NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1879 Endoscopic ultrasound guided biliary drainage for biliary obstruction**

Your information

Name:	Robert Colliver
Job title:	Consultant Interventional Radiologist
Organisation:	Royal United Hospital, Bath
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BSIR
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 7014893

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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

Click here to enter text.

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

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I am familiar with an affiliated procedure – PTC and drainage but not the current procedure or ERCP. It is not widely used but could become widely used over a decade or s in my opinion. This is not undertaken by my specialty As a Radiologist I am involved in the patient selection/appropriateness and as an Interventional radiologist there may be overlap between PTC nad drainage and this procedure.

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

Current management

5	Please describe the current standard of care that is used in the NHS.	ERCP + stent
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?	PTC and drainage. This is a more invasive technique with a reasonable high morbidity and mortality.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	An alternative treatment for patients who cannot
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes, those for whom ERCP is not possible.
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 fewer hospital visits and less invasive treatments.
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)	More
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)?	More
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Minimal if any infrastructure changes.

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	Injury to bowel. As a rough guess 1- 1.5% risk of significant complication.
15	Please list the key efficacy outcomes for this procedure/technology?	Technical success in unblocking the biliary system.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Increased invasiveness compared with ERCP. Technical skilled required.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	no
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK.

		Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Liver intervention (BSIR supported conference) Birmingham 2019
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)?	Unkown but potentially 10% of ERCP workload.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	no

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

Further comments

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

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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:	**Robert Colliver**
Dated:	**30/08/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1879 Endoscopic ultrasound guided biliary drainage for biliary obstruction**

Your information

Name:	Dr Martin James
Job title:	Consultant Hepatologist & Gastroenterologist
Organisation:	Nottingham University Hospitals NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BSG, BASL, EASL, RCP
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 4089298

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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? 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 clinical lead for endoscopy at Nottingham University Hospitals NHS Trust (NUH). I am an HPB specialist endoscopist as part of my role as consultant in Gastroenterology and Hepatology, and have been a substantive consultant at NUH since 2008. I perform over 300 echoendoscopies (EUS) and 200 ERCP endoscopy procedures each year. I have lead an HPB endoscopy training programme with national and international fellows for over 10 years. I have been using lumen apposing metal stents (“LAMS”) for approximately 5 years, initially for draining pancreatic fluid collections (PFC) and in the last 3 years for EUS-assisted biliary drainage (EUS-BD). I have performed over 30 EUS-BD, the majority being cholecdochoduodenostomy (CCD) from the first part of the duodenum. Increasing training and experience with LAMS has expanded their use in step-up management of peri-pancreatic fluid collections in the UK, gaining familiarity and high technical success in placing such stents. Several UK centres have clinicians who now also perform EUS-BD for malignant biliary obstruction. Most EUS endoscopy clinicians are gastroenterologists, but also includes some HPB surgeons and HPB radiologists. Patient selection is through careful consideration at HPB MDTs (and after considering other alternatives such as percutaneous trans-hepatic biliary drainage (PTBD) or surgery) or through vetting referrals for ERCP and/or EUS endoscopy. This is usually performed by senior members of the HPB endoscopy team including consultants and/or advanced fellows in HPB endoscopy.

	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 clinical research on this procedure involving patients (not healthy volunteers). I have published this clinical research. I have published with others a safety and feasibility study of EUS-BD (Gastrointest Endosc. 2021 Aug;94(2):321-328) and reported the UK experience more widely using LAMS in PFCs (Endosc Int Open. 2018 Mar;6(3):E259-E265; Gut 2022 May;71(5):850-853) and EUS-BD (Gastrointest Endosc. 2022 Mar;95(3):432-442).

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 biliary drainage has been available for over 15 years using a variety of endoscopy accessories. However, interest in, ease of delivery and technical/clinical success has recently expanded and improved with the development of cautery-tipped, single-stage accessories to place LAMS without the need for guidewire exchange or the use of multiple accessories (e.g. cystotome, rigid or balloon dilators, plastic stents) to achieve biliary drainage. This single-stage LAMS CCD procedure using innovative electrically enhanced cautery-tipped accessories has been a major development reducing procedure time and simplifying EUS-BD procedures in the UK, Europe and worldwide. Trans-gastric EUS-assisted biliary stenting or drainage ("hepatico-gastrostomy", HG) with fully or partially covered mesh self-expanding metal stents (SEMS) is used less frequently in the UK and usually necessitates GA or propafol sedation which is not currently universally available. The HG procedure does not routinely deploy LAMS stents but requires trans-gastric needle puncture of obstructed left intrahepatic ducts, guidewire placement into the biliary tree and dilation of a track before either antegrade trans-papillary or trans-gastric biliary stent placement. HG is more time-consuming and technically demanding than LAMS CCD placement from the duodenum. In summary: 1. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. (**Choledochoduodenostomy (CCD) EUS BD**) 2. A major variation on an existing procedure, which is likely to alter the procedure's safety and efficacy. (**Hepatico-gastrostomy (HG) EUS BD**) Safety and efficacy of both procedures relies on the expertise, training & skill of advanced endoscopists and should not be embarked on without appropriate training, mentorship, support and appropriate integration of services with HPB interventional radiology and HPB surgery.

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?	After failed ERCP stenting, these procedure are considered alternatives to replace either percutaneous trans-hepatic biliary drainage (PTBD or PTC), or more rarely palliative bypass surgery. However further clinical trial are required in this area. Not all cases would be suitable for EUS BD and PTBD may still be required in certain cases (e.g. right sided intrahepatic biliary obstruction which cannot easily be accessed and drained using EUS BD), where the diameter of the common bile duct (CBD) was too narrow despite obstruction to allow stent placement (e.g. <14mm CBD diameter) PTBD would continue in centres where advanced interventional EUS expertise or networks are not available Several recent studies have published comparative studies or meta-analysis of EUS BD and PTC, showing at least comparable technical success with fewer complications using EUS BD in expert centres: 1: Wang Y et al. Comparing Outcomes Following Endoscopic Ultrasound-Guided Biliary Drainage Versus Percutaneous Trans-hepatic Biliary Drainage for Malignant Biliary Obstruction: A Systematic Review and Meta-Analysis. J Laparoendosc Adv Surg Tech A. 2022 Jul; 32(7):747-755. 2: Ginestet C et al. EUS-guided biliary drainage with electrocautery-enhanced lumen-apposing metal stent placement should replace PTBD after ERCP failure in patients with distal tumoral biliary obstruction: a large real-life study. Surg Endosc. 2022 May;36(5):3365-3373. 3: Hayat U et al. EUS-guided v percutaneous trans-hepatic cholangiography biliary drainage for obstructed distal malignant biliary strictures in patients who have failed endoscopic retrograde cholangiopancreatography: A systematic review and meta-analysis. Endosc Ultrasound. 2022 Jan-Feb;11(1):4-16.

Current management

5	Please describe the current standard of care that is used in the NHS.	Following appropriate biliary imaging (usually a combination of USS, CT and/or MRI scanning), ERCP is used to obtain brush cytology samples followed by plastic or metallic stenting to achieve biliary drainage in patients with malignant biliary obstruction. Where this

		initial ERCP fails, repeat either ERCP is attempted or PTBD is performed with appropriate risk stratification and case selection. In highly selected patients with biliary obstruction but with modest bilirubin levels (e.g. <200mmol/L) and radiologically operable disease patients may be offered “fast-track” surgical assessment and resection either on the basis of radiology or pre-operative EUS and sampling (but not ERCP or EUS drainage) to achieve a pre-operative cytological diagnosis of cancer.
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 a range of uncovered or fully covered SEMS stents and LAMS available. Biliary drainage of malignant obstruction is treated either with ERCP, EUS BD, PTBD or open or laparoscopic surgery.

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?	Single stage procedure in endoscopy to accurately stage disease followed by tissue acquisition from the cause of biliary obstruction, with drainage achieved either using ERCP, or if this fails, EUS BD. If further clinical trials support the high technical & clinical success of EUS-BD with an acceptable safety profile, selected cases may proceed directly to EUS staging/tissue sampling and drainage using EUS BD without having to undertake primary ERCP (with its adherent risk including pancreatitis, perforation, bleeding and death). This may shorten procedure time considerably using a single modality for staging, sampling and biliary drainage. Clinical studies are required to confirm the safety of this approach without compromising subsequent surgery with curative intent (e.g. Whipple's pancreas resection). At present this approach would be limited to specialist tertiary centres where the skills, expertise, training and facilities allow this approach.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients deemed inoperable (e.g. radiologically locally advanced or metastatic disease, or those with poor performance status precluding consideration of biliary or pancreatic surgery) may proceed directly to EUS BD following failed ERCP and instead of PTBD, or potentially as a primary EUS procedure to achieve biliary 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 – the paradigm for staging, tissue acquisition and biliary drainage could be challenged by this technology and procedure, although relatively few UK centres and endoscopists perform this procedure at present. In addition, tissue sampling to confirm cancer has higher sensitivity with EUS FNA/B sampling of solid pancreatic lesions (>90%) compared to ERCP biliary brush cytology (50-60%) and can be performed at the time of EUS BD. Both these considerations could lead to fewer procedures or hospital visits for patients undergoing investigation and 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	This would need formal cost analysis modelling to determine accurately. Upfront costs for EUS BD would include investment in EUS platforms, echoendoscopes, training and service development, consumables (including the costs of LAMS or other stents), endoscopist direct

	standard care, or about the same? (in terms of staff, equipment, care setting etc)	clinical care PAs and the unit costs of endoscopy rooms or theatre staff, procedure duration, hospital length of stay and need for repeat procedures or treatment of complications. The main comparator groups would be repeat ERCP, PTBD using interventional radiology or HPB surgery.
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 number of EUS BD for failed ERCP (or as potentially as primary treatment modality) would increase in tertiary centres where this is available (potentially with an increase in tertiary referrals from networking hospitals within the HPB cancer catchment areas) and PTBD would decrease. The proportion of patients who undergo HPB surgical resection after presenting with malignant biliary obstruction (either pancreatic cancer or cholangiocarcinoma) is <20%. In the UK, ERCP for malignant biliary obstruction accounts for approximately 35% of 50,000 cases each year (i.e. approx.18,000 cases). The ERCP failure rate in achieving biliary drainage varies across the UK between approximately 5-25% (i.e. 900-4500 cases pa). There is therefore high demand for access to safe and effective ways to achieve biliary drainage following failed ERCP or in those not suitable for surgery. Biliary drainage is also often essential for treating symptoms of obstruction and to allow improvements in jaundice to allow neoadjuvant or palliative chemotherapy. The current costs of ERCP metallic stents is approximately £700, LAMS stents for EUS BD approx. £2-2.5k. HRG tariffs or reimbursement for EUS BD often does not reflect all consumable or unit costs for the procedures (especially if NHS trusts are on “block” contracts) and this would needs to be ratified if the procedure was to be expanded and appropriately funded in future at an acceptable cost.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Improved access to expertise and training in EUS BD; awareness of this procedure amongst referring teams of EUS BD as a treatment option in the context of failed ERCP biliary drainage. Increasing access to propafol or GA-assisted biliary endoscopy Timely and effective MDT discussions to triage appropriate patients appropriate modalities for biliary drainage Clinical studies to determine patient’s views of the advantages, benefits and disadvantages of different treatment modalities.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Not all hospital trusts or regions have access to EUS services. The expertise for interventional EUS BD is not widely available currently in the UK, even amongst those regularly performing diagnostic EUS. However, training and awareness of this procedure is increasing with several UK centres jointly publishing their outcomes recently. Training in EUS BD should start with those familiar using LAMS stents for other indications (e.g. pancreatic fluid collections) and with broad experience in EUS already.

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	In our published collaborative UK study of EUS BD in 120 patients, technical success was achieved in 90.8% and clinical success (reduction of serum bilirubin to <50% of original value within 14 days) was achieved in 94.8% of patients. The adverse event rate was 17.5% including cholangitis, blacked stents, pneumoperitoneum or perforation and bile leaks. . Biliary re-intervention after initial technical success was required in 9 patients (8.3%). These are similar rates of adverse events reported in other studies. 1: Venkatachalapathy SV et al. Utility of palliative EUS-guided biliary drainage using lumen-apposing metal stents: a prospective multicentre feasibility study (with video). Gastrointest Endosc. 2021 Aug;94(2):321-328. 2: On W et al. EUS-guided choledochoduodenostomy with electrocautery-enhanced lumen-apposing metal stents in patients with malignant distal biliary obstruction: multicentre collaboration from the United Kingdom and Ireland. Gastrointest Endosc. 2022 Mar;95(3):432-442.
15	Please list the key efficacy outcomes for this procedure/technology?	1. Technical success of stent placement. 2. Relief of biliary obstruction – reduction or normalisation of bilirubin levels 3. Control of symptoms (e.g. jaundice, nausea, pain, pruritus, sepsis) 4. Morbidity (including all related complications) and 30d and long-term mortality 5. Need for re-intervention for stent dysfunction or recurrent obstruction
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Are the procedure-related complications and associated morbidity and mortality acceptable compared to the current standard of care (e.g. primary or repeat ERCP, PTBD, surgical resection or biliary bypass)? Are the complications more or less frequent or higher/lower in severity than treatments?

17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	There is a need for further studies to determine the safety and efficacy of these procedures in the current paradigm and their place in treatment pathways for malignant biliary obstruction including: 1. Direct RCT comparison of safety and efficacy of EUS BD with PTBD following failed ERCP 2. Utility of EUS BD only after failed ERCP or as primary biliary drainage modality in potentially operable patients 3. EUS BD using CCD v HG in malignant biliary obstruction
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	1: Venkatachalapathy SV et al. Utility of palliative EUS-guided biliary drainage using lumen-apposing metal stents: a prospective multicentre feasibility study (with video). Gastrointest Endosc. 2021 Aug;94(2):321-328. 2: On W et al. EUS-guided choledochoduodenostomy with electrocautery-enhanced lumen-apposing metal stents in patients with malignant distal biliary obstruction: multicentre collaboration from the United Kingdom and Ireland. Gastrointest Endosc. 2022 Mar;95(3):432-442. 3: Zhao X et al. Clinical value of preferred endoscopic ultrasound-guided antegrade surgery in the treatment of extrahepatic bile duct malignant obstruction. Clinics (Sao Paulo). 2022 Mar 12;77:100017. 4: Itonaga M et al. Comparison of endoscopic ultrasound-guided choledochoduodenostomy and endoscopic retrograde cholangiopancreatography in first-line biliary drainage for malignant distal bile duct obstruction: A multicentre randomized controlled trial. Medicine (Baltimore). 2021 Mar 26;100(12):e25268.

		5: Minaga K et al. Comparison of the efficacy and safety of endoscopic ultrasound-guided choledochoduodenostomy and hepaticogastrostomy for malignant distal biliary obstruction: Multicentre, randomized, clinical trial. Dig Endosc. 2019 Sep;31(5):575-582. 6: Park JK et al. Efficacy of EUS-guided and ERCP-guided biliary drainage for malignant biliary obstruction: prospective randomized controlled study. Gastrointest Endosc. 2018 Aug;88(2):277-282. 7: Paik WH et al. EUS-Guided Biliary Drainage Versus ERCP for the Primary Palliation of Malignant Biliary Obstruction: A Multicentre Randomized Clinical Trial. Am J Gastroenterol. 2018 Jul;113(7):987-997. 8: Bang JY et al. Stent placement EUS or ERCP for primary biliary decompression in pancreatic cancer: a randomized trial (with videos). Gastrointest Endosc. 2018 Jul;88(1):9-17. 9: Lee TH et al. Similar Efficacies of Endoscopic Ultrasound-guided Transmural and percutaneous Drainage for Malignant Distal Biliary Obstruction. Clin Gastroenterol Hepatol. 2016 Jul;14(7):1011-1019.e3. 10: Park DH at al. Feasibility and safety of a novel dedicated device for one-step EUS-guided biliary drainage: A randomized trial. J Gastroenterol Hepatol. 2015 Oct;30(10):1461-6. 11: Artifon EL et al. Hepaticogastrostomy or choledochoduodenostomy for distal malignant biliary obstruction after failed ERCP: is there any difference? Gastrointest Endosc. 2015 Apr;81(4):950-9. 12: Artifon EL at el. Biliary drainage in patients with unresectable, malignant obstruction where ERCP fails: endoscopic ultrasonography-guided cholecdochoduodenostomy versus percutaneous drainage. J Clin Gastroenterol. 2012 Oct;46(9):768-74. 13: Varadarajulu S at al. Prospective randomized trial comparing EUS and EGD for transmural drainage of pancreatic pseudocysts (with videos). Gastrointest Endosc. 2008 Dec;68(6):1102-11.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	**Currently active or recruiting trials (www.clinicaltrials.gov):** 1: Endoscopic Versus Radiologic Biliary Drainage for Peri-hilar Malignant Obstruction Nancy Hospital Centre, Nancy, France https://ClinicalTrials.gov/show/NCT05078801 2: EUS-Guided Choledochoduodenostomy Versus ERCP for Primary Biliary Decompression in Distal Malignant Biliary Obstruction

		Specialized Medical Hospital, Mansoura, Dakahlia, Egypt https://ClinicalTrials.gov/show/NCT04898777 3: Feasibility of EUS-guided Biliary Drainage With LAMS for the Treatment of Patients With Distal Malignant Biliary Obstruction Humanitas Mater Domini, Castellanza, Italy https://ClinicalTrials.gov/show/NCT04723199 4: LAMS Choledochoduodenostomies: With or Without Coaxial Plastic Stent Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Barcelona, Catalonia, Spain. Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Barcelona, Spain https://ClinicalTrials.gov/show/NCT04595058 5: Eus-giuded Biliary Drainage With EC-lams vs ERCP as a Primary Intervention for Endoscopic Treatment of Patients With Distal Malignant Biliary Obstruction Endoscopy Unit, Humanitas Research Hospital, Rozzano, Milano, Italy https://ClinicalTrials.gov/show/NCT04099862 6: Efficacy and Safety of Lumen Apposing Metal Stents Endoscopy Unit, Humanitas Research Hospital, Rozzano, Milano, Italy. Humanitas Research Hospital, Milano, Italy https://ClinicalTrials.gov/show/NCT03903523 7: EUS Biliary Drainage vs. ERCP University of Calgary, Calgary, Alberta, Canada. University of Alberta, Edmonton, Alberta, Canada. Vancouver General Hospital, Vancouver, British Columbia, Canada. St-Paul Hospital, Vancouver, British Columbia, Canada. The Ottawa Hospital, Ottawa, Ontario, Canada. St-Michael's Hospital, Toronto, Ontario, Canada. Centre Hospitalier Universite de Montreal, Montréal, Quebec, Canada. McGill University Health Centre, Montréal, Quebec, Canada. Hopital Charles Lemoynes, Montréal, Quebec, Canada. Jewish General Hospital, Montreal, Canada. Hôpital Privé des Peupliers, Paris, France https://ClinicalTrials.gov/show/NCT03870386 8: Ultrasound-guided Percutaneous Biliary Drainage Versus Endoscopic Ultrasound-guided Biliary Drainage Tertiary referral hospital: Theresienkrankenhaus und St. Hedwig Hospital, Mannheim, Germany https://ClinicalTrials.gov/show/NCT03546049 9: Endoscopic Ultrasonography Guided Biliary Drainage https://ClinicalTrials.gov/show/NCT03195075

		10: EUS BD vs ERCP TP for Pancreatic Cancer Weill Cornell Medical College, New York, New York, United State https://ClinicalTrials.gov/show/NCT03063554 11: Percutaneous Trans-hepatic Cholangiography Versus Endoscopic Ultrasound Guided Biliary Drainage. UZ Leuven, Leuven, Belgium https://ClinicalTrials.gov/show/NCT01686425

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 proportion of patients who undergo HPB surgical resection after presenting with malignant biliary obstruction (either pancreatic cancer or cholangiocarcinoma) is <20%. In the UK, ERCP for malignant biliary obstruction accounts for approximately 35% of 50,000 cases each year (approx.18,000 cases). The ERCP failure rate in achieving biliary drainage varies across the UK between approximately 5-25% (i.e. 900-4500 cases pa). There is therefore high demand for access to safe and effective ways to achieve biliary drainage following failed ERCP or in those not suitable for surgery. Biliary drainage is also often essential for treating symptoms of obstruction and to allow improvements in jaundice to allow neoadjuvant or palliative chemotherapy. If EUS BD was adopted for both primary biliary drainage and following failed ERCP, there would clearly be much higher demand, although this demand currently could not be met across UK hospitals due to therapeutic EUS skills shortage and the costs of consumables.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The requirement for high volume previous EUS experience in operators and appropriate careful case selection to achieve high rates of safe, effective biliary drainage, low complication rates, whilst keeping future treatment options open.
23	Are you aware of any issues which would prevent (or have prevented) this	1. It is essential that those performing EUS have adequate experience and safety outcomes in diagnostic EUS including tissue sampling (e.g. FNA/B) and satisfactory baseline

	procedure/technology being adopted in your organisation or across the wider NHS?	therapeutic experience using LAMS in larger targets (e.g. pancreatic fluid collections, gallbladder drainage) before starting EUS-BD training. 2. All those starting EUS-BD procedures should undergo formal training to understand the different elements of EUS-BD techniques compared to pancreatic fluid collection drainage, training on simulators and/ or animal models and with appropriate mentor support from other networking centres. 3. There should be functional MDT interactions, discussion and support with allied specialists, such as HPB surgery and interventional radiology 4. Endoscopists should be familiar with and competent at stent removal and treating the more frequent stent-related complications (e.g. bleeding, bile leak, blocked or misplaced stents, buried or migrated stents.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	1. Comparative safety and efficacy study of EUS-BD versus percutaneous biliary drainage (PTDB) following failed ERCP, including PROMS (e.g. patient pain scores, symptom control, patient satisfaction, length of stay) and cost-effectiveness 2. Comparative study of ERCP versus EUS-BD in primary drainage in patient with potentially operable and non-operable biliary obstruction. 3. Safety and efficacy of hepatico-gastrosctomy (HG) versus choledochoduodenostomy (CCD) for malignant biliary obstruction.
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:** 1. Technical success of stent placement at index procedure 2. Clinical success of biliary drainage (change or normalisation in bilirubin, symptoms improvement and other PROMS (e.g. quality of life) at 7 and 30 days 3. Patient survival 4. Access to further palliative (e.g. chemotherapy) or curative (e.ge surgical resection) therapies **Adverse outcome measures:** Complications: including stent mal-deployment, pain and patient experience, infection, perforation, readmission, need for re-intervention, length of stay, 30-day mortality.

26	Is there any other data (published or otherwise) that you would like to share with the committee?	I have listed relevant peer-reviewed publications elsewhere (sections 19) and also data on local and UK national treatment success and complications (section 14).

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I would be happy to discuss or clarify any aspects of this report, where necessary.

NICE National Institute for Health and Care Excellence

Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Indirect	I am involved in delivering training and teaching in therapeutic EUS biliary and pancreatic interventions (including EUS BD) supported by Boston Scientific Ltd. I am involved in ERCP & EUS teaching and training courses supported by Cook Medical, Olympus, Pentax, ERBE, Aquilant, and Purastat.	**1.1.2017**	**Ongoing**
Choose an item.			
Choose an item.			

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Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Dr Martin James**
Dated:	**August 14th 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1879 Endoscopic ultrasound guided biliary drainage for biliary obstruction**

Your information

Name:	Dr Matthew Huggett
Job title:	Consultant Gastroenterologist and HPB Physician
Organisation:	Leeds Teaching Hospitals NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BSG, RCP, PSGBI
Nominated/ratified by (if applicable):	BSG
Registration number (e.g. GMC, NMC, HCPC)	GMC: 6074246

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 have been performing EUS-guided biliary drainage since 2016 and am the most experienced user of this technology in the UK, having performed around 70 procedures. I perform EUS-guided cholechoduodenostomy, hepaticogastrostomy, rendezvous and gallbladder drainage. I was the lead author on the recently published UK series which was also the largest published series worldwide (Gastrointest Endosc 2022 Mar;95(3):432-442.) I have taught on EUS-guided biliary drainage courses and acted as a proctor for several endoscopists who have set up this technology in their units around the UK. Through my work as Chair of the BSG Pancreas Committee, Secretary of the Pancreatic Society of Great Britain and Ireland, faculty on EUS and ERCP JAG courses, and Section Chair on the JAG EUS DELPHI process document, I believe I am well placed to comment on the use of this technology in the UK. The technology is now used in a number of major tertiary HPB centres by HPB endoscopists (mainly Gastroenterologists, but also a few radiologists and surgeons). I can see that there is significant enthusiasm for further units to set up similar services.

	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 clinical research on this procedure involving patients or healthy volunteers. I have published this research.
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. However, there is a lack of RCT evidence.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It would be in addition to existing standard care at present.

Current management

5	Please describe the current standard of care that is used in the NHS.	At present the standard of care for drainage of an obstructed biliary tree is ERCP, followed by PTC is this fails. EUS-guided biliary drainage has begun to replace PTC in some units.

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, other than standard of care mentioned above.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	When ERCP fails- reduced number of procedures, reduced morbidity, reduced length of stay, reduced costs.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with distal biliary obstruction where ERCP fails.
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- as above.
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)	Technology cost is more expensive but total health care costs likely less.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Cost of the technology is significantly higher. Will need staff (endoscopist) training and support during first procedures.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None- provided centre has EUS and ERCP facilities.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	New adopters should go on a training course and then have support for their first procedures and have a mentor to discuss cases. MDT support will also be needed.

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	These are outlined in our paper Gastrointest Endosc 2022 Mar;95(3):432-442. Namely: Perforation Bile leak Cholangitis Bleeding Stent maldeployment Stent migration
15	Please list the key efficacy outcomes for this procedure/technology?	Drainage of biliary tree with avoidance of cholangitis, normalisation of serum bilirubin.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Safety profile not determined by large RCTs yet, so this remains an uncertainty. A UK-based RCT is needed against SoC.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. Mostly HPB centres.

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.	Our series is recently published and is the largest to date. Gastrointest Endosc 2022 Mar;95(3):432-442.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	There are 3 or 4 international RCTs listed on the clinical trials database.

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)?	Around 15% of ERCPs fail. Approximately 50,000 ERCPs are performed in the UK every year.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Only training.
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?	As above.

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	1) Comparison with PTC after failed ERCP in a RCT. 2) How this technology could be safely used pre-operatively in patients going for resection of pancreatic cancer.
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: Normalisation of serum bilirubin Time to first oncological treatment Successful surgery Length of stay Cost (total episode cost) PROMs/ QOL Adverse outcome measures: As per ESGE lexicon for adverse events
26	Is there any other data (published or otherwise) that you would like to share with the committee?	No

Further comments

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

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Key opinion leader for Boston Scientific, faculty on training courses and paid honoraria	**2016**	**Continuing**
Direct - financial	Olympus, faculty on training courses and paid honoraria	**2015**	**Continuing**
Direct - financial	Cook, faculty on training courses and paid honoraria	**2016**	**Continuing**

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Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Matthew Huggett**
Dated:	**15th August 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1879 Endoscopic ultrasound guided biliary drainage for biliary obstruction**

Your information

Name:	Dr Simon Rushbrook
Job title:	Consultant Hepatologist
Organisation:	Norfolk and Norwich university Hospitals NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BASL
Nominated/ratified by (if applicable):	Dr Rebecca Jones
Registration number (e.g. GMC, NMC, HCPC)	4443447

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

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

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

Click here to enter text.

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

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am currently a consultant Hepatologist and interventional endoscopist at the Norfolk and Norwich University Hospitals. I completed my Endoscopic Ultrasound and ERCP fellowships at Cambridge University Hospitals in 2010. Since then, I have done interventional EUS and ERCP at NNUH. For the last 2 years our institution has started to selectively undertake EUS guided biliary drainage for selected patients. Furthermore, I currently sit on the BASL Cholangiocarcinoma committee and am currently preparing the Endoscopic guidelines for this BSG document where the place for this technology will be discussed. I therefore have both a practical and research understanding about the place of this technology with both the associated risks and benefits.
	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?	At present the EUS community is starting a prospective register of this technology for audit purposes. However, a number of centres are already using this technology in large hepatobiliary units that have associated expertise in EUS. If required a list of these centres could be requested by the corresponding audit lead.
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	This technology is only applied in established EUS centres having discussed the case at an associated Hepatobiliary/Pancreatic MDT.
	– If your specialty is involved in patient selection or referral to another specialty for this	Both HPB surgeons and physicians are principally involved in these decisions though to place such a stent.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure in preparation for the UK Cholangiocarcinoma guidelines which will be published in GUT when completed later this year.
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):	It is innovative and it does have significant advantages over both PTC and ERCP in certain situations. Novel and of uncertain safety and efficacy, but in many units is now a standard of care in a highly selected population of patients with malignant biliary obstruction.
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 – it certainly can replace PTC and ERCP in certain clinical situations.

Current management

5	Please describe the current standard of care that is used in the NHS.	At present most patients with distal malignant biliary obstruction are stented with ERCP. If a ERCP fails PTC is often used next in the treatment algorithm. Of course EUS guided biliary drainage is a sensible option in these cases and avoid the associated risks of PTC – which can be considerable. In addition for selected cases of hilar obstruction – where PTC

		is normally chosen as primary therapy there is the choice of placing a stent into the liver directly from the left side principally through gastric access.
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?	1) Avoid PTC 2) It could prevent a local complication in an operable patient – which could then convert them to inoperable – ie ERCP induced pancreatitis or perforation.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those with malignant distal biliary obstruction.
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 – in the sense that it could become second line instead of PTC. Or even first line in some 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 suspect less overall. I would imagine in the future if a distal malignant biliary obstruction couldn't be stented – a operator would simply change to an EUS guided approach and complete the task.
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 only cost would be that of the Hotaxios system, which tends to be the preferred choice of stent to use. Centres doing this procedure – will already have the associated EUS console and Linear echoendoscope. It will be this cost that will need to be evaluated against the alternative which is essentially PTC.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None – as it is done in established endoscopy units.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes – most people have learnt how to place these stents during fellowships or on established course.

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	Major risks are Stent slippage Bile leak Haemorrhage Cholangitis
15	Please list the key efficacy outcomes for this procedure/technology?	Resolution of jaundice
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Rates of complications compared to PTC
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not really – more its place in the treatment algorithm over PTC.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	This will be done in most centres that offer Endoscopic Ultrasound – around 40 centres I would expect.

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.	I am not aware of any over and above those that would be found on PUBMED, etc.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	There is a national EUS Audit planned lead by my colleagues in Newcastle.

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)?	Difficult – but if you estimate that around 10% of distal malignant biliary obstruction may have a failed ERCP – we should be able to work this backwards.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	None
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 major limiting factor is that a centre has to undertake interventional EUS guided procedures.

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Head to head study with PTC would be the most important study I would imaging for distal malignant biliary obstruction.
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: Resolution of jaundice Adverse outcome measures: Rates of bile leak post insertion Rates of cholangitis post insertion Rates of haemorrhage post insertion
26	Is there any other data (published or otherwise) that you would like to share with the committee?	None that I am aware of.

Further comments

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

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Declarations of interests

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

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

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Simon Rushbrook**
Dated:	**12/08/2022**