

**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](mailto:azad.hussain@nice.org.uk) and [IPSA@nice.org.uk](mailto:IPSA@nice.org.uk)

**Procedure Name:** **Bioprosthetic plug insertion for closing an anal fistula**

Name of Specialist Advisor: Harriet Owen

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:**

Bioprosthetic plug insertion for treating anal fistula

**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:**

This procedure is carried out in centres with a specialist interest in anal fistula, some centres have more experience than others. The procedure has been grouped together for research and analysis with fibrin glue, which I believe to be an error as fibrin glue had near 80-100% failure rate and was quickly withdrawn from general use around 15 years ago.

**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:**

My Research (MSc and MD) was into anal fistula, not specifically the anal fistula plug, however I am continually auditing our department results.

**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:**

Currently mostly performed in specialist centres

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

Long term loose seton or other sphincter sparing procedure, such as LIFT (ligation of intersphincteric fistula track) or advancement flap

**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:**

Specialist centres at present

## **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)

Recurrence of the fistula, similar to other “sphincter-sparing procedures”, reported recurrence varies, overall 50%.

Champagne, B. J., L. M. O'Connor, et al. (2006). "Efficacy of anal fistula plug in closure of cryptoglandular fistulas: long-term follow-up." *Dis Colon Rectum* 49(12): 1817-21.

van Koperen, P. J., A. D'Hoore, et al. (2007). "Anal fistula plug for closure of difficult anorectal fistula: a prospective study." *Dis Colon Rectum* 50(12): 2168-72.

Ky, A. J., P. Sylla, et al. (2008). "Collagen fistula plug for the treatment of anal fistulas." *Dis Colon Rectum* 51(6): 838-43.

Kockerling, F., N.N. Alam, et al. (2015). "Treatment of Fistula-In-Ano with Fistula Plug – a Review Under Special Consideration of the Technique" *Front Surg* 2015; 2: 55.

In well selected patients with non-Crohn’s anal fistula who have a loose seton for 6 weeks or more and pre-operative MRI to exclude secondary extensions we are achieving 70% success, 30% recurrence, not yet published. The benefit is there is minimal risk to continence unlike the other procedures.

2. Anecdotal adverse events (known from experience)

Reports of plug falling out, I have no personal experience of this.

3. Theoretical adverse events

### **4.2 What are the key efficacy outcomes for this procedure?**

A near-no harm procedure that has at least 50% chance of success which does not affect continence or prevent future treatments should it fail.

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

Recurrence, which does not preclude future treatment.

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

The first few cases should be performed alongside a surgeon with prior experience, the company representative should attend for the first few cases to ensure the surgeon and scrub team are clear on the technique. It is not a taxing procedure, the complexity is in patient selection.

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

The FIAT trial (PI Prof David Jayne, University of Leeds) examined efficacy of anal fistula plug compared to standard treatment, outcome awaited, no registries that I am aware of. Has Prof Jayne been asked for his comments?

**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).**

Prof David Jayne FIAT trial

**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.**

**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:**

Assessment of symptoms, clinical examination for healing at 3,6, and 12 months. MRI scan if symptoms of anal fistula return to examine for recurrence. In a research capacity, MRI at 12 months would be ideal, however NHS financial limitations preclude this.

**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:**

Most plug extrusion occurs within 4 weeks, there is pain for the first 10 days managed with analgesia and laxative, no other complication other than recurrence reported.

## **6 Trajectory of the procedure**

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

The procedure has been available for 10 years and is performed in specialist interest centres, I do not know the overall numbers that are being performed.

### **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:**

When successful, a major impact on a relatively small number of patients.

## **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?**

Suggest contact Prof David Jayne at Leeds University if not already done so.

## **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.

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## 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<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

- |  |  |
|--|--|
| <b>Consultancies or directorships</b> attracting regular or occasional payments in cash or kind  | <input type="checkbox"/> YES           |
|  | <input checked="" type="checkbox"/> NO |
| <b>Fee-paid work</b> – any work commissioned by the healthcare industry – <b>this includes income earned in the course of private practice</b>   | <input type="checkbox"/> YES           |
|  | <input checked="" type="checkbox"/> NO |
| <b>Shareholdings</b> – any shareholding, or other beneficial interest, in shares of the healthcare industry  | <input type="checkbox"/> YES           |
|  | <input checked="" type="checkbox"/> NO |
| <b>Expenses and hospitality</b> – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences | <input type="checkbox"/> YES           |
|  | <input checked="" type="checkbox"/> NO |

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<sup>1</sup> ‘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).

**Investments** – any funds that include investments in the healthcare industry  YES

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 Advisor 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.

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Interventional Procedures Programme

**Specialist Adviser questionnaire**

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**Please respond in the boxes provided.**

**Please complete and return to:** [azad.hussain@nice.org.uk](mailto:azad.hussain@nice.org.uk) and [IPSA@nice.org.uk](mailto:IPSA@nice.org.uk)

**Procedure Name:** **Bioprosthetic plug insertion for closing an anal fistula**

Name of Specialist Advisor: Phil Tozer

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?**

All the existing sphincter preserving procedures would be alternative (including advancement flap, LIFT, VAAFT and FiLaC etc.) as would fistulotomy in some cases.

#### **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)

The main risk is failure/recurrence of the fistula. This is probably in the order of 50% in cryptoglandular disease and higher still in Crohn's disease.

2. Anecdotal adverse events (known from experience)

Plugs seem sometimes to make the fistula wider and increase symptoms.

3. Theoretical adverse events

#### **4.2 What are the key efficacy outcomes for this procedure?**

In cryptoglandular fistula, The literature describes a very broad range of success rates but 50% is a fair guess and I would not argue that it is higher. In Crohn's disease the best evidence is from a Getaid RCT which suggested no benefit above place.

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

Proponents argue it is higher and that failures are often due to poor technique or patients selection. Some opponents suggest that it is very rarely effective in the long term. I take the view that the truth lies between the two, and that the success rate may be in the order of 50% but the literature is heterogenous and the true efficacy remains hard to determine, in my view.

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

Brief training in the technique. Standard minor operating environment. The plug itself is the main additional cost.

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

The best evidence probably comes from the FIAT study which has not yet reported.

#### **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).**

The FIAT study has been presented but not published and may fall into this category. The FIAT investigators could be contacted to obtain the FIAT data.

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

The initial success rates were high and then fell away fast. The main proponents claimed this was due to technique and a consensus statement was produced to try to standardise this. I do not know if proponents still feel the technique is poorly executed.

**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:**

**Long term fistula closure – clinically and radiologically (the latter is conspicuous by its absence)**

**There is no good QoL measure in fistula disease at the moment but FIQL has been used**

**Recurrence, abscess formation, rescue antibiotics and rescue surgery are sometimes used to represent failure of treatment**

**Plug extrusion is sometimes used as an early process outcome**

**Pain post op is sometimes measured**

**Continence is a common outcome measure**

**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:**

**Plug extrusion early, abscess formation, rescue medication/surgery – all short term**

**Abscess or fistula recurrence – longer term (usually 6-12 months)**

**6 Trajectory of the procedure**

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

I think it has done its spreading in the UK

**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?**

Comparison with other SPPs is important

**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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Do you or a member of your family<sup>1</sup> 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 industry  **YES**  
 **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**

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<sup>1</sup> ‘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).

**Support by the healthcare industry or NICE** that benefits his/her position or department, eg grants, sponsorship of posts

- NO**
- YES**
- NO**

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

**Comments:**

I've answered no because I assume that the conflict of interest would be a relationship with a plug company. I have no such relationship. I have received speakers and consultancy fees from Takeda, who produce stem cells for use in Crohn's anal fistula. I do not believe this is a conflict because it is only an issue in Crohn's anal fistula. Also, I do not place plugs in either my NHS or private practice. Please let me know if any of this is considered a conflict of interest and I will be happy to amend the form. I do not believe it is.

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

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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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- 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 Advisor 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](mailto:azad.hussain@nice.org.uk) and [IPSA@nice.org.uk](mailto:IPSA@nice.org.uk)

**Procedure Name:** **Bioprosthetic plug insertion for closing an anal fistula**

Name of Specialist Advisor: Toby Hammond

Specialist Society: Association of Coloproctology of Great Britain and Ireland

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

Yes.

**1.1 Does the title used above describe the procedure adequately?**

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

**Comments:**

**Bioprosthetic plug insertion for the management of an anal fistula**

**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?

**Yes**

**Comments:**

As the benefits of the bio-prosthetic plug are still debatable

**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 done this procedure at least once ✓

**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 taken part in patient selection or referred a patient for this procedure at least once ✓

**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 clinical research on this procedure involving patients or healthy volunteers ✓

**Comments:**

I was involved in recruiting for the FIAT study

**3 Status of the procedure**

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

✓ Definitely novel and of uncertain safety and efficacy.



**Comments:**

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

As this is a sphincter conserving procedure the comparator should be any established sphincter conserving procedure which the individual surgeon is most accomplished

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

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

**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)

Post procedural pain, perianal sepsis, fistula recurrence (Xu Y, Tang W. Comparison of an anal fistula plug and mucosa advancement flap for complex anal fistulas: a meta-analysis. ANZ J Surg. 2016;86(12):978-982)

2. Anecdotal adverse events (known from experience)

Post procedural pain, perianal sepsis, fistula recurrence

3. Theoretical adverse events

**4.2 What are the key efficacy outcomes for this procedure?**

Patient satisfaction  
Fistula healing  
No continence disturbance

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

Limited success rate – at best 50%

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

Unsure –but little required as is fairly basic technique

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

FIAT study

**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).**

FIAT study results due to be published shortly

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

Not that I'm aware of

**5 Audit Criteria**

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

Outcome measures:  
Patient satisfaction  
Fistula healing  
Continence disturbance  
Other adverse events

**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:**

Ideally a specific anal fistula QoL questionnaire such as:

Ferrer-Márquez M1, Espínola-Cortés N, Reina-Duarte A, Granero-Molina J, Fernández-Sola C, Hernández-Padilla JM. Design and Psychometric Evaluation of the Quality of Life in Patients With Anal Fistula Questionnaire. Dis Colon Rectum. 2017 Oct;60(10):1083-1091

**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:**

Pain, bleeding & discharge up to 1 month  
Fistula recurrence up to 2 years

**6 Trajectory of the procedure**

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

Limited

**6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):**

√ A minority of hospitals, but at least 10 in the UK.

**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:**

√ 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?**

Best resource is FIAT study

## 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.

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#### 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<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

**Consultancies or directorships** attracting regular or occasional payments in cash or kind   **√NO**

**Fee-paid work** – any work commissioned by the healthcare industry –   **√YES**

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<sup>1</sup> ‘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).

**this includes income earned in the course of private practice**   
**Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry   **√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   **√NO**

**Investments** – any funds that include investments in the healthcare 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?   **√NO**

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

**Fellowships** endowed by the healthcare industry   **√NO**

**Support by the healthcare industry or NICE** that benefits his/her position or department, eg grants, sponsorship of posts   **√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

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