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: De	eonee.Stanislaus@nice.org.uk
Prod	cedure Name:	Electrically-stimulated intravesical chemotherapy for superficial bladder cancer
Nam	e of Specialist Advisor:	Mr John Mcgrath
Specialist Society:		British Association of Urological Surgeons (BAUS)
1	Do you have adequate kno	owledge of this procedure to provide advice?
	Yes.	
	No – please return the form	n/answer no more questions.
1.1	Does the title used above of	describe the procedure adequately?
\boxtimes	Yes.	
	No. If no, please enter any o	other titles below.
Con	nments:	
2	Your involvement in the pr	rocedure
2.1	Is this procedure relevant	to your specialty?
	Yes.	
	Is there any kind of inter-sp	pecialty 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.			
Comr	ments:			
patie pleas	The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.			
2.2.1	If you are in a specialty that does this procedure, please indicate your experience with it:			
	I have never done this procedure.			
	I have done this procedure at least once.			
	I do this procedure regularly.			
Comr	nents:			
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.			
Comr	ments:			
	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.			
	volunteers.			

	Other (please comment)		
Comments:			
3	Status of the procedure		
3.1	Which of the following best describes the procedure (choose one):		
	Established practice and no longer new.		
	A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.		
	Definitely novel and of uncertain safety and efficacy.		
	The first in a new class of procedure.		
Com	nments:		
3.2	What would be the comparator (standard practice) to this procedure?		
Eithe	er intra-vesical BCG or 'cold' installation of mitomycin		
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.		
Com	nments:		
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)

Frequency, urgency and dysuria. Blood in the urine. Reaction to mitomycin. Urinary infection. Catheter-related trauma.

2. Anecdotal adverse events (known from experience)

Mitomycin ulceration in the bladder

3. Theoretical adverse events

N/A

4.2 What are the key efficacy outcomes for this procedure?

Recurrence of bladder tumour (TCC)

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

Yes. The treatment has not been widely evaluated in multicentre, randomised trials. The HYMN trial explored the use of heated MMC but closed early to recruitment. New technologies have superseded the original hyperthermia devices. If this review also includes EMDA, the literature around EMDA has previously been dominated by single centre and non-randomised studies.

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

Support by the industry suppliers or from colleagues already performing the procedure.

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

HIVEC trials. The HYMN trial is closed.

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. Will be reviewing abstracts for the BAUS Annual Meeting shortly and may be able to provide an update

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

It is felt to be safe but it's exactly role in NMIBC remains unclear. Should it just be for patients unwilling or unfit for radical treatment? Or should it be offered as an alternative to BCG in high risk NMIBC?

5 Audit Criteria

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

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

I would suggest reviewing the trial designs in HYMN and HIVEC as they will give a good overview of outcome measures and adverse events etc.

Cancer metrics:

- **1. Recurrence**: Disease recurrence at check cystoscopy
- **2. Progression**: Progression-free survival patients treated will have NMIBC at diagnosis so it would be important to know what percentage progress to MIBC or to radical treatment because of uncontrolled NMIBC

NB: The HYMN Trial included:

Primary outcome measures:

- Disease-free survival time
- Complete response rate at 3 months, in the subgroup of trial patients with CIS.

Secondary outcome measures:

- Recurrence-free survival time
- Progression-free survival time
- Overall survival time
- Disease-specific survival time
- Safety and tolerability of HM
- Quality of life
- Cost effectiveness
- 5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Urinary symptoms – IPSS scores? Urinary infection Haematuria Catheter-related problems Mitomycin-related side-effects

6 Trajectory of the procedure

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

It would be rapidly adopted if seen as an alternative to BCG. For now, there will be a continued uptake of the procedure – particularly as the installation device is more compact, less temperamental and reproducible compared to early devices on the market.

6.2 (choo	This procedure, if safe and efficacious, is likely to be carried out in se one):
\boxtimes	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	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.
Comn	nents:
7	Other information
7.1 NICE	Is there any other information about this procedure that might assist in assessing the possible need to investigate its use?
	alist nurses largely deliver this treatment. They may already be known to NICE ecommendations are needed to join the group, I am happy to recommend uals.
8	Data protection and conflicts of interest
8. Dat	a protection, freedom of information and conflicts of interest
8.1 Da	ata Protection
The in	formation 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:

	YES
\boxtimes	NO
	YES
\boxtimes	NO
	YES
\boxtimes	NO
	YES
\boxtimes	NO
	YES
\boxtimes	NO

7

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).

you have a personal non-pecuniary interest – for example have you add 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 in	dustry		YES
		\boxtimes	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 a nature of the conflict(s) below.	above statements, please desc	cribe	the
Comments:			
Thank you very much for your help.			
Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair	Professor Carole Longson, D Centre for Health Technology Evaluation.		or,

Jan 2016

8

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.

Please respond in the boxes pro	ovided.		
Please complete and return to: De	eonee.Stanislaus@nice.org.uk		
Procedure Name:	Electrically-stimulated intravesical chemotherapy for superficial bladder cancel		
Name of Specialist Advisor:	Mr Tim O'Brien		
Specialist Society:	British Association of Urological Surgeons (BAUS)		
1 Do you have adequate kno	wledge of this procedure to provide advice?		
x□ Yes.			
☐ No – please return the form	n/answer no more questions.		
1.1 Does the title used above d	lescribe the procedure adequately?		
x□ Yes.			
☐ No. If no, please enter any o	No. If no, please enter any other titles below.		
Comments:			
2 Your involvement in the pr	ocedure		
2.1 Is this procedure relevant t	to your specialty?		
x□ Yes.			
☐ Is there any kind of inter-sp	ecialty controversy over the procedure? NO		

	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:	
withir	the bladder cancer specialist nurses deliver the procedure. Theya re employed urology and are familiar with intravesical treatments eg bcg, mitomycin	
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:	
□x	I have never done this procedure.	
	I have done this procedure at least once.	
	I do this procedure regularly.	
Com	ments:	
	THE NURSES DO IT	
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.	
□x	I take part in patient selection or refer patients for this procedure regularly.	
Com	ments:	
Patients discussed in mdm and then recommended based on operative findings, pathology, previous history and patient choice.		
2.3	Please indicate your research experience relating to this procedure (please choose one or more if relevant):	
□x	I have done bibliographic research on this procedure.	
	I have done research on this procedure in laboratory settings (e.g. device-related research).	
□x	I have done clinical research on this procedure involving patients or healthy	

□ □ x □ Com	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. Imments: work most urologists who do bladder cancer. This procedure, only a small ber.			
x	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.			
	10% to 50% of specialists engaged in this area of work. Fewer than 10% of specialists engaged in this area of work.			
	10% to 50% of specialists engaged in this area of work.			
	More than 50% of specialists engaged in this area of work.			
3.3	Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):			
passive diffusion of mitomycin delivered via a standard urethral catheter. This si a special catheter which allows the drug to be placed into the bladder and the electrical stimulation applied				
3.2	What would be the comparator (standard practice) to this procedure?			
	a new way of delivering mitomycin. So in a sense new and old !!			
Com	iments:			
	The first in a new class of procedure.			
	Definitely novel and of uncertain safety and efficacy.			
□х	A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.			
	Established practice and no longer new.			
3.1	Which of the following best describes the procedure (choose one):			
3	Status of the procedure			
on p	we published our results in the journal of urology and have presented our work on pre TURBT EMDA and sequential therapy at BAUS			
Com	ments:			
_	Other (please comment)			

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:

Adverse events reported in the literature (if possible please cite literature)
any of the di stasi papers on EMDA are the best on side effects &
complications

Skin burns

Pain in the bladder during stimulation

The side effects of mitomycin

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

Extravasation of mitomycin

4.2 What are the key efficacy outcomes for this procedure?

Recurrence rates of bladder tumours

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

Two groupds have published. The di stasi group in lancet oncology and our group from guys in Journal of urology. Both groups reported excellent results.

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

It is very easily learnt. Not a technically demanding procedure. One visit to a dept that performs it would allow a team to commence. Distance back –up from an experienced team could then mentor the team introducing the technique

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

none in progress

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).

abstracts of baus meeting 9 published in bjui) when Christine gan presented her work on pre –op emda mitomycin

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 really controversy. Not sure why the randomised data from di stasi has not convinced more people to do it. We decided not to do a second randomised trial but to make it our standard of care and then published our outcomes which were excellent, possibly the lowest recurrence rates ever described for high risk nmibc.

5 Audit Criteria

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

Tolerability – pain levels in treatment & completion of course. Burns.

Efficacy – recurrence and progression

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

Recurrence and progression of tumour.

Death from bladder cancer

% of patients who preserved their bladders

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Complications: pain and lower urinary symptoms post treatment and at 6 weeks post treatment
Burns on skin
Cystectomy for symptoms (rare)

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

if approved, quickly as its cheap and easy to learn

6.2 (choo	I his procedure, if safe and efficacious, is likely to be carried out in se one):
□ x	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.
Com	ments:
6.3 of pa	The potential impact of this procedure on the NHS, in terms of numbers tients eligible for treatment and use of resources, is:
	Major.
□x	Moderate.
	Minor.
The t	ments: echnology is cheap. The number of patients is large. The catheters are more nsive than standard passive diffusion catheters.
7	Other information
7.1 NICE	Is there any other information about this procedure that might assist in assessing the possible need to investigate its use?
	not really
8	Data protection and conflicts of interest
8. Da	ta protection, freedom of information and conflicts of interest

8.1 Data Protection

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

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

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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 payments in cash or kind		YES XNO	
Fee-paid work – any work commissioned by the healthcare industry – this includes income earned in the course of private practice		xYES	
and included income carried in the course of private practice		NO	
Shareholdings – any shareholding, or other beneficial interest, in		YES	
shares of the healthcare industry		xNO	
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for		YES	
accommodation, meals and travel to attend meetings and conferences		xNO	
Investments – any funds that include investments in the healthcare		YES	
industry		xNO	
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	
		xNO	
Do you have a non-personal 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	
		xNO	
If you have answered YES to any of the above statements, please describe the			

nature of the conflict(s) below.

7

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).

Comments:

I see private patients who need treatment for non muscle invasive bladder cancer and we use emda to treat them 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
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- 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.