View results

Respondent

69 Anonymous

27:03
Time to complete

1. Project Number and Name - (Can be found on email) *

IP2024 Targeted Muscle Reinnervation for refractory pain after limb amputation

Your information

2. Name: *

Jeff Crew

3. Job title: *

Prosthetist

4. Organisation: *

NHS

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BAPO

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

M475

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further inform ation about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

    Some patients I see have had TMR surgical procedure

11. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

    Patients that have had the TMR procedure have had mixed results but majority are happy.

12. 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 published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Very innovative to a very common complex problem

16. Which of the following best describes the procedure:

- (●) 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.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Used in addition to existing standard care

Current management

18. Please describe the current standard of care that is used in the NHS.

Various prescribed medications and non invasive interventions such as compression stump socks and use of tens machine

19. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

Free from or reduced pain

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Phantom limb pain sufferers

22. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

More widely used

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Greater awareness among referrers for the procedure

Safety and efficacy of the procedure/technology

25. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Possible recurrence of pain

26. Please list the key efficacy outcomes for this procedure/technology?

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

30. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

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

32. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

33. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

This surgical procedure needs a large number of successes to be significant. How and when to measure outcomes in the long term needs to be established

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

37. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

No interests declared

39. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

    Please note, all declarations of interest will be made publicly available on the NICE website. *

    - (●) I agree
    - ( ) I disagree

Signature

40. Name: *

    Jeff crew

41. Date: *

    20/02/2024

View results

Respondent

109 Anonymous

37:59
Time to complete

1. Project Number and Name - (Can be found on email) *

Targeted Muscle Reinnervation for refractory pain after limb amputation (IP2024)

Your information

2. Name: *

Keith Anderson

3. Job title: *

Consultant Plastic Surgeon

4. Organisation: *

Cambridge University Hospital NHS FT

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

FRCSEd(Plast), BAPRAS full membership

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 4033125

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I am familiar with the techniques of targeted muscle re-innervation. I formally applied through our Trust process for introducing a new procedure to the Trust successfully being authorised to carry out the surgery. I have been doing these procedures for the last 2 years currently with 1 -2 cases referred per month. I have a database to carry out local audit but numbers are currently low with full pre and post operative data points.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

The vascular and orthopaedic surgeons and rehab physicians at my trust that I work closely with are interested in the procedure and developing the service further.
Currently I am the only surgeon formally authorised to carry it out but I know of others that have tried it
I hope to report results soon such to convince Rehab team I can achieve results close to those quoted in the literature as there remains scepticism .

13. 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).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) No
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. Does this have a multi-indication?

Residual pain in the presence of a confirmed neuroma and reproduction of intense pain with stimulation of the neuroma.

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

remains a novel approach to a very difficult clinical management problem. Has the potential to revolutionise the management of amputation pain.

18. Which of the following best describes the procedure:

- (●) 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.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

My preference would be for this to be an addition to standard care in a selected group of patients. Others prefer looking at expanding this to become routine in primary amputation care.

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

The addition of Regenerative Peripheral Nerve Interface using a free muscle graft has potential to improve results.

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

No

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Reduction of analgesic requirements, also in severe cases the procedure could allow resumption of use of prosthetic limb and the psychosocial benefits of improving ones disability.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

All lower limb amputees with pain and confirmed neuroma

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Done at an earlier stage could benefit the system through fewer visits , fewer prosthetic issues, lower analgesic requirements, earlier return to work.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Full operating theatre facility. No changes required

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

I do think surgical workshops and training would need to be developed to expand use. I know of people that have done a "few" and this is not appropriate. A network of mentoring and advisory groups should be established.

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

Recurrence - low
Surgical complications such as infection/ seroma/ haematoma - low but personal audit not ready to report
Safe with few specific operative complication

30. Please list the key efficacy outcomes for this procedure/technology?

I am noticing lower analgesic requirement
Patient satisfaction is high
Dont have long enough follow up for further conclusion

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

None

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Some practitioners are not getting the results expected.

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

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

    Not aware.

36. Please list any other data (published and/or unpublished) that you would like to share.

    Not ready

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    In my experience about 2/3 of those referred to me.
    As a Major trauma centre with big Rehab and Vascular department I expect 20 to 30 eligible cases per year. I currently have the capacity for about 15 to 20 cases per year.
    The estimated number overall would potentially be huge depending on referral criteria and whether the argument for primary TMR in trauma or vascular cases was won.

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Analgesic requirement - 1 year assessment point, long term 2-3 yr
    QOL - Return to work/ Time in prosthesis, I don't have a specific score in my use
    VAS Pain Diary , scoring points 6mths, 1 year , 2-3yr

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Infection and risk of higher level amputation
New neuroma formation - recurrence of pain

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

I do think that the procedure should be expanded nationally but it should be regulated in some form to maintain standards. I have seen attempts to carry this out without specific training. The procedure is poorly understood by many so increasing awareness and education would be key to success for the patient population.

Declarations of interests

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41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

None

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Keith Anderson

45. Date: *

24/09/2024

View results

Respondent

72 Anonymous

18:47
Time to complete

1. Project Number and Name - (Can be found on email) *

IP2024 Targeted Muscle Reinnervation for refractory pain after limb amputation

Your information

2. Name: *

mark thoburn

3. Job title: *

clinical lead prosthetist

4. Organisation: *

blatchford / MoD

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BAPO ISPO

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

PO02190

How NICE will use this information:

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- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further informa tion about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

    I am aware of the procedure, and have treated a limited number of patients that have received the procedure

11. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

    I am aware of this procedure being used for treatment of phantom pain and significant long standing nerve pain in amputees

12. 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 published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

in my experience the TMR procedure has been in common use for a number of years now, and may be seen by some surgeons as a standard procedure to reduce the likelyhood of ongoing refractory pain post amputation

16. Which of the following best describes the procedure:

- (●) 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.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Current management

18. Please describe the current standard of care that is used in the NHS.

unknown

19. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

no

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

reduced pain and consequently improved life

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

potential for use in any amputee to prevent the growth of neuromas post amputation

22. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

this surgery does have the potential to reduce need for repeated neuroma removal surgery, or indeed other surgeries/ treatments for nerve and phantom pain in amputees

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

none to my knowledge, but I am not a surgeon

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

this is a surgical procedure, and as a prosthetist I am unable to comment

Safety and efficacy of the procedure/technology

25. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    in my experience the only significant risk would be that the procedure did not provide the expected outcome

26. Please list the key efficacy outcomes for this procedure/technology?

    reduction in pain score. improvement in limb use / comfort

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    none

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    not to my knowledge

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

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

32. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

33. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

in principle all amputees, I do not have figures for the number of amputations in the Uk each year

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

none

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

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- [ ] Non-financial: professional
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- [ ] Indirect
- [x] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

n/a

39. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

    Please note, all declarations of interest will be made publicly available on the NICE website. *

    - (●) I agree
    - ( ) I disagree

Signature

40. Name: *

    mark thoburn

41. Date: *

    26/02/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP2024 Targeted Muscle Reinnervation for refractory pain after limb amputation**

Your information

Name:	**Norbert Kang-Budialam**
Job title:	**Consultant Plastic Surgeon**
Organisation:	**Royal Free Hospital, Hampstead**
Email address:	[redacted]
Professional organisation or society membership/affiliation:	**BSSH, BAPRAS, RCS (England)**
Nominated/ratified by (if applicable):	**Click here to enter text.**
Registration number (e.g. GMC, NMC, HCPC)	**3336999**

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

X I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	**I am an international acknowledge expert on the technique of targeted muscle reinnervation (TMR) surgery. I have been carrying out this surgery for >10 years. I have performed the procedure in >100 patients.** **I use this procedure at least once a month in the NHS and in the private sector.** **This procedure is not widely used in the NHS, but the speed of uptake is likely to be large amongst those who have the necessary skills to use the techniques and knowledge on when and how to apply the procedure.** **In the UK, the procedure is only performed by plastic surgeons.**
2	– Please indicate your research experience relating to this procedure	**I perform this procedure routinely. I am also the author or co-author on multiple research papers published on TMR surgery in human subjects.**

	(please choose one or more if relevant):	
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	**The title is fine.** **The proposed indication for surgery is appropriate.** **From my perspective, TMR surgery should be established practice after amputation and should not be considered as something "new". However, trying to change standard practice is always difficult, especially since TMR surgery requires surgical skills and knowledge that are not easily acquired. Moreover, nerve surgery is not something that would be done instinctively by the surgeons who are often involved in amputation surgery (especially not vascular or orthopaedic surgeons). So, incorporating TMR surgery into routine practice will require one or more of the following:** **1) Significant re-education of vascular or orthopaedic surgeons** **2) Better team working to have vascular or orthopaedic surgeons working more closely with plastic surgeons** **3) Have all amputations (emergency or elective) carried out by plastic surgeons** **TMR surgery is not easy to do well and if done badly, it can mean that the pain-relieving value of the procedure may be completely lost. Revising a TMR procedure that has been done badly is always difficult and if it has been done very badly, it may result in complications (such as an insensate stump) which cannot be easily reversed and this may result in long-term problems for rehabilitation of the patient.**
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	**It should be considered as an addition to the existing standard of care (an amputation).**
5	Have there been any substantial modifications to the procedure technique or,	**There are no devices involved in TMR surgery (other than an intra-operative nerve stimulator and knowledge on how this works). It is purely a technique driven procedure, dependant on the skill and knowledge of the surgeon.**

	if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	**Currently, there is no guidance on the routine use of TMR surgery in the NHS.**

Current management

6	Please describe the current standard of care that is used in the NHS.	**The current standard of care is to amputate a limb and to perform a "traction neurectomy" on any of the nerves encountered during the amputation. Traction neurectomy involves pulling hard on the ends of the nerves at the time of surgery. While holding the nerves hard under tension (hence "traction"), the surgeon cuts through the nerves (hence "neurectomy") with a knife and allows the nerves to retract into the soft-tissues. The hope is that the nerves heal and are buried deeply in the soft-tissues away from the end of the stump so that they do not then become problematic.** **Unfortunately, after traction neurectomy, 100% of the patients develop a neuroma. The neuroma that forms is painful and sensitive in about 80% of amputees, resulting in a painful and sensitive area on the residual limb. This is neuroma pain (NP). However, it only interferes with function in about 20 – 30% of amputees (mainly lower limb amputees) who have to force their residual limb into a tight-fitting socket in order to be able to walk. The remaining patients with NP just put up with their pain since most of them don't know that there is an alternative solution or prefer to take medication to relieve their NP.** **Abnormal perceptions from the nerve stumps also leads to the development of phantom limb pain (PLP) which is pain which is perceived by the amputee to be arising in the absent parts of the limb. Phantom limb sensation (PLS) is present in >80% of amputees. However, PLS only becomes disabling and painful (true PLP) in about 20- 30% of patients leading to chronic misuse of opiates and anti-neuritic agents in a significant proportion of amputees, in a vain attempt to relieve their discomfort.** **Until the development of TMR surgery, there were no reliable, reproducible, and durable surgical techniques for relieving PLP or NP. Instead, many patients have had to endure (and still endure) a variety of different techniques which vary in the extent of their destructiveness including cryotherapy nerve ablation, dorsal root sectioning, insertion of**

		nerve stimulators, steroid injections, and repeated traction neurectomy. None of these work reliably to relieve PLP. **The data we have now shows that TMR surgery can result in complete abolition of most NP in both upper and lower limb amputees and relief of PLP which approaches 80% in the upper limb and 40% in the lower limb. In many cases, upper limb amputees who have undergone TMR surgery can stop their opiate and anti-neuritic medication altogether.** **Unfortunately, most amputees in the NHS (currently) do not undergo TMR surgery after their amputation because most amputations are performed by surgeons who either know nothing about TMR surgery or do not have the skills to perform the surgery. Even if they do know something about TMR surgery, they rarely make the effort to refer the patient onto specialists who can perform the surgery. It is difficult to know why this may be the case but could be to do with:** **1) It is usually not part of their normal training curriculum and so is not part of their knowledge and understanding and/or is not considered "standard" of care.** **2) Referral pathways do not exist since there are no plastic surgeons with the necessary skills as part of the amputation team.** **3) The rehabilitation teams are not aware of the benefits of TMR surgery or are sceptical about its value.** **4) Amputees are unaware of TMR surgery and its benefits and do not request it.**
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	**There are no competing surgical techniques/technologies other than a regenerative peripheral nerve interface (RPNI) procedure which is essentially a "mini-TMR" using non-vascularised muscle grafts.** **RPNI surgery is easier to perform but the effectiveness of RPNI for relieving NP and PLP is about 50% less compared to TMR surgery. This is because the muscle grafts are non-vascularised and there is no guarantee that the grafts survive. In contrast, TMR uses vascularised muscle targets with their own blood supply.**

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	**1) Reproducible, predictable, and durable relief from both NP and PLP after amputation.** **2) Decrease the burden of chronic pain in the amputee population.** **3) Reduce the NHS drugs bill for chronic pain amongst the amputee population.**
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	**All amputees may benefit from this surgery, even the ones who (currently) just put up with their neuroma or phantom limb pain and/or use medication to control their pain instead of proceeding to surgery.**
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	**TMR surgery has the potential to result in a major change to current healthcare systems. Instead of relying on very invasive or destructive surgical techniques such as cryotherapy ablation of nerves or dorsal root sectioning for patients with intractable NP or PLP after amputation, we can use TMR surgery which actually works and does not burn bridges for other reconstructive interventions in the future.** **It could lead to less reliance on medications to control NP or PLP leading to fewer drug-related complications.**
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	**The following changes are required:** **1) Change the attitudes of non-plastic surgeons to allow TMR to be done as part of the standard of care rather than just an optional extra.** **2) Increase the number of amputations performed by plastic surgeons rather than other specialities like vascular or orthopaedic surgeons.** **3) Increase the amount of operating time available to allow TMR surgery to be done more routinely on existing lists.** **4) Training of existing plastic surgeons to make TMR surgery part of the surgical curriculum.**
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	**Specific training in TMR surgery is required to perform the surgery safely and effectively. At the Royal Free, I have already organised several training days for TMR surgery (unpaid and unsupported by either the Royal Colleges or anyone else!!).**

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	**The potential harms of TMR surgery include:** **1) Failure to do the surgery correctly leading to failure to relieve NP or PLP which may discredit the technique.** **2) Failure to understand the potential risks and complications including:** **a. Infection (25%)** **b. Haematomas (<1%)** **c. Anaesthesia or part or all of the residual limb (should be <1%)** **d. Worsening of NP (uncommon)** **e. "unmasking" of NP from other nerves after the initial TMR surgery (10 – 20%)** **f. Worsening of PLP (100% of patients but usually only temporary – months)** **3) Loss of function of the target muscles.**
14	Please list the key efficacy outcomes for this procedure/technology?	**The key efficacy measures are simple:** **1) Sustained relief of NP** **2) Sustained relief of PLP**
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	**The key uncertainties are:** **1) Who should do this surgery? Should it only be plastic surgeons or should all surgeons who perform amputations be trained in TMR surgery?** **2) Whether TMR surgery should be done through the end of the stump or more proximally?** **3) What techniques should be used to salvage outcomes where the TMR surgery failed either partially or totally?**
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	**What is the value of rehabilitation services after TMR surgery to reinforce the benefits for relief of PLP? Especially in terms of the use of equipment for virtual or augmented reality interventions to reinforce the new pathways created by TMR surgery.**
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	**In my opinion, it should be possible to ensure that the skills are available to perform TMR surgery reliably and reproducibly after a routine amputation (especially after lower limb amputation) in every plastic surgery unit in the UK. However, there should also be a few centres (<10) where the skills are available to perform TMR surgery in more challenging cases – especially in the upper limb.**

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	**1) Any publications on TMR surgery with either Todd Kuiken, Greg Dumanian or Jason Souza as authors** **2) A consecutive series of TMR cases for relief of NP and PLP: UK perspective** **3) Advances in upper limb loss rehabilitation; the role of targeted muscle reinnervation and regenerative peripheral nerve interfaces** **4) An analysis of pain and quality of life in patients undergoing targeted muscle reinnervation (TMR) following upper limb amputations**
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	**At the Royal Free, I am currently running an RCT of the efficacy of TMR in prophylactic prevention of NP and PLP after below knee amputation.**
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	**8000 (new) lower limb amputees every year** **300 (new) upper limb amputees every year** **All the amputees from previous years!!**

22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	**Beneficial outcome measures:** **1) Relief from NP before and after TMR surgery** **2) Relief from PLP before and after TMR surgery** **3) Use of pain-relieving medication before and after TMR surgery** **4) Use of a prosthesis (especially lower limb) before and after TMR surgery** **Adverse outcome measures:** **1) Time off work after surgery** **2) Need for return to theatre for complications** **3) Need for additional nerve surgery for continuing nerve-related pain** 4) **New problems with prosthesis fitting after TMR surgery**

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	**We need new HRG codes to be generated so that the procedure can be properly costed.**

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	None		
Choose an item.			
Choose an item.			

X I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	Norbert Kang-Budialam
Dated:	13th February 2024

View results

Respondent

107 Anonymous

13:49
Time to complete

1. Project Number and Name - (Can be found on email) *

IP2024

Your information

2. Name: *

Shehan hettiaratchy

3. Job title: *

Prof

4. Organisation: *

Imperial College

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

NHS

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

4120915

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Perform this routinely

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

I perform this routinely. It tends to be performed mainly by my specialty (plastic and reconstructive surgery)

13. 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.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) No
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Appropriate

16. Does this have a multi-indication?

No- mainly peripheral nerves

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This has been used globally for the last 15 years but is a novel approach using existing techniques

18. Which of the following best describes the procedure:

- (●) 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.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

In addition to standard care

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

Varied approach to nerves but most involve division under traction

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

Numerous other described techniques

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Decreased pain post amputation

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Post amputation neuropathic pain

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes - might decrease the incidence of chronic pain in this cohort

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Wider spread microsurgical capability

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes- technique training and ability to do microsurgery

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Worsening of pain, change in residual limb volume

30. Please list the key efficacy outcomes for this procedure/technology?

Decreased pain, increased functionality, decreased need for chronic pain medication, improved psychological well being

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Indication not clear, ie as a primary procedure for all amputations or as a secondary for those with chronic pain. Not clear TMR vs RPNI

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Indication as above

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    We have a paper in press that is a meta-analysis of all the data

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

    Not that I'm aware of currently

36. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    20-30% of amputations

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Pain
    Mobility
    Medication use
    Psychological status

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

All of the above

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

This is a useful technique but the indication needs to be determined- is it for all amputations or just symptomatic patients

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

Nil

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Shehan Hettiaratchy

45. Date: *

16/09/2024

View results

Respondent

66 Anonymous

54:00
Time to complete

1. Project Number and Name - (Can be found on email) *

IP2024 Targeted Muscle Reinnervation for refractory pain after limb amputation

Your information

2. Name: *

Tomas Madura

3. Job title: *

Consultant plastic and peripheral nerve surgeon

4. Organisation: *

Queen Elizabeth Hospital Birmingham

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Association of Plastic Reconstructive and Aesthetic Surgeons, British Society for Surgery of the Hand

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

6127146

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

    Yes

11. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

I have used the procedure to treat nerve-injury related pain

The procedure is new to the NHS but there is a widening adoption with the procedure being done after limb amputation as well.

The procedure is typically performed by surgeons treating neuropathic pain and performing limb amputations - plastic surgeons mainly, peripheral nerve trained orthopaedic surgeons, possibly neurosurgeons if focused on the peripheral nervous system (more common in the USA)

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

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

13. Does the title adequately reflect the procedure?

- ○ Yes
- ◉ The procedure can be (and is) widely used to treat nerve-injury related pain outside of th

14. Is the proposed indication appropriate? If not, please explain

Yes, but should be expanded as above

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Novel approach

16. Which of the following best describes the procedure:

- ○ 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.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Replace

Current management

18. Please describe the current standard of care that is used in the NHS.

For amputation it is traction neurectomy for amputation
For treating of neuroma-related pain it is capping or implantation of the nerve stump into the muscle or bone

19. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

No

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

Amputation setting - less residual limb pain after amputation, less phantom limb pain
Nerve-injury related pain settings - less pain and fewer surgical procedures to treat pain
Both are potentially tied to decrease in consumption of analgesics and neuropathic pain medication and improved life quality

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

As above

22. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    It could decrease patient pain and suffering following a limb amputation or a nerve injury associated with neuropathic pain.
    This is a chronic problem which results in prolonged treatment by surgical teams, pain clinics and prosthetic services

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    No change in facilities but increase theatre time for amputation and special training of surgeons

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Yes, microsurgery knowledge

Safety and efficacy of the procedure/technology

25. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Temporary increase in postoperative pain
    Increase in procedure time which can be critical in patients who are poorly of face potential problems related to the healing of surgical wound

26. Please list the key efficacy outcomes for this procedure/technology?

Decrease in pain leading to reduced need for health care involvement and increase return to productive life

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Little evidence of the efficacy. Only one RCT which showed significance only in improved phantom limb pain score. However, the baseline of control group pain score was significantly lower that the treatment group, hence the improvement was not so dramatic. The analysis in the study however failed to quantify the pre-treatment difference between the groups, thus the conclusions may not be fully valid.

The evidence regarding the treatment of neuropathic pain is even weaker with a few observational studies with bias on several levels

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

The procedure in my opinion has not demonstrated its effectiveness sufficiently enough. There is a drive for adoption starting in the US where this procedure is exceptionally well renumerated.

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ 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.

Abstracts and ongoing studies

30. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    -

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

    Not to my knowledge

32. Please list any other data (published and/or unpublished) that you would like to share.

    -

Other considerations

33. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    All the limb amputation patient potentially but it remains to be established whether dysvascular amputation would be a part of target population because of their co-morbidities.

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Short term outcomes
surgery length
wound healing and associated complications

Long term at 1 years
level of residual limb pain
level of phantom limb pain
prothesis wearing time
analgesia
Suitable quality of life measure

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

as above

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

None

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

37. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

No interestes to declare

39. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (•) I agree
- ( ) I disagree

Signature

40. Name: *

Tomas Madura

41. Date: *

15/02/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP2024 Targeted Muscle Reinnervation for refractory pain after limb amputation

Your information

Name:	**Yazan Al-Ajam**
Job title:	**Consultant Plastic Surgeon**
Organisation:	**Royal Free Hospital, London.**
Email address:	[redacted]
Professional organisation or society membership/affiliation:	**BSSH, RCS (England)**
Nominated/ratified by (if applicable):	**Click here to enter text.**
Registration number (e.g. GMC, NMC, HCPC)	**6053136**

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

X I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	**I am a Consultant Plastic and Reconstructive Surgeon and a Hand Surgeon. I have extensive experience with TMR surgery, being part of a team of plastic surgeons at the Royal Free Hospital who perform this operation on a routine basis. Within this team, I have published and presented extensively on the topic. I have carried out TMR on both upper and lower limb patients.** **As the evidence increases on the effectiveness of this procedure for the treatment of both neuroma and phantom limb pain, the speed of uptake will likely increase. This will be of great interest among professionals who treat amputees (both upper and lower). Its uptake among Plastic Surgeons will be increase as the evidence continues to increase and these surgeons learn the necessary skills to apply it to their patients.** **Only Plastic Surgeons are performing this procedure.**
2	− Please indicate your research experience relating to this procedure	**I have performed TMR surgery during my PhD, and have published on this in both peer reviewed journals in both animal and human subjects. I am involved in an RCT looking at the effectiveness of TMR in lower limb amputees.**

	(please choose one or more if relevant):	
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	**Yes** **Yes** **The current 'gold standard' for the treatment of nerves at the time of amputation is to perform traction neurectomy. This allows the nerve to retract back, deep into the tissue, providing 'cushioning' of the nerve in an effort to reduce discomfort from pressure applied to it within an amputation socket. Unfortunately, traction neurectomy does nothing to address the formation of a neuroma. TMR, on the other hand, redirects a blind-ending nerve to the motor branch of a nearby muscle, giving the nerve a target 'organ' and in so doing treats the underlying cause of neuroma formation, reducing both neuroma and phantom limb pain. This represents a complete departure in how nerves are addressed in the context of limb amputation.** **I would like to regard TMR as no longer new. However, it is far from established practice. For several reasons; the skill set required to perform TMR surgery is not intuitive to vascular or orthopaedic surgeons who perform amputations. These skills can be taught to these specialties. Alternatively, amputations could be done as a joint cases involving a Plastic Surgeon trained in TMR surgery.** **Having done TMR surgery in both upper and lower limbs, we have good evidence (and have published on this) to suggest that done properly, TMR can make a significant difference in pain levels for these patients, many of whom suffers for a lifetime with nerve-related pain. Conversely, we have also seen patients on whom TMR has been performed, with poor outcomes. On re-operating on these patients, it was clear that TMR was not carried out as it should have been done, and TMR is therefore not a procedure where someone can just have a go, without understanding the nuances of the operation.**
4	Does this procedure/technology have the potential to replace current standard care or	**It would be considered as an addition to the existing standard of care (an amputation).**

	would it be used as an addition to existing standard care?	
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	**There is no current guidance on the use of TMR in amputees in the NHS.**

Current management

6	Please describe the current standard of care that is used in the NHS.	**The current standard of care at the time of amputation is to identify all nerves and perform a traction neurectomy (see explanation in section 3). This allows nerves to retract deep into the soft tissue, providing sufficient padding to the nerve and cushioning it from external pressure. However, this does not stop or reduce the likelihood of neuroma formation, and up to a third of patients will experience painful, problematic neuromata (and phantom limb pain) that interfere with their daily function. This is more of an issue in lower limbs, since this need to fit into a very tight-fitting socket, to allow secure attachment of a prosthesis to the amputation stump. These patients either put up with their pain, reduce the use of their prosthesis, and/or go on life-long medications to try and control this pain. These medications (e.g. pregabalin or gabapentin) can cause many side effects, including drowsiness, brain fog, and fatigue.**
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	**An alternative technique to TMR is called regenerative peripheral nerve interface (RPNI). In this surgical technique, the blind-ending nerve is directly neurotised to a small block of free muscle tissue. This muscle acts as a free graft, picking up a blood supply from the surrounding tissue, and eventually also picking up a nerve supply from the nerve that is directly implanted into it.** **While this technique is technically easier to perform than TMR, its effectiveness is not as good as that of TMR (around 50% as effective). My preference, especially in lower limb, is to**

		perform TMR, with RPNI reserved for instances where there are insufficient target muscles for TMR.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	**1) Reliable, reproducible, long term relief from neuroma and phantom limb pain (in both lower and upper limb amputation).** **2) Reduction in the use of pain medications (and in a large proportion of patients, complete absence of the need for life-long pain medications).** **3) Reduce visits to chronic pain team with cost savings related to cessation of prescription-grade pain medications.**
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	**TMR can benefit all patients with amputations (or those requiring an amputation).**
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	**TMR can reduce the use of the chronic pain service, including associated costs related to life-long medications.** **In patients that have chronic, intractable pain, which are successfully treated with TMR, this means rehabilitating these patients back to work.** **The psychological impact of ameliorating/eliminating chronic pain cannot be overstated.**
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	**1) The recognition that TMR is far more effective than the standard of care (traction neurectomy.** **2) The recognition that TMR needs to be performed by surgeons trained in this discipline.** **3) Regarding an amputation as a joint operation (or one that is done more so by Plastic Surgeons that can do TMR at the same time).** **4) Establishing a training pathway for surgeons that perform amputations and would like to learn TMR.**
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	**Formal TMR training is required, backed by the Royal College of Surgeons and BAPRAS.**

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	**The biggest potential harm of TMR is one that is poorly performed with no benefit to the patient, or even worsening of their symptoms. This risks discrediting an effective procedure by having it done by ill-trained surgeons who will just 'give it a go'.** **Generic risks related to surgery also include bleeding, infection, haematoma. Specific to TMR, it results in a change in the sensation of the stump, temporary worsening of symptoms (both phantom limb pain, sensation, and neuroma pain).**
14	Please list the key efficacy outcomes for this procedure/technology?	**1) Reduction in neuroma and phantom limb pain (primary outcomes)** **2) Reduction in pain medication use (secondary outcome).**
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	**In experienced hands, TMR is effective. To optimise the success of the procedure, we need to be asking:** **1. Who should be performing surgery and how to ensure their training is adequate.** **2. What to do when surgery is not effective.**
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	**There is no current consensus on whether further adjuncts to TMR, for example, augmented reality, and the role rehabilitation plays in post-surgery pain optimisation.**
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	**A minority of hospitals, but at least 10 in the UK.** **While the technique of TMR can be taught and applied in many centres, certain cases where patients have had previous unsuccessful interventions, or where a ceratin level of expertise is necessary, these should be done in specialised centres. This is especially true of upper limb TMR, and in these cases they are likely to be less than 10 in the country.**

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	**Greg Dumanian and Jason Souza have published extensively on TMR. Todd Kuiken was the rehab physician who initially came up with the concept, although he is not a surgeon and the nuances of doing it is better explained by the surgical team.** **- A consecutive series of TMR cases for relief of NP and PLP: UK perspective** **- Advances in upper limb loss rehabilitation; the role of targeted muscle reinnervation and regenerative peripheral nerve interfaces** **- An analysis of pain and quality of life in patients undergoing targeted muscle reinnervation (TMR) following upper limb amputations**
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	**We are recruiting patients for a RCT at the Royal Free Hospital comparing TMR with traction neurectomy in the control of both phantom limb and neuroma pain.**
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	**Approximately 8000 new amputees per year in the UK (mostly lower limb).** **There is also a considerable cohort of patients (difficult to quantify), who have already had an amputation and suffering with intractable neuroma and/or phantom limb pain.**
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life	**Beneficial outcome measures:** - **Improvement in neuroma/phantom limb pain.** - **Reduction in analgesia use.** - **Reduction in outpatient visits to pain team.**

	measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	- **Improvement in ability to use prosthesis after TMR (duration of prosthetic use, 6 min walk test).** **Adverse outcome measures:** - **No improvement/worsening of symptoms.** - **Revision surgery if no improvement/worsening of symptoms.** - **Return to theatre for infection/haematoma, etc.** - **Change in the size/shape of the stump or issues related to change in sensation of the stump, all of which may result in increased visits to the orthotics department to optimise fitment of the socket.**

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	**There aren't any codes for TMR, and this glaring omission needs to be addressed.**

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	None		
Choose an item.			
Choose an item.			

X I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Yazan Al-Ajam**
Dated:	**20th February 2024**

View results

Respondent

106 Anonymous

109:44
Time to complete

1. Project Number and Name - (Can be found on email) *

IP2024

Your information

2. Name: *

Alexandra Crick

3. Job title: *

Consultant Plastic and Reconstructive Surgeon

4. Organisation: *

Salisbury Hospital NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

RCSEd

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

3680162

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I have undertaken this procedure since 2020, 15 cases this year so far, upper and lower limb, salvaged limbs and amputees.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

There are colleagues undertaking this procedure in other units but not every unit. Numbers are expanding particularly amongst my military colleagues. Not many colleagues have a sub specialty interest in amputation, secondary reconstruction of the residual limb. Those that I am aware of are plastic surgery colleagues.

13. 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 published this research.
- [ ] I have had no involvement in research on this procedure.
- [x] I am prospectively auditing my own outcomes

14. Does the title adequately reflect the procedure?

- ( ) Yes
- ( ) No
- (•) RPNI is a closely related procedure that is often combined with TMR

15. Is the proposed indication appropriate? If not, please explain

Yes, the indication is relief of pain but also prevention of pain if undertaken prior or at the time of amputation.

16. Does this have a multi-indication?

Less commonly indicated in non amputees.

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Concept translated from its use for patients with proximal upper limb amputation. TMR was undertaken to provide muscle activity that could be sensed and used to direct movement of myoelectric prosthesis. Relief of pain was an unexpected side effect.
Innovative concept as a potential solution to intrusive nerve related pain in amputees.
First described in literature 40 years ago. Established practice in USA before translation to UK.

18. Which of the following best describes the procedure:

- (●) 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.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Likely to expand to become standard practice for nerve related pain in established amputees. Practice for primary amputation likely to remain much more varied due to the spectrum of specialties undertaking amputation.

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

As mentioned before, the combination of RPNI (regenerative peripheral nerve interface ie direct implantation of the nerve into muscle) with TMR.

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

Non-operative management of pain inc psychological interventions, medication, revision prosthetic fit or use, nerve ablation, implanted nerve stimulators (peripheral, spinal nerve, spinal cord), revision amputation nerve more proximally.

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

partial or more complete relief of nerve related pain

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Higher functional demand amputees likely to gain most re increased activity but pain affects all other aspects of living so relief of pain is appreciated by all.

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Relief of pain will lead to reduced demand on the NHS re appointments and medication and on our welfare system.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Microsurgical expertise and facility.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Microsurgical expertise and facility.

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

30. Please list the key efficacy outcomes for this procedure/technology?

Pain relief but also prosthetic rehabilitation for amputees.

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

One of the inevitable outcomes of TMR within the popliteal fossa for transtibial amputees is scar that is vulnerable when donning of prosthesis but more importantly additional muscle wasting. There is loss of residual limb volume requiring additional socket revisions in the months following surgery and bone becomes more prominent and therefore more vulnerable to pressure injury within the socket in the long term.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Few long term outcome studies re longevity of pain relief

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    None in addition to a standard literature search

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

    ClinicalTrials.gov, NCT05009394
    International randomised control trial comparing TMR, RPNI and active control

36. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    Potentially, majority of amputees.

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Pain relief, reduction medication, improved prosthetic rehabilitation, improved sleep, mood, cognition, improved social function, improved ability to work

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Problems related to scar, loss of residual limb volume and therefore prosthetic rehabilitation, incomplete relief of pain esp spontaneous phantom pain, recurrence of pain esp neuroma related pain

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

I hope that you have included a pain specialist familiar with amputees eg Alex Kumar, Chelsea and Westminster and an amputee rehabilitation specialist eg Fergus Jepson, Preston

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

None

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Alexandra Crick

45. Date: *

09/09/2024

View results

Respondent

68 Anonymous

15:44
Time to complete

1. Project Number and Name - (Can be found on email) *

Newly Notified Procedure: IP2024 Targeted Muscle Reinnervation for refractory pain after limb amputation

Your information

2. Name: *

Anne Sillitoe

3. Job title: *

Senior Prosthetist

4. Organisation: *

NHS GGC

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BAPO HCPC

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

PO00544

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further informa tion about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

Vaguely

11. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

Not undertaken by my profession.
A few of our patients have had it done. Unsure of the referral process, but we would refer to our rehab consultant in the first instance, then she would refer on.
If successful, uptake would be good amongst patients with problematic neuromas.

12. 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 published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a novel approach to a tricky aspect of being an amputee. I feel it has merit as a solution for nerve problems

16. Which of the following best describes the procedure:

- (●) 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.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

addition

Current management

18. Please describe the current standard of care that is used in the NHS.

Pain management, using medication or other surgical procedures.

19. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

not aware

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

Our patient who have had it done express pain relief and therefore, an ability to comfortably walk on a prosthetic limb, where they could not before

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Any patient with problematic nerve pain

22. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes - potentially fewer sockets for the patient, which means fewer visits and less alternative pain medication

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

I believe existing facilities (theatres) would suffice

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes

Safety and efficacy of the procedure/technology

25. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Increased nerve pain in the first instance, which decreases over time

26. Please list the key efficacy outcomes for this procedure/technology?

    not sure

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    none that I know of

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    not that I know of

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

30. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

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

32. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

33. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

maybe 10 out of 2000?

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

socket comfort score prior to and a year after the procedure

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

Our patient have had great success with this procedure. Time will tell.

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

37. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

none

39. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

    Please note, all declarations of interest will be made publicly available on the NICE website. *

    - (●) I agree
    - ( ) I disagree

Signature

40. Name: *

    Anne Sillitoe

41. Date: *

    20/02/2024