NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1184/2 - Transanal total mesorectal excision for rectal cancer**

Your information

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Professional organisation or society membership/affiliation:	ACPGBI
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4591962

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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

Click here to enter text.

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

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am a colorectal surgeon and I have introduced this operation at our trust in 2017. I also led a national pilot training programme in the UK for this procedure. We published the outcome of the first phase in Colorectal Dis January 2020. I have also published widely in the fields of developing training curriculum, Assessment tools and outcome from the international registry.
	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 did perform this procedure between 2017- 2020 and stopped this technique following the statement from ACPGBI suggested to pause the practice of TaTME in the UK. I am currently a member of a TaTME working group in England, collating the national data of the procedure to examine the long term oncological outcomes (loco-regional recurrences). This is in response to the negative publication from Norway which showed oncological concerns with high level of loco-regional recurrences following this procedure. 1-I am aware of how widely the procedure been performed in England from the data that are entered into the international TaTME registry. We are currently collating the data of 500 TaTME cases which were performed in England from 2015-2020 from 15 centres (each centre performed more than 15 cases). 2-At Yeovil, I introduced this procedure which I do along with other colorectal surgeons. 3- At Yeovil, we performed 15 cases of this procedure.

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. Yes- see attached I have done research on this procedure in laboratory settings (e.g. device-related research). I have developed a training pathway for this procedure which has been widely used and was piloted/ validated in the lab settings. This has been highly cited as the agreed training curriculum for TaTME. I have attached the manuscript. I have done clinical research on this procedure involving patients or healthy volunteers. I have published the outcome of the pilot training centres (short term outcomes- see attached) and contributed to many of the publications of the international registry on TaTME outcomes. The main message of our research is that this procedure should be introduced according to a structured training programme and involves a formal mentorship period where an expert observe and assist the novice at their centre until they reach a safe independent level. We also designed the relevant objective assessment tools that can guide this transition and independency. I have published this research. Yes- see above 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):	TaTME is relatively a novel technique that has been clinically introduced over 10 years. It aims to improve the quality of cancer resection (clearance), especially in the lower 1/3 of rectal cancer. Technically, this operation is demanding and requires comprehensive experience in minimally invasive surgery as surgeons have to perform the trans anal part (the novel part) through a single port. Also, a formal training is required for this operation which includes formal mentorship prior to independent practice. We adopted this pathway in the national pilot training programme and we recommended it for safe dissemination of this technique. Definitely novel and of uncertain safety and efficacy. We are still awaiting results from large RCT (COLOR III) to provide high level evidence about the benefits and outcomes of this technique. In the meantime, the long term outcomes of the cases that were performed in the UK/ England requires an urgent audit and I would be very happy to discuss this further with you.

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?	I think this technique may have a role to complement (rather than to replace) the existing modalities, including open, laparoscopic or even robotic techniques of removing rectum.

Current management

5	Please describe the current standard of care that is used in the NHS.	As far as I am aware, the practice in the NHS of this procedure has largely stopped following the ACPGBI publications. The ACPGBI was not based on reviewing of the outcomes of the English/ British data but was a reactional statement, following the Norwegian paper in BJS (see attached).
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?	Not really. People confuse robotic techniques with TaTME. Robotic platforms make laparoscopic surgery easier to perform and is not a replacement of TatME. TaTME is an alternative approach of dissecting the lower part of the rectum, aiming to enhance cancer clearance. I could see in future, TaTME will be carried out robotically.

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?	Enhance cancer clearance of low rectal cancer tumours especially in obese male with narrow pelvis (with or without chemo radiotherapy) as it provides a wider view and better visualisation of dissection plans. Additionally, it can allow accurate division of the bowel distally with a potential lower rate of positive distal margins.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes- see point 7
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- should be performed in centres with expertise and the volume and surgeons undergo formal training and mentorship. Also, all cases must be audited in the national bowel cancer audit. The intention of this procedure is to improve clinical outcomes including cancer clearance, but this still to be proven in RCTs.
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 does not incur huge additional cost, a part from the Gel port for the transanal part of the procedure (appx £300) +/- airseal for insuflation.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	No relevant evidence regarding the cost effectiveness of TaTME compared with open or LaTME for adult patients with rectal cancer. The additional cost of this procedure include Gelport appx £300 +/- Airseal for insufflation. Traditionally two teams are required to complete the procedure (one team form the top and one team from the bottom) but this is not essential requirement.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Team training is fundamental for the trans anal part – hence a formal mentorship period is required.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes- our pilot programme showed mentorship of 5 cases was enough to significantly reduce the time of the entire operation – specifically the transanal part.

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	Early adopters of this technique encountered rare but serious complications such as urethral injuries and or gas embolism which were not witnessed with conventional anterior resection. With training, these complications can be completely avoided and the data proved this. Oncological concerns however have been raised about increased the rate of local/ regional recurrence following this operation. Pursestring failure has been suggested to be responsible for this risk which highlights the importance of mentorship during this early phase of the learning curve considering the importance of a reliable pursestring suture to avoid leakage of faecal materials and or cancer cells during the perineal dissection. Finally, there are reported relatively higher rate of anastomotic leak, but this again needs to be stratified properly within the context of the real indication of this operation _ low rectal cancer- male narrow pelvis/ high BMI with or without chemoradiotehrapy. Further research is required to compare the clinical outcomes including anastomotic leak of those patients and patients undergoing TaTME to provide a true evidence of the actual benefits/ harm.
15	Please list the key efficacy outcomes for this procedure/technology?	Improve the dissection view of the lower third of rectal cancer, with the wider, direct view and therefore possibly allowing better dissection, with early promising results. This should be measured by higher rate of R0 and distal margin clearance due to precision of the distal resection of the rectum in relation to the cancer
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	See above The main concern is related to the potential oncological safety (2year oncological outcomes), which needs to be evaluated in the UK/ England.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	A statement issued by the ACPGBI exec asking to pause the practice of this operation in the UK but was not underpinned by any evidence or data from the UK. Additionally, the TaTME working work in the UK felt that the statement was not discussed with any TATME experts (nether in the UK nor abroad) as none of the authors of the statement performed the procedure. This statement also did not provide any solution about the future of this operation in

		the UK and but negatively and currently there is a state of confusion among surgeons in England about this operation. Hence, all efforts are required to audit the data in England and answer the question of whether there is an oncological concern with the outcomes of UK patients or not.
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.	There are plethora of evidence about this procedure but I have attached a number of manuscripts which we have published on this topic including the results of the initial pilot training programme in the UK. I have also attached the manuscript from Norway and the ACPGBI paper for your information.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yes, the international registry which contains over 5000 cases worldwide

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an	Very hard to provide an accurate figure but according to the latest NBOCA 2020 data, 3899 patients underwent major resection for their rectal cancers. Approximately 1/3 or ¼ of those patients could benefit of this operation (between 700-1000 cases a year).

	estimated number, or a proportion of the target population)?	
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?	A multi-centre RCT (COLOR III) already recruiting and will answer all the oncological concerns about this operation, but until then we need to audit the national data in England with primary endpoint local/ regional recurrence at 2 years. Further research is required to address quality of life after TaTME
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: Sphincter preservation for low rectal cancer Adverse outcome measures: Rate of operative events (recorded according to the EAES classification of reporting on operative events). Rate of anastomotic leak at 30 days Functional outcomes at 1 and 2 years Oncological outcomes compared to all three modalities (open/ lap and robotic)- 2 and 5 year disease free survival, local recurrence and overall survival.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Many thanks for asking me to complete this report. I feel it is a timely task and a step forward towards solving the current dilemma with this technique in the UK. I would be very happy to work with you to try answer those questions to support the surgical practice in the UK for the safety of our patients.

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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.			

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:	**Nader Francis**
Dated:	**20th April 2020**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1184/2 - Transanal total mesorectal excision for rectal cancer**

Your information

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Organisation:	Cambridge University Hospitals NHS Foundation Trust
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Professional organisation or society membership/affiliation:	Co-Clinical Lead, National Bowel Cancer Audit; Past president, Association of Coloproctology of Great Britain and Ireland
Nominated/ratified by (if applicable):	By invitation
Registration number (e.g. GMC, NMC, HCPC)	4035495

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

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	Familiar with technology but have chosen not to use due to concerns raised about safety. Undertake rectal cancer surgery, both TME and beyond TME, within specialist practice at tertiary referral centre. Fearnhead NS, Acheson AG, Brown SR, Hancock L, Harikrishnan A, Kelly SB, Maxwell-Armstrong CA, Sagar PM, Siddiqi S, Walsh CJ, Wheeler JMD, Abercrombie JF; Association of Coloproctology of Great Britain, Ireland (ACPGBI) Executive, Getting It Right First Time (GIRFT). The ACPGBI recommends pause for reflection on transanal total mesorectal excision. Colorectal Dis. 2020 Jul;22(7):745-748. International expert consensus guidance on indications, implementation and quality measures for transanal total mesorectal excision. TaTME Guidance Group Colorectal Dis. 2020 Jul;22(7):749-755. Yes. No. Not applicable.

	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 published this research. See references above,
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):	Novel approach but there are other ways of delivering procedure. Definitely novel and of uncertain safety and efficacy.
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?	addition

Current management

5	Please describe the current standard of care that is used in the NHS.	Laparoscopic, open or robotic transanal mesorectal excision of rectal 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?	Robotic surgery Transanal procedure is carried out as dual surgeon procedure, one operating from abdominal approach and second from perineum

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?	Uncertain at this point
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Possibly
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?	Current international concern is about short and long-term adverse outcomes. Innovators have addressed these concerns with changes to procedure to try and reduce the learning curve and also mitigate against local recurrence with double purse-string technique.
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)?	Equivalent
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Training Equipment

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

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	Please see: Fearnhead NS, Acheson AG, Brown SR, Hancock L, Harikrishnan A, Kelly SB, Maxwell-Armstrong CA, Sagar PM, Siddiqi S, Walsh CJ, Wheeler JMD, Abercrombie JF; Association of Coloproctology of Great Britain, Ireland (ACPGBI) Executive, Getting It Right First Time (GIRFT). The ACPGBI recommends pause for reflection on transanal total mesorectal excision. Colorectal Dis. 2020 Jul;22(7):745-748. • Increased multifocal recurrence • Air embolism • Urethral injuries
15	Please list the key efficacy outcomes for this procedure/technology?	Complications Disease free survival PROMs
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Major safety concern raised by several countries including Norway, UK and Netherlands.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Efficacy of purse string in preventing tumour spillage in pelvis
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. But procedure has already been used in several low volume 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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	International transanal TME Registry – curator Mr Roel Hompes (incorporates original UK Registry curated by Pelican Centre, Basingstoke)

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% rectal cancer patients
22	Are there any issues with the usability or practical aspects of the procedure/technology?	
23	Are you aware of any issues which would prevent (or have prevented) this	Safety concerns

	procedure/technology being adopted in your organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	NCRAS has already offered to examine UK patient outcomes in International Registry
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: 1 and 3 year local recurrence rates Intra-operative complications 30 day morbidity and mortality

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.			

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Print name:	**Nicola Fearnhead**
Dated:	**17 March 2021**