

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: Deonee.Stanislaus@nice.org.uk

Procedure Name: **Bronchial thermoplasty for severe asthma**

Name of Specialist Advisor: Dr James Paton

Specialist Society: British Paediatric Respiratory 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:

I have never taken part in selection so far but would consider it for a relevant patient

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.

x Other (please comment)

Comments:

I commissioned an article on the procedure for the Journal Breathe

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?

Other treatments for severe asthma e.g. omalizumab

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:

Only done in specialist centres

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)

File attached

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

4.2 What are the key efficacy outcomes for this procedure?

Exacerbations

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

What is its role in children and young people

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

Not known in detail

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

Not known in detail

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?

No

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:

Exacerbations; side effects

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:

Not known in detail

6 Trajectory of the procedure

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

Moderately quickly

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:

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?

Not Known

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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 | <input type="checkbox"/> YES |
| | <input checked="" type="checkbox"/> NO |
| Fee-paid work – any work commissioned by the healthcare industry – this includes income earned in the course of private practice | <input type="checkbox"/> YES |
| | <input checked="" type="checkbox"/> 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).

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:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

Conflicts of Interest for Specialist Advisers

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

- 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
- 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

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

3 **Personal family interest**

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

5 **Non-personal interests**

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

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist 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: Deonee.Stanislaus@nice.org.uk

Procedure Name: **Bronchial thermoplasty for severe asthma**

Name of Specialist Advisor: Dr Robin Gore

Specialist Society: British Thoracic 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:

The safety seems quite well established. There is an excess of asthma exacerbation within the first few weeks after treatment, but exacerbation rates then reduce compared to placebo. 5 year follow-up safety data from the active arm of the original AIR-2 trial indicate good long-term safety to this time point. (Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma. Wechsler, M. et al. J Allergy Clin Immunol. 2013 Dec;132(6):1295-302.)

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

There is no comparator. This is a unique procedure, in which the airways are treated with heat – a method that is fundamentally different to any pharmacotherapy.

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)

Adverse respiratory effects occurred in a much higher proportion of those in the active arm of the randomised controlled trial, than those having a bronchoscopy with a sham intervention (application of BT probe but not energised.) (Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, sham-controlled clinical trial. Castro, M et al. Am J Respir Crit Care Med. 2010 Jan 15;181(2):116-24.) These effects occurred within the first few weeks after treatment, and mostly on the day of bronchoscopy. Effects occurred in 85% of BT-treated patients (1 per bronchoscopy) and 76% of sham-treated patients (0.7 per bronchoscopy). Events were severe in 3.1% of actively treated patients, and in 1.5% of control subjects. 8.4 % of BT-treated patients and 2% of sham-treated controls were admitted. Side effects included wheeze, asthma exacerbation, haemoptysis, chest pain. All resolved with standard therapy.

2. Anecdotal adverse events (known from experience)

The patient with asthma who has bronchiectasis as a comorbidity tends to suffer from the procedure, with more airway exacerbations. This is now recognised and most practitioners would not offer this treatment to those with this comorbid condition. Although not widely reported, this is well-known among operators / within the severe asthma medical community.

3. Theoretical adverse events

Asthma exacerbation. Haemoptysis. Lower respiratory tract infection. Focal bronchiectasis at site of treatment (not observed in practice).

4.2 What are the key efficacy outcomes for this procedure?

The key efficacy outcomes should be:

- A reduction in asthma exacerbation frequency
- A reduction on long-term oral corticosteroid dose
- An improvement in asthma-specific quality of life
- Improvement in days missed from work

In terms of what has been proven, the only randomised study (Castro et al) demonstrates:

- Improvements in severe exacerbations: In the post-treatment period (t + 6 weeks to 52 weeks from final treatment), there was a 32% reduction in severe exacerbations in the active treatment ITT group compared to the sham treated group.
- Improvements in emergency dept admission (In the 12 months after first treatment, the number of ED visits for asthma in the active treatment ITT group was 0.13, compared to 0.45 in the sham-treated group.
- Improvement in AQLQ: 19% more individuals in the active treatment ITT group had a clinically significant improvement in AQLQ than in the sham group)
- Improvement in days missed from work (individuals in the active treatment ITT group had a clinically significant improvement in days / year off work due to asthma, compared to the sham-treated group: 1.3 vs 3.9 days year)

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

- Initial (animal) data suggested that bronchial thermoplasty would result in an improvement in bronchial reactivity. This has not been shown in the human studies
- The long-term study of efficacy reporting results out to 5 years post-treatment only reported results from the active-treatment group. Therefore, although there appears to be maintenance at 5 years of the beneficial effect seen at 12 months in terms of severe asthma exacerbation reduction, there is no data for comparison from the sham-treated group.
- In a recent paper, Pretolani et al (Pretolani, M. et al. Effectiveness of bronchial thermoplasty in patients with severe refractory asthma: Clinical and histopathologic correlations. J Allergy Clin Immunol. 2017 Apr;139(4):1176-1185.) studied a population with very severe asthma. Once again, there were very positive clinical benefits to treatment in terms of exacerbation frequency, oral steroid use, and asthma-specific quality of life, but there was no sham-treated control group.
- There is as yet no head-head comparison of biological therapies (anti-IgE and anti-IL5) with the use of bronchial thermoplasty, although one comparison of BT with anti-IgE therapy, an indirect meta-analysis, has been published (Niven RM et al. Indirect comparison of bronchial thermoplasty versus omalizumab for uncontrolled severe asthma. J Asthma. 2017 Jul 14:1-9.)
- There is as yet no randomised trial of the use of BT as a supplementary treatment to the use of biological therapies.

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

- Operators are, and need to be trained in specialist asthma centres. On-site access to an intensive care unit is needed, should there be a severe asthma exacerbation in the immediate post-therapy period.
- Patients should be treated by the physician / team who knows them and treatment optimised in the days prior to the procedure, usually with high-dose oral steroids.

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

- British Thoracic Society Severe Asthma Registry contains details of patients who have had bronchial thermoplasty.

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).

British Thoracic Society 2017: 1 abstract from Hince et al: "Bronchial thermoplasty maintains a long-term reduction in peripheral blood eosinophils in severe asthma." Published in Thorax 2017 November edition. Abstract P13. Details of 13 patients treated with BT whose blood eosinophil counts reduced significantly after BT treatment.

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

No. Data is collected on patients who have the procedure and submitted to the UK severe asthma registry, in accordance with the arrangements required for this relatively new procedure.

There is a lack of data on the effects of the procedure when combined with biological therapy. The treatments are being used in the manner, and research on this will be helpful in the future.

5 Audit Criteria

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

- Admissions per year
- Exacerbations / year requiring oral steroids
- Asthma – specific quality of life
- Measures of asthma control (eg ACT-7)
- Oral corticosteroid dose

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:

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:

Within the first 6 weeks of the bronchoscopy, and mostly within the first 24 hours, there is an increased risk of:

- Lower respiratory tract symptoms, admission to hospital with an asthma exacerbation, cough, wheeze.

An increased risk of late effects has not been identified (randomised data to 12 months post-treatment).

Patients with bronchoscopy have a worsening of airways control after treatment and this group is now excluded by most operators.

6 Trajectory of the procedure

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

Currently, around 50 patients / year have BT performed in the UK. If no further randomised evidence is published, this number is unlikely to significantly increase. Otherwise, however, we might see quite significant increases.

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:

At present, there is a reticence among many severe asthma physicians to refer patients for BT, perhaps because the original benefits seen in quality of life were small, and because the criteria for referral remain imprecise, as opposed to antibody treatments. However, should the evidence base change, and there be clear evidence of benefit from combined treatment with BT in addition to a biological therapy then the number of patients referred for the procedure could significantly increase. It is not possible to estimate the number of patients that might be eligible. Currently, around 50 patients / year have BT performed in the UK. If no further randomised evidence is published, this number is unlikely to significantly increase. Otherwise, however, we might see quite significant increases.

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?

No.

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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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 | <input checked="" type="checkbox"/> YES |
| | <input type="checkbox"/> NO |
| Fee-paid work – any work commissioned by the healthcare industry – this includes income earned in the course of private practice | <input type="checkbox"/> YES |
| | <input checked="" type="checkbox"/> NO |
| Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry | <input type="checkbox"/> YES |
| | <input checked="" type="checkbox"/> NO |
| Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, | <input checked="" type="checkbox"/> 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).

- meals and travel to attend meetings and conferences **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.

The nature of payments is set out below. *I don't believe these are at all related to the technology being appraised, but are included for clarity:*

Comments:

1. Funded by Novartis Pharmaceuticals to attend 2-day clinical leadership course in Solihull, October 2017 as a delegate. Two night's accommodation included in standard hotel.
2. One-off fee paid by grant-giving body (BBSRC) to conduct aeroallergen research (Imperial College UK) on study of temperature-controlled laminar airflow in patients with eczema. (Consultancy). 2015-2016.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

Conflicts of Interest for Specialist Advisers

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

- 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
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 - 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.