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:	**Reinforcement of permanent stomas with mesh to prevent parastomal hernias**
Name of Specialist Advisor:	Dr Neil Smart
Specialist Society:	Association of Coloproctology of Great Britain & 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:

Lead author of ACPGBI guidelines on the topic. Contributing author to European Hernia Society guidelines on the topic. Chief Investigator of the NIHR funded CIPHER study (14/166/01).

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:

Depending upon which type of permanent stoma you refer to, all of the above may apply.

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

No mesh placement. But how a non-mesh stoma is constructed is subject to an estimated > 300 variations!

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:

Based on current data in the NIHR funded CIPHER study

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)

Infection (<5%)

Erosion (<1%)

Fistulation (<1%)

Mesh removal (<1%)

2. Anecdotal adverse events (known from experience)

Adhesions causing bowel obstruction.

3. Theoretical adverse events

Delays rather than prevents PSH formation. When PSH does occur, the bowel gets stuck to the mesh and is consequently much more difficult to repair, requiring bowel resection / ITU stay etc.

4.2 What are the key efficacy outcomes for this procedure?

Prevention of PSH formation according to clinical exam
Prevention of PSH formation according to CT exam
Prevention of PSH formation according to the patient
Severity of PSH if it does occur
Complexity of PSH repair if it is required
PSH repair rate
Quality of life (disease specific & generic)
Health economics

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

Yes. The current RCTs are heterogeneous in quality and in terms of outcome. Follow up has been relatively short. Long term effectiveness unknown. Who benefits unclear. Data limited to cancer patients in elective surgery and only colostomies. Huge uncertainty about all benign conditions, non-elective patients and ileostomies / urostomies. The optimal mesh type and location of the mesh within the abdominal wall is unknown.

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

Very little, it is an extension of common hernia surgery practice. Simulation models exist to practice placement of mesh if required.

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

PREVENT (Dutch RCT)
STOMAMESH (Swedish)
StomaCONST (Danish / Swedish)
CIPHER (NIHR funded UK Study – ongoing. Has recruited > 350 patients todate. Aim is for 4000 patient from >70 UK hospitals.
I believe there is another Finnish study on going (CI is Tero Rautio)

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 trial protocol of the above Finnish study has been submitted to Trials recently, but then withdrawn.

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

Loads! Hence the CIPHER Study. It isn't just those who have mesh placed we need to know more about, it is those without mesh too.

Best way to create a stoma is completely unknown. May substantially impact on the effect size of mesh prophylaxis. What mesh? Where? What Size? How placed? What size & shape of mesh trephine etc Is a mesh even needed at all if extraperitoneal routing of the afferent stomal limb is used. If the stoma is created properly (whatever that may be) does the benefit of prophylactic mesh disappear? Are PSH that occur after mesh more difficult to fix?

The CIPHER study is aiming to have over 70 sites (currently 52 open, > 10 further SIV planned, if we convert all EOI into active sites, should be over 80) covering hospitals that serve > 50% of the population. It should be truly representative of the NHS and the UK population.

5 Audit Criteria

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

Please see the CIPHER study. It is essentially already doing this

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:

Please see the CIPHER study. It is essentially already doing 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:

Infection up to 30 days
Erosion / fistulation / chronic pain etc - lifelong

6 Trajectory of the procedure

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

In the UK, VERY slow. The current mesh adverse publicity has all but stymied the adoption of this technique. Furthermore, the EHS & ACPGBI guidelines differ in their appraisal of the literature, with the ACPGBI much more circumspect about the quality of the evidence and hence more guarded in its advice. The recent Cochrane review is even more sceptical regarding mesh.

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:

Every hospital that has general surgery will make stomas.

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:

Possibly 10000 new permanent stomata per year in the UK

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?

The CIPHER Study trial protocol (available from cipher-study@bristol.ac.uk) and CRFs

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.

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:

[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).

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**
	☐	**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:

1. Lecturers fees for abdominal wall reconstruction (in general) paid by Medtronic
2. Lecturers fees for abdominal wall reconstruction (in general) paid by WL Gore
3. Lead author of ACPGBI parastomal hernia guideline group – published position statement in Colorectal Disease 2018.

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.