

National Institute for Health and Care Excellence

IP1937 Vaginal natural orifice transluminal endoscopic surgery for hysterectomy and adnexal surgery

IPAC date: 10th August 2023

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Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
				Please respond to all comments
1	██████████ Consultee 1 Endometriosis UK		Consider wording as: Hysterectomy may be a treatment for gynaecological conditions. The term is a treatment may suggest their is only one treatment option available.	Thank you for your comment. The Committee amended the wording to indicate that hysterectomy may be a treatment option for benign gynaecological conditions.
2	██████████ Consultee 1 Endometriosis UK		Vaginal transluminal endoscopic surgery is one way of doing hysterectomies and adnexal surgery. Again gives the reader insight that there are other options of treatment.	Thank you for your comment. The Committee has adopted this suggestion in the guidance.

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3	██████████ Consultee 2 Specialist Adviser		Can you edit to: "Vaginal Natural Orifice Transluminal Endoscopic surgery" to keep it as consistently vNOTES	Thank you for your comment. The Committee has maintained the shortened procedure title that was decided at an earlier stage of the guidance development.
4	██████████ Consultee 3 Specialist Adviser		This technique does also allow doing other surgical procedure like cholecystectomy	Thank you for your comment. The Committee has not included this procedure at this time because it did not feature in the evidence review.
5	██████████ Consultee 1 Endometriosis UK		To consider adding adenomyosis as a condition when listing gynaecological conditions within document.	Thank you for your comment. Note: comments 5, 6 and 7 are the same although they are addressing different sections of the guidance. The Committee has amended the language to say "include, but are not limited to," in section 2.1.
6	██████████ Consultee 1 Endometriosis UK		Consider adding adenomyosis as a condition within this list of gynaecological conditions.	Thank you for your comment. The Committee has amended the language to say "include, but are not limited to," in section 2.1.
7	██████████ Consultee 1 Endometriosis UK	2.1	Consider adding adenomyosis to list of gynaecological conditions.	Thank you for your comment. The Committee has amended the language to say "include, but are not limited to," in section 2.1.
8	██████████ Consultee 4 Applied Medical	2.5	This is describing the steps for a hysterectomy. For adnexectomy it is limited to an incision posteriorly from the cervix.	Thank you for your comment. Note: comments 8 and 9 are the same although they are addressing different sections of the guidance. This section of the guidance is intended to be a brief summary of the way the procedure may be done.
9	██████████ Consultee 4 Applied Medical		This is describing the steps for a hysterectomy. For adnexectomy it is limited to an incision posteriorly from the cervix.	Thank you for your comment. This section of the guidance is intended to be a brief summary of the way the procedure may be done.

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10	██████████ Consultee 4 Applied Medical	2.5	We strongly recommend to verify if the keyhole instrument port that is used in the procedure has a transvaginal indication. Consider adjusting this wording to: "...a keyhole instrument port with transvaginal indication is then inserted to improve access and visibility."	Thank you for your comment. The Committee has amended the indication of the keyhole port in line with the comment.
11	██████████ Consultee 4 Applied Medical	3.1	More recent evidence to add: - Chaccour et al. Hysterectomy Using Vaginal Natural Orifice Transluminal Endoscopic Surgery Compared with Classic Laparoscopic Hysterectomy: A New Advantageous Approach? A Systematic Review on Surgical Outcomes. Gynecol Obstet Invest. 2023; 1–10. - Tekin et al. Implementing the transvaginal natural orifice transluminal endoscopic surgery (vNOTES) “first” strategy in benign gynecological surgeries. Arch Gynecol Obstet. 2023; 307(4):1007-1013.	Thank you for your comment. Note: comments 11 and 12 are the same although they are addressing different sections of the guidance. The studies were published following the preparation of the overview for IPAC1. Both studies have been added to the overview. The Committee discussed this evidence and no further changes were made to the main recommendations.
12	██████████ Consultee 4 Applied Medical		More recent evidence to add: - Chaccour et al. Hysterectomy Using Vaginal Natural Orifice Transluminal Endoscopic Surgery Compared with Classic Laparoscopic Hysterectomy: A New Advantageous Approach? A Systematic Review on Surgical Outcomes. Gynecol Obstet Invest. 2023; 1–10. - Tekin et al. Implementing the transvaginal natural orifice transluminal endoscopic surgery (vNOTES) “first” strategy in benign gynecological surgeries. Arch Gynecol Obstet. 2023; 307(4):1007-1013.	Thank you for your comment. The studies were published following the preparation of the overview for IPAC1. Both studies have been added to the overview. The Committee discussed this evidence and no further changes were made to the main recommendations
13	██████████ Consultee 3 Specialist Adviser	1.2	it is safer to obtain training, and certification recognised by the professional scientific bodies like the BSGE/RCOG to ensure standardised surgical technique	Thank you for your comment. The Committee has not endorsed any specific certification. Sections 1.4 and 1.5 state that specific training in the procedure is needed.

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14	██████████ Consultee 3 Specialist Adviser	3.5	In my personal experience proctoring enhances safety and identify surgical environment and engage the nursing staff in the best efficient flow for the procedure	Thank you for your comment. The Committee has not recommended proctoring for this procedure. Sections 1.4 and 1.5 state that specific training in the procedure is needed.
15	██████████ Consultee 4 Applied Medical	3.5	Our experience is that depending on the clinician's background, skills and experience, not everyone desires and/or requires mentoring post-course. Our suggestion would be to have mentoring available upon clinician's request.	Thank you for your comment. The Committee acknowledged that the mentoring requirement is a feature of the special arrangements guidance and not specific to this procedure. Accordingly, no change to the procedure guidance was made.
16	██████████ Consultee 4 Applied Medical	3.6	Will data that is being inserted by clinician's into the audit tool be stored centrally and/or used by NICE for the purpose of further research and potential future updating of this guidance?	Thank you for your comment. The audit tool is for collecting outcomes at a local level and the data is not stored centrally. The guidance may be updated on publication of further evidence in peer-reviewed literature, and this could include audit data.
17	██████████ Consultee 2 Specialist Adviser	3.7	Actually should be severe PID with frozen pelvis and sever endometriosis or rectovaginal endometriosis (as superficial or early endometriosis is not a contraindication. Contraindications for vNOTES: 1. Rectovaginal endometriosis 2. A history of rectal surgery 3. A history of a severe PID 4. A history of pelvic radiotherapy 5. A history of a previous total hysterectomy 6. A history of a mesh sacrocolpopexy 7. Ovarian cancer	Thank you for your comment. The Committee noted that their list in 3.6 is non-exhaustive and has amended the wording to reflect this.
18	██████████ Consultee 3 Specialist Adviser	3.7	also pregnancy, lack of consent, pelvic radiotherapy	Thank you for your comment. The Committee noted that their list in 3.6 is non-exhaustive and has amended the wording to reflect this.

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19	██████████ Consultee 4 Applied Medical	3.7	Per Kapurubandara et al. endometriosis itself is not a contraindication. However, rectovaginal endometriosis is. (Reference: S. Kapurubandara, L. Lowenstein, H. Salvay et al. Consensus on safe implementation of vaginal natural orifice transluminal endoscopic surgery (vNOTES). European Journal of Obstetrics & Gynecology and Reproductive Biology. 2021; 263: 216–222.)	Thank you for your comment. The Committee noted that their list in 3.6 is non-exhaustive and has amended the wording to reflect this.
20	██████████ Consultee 4 Applied Medical	3.8	We strongly recommend to verify if the ports available or promoted in the European/UK market have a transvaginal indication.	Thank you for your comment. The Committee has amended the indication of the keyhole port in line with the comment.
21	██████████ Consultee 3 Specialist Adviser	3.3	I don't agree with the outcome of prolapse in the short term as it is even measured as short term outcome in other kind of hysterectomies. This can confuse patients and practitioners. The vaginal elements of the procedure is similar to the vaginal hysterectomy. Vault healing (granulation tissue, or dehiscence can be considered here instead) as it does correlate with return to full function(sex, swimming)	Thank you for your comment. The Committee has not changed the safety outcomes in 3.3.
22	██████████ Consultee 3 Specialist Adviser	3.9	it is indeed difficult and confusing to capture long term data about prolapse even for other modalities of hysterectomies. This technique is very similar to vaginal hysterectomy in multiple aspects	Thank you for your comment.
23	██████████ Consultee 4 Applied Medical	3.9	Besides the use of a transvaginal access device and laparoscopic equipment, the procedural steps of a vNOTES hysterectomy are the same as that of a vaginal hysterectomy. Also, the vaginal vault can be closed to the clinician's preference as he/she would at the end of a vaginal hysterectomy. Therefore, we do not expect to see any differences in rates of vaginal prolapse following a	Thank you for your comment.

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			vNOTES hysterectomy compared to the accepted and recommended vaginal hysterectomy.	
24	██████████ Consultee 3 Specialist Adviser	3.10	the physiological benefits of the procedure include shorter duration, lower head down, less blood loss, less pressure, requiring less pain control in addition to avoiding anterior abdominal wall vascular injuries. However doing high BMI cases above 50 requires expertise and MDT approach. Learning Vnotes and immediate application on complex cases can put patients at risk.	Thank you for your comment. Section 1 includes recommendations on training and use of a multidisciplinary team.
25	██████████ Consultee 4 Applied Medical	3.10	For the same reasons, the vNOTES procedure has shown to be of benefit to patients with large uteri. It provides better vision compared to the laparoscopic approach, as the uterus can be pushed cranially, away from the surgical field. It also allows for easier vaginal extraction of the uterus compared to having to morcellate the uterus when extracting it following laparoscopy. Additionally, compared to a vaginal hysterectomy of a large uterus, vNOTES provides better access and vision. (Reference: Wang et al. Transvaginal natural orifice transluminal endoscopic surgery (vNOTES) hysterectomy for uterus weighing ≥1 kg. BMC Surgery. 2020; 20:234.)	Thank you for your comment. The Committee has not added large uteri to comment 3.9 based on the evidence review.
26	██████████ Consultee 5 Specialist Adviser		In ██████████ we have performed 24 vNOTES hysterectomies. They would have had laparoscopic hysterectomy previously. This is not an RCT but we have noted that they have less pain postoperatively, an average of less than 2 out of 10 on visual analogue score at the time of discharge. As you said in the meeting (I had IT issues and heard the end of the discussion), length of stay has lots of variables including bed pressures (in ██████████ there is a tendency to keep patients in to save the bed for elective surgical patients the next day), lack of specialist nurses (our gynae ward had been taken over by elderly medicine for 3	Thank you for your comment. The Committee welcomes this additional information.

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			<p>years) etc etc. However, the vast majority of our patients have gone home within 24 hours and half within 12 hours</p> <p>There have been no visceral injuries, one transfusion with a fibroid uterus, no other complications</p> <p>Patients in [REDACTED] are now choosing vNOTES instead of a laparoscopic approach – they prefer to avoid scars and we have had no negative feedback postoperatively</p> <p>I agree that the training and support provided by Applied Medical has been exemplary</p> <p>I am really disappointed to have missed the discussion as I would have been able to add our experience of hysterectomy which is very positive. My apologies again</p>	
27	[REDACTED] Consultee 4 Applied Medical		The link does not work. The only specialist advice questionnaire that was available to download on the other website only contains the input of 1 expert (Mr [REDACTED]) instead of 13.	Thank you for your comment. The problem will be resolved when the final guidance is published.

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