

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read [Conflicts of Interest for Specialist Advisers](#). Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: **Minimally invasive radical hysterectomy for early stage cervical cancer**

Name of Specialist Advisor: Andrew Nordin

Specialist Society: British Gynaecological Cancer Society

1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

Yes.

No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

Is there any kind of inter-specialty controversy over the procedure?

- No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

Results of LACC trial and recent NCRAS report (of which I am an author) have indicated a survival benefit for traditional open vs MAS radical hysterectomy. It remains unclear if this relates to a selected set of tumour criteria or if it applies to all cases managed by radical hysterectomy.

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

The frequency of radical hysterectomy procedures is reducing as the effects of screening and HPV vaccination reduce the incidence of the disease, and there is also increasing use of primary chemoradiotherapy for larger / higher risk tumours. I have performed the vast majority of radical hysterectomy procedures (open and MAS) in my centre for the past 20 years, with principally MAS procedures over recent years until the recent publications.

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

I have collaborated in epidemiological research with NCRAS on this procedure.

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

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

Open radical hysterectomy (ie by laparotomy)

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

>50% of procedures identified in the NCRAS review from 2013 – 2016 were done by MAS

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)
Increased risk of recurrence and death from cervical cancer (HR 3-6 in the published papers) – the cause is unclear at this time but further research is ongoing
2. Anecdotal adverse events (known from experience)
3. Theoretical adverse events

4.2 What are the key efficacy outcomes for this procedure?

Overall survival and disease-specific survival

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

As above

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

Is only performed by subspecialist gynaecological oncologists, as is radical hysterectomy by laparotomy.

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

See above – I forwarded the relevant documents to NICE when we published the NCRAS report and BGCS guidance in May 2019

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?

As above – there is now uncertainty about whether the MAS procedure should be abandoned or whether there are certain cases (and certain specific techniques) where it may be safe from an oncological perspective. There are definite short term patient benefits wrt surgical morbidity and post-op recovery.

5 Audit Criteria

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

I am co-author of two NCRAS project proposals to further investigate this procedure using cancer registration data

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:

COS-D & HES data collection provides data on all cases nationally, and can provide valuable insight which would be of interest internationally

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:

The main issue relates to disease recurrence and survival. Surgical complications (short and long term morbidity) occur with both open and MAS radical hysterectomy, but in general these are likely to be less from MAS procedure.

6 Trajectory of the procedure

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

Currently the use is markedly reduced due to the recent publications.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.

- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

All gynaecological cancer centres (appx 42 in England); may be a role for further centralisation due to reducing numbers of patients requiring radical hysterectomy – subject to NHSE Specialist Commissioning Review

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

- Major.
- Moderate.
- Minor.

Comments:

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?

As above – already forwarded to NICE

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. For more information about how we process your personal data please see our [privacy notice](#)

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

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

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

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

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

Consultancies or directorships attracting regular or occasional payments in cash or kind YES
 NO

Fee-paid work – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** YES
 NO

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry YES
 NO

Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences YES
 NO

Investments – any funds that include investments in the healthcare industry YES
 NO

Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? YES
 NO

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry YES
 NO

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).

Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts

YES

NO

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

I perform private practice and occasionally will perform a radical hysterectomy procedure in this context.

I am the president of the British Gynaecological Cancer Society and co-authored professional and lay guidance on this procedure following the recent publications.

I am a clinical advisor to NICE and co-author research on this procedure.

Thank you very much for your help.

**Dr Tom Clutton-Brock, Interventional
Procedures Advisory Committee Chair**

**Mark Campbell
Acting Programme Director
Devices and Diagnostics**

June 2018

Conflicts of Interest for Specialist Advisers

- 1 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**
 - 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
 - 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.
- 2 **Personal pecuniary interests**
 - 2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as ‘**specific**’ or to the industry or sector from which the product or service comes, in which case it is regarded as ‘**non-specific**’. The main examples are as follows.
 - 2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.
 - 2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
 - 2.2 No personal interest exists in the case of:
 - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
 - 2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

- 3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.
- 3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- 3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.
- 3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).
- 3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)
- 3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 3.2 No personal family interest exists in the case of:
- 3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- 3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

- 4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review
- 4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence
- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

5 **Non-personal interests**

- 5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as '**specific**,' or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as '**non-specific**'. The main examples are as follows.

- 5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.
- 5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:
- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
 - a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Advisor is responsible. This does not include financial assistance for students
 - the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
 - one or more contracts with, or grants from, NICE.
- 5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

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Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: **Minimally invasive radical hysterectomy for early stage cervical cancer**

Name of Specialist Advisor: Christina Fotopoulou

Specialist Society: British Gynaecological Cancer Society

1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

Yes.

No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

Is there any kind of inter-specialty controversy over the procedure?

- No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.

- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

Established practice since many years, however new knowledge of its oncologic safety

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

Open radical hysterectomy (per laparotomy)

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

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)

There has been a large prospective randomised trial by Ramirez et .al. NEJM 2019, that showed a 6 times worse long term mortality from their cancer in patients who had a laparoscopic surgery. Since then many retrospective audits have followed that confirmed these findings. It is unclear why this the case and further confirmatory trials will follow.

2. Anecdotal adverse events (known from experience)

Nothing unusual from the normal

3. Theoretical adverse events

Theoretical adverse events are not valid in a surgical procedure

4.2 What are the key efficacy outcomes for this procedure?

Good oncologic and surgical outcome

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

Yes, the randomised trial quoted above (Ramirez et.al NEJM 2019) showed a significantly worse oncologic survival in those patients who underwent the minimal invasive procedure. Complication rates and QoL data were equal between both arms

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

The same like in every other laparoscopic surgery.

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

Ramirez et.al NEJM 2019 (published)
SUCCOR study (NCT03958305)
RACC study (NCT03719547)

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).

Mentioned above

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 unclear why the minimal invasive arm has such a worse oncologic outcome. Further confirmatory trials are warranted to clarify this

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:

PFS, OS, types of relapse, QoL, postoperative treatment needed (chemo and radiotherapy)

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:

Surgical morbidity and mortality

6 Trajectory of the procedure

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

NA; this procedure is already spread and the question is whether it should be limited.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

NA: This operation is only being performed in cancer centres and will continue to be performed there.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

- Major.
- Moderate.
- Minor.

Comments:

With the HPV vaccination and screening programs incidence of cervical cancer declines

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?

All mentioned above

8 Data protection and conflicts of interest

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

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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

NO

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry YES

XNO

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

XNO

Investments – any funds that include investments in the healthcare industry YES

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.

Comments:

Advisory boards with honoraria from Roche, Tesaro, Ethicon, Olympus

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).

Thank you very much for your help.

**Dr Tom Clutton-Brock, Interventional
Procedures Advisory Committee
Chair**

**Mark Campbell
Acting Programme Director
Devices and Diagnostics**

June 2018

Conflicts of Interest for Specialist Advisers

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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
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- 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 Advisor 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 Advisors 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 [Conflicts of Interest for Specialist Advisers](#). Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Minimally invasive radical hysterectomy for early stage cervical cancer

Name of Specialist Advisor: Maghami Sadaf Ghaem

Specialist Society: British Gynaecological Cancer Society

1 Do you have adequate knowledge of this procedure to provide advice?

- Yes.
- No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

- Yes.
- No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

- Yes.
- Is there any kind of inter-specialty controversy over the procedure?

- No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.

- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

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

Open radical hysterectomy (in both open and Minimal invasive procedure pelvic lymph nodes may also be performed)

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

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)

All the complications associated with radical hysterectomy AND minimal invasive surgery

Infection

Wound infection

Urine infection

Vault infection

Other infections

Thrombosis

Bleeding

Vault haematoma

Damage to other organs: Bladder, Bowel, blood vessels, ureters

Difficulty in passing urine

Complications associated with lymph node dissection if preformed

Complications associated with oophorectomy if preformed

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Increase rate of damage to internal organs with minimal invasive surgery

4.2 What are the key efficacy outcomes for this procedure?

Shorter hospital stay (significantly)

Shorter time to back to normal activity and work

Less risk of thrombosis

Less risk of wound infection specially in more obese patients

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

Survival rates have not been previously evaluated in a randomised trial until recent study published in NEJM

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

Significant training in minimal invasive surgery, either laparoscopic equipment or a Robot

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

The two published papers from multi national trial and US data base (both in NEJM)
NCRAS data published by NCRAS as information at this stage
BJOG paper UK data from some hospitals

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?

Currently the controversy is around survival

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:

Operating time
Blood transfusion
Number of nights spent in hospital
Wound infection rate
Number of days before return to work
Disease free survival rate
Overall survival rate

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:

Blood transfusion within first week
Ureteric damage within 2-3 weeks
Bowel damage within a week
Wound infection within first two weeks
Difficulty voiding bladder within two weeks
Thrombosis within first two weeks

6 Trajectory of the procedure

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

Already in widespread use, around 70-80% of radical hysterectomies done using minimal invasive route

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

- Major.
- Moderate.
- Minor.

Comments:

Changing practice of going from minimal invasive to open procedure likely to add to NHS costs in view of days of hospital stay

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our [privacy notice](#)

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

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

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

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

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

Consultancies or directorships attracting regular or occasional payments in cash or kind **YES**
 NO
 YES

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).

- Fee-paid work** – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** **NO**
- Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry **YES**
 NO
- Expenses and hospitality** – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences **YES**
 NO
- Investments** – any funds that include investments in the healthcare industry **YES**
 NO
- Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? **YES**
 NO
- Do you have a **non-personal** interest? The main examples are as follows:
- Fellowships** endowed by the healthcare industry **YES**
 NO
- Support by the healthcare industry or NICE** that benefits his/her position or department, eg grants, sponsorship of posts **YES**
 NO

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

personal non-pecuniary interest: I have contributed to the British Gynae Cancer Society statements on the subject over the last 12 months.

I have given a talk on the subject presenting and summarising the evidence at the RCOG World Congress Gynae oncology surgical workshop.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

**Mark Campbell
Acting Programme Director
Devices and Diagnostics**

June 2018

Conflicts of Interest for Specialist Advisers

- 1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**
 - 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
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 - 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.
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- 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**

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 - a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Advisor is responsible. This does not include financial assistance for students
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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Minimally invasive radical hysterectomy for early stage cervical cancer

Name of Specialist Advisor: Robin Crawford

Specialist Society: British Gynaecological Cancer Society

1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

1.1 Does the title used above describe the procedure adequately?

Yes.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

Comments:

Expert guidance is appropriate for patients and commissioners

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 do this procedure regularly stopped doing Minimal access approach in October 2018 after NEJM papers from Ramires and Melamed

Comments:

See comment above

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 take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

I have done bibliographic research on this procedure.
 I have done clinical research on this procedure involving patients or healthy volunteers.

Comments:

Involved in NCRAS BGCS review of HES data 2013-2016 and NCRAS statement

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

Established practice and no longer new.

Comments:

Survival data is now available from RCT Canada England Korea and other health care economies showing the decreased survival with Minimal access approach

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

Open radical hysterectomy

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.

Comments:

Decreasing workload so should consider referral to centres with XS of 20- 30 cases pa shared by two specialists

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)

NEJM x2 31st October; AJOG in press,

2. Anecdotal adverse events (known from experience)

Recognition of early recurrences

3. Theoretical adverse events

Manipulating the cervix with cancer present

4.2 What are the key efficacy outcomes for this procedure?

Shorter LoS

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

Recent publications

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

Already set up in UK

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

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

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

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

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:**

Issue is the 4+ year survival

- 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:**

5 years see above

6 Trajectory of the procedure

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

Will probably stop happening

- 6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):**

- x A minority of hospitals, but at least 10 in the UK.**
- x Fewer than 10 specialist centres in the UK. (preferred option)**

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

x Minor. About 300-500 patients a year in England getting less

Comments:

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our [privacy notice](#)

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

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

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

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

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

Consultancies or directorships attracting regular or occasional payments in cash or kind YES

NO

Fee-paid work – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** YES

NO

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry YES

NO

Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences YES

NO

Investments – any funds that include investments in the healthcare industry YES

NO

Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? YES

NO

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry YES

NO

Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts YES

NO

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

¹ ‘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).

Thank you very much for your help.

**Dr Tom Clutton-Brock, Interventional
Procedures Advisory Committee Chair**

**Mark Campbell
Acting Programme Director
Devices and Diagnostics**

June 2018

Conflicts of Interest for Specialist Advisers

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3 **Personal family interest**

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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 Advisor 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
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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Minimally invasive radical hysterectomy for early stage cervical cancer

Name of Specialist Advisor: Thomas Ind

Specialist Society: British Gynaecological Cancer Society

1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

Yes.

No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your speciality?

Yes.

Is there any kind of inter-specialty controversy over the procedure?

- No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.

- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

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

Open radical hysterectomy for early stage cervical cancer

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

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)

Recent data has led to concerns regarding cancer survival

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

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

Thought to have less complications

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

Yes. Two papers in NEJM have brought into doubt concerns.

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

Advanced laparoscopic skills

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

Yes. RACE
SULLOP

- 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).

- Yes. Sarah Coleridge, Taunton & Somerset PHS Foundation Trust, BGS 2019 - survival outcomes following open and laparoscopic surgery for early stage cervical cancers in SW England.

- 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. uterine manipulators -
Sealing of Fallopian Tubes
Bagging of Gynaecology

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:

Survival.
Complications.

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:

Paraspinal injuries
bowel, bladder, sexual dysfunction
bleeding, thrombotic disease, infection,

6 Trajectory of the procedure

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

It was until recently the norm

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

- Major.
- Moderate. about 300 in UK a year
- Minor.

Comments:

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our [privacy notice](#)

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:

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

- Consultancies or directorships** attracting regular or occasional payments in cash or kind YES
 NO
- Fee-paid work** – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** YES
 NO
- Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry YES
 NO
- Expenses and hospitality** – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences YES
 NO
- Investments** – any funds that include investments in the healthcare industry YES
 NO
- Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? YES
 NO
- Do you have a **non-personal** interest? The main examples are as follows:
- Fellowships** endowed by the healthcare industry YES
 NO
- Support by the healthcare industry or NICE** that benefits his/her position or department, eg grants, sponsorship of posts YES
 NO

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

on two occasions I received a paid consultancy from Medtronic. I receive an income from private practice. I am a stakeholder of the Chelsea Outpatients Unit. I was last year a trustee of So's Cervical Cancer Trust. and Treasurer of British Gynaecological Cancer Society. I am Acting Programme Director Devices and Diagnostics past president of BIAAGS

Comments: *on two occasions I received a paid consultancy from Medtronic. I receive an income from private practice. I am a stakeholder of the Chelsea Outpatients Unit. I was last year a trustee of So's Cervical Cancer Trust. and Treasurer of British Gynaecological Cancer Society. I am Acting Programme Director Devices and Diagnostics past president of BIAAGS*

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
 Acting Programme Director
 Devices and Diagnostics

June 2018

whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

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 Adviser is responsible, but that is not received by the Specialist Adviser 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 Advisor 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.

Interventional Procedures Programme

Terms of reference for Specialist Advisers

Aims of the Interventional Procedures Programme

NICE's IP Programme assesses the efficacy and safety of interventional procedures, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately.

Interventional procedures are those used for diagnosis or treatments that involve incision, puncture, or entry into a body cavity or the use of electromagnetic or acoustic energy.

Interventional Procedures Advisory Committee

NICE guidance on interventional procedures is developed by an independent Interventional Procedures Advisory Committee (IPAC) made up of professionals working in the NHS and people who are familiar with the issues affecting patients and carers. The committee is chaired by Dr Tom Clutton-Brock and meets monthly.

The Interventional Procedures Advisory Committee is assisted by Specialist Advisers who provide advice and informed opinion about interventional procedures. Specialist Advisers are clinicians nominated by the professional organisations whose members use particular procedures. Specialist Advisers are selected because of their knowledge, special interest and experience of the clinical field: their advice compliments findings from research and aids IPAC in its decision making.

Clinicians and others are able to notify procedures to NICE via our website: more information on this process is available at <http://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-interventional-procedures-guidance/IP-notification-form>. NICE consults publicly on all guidance before it is issued. For further details of our process please refer to the Interventional Procedures Process Manual which can be accessed via <http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-interventional-procedures/Interventional-procedures-programme-process-guide.pdf>

Specialist Adviser Appointments

Specialist Advisers are appointed to the programme for a term of 3 years. This term is renewable and will automatically be restarted every time the adviser is re-nominated. Specialist Advisers are asked to complete and return a personal data form providing details of name, job title, mailing address, email, telephone, Specialist Societies and specialist interests.

In line with NICE's aim to be transparent the name of each Specialist Adviser and their Specialist Society will be published on the website <http://www.nice.org.uk/Get-Involved/Meetings-in-public/Interventional-Procedures-Advisory-Committee/Members> and in the procedure overview. A copy of each completed piece of specialist advice is sent to the nominating specialist society if requested.

In order to comply with the Data Protection Act, Advisers are also asked to sign and return a Data Protection form which agrees that their details may be held electronically.

Transparency is an important principle of NICE work and therefore the information you submit in your questionnaire 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

The role of Specialist Advisers

New procedures often have potential risks and benefits that are not yet fully described in the scientific literature. Specialist Advisers provide insight into these aspects of a procedure, sometimes supported by their accounts of clinical experience which complement the often limited published evidence.

Specialist Advisers may be asked to advise the IP Programme team and/or IPAC on the following aspects of individual procedures within their area of expertise or knowledge:

- the relevance to the Programme's remit of procedures notified to the Programme
- preparation of the procedure's scope and overview
- the development of an audit tool for the procedure where appropriate
- the development of a lay version of the guidance.

As a rule, requests for specialist advice to each individual Adviser are infrequent. Requests for Specialist Advice are sent by email in the form of a questionnaire. Specialist Advisers should complete the proforma using the attached pro forma (Word document). Specialist Advisers are given the option to receive this pro forma in hard copy if they prefer.

Specialist Advisers are asked to complete the questionnaire within one week of the request date. We ask that Specialist Advisers answer the questions based on their current knowledge; there is no need to undertake any specific research or review of the procedure. However additional literature may also be submitted.

We acknowledge that Specialist Advisers may not be aware of a procedure or may not feel confident that they have adequate knowledge or experience in a particular procedure to provide advice. In these cases we would ask the Specialist Adviser to tell us immediately (within 2 working days if possible).

Occasionally we may wish to contact Specialist Advisers for further advice, either by correspondence or by telephone. Exceptionally NICE may ask Specialist Advisers to attend a meeting of IPAC to offer advice about a procedure.

Conflicts of Interest

Specialist Advisers to the NICE Interventional Procedures Programme should note that under NICE's Code of Practice for Declaring and Dealing with Conflicts of Interests¹, if they have a **personal specific pecuniary interest** (see section 2 of Conflicts of Interest policy) or a **personal family specific interest** (see section 3 of policy) in a procedure,

¹ Introduced in May 2007
Last Updated Jan, 2016

they can offer advice to the Committee on that procedure at the discretion of the Committee Chair. The purpose of this is to preserve transparency and ensure that the development of NICE's Interventional Procedures guidance continues to be informed by the best available clinical advice.

Policy on Conflicts of Interest

Responsible Officer	Business Planning & Resources Director
Author	Governance Manager
First published	December 1999
Last version published	May 2007
Current version published	September 2014
Review date	September 2017
Version	2.5

Introduction

1. NICE is expected to achieve and maintain high standards of probity in the way it conducts its business. These standards include impartiality, objectivity and integrity, and the effective stewardship of public funds. Managing potential conflicts of interest is an important part of this process.
2. The effective management of conflicts of interests is an essential element in the development of the guidance and advice that NICE publishes. Without it, professionals and the public will lose confidence in our work.
3. This policy provides guidance on what interests need to be declared, who needs to declare them and when, and what action should be taken to avoid conflicts of interest influencing the conduct of NICE's business. Everyone referred to in this policy should ensure that they and those for whom they have responsibility understand their obligations to disclose all relevant interests.
4. For definitions of key terms used in this document, see the 'Definitions' section below. The forms to be used in declaring or signing off conflicts of interest are in appendices 1, 2 and 3.

Related legislation and guidance

5. The Cabinet Office Code of Conduct for Board members sets out standards to be applied by members of public bodies, including the management of conflicts of interest.
6. In addition, NICE is guided by the Nolan Principles as set out in the Institute's Code of Business Conduct. The principles are: selflessness, integrity, objectivity, accountability, openness, honesty and leadership.
7. The Bribery Act 2010 includes the offences of offering and or receiving a bribe. It also places specific responsibility on organisations to have in place sufficient and adequate procedures to prevent bribery and corruption taking place.

Scope of the policy

Who is covered by the policy

8. This policy applies, in its relevant sections, to the following groups:
- Board members and employees of NICE
 - Employees of NICE national collaborating centres
 - Committee chairs and members (including co-opted members) and remunerated expert advisers.
 - Appeal panel members.
 - Agency workers and contractors on temporary contracts or employed through an agency to work for NICE.
 - Secondees (those who are seconded to NICE from other organisations).
 - Employees of 'evidence contractors' working directly or indirectly to supply evidence that is used by the guidance-producing advisory bodies.

Recognising a conflict of interest

9. A conflict of interest arises when the judgement of someone involved in the work of NICE may be compromised, by the financial or other considerations set out in this policy.
10. To avoid public concern that any such interests might prejudice the integrity or impartiality of those involved in the business of NICE, this Code of Practice applies to all those who work at NICE and who are involved in the development of its guidance and the execution of its other functions.
11. The determination as to whether or not a declared interest is in conflict with the work of NICE will involve the application of this policy and will sometimes require careful judgement based on the facts and the nature of the business being conducted. In the event of doubt, it is best determined by considering how the interest will be perceived by an ordinary member of the public.
12. For the avoidance of doubt, the fact that an individual is living with a disease or condition, or has a family member who is in that position, is not regarded as a conflict of interest. (See Definitions for an explanation of 'family member'.)
13. This policy is intended as a guide to the kinds of interests that should be declared and when they should be declared. If in doubt, all interests should be declared.

Advisory committee members and appeal panel members

14. NICE advisory committee members should consider carefully if they have an interest in the matters under review by the committee that might unduly influence their judgement and objectivity. Particular care should be taken if the interest involves any payment or financial inducement from the commercial sector (see Definitions for an explanation of 'commercial sector') or any reputational interest related to positions held in other organisations, publications they have authored or public statements they have made.
15. It is recognised that many committee members will have some interaction with the commercial sector and while this should be declared, it does not necessarily preclude membership of an advisory body or work for NICE. Care should be taken to consider which aspects of the commercial sector definition are relevant to the business under consideration. This policy will guide those who may have such interaction and those who have to make decisions about the circumstances in which such interaction conflicts with their work for NICE.
16. The Chairs of advisory committees are in a special position in relation to the work of their committee and so may not have any specific financial or non-financial personal, non-personal or family interests.
17. The Chairs of advisory committees have discretion over the interpretation and application of this policy in their committees. In the event of uncertainty or where there is an unresolvable disagreement between the chair and a member of the advisory body, the view of the relevant NICE Director or authorised deputy must be sought. This is to ensure that NICE policies and process manuals are fully and consistently applied in the course of guidance production.
18. The Chair of an advisory committee should ensure that the members declare all relevant interests and take advice from senior staff at NICE where necessary. Declarations of interest and associated actions should be recorded to ensure transparency in the way the interest is handled.

Types of interests

19. Interests can be specific or non-specific and financial or non-financial. Financial interests can be personal or non-personal.
20. The different types of interest are explained below.

Specific and non-specific interests

21. When evaluating declarations of interest from members of NICE's committees, it is important to decide whether the interest is 'specific' or 'non-specific'.
22. An interest is 'specific' if it refers directly to the matter under discussion.

23. An interest is 'non-specific' if it does not refer directly to the matter under discussion.
24. For the purpose of applying this Code to committee members, the 'matter under discussion' will be defined before the committee is constituted, in the case of topic specific committees, or before a new topic is introduced, in the case of standing advisory bodies. Each programme at NICE will set out its arrangements for ensuring that the matter under consideration is clearly defined and made publicly available.

Personal financial interest

25. A personal financial interest, for the purposes of this policy, is one where there is or appears to be opportunity for personal financial gain or financial gain to a family member (See Definitions section for definition of 'family members') in the 12 months before joining an advisory committee or during the period of membership of an advisory committee. Financial interest means anything of monetary value, including payments for services, equity interests, including stocks, stock options or other ownership interests and intellectual property rights, including patents, and copyrights and royalties arising from such interests.
26. Examples include:
 - Any consultancy, directorship, position in or work (which is specific to the product or matter being discussed) in the commercial sector that attracts regular or occasional payments or benefits in kind such as hospitality.
 - Clinicians receiving payment from the commercial sector for undertaking a procedure while giving advice on that procedure to NICE.
 - Any fee-paid work commissioned by the commercial sector for which the individual receives payment or financial benefit in kind.
 - Any shareholdings in the commercial sector held by the individual.
 - A financial interest in a company's product that is, or may become, a competitor to the product under consideration.
 - Expenses or hospitality provided by the commercial sector beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences as set out in the NICE Hospitality Policy and Travel and Subsistence Policy.
 - Funds which include investments in the commercial sector that are held in a portfolio where the individual has the ability to instruct the fund manager as to the composition of the fund.

Non-personal financial interest

27. A non-personal financial interest involves payment or other benefit to a department or organisation in which the individual is employed but which is not received personally, in the 12 months before joining an advisory committee or during the period of membership of an advisory committee.

28. Examples include:

- A grant from a company for the running of a unit or department where the individual is employed.
- A grant or fellowship or other payment to sponsor a post or member of staff in the unit where the individual is employed.
- The commissioning of research or other work by, or advice from, staff who work in a unit where the individual is employed.
- Contracts with, or grants from, NICE.

Personal non-financial interest

29. A personal non-financial interest in the matters under consideration refers to an opinion on the matters under consideration published in the 12 months before joining an advisory committee or during the period of membership of an advisory committee.

30. Examples include:

- A clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review.
- A published statement in which the individual has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence.
- Authoring or co-authoring a document submitted as an evidence publication to a NICE advisory committee.
- Holding office in a professional organisation (see Definitions for an explanation of 'professional organisations'), charity or advocacy group with a direct interest in the matter under consideration.
- Other reputational risks in relation to a matter under review.

Special note on competitor interests

31. If a committee member is aware that a product under consideration is, or may become, a competitor of a product developed, manufactured, sold or supplied by a company in which the member has a current personal financial or family financial interest, they should declare an interest. The chair of the advisory body should consider whether the individual should take part in the proceedings.
32. The actions required at advisory committee meetings are set out in the table below.

Type of interest		Action
Personal financial	Specific	Declare and leave the meeting. In exceptional circumstances the chair may rule that they can attend to answer specific questions
	Non-specific	Declare and participate unless, exceptionally, the chair rules otherwise on advice from NICE
Personal non-financial	Specific	Declare: action is then at the discretion of the chair on advice from NICE, where necessary
	Non-specific	Declare and participate unless, exceptionally, the chair rules otherwise on advice from NICE
Non-personal financial	Specific	Declare and participate unless, exceptionally, the chair rules otherwise on advice from NICE
	Non-specific	Declare and participate unless, exceptionally, the chair rules otherwise, on advice from NICE

Board members, permanent and temporary staff at NICE, secondees at NICE and employees of the NICE national collaborating centres, evidence contractors and external experts

33. Each year, Board members, staff and NICE secondees and employees of NICE national collaborating centres must declare interests which are relevant and material in accordance with NICE's standing orders and this policy. New appointees should make the declaration on appointment.
34. Interests that should be regarded as relevant and material include:
- Directorships, including non-executive directorships held
 - Ownership or part-ownership of private companies, businesses or consultancies likely or possibly seeking to do business with the health or social care sector
 - Majority or controlling share holdings in organisations
 - A position of trust in a charity or voluntary organisation (see the Definitions) connected with the health or social care industry
 - Any connection with a voluntary or other organisation contracting for services with NICE.
35. NICE Board members and staff may not hold or acquire a financial interest, including shares, which can be managed at an individual company level in enterprises engaged in the commercial sector and will be asked to divest themselves of such interests on appointment, or as soon as is practical thereafter. Special arrangements are in place for existing staff employed prior to 16 May 2007 to manage any personal pecuniary interests.
36. Secondees will be required to declare their interests and prior to appointment. Depending on the nature of the interest, the secondment may be refused or the nature of the work they are able to undertake at NICE constrained. Secondees will be able to divest themselves of interests which either prevent or constrain the proposed secondment, if they wish.
37. Where, for a NICE employee, a potential conflict arises involving a family member's financial specific interest and it is impractical to re-arrange the employee's duties, their Director may waive the potential conflict of interest if in their opinion the risks to the efficiency of departmental business are greater than the risks arising from the potential conflict of interest. In all such cases the Director must prepare a conflict of Interest sign-off form stating what action, if any, is appropriate. This will be attached to the individual's declaration of interest form.

38. No special favour should be shown to an individual's family or acquaintances in awarding contracts of employment. All personal and professional relationships with job applicants should be declared except where the relationship can be assumed (for example for internal candidates). The selection process for any contract or position should at all times be objective and impartial.
39. Agency workers and staff on temporary contracts will be asked to declare their conflicts of interest on appointment. They will not be asked to divest themselves of any interests, but the Director responsible for their work may decide to restrict their duties where a conflict of interest arises. Temporary staff are under the same duty of confidentiality as permanent employees.

Evidence contractors

40. Evidence contractors (see Definitions for an explanation of 'evidence contractor') must declare any interests which may conflict with their work for NICE.
41. Evidence contractors retained to fulfil multiple projects must declare any interest that might conflict with their work for NICE in relation to each project at the time the work is referred to them.
42. Potential conflicts relate to both individuals and to the organisation and may fall under any of the categories set out in paragraphs 19-30.
43. The relevant NICE Director or their nominated deputy will be responsible for deciding whether any interest represents a conflict and the impact it may have on the ability of the contractor to fulfil the contract.

Expert advisers

44. Individuals with specific expertise are routinely invited to attend advisory committee meetings. They provide advice to the committee based on their role and experience. They may or may not work in the NHS and they may or may not have paid employment in health or social care, or in the commercial sector.
45. External experts will be asked to declare their interests at the point they are invited to give evidence. Every effort will be made to select experts who do not have a conflict of interest of a kind which would require a member of the committee to withdraw from the discussion. However, the relevant NICE Director has discretion to invite an expert with such a conflict where he or she is the only source of advice available and the work of the committee would be seriously compromised without their testimony.

46. External experts will be required to declare their interests at the beginning of their testimony at each meeting they are invited to attend. These may fall under any of the categories set out in paragraphs 19-30.

General information

When interests should be declared

	Declaration on appointment	Annual declaration	Declaration at advisory committee or Board meetings (as appropriate)
NICE board chair and non-executive directors	Yes	Yes	Yes
NICE employees, including temporary staff at NICE	Yes	Yes	Yes
NICE advisory body chair	Yes	Yes	Yes
NICE advisory body member	Yes	Yes	Yes
NCC employee	Yes	Yes	Yes
Evidence contractor	Yes	Yes (for multiple year contracts)	Yes
Expert adviser	yes	Not relevant	Yes

Recording of interests and their publication

47. A record is kept at NICE of:
- Declarations made by staff and others on appointment, as a new interest arises and through the annual declaration.
 - Declarations recorded in minutes of committee meetings, including details of the interest declared and whether the member took part in the proceedings.
48. Declarations of interest will be made publicly available on NICE's website, in the form of a statement of annual declarations, through the minutes of advisory bodies or in guidance publications.
49. The period of relevance for all declarations made by members of a NICE advisory committee is 12 months before joining and during the membership of the committee.
50. All declarations of interest are subject to disclosure under the Freedom of Information Act 2000.

Who to contact for advice

51. If anyone covered by this code is uncertain whether or not an interest should be declared or is unclear on the interpretation of this code of practice, he or she should seek advice as set out in the table below.

Who	Take advice from
Chair of Board	Chair of the Audit and Risk Committee
Board non-executive director	Chair of Board
Chief Executive	Chair of Board
Director	Chief Executive
Chair of advisory body	Centre Director or Programme Director
Member of advisory body	Chair of the advisory body
Employee of NICE, NCC employee, NICE secondee	Relevant director or the Governance Manager
Evidence contractor	Head of department in consultation with Centre Director
Expert Adviser	Chair of the relevant advisory body
Temporary and agency staff	Relevant director or the Governance Manager

Definitions

'Commercial sector' encompasses:

- Companies, partnerships and individuals who are involved in the development, manufacture, promotion, sale or supply of products or services which are advertised, promoted or marketed as treatments or as products contributing to the promotion or maintenance of good health.
- Companies involved in the sale of products which substantially affect public health, such as the food, alcohol and tobacco industries.
- Trade associations, both in the UK and elsewhere, representing companies involved with such technologies, products and services.
- Private social care providers
- GPs with a financial interest in an associated pharmacy or for-profit firm providing services to their Clinical Commissioning Group
- Companies, partnerships or individuals who are involved in the development and sale of knowledge products relevant to NICE's Evidence Resources directorate, that are, or may be, used by the NHS

'Competitor interest' refers to an interest in a company which produces a product which is a competitor to the one under consideration in guidance being produced by NICE and whose position is likely to be significantly influenced by the guidance.

'Family member' refers to a spouse or partner living in the same residence as the individual, as well as children and adults (who may or may not be living in the same residence) for whom the individual is legally responsible, (for example, an adult whose full power of attorney is held by the individual).

'Members' includes all advisory body members for the committees and groups

'Professional organisation' includes any organisation engaged in the medical, public health or social care sectors including the medical, nursing and midwifery Royal Colleges, NHS organisations, and universities.

'Voluntary organisation' refers to organisations that are 'not for profit' and non-governmental, and includes advocacy groups, charities and community groups.

'Evidence contractor' refers to organisations in the public and private sectors which provide evidence assessment services and methodological support to NICE.