readmission: a budget impact analysis. Endosc Int Open. 2022 Aug 15;10(8):E1073-E1079. doi: 10.1055/a-1819-8124. 2. Luo X, Sharaiha R, Teoh AYB. Endoscopic Management of Acute Cholecystitis. Gastrointest Endosc Clin N Am. 2022 Jul;32(3):527-543. doi: 10.1016/j.giec.2022.02.004. 3. Auriemma F, Fugazza A, Colombo M, Spadaccini M, Repici A, Anderloni A. Safety issues in endoscopy ultrasound-guided interventions using lumen apposing metal stents. Minerva Gastroenterol (Torino). 2022 Jun;68(2):177-185. doi: 10.23736/S2724-5985.21.02862-X.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	1. Endoscopic Ultrasonography (EUS) Guided Gallbladder Drainage With Two Months Stent Removal for Acute Cholecystitis: a Prospective Study – Italy. 2. Hong Kong Follow up Protocol After EUS Gallbladder Drainage for Acute Cholecistitis – Italy

		3. EUS-guided Gallbladder Drainage Instead of Laparoscopic Cholecystectomy for Acute Cholecystitis. A Feasibility Study. – China (active but not recruiting) 4. Fesibility of EUS-guided Gallbladder Drainage With a New-type of Electrocautery LAMS in the Treatment of Malignant Distal Biliary Obstruction – Italy 5. Prospective Registry Of Therapeutic EndoscopiC ultrasound – Italy 6. UK multicentre registry - UK

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)?	The UK performs around 50,000 – 70,000 cholecystectomies per year most of which are for cholecystitis. Acute cholecystitis is a frequent cause for admission to hospital. A recent analysis of the HES data showed that of the 99,000 admission for acute cholecystitis in one year in the UK, only 51% underwent surgery within one year from the admission. Patients who did not have surgery were more likely to be older and have more comorbidities. It is possible that these patients could be considered for endoscopic ultrasound guided drainage instead.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	If the above numbers are even close to accurate then the capacity for this in the current NHS climate is sorely lacking.
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?	The main issues are education of physicians and surgeons that this is a viable option and then which centres should provide this service and when.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Yes there are several uncertainties. The technical ability to do this procedure in the current centres does not mean that all patients have access.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term	Beneficial outcome measures: Technical success, clinical success, number per annum by centre and provider. Readmission rate. Reintervention rate. Quality of life

	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:	Reduction in pain Adverse outcome measures: Bleeding, perforation, infection, post procedure pain – immediate, short term and long term Need for other intervention eg radiology or surgery Most timescales would be <24hrs, 1 week and 1 month. 3, 6 and 12 month outcomes would also be of interest.
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Technically this is usually a very satisfactory procedure to perform and has good outcomes. However, when complications occur this is in patients who are often not suitable for rescue by surgery and therefore patient selection is vital.

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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
Indirect	Consultancy and honoraria for talks given for Viatris	**01/01/2021**	**ongoing**
Indirect	Consultancy and honoraria for talks given for Olympus	**01/01/2022**	**01/01/2023**
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:	**John Samuel Leeds**
Dated:	**25/09/2022**

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Professional Expert Questionnaire

Technology/Procedure name & indication: IP1912 Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis

Your information

Name:	Sharan Wadhwani
Job title:	Radiologist - Doctor
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Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	BSGAR
Registration number (e.g. GMC, NMC, HCPC)	GMC 6099184

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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 requestin g 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?	Experienced Radiologist, with tertiary/quarternary level practise in hepatobiliary imaging. Experienced EUS operator; familiar with technique but not currently performed in local unit.
	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	Current use nationally is non-uniform and limited in numbers/indications. No widespread consensus for use. Generally, this procedure is performed by EUS operators – including gastroenterologists, radiologists and surgeons with a therapeutic EUS interest. To date, we have had no requirement within our tertiary/quarternary unit for this procedure; established management including percutaneous drainage/stenting, endoscopic/EUS drainage or acute/hot surgery is utilised.

	indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. **I have had no involvement in research on this procedure.** Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	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?	Potentially yes to both questions.

Current management

5	Please describe the current standard of care that is used in the NHS.	Current standard of care includes surgical bypass or percutaneous/endoscopic/EUS hepatogastrostomy drainage.
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?	Internalisation of drainage rather than an external drainage catheter. Daycase procedure rather than general anaesthetic and open/minimally invasive surgery.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Palliative patients with inoperable pancreatic/biliary malignancy and obstructive biliopathy with no endoscopic/percutaneous option for drainage.
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, potentially; but in a minority of cases.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	I would expect this to cost the same as a percutaneous interventional radiology option, less than a surgical alternative.
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?	Existing high volume EUS centres should be able to accommodate this procedure. Smaller/lower volume centres may not.

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

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	Biliary leak, haemorrhage, recurrent infection/cholangitis. Stent migration/erosion. All approximately 1% risks (estimate).
15	Please list the key efficacy outcomes for this procedure/technology?	Improvement/normalisation of liver function tests in the short and medium term. Pain scores. Readmission rates due to sepsis and/or stent blockage..
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Medium to long term success rates with respect to stent patency and effective removal.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes – biliary reflux, recurrent infection, success rates over established alternative methods.
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.	No

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)?	Very few – difficult to quantify.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No

23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Research is currently limited by numbers treated. Larger samples with prospective follow up would be ideal, although this is difficult to achieve.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Adverse outcome measures:
26	Is there any other data (published or otherwise) that you would like to share with the committee?	No

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.			
Choose an item.			
Choose an item.			

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Print name:	**Sharan Wadhwani**
Dated:	**10/10/22**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1912 Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis

Your information

Name:	Wing Yan Liu
Job title:	Consultant Interventional Radiologist
Organisation:	University Hospitals Coventry and Warwickshire NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	General Medical Council Royal College of Surgeons of Edinburgh Royal College of Radiologists
Nominated/ratified by (if applicable):	British Society of Interventional Radiology
Registration number (e.g. GMC, NMC, HCPC)	GMC registration number: 6100966

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

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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 am familiar with the medical conditions that this procedure, i.e. Endoscopic ultrasound gallbladder drainage aim to treat. I have had vast experience in treating acute cholecystitis during my previous years in General Surgery and currently as an Interventional Radiologist. I am familiar with the risk, benefit and ongoing change in clinical guidelines in surgical (laparoscopic/open) cholecystectomy and percutaneous cholecystostomy, which are the two widely acceptable treatment options, traditionally and currently more readily available in most centres. I used to perform laparoscopic cholecystectomy, and now perform percutaneous cholecystostomy regularly. I am familiar with the referral pathway, indications, procedure techniques, potential complications and follow up management of both procedures. I work closely with Gastroenterologists who perform Endoscopic ultrasound (EUS) procedures. I am involved in the Hepato-Pancreato-Biliary multidisciplinary meetings (HPB MDM), where EUS procedures are discussed. EUS gallbladder drainage is not a widely used treatment for acute cholecystitis at present. It is only performed by small number of operators in limited centres, such as University College London Hospital. It is not currently available in my trust.

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 not undertaken research directly on this procedure, but have performed literature review on studies on endoscopic ultrasound gallbladder drainage. I have taken part in a national multicentre study on percutaneous cholecystostomy, "The Multicentre Audit of Cholecystostomy and Further interventions (MACAFI)", which is awaiting publication.
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):	EUS gallbladder drainage is a technique first described in the literature in 1993. A number of studies have been published since then, to compare this technique to other treatments for acute cholecystitis, such as percutaneous cholecystostomy and endoscopic transpapillary gallbladder drainage. EUS gallbladder drainage remains to be a procedure only offered by a small number of centres. It is not a routine procedure even in centres with experienced EUS practitioners. It is considered a novel approach to treat acute cholecystitis in most hospitals in the UK. 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 could be used as an alternative treatment option, in addition to existing standard care.

Current management

5	Please describe the current standard of care that is used in the NHS.	Patient with acute cholecystitis is generally admitted under General Surgery and will be commenced on intravenous antibiotics. For those patients whose clinical conditions do not improve or continue to deteriorate on medical treatment, surgical cholecystectomy or percutaneous cholecystostomy will be considered. For patients who are considered hight risk for surgery, percutaneous cholecystostomy is the treatment of choice in majority of NHS hospitals.

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?	Surgical (open/laparoscopic) cholecystectomy and percutaneous cholecystectomy are the two more widely used alternative treatments for acute cholecystitis that does not respond to conservative medical treatment. Endoscopic transpapillary gallbladder drainage is a less common alternative treatment. Surgical cholecystectomy is performed under general anaesthesia, often on the emergency theatre list. The patient is assessed by anaesthetist, considered fit for general anaesthesia and need to fast for 6 hours prior to the procedure. It is recommended that laparoscopic cholecystectomy for acute cholecystitis should be performed within 48 hours of symptom onset by surgeons specialised in gallbladder surgery. The complication risk is significantly higher if the procedure is performed beyond 48 hours or if it is performed by non-specialist in the acute phase. The procedure is completed via laparoscopic approach in majority of cases, and may be converted to open surgery in small number of complex cases. Percutaneous cholecystostomy is normally performed by Interventional Radiologists under local anaesthesia. Patients do not need to fast for the procedure. Percutaneous transhepatic approach is commonly used. Other approach is percutaneous approach directly into the gallbladder without puncturing through the liver. Cholecystostomy drain should be kept in for at least 6 weeks to allow tract maturation before drain removal. Patient can be discharged with the drain in situ. A cholecystogram may be performed to assess cystic duct patency before drain removal. Endoscopic transpapillary gallbladder drainage is performed by specially trained Endoscopists. It involves inserting a plastic stent through the ampulla and cystic duct into the gallbladder endoscopically. The procedure is performed either under general anaesthesia or sedation, hence the patients need to be fasted for at least 6 hours. The internal stent between the gallbladder and duodenum would need to be removed or exchanged endoscopically. EUS cholecystostomy would be performed by Endoscopists trained in EUS procedures. The procedure is expected to be performed under sedation. Patient will need to fast for 6 hours. Patient will undergo an upper gastrointestinal tract endoscopy, then a transmural stent would be inserted between the stomach/duodenum and the gallbladder to allow drainage. There will not be an external drain and the stent does not normal need to be removed.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	The procedure offer an alternative treatment option for patient with acute cholecystitis, especially for those not suitable for surgery. The recent meta-analysis has shown lower complication rate from EUS gallbladder drainage than percutaneous cholecystostomy. An internal stent is used for endoscopic transmural drainage, unlike percutaneous drainage that involve an external drain.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients who have difficulties to keep a percutaneous cholecystostomy drain in for 6 weeks, such as those with reduced mental capacity, limited mobility or inability to care for a drain, may particularly benefit from the procedure.
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, the procedure could be an alternative treatment for acute cholecystitis under specific circumstances. Studies have shown that it has higher technical success rate than Endoscopic transpapillary gallbladder drainage, and lower re-intervention rate than Percutaneous cholecystostomy. However, the published studies were performed in specialist centres which are experienced in this procedure, whilst the procedure is very operator dependent and technically demanding, these results should be treated with cautions.

10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	The procedure likely to cost the same as the current standard of care in the long run. The initial capital required for training and set-up will likely break even by the lower re-interventional rate.
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)?	The procedure will incur additional staff time, list time and procedure costs, as compared to the percutaneous cholecystostomy. The procedure time for EUS gallbladder drainage is expected to be longer than percutaneous cholecystostomy and the equipment cost is also likely to be significantly higher. Extra endoscopy lists will be required.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Extra endoscopy lists and staffs in endoscopy units, including emergency cover will be required.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. The procedure is technically demanding and will require specific training.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Potential complications includes: Bleeding, pain, infection, bile duct injury, bile leak, bowel perforation, peritonitis, stent migration, stent blockage, recurrence symptoms, death. Adverse events reported in literature: A study on EUS gallbladder drain using data on a retrospective international multi centre registry showed a 30-day adverse effect rate of 15.3% and 30-day mortality of 9.2%. [Teoh AY, Perez-Miranda M, Kunda R, Lee SS, Irani S, Yeaton P, Sun S, Baron TH, Moon JH, Holt B, Khor CJL, Rerknimitr R, Bapaye A, Chan SM, Choi HJ, James TW, Kongkam P, Lee YN, Parekh P, Ridtitid W, Serna-Higuera C, Tan DMY, Torres-Yuste R. Outcomes of an international multicenter registry on EUS-guided gallbladder drainage in patients at high risk for cholecystectomy. Endosc Int Open. 2019 Aug;7(8):E964-E973. doi: 10.1055/a-0915-2098. Epub 2019 Jul 24. PMID: 31367676; PMCID: PMC6656552.] Theorectical adverse events: The procedure involve creating a connection between the gallbladder and stomach/duodenum, i.e. a cholecystoduodenal fistula. This would likely lead to more adhesions around the gallbladder and the bowel, and makes any future surgical cholecystectomy or other abdominal surgery technically more difficult. The potential risk of complications from future abdominal operation could be higher as compared to percutaneous cholecystostomy. One study comparing the surgical time and incidence of intraoperative bleeding between patients who subsequently underwent laparoscopic cholecystectomy after EUS gallbladder drain and those had percutaneous cholecystostomy showed no significant difference in the surgical time or intraoperative bleeding. However, this was a retrospective study with sampling bias. There was great different in the number of patients in the two groups, i.e. EUS gallbladder drain (n=7) vs Percutaneous cholecystostomy (n=26). [McCarty, T.R., Hathorn, K.E., Bazarbashi, A.N. *et al.* Endoscopic gallbladder drainage for symptomatic gallbladder disease: a cumulative systematic review meta-analysis. *Surg Endosc* **35**, 4964–4985 (2021). https://doi.org/10.1007/s00464-020-07758-3]

15	Please list the key efficacy outcomes for this procedure/technology?	Technical success Clinical success Re-admission rate Re-intervention rate Rate of adverse event
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The studies showing satisfactory efficacy and safety of the procedures were from centres with established EUS gallbladder drainage service performed by experienced practitioners. This may not be representative for the outcomes when the procedures are performed by less experienced hands, as the procedure is extremely operator dependence. The procedure could potentially lead to serious or life threatening complications.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	There is no standardised training or audit standard for this procedure. Training would be difficult due to the current lack of EUS practitioner trained in this procedure and small number of eligible cases. There is no registry to monitor outcomes as the technique is being developed nationally.
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.	None
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	There is no current clinical trial or prospective registry for this procedure nationally or internationally.

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)?	up to 5% of patients presented to hospital with acute cholecystitis.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Accessibility of EUS list and availability of specifically trained EUS practitioner, in particular that this is an urgent/emergency 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?	Accessibility and availability of EUS list and EUS practitioner. Small number of eligible cases to allow adequate training.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Randomised controlled trial to investigate the technical success rate, operative/perioperative parameters and complication rate of subsequent laparoscopic cholecystectomy post EUS gallbladder drain versus that post percutaneous cholecystectomy in patients who are suitable for surgery when recovered from the acute presentation.
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: Short term - Clinical response, hospital discharge within 72 hours Long term - Time to recurrence (further episode of acute cholecystitis), uneventful laparoscopic cholecystectomy Adverse outcome measures: Early complication (within 7 days) - mortality, bile leak, bleeding, bowel perforation, further intervention Intermediate complication (within 30 days) - recurrent cholecystitis, bile leak, re-admission Late complication after 30 days - failed cholecystectomy, biliary stricture, stent migration or blockage
26	Is there any other data (published or otherwise) that you would like to share with the committee?	None

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	The outcomes of endoscopic gallbladder drain has been shown to be comparable and possibly more superior to other treatment options, i.e. higher technical success rate than endoscopic transpapillary gallbladder drain and lower re-intervention rate than percutaneous cholecystostomy. The procedure could be included as one of the treatment options for acute cholecystitis in selective cases. There are limitations in the current evidence in the literature, however, as these studies were mostly carried out in experienced centres with established techniques in the procedure. The procedure is not currently a common practice in the UK, therefore one should be cautious when applying these reported data onto UK practice. The procedure is operator dependence and technically demanding, therefore it should performed by specifically trained EUS practitioners. The long term effect on the technical success rate for subsequent laparoscopic cholecystectomy is uncertain, therefore the procedure should be reserved for patients who would not be suitable for surgical cholecystectomy even after the acute episode. This procedure could lead to increased pressure on endoscopy unit, and may require additional staffing, list time and equipment cost.

		Standardised training, audit standards and a national registry are highly recommended.

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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:	**WING YAN LIU**
Dated:	**11/10/2022**