## 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:	IP660/2 Surgical repair of vaginal wall prolapse using mesh		
Name of Specialist Advisor:	Mr Jason Cooper		
Specialist Society:	The British Society of Urogynaecology (BSUG)		
<ul> <li>Do you have adequate know</li> <li>X Yes.</li> <li>No – please return the form/a</li> </ul>	rledge of this procedure to provide advice?		
1.1 Does the title used above describe the procedure adequately?			
X□ Yes.			
No. If no, please enter any other titles below.			
Comments:			
2 Your involvement in the pro-	Your involvement in the procedure		
2.1 Is this procedure relevant to	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	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.
	I have done this procedure at least once.
<b>X</b>	I do this procedure regularly.
Com	ments:
	pecame a relatively common operation but for various concerns about enefit ratio has decreased in frequency
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.
Com	ments:
2.3	Please indicate your research experience relating to this procedure (please choose one or more if relevant):
<b>X</b>	I have done bibliographic research on this procedure.
	I have done research on this procedure in laboratory settings (e.g. device-related research).
Χ□	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	Comments:			
3	Status of the procedure			
3.1	Which of the following best describes the procedure (choose one):			
<b>X</b>	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.			
Com	ments:			
	A difficult question. It became common & therefore established in this country but is now less so. Other countries e.g. France still use it commonly.			
3.2	What would be the comparator (standard practice) to this procedure?			
A 'standard' vaginal repair (native tissue), although there is no standard technique! Really it is all vaginal repairs that do not use mesh.				
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.			
<b>x</b>	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.			
Com	ments:			
	decreasing. That is 10-50% of people working in this specific area 1.e. ynaecologists.			
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, haemorrhage, blood transfusion, re-operation i.e recurrence of the prolapse (up to 35% over 5 years), bladder, ureter or bowel injury, painful intercourse, unmasking of urine leakage, disturbance of bladder function, worsening or new backache due to position on the operating table, pelvic abscess, urinary retention, pain, deep vein thrombosis and pulmonary emboli. These are all risks of all mesh and non-mesh (native tissue) – repairs.

Specific to mesh repairs are the complications of the mesh itself. These are exposure of the mesh into the vagina (approx. 10%) which may require further surgery to remove a part or all of the mesh, or erosion or placement of the mesh into surrounding structures typically bowel or bladder.

- 2. Anecdotal adverse events (known from experience)
- 3. Theoretical adverse events

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

Treatment of prolapse and theoretical improved long-term success.

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

There are questions as to whether mesh repair is in fact any better than native tissue repair

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

Mentoring as in all surgical procedures would be expected. Ideally with laboratory or anatomy based simulation training.

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

There are a number of national and internationally registries. In the UK we have the BSUG Database that is run by BSUG, with no external funding. BSUG is a charity. There are a number of recent reports including the SCENIHR & Scottish Report.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

No

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

Risk/benefit ratio. Do the known complications of using mesh outweigh the putative long-term success.

#### 5 Audit Criteria

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

Long-term success is in my opinion the key - at least 5-year follow up. Without this we do not know if any increased risks of mesh are offset by long-term success and therefore less repeat operations (and all of the repeat risks of those repeat operations).

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

ICI-VS scores, many other questionnaires and objective clinical examination.

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

Mesh exposure, repeat prolapse surgery, new onset dyspareunia that must be compared to the incidence in native tissue repair surgery. Often this latter complication is mentioned as an independent risk with mesh repairs although it also occurs with all types of prolapse surgery.

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

Already widely utilised nationally and internationally, but now significantly contracted.

6.2 (choo	6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):		
<b>X</b>	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.			
Comn	Comments:			
The su	urgery is not particularly technically difficult			
6.3 of pat	The potential impact of this procedure on the NHS, in terms of numbers ients eligible for treatment and use of resources, is:			
<b>X</b>	Major.			
	Moderate.			
	Minor.			
Comn	nents:			
In my	own study, 12% of over 3000 women had a prolapse repair in their lifetime.			
7	Other information			
7.1 NICE	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. Dat	a protection, freedom of information and conflicts of interest			
8.1 Da	ata 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<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 <mark>X</mark> NO	
Fee-paid work – any work commissioned by the healthcare industry – this includes income earned in the course of private practice		YES <mark>X</mark> NO	
<b>Shareholdings</b> – any shareholding, or other beneficial interest, in shares of the healthcare industry		YES XNO	
<b>Expenses and hospitality</b> – any expenses provided by a healthcare industry company beyond those reasonably required for		XYES	
accommodation, meals and travel to attend meetings and conferences		NO	
<b>Investments</b> – any funds that include investments in the healthcare industry		YES	
ddd y	Ш	XNO	
Do you have a <b>personal non-pecuniary</b> interest – for example have you made a public statement about the topic or do you hold an office in		X YES	
a professional organisation or advocacy group with a direct interest in the topic?		NO	
Do you have a <b>non-personal</b> interest? The main examples are as follows:			
Fellowships endowed by the healthcare industry		YES	
		XNO	
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts		YES	
If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.			
Comments:			

<sup>&</sup>lt;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).

**Expenses and hospitality** - I have received fees for lecturing for a healthcare company (Astellas). They also sponsor a twice-yearly meeting for the North Midlands Urogynaecology Group, of which I am currently Chairman. I have previously attended courses on teaching how to use mesh, sponsored by mesh producing companies.

**Do you hold an office in a professional organisation** – I am currently the Honorary Secretary of the British Society of Urogynaecology

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology 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.

#### 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.

Plea	se respond in the boxes pro	ovided.
Plea	se complete and return to:	tristan.mckenna@nice.org.uk
Prod	cedure Name:	IP660/2 Surgical repair of vaginal wall prolapse using mesh
Nam	ne of Specialist Advisor:	Mr Alfred Cutner
Specialist Society:		The British Society of Urogynaecology (BSUG)
1	Do you have adequate kno	wledge of this procedure to provide advice?
$\boxtimes$	Yes.	
	No – please return the form	n/answer no more questions.
1.1	Does the title used above of	lescribe the procedure adequately?
	Yes.	
	No. If no, please enter any o	ther titles below.
Con	nments:	
Nee	d to separate out vaginal and	abdominal / laproscopic mesh
2	Your involvement in the procedure	
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:	
Relev	vant to urology and colrectal surgery as well	
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.	
	I have done this procedure at least once.	
$\boxtimes$	I do this procedure regularly.	
Comments:  Only refers to abdominal / laparoscopic mesh. Not done where refers to vaginal insertion of mesh		
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.	
Com	ments:	
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).	
$\boxtimes$	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	nments:		
Only	regards abdominal / laproscopic insertion not related to vaginal insertion		
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.		
$\boxtimes$	Definitely novel and of uncertain safety and efficacy.		
	The first in a new class of procedure.		
Com	nments:		
With	With regards vaginal insertion of mesh in terms of safety and indication.		
3.2	What would be the comparator (standard practice) to this procedure?		
Abdo	ominal / laparoscopic proocedures or vaginal surgery with native tissue.		
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.		
$\boxtimes$	Fewer than 10% of specialists engaged in this area of work.		
	Cannot give an estimate.		
Com	nments:		
In re	lation to vaginal insertion of mesh		
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:		

١.	Adverse events reported in the literature (ii possible please cite literature)
Ра	in / Extrusion / infection / bladder / bowel / sexual dysfunction. Schenir report
Sc	ottish review and NHS England review

- 2. Anecdotal adverse events (known from experience)
- 3. Theoretical adverse events
- 4.2 What are the key efficacy outcomes for this procedure?

Anatomical success and restoration of bladder / bowel / sexual function

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

Yes as risk benefit is not clearly deterined

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

vaginal surgery / cadavaric training. Should only be part of advanced specialty training

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

BSUG database

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

No

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

Yes. Requires specific training in terms of indications, councelling and technique

5 Please audite	Audit Criteria e suggest a minimum dataset of criteria by which this procedure could be ed.
5.1 outco	Outcome measures of benefit (including commonly used clinical mes, both short and long - term; and quality-of-life measures):
Use o	f BSUG database and submission of complications to MHRA
5.2	Adverse outcomes (including potential early and late complications):
Extrus	sion rates. Mesh removal. Pain and dyspareunia
6	Trajectory of the procedure
6.1 spread	In your opinion, how quickly do you think use of this procedure will d?
For va	ginal insertion of mesh usuage is likely to decline to only a few cases.
6.2 (choo	This procedure, if safe and efficacious, is likely to be carried out in se one):
	Most or all district general hospitals.
	A minority of hospitals, but at least 10 in the UK.
$\boxtimes$	Fewer than 10 specialist centres in the UK.
	Cannot predict at present.
Comm	nents:
6.3 of pat	The potential impact of this procedure on the NHS, in terms of numbers ients 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 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.

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

Consultancies or directorships attracting regular or occasional	$\boxtimes$	YES
payments in cash or kind		NO
Fee-paid work – any work commissioned by the healthcare industry –	$\boxtimes$	YES

<sup>&</sup>lt;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		NO
<b>Shareholdings</b> – any shareholding, or other beneficial interest, in shares of the healthcare industry	s	YES 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	,	YES
		NO
Investments – any funds that include investments in the healthcare industry		YES NO
Do you have a <b>personal non-pecuniary</b> 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 <b>non-personal</b> interest? The main examples are as follows	s:	
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 denature of the conflict(s) below.	escribe	the
Comments: Chair of BSUG. Paid consultant to Fannin. Paid to teach laparoscopic urogynaecology by Olympus & Ethicon. Paid consultancy work for Colopla Department received payment for teaching from Ethicon, Olympus and B practice and medico-legal work.		ivate
Thank you very much for your help.		
Dr Tom Clutton-Brock, Interventional Professor Carole Longson, Procedures Advisory Committee Chair Centre for Health Technolo Evaluation.		or,

Jan 2016

#### **Conflicts of Interest for Specialist Advisers**

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- 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.