## **Professional Expert Questionnaire**

Technology/Procedure name & indication: Percutaneous insertion of a cystic duct stent for acute cholecystitis (IP1560)

#### Your information

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Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 6075796

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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:	I am familiar with the procedure, having performed over 20 cases. I have published a case series from our institution covering the outcomes of 33 patients.
	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?	I am currently performing this procedure. It is used by some centres, as discussed when our case series was presented at the British Society of Interventional Radiologists Annual Meeting. I think that it will slowly become more commonplace as awareness of the procedure grows. I am not aware that this procedure is performed outside of radiology. All cases referred for this procedure are discussed with myself and my colleagues prior to consideration and decision made upon technical feasibility and patient factors.
	<ul> <li>Is this procedure/technology performed/used by clinicians in specialities other than your own?</li> </ul>	
	<ul> <li>If your specialty is involved in patient selection or referral to another specialty for this</li> </ul>	

	procedure/technology, please indicate your experience with it.	
2	<ul> <li>Please indicate your research experience relating to this procedure (please choose one or more if relevant):</li> </ul>	I have published a case series relating to 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?	Variation on a percutaneous transhepatic cholangiogram.
	Which of the following best describes the procedure (please choose one):	Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	An addition to existing standard care.

## Current management

5	Please describe the current standard of care that is used in the NHS.	Cholecystectomy or cholecystostomy
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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?	I am not aware of any.
	If so, how do these differ from the procedure/technology described in the briefing?	

## 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?	In those unfit for cholecystectomy, it reduces the risk of repeated episodes of acute cholecystitis and removes the need for a permanent external drain.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Frail patients, unfit for cholecystectomy.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?	It could lead to fewer hospital visits with repeated episodes of acute cholecystitis. It could lead to fewer visits for exchange or management of long-term cholecystostomy drains.
	Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	I believe it would cost 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)?	Likely to cost the same or less.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No change to facilities needed.

	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	I would expect that it can be performed by experienced interventional radiologists whom already perform complex biliary intervention.
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## Safety and efficacy of the procedure/technology

14	<ul> <li>What are the potential harms of the procedure/technology?</li> <li>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</li> <li>Adverse events reported in the literature (if possible, please cite literature)</li> <li>Anecdotal adverse events (known from experience)</li> <li>Theoretical adverse events</li> </ul>	<ul> <li>Biliary sepsis (10%)</li> <li>Small bowel obstruction secondary to migrated stent (1%)</li> <li>Recurrent cholecystitis due to passed stent (1-2%)</li> <li>Soft tissue collections (5%)</li> <li>Significant biliary leak (1%)</li> <li>Failure of procedure (can be estimated on pre-procedure imaging by assessing tortuosity of cystic duct)</li> <li>Loss of external cholecystostomy drain and therefore recurrent cholecystitis</li> </ul>
15	Please list the key efficacy outcomes for this procedure/technology?	Successful placement of cystic duct stent with demonstrable flow of contrast from gallbladder to duodenum on subsequent check tubogram. No future admission with acute cholecystitis.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No concerns
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not that I am aware.
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.

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## 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).	No recent presented work or abstracts that I am aware of.
	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)?	5 patients per 1 million population per annum
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?	None
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	None
25	<ul> <li>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</li> <li>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.</li> <li>Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:</li> </ul>	Beneficial outcome measures: Adverse outcome measures:

## Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	None
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#### **NICE** National Institute for Health and Care Excellence

#### **Declarations of interests**

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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 <u>NICE policy on declaring and</u> <u>managing interests</u> 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:	Naomi Hersey
Dated:	03/08/21