NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Endoscopic ablation for a pilonidal sinus**
Name of Specialist Advisor:	Jon Lund
Specialist Society:	Association of Coloproctology of Great Britain and Ireland

1 Do you have adequate knowledge of this procedure to provide advice?

☒ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☒ Yes.

☒ No. If no, please enter any other titles below.

Comments:
Also called endoscopic pilonidal sinus treatment (EPSiT) or video assisted pilonidal sinus ablation (VAAPS)

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☒ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:
Pilonidal sinus is mostly treated by General Surgeons, often, but not exclusively, with a special interest in coloproctology within the speciality of General Surgery. Some cases of pilonidal sinus are also treated by plastic surgeons, there will be regional variation, but the numbers treated by plastics will be low in comparison to the total.

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☒ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:
I have never performed endoscopic ablation for pilonidal sinus, and few in the UK or elsewhere have done so, as it requires high cost specialist equipment (including a very fine endoscope).
One of my main clinical and research interests is the treatment of pilonidal sinus disease. I will see 4-5 cases each week in my outpatient clinic. However, because of the special equipment required I have not performed endoscopic ablation treatment as the special scope is not available to us (which is the case fro all but a very few hospitals). The first line treatment I offer most of my patients with pilonidal sinus disease is with fibrin glue, so I very frequently take part in selection of patients with pilonidal sinus for a range of operative interventions, but never using endoscopic ablation. I am familiar with the technique from the literature.

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 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 had no involvement in research on this procedure.

☒ Other (please comment)

Comments:
I have published no research directly on endoscopic ablation but have published in the field of pilonidal sinus disease and minimally invasive treatments for this condition, listed below.

Fibrin glue is a quick and effective treatment for primary and recurrent pilonidal sinus disease. Sian TS, Herrod PJJ, Blackwell JEM, Hardy EJO, Lund JN. Tech Coloproctol 2018 DOI is 10.1007/s10151-018-1864-4

Fibrin glue obliteration is safe, effective and minimally invasive as first line treatment for pilonidal sinus disease in children. Hardy E, Herrod P, Sian T, Boyd-Carson H, Blackwell J, Lund JN, Quarmby JW. J Pediatr Surg. 2018 Sep 8. pii: S0022-3468(18)30546-3. doi: 10.1016/j.jpedsurg.2018.07.024.

Fibrin glue for pilonidal sinus disease. Lund J, Tou S, Doleman B, Williams JP. Cochrane Database Syst Rev. 2017 Jan 13;1:CD011923. doi: 10.1002/14651858.CD011923.pub2.

Less Is More in the Treatment of Pilonidal Sinus Disease. Lund JN. Dis Colon Rectum. 2017 Jan;60(1):e1.

Fibrin glue in the treatment for pilonidal sinus: high patient satisfaction and rapid return to normal activities. Elsey E, Lund JN. Tech Coloproctol. 2013 Feb;17(1):101-4. doi: 10.1007/s10151-012-0956-9. Epub 2012 Dec 6.

A randomised trial of fibrin glue vs surgery for pilonidal sinus disease: results and long term follow up. Catherine L Boereboom; Nicholas FS Watson; Sarah A Liptrot; Jonathan N Lund. Colorectal Disease. 2010 12(12):1281

Fibrin glue in the treatment of pilonidal sinus: results of a pilot study. Lund JN, Leveson SH. Dis Colon Rectum. 2005 May;48(5):1094-6.

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ 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.

Comments:

3.2 What would be the comparator (standard practice) to this procedure?

The standard (most commonly performed treatment in the UK for pilonidal sinus disease) remains wide excision with healing by secondary intention. However, other comparators to be considered would be primary off midline closure flap techniques (Bascom II or Karydakis procedures) or other novel minimally invasive techniques such as Fistula Laser Closure (FiLaC), fibrin glue or even henna powder (the latter not used to my knowledge in the UK).

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☒ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:
Very few centres have the necessary equipment to perform endoscopic ablation for pilonidal sinus, so the proportion of those preforming this procedure will be much less than 1%. However, all general surgery units in the UK will treat pilonidal sinus disease.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

   There are 2 recent (2018) systematic reviews/meta analyses:

   Endoscopic pilonidal sinus treatment: a systematic review and meta-analysis
   Emile, S.H., Elfeki, H., Shalaby, M. et al. Surg Endosc (2018) 32: 3754.
   https://doi.org/10.1007/s00464-018-6157-5

   And

   Outcomes of endoscopic pilonidal sinus treatment (EPSiT): a systematic review
   Tien, T., Athem, R. & Arulampalam, T. Tech Coloproctol (2018) 22: 325.
   https://doi.org/10.1007/s10151-018-1803-4

Complications include hematoma, infection, persistent discharge, and failure of healing. Range in published studies 0-11% (mean weighted 1.1%). Overall failure rate is reported as 8% (4% not responding to primary treatment and 4% recurring). Pain (the major other complication) scores are low post procedure and return to work occurs at 2.9 days.

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

The sinuses are irrigated with mannitol/glycine solution, although in small volumes and unlikely to cause adverse events

4.2 What are the key efficacy outcomes for this procedure?

Healing, recurrence, pain, patient satisfaction including cosmesis,

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

Only 1 RCT so far reported (Milone M, Fernandez LM, Musella M, Milone F (2015) Safety and efficacy of minimally invasive video-assisted ablation of pilonidal sinus: a randomized clinical trial. JAMA Surg 151(6):547–

553. https://doi.org/10.1001/jamasurg.2015.5233), so requires more evidence from high quality studies before this point can be answered with confidence.

4.4 What training and facilities are needed to do this procedure safely?

Facilities: Small calibre endoscope (e.g. 4mm fistuloscope) and support for maintenance and compatible viewing stacks. Instrumentation to allow hair removal via the fistuloscope and diathermy delivereable through the scope. Operating theatre and suitably trained theatre staff.
Training: A short course/preceptorship for new users. Monitoring of outcomes for new users until learning curve demonstrated complete.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

The only RCT registered on clincialtrials.gov is the one cited in 4.3. This compares VAAPS with off midline flap closure with primary outcome of infection. There are no relevant trials on the EU Clinical Trials registry and none on ISRCTN (search term pilonidal). There are no case registries for this technique to my knowledge.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

No

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

No

5 Audit Criteria
Please suggest a minimum dataset of criteria by which this procedure could be audited. Demographics (age, sex, BMI). Co-morbidities (esp diabetes). Social Habits (esp smoking). Previous surgery for pilonidal disease. Classification of pilonidal sinus disease (several similar systems available). Complications including haematoma and infection.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

primary healing at 6-12 weeks (examination)

Recurrence (at a minimum of 1 year – although recurrence/recrudescence can occur up to 20 years later)

Quality of life before and after treatment and between arms of any study. I would suggest seeking advice on the most appropriate tool, but a general score would be helpful (one of the iterations of Short Form or EQ 5D) and a more specific tool. Although there is not a pilonidal specific tool that I know of the Dermatology Life Quality Index (DLQI) might be considered.

Post procedure pain (for up to 2 weeks – patient reported via VAS diary or electronic daily input for worst pain)

Symptom resolution (pits will still be present in the natal cleft, although will be shallow and not lead to tracts – resolution of pain and discharge seems important to patients)

Cosmesis vs standard excisional treatments (PROM – tool to be decided in consultation with those with expertise – this is very important to young people who are the group who develop pilonidal sinus disease, and is a great driver for them to seek non excisional procedures)

Time to return to normal activities

Complications

Bargaining of chance of success vs advantages of minimally invasive surgery for patients in determining choice of outcome (validated tools exist for this)

Cost – this is important for this procedure as set up and maintenance costs may be high compared to other procedures. Overall economic evaluation to include aftercare, dressings and time off work to be performed for any trial of minimal invasive surgery for pilonidal disease versus excisional treatments.

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Infection (1-2 weeks)
Non healing (6 weeks)
Recurrence (by 1 year or longer – see above)

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

If high quality RCTs support promising early reports, the major barrier to generalisation is cost and access to specialist equipment required. Also, pilonidal sinus disease has a low profile and this is a challenge to change in practice. Informed patients will push for minimally invasive surgery but will often be only offered standard excisional surgery, often without primary closure, at their local hospital. Wide excision and healing by secondary intention remains the most common intervention for pilonidal sinus.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (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.

Comments:
See above on cost and availability of equipment

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☐ Moderate.

☒ Minor.

Comments:
Pilonidal sinus treatment modification will not make a significant impact on the NHS overall. However, a move to minimally invasive treatments will significantly reduce costs, improve time to return to normal activities and lead to increased patient satisfaction for those with this condition.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

X I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	☒	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	☒	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	☒	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	☒	**NO**
Investments – any funds that include investments in the healthcare	☐	**YES**

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

industry	☒	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	☒	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	☒	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	☒	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

June 2018

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 Personal family interest

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 Personal non-pecuniary interests

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as **'specific,'** or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as **'non-specific'**. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Endoscopic ablation for an pilinodal sinus**
Name of Specialist Advisor:	Mark Potter
Specialist Society:	Royal College of Surgeons

1 Do you have adequate knowledge of this procedure to provide advice?

☒ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☐ Yes.

☒ No. If no, please enter any other titles below.

Comments:

Probably best referred to as Endoscopic Pilonidal Sinus Surgery - EPSiT

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☒ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

I have performed this operation 5 times

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 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 had no involvement in research on this procedure.

☒ Other (please comment)

Comments:

I have done a limited literature review on the topic but no active reseach

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ 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.

Comments:

This is a relatively straight forward operation so I don't expect significant safety issues. The uncertainty is around outcomes

3.2 What would be the comparator (standard practice) to this procedure?

Excision and primary closure of pilonidal sinus. There are a number of different techniques for excision and primary closure eg Bascom's operation, Karydakis flap, Limberg flap and similar so careful consideration would have to be given to the structure of any comparison.

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☒ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

Not widely adopted yet probably due to lack of equipment and uncertainty over outcomes

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

   None reported in the observational series

2. Anecdotal adverse events (known from experience)

   Recurrence from own experience

3. Theoretical adverse events

   Tissue necrosis from ablation of tract

4.2 What are the key efficacy outcomes for this procedure?

Complete wound healing, return to work, wound breakdown, recurrence, wound infection,

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

Yes the outcomes are limited to cases series and historical controls. No RCTs reported or underway that I can find. My personal experience is not as good as the reported outcomes.

4.4 What training and facilities are needed to do this procedure safely?

It is a straightforward operation that can be learnt in a day under instruction from a colleague. Specialized equipment is required.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

I am not aware of any ongoing RCT. I know that Mr R Rajaganeshan Consultant Surgeon St Helens and Knowsley Teaching Hospital, Aintree was looking to set up a registry. I am not sure if has any data.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

None

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

No controversy about the way the operation is done. Just uncertainty about outcomes

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

Pre operative data regarding extent of disease would be needed to allow comparison between EPSiT and excision and closure. Main outcome measures would be**:**
Return to work – not easily measured unless prospectively collected
Recurrence rates - again would need to be prospectively collected
Number of operations -. It is hoped that EPSiT is more effective and would reduce the number of operations required to treat pilonidal disease by reducing wound breakdown complications or recurrence – only going to get this data from appropriate RCT which would allow a cost effectiveness analysis

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Wound infection – up to 2 weeks after surgery
Wound break down – up to 2 months after surgery
Recurrence - 2 months after surgery and beyond with no time limit

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

2- 5 years If outcomes can be validated it will catch on quickly provided a cost benefit to the NHS can be established. Acquiring this data may take time

6.2 This procedure, if safe and efficacious, is likely to be carried out in (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.

Comments:

Could be a simple day case general anaesthetic operation with significant cost benefits to NHS and society if the good outcomes reported can be reproduced.

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☐ Moderate.

☒ Minor.

Comments:

Great benefits to affected patients but incidence of disease is not high ~ 26/100,000. However it affects the young working population the most.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

No

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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	☒	**NO**
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☐ **YES**

☒ **NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

June 2018

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3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

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These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

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4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

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- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Endoscopic ablation for an pilinodal sinus**
Name of Specialist Advisor:	Rajasundaram Rajaganeshan
Specialist Society:	Association of Coloproctology of Great Britain and Ireland

1 Do you have adequate knowledge of this procedure to provide advice?

■ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

■ Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

■ Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

■ I do this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 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 had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

■ 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.

Comments:

3.2 What would be the comparator (standard practice) to this procedure?

excision of pilonidal sinus

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

■ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

none

2. Anecdotal adverse events (known from experience)

infection

3. Theoretical adverse events

4.2 What are the key efficacy outcomes for this procedure?

wound healing and reduced morbidity

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

recurrence

4.4 What training and facilities are needed to do this procedure safely?

attend a course followed by mentoring through the first few cases until confident to perform independently

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

no currently undertaking PEVES trial at St helens & knowsley NHS trust to compare excsion versus pilonidal sinus treatment

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

our series is not published yet

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

yes

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

wound healing rate infection rate and return to work and long term recurrence

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

infection bleeding and pain

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

very quickly

6.2 This procedure, if safe and efficacious, is likely to be carried out in (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.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

■ Major.

☐ Moderate.

☐ Minor.

Comments:

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

procedure can be performed under local anaesthetic thereby reducing the risk to patients and long term outcomes with laser hair depiltion might be better than excsion

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☑ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

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