

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Geeta Kumar"/>
Job title:	<input type="text" value="Consultant Gynaecologist"/>
Organisation:	<input type="text" value="Wrexham Maelor Hospital, BCUHB, N Wales"/>
Email address:	<input type="text" value="Click here to enter text."/>
Professional organisation or society membership/affiliation:	<input type="text" value="NA"/>
Nominated/ratified by (if applicable):	<input type="text" value="NA"/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="4577995"/>

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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2	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have done bibliographic research on this procedure.</p> <p>I have done research on this procedure in laboratory settings (e.g. device-related research).</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers.</p> <p>I have published this research.</p> <p>I have had no involvement in research on this procedure.</p> <p>Other (please comment)</p>
3	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>It's been in use now for quite a few years and deemed as the current standard and perhaps the only safe way of removing submucosal fibroids</p> <p>Established practice and no longer new.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p> <p>Definitely novel and of uncertain safety and efficacy.</p> <p>The first in a new class of procedure.</p>
4	<p>Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?</p>	<p>The only alternative of resection of fibroids with diathermy is now rarely used as far as I am aware and majority use hysteroscopic morcellation for submucosal fibroids using mechanical cutting</p>

Current management

5	Please describe the current standard of care that is used in the NHS.	As stated above
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?	Safe removal of submucosal fibroids for women with HMB, fertility issues, polyps etc to relieve symptoms—out-patient or day case avoiding hospital stay
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	As above
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?	As above Less invasive
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)	Same
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)?	Same
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Monitor outcomes, complications, use by trained staff only, use of standardised equipment

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, I expect this to be used by those trained in advanced hysteroscopic training
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Safety and efficacy of the procedure/technology

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>Uterine trauma, inability to remove fibroid completely, regrowth of fibroids, expulsion of fibroid polyp after partial resection</p> <p>? potential theoretical risk of spread of malignant tissue via tubal ostia into peritoneum</p>
15	Please list the key efficacy outcomes for this procedure/technology?	Visual confirmation of uniform uterine cavity & relief of symptoms
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	As above in 14
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As stated –theoretical adverse effect
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	<p>Most or all district general hospitals. ----By trained specialists</p> <p>A minority of hospitals, but at least 10 in the UK.</p> <p>Fewer than 10 specialist centres in the UK.</p>

		Cannot predict at present.
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Abstracts and ongoing studies

19	<p>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).</p> <p>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.</p>	
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	

Other considerations

21	<p>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)?</p>	NK but significantly high numbers
22	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	The technology in terms of actual instruments could do with some improvement and development e.g Myosure—which is widely used is rather cumbersome and not user-friendly but with lack of alternative options, remains the choice for many.

23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Research into recurrence rates and any difference in staging of subsequent endometrial carcinoma
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - 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: 	<p>Beneficial outcome measures:</p> <ol style="list-style-type: none"> 1) Symptom relief & improved QOL for women with HMB and submucosal fibroids 2) Hysterectomy rates amongst women treated with morcellation of fibroids within 5 years of initial surgery 3) Day case surgery rates of this procedure—expect to be 100% 4) Fertility rates post-morcellation of submucosal fibroids <p>Adverse outcome measures:</p> <ol style="list-style-type: none"> 1) Overnight admission due to excessive bleeding 2) Uterine perforation rates 3) Regrowth of fibroids within 2 years of initial surgery

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I use this regularly in my practice and find it very helpful. The only change I would like to see is – ease of instrumentation as the existing device (one of them -Myosure) is very effective but mechanically cumbersome to use. Refinements are in progress as I understand.
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Declarations of interests

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

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

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

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

Print name:	<input type="text" value="Geeta Kumar"/>
Dated:	<input type="text" value="8.12.2020"/>

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1056/3 - Hysteroscopic morcellation of uterine fibroids

Your information

Name:	Dr.S.Arutchelvam
Job title:	Consultant
Organisation:	Mid Cheshire Hospital NHS Foundation Trust
Email address:	
Professional organisation or society membership/affiliation:	RCOG BSGE
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	5202559

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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

<p>1 Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none">- 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.	<p>Yes. Practicing for the last 2 years</p> <p>Currently using it</p> <p>Currently many trusts are performing the procedure</p> <p>The speed of uptake will be high</p> <p>No</p>
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2	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	I have done bibliographic research on this procedure.
3	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>Novel Approach. Can be performed in outpatient ambulatory settings</p> <p>Definitely novel and of uncertain safety and efficacy.</p>
4	<p>Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?</p>	Yes. It can replace the current standard of care

Current management

5	<p>Please describe the current standard of care that is used in the NHS.</p>	Trans Cervical Resection of Fibroid as day case in theatre
6	<p>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?</p> <p>If so, how do these differ from the procedure/technology described in the</p>	<p>TCRE</p> <p>Hysteroscopic resection of fibroid involves only mechanical morcellation rather than diathermy used in TCRE. Needs only single insertion. Risk of complications like thermal injury is nil</p>

briefing?	
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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?	Can be performed in outpatient setting and well tolerated. Avoids GA .Fewer Hospital visits.Rapid recovery.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients unfit for GA. Patients not keen on undergoing major invasive procedure like Hysterectomy
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 Definitely improve clinical outcome and cost effective to the health care system
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)	From my experience ,did find most patients are tolerating the procedure very well in outpatient settings and cost effective
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)?	Staff and Care setting is the same. Needs initial investment in equipment
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Procedure can be performed without need to change any existing facilities
13	Is any specific training needed in order to	Yes.

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

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>Fluid overload</p> <p>Risks of injury to uterus and internal organs</p> <p>So far no untoward adverse events happened in my experience</p> <p>? Risk of malignancy spread</p>
15	Please list the key efficacy outcomes for this procedure/technology?	Symptoms relief and Improved QOL
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	-
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	-
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

19	<p>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).</p> <p>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.</p>	-
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	-

Other considerations

21	<p>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)?</p>	Depending on the case load in the population
22	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	Nil
23	<p>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?</p>	No

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Yes regarding? spread of malignancy
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - 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: 	<p>Beneficial outcome measures:</p> <p>3,6 and 12 month FU to review symptoms Patient questionnaire regarding symptom relief and satisfaction</p> <p>Adverse outcome measures:</p> <p>Early :3 and 6 months Late: Yearly</p>

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	From my experience find it useful and safe procedure
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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.	nil		
Choose an item.			
Choose an item.			

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Print name:	Dr.Satthiyabam Arutchelvam
Dated:	29/12/20