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	Please respond in the boxes provided.		
Plea	se complete and return to:	tristan.mckenna@nice.org.uk	
Procedure Name:		IP372/2 Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair	
Nam	e of Specialist Advisor:	Dr Cutner	
Specialist Society:		Royal College of Obstetricians and Gynaecologists (RCOG)	
1	Do you have adequate know	vledge 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 other titles below.		
Com	nments:		
Sacr	ohysteropexy as the overall ter	m would be better	
2	Your involvement in the procedure		
2.1	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	ant to Urogynaecologists and female urologists
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 a 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.
\boxtimes	I do this procedure regularly.
Comi	nents:
I have	e done over 100
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.
\boxtimes	I take part in patient selection or refer patients for this procedure regularly.
Comi	ments:
I rece	ive many tertiary referrals fior this procedure
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).
\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	ments:
	elian AS, Vashisht A, Sambandan N2, Cutner A. Laparoscopic wrap round mesh ohysteropexy for the management of apical prolapse. Int Urogynecol J. 2016
3	Status of the procedure
3.1	Which of the following best describes the procedure (choose one):
\boxtimes	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:
prog	is now part of subspecialty training in urogynaecology in the RCOG training ram. It is one of the treatment options that women with uterine prolapse should ffered.
3.2	What would be the comparator (standard practice) to this procedure?
Vagi	nal hysterectomy and repair or sacrospinous hysteropexy.
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.
\boxtimes	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.
This	iments: is carried out in most subspecialty training units in urogynaecology in the UK. er less specialist units have started to adopt it.
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)

This procedure is commonly performed laparoscopically. Thus all the risks of laparoscopic surgery exist. There are risks associated with dissecting the sacral promontary and other risks are similar to sacrocolpopexy. Mesh risks are less.

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

Risks of performing a hysterectomy in a patient after a hysteropexy.

4.2 What are the key efficacy outcomes for this procedure?

Resolution of prolapse symptoms.

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

Several large series are now present in the literature. Different methods of performing the surgery may result in different outcomes.

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

Training exists within the RCOG subspecialty training program

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).

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

Wrap round mesh hysteropexy has the largest data cohort of results.

5 Please audite	Audit Criteria suggest a minimum dataset of criteria by which this procedure could be d.
5.1 outcor	Outcome measures of benefit (including commonly used clinical mes, both short and long - term; and quality-of-life measures):
ICIQ-V bowel.	S to assess prolapse impact on vaginal symptoms, sex, bladder and
5.2	Adverse outcomes (including potential early and late complications):
surgic	al complicatipons, mesh complications
6	Trajectory of the procedure
6.1 spread	In your opinion, how quickly do you think use of this procedure will 1?
Patient take-up	t demand for choice and satisfaction with outcome is resulting in increased o.
6.2 (choos	This procedure, if safe and efficacious, is likely to be carried out in se one):
	Most or all district general hospitals.
\boxtimes	A minority of hospitals, but at least 10 in the UK.
	Fewer than 10 specialist centres in the UK.
	Cannot predict at present.
Comm	ents:
This re	quires an understanding of urogynaecology and advanced laaproscopic skills.
6.3 of pati	The potential impact of this procedure on the NHS, in terms of numbers ents eligible for treatment and use of resources, is:
\boxtimes	Major.
	Moderate.
	Minor.
Comm Quicke	ents: or recover and lower recurrence rates may result in reduced costs.

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?

This is also being commissioned via specialist commissioning in England

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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

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

Do you or a member of your family 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
Investments – any funds that include investments in the healthcare industry		NO 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 description at the conflict(s) below.	cribe	the
Comments: Chair of BSUG, Advisor to Fannin and Coloplast, funding and payment for to Stryker, Olympus. Thank you very much for your help.	eachi	ing
Dr Tom Clutton-Brock, Interventional Professor Carole Longson, De Centre for Health Technology Evaluation.		or,
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.
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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

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Plea	se respond in the boxes prov	vided.
Pleas	se complete and return to:	tristan.mckenna@nice.org.uk
Proc	edure Name:	IP372/2 Insertion of mesh uterine suspension
		sling (including sacrohysteropexy) for uterine prolapse repair
Nam	e of Specialist Advisor:	Dr Jackson
Spec	cialist Society:	Royal College of Obstetricians and Gynaecologists (RCOG)
1	Do vou have adequate know	/ledge of this procedure to provide advice?
		3
Y	Yes.	
	No – please return the form/	answer no more questions.
1.1	Does the title used above de	escribe the procedure adequately?
Y	Yes.	
	No. If no, please enter any oth	ner titles below.
Com	ments:	
2	Your involvement in the pro	cedure
2.1	Is this procedure relevant to	your specialty?
ΥΠ	Yes.	

N	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:	
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.	
Y _	I do this procedure regularly.	
Com	ments:	
I do >	-100 cases per annum	
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.	
Y _	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).	

Y 🗀	volunteers.
	I have had no involvement in research on this procedure.
	Other (please comment)
Com	ments:
I hav	e published on this procedure; cohort studies and RCT vs hysterectomy
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.
Y _	Definitely novel and of uncertain safety and efficacy.
	The first in a new class of procedure.
Com	ments:
pract	e 10 years clinical experience with this procedure, it has become established ice in our Urogynaecology Unit (Oxford), following favourable audit with shed safety and efficacy outcomes.
	ever, not established in all Units, the consensus view within the Urogynaecology nunity is that this remains a novel treatment of uncertain safety and efficacy
3.2	What would be the comparator (standard practice) to this procedure?
Hyste	erectomy
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.
Y _	Fewer than 10% of specialists engaged in this area of work.
	Cannot give an estimate.
Com	ments:

There is a trend towards this procedure, but it is standard practice within less than 6 units in UK at present.

Less than 10% of Urogynaecologists regularly perform this surgery rather than hysterectomy

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)

Nil reported

2. Anecdotal adverse events (known from experience)

My own unit's 10 year experience indicates less risk than hysterectomy, but advanced laparoscopic skills required.

1:1000 risk sacral discitis in our experience

No mesh complications in >1000 cases in our unit

3. Theoretical adverse events

Risks are those associated with any surgery, specific risks are related to sacral promontory mesh fixation (Vascular damage and discitis)

Mesh complications

4.2 What are the key efficacy outcomes for this procedure?

Recurrent apical prolapse

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

Limited published data to date

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

Laparoscopic theatre

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

VUE study; multicentre study hysterectomy vs uterine conservation

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

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

None

We have submitted a 550 patient safety data paper to IUGA Journal for consideration of publication. This will add very important data to this field

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, centres doing this procedure will also discuss hysterectomy and are aware of Montgomery 2015

5 Audit Criteria

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

Perioperative Complications
Repeat apical surgery within 24 months

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

ICIQ-VS symptom change Repeat apical surgery

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

Perioperative complications Late mesh complications

6	Trajectory of the procedure
6.1 sprea	In your opinion, how quickly do you think use of this procedure will d?
	spread acceptance and adoption within next 5-10 years, replacing rectomy
6.2 (choo	This procedure, if safe and efficacious, is likely to be carried out in se one):
Υ□	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.
Comr	nents:
Curre	ntly fewer than 10 specialist scentres
hyste	es need advanced laparoscopic skills. If data shows superior to rectomy, and superceeds hysterectomy, many centres will need to by this technique.
	gous to laparoscopic cholecystectomy; skills are acquired in centres accepted technique
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:
Y	Major.
	Moderate.
	Minor.
Comr	nents:
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?	
Litera	ture published
8	Data protection and conflicts of interest

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

8.1 Data Protection

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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	□ N	NO
Fee-paid work – any work commissioned by the healthcare industry – this includes income earned in the course of private practice N Shareholdings – any shareholding, or other beneficial interest, in shares		YES
	□ N	NO
Shareholdings – any shareholding, or other beneficial interest, in shares		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).

	N	
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation	on,	YES
meals and travel to attend meetings and conferences		NO
Investments – any funds that include investments in the healthcare		YES
industry	N	NO
Do you have a personal non-pecuniary interest – for example have y 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?	e 🗆 N	NO
Do you have a non-personal interest? The main examples are as follows:	ows:	
Fellowships endowed by the healthcare industry		YES
	□ N	NO
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts		YES
	N	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 Professor Carole Longsor Centre for Health Technology Evaluation.		or,
10040		

Jan 2016

Conflicts of Interest for Specialist Advisers

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- 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

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- 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.