NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Abu Imad Hasib Ahmed
Job title:	Consultant Obstetrician and Gynaecologist
Organisation:	Medway NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	RCOG 105025 BSGE 536 GMC 3167957
Nominated/ratified by (if applicable):	BSGE 536
Registration number (e.g. GMC, NMC, HCPC)	GMC 3167957

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

I consent to this

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 V-NOTES and am awaiting Organisational Governance learance to introduce the technique at our hospital. I have assisted in a number of cases and I will be setting up a proctored list at Medway in the near future. I have assisted in cases with a UK Expert Mr Elias Kovoor. I am in the process of introducing the technique at Medway Maritime Hospital, Gillingham, Kent. The technique is available at our neighbouring Darenth Valley Hospital. It is also available at Kings College Hospital and Homerton Hospitals, London. I would expect fast uptake of the technique as the patient benefits are easily apparent, no abdominal incisions, early discharge and reduced analgaesic requirement. The technique is the subject of an RCT at Darenth Valley Hospital. Similar technology is used in colorectal surgery. My speciality will be performing the technique after formal introduction. I and a colleague have received hands-on training and we will be proctored by Mr Elias Kovoor.

	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. 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):	A minor variation on an existing procedure, which is unlikely to alter the procedure's 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?	Yes, V-NOTES should replace other forms of benign laparoscopic hysterectomy except when access to the Pouch of Douglas is not possible, e.g. in cases of rectovaginal endometriosis.

Current management

5	Please describe the current standard of care that is used in the NHS.	The current standard is laparoscopic or open hysterectomy.

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?	An alternative to V-NOTES hysterectomy will be Robotic Hysterectomy but there is much more equipment required at significant cost. The Robotic technique requires many laparoscopic ports with a bespoke theatre set-up.

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?	
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	
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?	
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)	
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)?	
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	

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

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	
15	Please list the key efficacy outcomes for this procedure/technology?	
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. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK.

		Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

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)?	
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 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?	
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.			

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Print name:	**Abu Imad Hasib Ahmed**
Dated:	**15/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Elias kovoor
Job title:	Consultant in Obstetrics and Gynaecology
Organisation:	Darent Valley Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	RCOG, GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC- 6063474

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1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	Familiar with the technique. I do this routinely in my practice – roughly 20-24 cases per year I have also trained 3-4 other consultants in our unit.

	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):	**Hysterectomy and Adenextomy via transvaginal natural orifice transluminal endoscopic surgery (vNOTES): A UK perspective with a case series of 33 patients** Rebecca Karkia[1], Tara Giacchino[2], Jody Taylor[2], Ammara Ghaffar[2], Abishek Gupta[2], Elias Kovoor[2] Currently doing an RCT on V NOTES hysterectomy vs Total lap hysterectomy- In the recruitment stage,
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):	A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. This involves vaginal and laparoscopic approach combined together into one approach.
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 could replace laparoscopic hysterectomies for benign conditions excluding endometriosis. It could also replace laparoscopic assisted vaginal hysterectomies which involves additional laparoscopic approach through the abdomen to remove ovaries and tubes

Current management

5	Please describe the current standard of care that is used in the NHS.	Currently this procedure is offered to selected patients. Pre op and post op care is same as any laparoscopic hysterectomies. Specific patient information in the form of leaflets are given to patients at the time of couselling

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?	Yes Laparoscopic total hysterectomies and Laparoscopic assisted vaginal hysterectomies

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?	Less pain, quicker procedure, no abdominal incisions hence quicker return to normal activities
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	All patients having hysterectomy for benign conditions and stage 1 endometrial and cervical cancers. Excluding endometriosis, large fibroids, significant pelvic adhesions, rectal surgery Particularly useful for patients with high BMI as in endometrial hyperplasias and stage 1 endometrial cancer Also particularly useful for patients with previous midline laparotomies, hernia repairs with mesh where significant anterior abdominal wall adhesions are expected and would make a laparoscopic approach more difficult
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- the main benefits are less pain, quicker recovery and less operating time .
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)	Cost is same as laparoscopic hysterectomies but if you consider the shorter operating times and the use of only one assistant rather than 2 for laparoscopic hysterectomies, then its cheaper than laparoscopic hysterectomies. Please see my table for cost comparision- please check operating time and cost of second assistant

			TLH **12mm trocar- £20** **5mm trocar x3- £25** **Manipulator- £ 40** **Suction irrigation- £11** **Vessel sealer-(ligasure) £383** **Stratifix- £37** **Total cost- £ 516**	**V note** **Gelport- £237** **Vessel** **Sealer- £ 383 (ligasure only or just bipolar as cannot use thunderbeat)** **Total cost- £620** **Time saved- 15-20mts (based on RCT)- which translates to at least £200** **So actual cost would be £420** Cost of second assistant- SHO rates 55/hr

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 impact
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Only equipment
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?	Risks are same as any hysterectomies- ie infection, bleeding, injuries.

	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	Bladder injuries- 1-2 in 100 Ureteric- 1 in 100 Bowel- 1 in 100 Of the total 250 (approx.) cases 2 bladder perforations- all repaired uneventfully 2 ureteric injuries- one required stent and the other required re implantation One intra op bowel injury- repaired laparoscopically- uneventful outcome
15	Please list the key efficacy outcomes for this procedure/technology?	Conversion rates,(conversion to laparoscopy, or vaginal or laparotomy), complication rates
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	nil
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):	All hospital-

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	• HALON-hysterectomy by transabdominal laparoscopy or natural orifice transluminal endoscopic surgery: a randomised controlled trial (study protocol). Baekelandt J, De Mulder PA, Le Roy I, Mathieu C, Laenen A, Enzlin P, Weyers S, Mol BW, Bosteels JJ.BMJ Open. 2016 Aug 12;6(8):e011546. doi: 10.1136/bmjopen-2016-011546.PMID: 27519922 **Free PMC article.** Clinical Trial.

	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.	• Adnexectomy by vaginal Natural Orifice Transluminal Endoscopic Surgery versus laparoscopy: results of a first randomised controlled trial (NOTABLE trial). Baekelandt J, De Mulder PA, Le Roy I, Mathieu C, Laenen A, Enzlin P, Morlion B, Weyers S, Mol B, Bosteels J.BJOG. 2021 Oct;128(11):1782-1791. doi: 10.1111/1471-0528.16838. Epub 2021 Jul 27.PMID: 34246198 Clinical Trial. • Hysterectomy by transvaginal natural orifice transluminal endoscopic surgery versus laparoscopy as a day-care procedure: a randomised controlled trial. Baekelandt JF, De Mulder PA, Le Roy I, Mathieu C, Laenen A, Enzlin P, Weyers S, Mol B, Bosteels J.BJOG. 2019 Jan;126(1):105-113. doi: 10.1111/1471-0528.15504.PMID: 30325565 Clinical Trial. • Postoperative outcomes and quality of life following hysterectomy by natural orifice transluminal endoscopic surgery (NOTES) compared to laparoscopy in women with a non-prolapsed uterus and benign gynaecological disease: a systematic review and meta-analysis. Baekelandt J, De Mulder PA, Le Roy I, Mathieu C, Laenen A, Enzlin P, Weyers S, Mol BW, Bosteels JJ.Eur J Obstet Gynecol Reprod Biol. 2017 Jan;208:6-15. doi: 10.1016/j.ejogrb.2016.10.044. Epub 2016 Oct 29.PMID: 27880893 Review. • Systematic Review and Meta-Analysis on Hysterectomy by Vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) Compared to Laparoscopic Hysterectomy for Benign Indications. Housmans S, Noori N, Kapurubandara S, Bosteels JJA, Cattani L, Alkatout I, Deprest J, Baekelandt J.J Clin Med. 2020 Dec 7;9(12):3959. doi: 10.3390/jcm9123959.PMID: 33297354 **Free PMC article.** Review.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	NOVEL study – RCT considering quality of recovery for V NOTES vs Laparoscopic hysterectomies. Currenlty in recruitment stage

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)?	10-15% of hysterectomies
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Yes – needs 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?	Training Experience in vaginal/ laparoscopic hysterectomies
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	
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

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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.			

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Print name:	**Elias kovoor**
Dated:	**31/01/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Click here to enter text. Haissam Moukarram
Job title:	Click here to enter text. Consultant Gynaecologist
Organisation:	Click here to enter text. North Cumbria Integrated Care
Email address:	Click here to enter text. [redacted]
Professional organisation or society membership/affiliation:	Click here to enter text. BSGE
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. 6040479

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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 have started doing the v NOTE surgery since March 2022. Currently doing the procedure independently.
	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	There is wide interest in the procedure No

	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 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.
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 will be used as an addition to existing standard of care

Current management

5	Please describe the current standard of care that is used in the NHS.	The current standard of care is abdominal laparoscopic approach

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- Less post operative pain 2- same day discharge 3- less risk of operative complications
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Increased BMI Patients who have abdominal surgery(to avoid abdominal entry)
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 Less post operative pain
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)	Potentially less cost as it requires 1 assistant compared to 2 assistants in the abdominal laparoscopic route
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)?	Almost same cost of equipment but less staff involved. Earlier discharge with potential savings.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	none

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

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	Less post operative and intra operative complications compared to Laparoscopic and abdominal route.
15	Please list the key efficacy outcomes for this procedure/technology?	Less post operative pain Potential better patient satisfaction
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Uncertain: the use for oncology procedures
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The use for oncology patients
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	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.	ESGE BSGE
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not aware

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)?	About 100 patients in a general district hospital
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	Not suitable for patients with severe endometriosis or severe PID

	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?	Use for oncology patients
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: Post operative pain score Time to discharge from hospital Complication Cosmetic satisfaction for patients(no abdominal incisions) Adverse outcome measures: Early (first 2 weeks) 1-Post operative infection 2-ureteric, bladder, and bowel injury 3- bleeding, 4- VTE Late: after 2 weeks Infection Hematomas VTE Dyspareunia

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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Choose an item.			

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Print name:	**Click here to enter text.haissam moukarram**
Dated:	**Click here to enter text.15/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Mr Hany Habeeb
Job title:	Consultant Gynaecological Surgeon
Organisation:	The Medway Maritime Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Society of Gynaecological Endoscopy (BSGE)- British Society of Gynaecological Imaging- British Society of Gynaecological Ultrasound.
Nominated/ratified by (if applicable):	BSGE
Registration number (e.g. GMC, NMC, HCPC)	4396545

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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 a Gynaecological surgeon of twenty five years of experience both in advanced laparoscopic and vaginal surgery. I have been receiving information from some colleagues who have trialled the procedure in their own institutions and also I received a video showing the procedure in details from a friend who is practising overseas. I have not personally used the technique. Having spoken with several colleagues who have been involved in this procedure, the reports seems encouraging. However, the indications, safety and comparison with existing techniques are yet to be determined.

	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 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):	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?	No but it will be an alternative in certain cases.

Current management

5	Please describe the current standard of care that is used in the NHS.	Currently, there are three hysterectomy techniques used in gynaecological practice. These are abdominal, vaginal and laparoscopic. The choice of the hysterectomy type depends on the indication and surgeon's experience.

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 alternatives but as mentioned above. However, it would be good to add more as different patients will need different approaches.

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?	It will provide a minimally invasive approach through a natural orifice and without abdominal scars.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	May be suitable for women who are at high risk of abdominal/ laparoscopic hysterectomy due to medical co-morbidities.
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?	The procedure will increase the number of patients who can have a hysterectomy and who in the past may have been denied the procedure due to factors such as raised BMI. It will modify the current pathway and also improve patient's outcome by virtue of quick recovery.
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)	Although I don't know the exact cost, I think it will be comparable to the standard total laparoscopic hysterectomy.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	The procedure will take longer to perform at the beginning as with all new techniques. This may impact on theatre time and efficiency until the surgeons are up to speed with the procedure. This may take one to two years.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Due to the anticipated longer time the procedure will take, it would be advisable to provide more theatre time and space during the learning phase.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, in line with any new procedure. The surgeons also need to be familiar with vaginal surgery as well.

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	The risks are the same as any other hysterectomy type. In my view, potential difficulties may be encountered if there are unexpected adhesions. These difficulties can be avoided in the laparoscopic hysterectomy.
15	Please list the key efficacy outcomes for this procedure/technology?	Improving access in a difficult vaginal hysterectomy
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Length of stay Recovery time
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	More clarity is needed regarding indications
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..

		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.	I am not aware of any recent abstracts related to the subject bur I am aware of a meta analysis which showed no difference in the outcomes between this procedure and the standard techniques.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not known

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)?	I work in a large DGH . I would expect around 30 cases every year to be eligible for the procedure.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The equipment used will be disposable. The staff needs to be trained in order to support the surgeons whilst operating.

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?	Not known
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	More randomised trials
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. Recovery time 2. Ergonomics 3. Blood loss Adverse outcome measures: 1. Intra/ postoperative complications 2. Duration of procedure 3. Future pelvic organ prolapse
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,	None

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
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:	**Mr Hany Habeeb**
Dated:	**19/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Dr Inna Sokolova MSc FRCOG
Job title:	Consultant Gynaecologist
Organisation:	NHS Ayrshire and Arran
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Obstetricians and Gynaecologists, General Medical Council, British Society of Gynaecological Endoscopy, European Society of Gynaecological Endoscopy, British Society of Urogynaecologists , International Urogynaecology Association
Nominated/ratified by (if applicable):	BSGE
Registration number (e.g. GMC, NMC, HCPC)	6063527

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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 familiar with the vaginal natural orifice transluminal endoscopic surgery (vNOTES) procedure as I started introducing it into my practice in 2019. Having performed all types of laparoscopic hysterectomies and adnexal surgery for over 10 years as consultant, both in NHS and privately, I saw some advantages in this technique. After completing my MSc degree in advanced gynaecological endoscopy with Merit, I successfully introduced single-port laparoscopic surgery into my practice 5 years ago. As a urogynaecologist, it was only natural for me to consider vNOTES as a vaginal single port surgery. I initially arranged several supervised training sessions with one of the early adopting surgeons, who is experienced in this technique. This short-term apprenticeship followed the attendance of the partially sponsored industry webinar and workshop on this procedure. I am now confident in performing this procedure independently and incorporated it into my routine surgical practice. The learning curve, however, may be variable in different situations.
	Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the	I would expect that between 10-15 surgeons in the UK have already incorporated the vNOTES technique into their surgical practice. Currently I am the only surgeon employing this technique in Scotland. I expected the speed of uptake to be high, however, it slowed down due to the pandemic. Industry continues to promote the technique with regular training courses. The sponsored workshops are usually attended by at least 12 surgeons at a time.

	NHS or what is the likely speed of uptake?	Therefore, with the NHS recovery from the pandemic I would expect the speed of introduction to catch up.
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	This procedure is only performed by gynaecologists. No other disciplines are involved in patient selection for this procedure.
	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	Patient selection is highly important for this procedure. This approach works best for patients with mobile uterus and has added benefits for both the patient and the surgeon in cases of high BMI, large fibroids and adnexal cysts and masses. However, patients who have conditions which can obliterate the pouch of Douglas e.g., endometriosis, may not be the perfect candidates for the vNOTES approach that requires full access to this pouch.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done my own Bibliographic research on this procedure, and I am prospectively collecting the data for my “learning curve audit”. The data will help provide a real-world example of how this procedure could be incorporated into clinical practice.
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?	This procedure represents a novel approach and requires proficiency in both laparoscopic and vaginal surgery techniques. While this procedure follows the same steps as total laparoscopic hysterectomy, the sequence is in a reverse order.
	Which of the following best describes the procedure (please choose one):	I feel this procedure should be classified as” Definitely novel and of uncertain safety and efficacy” however a gynaecological surgeon who is proficient in both single-port laparoscopic surgery and vaginal surgery may consider this as a minor variation of their existing procedures.
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?	This procedure has the potential to be a very useful addition to the existing standard of care. It is expected to have the same efficacy as the standard procedure with the added benefit of better visualisation and less risks e.g., better safety. The added cost however may be prohibitive of a large scale roll out.

Current management

5	Please describe the current standard of care that is used in the NHS.	The current standard of care that this technique may compete/ complement is a laparoscopic abdominal surgery. This leads, comparatively, to abdominal scars and significant abdominal trauma. For select group of patients, the vaginal approach may be more appropriate, for example in the case of uterine prolapse. The vaginal approach is limited in removal of the ovaries particularly if there are pelvic adhesions and removal of the uterus itself particularly in the presence of the fibroids.
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 is no other natural orifice approach to hysterectomy and adnexectomy other than vNOTES. However, there is a single-port laparoscopic approach to hysterectomy and adnexal 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?	Intraoperative: potentially shorter duration of surgery Immediate postoperative: less pain, less use of painkillers, potentially shorter hospital stay. Long term postoperative: no abdominal scars, no risk of abdominal incisional hernia, potentially quicker return to daily activities.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with high BMI would be a particular group that would benefit from this technique as it allows to mitigate some of the increased risks of laparoscopy associated with high BMI. Patience with large fibroid uterus, particularly if there are suspicions of malignancy, would also benefit from this technique as morcellation is done by cold knife rather than using a mechanical morcellator, therefore the risk of up-staging with vNOTES is almost non-existent. Women with COPD, for example, may also be a group who benefits from the vNOTES as it does not require steep head down tilt like the TLH procedure, which may compromise their cardiopulmonary function.
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?	The procedure has the potential to change the current pathway by adding an intermediate step between a standard vaginal operation and a total abdominal/ laparoscopic approach. The procedure is certainly less invasive than the total laparoscopic hysterectomy. It is however as invasive as the vaginal hysterectomy procedure, but with the added benefit of better visualisation to deal with technically difficult situations for example extensive pelvic adhesions or large fibroid uterus or high BMI or ovarian cysts. Outcomes in terms of recovery are expected to be better, particularly for the group of patients mentioned above. It could therefore lead to shorter hospital stay and quicker return to normal activities.

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)	While the equipment will cost more in comparison to vaginal hysterectomy, such costs are expected to be similar to those of total laparoscopic hysterectomy.
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)?	See above
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	There are no needs to change clinical facilities to perform this approach safely. Training of surgeons and theatre assistant and scrub nurse will however be required.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	See above

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)	List of adverse events: • There does not appear to be any adverse events inherent to the use of the vNOTES device itself. • However, all the adverse events that had already been reported with the vaginal hysterectomy and the total laparoscopic hysterectomy procedure have also been reported with the vNOTES approach. • In the HALON trial, 1 out of 35 patients (3%) in the vNOTES group suffered a bladder injury.

	Theoretical adverse events	The vNOTES procedure had been reported to be associated with relatively higher risk of bladder damage. The literature is not clear on the mechanism by which this damage occurs. In my view, bladder dissection away from the cervix and the lower part of the uterus is the step at which bladder damage could take place. I suspect this is a skill-related incident, and it should not be an issue with experienced surgeons. In any case, repair of bladder damage should not have any long-term problem for the patient.
15	Please list the key efficacy outcomes for this procedure/technology?	• Operating time • Use of painkillers • Length of hospital stay • Return to normal activities • Risk of wound infection • Estimated blood loss • Post hysterectomy prolapse • Risk of incisional hernia
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Efficacy is expected to be largely the same as the standard treatment. There will be safety issues if this technique is introduced without proper training for example bladder injury, in terms of organ damage for example.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The only controversy is the perception of increased costs if used for routine standard procedures that may not require this approach. The learning curve duration remains a controversy and it depends on several factors, mainly the prior skill of the surgeon.

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.	I recently attended an annual conference of ESGE in Lisbon in October 2022 and the following abstracts were presented on this procedure: **Sentinel node biopsy by retroperitoneal transvaginal natural orifice transluminal endoscopic surgery (vNOTES) in gynaecological malignancies: technique description and perioperative outcomes** *Yannick Hurni[1], Clarisse Peter[2], Daniela Huber[1,2]* **Vaginal natural orifice transluminal endoscopic surgery (vNOTES): a prospective multicentre study to evaluate feasibility and post-operative outcome** *Francesca Massimello[1], Maria Lieta Interdonato[2], Paolo Mannella[1], Paolo Scollo[3], Mario Giuseppe Meroni[2], Tommaso Simoncini[1]* **Initial experience of V-NOTES in gynaecology** *Estela Marquez Muñoz[1], Antoni Pessarrodona Isern[2], Ana Paula Velez Vintimilla[1], Jordi Cassado Garrida[3], Marta Hinarejos Companyo[1], Jordi Rodriguez Gonzalez[3]* **How to solve obstacles in initial cases of vaginal NOTES hysterectomy: Indonesia experience** *Ferry Darmawan[1], Ichnandy Arief Rachman[2]* **Vaginal natural orifice transluminal endoscopic surgery (vNOTES): a prospective multicentre study to evaluate feasibility and post-operative outcome** *Francesca Massimello[1], Maria Lieta Interdonato[2], Paolo Mannella[1], Paolo Scollo[3], Mario Giuseppe Meroni[2], Tommaso Simoncini[1]*
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)?	NHS Digital data showed that nearly 8500 vaginal hysterectomy procedures and over 26000 abdominal hysterectomies were performed in England & Wales in 2019-2020. It is expected that at least 20% of these women would be eligible and would benefit from the vNOTES procedure.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Training remains a key issue for this procedure. While the manufacturer will confirm it is easy to learn, the learning curve is highly variable and is inevitably associated with at least intra operative adverse events initially. It is necessary that surgeons who perform this procedure should be proficient in the standard laparoscopic technique as well as the vaginal approach. It is however desirable that surgeons have experience with single port laparoscopy.
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?	Training will be the prohibitive factor to prevent this procedure form being widely adopted. While there were no issues in introducing this procedure in my hospital, I would expect a relatively lower skill level of training in laparoscopic surgery and/ or vaginal surgery to slow down the introduction of this procedure and with the potentially increased risk of intra operative organ damage.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	An adequately powered RCT of standard vaginal hysterectomy or laparoscopic hysterectomy and/ or adnexal surgery and vNOTES. Investigate the digital solution for data collection. A procedure code needs to be created which will facilitate that retrospective audit of the procedures performed all over the UK.
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	Beneficial outcome measures: Operation time Length of hospital stay Return to normal activities Pain score (pain questionnaire)

	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:	Use of painkillers Body image impact Recurrences of ovarian cysts Improvement in quality-of-life questionnaire in relation to heavy menstrual bleeding, pelvic organ prolapse and pelvic pain Residual ovary syndrome Adverse outcome measures: Intra operative organ damage Post hysterectomy vault prolapse Blood loss Return to theatre Conversion to laparotomy or laparoscopy Development of hematoma Wound infection
26	Is there any other data (published or otherwise) that you would like to share with the committee?	N/A

Further comments

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

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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
Non-financial professional	I attended the vNOTES training course partially sponsored by Applied Medical (the manufacturer of GelPoint used in vNOTES procedure)- the company sponsored travel and accommodation and I self-funded the course fee.	**September 2021**	**September 2021**
Non-financial professional	Applied Medical sponsored my mentor for vNOTES procedure to facilitate my first apprenticeship session in my hospital.	**December 2021**	**December 2021**
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 Inna Sokolova**
Dated:	**14/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Mayank Madhra
Job title:	Consultant Obstetrician and Gynaecologist
Organisation:	NHS Lothian
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6134694

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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	Currently working in a tertiary BSGE-accredited endometriosis centre. Ongoing clinical workload with advanced/complex laparoscopy focused on benign gynaecology.

	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 had no involvement in research on this procedure.
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):	A minor variation on an existing procedure, which is unlikely to alter the procedure's 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?	In addition to.

Current management

5	Please describe the current standard of care that is used in the NHS.	Laparoscopic or laparoscopic assisted surgery is the current standard.

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?	Nil.

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?	Less pain and faster recover compared to current standard.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	More elderly/co morbid. In theory helpful for all.
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?	Probably not, based on the way the procedure is described in the attached documentation. I might be harder to give local anaesthetic with this procedure compared to current standard.
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)	About the 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)?	Learning curve. Time equivalent in theatre after this, and the gain might be in length of stay and time of return to work.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Minimal changes required.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	This should probably be undertaken initially by consultants with both urogynaecological and laparoscopic experience.

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 advertent rectal injury with placement of laparoscope in women with obliteration of Pouch of Douglas. This seems better to suited to women with smaller adnexal masses. Conversion to standard laparoscopic approach in the event of compilations might avoid conversion to laparotomy in some cases.
15	Please list the key efficacy outcomes for this procedure/technology?	?
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?	No.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	-
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

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)?	Perhaps 30% of women undergoing laparoscopic hysterectomy.
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 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?	
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,	-

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
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:	**Mayank Madhra**
Dated:	**05.12.2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Mohamed Shahin
Job title:	Consultant Obstetrician & Gynaecologist
Organisation:	University Hospitals of north Midlands NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC, BSGE
Nominated/ratified by (if applicable):	BSGE
Registration number (e.g. GMC, NMC, HCPC)	GMC 7175650

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?	I am familiar with the vNOTES as I was following progress over the last 5-6 years and attending relevant webinars and meetings from various societies and countries. I did the theory and simulation training on the currently marketed device in UK. I am fully aware of the technical steps, challenges, troubleshooting, managing complications, … etc related to the procedure.
	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 aware that few hospitals in the UK are already using it. The main limiting factor to the speed of uptake is having trained consultants who have experience, skill and attitude in both vaginal and laparoscopic surgery (With some mental readiness with single port orientation). The main problem is that Laparoscopic surgery replaced a lot of vaginal surgery (despite the evidence of cost and safety of vaginal surgery over laparoscopic). The principles of NOTES surgery is used but other specialties and I am aware that Colorectal surgeons use the similar devices for NOTES surgery. There are rNOTES, uNOTES, gNOTES, … etc.

	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):	The vNOTES is hybrid procedure between laparoscopic and vaginal surgery. It needs both skills and knowledge of procedure. It needs some adjustment to the technique and orientation to the anatomy and procedure from the vaginal aspect. It provides all the benefits of laparoscopic and vaginal surgery, with quick recovery, les pain, but with the addition of avoiding any abdominal wall skin incisions and avoids laparoscopic entry complications (which is the main laparoscopic risk). Established practice and no longer new. √ **A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.** Definitely novel and of uncertain safety and efficacy. The first in a new class of procedure.

4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It would be used as an addition not as a replacement of current procedures. So, likely Hysterectomy would be VH, if no suitable, think vNOTES, if not suitable, then think TLH, ….etc.

Current management

5	Please describe the current standard of care that is used in the NHS.	Current standard is Vaginal Hysterectomy if no contraindications, otherwise laparoscopic hysterectomy (which is overutilized at the expense of vaginal hysterectomy). For adnexal surgery: Laparoscopic management is the current standard in UK.
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?	I am not aware of any, but the early attempts were using surgical gloves (in low resources countries). There is a company that is marketing a device that is specifically made for vNOTES 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?	– Less wound infection – Fewer abdominal wall hernias – Less abdominal wall pain – No trocar-related complications – Quicker recovery – Shorter hospitalization – Reduced healthcare costs – Better Ergonomics – Ability to remove fallopian tubes and ovaries – Reduced complications related to prior abdominal surgery
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Abnormal Uterine bleeding and Heavy menstrual bleeding. Endometrial hyperplasia Raised BMI
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, it can improve outcomes as above. – Cosmetic results – No trocar site complications – No abdominal wall trauma – One assistant – Better ergonomics – No adhesiolysis needed in case of previous abdominal surgery
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)	It can cost the same or less than the current procedure (compared to laparoscopic procedures) with the main cost saving on the uterine manipulator and vaginal cuff device e.g. McCartney tube. But, a straightforward vaginal hysterectomy is still the most cost effective option. It is important not to get the vNOTES to replace VH which will add to the costs and risks. The aim of vNOTES is to extend the indications of VH and overcome some of limitations of VH.

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)?	It can cost the same or less than the current procedure (compared to laparoscopic procedures) with the main cost saving on the uterine manipulator and vaginal cuff device e.g. McCartney tube.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Same operating theatres and same trays. There is an option to modify a custom operating theatre set for vNOTES if there is a regular caseload.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, this is the most important aspect: 1- Good Vaginal surgery experience, competent and regular Vaginal Hysterectomy . 2- Good Laparoscopic experience, preferably with awareness to single port surgery. 3- Full simulation and training in using the device of choice for vNOTES. 4- Proctorship/Mentor to support the implementation and first few cases.

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	Same adverse events for Vaginal Surgery / Vaginal Hysterectomy: Bleeding, infection, organ injury (the most common is bladder injury), bowel or ureter. Vaginal wound complications and dehiscence.
15	Please list the key efficacy outcomes for this procedure/technology?	

16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The main concern is the tendency to use it to replace a straightforward vaginal hysterectomy.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	I am not aware of any.
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.	**HALON trial: Hysterectomy by transvaginal natural orifice transluminal endoscopic surgery versus laparoscopy as a day-care procedure: a randomised controlled trial** Authors: Baekelandt J et al., British Journal of Obstetrics and Gynecology, 2019 Study Design: RCT (Level 1), Population: N=70 **Systematic review and meta-analysis on hysterectomy by vaginal natural orifice transluminal endoscopic surgery (vNOTES) compared to laparoscopic hysterectomy for benign indications** Authors: Housmans S et al., Journal of Clinical Medicine, 2020 Study Design: Systematic Review (Level 1) **Hysterectomy by transvaginal natural orifice transluminal endoscopic surgery (NOTES): a series of 137 patients** Authors: Lee CL et al., Journal of Minimally Invasive Gynecology, 2014 Study Design: Prospective observational study (Level 2), Population: N=137 **The comparison of surgical outcomes following laparoscopic hysterectomy and vNOTES hysterectomy in obese patients**

		Authors: Kaya C et al., Journal of Investigative Surgery, 2021 Study Design: Cross-sectional study (Level 4), Population: N=83 **Benign gynaecological procedures by vaginal natural orifice transluminal endoscopic surgery (vNOTES): Complication data from a series of 1000 patients** Authors: Baekelandt J & Kapurubandara S, European Journal of Obstetrics & Gynecology and Reproductive Biology, 2020 Study Design: Prospective observational study (Level 2) **NOTABLE trial: Adnexectomy by vaginal natural orifice transluminal endoscopic surgery versus laparoscopy: results of a first randomised controlled trial** Authors: Baekelandt J et al., British Journal of Obstetrics and Gynecology, 2021 Study Design: RCT (Level 1), Population: N=67 **vNOTES hysterectomy for large uteri: a retrospective cohort study of 114 patients** Authors: Nulens et al., Journal of Minimally Invasive Gynecology, 2020 Study Design: Retrospective cohort study (Level 3), Population: N=114 **Consensus on safe implementation of vaginal natural orifice transluminal endoscopic surgery (vNOTES)** Authors: Kapurubandara S et al., European Journal of Obstetrics & Gynecology and Reproductive Biology, 2021 Study Design: Expert opinion (Level 5)
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not I am aware of.

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)?	I think it can take 30% of Laparoscopic Hysterectomy cases to be done vNOTES instead. Same applies to the adnexal surgery initially.

22	Are there any issues with the usability or practical aspects of the procedure/technology?	As above.
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?	Will best need to have a database / 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: – Pain scores. – Discharge home. – Return to activities. Adverse outcome measures: – Conversion to Laparoscopic surgery – Return to theatre – Excessive bleeding – Failed procedure – Organ damage
26	Is there any other data (published or otherwise) that you would like to share with the committee?	None

Further comments

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

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Indirect	I have attended a Hands-on 2 days course that was organised by a group of consultants with the support of Applied medical. I approached to book the course for my learning and training development rather than being approached by the company representative. **I paid for the course in full** from my Trust Study budget as the company does not sponsor the course. The company provided the refreshments and meals during the course as well as accommodation (within the reasonable expenses/hospitality as set out by NICE.		
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:	**Mohamed Shahin**
Dated:	**25/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)

Your information

Name:	Oscar Barnick
Job title:	Obstetric and Gynaecology Speciality Registrar ST5
Organisation:	Maidstone and Tunbridge Wells NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC, BSGE
Nominated/ratified by (if applicable):	BSGE
Registration number (e.g. GMC, NMC, HCPC)	GMC - 7496852

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 have 2 years of experience working with a Consultant (Elias Kovoor) at Darent Valley Hospital, who was the first consultant in the UK and NHS to be performing these operations. I have assisted in at least 30 of these operations as first or second assistant. I have attended a vNOTE course run by Applied Medical teaching new Consultants how to perform the operation. I then helped a new Consultant from a different trust set the procedure up at his unit and assisted him in the first few operations. I am aware that it is not widely used in the NHS, and that uptake has been quite slow.

	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, as part of an MCh in Surgery of O&G I have done clinical research on this procedure involving patients or healthy volunteers as part of an ongoing RCT at Darent Valley Hospital. The results are not yet published.
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 in The Netherlands, but in the UK it is novel to many.
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 used as an additional type of operation offering surgeons and patients a choice in the route of surgery for common operations including hysterectomy and adnexal surgery. It would not replace traditional laparoscopic or open routes completely.

Current management

5	Please describe the current standard of care that is used in the NHS.	Laparoscopic, laparoscopic vaginal assisted or open procedures.

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 aware of any.

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?	No visible scars, reduced post operative pain, faster healing, reduced blood loss
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Obese patients in whom abdominal access is difficult. Multiparous patients who require hysterectomy and adnexectomy
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, it could be expected to lead to reduced length of stay in hospital and faster operative times with reduced blood loss
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)	About the same – similar pre op and intra op costs. Potential reduced costs in the post op period with lower pain and infection/complication rates.
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)?	About the same
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Very minimal, a small change in laparoscopic kit to include the correct equipment required for vaginal access.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	vNOTE course required to teach entry and exit techniques, which are commonly used by vaginal surgeons for other operations in the NHS so are often familiar, and also for equipment use, set up and staff positioning in theatre

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	Standard risks of surgical procedures similar to this including risk of infection, bleeding (requiring transfusion), DVT/PE. Specific to this surgery includes potential for post operative dyspareunia and impaired sexual function (both uncommon). Risk of bladder and bowel injury rare ~ 1,1000), risk of conversion to laparoscopic or open procedures, risk of vesicovaginal fistula (very rare – RCT one conversion https://doi.org/10.3390/jcm9123959).
15	Please list the key efficacy outcomes for this procedure/technology?	Duration of surgery, Intra- or postoperative complications, length of hospital stay in days, readmission after discharge, postoperative pain, dyspareunia, sexual wellbeing and quality of life, financial costs
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 of
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	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.	**The NOVEL Study: VNOTES vs TLH - 20/PR/0994**

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)?	20-50% of women undergoing hysterectomy/adnexectomy for benign disease
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?	The lack of vaginal surgery training has limited the applicability of this, as there are few surgeons comfortable with vaginal access
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:	Outcome measures: Intra-operative - surgical time, completion of proposed surgery, blood loss, conversion rate, immediate complications Post operative (short term) 24-48 hrs - pain (APS questionnaire), hospital stay, delayed complications Post operative (long term) 12 weeks– QoL (QoR15), dyspareunia (FSFI 6)
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
Non-financial professional	I am a member of a research team on the ongoing NOVEL study,		
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.

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Print name:	**Oscar Barnick**
Dated:	**03/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Oudai ALI
Job title:	Consultant OG
Organisation:	Epsom General Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6035014

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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?	I am efficient in performing the procedure for various indications and able to use the concept for complex cases. I also teach the procedure in theory and also on simulation and I mentor surgeons on the performing the procedure. I am exceptionally familiar with the products needed to perform the procedure and how to troubleshoot and feedback regarding the products developments and adjustments.
	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?	The UK has now several centres using and adopting the novel surgical concept. I anticipate accelerated uptake. The UK is second to France in Europe in the uptake of the procedure.
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	The Vnotes is mainly used gynaecologist to perform hysterectomy and adnexal surgery. The other application for Vnotes concept is by the general surgeons to perform cholecystectomy in female patients. There is great advantage of the Vnotes in performing appendectomy.
	– If your specialty is involved in patient selection or referral to another specialty for this	The patient selection is primarily done by gynaecology surgeons. The procedures is particularly useful in cases with previous laparotomies and abdominal meshes as it avoids abdominal wounds

	procedure/technology, please indicate your experience with it.	and reduces the risks of further injuries. I performed many procedures in that regards and I also performed necessary adhesiolysis to achieve the assigned target.
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 published this research. I am part of the gynaecology oncology research group
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):	This is a novel concept compared to the current standards. It is a combination of laparoscopy and vaginal approach to achieve a surgery without a visible scar. 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?	With there is no contraindication this procedure will the default option to offer hysterectomy and adnexal surgery and it will gradually replace laparoscopic approach, however it requires certified training to acquire standardised skills.

Current management

5	Please describe the current standard of care that is used in the NHS.	The current practice to use multiport laparoscopy to achieve hysterectomy and adnexal surgery. The other option is to offer robotic surgery especially in high BMI cases.

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?	This procedure is the least traumatic approach after vaginal hysterectomy. It overcomes the limitations of the vaginal hysterectomy.

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?	This is surgery without visible scar, comparing like for like, it offers less pain , less blood loss, less operative time and offers same day discharge.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patient who have previous laparotomies, adhesions, fibroids, and previous sections.Also patients with high BMI and comorbidities as the procedures can be done with less intrabdominal pressures.
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?	This procedure is excellent for same day hysterectomy and it will improve productivity and efficiency with better patient satisfaction.
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)	This procedure is equivalent in cost to laparoscopic hysterectomy.It can save on theatre time by 30 min at least comparing like for like.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	The procedure can be done with one assistant This is huge saving as the third assistant is an issue in most of the trust. It also saves on using monopolar energy and uterine manupliators as well as no laparoscopic ports.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The procedure requires training of the surgeons and the staff to achieve the required efficacy of the procedure. It requires less instrument and slimer surgical trays.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	There is specific standardised training that involves theory, simulation and then mentoring and proctoring organised by Applied Medical.

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	The rate of complications in 1000 cases done in a center of excellence in Belgium was 5.2% Total ; 1.4% intraop, 3.8% postop . Comparing like for like there is slight increased risk of bladder injury compared to laparoscopic hysterectomy. (Baekelandt J, De Mulder PA, Le Roy I, Mathieu C, Laenen A, Enzlin P, Weyers S, Mol BW, Bosteels JJ. HALON-hysterectomy by transabdominal laparoscopy or natural orifice transluminal endoscopic surgery: a randomised controlled trial (study protocol). BMJ Open. 2016 Aug 12;6(8):e011546. doi: 10.1136/bmjopen-2016-011546. PMID: 27519922; PMCID: PMC4985989.) There are reports of bladder and bowel injury as well as infection and hip pain. There may be higher postoperative vaginal pain The theoretical risk of endometrial cancer cells spilled from the cervix. There is the risk of dyspareunia in Vnotes adnexal surgery.
15	Please list the key efficacy outcomes for this procedure/technology?	Less operative time and blood loss with equivalent cost. The procedure is less stressful for the staff as the surgeon is sitting and it is more ergonomic than laparoscopy.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	There is the issue of burnt out endometriosis that is accidently found during the procedure
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	We don’t know with the availability of the many routes to perform hysterectomy or adnexal surgery what do the patients prefer especially in nulliparous young women with adnexal masses.

		There is no clarity about Vnotes in cases with previous hysterectomy
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	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.	BSGE 2022 Abstract ID: 189 Making vNOTES easy – using a uterine manipulator through a fourth Port in vNOTES hysterectomy, the Haider technique Oudai Ali, Abdullatif Elfituri, Haider Jan Epsom & St Helier's University Hospitals NHS Trust, London, United Kingdom Abstract ID: 186 Hug-Push-Lift-Cut; demonstrating the various components of the safe use of Energy devices in VNotes Hysterectomy Oudai Ali Epsom and St Helier University Hospital NHS trust, London, United Kingdom Abstract ID: 196 Transvaginal Natural Orifice Transluminal Endoscopic (vNotes) hysterectomy: Short term outcomes in the first ten cases in our unit. Abdullatif Elfituri, Haider Jan, Oudai Ali Epsom & St Helier's University Hospitals NHS Trust, London, United Kingdom Abstract ID: 184 Is Palmer's Point really safe laparoscopic entry in cases with previous midline incision? video of a Vnotes hysterectomy with extensive bowel adhesions following previous laparotomy for bowel stricture demonetarising the safety and advantage of Vaginal natural orifice approach Oudai Ali, Abdullatif Elfituri, Haider Jan Epsom and St Helier university Hospital NHS trust, London, United Kingdom

20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	There is inotes registry of the procedure and complication

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)?	In the population that requires hysterectomy or adnexal surgery for various indications I estimate that 40 t0 60 % will need to be offered this approach if there is a structure of commissioning, governance and certification in place. There rest will be better with standard approaches like in oncology advanced cancer cases, endometriosis, or urogynaecology.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The Device of Gelpoint is essential for the procedure and it is designed to be used once. There is going to be a consideration of the disposing and caring of the environment in managing such consumables.
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 issue is to adopt a philosophy of surgery that will put the patient in the centre of care and involve patient informed choice. There was a healthy analysis of the of the risks/benefits and the technique.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Application of vnotes in oncology
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.	Beneficial outcome measures: Pain scores postoperatively, including rescue analgesia and time in recovery Patients' satisfaction surveys including body image scores (pre and postoperative) Sexual functions scores, incidence of granulation tissue Same day discharge and readmission rate POPQ scores for cases involving prolapse correction Timings of the different phases of the vnotes

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: Blood loss, HB drop. Transfusion, readmission Bowel injury, bowel dysfunction Urological injuries, dysfunction Conversion rate Infection rate (early, late, abscess) Unexpected adhesions, endometriosis
26	Is there any other data (published or otherwise) that you would like to share with the committee?	Please refer to the Halon and the Notable trials.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	The procedures fit well with the definition of the surgery as a calculated injury to the anatomy in the least traumatic way. The patient recovery is more efficient as they don't have torsional pain. This procedure avoids injury o the anterior abdominal wall vascular and neural anatomy and risk of hernias which can be underestimated.

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
Choose an item.	I help in educational event supported by Applied Medical	**2020**	
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:	**Oudai ALI**
Dated:	**13/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Ms Rebecca Karkia
Job title:	Senior Clinical Fellow in Gynaecological Oncology
Organisation:	Royal Surrey NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Member of the Royal College of Obstetricians and Gynaecologists (MRCOG)
Nominated/ratified by (if applicable):	Mr Martin Hirsch
Registration number (e.g. GMC, NMC, HCPC)	7456149

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 procedure/technology, please indicate your experience with it.	At the time of my experience with VNOTES hysterectomy and adnexectomy I was a trainee in Obstetrics and Gynaecology. Two consultants who had experience of this procedure under the tutelage of Jan Baeklandt (an early adopter of this technique) went to the new procedures committee within their hospital trust and gained authorisation to start piloting VNOTES. Both of these surgeons were highly competent in vaginal surgery and minimally invasive surgery. Both surgeons felt this was a procedure best offered to those who weren't perfectly suited to a vaginal hysterectomy or total laparoscopic hysterectomy i.e. those patients with no vaginal descent or who needed concurrent adnexectomy or those patients with anaesthetic complications who that couldn't tolerate deep Trendelenburg, higher intraoperative pressures or who those who had had midline laparotomy/ mesh hernia repair at the umbilicus. My involvement with VNOTES was that I witnessed or assisted in most of the first 33 VNOTES procedures. I witnessed the surgical learning curve of these two consultant practicioners. It should be noted that I never performed this procedure myself. Knowing that I would be first author to a case series I collected intra-operative and post-operative data meticulously in order to assess the feasibility of this new procedure. This was back in 2018 when this was even more novel and to our knowledge the first time the procedure was adopted in the UK NHS setting. After publishing our case series with the first 33 procedure performed over two sites over one year, I also did an oral presentation for BSGE in Vienna in 2019 where I discussed the procedure, its merits and the barriers to adoption of the technique. During this conference there was also a symposium on VNOTES where many of the international adopters of the technique discussed its merits and limitations.

		After publishing the first UK case series on VNOTES I went on to publish a literature review entitled “Is the scar-less hysterectomy with Natural Orifice Transluminal Endoscopic Surgery (NOTES) the future of benign gynecological surgery? A Review of the literature” assessing all of the potential indications for the VNOTES approach within Gynaecology. Whilst I am aware that other surgical specialities have trialled VNOTES, I have no personal or theoretical knowledge of it being performed by clinicians working within a UK NHS setting in specialities other than Gynaecology. Since publishing our experiences of VNOTES I have become aware of multiple institutions adopting the VNOTES approach, however in my opinion the procedure has been slow in its uptake. In the U.K this is likely due to a low number of skilled practitioners who are training other people. It is also highly encouraged by practitioners as well as Applied medical the company who market the kit that those wishing to adopt this procedure learn the technique on a training course in Belgium with experts on VNOTES. This is to try and ensure that the early adopters of the technique learn the safest approaches and do not damage the reputation of the VNOTES approach.
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 clinical research on this procedure involving patients or healthy volunteers.* *I have published this research.* I Published a case series on the subject as well as a literature review on VNOTES applications within gynaecology.
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?	*A minor variation on an existing procedure, which is unlikely to alter the procedure’s safety and efficacy.* Those undertaking the procedure must be competent to perform vaginal hysterectomy safely as the procedure requires performing a colpotomy. Due to the use of laparoscopic instruments adopters of this technique should also be competent to perform a laparoscopic assisted vaginal hysterectomy or total laparoscopic hysterectomy.

	Which of the following best describes the procedure (please choose one):	If the surgeon is competent in all of the above then the novel aspect of this procedure is the order of the surgical pedicles ligated and the vision and approach being from the caudal to cranial aspect rather than cranial to caudal.
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?	There is no convincing argument yet that suggests VNOTES should replace the current standard of care i.e. vaginal hysterectomy or laparoscopic hysterectomy if these can safely be performed on a patient. What is clear from the literature is that is that an open hysterectomy or adnexectomy versus laparoscopic or vaginal approach is associated with increased estimated blood loss, increased need for transfusion, increased opiate analgesia requirements, longer length of hospital stay, reduced enhanced recovery adoption and longer return to baseline function. Therefore, in the event that an open approach is being considered by a clinician due to perceived non-safety of the former approaches, VNOTES often offers a better solution.

Current management

5	Please describe the current standard of care that is used in the NHS.	In benign cases which require a hysterectomy the common alternatives in NHS practice are a) Vaginal hysterectomy b) Laparoscopic hysterectomy c) open hysterectomy d) robotic hysterectomy. Robotic hysterectomy is the least commonly performed of the above approaches. Vaginal hysterectomy is commonly performed in line with the Cochrane review but is more likely to be performed if there is vaginal descent and/or if it is not essential to perform concurrent adnexectomy. In cases which require adnexectomy without hysterectomy the common surgical approach is a) Laparoscopic surgery b) open surgery. Often the indication for adnexectomy is an ovarian cyst. Laparoscopic surgery will usually be offered in the event that the cyst can be safely be removed without rupture or the cyst is highly likely to be benign and non-harmful in the event of cyst rupture. If adnexectomy is performed for cases of ectopic pregnancy then it is at the discretion of the surgeon as to whether to perform the procedure as an open or laparoscopic approach. Most minimally invasive trained surgeons will perform salpingectomy laparoscopically if there is not a strong suspicion of large volume hemoperitoneum.

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?	My current clinical work is as a senior clinical research fellow in a robotic gynaecological oncology epicentre. It is my opinion that technically speaking robotic surgery can be performed instead of VNOTES hysterectomy in almost all circumstances. Robotic surgery can be undertaken safely in super obese patients whereas conventional laparoscopy often is technically very challenging. Hysterectomy and adnextomy can be performed robotically operating at lower pressures of 8-10mmHg which is important in patients with chronic airway diseases such as COPD. This is unlike traditional laparoscopy where often it cannot safely be performed. Robotic surgery can also be performed where there is mild moderate severe or no vaginal decent with no change in technical difficulty. Robotic surgery usually does however require a steep Trendelenburg position in order to keep the small bowel out of the pelvis. Once the operating table position has been set it is not usually possible to adjust the position of the bed. I have personally witnessed VNOTES performed successfully and easily in patients where next to no Trendelenburg can be performed or where steep Trendelenburg position is used momentarily to place the small bowel higher in the abdominal cavity before returning to supine position. This is often achieved by using one large surgical pack and physically holding the bowel in the abdomen whilst operating caudally to the bowel. In comparison to VNOTES the cost of operating robotically is much higher.

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) Reduced post-operative pain: In the case series that I published I witnessed VNOTES surgery to be associated with very minimal post-operative pain and very quick return to baseline function. A day case VNOTES hysterectomy is entirely possible and is now the standard of care in the institution our case series was first reported. This is potentially due to less diaphragmatic pain from insufflation, or the use of advanced vessel sealing devices over conventional knot tying in vaginal surgery. 2) Scarless abdominal surgery: Especially nice for young patients who may not scars on their abdomen. 3) A possibly safer procedure for high anaesthetic risk patients due to low pressures and Trendelenburg 4) No risk of major vascular injury from laparoscopic surgery – A rare but potentially fatal event
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	1) High BMI patients 2) Patients with respiratory compromise who are considered high risk for Trendelenburg and minimally invasive operating pressures 3) Patients with abdominal mesh due to hernias 4) Patients requesting abdominally scarless surgery
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?	It could make day case hysterectomy the standard of care for the majority of patients. It could potentially reduce the number of abdominal wall hernias that result as a consequence from the alternative routes.
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)	In comparison to open surgery VNOTES is likely to cost more in terms of surgical kit used but less overall when days of hospital admission are factored in. In comparison to vaginal surgery VNOTES is more expensive in terms of the surgical kit used and likely to be equivocal or marginally better in terms of length of hospital stay associated costs. In comparison to conventional laparoscopy VNOTES is likely to be similar in terms of cost or potentially fractionally more as a vaginal hysterectomy kit and laparoscopic kit is needed. This is largely due to the price of the ring retractor and overlying Gelseal cap which is not used in

		laparoscopic or vaginal surgery. This is the only unique piece of kit associated with VNOTES. However, the technique has been described without the use of this kit using a ring retractor and a surgical glove only in lower resource settings.
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 resource impact of this procedure is extremely low. VNOTES can only have one surgical assistant and one scrub nurse whereas laparoscopy or vaginal hysterectomy may often have two assistants and one scrub nurse. If this is to be factored in to the overall cost of the procedure then this may make VNOTES overall similarly priced. There is little to no additional training required for surgical assistants or scrub team. There is little to no additional training required for staff caring for patients post-operatively. In the trust I worked in who adopted this procedure as an adjunct to clinical practice there was no difficulty in implementing from the point of view of the associated costs. A business case was easy to make.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Correct patient selection and primary surgeon training are the major requirements for safely adopting this procedure into routine clinical practice.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training should be implemented by other surgeons who have mastered the procedure and who are familiar with the rate limiting steps of the procedure such as the instances where colpotomy cannot safely be undertaken.

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)	The consent form for this procedure should state the following risks: “Post-operative pain, surgical haemorrhage, infection, venous thromboembolism, damage to vessels, viscera (urinary tract, bowels), return to theatre and conversion to laparotomy or laparoscopic approach. In those patients with deep infiltration endometriosis that is likely to be affected the rectosigmoid pouch, this is not a recommended approach due to the risk of visceral injury. Similarly those patients with multiple caesareans may be at increased risk of bladder injury due to adhesions of the utero-vesical fold. In the case series that I authored the most common complication was urinary tract infection

	Theoretical adverse events	requiring oral antibiotics and the most severe complication was estimated blood loss of <1000mls.
15	Please list the key efficacy outcomes for this procedure/technology?	Technical suitability in patients with obesity and those patients at anaesthetically high risk for operating at high pressure or in deep Trendelenburg, reduced post-operative pain, cosmesis (scarless abdominally).
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The incidence of visceral injury
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The oncological safety of performing this procedure for indications such as early stage endometrial cancer needs to be established.
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	Oral Presentation Oct 2018: Hysterectomy and Adenextomy via transvaginal natural orifice transluminal endoscopic surgery (vNOTES): A UK perspective with a case series of 33 patients. European Society of Gynaecological Endoscopists Conference, Vienna. Poster presentation June 2019: Hysterectomy by Vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES)- The Initial U.K Experience". RCOG Congress, London May 2019: Don't stop me now! vNOTES hysterectomy: the innovative approach to a bog-standard hysterectomy. BSGE Conference, Newport

	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.	HALON (Hysterectomy by Trans-Abdominal Laparoscopy or Transvaginal NOTES): A Randomized Controlled Trial

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)?	60-90% of those females undergoing hysterectomy or adnexectomy for benign indications.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	I have witnessed that the retractor made by Applied Medical with the Gelseal cap is very easy to use. Standard laparoscopic devices can be used with this procedure and therefore are surgeon dependant. Anecdotally I have come across surgeons working in low resource settings who have used a glove to maintain pneumoperitoneum and insert laparoscopic devices through.
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?	To my knowledge the results of a randomised controlled trial where sham incisions were used to randomise patients to laparoscopy or VNOTES is unpublished. I would say that safety data from the UK is the major barrier to lack of adoption of this approach in the UK as well as there being a relatively small number of UK professionals who can train this technique.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	A prospective trial and or a systematic review +/- meta-analysis
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term	Beneficial outcome measures: Short term: Post-operative pain score (VAS) Length of stay (days)

	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:	Estimated blood loss (mls) Intra-operative pressure used to maintain pneumoperitoneum Angle of Trendelenburg Long term: Improved cosmesis (scarless surgery) Clavien-Dindo Complication score Adverse outcome measures: Early: EBL, intraoperative injuries, conversions to open surgery, return to theatre, visceral injuries, vascular injuries, transfusion requirements Later: Ureteric injury Thermal injuries from energy sources
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,	

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
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:	**Rebecca Karkia**
Dated:	**02/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)**

Your information

Name:	Russell Luker
Job title:	Consultant Gynaecologist
Organisation:	Royal United Hospital NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	RCOG/BSGE
Nominated/ratified by (if applicable):	NICE Invitation
Registration number (e.g. GMC, NMC, HCPC)	4552642

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 appointed as the non-practising expert on this panel. I have no prior experience.
	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?	No Very few use it, Spee of uptake likely to be slow.
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	Yes
	– If your specialty is involved in patient selection or referral to another specialty for this	No.

	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. X 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):	Moderately 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.X 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?	Both

Current management

5	Please describe the current standard of care that is used in the NHS.	Abdominal, vaginal or laparoscopic hysterectomy or adenexal surgery.
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?	Reduced abdominal scars
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Breast reconstruction patients and the vain.
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?	Possible
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)	Possible
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)?	Similar
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Negligeable

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	Collateral organ damage, Reduced ability to control unexpected haemorrhage.
15	Please list the key efficacy outcomes for this procedure/technology?	Patient satisfaction. Surgical time, Inpatient stay, complication rates, return to theatre rates, Pain scores. Infection rates.Cost.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Above
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. X

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.	

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)?	
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 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?	
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
Indirect	Consulting Expert for Fannin a surgical equipment company who does not manufacture equipment for this kind of procedure.	**2021**	**Ongoing**
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:	**Russell Luker**
Dated:	**02/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)

Your information

Name:	Tracy L Jackson
Job title:	Consultant Gynaecologist
Organisation:	The Leeds Teaching Hospitals NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BSGE/RCOG
Nominated/ratified by (if applicable):	BSGE
Registration number (e.g. GMC, NMC, HCPC)	GMC 3274930

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?	I have performed eleven vaginal natural orifice transluminal endoscopic surgery (vNOTES) hysterectomy and bilateral salpingo-oophorectomy procedures with my consultant urogynaecologist colleague, Dr Fiona Marsh, in Leeds since 29.04.22. All women undergoing hysterectomy and bilateral salpingo-oophrectomy with vNOTES have had their procedure completed with no need to transfer to laparotomy or TLH (total laparoscopic hysterectomy). This is scar free surgery with an excellent recovery rate, minimal pain (average VAS pain scores 1.3/10) and the vast majority of women going home on the same day as their surgery
	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	There are approximately 75 surgeons trained on vNOTES in the UK so far. Of these, 25 are actively using vNOTES. A large percentage of those surgeons who have not started are awaiting business approval from their local hospitals. It is yet to be confirmed, but it looks like the BSGE will have vNOTES on their scientific program. As a result, we expect there to be an increase in demand and the uptake of this procedure. vNOTES is only performed by gynaecologists in the UK The patient selection is the same as for laparoscopic hysterectomy, the only contraindication is severe adhesions in the Pouch of Douglas usually related to previous bowel surgery or severe endometriosis

	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):	This is a novel approach to allow an extension of vaginal surgery into the peritoneal cavity using endoscopic instruments traditionally used via the abdominal wall. However, both vaginal and laparoscopic surgery are very well established with proven efficacy and safety. Clinicians performing this procedure need skills in both vaginal and laparoscopic surgery 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?	This would be used as an addition to existing standard care

Current management

5	Please describe the current standard of care that is used in the NHS.	Hysterectomy is performed abdominally, vaginally and laparoscopically. vNOTES hysterectomy would replace some total laparoscopic hysterectomies and some abdominal hysterectomies. Management of ovarian cysts and tubal ectopic pregnancies is currently largely laparoscopic, vNOTES may be employed in these cases although we have no experience of this as yet in Leeds
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?	Compared to traditional laparoscopic procedures vNOTES results in less pain, absence of trocar related injuries, absence of abdominal scars, same day discharge. This addresses the drawback of difficult access during vaginal hysterectomies and allows removal of tubes and ovaries vaginally if required
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those with high BMI and previous laparotomy. Patients who would react adversely to high intra-abominal pressures and being in steep head down position
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?	vNOTES will be associated with an increase in same day discharge which benefits the healthcare system by freeing up beds and improving flow. The scarless approach is 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)	The reduced length of stay immediately reduces costs. The equipment is cheaper than existing laparoscopic equipment. One assistant is required rather than two for vNOTES hysterectomy compared with total laparoscopic hysterectomy
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 cost in staff and equipment is comparable although only one surgical assistant is required rather than two for laparoscopic hysterectomy. The reduction in length of stay is a significant saving (although the aim from GIRFT data is that 80% of laparoscopic hysterectomies should be day cases, this is not happening in many centres). Theatre time is also reduced. The reduced postoperative pain leads to reduced prescription of analgesia postoperatively
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No changes

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	The surgical skills required are not new to those competent in vaginal and laparoscopic surgery. Training is required in insertion of the device, Gelpoint, which fits in the vagina and provides a seal to keep the gas in the peritoneal cavity. We achieved this through an online course with an App allowing multiple videos to be viewed. We also attended a face to face course in Dartford in Kent with the experienced vNOTES surgeons, Jan Baekelandt and Elias Kovoor. Fiona Marsh and I trained our theatre team in a half day session

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	Vaginal notes (VNOTES) is similar to both laparoscopic hysterectomy and vaginal hysterectomy and the complications are similar. According to the Cochrane review on hysterectomy for benign conditions (August 2015), both LH (laparoscopic hysterectomies) and VH (vaginal hysterectomies)had better outcomes than abdominal hysterectomies in terms of return to normal activities, patient satisfaction and quality of life, but LH had more urinary tract injuries than VH. The recommendation was to perform VH whenever possible. There is no evidence to suggest any increase in complication rates when VH is compared with LH. When VH was compared with Abdominal hysterectomies there was an increase in bladder injuries. In one of the largest series of vaginal NOTES hysterectomy of 137 pts, 2 pts had unintended cystostomy. In 5 pts colpotomy (entry into the pelvis via the vagina) was unsuccessful. These pts were treated laparoscopically without conversion to laparotomy. 3.6% had minor problems like febrile morbidity, urinary retention which resolved with conservative management
15	Please list the key efficacy outcomes for this procedure/technology?	**1. Besides avoiding visible scars vNOTES allows more women to undergo hysterectomy as a day-care surgical procedure.** vNOTES also provides the following: • Shorter duration of hysterectomy procedure, 41 versus 75 minutes • More women left the hospital within 12 hours of having a hysterectomy, 77 versus 43% • Shorter length of hospital stay, 0.8 versus 1.3 days

		• Less total amount of analgesics used during the first 7 days following surgical treatment, 8 versus 14 units • Less postoperative complications, 9 versus 37% Baekelandt J, et al. Hysterectomy by Transvaginal Natural Orifice Transluminal Endoscopic Surgery versus laparoscopy as a day-care procedure: a randomised controlled trial. BJOG 2019 Jan;126(1):105-113. **2. The duration of operation, mean amount of blood loss, and postoperative stay are significantly less** How vNOTES compares to LAVH: • Less blood loss, 191.8 ± 201.3 versus 324.6 ± 242.4 mL • Shorter operating time, 76.7 ± 25.0 versus 98.4 ± 39.5 minutes • Shorter postoperative stay, 2.1 ± 0.5 versus 2.5 ± 1.1 days Wang CJ, et al. Hysterectomy via transvaginal natural orifice transluminal endoscopic surgery for nonprolapsed uteri. Surgical Endoscopy 2015 Jan; 29(1):100-7. **3. vNOTES hysterectomy broadens the indications for vaginal hysterectomy and helps overcome its limitations, while the NOTES approach avoids abdominal wall-wounds and trocar-related complications.** Other advantages noted in this study: • Short operating times, 56 minutes for hysterectomy and 25.5 minutes for adnexal surgery • No perioperative complications • Low pain scores 6 and 24 hours postoperatively Baekelandt J, et al. GelPOINT (Applied Medical) is a Suitable Port for Transvaginal NOTES Procedures. Journal of Gynecologic

		Surgery 2016; 32(5): 257-262. **4. Performing hysterectomy using transvaginal NOTES is generally beneficial, with a short operative time and high patient satisfaction with no abdominal wound** Other advantages compared to conventional vaginal surgery and laparoscopy: • Short operative time, 88.2 minutes • Earlier blockage of the uterine vessels compared to laparoscopy • Clearer visibility than vaginal surgery Lee CL, et al. Hysterectomy by Transvaginal Natural-Orifice Transluminal Endoscopic Surgery (NOTES): A Series of 137 Patients. Journal of Minimally Invasive Gynecology 2019 Oct; 21(5): 818 – 824
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	There are no uncertainties or concerns - surgical complications such as bleeding, infection, visceral injury all occur but at lower rates than those for laparoscopic or vaginal hysterectomy
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	Please find attached information about vNOTES content from the following congresses:

	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.	○ European Society for Gynaecological Endoscopy (ESGE) congress, October 2-5, 2022 ○ American Association of Gynecologic Laparoscopists (AAGL) conference, December 1-3, 2022 – *taking place next week* ○ French congresses ▪ Société de Chirurgie Gynécologique et Pelvienne (SCGP), Sep 21-23, 2022 ▪ Daniel Dargent, Nov 24-25, 2022
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Ongoing trials per clinicaltrials.gov: ○ Wassen M., The Netherlands. Vaginal Hysterectomy Versus Vaginal Assisted NOTES Hysterectomy (VANH): a Randomised Controlled Trial Link: Vaginal NOTES Hysterectomy Versus Vaginal Hysterectomy - Full Text View - ClinicalTrials.gov ○ Mansoor A., France. Tolerance of the vNOTES Surgical Technique in Total Hysterectomy for Benign Lesion. Clinical Trial of Non-inferiority Compared to the Laparoscopic Technique. Link: Tolerance of the vNOTES Surgical Technique in Total Hysterectomy for Benign Lesion. Clinical Trial of Non-inferiority Compared to the Laparoscopic Technique. - Full Text View - ClinicalTrials.gov ○ Karampelas S., Belgium. Vaginal Natural Orifice Trans-luminal Endoscopic Surgery (vNOTES) Salpingectomy for Tubal Sterilization: Clinical Outcomes and Learning Curve Analysis: A Multicentre Prospective Study Link: Vaginal Natural Orifice Trans-luminal Endoscopic Surgery Salpingectomy for Tubal Sterilization: Clinical Outcomes and Learning Curve Analysis - Full Text View - ClinicalTrials.gov ○ Mohr-Sasson A., USA. Does BMI Influence Pain Follow vNOTE Surgery (BMIVNOTES) Link: Does BMI Influence Pain Follow vNOTE Surgery - Full Text View - ClinicalTrials.gov

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)?	Anyone eligible for total laparoscopic hysterectomy would be eligible for vNOTES hysterectomy unless they had dense adhesions in the Pouch of Douglas. Those having vaginal surgery for prolapse who wish to have removal of tubes and ovaries would be eligible. As we move into adnexal surgery then acute gynaecological cases such as ruptured ectopic pregnancy and ovarian torsion would be eligible
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The equipment is very user friendly, inexpensive, easy to master
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 procedure requires both vaginal and laparoscopic surgical skills. The reduction in years of training and hours per week, combined with specialisation into different areas at an early stage, has led to qualified gynaecologists being unlikely to have both skills. Although Fiona Marsh and I do have both skills, the collaboration between urogynaecology (Fiona) and general gynaecology (me) has been invaluable and, we feel, this would be the ideal set up in any unit
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Data collection is ongoing, the randomised controlled trial had relatively small numbers but the outcome data was convincing
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.	Beneficial outcome measures: Short term - length of procedure, blood loss reduced, intraoperative complications reduced, postoperative pain and use of analgesia reduced, length of stay in hospital reduced Long term - patient satisfaction, return to normal activities Adverse outcome measures: Early - intraoperative complications such as visceral injury, conversion to laparoscopy or laparotomy, blood loss

	− Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Late - postoperative infections, VTE - over a 6 week period
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

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.	I have no conflicts of interest to declare		
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:	**Tracy L Jackson**
Dated:	**24 November 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery (IP1937)

Your information

Name:	Wai YOONG
Job title:	Consultant Obstetrician and Urogynaecologist
Organisation:	North Middlesex University Hospital, London
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BSGE/RCOG
Nominated/ratified by (if applicable):	BSGE
Registration number (e.g. GMC, NMC, HCPC)	GMC 3196490

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:

NA

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 been doing VNOTES for 6 months and have been to Imelda Hospital in Bonheiden, Belgium for further training to improve skillset with Professor Jan Baekelandt. I am familiar with the procedure. My main interest is VNOTES for sterilisation, ectopic pregnancy, ovarian cystectomy and oophorectomy as well as conventional hysterectomy. .
	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	Not widely used in the UK at the moment. Discussing with Applied Medical, which supplies the Gelpoint (necessary kit for the technique), there are probably between 20 and 25 gynaecologists performing this procedure in the UK. While truly minimally invasive as the access is through a natural orifice (vagina), there are very few “proctors” or mentors to support clinicians who are starting to do the procedure. Speed of uptake is therefore limited. Procedures such as appendectomy and cholecystectomy have also done by general surgeons via transgastric route, transanal and transvaginal routes but its efficacy and safety remains under review. **Natural-orifice transluminal endoscopic surgery.** S Atallah, B Martin-Perez, D Keller, J Burke, L Hunter**.** *British Journal of Surgery*, Volume 102, Issue 2, January 2015, Pages e73–e92, https://doi.org/10.1002/bjs.9710

	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 am the first author of a commentary on VNOTES which has been accepted for publication in The Obstetrician and Gynaecologist (will be published in 2023). I am done clinical research on this procedure involving patients and am currently collecting data on my VNOTES cases of salpingectomy for ectopic pregnancy.
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):	VNOTES is a variation of existing traditional techniques in that it combines the truly minimal access approach of vaginal surgery with excellent visual optics and endoscopic sealing devices that are used in conventional laparoscopic gynaecology surgery. A Gelpoint platform is inserted after the initial colpotomy is performed: this provides a seal allowing insufflation of carbon dioxide to achieve a pneumoperitoneum. A laparoscope and two (or three) instruments are then introduced through the platform and the subsequent technique is similar to that of single port surgery. Thus, I consider VNOTES a variation and amalgamation of existing techniques (vaginal combined with endoscopic surgery). There is a learning curve and the risks are those associated with conventional vaginal surgery and laparoscopy.
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?	This would be an addition to and complements existing standards such as vaginal hysterectomy and TLH/ LAVH. It is particular indicated in benign gynaecology conditions in women of high BMI when it may avoid laparotomy and trocar complications. The vaginal approach is much more accessible in such women. Further, the insufflation pressure is lower (10-12mm) than conventional laparoscopy, reducing anaesthetic ventilatory issues and CO2 embolism.

		I feel that it is a better technique than TLH and LAVH in women of high BMI. There is also a role in more intermediate procedures such as salpingectomy for ectopic pregnancy and sterilisation as it avoids abdominal trocar incisions and is associated with less postoperative pain and shorter inpatient stay.

Current management

5	Please describe the current standard of care that is used in the NHS.	Hysterectomy: Gold standard for benign indications with normal sized uterus would be vaginal hysterectomy, followed by laparoscopic hysterectomy Ovarian cyst: Gold standard in benign cases would be laparoscopic ovarian cystectomy or oophorectomy Ectopic pregnancy: Gold standard would be laparoscopic salpingectomy Sterilisation: Gold standard would be laparoscopic occlusion with Filshie clips or laparoscopic bilateral salpingectomy
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?	Uses natural orifices, hence avoiding the risks associated with abdominal trocar injuries and trocar herniation. Excellent view using fibreoptic technology Simple retrieval of excised specimens through the vagina, particularly in cases of dermoid cysts. Less likelihood of spillage and obviates the need to extend the incision for larger specimens eg uterus Lower insufflation pressures of 10-12mm Hg Lower visual analogue pain scores and thus shorter length of stay and return to daily activities
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	High BMI Benign gynaecology conditions such as ovarian cyst, ectopic pregnancy, sterilisation
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?	Reduced postoperative pain, leading to shorter length of stay (over 70% <12 hours stay) Less trocar complications Less invasive, thus better cosmesis Quicker return to daily activities compared to conventional laparoscopy due to avoidance of trocars
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 additional capital costs is minimal as the technique uses laparoscopic equipment and video/ insufflation stack systems that are usually already available in most units. There is no necessity for extra staff. Thus, as a whole, the cost is either comparable or slightly more than TLH/LAVH, primarily due to cost of Gelpoint platform. Our own hospital calculations suggest that VNOTES salpingectomy for ectopic pregnancy will cost approx. £150 more than conventional laparoscopic salpingectomy using 3 trocars (mainly due to cost of the Gelpoint platform). However, this is offset by shorter length of stay (length of stay of VNOTES is similar to vaginal surgery) and more rapid return to normality compared to

		laparoscopy. For VNOTES, additional disposable trocars are not necessary as the Gelpoint set comes with 3 trocars (the set typical costs approx. £279).
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)?	Resource impact has not been well documented. Two studies discussed financial costs comparing VNOTES with LAVH and TLH. Wang (see reference 9 later) reported that the mean hospital charge for a VNOTES case was approximately 5000 New Taiwan Dollars (£130) more than LAVH and this was primarily driven by the price of disposable Alexis Retractors and energy devices, while Baekelandt (see reference 5 later) estimated that VNOTES and TLH incurred similar cost variables. That theatre operating time was significantly shorter with VNOTES and that most patients undergoing the procedure were discharged 0.5 days earlier and needed less postoperative analgesia were often not factored into the cost calculations. Little is also known about the relative loss of income and productivity in women undergoing LAVH and TLH when compared to V-NOTES as the latter group is likely to return to daily activity more rapidly.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Minimal extra equipment, staff or facilities.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, early studies suggest that this is a technique for an already experienced vaginal and or laparoscopic surgeon. Learning curve likely to be >20 cases.

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	Similar to conventional vaginal surgery: injury to organs eg ureters, bladder or bowel; bleeding; infection. Housmans and colleagues published a review comprising one RCT and five cohort control trials and according to her, the risks are comparable to TLH. She has used the Clavien-Dindo classification of complications and the reported risks for VNOTES hysterectomy include wound and pelvic infection, blood transfusion, vesico-vaginal fistula (n=1), pulmonary embolus (n=1) and reintervention because of bleeding. Systematic Review and Meta-Analysis on Hysterectomy by Vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) Compared to Laparoscopic Hysterectomy for Benign Indications. **Housmans S**, Noori N, Kapurubandara S, Bosteels JJA, Cattani L, Alkatout I, Deprest J, Baekelandt J.J Clin Med. 2020 Dec 7;9(12):3959. doi: 10.3390/jcm9123959
15	Please list the key efficacy outcomes for this procedure/technology?	Shorter in patient stay More cosmetic Less need for pain medication More rapid return to activity Improved patient satisfaction due to all above
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Clinicians wishing to start VNOTES should already be experienced vaginal and or laparoscopic surgeons. We do not have sufficient trainers to directly mentor clinicians wishing to start this procedure.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Published data mainly retrospective cohort control studies (level IV) and two single centre RCTs (as far as I know).

18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present. Currently I believe that VNOTES is done in between 20-25 centres in the UK but the numbers performed vary between them (this is informal data from Applied Medical, which supplies the Gelpoint platform for the procedure).

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.	References 1. Baekelandt J, Kapurubandara S. Benign Gynaecological procedures by vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES): Complication data from a series of 1000 patients. Eur J Obstet Gynecol Reprod Biol. 2021 Jan; 256:221-224. 2. Su H, Yen CF, Wu KY, Han CM, Lee CL. Hysterectomy via transvaginal natural orifice transluminal endoscopic surgery (NOTES): Feasibility of an innovative approach. Taiwanese Journal of Obstetrics and Gynecology Volume 51, Issue 2, June 2012, Pages 217-221 3. Von Delius S, Schorn A, Grimm M, Schneider A, Wilhelm D, et al. Naturalorifice transluminal endoscopic surgery: low-pressure pneumoperitoneum is sufficient and is associated with an improved cardiopulmonary response (PressurePig Study). Endoscopy 2011;43(9):808–15. https://doi.org/10.1055/ s-0030-1256559

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7. Kaya C , Alay I, Cengiz H, Baghaki S , Aslan O, Ekin M, Yasar L. Conventional Laparoscopy or Vaginally Assisted Natural Orifice Transluminal Endoscopic Surgery for Adnexal Pathologies: A Paired Sample Cross-Sectional Study.. J Invest Surg 2021 Nov;34(11):1185-1190
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9. Wang CJ, Huang HY, Huang CY, Su H. Hysterectomy via transvaginal natural orifice transluminal endosocopic surgery for non prolapsed uteri. Surg Endosc Others Interv Tech 2015; 29: 100-7

		10. Kapurubandara S, Lowenstein L, Salvay L, Herijgers A, King J, Baekelandt J. Consensus on safe implementation of vaginal natural orifice transluminal endoscopic surgery (vNOTES). Eur J Obstet Gynecol Reprod Biol 2021; 263: 216–22 11. Wang CJ, Go J, Huang HY, Wu KY, Huang YT, Liu YC, Weng C. Learning curve analysis of transvaginal natural orifice transluminal endoscopic hysterectomy. BMC Surgery 2019 (19): 88
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Data registry for VNOTES via www.notesurgery.org (recommended) A major prospective RCT of VNOTES vs laparoscopic salpingectomy for ectopic pregnancy is recruiting patients. This is the vNOTES Transvaginal Endoscopic Surgery Versus Laparoscopy (NOTRANDO) which started in 2020 and due for completion in Feb 2023.

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)?	In my opinion, at least 50% of cases of ectopic pregnancies, ovarian cysts and hysterectomies currently being done through the laparoscopic route can be performed by VNOTES (with no increase in complication rates and theatre duration).

22	Are there any issues with the usability or practical aspects of the procedure/technology?	There are certain important exclusion criteria: a) severe endometriosis obliterating the cul de sac or dense pelvic adhesions where colpotomy is fraught with the risk of inadvertent bladder or bowel injury, b) international continence society (ICS) classification Stage III or IV uterovaginal prolapse, c) previous colorectal surgery, d) gynaecological malignancy, e) uterus > 20 weeks size, f) pelvic radiotherapy, g) history of a previous total hysterectomy, h) previous mesh sacrocolpopexy and i) virginity.
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?	Surgeons performing this procedure need to be experienced and properly trained as there is still limited data. They will need to audit their outcomes and register their cases onto an international registry.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	a) Likelihood of long term vaginal pain from colpotomy b) For VNOTES adnexectomy via posterior colpotomy incision, can a repeat procedure via the same incision be done safely in the future?
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	Beneficial outcome measures: Duration of operation; length of stay; pain scores (at 6 hours, 12 hours, 24 hours and 7 days); QOL; time taken to get back to normal activity Adverse outcome measures: Intraoperative complications eg organ injuries and haemorrhage needing conversion to laparotomy

	procedure timescales over which these should be measured:	Early: pyrexia, pelvic infection, UTI, wound infection, allogenic blood transfusion Late: fistula, pelvic pain, thromboembolic disease including PE
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,	VNOTES is a good technique which allows vaginal access (no abdominal trocar incisions) but also combines this with fibreoptic technology (which gives excellent vision) and endoscopic surgical instruments. I feel that my experience as a vaginal surgeon helped me learn the procedure relatively quickly. Even so, I feel that 20 cases would comprise a good learning curve for a clinician. The proctors who were assigned to mentor my first few cases were not able come down to my unit and I had to resort to performing my first few cases relying on my own experience and skills.

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Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Indirect	Hotel accommodation when I attended VNOTES training course was sponsored by Applied Medical. The course fee itself was paid by myself.	**Dec 2021**	
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:	**Wai Yoong**
Dated:	**19/11/2022**