NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Microwave ablation for the treatment of liver metastases (381/3)**
Name of Specialist Advisor:	**Dr David Breen**
Specialist Society:	**British Society of Gastrointestinal and Abdominal Radiology**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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:

These procedures are increasingly, and perhaps better performed, under imaging guidance for adequate treatment completion. This increasingly involves the use of specialist imaging software.

The next two 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 which does this procedure, please indicate your experience with it:

☐ I have never performed this procedure.

☐ I have performed this procedure at least once.

☑ I perform this procedure regularly.

Comments: I run one of the longest established ~~[illegible]~~ services for this procedure in the UK.

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: Cases are referred into ourselves in interventional Radiology for consideration of this treatment, widely from other centres.

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

☐ I have undertaken bibliographic research on this procedure.

☑ I have undertaken research on this procedure in laboratory settings (e.g. device-related research).

☐ I have undertaken 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 published clinical work in this area, performed bovine dosimetry work and co-authored international guidelines, (including an HTA systematic review).

3 Status of the procedure

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

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

Comments: Microwave ablation is increasingly established and has largely taken over from radiofrequency ablation.

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

Radiofrequency ablation. (RFA).

3.3 Please estimate the proportion of doctors in your specialty who are performing 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.
- [x] Fewer than 10% of specialists engaged in this area of work.
- [ ] Cannot give an estimate.

Comments: This is largely centred in large IR units and HPB centres. Specialist commissioning is looking to centre this practice in the ~25 fully operate HPB service centres.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Theoretical adverse events

2. Anecdotal adverse events (known from experience)

Very Occasional pneumothorax and diaphragmatic injury.

3. Adverse events reported in the literature (if possible please cite literature)

Thermal Bowel injury (~0.5%)
Biliary injury (<0.5%)
Bleeding / vascular injury (~0.5%)

4.2 What are the key efficacy outcomes for this procedure?

Disease eradication as documented radiologically.
Liver Progression-free survival
Overall survival.

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

Concerns centre around complete tumor eradication and the possibility of local tumor recurrence.

4.4 What training and facilities are required to undertake this procedure safely?

Careful training under the guidance of an experienced proctor should be a baseline requirement. This in addition to CME and didactic teaching.

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

Numerous single centre trials but little randomized data (against surgical resection).
See: Solbiati Radiology (2012) 265: 958, Gillams Eur Radiol (2009) 19: 1206, Shibata Cancer (2000) 89: 276, Rivers Ann Oncol (2012) 23: 2619

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, e.g. PUBMED? (This can include your own work). If yes, please list.

Please see Theo Ruers data from the CLOCC (EORTC 40004) study presented at ASCO 2015, (this centres on RFA but is applicable).

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

There are considerable training and QA issues. (I would need to discuss 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):

Local PFS, Global PFS and OS.

(Please see our HTA Systematic Review – Lorcman, HTA (2014) 18: 1-283).

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

Complications should be recorded to an in-house database using either Clavien-Dindo criteria or CTCAE – 4.0.

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

Relatively rapid. On occasions as a replacement for surgery in small volume disease and perhaps more so as an adjunct to systemic chemotherapy (see CLOCC study).

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: Specialist commissioning of HPB services has a model for appropriate deployment in hand.

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:

If practised correctly this procedure has a major role to play in the management of metastatic liver disease (from a number of different primaries).

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?

Please contact me if you require further discussion.

8 Data protection and conflicts of interest

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

A copy of the completed Specialist Adviser advice will be sent to the Specialist Society who nominated the Specialist Adviser.

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

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

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the "Conflicts of Interest for Specialist Advisers" policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

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[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

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

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

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

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

Investments – any funds which include investments in the healthcare industry ☐ YES ☑ NO

Do you have a **personal non-pecuniary** interest – eg 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.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

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

February 2010

Conflicts of Interest for Specialist Advisers

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

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

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 Personal family interest

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 Personal non-pecuniary interests

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

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

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

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

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Microwave ablation for the treatment of liver metastases (381/3)**
Name of Specialist Advisor:	**Elizabeth O'Grady**
Specialist Society:	**British Society of Interventional Radiology**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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:

The committee may wish to consider whether they wish this guidance to cover all metastases. Most experience relates to treatment of colorectal liver metastases, although other types have been treated successfully.

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 two 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 which does this procedure, please indicate your experience with it:

✓ ☐ I have never performed this procedure.

☐ I have performed this procedure at least once.

☐ I perform 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 am an interventional radiologist member of our regional HPB MDT, deciding on patient treatment pathways, and reviewing patients post procedure imaging, although I do not perform ablation myself

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

☐ I have undertaken bibliographic research on this procedure.

☐ I have undertaken research on this procedure in laboratory settings (e.g. device-related research).

☐ I have undertaken 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 that procedure's safety and efficacy.

✓ ☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:
Microwave ablation is one of the newer of a range of ablation techniques.
Further work is needed to assess the long term outcomes of this treatment.
Studies (randomised controlled trials) comparing RFA, microwave and newer ablation techniques such as IRE are needed.
Literature available so far suggests that is it a safe procedure compared to e.g. RFA

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

Radiofrequency ablation
Surgery (where applicable – most ablations are performed on patients not suitable for surgery or sometimes in addition to surgical resection)

3.3 Please estimate the proportion of doctors in your specialty who are performing 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 are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Theoretical adverse events

Pain, fever

Haemorrhage

Damage to adjacent structures including lung, diaphragm, biliary tree, bowel

Impaired liver function

Fever

Infection

Needle track seeding

Fluid collections – pleural or ascitic.

Death

2. Anecdotal adverse events (known from experience)

Residual tumour / local recurrence

We have seen liver abscess, haemorrhage and pneumothorax post MWA. Anecdotally the rate of haemorrhage and pneumothorax is slightly less than with RFA as the probe is smaller.

The probe for MWA is less rigid than an RFA probe. There is a point of weakness where the silicon antennae in attached to the shaft. Iam told that there have been cases reported elsewhere of fracture. We have not seen this, but have send bend/ kink of the probe at this point.

We have noted some increase segmental vascular thrombosis on post procedure follow up imaging (an incidental finding) more with RFA than post RFA.

3. Adverse events reported in the literature (if possible please cite literature)

International multicentre p study on Microwave ablation of liver tumours; preliminary results - D. Lloyd et al, HPB 2011, 13, 579–585

Reviewed patients undergoing Operative/open Microwave ablation (MWA)

Major adverse events rate 8.3%

Residual tumour 2.9%

Microwave coagulation therapy for multiple hepatic metastases from colorectal carcinoma, Shibata et al, Cancer Volume 89, Issue 2, pages 276–284, 15 July 2000

Reported rates of complications in 62 patients undergoing MWA at laparotomy, of

7% (1 patient) liver abscess

7% (1 patient) bile duct injury.

Microwave ablation with or without resection for colorectal liver metastases, S Stattner, et al, EJSO, 39 (2013(844-849

This review of patients undergoing open MWA reported

Local recurrence rate for MWA – 4% all adjacent to Middle or Right hepatic vein.

CT-guided percutaneous microwave ablation of liver metastases from Nasopharyngeal carcinoma , X Li, J Vasc Interv Radiol. 2013; 24(5):680-4.

Of 18 patients who underwent 27 MWA procedures the following major complications were observed:

Pneumothorax - 1 patient

Pain post procedure – 2 patients

4.2 What are the key efficacy outcomes for this procedure?

Control of primary tumour (residual tumour rate defined as absence of any tumour on first post procedure imaging)
Rates of local recurrence,

Rate of significant adverse events
Procedure related death.

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

Further information required about residual tumour rates and local recurrence rates for MWA compared to RFA, and other local ablative techniques for percutaneous ablation.

4.4 What training and facilities are required to undertake this procedure safely?

HPB MDT support to select suitable patients

Microwave machine plus disposable probes, image guidance (CT or US), anaesthetic support usually GA.

Operators need to be trained in image guided procedures as well as in the operation of the microwave machine.

Good quality follow up imaging (CT, MR) to assess response and recurrence.

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

Not to my knowledge

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, e.g. PUBMED? (This can include your own work). If yes, please list.

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?

More information is required about outcomes from percutaneous procedures.

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):

Procedure time

Morbidity.
Length of stay

Technical success (residual tumour rate)

Local recurrence rates
Tumour free survival period
Overall survival / 5 year survival rates.

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

Procedure related complications, especially major adverse events

- Haemorrhage, infection, (early)
- bile duct injury, bowel injury (later)

Procedure related deaths

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

Results reported so far show similar rates for significant (major) complication rates.
Once residual tumours rates and local recurrence rates are confirmed as equal to or better than RFA for percutaneous procedures in view of shorter procedure times, and larger zones of ablation this is likely to become the preferred method of ablation for most cases in centres performing ablative treatments for liver metastases (regional referral units for HPB surgery).

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:

1. Likely to be limited to liver surgery centres, in the most part.

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:

As microwave ablation is likely to be used instead of other ablative techniques in specialist HPB centres, the number of additional machines will be

limited. As procedure times for microwave are less than for RFA there are potential savings related to increase patient though put and reduced waiting lists.

Compared to RFA there is a theoretical potential for reduced rates of local recurrence due to larger zone of ablation, and reduced heat sink effect, in lesions in close proximity to major vessels.

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

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

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

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the "Conflicts of Interest for Specialist Advisers" policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	✓ ☐	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	✓ ☐	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	✓ ☐	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	✓ ☐	**NO**
Investments – any funds which include investments in the healthcare industry	☐	**YES**
	✓ ☐	**NO**
Do you have a **personal non-pecuniary** interest – eg 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.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

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

February 2010

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.

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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.

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2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 Personal family interest

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 Personal non-pecuniary interests

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

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

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

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

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Microwave ablation for the treatment of liver metastases (381/3)**
Name of Specialist Advisor:	**Dr Nadeem Shaida**
Specialist Society:	**British Society of Gastrointestinal and Abdominal Radiology**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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: There is a debate between Radiofrequency Ablation (RFA) of liver tumours + Microwave Ablation of liver tumours (MA). I currently perform RFA regularly and am considering the switch to MA.

The next two 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 which does this procedure, please indicate your experience with it:

☑ I have never performed this procedure.

☐ I have performed this procedure at least once.

☐ I perform this procedure regularly.

Comments: See above. I perform RFA instead but am looking to switch to MA.

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: See above - RFA yes. At yet no MA.

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

☑ I have undertaken bibliographic research on this procedure.

☐ I have undertaken research on this procedure in laboratory settings (e.g. device-related research).

☐ I have undertaken clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments: As I look to potentially switch techniques, I have extensively researched the case for/against MA.

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 that procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments: The difference to RFA (which is well established) is in the mechanism of generating the thermal injury to the liver.

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

RFA.

3.3 Please estimate the proportion of doctors in your specialty who are performing 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: Less than half I would estimate.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Theoretical adverse events

(a) Liver failure - Low <1%.
(b) Bleeding - Same as RFA/biopsy (low 1-2%)
(c) Bile duct injury - Low
(d) Liver abscess/infection - Low.
(e) Tumour Seeding - Very low
(f) Portal vein thrombosis - low.
(g) Diaphragmatic injury - Low but depends on lesion.
(h) Mortality - Lv. low.

2. Anecdotal adverse events (known from experience)

Portal vein thrombosis, diaphragmatic injury, bleeding

3. Adverse events reported in the literature (if possible please cite literature)

Haemothorax, intractable pleural effusion, tumour seeding

Ref: Complications after percutaneous ablation of liver tumour: a systematic review
CAHAT E, ESHKENAZY R, ZENDEL A, ZAKAI BB, MADE M, DEEZNIK Y, ARICHE A
Hepatobiliary Surg Nutr. 2014 Oct; 3(5): 317-23

4.2 What are the key efficacy outcomes for this procedure?

- Tumour response as assessed by RECIST criteria.
- Overall survival

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

Size of lesion restricts treatability (as it does for RFA).

4.4 What training and facilities are required to undertake this procedure safely?

- Interventional or in some cases Gastrointestinal Radiologists or those with the skills required i.e. the ability to target a lesion under imaging. Most commonly this will be under US guidance ∴ radiologists with the necessary training are required
- It can be performed under most imaging modalities, however most commonly under US. CT/MRI are also possible. Although not mandatory, most operators will require general anaesthesia

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

Not to my knowledge

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, e.g. PUBMED? (This can include your own work). If yes, please list.

Not known.

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

- The main issue is the comparison with RFA.
- Theoretically MA offers a "better" burn in that RFA can be limited by the "heat sink" effect where lesions close to vessels have the heat carried away + therefore do not burn as well. MA is not patient to that effect.
- Secondly, MA offers a shorter duration of treatment which mean multiple lesion can be treated in one session.

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):

Tumour response - Complete & partial

Survival benefit - at say 3 or 5 year.

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

- Bleeding (Hb drop, need for transfusion).
- Vessel injury (as evidenced on follow up imaging)
- Failure to treat (follow up imaging).
- Death.

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

Moderate - Ablation is done in relatively specialised centres.
- The RFA community I think is keen to switch over if they have not done so already but factors such as equipment costs may be holding them back.

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

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

Comments:
Liver centres are likely to adopt this technology eventually.

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.
- [x] Minor.

Comments: Surgical resection remains the treatment of choice. For those not suitable ablative techniques could be considered.

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

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

A copy of the completed Specialist Adviser advice will be sent to the Specialist Society who nominated the Specialist Adviser.

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

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

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the "Conflicts of Interest for Specialist Advisers" policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐ YES	☑ NO
Fee-paid work – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice**	☐ YES	☑ NO
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐ YES	☑ NO
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐ YES	☑ NO
Investments – any funds which include investments in the healthcare industry	☐ YES	☑ NO
Do you have a **personal non-pecuniary** interest – eg 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.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

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

February 2010

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Microwave ablation for the treatment of liver metastases (381/3)**
Name of Specialist Advisor:	**Peter Littler**
Specialist Society:	**British Society of Interventional Radiology**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

X Yes.

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

1.1 Does the title used above describe the procedure adequately?

X Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X Yes.

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

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

Comments:

The next two 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 which does this procedure, please indicate your experience with it:

☐ I have never performed this procedure.

☐ I have performed this procedure at least once.

X I perform 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.

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

Comments:

I take part in a fortnightly ablation clinic . During this clinic I assess patients together with surgical and hepatology colleagues to decide on ablation or other loco-regional therapy options.

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

☐ I have undertaken bibliographic research on this procedure.

☐ I have undertaken research on this procedure in laboratory settings (e.g. device-related research).

☐ I have undertaken clinical research on this procedure involving patients or healthy volunteers.

X 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.

X A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

Although this is becoming established practice its evidence base is fairly small but increasing.

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

Radiofrequency ablation, another more established thermal ablative technique.

3.3 Please estimate the proportion of doctors in your specialty who are performing 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.

X Cannot give an estimate.

Comments:

This procedure will be largely carried out in tertiary level regional centres by one or two consultants.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Theoretical adverse events

Bleeding, bile leak, biliary injury, vascular injury, infection, damage to surrounding structures (bowel, gallbladder etc). Mortality (quoted at 1 in 500).

2. Anecdotal adverse events (known from experience)

Rare biliary injury. Can happen with any thermal ablation. Case selection can reduce risks markedly.

3. Adverse events reported in the literature (if possible please cite literature)

Major complications 2.9%

Minor complications 7. 3%

Mortality 0 % (other papers report 0.2%)

Livraghi T et al CVIR 2012 Aug;35(4):868-74.

This pools cases of MWA for primary and secondary liver tumours.

4.2 What are the key efficacy outcomes for this procedure?

Response rate, local recurrence rate, progression free and overall survival.

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

No, although literature is mostly retrospective cohort data. The available data points to similar outcomes to RFA. Personally, this is no surprise.

4.4 What training and facilities are required to undertake this procedure safely?

Industry sponsored / arranged workshops, in-house training and proctoring of cases and any additional clinical support.

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

LOTCOL study, now recruiting. Small numbers , not exclusively microwave.

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, e.g. PUBMED? (This can include your own work). If yes, please list.

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. Normal clinical governance applies.

5 Audit Criteria

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

The patient pathway , complications major and minor, incidence of incomplete treatment and local recurrence, progression free and overall survival and patent satisfaction.

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

Response on cross sectional imaging
Progression free and overall survival.
Quality of life measures.

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

Complication rate inc 30 day mortality

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

Fairly rapid. It is easier to use than RFA and has potential benefits in that it suffers less heat sink effect. In the UK many centres have already, or are in the process of transferring to use microwave rather than RFA for liver ablation.

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

☐ Most or all district general hospitals.

X A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

Should be tertiary centres only in my view.

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.

X Minor.

Comments:

As a potential alternative to surgery, this procedure is likely to be significantly cheaper.

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

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

A copy of the completed Specialist Adviser advice will be sent to the Specialist Society who nominated the Specialist Adviser.

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

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

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the "Conflicts of Interest for Specialist Advisers" policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional **X** **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).

payments in cash or kind	☐	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	**X**	**YES**
	☐	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	X	**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**
	X	**NO**
Investments – any funds which include investments in the healthcare industry	☐	**YES**
	X	**NO**
Do you have a **personal non-pecuniary** interest – eg 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**
	X	**NO**

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

Fellowships endowed by the healthcare industry	☐	**YES**
	X ☐	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	X	**NO**

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

Comments:

I have done some consultancy work for BTG PLC. This company develops and sells interventional oncology products but no ablation devices so there is no conflict of interest. I have once proctored for Angiodynamics on an Irreversible Electroporation case. They do sell the microwave machine I use but I do not feel there is a conflict of interest relating to the proctoring of a different ablative technology.

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

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

February 2010

Conflicts of Interest for Specialist Advisers

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

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

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 Personal family interest

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 Personal non-pecuniary interests

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

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

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

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

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.