NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read <u>Conflicts of Interest for Specialist Advisers</u>. 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:		tristan.mckenna@nice.org.uk	
Procedure Name:		IP728/2 Infracoccygeal sacropexy using mesh for uterine prolapse repair	
Nam	e of Specialist Advisor:	Mr Moran	
Specialist Society:		The British Society of Urogynaecology (BSUG)	
1	1 Do you have adequate knowledge of this procedure to provide advice?		
\boxtimes	Yes.		
	No − please return the form/answer no more questions.		
1.1	1.1 Does the title used above describe the procedure adequately?		
	Yes.		
	No. If no, please enter any oth	ner titles below.	
AS th	ments: nis is a mesh sling procedure ra for vaginal vault prolapse'	ther mesh sheet, I would prefer ' IS using a mesh	
2	Your involvement in the pro-	cedure	
2.1	Is this procedure relevant to	your specialty?	
\boxtimes	Yes.		

\boxtimes	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.
Com	ments:
patie pleas	next 2 questions are about whether you carry out the procedure, or referents for it. If you are in a specialty that normally carries out the procedure see answer question 2.2.1. If you are in a specialty that normally selects or spatients 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.
\boxtimes	I have done this procedure at least once.
	I do this procedure regularly.
main	
	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.
I pick	ments: oup the occasional patient who I feel may benefit and refer to a colleague in local tertiary centre.
2.3	Please indicate your research experience relating to this procedure (please choose one or more if relevant):
\boxtimes	I have done bibliographic research on this procedure.
	I have done research on this procedure in laboratory settings (e.g. device-related research).

Ш	volunteers.		
	I have had no involvement in research on this procedure.		
	Other (please comment)		
Con	nments:		
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.		
Con	nments:		
3.2	What would be the comparator (standard practice) to this procedure?		
Eith	er		
she	1)vaginal procedure- sacrospinous fixation or posterior vaginal wall mesh sheet procedure with infracoccygeal fixation or sacrospinous fixation 2)Abdominal mesh sacrolpopexy		
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.		
Con	nments:		

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)

Risk of adverse event is realted to patient choice, training and experience of the surgeon. Overall rates of complications are between 5-10%

2. Anecdotal adverse events (known from experience)

Unable to comment – now a different procedure with different mesh

3. Theoretical adverse events

Mesh extrusion/erosion, Chronic pain, trauma to adjacent structures, painful sexual intercourse

4.2 What are the key efficacy outcomes for this procedure?

Patient satisfaction and comfort Secondary outcomes- objective prolapse assessment and complication; Long term prolapse recurrence risk

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

Long term issues of employing a vaginal mesh

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

Training in advanced pelvic surgery, supervised procedures and staged learning; Adequate case volume per year essential eg 10 or more cases per year or part of a trial.

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

I am not aware

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).

I am not aware of any recently.

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 to my knowledge

5 Audit Criteria

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

I would suggest as a minimum completing the data pages on the BSUG database- this should collect all the relevant data you require in the short term. Long term follow up would be ideal – say up to 5 years but is highly impracticable.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures):

Refer BSUG database

5.2 Adverse outcomes (including potential early and late complications):

Utilise the IUGA/ICS mesh complications grading of complications and report to MHRA

6 Trajectory of the procedure

Comments:

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

Very slowly and may not increase above current levels.

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.	
\boxtimes	Cannot predict at present.	

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.		
\boxtimes	Minor.		
Comm	nents:		
7	Other information		
7.1 NICE i	Is there any other information about this procedure that might assist n assessing the possible need to investigate its use?		
	I am not aware of any unless there is collected data from the national BSUG dataset already- you could request this data from BSUG		
8	Data protection and conflicts of interest		
8. Data	a protection, freedom of information and conflicts of interest		
8.1 Da	ta 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 family¹ have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional		YES
payments in cash or kind	\boxtimes	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		YES
of the healthcare industry	\boxtimes	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		YES
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		YES
	\boxtimes	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:

I have received travel bursuries, meeting sponsorship and lecturing income from Astellas within the past year.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Professor Carole Longson, Director, Centre for Health Technology

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).

Procedures Advisory Committee Chair Evaluation.

Jan 2016

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.

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Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided. tristan.mckenna@nice.org.uk Please complete and return to: IP728/2 Infracoccygeal sacropexy using mesh Procedure Name: for uterine prolapse repair Mr Toozs-Hobson Name of Specialist Advisor; Specialist Society: The British Society of Urogynaecology (BSUG) Do you have adequate knowledge of this procedure to provide advice? 1 X Yes. No - please return the form/answer no more questions. Does the title used above describe the procedure adequately? X Yes. No. If no, please enter any other titles below. Comments: Your involvement in the procedure 2 Is this procedure relevant to your specialty? X 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.	
Com	nments:	
patie plea	next 2 questions are about whether you carry out the procedure, or referents for it. If you are in a specialty that normally carries out the procedure se answer question 2.2.1. If you are in a specialty that normally selects or spatients 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.	
X	I have done this procedure at least once.	
	I do this procedure regularly.	
	Ments: VORMS INFREQUENTLY DONG. USUALU IN PRODUNTAL/ LAMAROSCOPIC APPROVALM	
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.	
M	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.	
Com	ments:	
2.3	Please indicate your research experience relating to this procedure (please choose one or more if relevant):	
\boxtimes	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)
Com	ments:
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.
X	Definitely novel and of uncertain safety and efficacy.
	The first in a new class of procedure.
Com	ments:
3.2	What would be the comparator (standard practice) to this procedure?
	LAPAROSCOPIC SPACROMYSTEROPEXY
	OR SACROSPINOUS MYSTOROPERS
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.
X	Fewer than 10% of specialists engaged in this area of work. FAR TWICK
	Cannot give an estimate.
Com	ments:
4	Safety and efficacy
4.1	What is the potential harm of the procedure?
	se list adverse events and major risks (even if uncommon) and, if possible, nate their incidence, as follows:

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

SEE SECOVIME REPORT

2.	Anecdotal adverse events (known from experience)
3.	Theoretical adverse events
4.2	What are the key efficacy outcomes for this procedure? 1MPROVEMENT IN PROLAWS C-
4.3	Are there uncertainties or concerns about the efficacy of this procedure? If so, what are they? ARHUME + COMPLICATION RATEO
4.4	What training and facilities are needed to do this procedure safely? ATTOWN CADAVALIC TEANING TOWNSTORSH W
4.5	Are there any major trials or registries of this procedure currently in progress? If so, please list.
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).
4.7	Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

BSMG DATABAKE

audited.

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

outcomes, both short and long - term; and quality-of-life measures):
BSUG DATABATE
5.2 Adverse outcomes (including potential early and late complications): MUSH COMPLICATIONS
6 Trajectory of the procedure
6.1 In your opinion, how quickly do you think use of this procedure will spread?
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: VORY DIFFICULT TO PREDICT
Comments: VORY DIFFICULT TO PREDICT PORTURES ASKING BOSTON SCIENTIFIC HOW MANY MOSPITALI BUY THIS PRODUCT
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: PATIENT DRIVEN ITIS NOT A
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.

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).

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Do you or a member of your family¹ have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional		YES
payments in cash or kind		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	X	YES
of the healthcare industry		NO

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).

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 he	althcare 🛚 🗵	YES
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
	\square	NO
Support by the healthcare industry or NICE that benefits	his/her	YES
position or department, eg grants, sponsorship of posts		NO
If you have answered YES to any of the above statement nature of the conflict(s) below.	ıts, please descrik	e the
Comments:		
Thank you very much for your help.		
	ole Longson, Direction Ith Technology	etor,
Jan 2016		
	4.10	
SEE DEIMLS ON IP 21	68/2.	

Conflicts of Interest for Specialist Advisers

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- 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.