

**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:** **Robotic-assisted kidney transplant (IP1540)**

Name of Specialist Advisor: Mamode Nizam

Specialist Society: NHS Blood and Transplant

**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:**

No-one in the UK does this regularly as it is a very new procedure

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

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

**Comments:**

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

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

Other (please comment)

**Comments:**

### **3 Status of the procedure**

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

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

**Comments:**

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

Open renal transplant surgery

#### **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 2 centres in the UK currently performing this

### **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)

Renal artery and vein thrombosis, torsion of the transplant, delayed graft function, loss of vascular control, ocular oedema and visual impairment

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

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

1 year graft survival, eGFR at 1 year

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

Unclear about whether prolonged warm ischaemia affects graft function

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

Need a robot. Basic robotic training programme exists. Mentoring needed from overseas surgeons

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

European registry

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

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

Yes- American Transplant Congress last 3 years

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

Yes- uncertain whether it is safe.

**5 Audit Criteria**

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

**Graft survival, eGFR**

**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:**

**Length of hospital stay, analgaesia use**

**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:**

**Graft loss in first 30 days and first year, delayed graft function**

**6 Trajectory of the procedure**

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

Likely very quickly- will probably become standard of care in 5 years

**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:**

There are 23 transplant centres, most will probably take it up if initial experience is successful

**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?

## 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.

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

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

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

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

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

Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

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<sup>1</sup> ‘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 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:**

Previous unrestricted educational grant from Astellas for trial of Rituximab, consultancy work for Alexion regarding Eculizumab, nothing on robotics.

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:    Robotic assisted kidney transplantation**

Name of Specialist Advisor:    Mr Colin Wilson

Specialist Society:    British Transplantation 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:**

I am part of a team that are considering whether to offer this procedure or not

**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:**

Around 200 procedures performed worldwide

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

Open kidney transplantation

#### **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:**

I am aware of 5 centres worldwide offering this procedure

### **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)

Renal vein thrombosis (<1%), renal artery thrombosis (<1%), bowel injury (<1%), port site hernia (no reliable data), torsion or twisting of the kidney (theoretical risks- no reported case of which I am aware), conversion to the standard open surgery (1-2%). Abstracts from recent conferences attached.

2. Anecdotal adverse events (known from experience)

None personally known to me

3. Theoretical adverse events

As above

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

Standard kidney transplant metrics- 1 year graft survival, patient mortality, glomerular filtration rate.

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

No

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

Access to a da Vinci robotic console, cadaveric laboratory, mentoring

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

No

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

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

Yes, see attached

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

Open kidney transplantation is a safe and effective procedure with a long track record of clinical effectiveness. It is unclear who would benefit from robotic assisted kidney transplantation. The current thoughts are that overweight or obese patients,

who would require a large incision for transplantation, would be the most likely to benefit. There are no randomised trials yet available to guide decision making.

## **5 Audit Criteria**

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

Duration of robotic procedure, cold ischaemic time for the kidney graft (mins), warm ischaemic time (minutes)- time taken to perform the intra-corporeal stitching, incidence of delayed graft function, hospital stay, operative complications, readmission rates, late operative morbidity (late complications- hernias, renal artery stenosis etc)

**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:**

Immediate function rate, rate of creatinine fall; 1, 3, 6 and 12 month GFR and serum creatinine

**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:**

Intraoperative blood loss, renal artery/vein thrombosis rate (1 month), graft nephrectomy rate (1 month), conversion to open procedure (%), ureteric leak/ stenosis (1 month), re-operation rate, wound infection, post-operative analgesic use,

## **6 Trajectory of the procedure**

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

Within 5 years I estimate 5 centres in the UK will be performing the procedure

**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:**

In the United Kingdom 2015/16 3,265 kidney transplants were performed. If all these were to be performed robotically at £5,000 extra per case, then this would amount to an extra £16.3 million. If the 260 pancreas transplants were also performed robotically this would add further costs see TTS\_2016 abstract 554.1.

**7 Other information**

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

**8 Data protection and conflicts of interest**

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

**8.1 Data Protection**

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Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

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

NO

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

NO

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

NO

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

NO

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

NO

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

NO

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

**Fellowships** endowed by the healthcare industry  YES

NO

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

NO

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

**Comments:**

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.**

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<sup>1</sup> ‘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).

**Jan 2016**

## Conflicts of Interest for Specialist Advisers

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### 3 **Personal family interest**

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

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- 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.

**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:**                                **Robotic assisted kidney transplantation**

Name of Specialist Advisor:                Chris Watson

Specialist Society:                            NHS Blood and Transplant

**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:**

We regularly select patients for kidney transplantation, but not performed in this way

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

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

Other (please comment)

**Comments:**

### **3 Status of the procedure**

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

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

**Comments:**

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

Kidney transplantation by open surgery

#### **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:**

I believe it is only being undertaken at Guys and the Royal Free Hospitals in London

### **4 Safety and efficacy**

#### **4.1 What is the potential harm of the procedure?**

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

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



Increased time to perform anastomosis – known to affect outcomes (Heylen et al, Am J Transplant 2017;17:724)

Head and neck oedema when Trendelenberg position (head down) used to facilitate vision. Many renal patients have had previous neck lines and may have SVC or jugular vein stenosis, so are predisposed to oedema if head down Sood et al. Transplantation 2015;99:316). This has a risk of complicating attempts at extubation (laryngeal oedema).

## 2. Anecdotal adverse events (known from experience)

Kidney transplant using the robot are intraperitoneal. Intraperitoneal kidneys are more difficult to biopsy, and biopsy is more likely to be associated with bleeding complications because of the loss of tamponade. Renal biopsy is an important aspect of post transplant management.

Potential for an intraperitoneal kidney to undergo torsion.

## 3. Theoretical adverse events

Equipment failure

Increased incidence of delayed graft function requiring dialysis support – due to prolonged anastomosis time

Pneumoperitoneum may adversely affect renal reperfusion – this was proposed in the report of the first series who observed a higher creatinine on discharge (Oberholzer et al, Am J Transplant 2013;13:721).

Lack of haptic feedback preventing selection of optimal position for clamping recipient artery and siting anastomosis. Elderly renal patients frequently have significant vascular disease so being able to palpate the artery before occluding it for implantation is very desirable.

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

### Patient:

Wound pain

Wound infection rate

Length of stay

Blood loss

Need for reoperation

### Transplanted Kidney

Vascular thrombosis

Primary non function rate

Delayed graft function rate

Kidney graft survival

Patient survival

eGFR at a time period post transplant, say 3 or 12 months

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

1. Vascular anastomosis – joining the renal artery and vein to the recipient's external iliac artery and vein  
There are concerns regarding the length of time it takes to do the vascular anastomoses. There is increasing evidence that the longer it takes to implant a kidney the poorer its long term outcome. Also the quality of the anastomosis (whether it bleeds) and the risk of damage to the native external iliac artery. The latter may happen with open surgery, but there is greater tactile feedback so less likelihood of inadvertent placement of the clamps or arteriotomy in an area of atheroma
2. Torsion – there is a risk that the kidney can twist around its vascular pedicle. This is avoided in open surgery by placing the kidney in the extraperitoneal space. While this is possible laparoscopically, it makes the procedure more difficult and most of the early reports of robotic transplantation involve intraperitoneal placement

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

Competence at laparoscopy

Familiarity with and competence in using the robot – in the UK this will usually be urologists using the robot for prostate surgery

Competence in open kidney transplantation

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

I do not know of any registries internationally or nationally

I do not know of any trials

**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?**

It is important to distinguish totally robotic from robot assisted, where there is a large incision and the ability to apply clamps to vessels from outside.

In the UK it is currently being done by less than a handful of surgeons.

I do not think it is widely seen as something for the future, but I am aware that many thought the same of laparoscopic cholecystectomy which is now standard practice, as is laparoscopic colorectal surgery.

The main selling point of the robot is its use for patients who are morbidly obese, a group that is often excluded from open renal transplantation

## **5 Audit Criteria**

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

Need for dialysis in first week post transplant

Patient and graft survival at one year

Renal function at one year

**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:**

as above.

PROMS – there are a number of renal specific QOL instruments developed by Prof Clare Bradley from Royal Holloway that should be considered. These have been used in a recent NIHR funded ATTOM study and are well validated on a dataset of over 1000 patients

**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:**

Vascular anastomosis time – this needs to compare like with like, ie, kidneys with single vessels and a healthy Carrel patch of aorta, for example.

Delayed graft function – the need for dialysis in the first 7 days post transplant

Length of stay.

3 and 12 month graft and patient survival.

## **6 Trajectory of the procedure**

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

- It is limited by the availability of the robot, and expertise in using it, expertise in laparoscopic surgery, and the nature of transplant surgery.
- While most surgical trainees and young consultants will have grown up on laparoscopic surgery, many of the more senior consultants do not routinely do laparoscopic procedures; they very rarely if ever do robotic surgery.
- Transplant surgery is an emergency procedure, often done out of hours with junior anaesthetic and theatre staff who may not be familiar with setting up and using the robot

**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:**

There are only 23 kidney transplant centres in the UK

**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:**

We do around 3000 kidney transplants each year in the UK, 2000 of which are from a deceased donor and done as emergencies, and 1000 of which are from living donors and so done on an elective operating list. In reality I see this as being primarily something done on an elective list, so that means a living donor transplant.

**7 Other information**

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

**8 Data protection and conflicts of interest**

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

**8.1 Data Protection**

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

X

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

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

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

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

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

Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

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

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

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

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

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

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

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

**Fellowships** endowed by the healthcare industry  **YES**  
 **NO**

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

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

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

**Comments:**

Consultancy: Occasional consultancy to OrganOx Ltd, manufacturer of a machine for the Normothermic preservation of the liver.

Personal non-pecuniary interest: I chair the Kidney Advisory Group (KAG) of NHS Blood and Transplant (NHSBT). KAG advises NHSBT on policy in relation to kidney transplantation in the UK. KAG has never discussed the topic under consideration.

Support by the Healthcare industry: within the last 3 years I have received a grant from Astellas Pharma to my department to conduct a trial in kidney preservation

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.

**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:**                                      **Robotic assisted kidney transplantation**  
**Name of Specialist Advisor:**                      Mr Neal Banga  
**Specialist Society:**                                      British Transplant Society (BTS)

**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:**

I have performed 8 of these procedures in the last 11 months, approximately one every 6 weeks

**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:**

This does not really fit into any of these categories. It is a procedure using the da Vinci robot (used in dozens of other procedures) to perform renal transplantation, which has been an established open operation for 40 years. The efficacy of renal transplantation is not in doubt. The capability of the da Vinci robot in reconstructive operations such as cystectomy or partial nephrectomy has been demonstrated. The only issue is the safety of the recipient and the donor organ whilst undergoing this.

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

Standard open kidney transplantation

#### **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 2 centres in UK performing this procedure (Royal Free and Guy's).

### **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)

Sood et al, Minimally Invasive Kidney Transplantation: Perioperative Considerations and Key 6-Month Outcomes. Transplantation (2015) – 67 patients

Conversion to open procedure (0%)

Exploration for bleeding post-operatively – not reported

Graft loss (0%)

Breda A, et al. Robot-assisted Kidney Transplantation: The European Experience. Eur Urol (2017) – 120 patients

Conversion to open procedure (1.7%)

Exploration for bleeding post-operatively (4.2%)

Graft loss - thrombosis (4.2%)

2. Anecdotal adverse events (known from experience)

Longer operative time and warm ischaemia time

3. Theoretical adverse events

As above

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

- graft survival at one year (+)

- GFR at one year (+)

- patient survival at one year (+)

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

No – the data from Chicago shows equivalent survival and function between open and robotic transplant grafts at 3 years

(Garcia-Roca et al. Single Center Experience With Robotic Kidney Transplantation for Recipients With BMI of 40 kg/m<sup>2</sup> Or Greater: A Comparison With the UNOS Registry. Transplantation 2016)

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

Should only be performed in specialist robotic surgery centres with an active transplant programme, by surgeons trained in renal transplantation and robotic surgery.

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

European Registry (Breda, Spain)

Vattikuti Institute Quality Initiative

- 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?**

The procedure is currently only being performed in specialist centres with expertise in both kidney transplantation and robotic surgery

## **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:**

Delayed graft function rate  
One year graft and patient survival  
One year GFR

- 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:**

Intra-operative bleeding and conversion to open procedure  
Early graft loss  
Return to theatre in the first month for bleeding or concern about graft

## **6 Trajectory of the procedure**

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

It is gaining popularity, but its spread will be limited by the number of surgeons who have experience in both surgery and robotic transplantation

- 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:**

There are only 25 kidney transplant centres in the UK.

**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:**

Once the learning curve has been traversed and the safety and efficacy of the procedure has been demonstrated by the UK units performing it, then this procedure has the potential to revolutionise renal transplantation in some patients:

- 1- patients undergoing uncomplicated living donor transplantation can do so with smaller wounds, faster recovery and less wound-related morbidity
- 2- patients currently excluded from kidney transplantation due to obesity may be transplantable using the robotic-assisted technique

**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.

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

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## 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).

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Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

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

NO

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

NO

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

NO

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

NO

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

NO

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

NO

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

**Fellowships** endowed by the healthcare industry  YES

NO

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



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

**YES**

**NO**

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

**Comments:**

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.