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:	**Nerve transfer for restoration of upper limb function in tetraplegia**
Name of Specialist Advisor:	Mr Dominic Power
Specialist Society:	British Association of Plastic Reconstructive and Aesthetic Surgeons

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:

There is the option to also undertake this procedure for improving trunk control and secondary respiratory muscle for cough assistance in some patients

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:

I am a hand surgeon and specialise in nerve surgery. Some upper limb reconstruction in tetraplegic patients is undertaken by hand surgeons who use tendon transfer and tenodesis procedures alone. The two can be combined to gain a greater functional level.

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:

Cases are infrequent and I have performed this procedure on 8 upper limbs in Birmigham

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 assess patients as part of a multidisciplinary team.

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

☒ I have done bibliographic research on this procedure.

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

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

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

☐ Other (please comment)

Comments:

I have done an extensive titerature review and defined an evidenced based outcome assessment pathway which we use for patients.

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:

Nerve transfer is a mainstream reconstruction technique for specialist nerve surgeons. The use in tetraplegia is still novel and limited outcome data is avaialble.

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

Functional gains from tenodesis and tendon transfer procedures. The reconstruction of th eupper limb using these techniques is well described with good evidence although uptake in the UK is low. Nerve transfers confer additional gains when combined.

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:

To my knowledge there are only 3 surgeons in the UK who have performed this procedure in tetraplegic patients.

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)

Surgery on tetraplegic patients is challenging and there are specific risks of autonomic dysreflexia as well as general risks of pulmonary embolism and respiratory compromise that are higher in this patient group.

2. Anecdotal adverse events (known from experience)

Donor muscle weakness. This can be permaent or temporary dependent on the procedure performed and the technique used for donor nerve harvest.

3. Theoretical adverse events

No recovery due to poor donor nerve, denervated recipient nerve, surgery performed too late or technical failure of the nerve co-aptation.

4.2 What are the key efficacy outcomes for this procedure?

Improved functioning level as demonstrated by a graduated upper limb score. Active elbow extension and active flexion and extension phase of grip for the hand are typical functional gains in a C6 level tetraplegic (ICHT Grade IC4 or IC5 Triceps minus).

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

There are tendon transfer optiond for triceps (Moberg Deltoid to triceps) which function well. There are some tendon transfer options for finger flexion or key pinch with brachioradialis. No trials compare tendon or combined transfers.

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

Standard operating facilities nerve stimulation and operating microscope. Anaesthesia experience intetraplegia. Experience in nerve transfer surgery. Understaning electromyography in combined upper and lower motor neurone dysfunction.

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

Not in the UK. There is a trial of supinator to postererior interosseus nerve transfer registered at the University of British Columbia, Canada.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

No

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

Yes. The is controversy over timing. In a lower motor neurone lesion there is a need for early time critical nerve transfer by 9 months from injury. Most rehabilitation specialists and reconstructive tetraplegia surgeons offer tendon surgery after 1-2 yrs

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:

Canadian Occupational Performance Measure; Capabilities of the Upper Extremity Instrument; SCIM; MRC motor grade; Monofilament sensory assessment;

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:

Perioperative complications should include 30 day respiratory complications, 90 day pulmonary embolic. Motor function in donor should be assessed at 2 weeks to establish morbidity.

6 Trajectory of the procedure

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

Slowly. There are around 500 new tetraplegic patients in the UK per annum. Approximately 200 may be suitable. Currently fewer than this receive any surgery. The specialist nerve surgery and complex decision making need MDTs in a few key centre.

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:

I would suggest that there is only enough work for around 5-6 centres in the UK. Currently the spinal injury centres are not all located close to specialist nerve centres. Combination treatment near a spinal injury centre would be optimum in my opinion.

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:
However it should be noted that there are some chronic cases where there is upper motor neurone dysfunction in muscles that could still be aygmented late with a nerve transfer (SPIN transfer for finger extension).

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?

There are some centres with caonsiderable expertise that have published. Notably Jan Friden (Sweden + Switzerland Tetrahand), Natasha Van Zyl (Australia), Ida Fox (USA) and Jayme Bertelli (Brazil).

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.

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[1] 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**

[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).

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:
I raised the issue of nerve transfers with NICE a few years ago prior to establishing a service. At that stage I was informed that it was a variation of an established procedure. I chaired a Special Interest Group at the BSSH in the UK + discussed my view
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 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.

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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: **Nerve transfer for restoration of upper limb function in tetraplegia**

Name of Specialist Advisor: Miss Grainne Bourke

Specialist Society: British Society for Surgery of the Hand (BSSH)

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?

In my opinion the main controversy with nerve transfers in Tetraplegia.is around chosing the best time to perform the nerve transfer. This is particularly the case in those cases with an incomplete Spinal Cord Injury and when there may be potential for recovery of hand and wrist movement and feeling spontaneously. However this can take up to 2 years or more to recover and the optimum time for nerve transfer is within the 6-12 months following injury. This decision is compounded by the levels of injury : above the injury site both upper and lower motor neurons will be functioning; at the level of the injury there will be a combination of upper and lower motor neuron injury ; below the level of the injury there will upper motor neuron loss but the lower motor neuron and spinal connection will still be intact.
However this controversy will not be relevant to all cases of tetraplegia at the cervical cord level as in some cases the potential for spontaneous recovery of movement in the hand will be negligible. In these cases potential for some recovery of movement in the hand is a new concept.

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

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

x I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

I have taken part in patient selection or referred a patient for this procedure at least once.

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

Comments:

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

☐ I have done bibliographic research on this procedure.

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

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

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.

☐ 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.

x The first in a new class of procedure.

Comments:

Nerve transfers for Tetraplegia add the potential for below elbow movement in some cases of Spinal cord injury.. By using working nerve that duplicate function in the shoulder and elbow the nerve transfers allow the transfer of nerve fascicles to denervated or paralysed muscles below the elbow. This has the potential to revolutionise the recovery for those cases with no wrist or hand movement. It also means that movement can be transferred to more than one muscle allow better functional capacity. Better Volitional control can also be achieved.
Nerve transfer techniques are not new and are established practice in traumatic peripheral and brachial plexus injures. It is their use in Tetraplegia that is a new concept .Most of the cases in Tetraplegia have been done in the last 10 years.

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

The standard practice is tendon transfers – dividing a tendon distally near its point of function and transferring it.
In some cases tendon transfers are not an option so this technique has the potential to add function where previously there was no solution.

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.

X Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Paraesthesia
Hand (N Y). 2015 Mar;10(1):60-7. Use of peripheral nerve transfers in tetraplegia: evaluation of feasibility and morbidity.
Fox IK[1], Davidge KM[2], Novak CB[3], Hoben G[1], Kahn LC[4], Juknis N[5], Ruvinskaya R[5], Mackinnon SE[1].

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Weakness in a functional power of the donor nerve

No or little movement or improvement after the transfer

4.2 What are the key efficacy outcomes for this procedure?

Better upper limb function in patients with Tetraplegia.

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

Outcome from Trials and case series that have already been performed will add evidence about the efficacy.

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

Mutlidisciplinary team experienced in managing cases of tetraplegia \ spasticity and experts in nerve surgery and rehabilitation after nerve surgery and spinal cord injury.

4.5

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

NCT01714349, Restoring Hand Function Using Nerve Transfers in Persons with Spinal Cord Injury

NCT01579604 Nerve Transfer Reconstruction in the Tetraplegic Upper Extremity
ACTRN12615000179538The Victorian Spinal Cord Service at Austin Health in Melbourne, Australia

4.7 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

4.8 Hand Clin. 2016 May;32(2):227-42. Fox IK[1]. Nerve Transfers in Tetraplegia

4.9 J Brachial Plex Peripher Nerve Inj. 2015 Dec; 10(1): e34–e42 Review of Upper Extremity Nerve Transfer in Cervical Spinal Cord InjurySarah A. Cain,[1] Andreas Gohritz,[2,3] Jan Fridén,[2,4] and Natasha van Zyl[1]

4.10 Hand (N Y). 2015 Mar; 10(1): 60–67. Use of peripheral nerve transfers in tetraplegia: evaluation of feasibility and morbidity Ida K. Fox, Kristen M. Davidge, Christine B. Novak, Gwendolyn Hoben, Lorna C. Kahn, Neringa Juknis, Rimma Ruvinskaya, and Susan E. Mackinnon

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

no

5 Audit Criteria
Please suggest a minimum dataset of criteria by which this procedure could be audited.
Demographics\timing of injury\ surgery\follow up, preoperative and postoperative muscle grades\ functional assessment\ operative and postoperative complications.

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:
MRC muscle grades
Disability of Arm, Shoulder and Hand. (DASH)
Spinal Cord Independence measure
Canadian Occupational Performance Measurement
Sollerman Hand Function Test
Patient Reported Outcomes Measures

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:

Standard complications
Bleeding , infection, chest infection,
deep venous thrombosis, wound breakdown

Specific complications
Immediate and early:
Pain
Paraesthesia
Weakness in the donor muscle
Late:
No improvement on the recipient muscle
Residual weakness or altered cutaneous sensation in the donor nerve distribution
Residual paraestheisa

6 Trajectory of the procedure

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

It is already being carried out in a number of specialist centres. The experience in these UK centres will increase. It is likely that a few other similar specialist centres will also add this procedure to their repertoire in the management of people with Tetraplegia.

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.

x 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.

x Minor.

Comments:
This a small numbers of cases. About 40-80 per million cases of Tetraplegia occur every year and only some of these will be eligible for nerve transfer surgery.

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?

Yes . The draft procedure description needs to be edited. It is not accurate..

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.

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

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

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

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

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

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

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

☐ **YES**

x **NO**

Fee-paid work – any work commissioned by the healthcare industry **–**

☐ **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).

this includes income earned in the course of private practice	x	**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 that include investments in the healthcare industry	☐	**YES**
	x	**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**
	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:

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).

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

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

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

2.2 No personal interest exists in the case of:

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

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

3 Personal family interest

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 Personal non-pecuniary interests

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read 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:	**Nerve transfer for restoration of upper limb function in tetraplegia**
Name of Specialist Advisor:	Mr Tim Hems
Specialist Society:	British Society for Surgery of the Hand (BSSH)

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.

☐X 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:

Nerve transfers are carried out by Orthopaedic or Plastic Surgeons who are often Hand Surgeons and have an interest in peripheral nerve injury.

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.

☐**X** 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.

☐**X** 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 regularly assess tetraplegic patients for other reconstructive procedures for the upper limb including tendon transfers.

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

☐**X** I have done bibliographic research on this procedure.

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

☐ 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.

☐**X** Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

Nerve transfers are well established for treatment of peripheral nerve injuries and brachial plexus injuries, but are new for tetraplegia.
Nerve transfers offer potential as an addition reconstructive option for the upper limb in tetraplegia which may have advantages over existing procedures for some patients. However, careful evaluation is needed as nerve transfers are introduced.

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

Tendon transfer 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.

☐**X** 10% to 50% of specialists engaged in this area of work.

☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

This is an estimate of surgeons doing reconstructive surgery for the upper limb in tetraplegia. This is a specialised area of Hand Surgery with only 10 to 20 surgeons in the UK.

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)

Loss of function in the muscles innervated by donor nerves for the transfer,

Eg. Deltoid weakness.

For elbow extension branches of the axillary nerve may be transferred to nerves to triceps. If too many branches to the deltoid muscle are used then weakness will result.

Bertelli JA[1], Ghizoni MF.
Nerve transfers for elbow and finger extension reconstruction in midcervical spinal cord injuries.
J Neurosurg. 2015 Jan;122(1):121-7. doi: 10.3171/2014.8.JNS14277.

Co-contraction between donor nerve function and restored function,

After a nerve transfer the restored function tends not to be independent of the original function of the donor nerve, which can give problems with control of movement.

Eg. After transfer of nerves to the supinator muscle to the posterior interosseous nerve for finger extension, supination may occur with finger extension. This is a major functional disadvantage. Bertelli and Ghizoni have reported performing radioulnar bone fusion to prevent the unwanted supination, which is likely to damage overall function in a tetraplegic.

Bertelli JA[1], Ghizoni MF.

Nerve transfers for elbow and finger extension reconstruction in midcervical spinal cord injuries.
J Neurosurg. 2015 Jan;122(1):121-7. doi: 10.3171/2014.8.JNS14277.

2. Anecdotal adverse events (known from experience)

Difficulties ascertaining the level of function in the donor nerves for transfer before surgery. May be found at operation to be unsuitable for transfer.

3. Theoretical adverse events

Compromise of other reconstructive options.

Eg. Weakness of brachialis muscle.

If the nerve to the brachialis is used for transfer, then elbow flexion is unlikely to be significantly weakened. However, this procedure would preclude the future use of the biceps muscle as a tendon transfer for elbow extension.

4.2 What are the key efficacy outcomes for this procedure?

Whether active movement is gained in the target muscles –
Eg. Triceps – elbow extension
Wrist or finger extension.

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

Yes. There is a lack of reported outcomes with sufficient numbers and assessing whether an effective increase in limb function has been achieved.

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

Patient selection depends on experience and knowledge of managing patients with tetraplegia.

Hospital wards with staff experienced in managing tetraplegic patients. Therefore best to be performed at spinal cord rehabilitation centres.

Operating theatre with access to intra-operative neurophysiology and an operating microscope.

Hand / Orthopaedic /Plastic surgeon trained in surgery on peripheral nerves, including nerve repairs and nerve transfers.

Knowledge of the detailed anatomy of the nerves involved in the transfer.

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, 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?

There has been recent enthusiasm regarding nerve transfers for tetraplegia. However, it is important that surgeons considering nerve transfers are familiar with the established tendon transfer procedures. The outcomes of nerve transfers should be compared with those of tendon transfer.

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:

Active range of movement and measurement of force of reconstructed movement.
Assessment of the ease of control of the movement.
Task based assessments of upper limb function, eg. Canadian Occupational Performance Measure.
Assessment of care costs.
Comparison with outcomes of traditional reconstructions, including tendon transfers.

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:

Anaesthetic / early general complications.
Loss / compromise of existing functioning muscles.

6 Trajectory of the procedure

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

Uncertain. Hopefully this will depend on outcomes reported and published.

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.

☐X 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.

☐X Minor.

Comments:

7 Other information

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

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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

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

Do you or a member of your family[1] 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.

[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).

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.

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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.

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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.

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4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Nerve transfer for restoration of upper limb function in tetraplegia**
Name of Specialist Advisor:	Mr Tony Heywood
Specialist Society:	British Association of Plastic Reconstructive and Aesthetic Surgeons

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:

Nerve transfer is a technique that involves transferring nerve branches from functioning muscles that can spare them and attaching them to nerves supplying paralysed muscles that would have useful functions. If axons successfully grow into the recipient nerve and re-innervate the paralysed muscle then useful function may be regained. They are time limited by the deterioration that takes place in denervated muscles that makes them incapable of being re-innervated after a period (thought to be in the region of 12-18 months)

A number of transfers have been described for restoration of various functions in the tetraplegic upper limb, some of them to provide functions that cannot be restored by means of conventional tendon transfer surgery, some to provide a degree of function that is of better quality than what can be achieved with tendon surgery, and some to provide an alternative to tendon surgery that might achieve the same result but using a surgically less major operation. The following 3 examples are nerve transfers that I believe have the most obvious benefits and that I would choose to start offering first to suitable patients.

An example of the first category would be a musculo-cutaneous nerve (brachialis) branch transfer to a wrist extensor muscle in a patient with a C5 cord injury in whom there are no working muscles below elbow level and for whom there is no good alternative for regaining active wrist extension, which is the key movement for achieving any useful grip.

An example of the second category would be the transfer of posterior interosseous nerve branches to the supinator muscle on to the distal end of the same nerve in order to re-innervate the digital (and ulnar sided wrist) extensor muscles. This can restore active independent finger and thumb extension, and more balanced wrist extension, which otherwise can only be restored either by fixing the extensor tendons on to the radius so that wrist flexion by gravity causes finger and thumb extension by a tenodesis action, a much cruder level of function than would be obtained by reinnervation, or in theory by transfer of an active muscle (although in practice one would not sacrifice an active muscle for this purpose).

An example of the third category would be the transfer of axillary nerve (teres minor) branches on to a triceps muscle branch to restore elbow extension power, which is the other key movement for the tetraplegic limb because it restores control of where the hand can reach. The alternative (currently standard) procedure for this is either to transfer part of the deltoid muscle on to the triceps using a tendon graft, or to transfer the biceps on to the triceps tendon. Both of these procedures, like most tendon transfers, involve much more surgical dissection than the nerve transfer alternative, and a much more prolonged and complex post-operative rehabilitation period. This and other nerve transfers involve comparatively much less dissection, and recovery from the surgery essentially is complete once the wound has healed, so that there should be only a short interruption in the overall rehabilitation process, which can then continue as before while nerve regeneration is awaited. If unsuccessful then conventional tendon transfer surgery for elbow extension is still available and can be done at any time in the future.

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?

☐**X** 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 procedure would be done by hand/upper limb surgeons with a specialist practice providing a surgical rehabilitation service for patients with tetraplegia, generally within or closely allied to a spinal injury unit, and nerve transfers would form part of a range of surgical measures available to improve hand and upper limb function. This service, which mainly involves various tendon transfers and tenodeses, is currently available in a number of units in the uk. For example, at Stoke Mandeville Hospital where I work there has been an upper limb clinic and a surgical rehabilitation programme since 2003. In the uk (with the exception of Edinburgh during the 1970s) this service developed comparatively late compared to some countries, notably in Europe Sweden and France, and there may still be spinal injury rehabilitation specialists in the country who have reservations about the value of upper limb surgery for these patients, but I have never met any and all the spinal injury consultants at Stoke Mandeville refer patients to the upper limb clinic, so controversy would be too strong a word.

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

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

☐**X** I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

I have performed 3 types of nerve transfer in a cadaver only (teres minor to triceps, brachialis to extensor carpi radialis longus, and supinator to distal posterior interosseous nerve – to digital extensors)

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.

☐**X** 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:
At Stoke Mandeville I and a colleague are currently writing a submission for the hospital New Procedure Committee, in the hope of being able to offer nerve transfer surgery to suitable individuals within the next 6-12 months. This will involve reviewing patients during the first 3-6 months after their spinal cord injury (which previously we have been unable to do because of staffing and workload/capacity shortcomings), in

order to identify those who might benefit and offer the surgery if they want. Arguably as nerve transfer is widely used in peripheral nerve reconstruction it might be said that its use in tetraplegia is simply another application of a well-established technique, but we have decided to follow the standard hospital process for 'new procedures' in order to avoid any suggestion of having bypassed the process

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

☐X I have done bibliographic research on this procedure.

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

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

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

☐X Other (please comment)

Comments:
I have also attended courses and lectures on nerve transfer surgery and discussed it with surgeons experienced in the technique

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 the procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:
Nerve transfer is a technique that can be applied to a number of different nerve/muscle combinations with the aim of restoring function to various paralysed muscles, but the principle – of re-innervating paralysed muscles with axons taken from the nerves supplying non-paralysed muscles that can spare them – is exactly the same in all cases, irrespective of the cause of the paralysis

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

Standard practice in general would be a tendon transfer or a tenodesis, but there are situations in which nerve transfer might restore functions, or a quality of function, that is currently not achievable by tendon transfer (see examples under 1.1)

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.

☐X Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

As under 2.1, this procedure would only be done by surgeons specialising in treatment of the tetraplegic upper limb, and among the small number who already do this a minority are currently doing nerve transfers. Many more hand and upper limb surgeons are doing nerve transfers for brachial plexus and peripheral nerve trauma

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)

The literature suggests the morbidity is very low

2. Anecdotal adverse events (known from experience)

I have not seen or heard of any, only failure of the target muscle to regain useful function

3. Theoretical adverse events

The full range of anaesthetic, general, and local complications that can occur following surgical procedures of any kind.

Failure of the target muscle to function

Problematic weakness due to denervation of the donor muscle

4.2 What are the key efficacy outcomes for this procedure?

The main outcome measure is recovery of useful voluntary function (generally minimum MRC grade 3/5 strength) in a previously paralysed muscle or muscles.

The most widely accepted outcome measure for tetraplegic upper limb surgery is the Canadian Occupational Performance Measure (COPM), a patient self-assessment tool, and this would also be applicable to nerve transfer surgery, but only after the individual surgical rehabilitation programme had been completed, which may not be until additional tendon surgery has also been undertaken, which itself may not be done until a year or more following the nerve surgery, and it would be difficult to

attribute any degree or type of functional improvement specifically to the nerve transfer.

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

Reports of successful restoration of muscle function are in general anecdotal case reports or small case series and there is uncertainty about what proportion of patients deemed suitable for a particular nerve transfer will regain useful function, about how early transfers can reasonably be done (as this depends upon a reasonable level of certainty about the completeness of the cord injury and absence of potential for spontaneous recovery), and about how long after the initial cord injury any success can be expected. Anecdotally some nerve transfers have been done at a relatively late (12 months+) stage after injury because they have been offered to patients keen to try despite the theoretical probability of a poor result. Defining patient selection criteria and their corresponding expected outcomes is one area of research that will be important for this group of procedures

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

1. Medical and nursing facilities to care for tetraplegic patients in the peri-operative and post-operative rehabilitation period. Because there is a time limit on when a neve transfer can be done with any expectation of success, the majority are likely to be done during the first year following the cord injury, and in most or many cases the patient will still by that stage be in a specialist unit undergoing a general period of rehabilitation
2. Surgeons need training and expertise in reconstructive nerve surgery in general, including microsurgical expertise and experience of nerve repair, nerve grafting (although this is not often used as part of nerve transfer surgery), and knowledge of the principles and surgical anatomy of individual tranfers. Many hand/upper limb surgeons would fulfil these criteria, but nerve transfers for tetraplegics should be part of an overall rehabilitation programme and therefore performed by surgeons providing the full range of restorative surgery for tetraplegics, including tendon transfers etc, in a specialist unit.

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

Not that I know of

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).

The IFSSH Scientific Committee on Nerve – Spinal Cord Injury report (2014) provides a very good overview of the current status of restorative surgery for the

upper limb in tetraplegia, mainly reviewing the role of tendon surgery, but also putting nerve transfer surgery in its context within the range of treatment possibilities (see in particular pages 9 and 17)

Ward J (Supervisor Dominic Powell) Lit review, clinician survey, and treatment algorithm. University of Birmingham MSc (Functional and Clinical Anatomy) 2015 or 2016 (apologies I have only read a draft version but Dominic Powell will probably have provided details in his report)

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?
Nerve transfers are not being done widely in the uk. The surgeons who do or might do it are in general agreement that it should become available to suitable patients in specialist centres, with careful recording of data to permit auditing and outcome assessment. This has been discussed at (so far informal) meetings between surgeons and also with spinal injury consultants

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.
General patient data age sex medical history etc
Injury history, cord injury level and completeness (ASIA)
Standard International Classification of Surgery of the Hand in Tetraplegia (ICSHT)
Clinical and electrophysiological documentation of activity – strength and control - in target and 'donor' muscles
General functional assessment of a set of daily activities – eating, drinking, washing, grooming, dressing, catheter management, transfers, wheelchair control (but nb maximum potential return of abilities may not have been reached at the time of decisions about nerve transfer)
Canadian Occupational Performance Measure (but nb final outcome not measurable until full surgical programme completed)
Recording of complications/adverse outcomes

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
- short-term – recovery of useful voluntary control in paralysed muscle/muscles
- long term COPM

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:

General – eg chest (infection, PE), cardiovascular, bleeding, wound infection, healing problems, per-operative nerve damage (surgical or anaesthetic nerve block) – up to ?1 month post-operation
Specific – failure of re-innervation

6 Trajectory of the procedure

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

Because of the limited number of specialist centres and clinical teams involved, and the relatively small number of patients, it could become available to most or all potential patients within a very short time (perhaps 2-3 years) if the capacity to see and treat them is made available and the case for treatment generally accepted

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.

☐X Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

As above in 2.1. Should be carried out by specialist teams in specialist centres

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:
But the potential benefits to individual patients, when done as part of an overall programme of surgical rehabilitation, are major

7 Other information

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

Not that I can think of

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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

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

Do you or a member of your family[1] 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	☐ 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).

industry ☐ 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:
I have read the attached explanatory notes about conflicts of interest and am not sure whether the questions to which I have answered yes do in fact apply to me.

I have a private practice which is organised financially as a limited company Tony Heywood Ltd, of which I and my wife are directors, and in which I am the only practitioner, and I receive fees for private medical work. This rarely involves tetraplegic patients but I have recently been referred a small number of patients for assessment and advice about the potential benefits of tendon transfer surgery. I have not undertaken any surgery on a private basis but I may do in future, and if so this would be carried out at Stoke Mandeville Hospital. I receive fees for these consultations and would receive fees for performing any surgery.

In the event that nerve transfer surgery for tetraplegic patients becomes available at Stoke Mandeville it is possible that I might undertake it privately and be paid for this also, but as any nerve transfer surgery is likely to be performed during the first year post-injury, when the patients are likely still to be in hospital as NHS patients, I think it is unlikely I shall do any nerve transfer surgery privately.

I have a non-pecuniary interest in that I am a consultant in a specialist unit that provides a surgical upper limb service for tetraplegic patients, and the department or hospital will have an interest in any procedures that are additional to those already provided. My understanding of the commissioning process however is that any surgical procedure of this sort would come within the umbrella of providing the overall rehabilitation programme, and I am not certain whether any additional income would accrue as a result of doing nerve transfers

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 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.