View results

Respondent

1 Anonymous

09:18
Time to complete

Your information

1. Name: *

Charles Willis-Owen

2. Job title: *

Consultant Orthopaedic Surgeon

3. Organisation: *

University Hospitals Dorset

4. Email address: *

5. Professional organisation or society membership/affiliation: *

FRCS

6. Nominated/ratified by (if applicable):

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

4731210

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

8. 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.

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

   Are you familiar with the procedure/technology?

   I use it regularly

10. 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.

    Used in knee surgery in difficult cases on a frequent basis.

11. 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

12. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) Other

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

It is for full thickness articular cartilage defects

14. 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 well established - it was innovative 15 years ago!

15. 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.

16. 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 is the current standard of care. NICE guidance is well out of date

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

no

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

There is more evidence

Current management

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

Chondrotissue is it

20. 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 many similar products, none have such good results,

Potential patient benefits and impact on the health system

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

It is the only current evidence-based solution for this problem - the alternative is neglect.

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

23. 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 is better than neglect. Probably reduces need for later joint replacement

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

Orthopaedic theatre, staff and skills - nothing more

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

It does need some basic training

Safety and efficacy of the procedure/technology

26. 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

    Nil known

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

    PAin function and resolution on imaging

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

    Not uncertain

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

    No

30. 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

31. 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.

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

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

Other considerations

34. 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)?

    5000

35. 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.

    PROMS. ICRS grading

36. 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

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

    This is an established cheap clinically effective treatment in widespread use.

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.

38. Type of interest: *

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

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

40. 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

41. Name: *

Charles Willis-Owen

42. Date: *

17/02/2023

View results

Respondent

5 Anonymous

24:57
Time to complete

Your information

1. Name: *

Ejaz mughal

2. Job title: *

Consultant Orthopaedic and sports knee surgeon

3. Organisation: *

Royal Wolverhampton NHs Trust

4. Email address: *

5. Professional organisation or society membership/affiliation: *

General Medical Council

6. Nominated/ratified by (if applicable):

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

4323574

How NICE will use this information:

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8. 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.

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

   Are you familiar with the procedure/technology?

   Yes

10. 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 been using this for a few years now and continue to use it.

11. 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.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

Yes it is

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

I would describe it as an enhanced variation of a standardised technique.

15. 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.

16. 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 used as an addition to existing standard care

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

Not that I am aware of.

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

It has only provided further evidence of its safely and efficacy.

Current management

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

Microfracture alone

20. 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?

Chondroglide along with AMIC is the alternative procedure.

Potential patient benefits and impact on the health system

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

Enhanced articulate cartilage regeneration for focal defects in the knee joint. So better medium term (5year) results expected.

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

Patients in whom microfracture alone havs not worked and in those patients who have focal defects affecting the patellofemoral joint in particular.

23. 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?

    There is no doubt this procedure should improve outcomes at least in the mid term (5 year results) with less recourse to further invasive surgery

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

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

    Existing orthopaedic operating theatres are sufficient for this procedure.

Safety and efficacy of the procedure/technology

26. 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

    No harms have been identified. It is extremely safe.

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

Improved pin relief and return to normal or near normal function

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

No uncertainties.

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

No controversy exists

30. 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

31. 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.

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

    No

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

Other considerations

34. 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)?

    5 per year

35. 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.

    Long term clinical outcomes are most important and should be collected 12 months following the procedure and then 6 months for a year and then annually for up to 5 years. Oxford knee scoring is simple and widely used as a scoring system for degenerative knee pain. Along side visual analogue scoring system.

36. 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 rates within the first 3 months needs to be recorded

Further comments

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

    I usually perform this procedure as an adjunct to osteotomy surgery to off load the part of the joint requiring the chondrotissue graft. Given this I assume this procedure should only be carried out in centres when osteotomy surgery is routinely performed.

Declarations of interests

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38. Type of interest: *

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

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

None to be disclosed.

40. 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

41. Name: *

    Ejaz Mughal

42. Date: *

    02/03/2023

View results

Respondent

3 Anonymous

35:07
Time to complete

Your information

1. Name: *

Jamie Arbuthnot

2. Job title: *

Consultant Surgeon

3. Organisation: *

University Hospitals Birmingham

4. Email address: *

5. Professional organisation or society membership/affiliation: *

BOA, BASK

6. Nominated/ratified by (if applicable):

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

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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 information about the procedure/technology and/or your experience.

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

   Are you familiar with the procedure/technology?

   I have used numerous techniques to repair cartilage defects in the past 18 years including MACI and "patch" type repairs
   I have used 38 chondrotissue grafts

10. 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 use it currently for certain defects
    My colleagues use it too
    It is not a frequently used technique as only certain parameters are appropriate
    Patients are referred to us by GP's or self refer

11. 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.
- [ ] Other

12. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) Other

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

yes - well aligned joints (knee) which are stable and with localised chondral defects greater than 2cm squared

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

A natural progression from marrow stimulation technoques to attempt to support the developing cartilage regenerate

15. 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.

16. 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 other techniques for appropriate patients

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

No

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

No

Current management

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

Marrow stimulation techniques alone mainly

20. 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?

Yes - several different "patches" are available of different materials each intended to induce and support cartilage regeneration

Potential patient benefits and impact on the health system

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

Improved cartilage regeneration
Capacity to treat larger defects than those suitable for microfracture

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

Stable
Well aligned
Localised cartilage defect larger than 2 cm squared

23. 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?

    Significant potential to improve return to work for younger patients

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

    MRI
    Theatre

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

    Yes - training

Safety and efficacy of the procedure/technology

26. 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

    Patch displacement
    Displacement of fixation pins
    Failure of regenerate

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

Cartilage quality regenerate
Functional outcome improvements

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

Difficult to appraise different cartilage defect repair techniques as very variable group of patients

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

See above

30. 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

31. 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.

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

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

Other considerations

34. 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)?

    15 p.a. in our catchment (1,000,000)

35. 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.

    Functional outcome score
    MRI cartilage assessment score

36. 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:

    Re-operation rate will be about 20% within 2 years

Further comments

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

    Fixation method needs scrutiny (pins; fibrin glue etc)

Declarations of interests

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

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

None

40. 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

41. Name: *

Jamie Arbuthnot

42. Date: *

22/02/2023

View results

Respondent

4 Anonymous

41:02
Time to complete

Your information

1. Name: *

Kevin Cheah

2. Job title: *

Consultant Orthopaedic Surgeon

3. Organisation: *

Nuffield Health Brentwood, Essex CM15 8EH

4. Email address: *

5. Professional organisation or society membership/affiliation: *

UK Biological Knee Society

6. Nominated/ratified by (if applicable):

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

GMC 2854483

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 information about the procedure/technology and/or your experience.

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

   Are you familiar with the procedure/technology?

   Yes. I started with stem cell surgery on the knee joint initially in collaboration Professor George Bentley at the Royal National Orthopaedic Hospital viz ACI and then MACI. I have since progressed to using Chondrotissue as this is a 1 stage procedure, cheaper and gives my patients a good clinical results. I presented my results at the national meeting in Manchester (UK Biological Society)

10. 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 in full time Private Practise since 2002 but I am aware of my colleagues who undertake this procedure within the NHS particularly at the Royal National Orthopaedic Hospital in London as well as in Wales.

11. 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

12. Does the title adequately reflect the procedure?

- ( ) Yes
- ( ) Other

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

Yes

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

Compared to standard practise of micro fracture, cartilage stem cell implantation is innovative but I and many of my colleagues have been using this techniques for the last 15-20 years. There has been improvements in the technique. At this stage, I was hoping that NICE would have already all published data and approve this technique if the patients fulfil the criteria.

15. 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.

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

For the patient with the correct clinical/radiological criteria, it can be considered to replace current standard care albeit the cost implications

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

Not for the last 5 years

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Current management

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

I am not working in the NHS

20. 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?

I do not work in the NHS

Potential patient benefits and impact on the health system

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

Good/excellent long term results and gain in financial terms for the NHS as patients do not have to be re-referred over and over with recurrent nee symptoms

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

Young adults below the age of 50
Not overweight and non smoker

23. 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?

    As per my answer in Q21

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

    Funding!

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

    Potential surgeons wishing to undertake this procedure should have a mentor

Safety and efficacy of the procedure/technology

26. 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

    As with every surgery involving the lower limbs:
    Thrombo-embolism, infection

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

Patients return to their normal ADL including returning to sports

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

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

30. 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

31. 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.

    Please visit the website of the UK Biological Knee Society

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

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

Other considerations

34. 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 practise and locality in Essex, I estimate around 5 a year

35. 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.

All patients undergoing this procedure should be on the cartilage registry, similar to the NJR for joint replacement

36. 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:

None to date

Further comments

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

A decision should be made to confirm that this technique is NOT experimental anymore

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.

38. Type of interest: *

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

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

N/A

40. 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

41. Name: *

Kevin Cheah

42. Date: *

22/02/2023

View results

Respondent

16 Anonymous

4144:37
Time to complete

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

GID-IPG10364 Microstructural scaffold for knee chondral defects

Your information

2. Name: *

Nick Howells

3. Job title: *

Consultant Orthopaedic Knee Surgeon and Honorary Senior Lecturer

4. Organisation: *

North Bristol NHS Trust and University of Bristol

5. Email address: *

6. Professional organisation or society membership/affiliation: *

British Orthopaedic Association , British Association for Surgery of the Knee

7. Nominated/ratified by (if applicable):

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

GMC 6079818

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?

My clinical practice involves being the lead for the knee cartilage service at North Bristol Trust which is a a commissioned specialist cartilage centre. In this role I have broad clinical experience of all surgical techniques for the management of symptomatic chondral defects and have developed an evidence based algorithm for management which we apply to all cases. This algorithm involves the use of microstructural scaffolds but also the use of other funded and evidence based techniques. My practice is independent of any particular technique or bias towards one technique, one implant or supplier.
I have an extensive experience of the use of microstructure scaffold for cartilage defects on the knee and have performed one of the highest volumes of the procedure in the company.
I have run a number of training courses teaching the technique to other surgeons and have given a number of educational lectures discussing the technique

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 currently using the technique.

I have good knoweledge backed by reliable data as to how widely the procedure is performed in the UK.
I have this knowledge because of involvement with the below research work:

Following the previous NICE Evidence synthesis on this topic, there was an NIHR HTA commissioned call to
"Compare the clinical and cost-effectiveness of scaffold insertion following microfracture versus microfracture alone for the treatment of patients with chondral or osteochondral knee defects"

University of Bristol were successful in applying for this commissioned call in 2019 and the SISMIC study -A Randomised Controlled Trial of Scaffold InSertion and MIcrofracture Compared to Microfracture Alone for the Treatment of Chondral or Osteochondral Defects of the Knee. NIHR127849 was commenced.

I was clinical lead for this multi centre RCT. The trial was unfortunately severely affected by the impact of the COVID 19 pandemic and incurred significant and costly delays. As a result of this NIHR made the difficult decision to unfortunately withdraw funding for the trial before any meaningful amount of recruitment could be completed.

12. 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.
- [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
- ( ) 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?

I would suggest that it is a minor variation but with good evidence to support its utilisation over current standard of care.

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?

Standard of care currently is micro fracture or debridement for small and moderate lesions and chondrocyte implantation or allograft for much larger lesions. This has the potential to fill the middle ground and replace standard of care for all moderate and some small lesions with debridement reserved for the v small and treatment unchanged for the much larger lesions

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

Not really. Debridement is performed more commonly and micro fracture less commonly under the scaffold. Techniques have been developed for a more minimally invasive technique but ultimately the broad technique is similar

19. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

There has been a considerable amount of additional supporting evidence published since the last guidance.

20. Do you think the guidance needs updating?

Yes definitely

Current management

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

Debridement or microfracture for small lesions, chondrocyte implantation or allograft for large lesions

22. 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

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

Improvement in pain function and quality of life. A more sustained and durable cartilage repair that will improve symptoms for a more reliable time frame. This has clear clinical and health economic benefits

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

All patients with a symptomatic chondral defect resistant to non operative measures that is of moderate size after discussion with the patient of all treatment options

25. 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 the research evidence to support improved clinical outcomes and my sustained treatment effect that would reduce health economic burden and potentially reduce need for more invasive treatments later

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

    No changes to existing facilities

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

    Any knee surgeon capable of performing current techniques for arthroscopic cartilage surgery would have the clinical expertise to perform this procedure

Safety and efficacy of the procedure/technology

28. 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

    Adverse events and risks relevant to any chondral surgery of the knee. i.e Failure of chondral regeneration, ongoing pain, swelling, stiffness and poor function. Perioperative risks such as Infection, Bleeding, VTE. Nil exclusive to this procedure that I am aware of

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

Improvement in pain, function and quality of life. ICRS have deemed the KOOS score to be the best PROM for assessment of efficacy outcomes following chondral surgery

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

The ultimate natural history and longevity of symptom improvement is not certain. The upper size limit of lesion for use of this technology and which cases this technology can be used as a safe and efficacious cost effective single stage treatment alternative can be used rather than the more expensive autologous chondrocyte implantation

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

no

32. 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

33. 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.

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

    Following the previous NICE Evidence synthesis on this topic, there was an NIHR HTA commissioned call to
    "Compare the clinical and cost-effectiveness of scaffold insertion following microfracture versus microfracture alone for the treatment of patients with chondral or osteochondral knee defects"

    University of Bristol were successful in applying for this commissioned call in 2019 and the SISMIC study -A Randomised Controlled Trial of Scaffold InSertion and MIcrofracture Compared to Microfracture Alone for the Treatment of Chondral or Osteochondral Defects of the Knee. NIHR127849 was commenced.

    I was clinical lead for this multi centre RCT. The trial was unfortunately severely affected by the impact of the COVID 19 pandemic and incurred significant and costly delays. As a result of this NIHR made the difficult decision to unfortunately withdraw funding for the trial before any meaningful amount of recruitment could be completed.

    Although the trial was unable to deliver the evidence that would ultimately have helped with the planned updated NICE review I think that the process of being involved with this over the last 5 years has led to a considerable amount of additional learning which could provide useful information to the review panel hence I would be happy to be involved.

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

Other considerations

36. 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)?

The work that went into the development of the SISMIC trial identified up to 10000 patients in the UK per year that undergo treatment for symptomatic articular cartilage injuries of the knee. This treatment would unlikely be appropriate for all 10000 patients but would fit in to an algorithm of treatment options with as many as 1/3 - 1/2 of patients being appropriate for this procedure.

37. 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.

KOOS as most useful clinical outcome measure. Other useful outcomes include IKDC, Tegner/Lysholm, EQ5D, WPAI (Work productivity and Activity Impairment)
Useful assessments at 1, 2, 5, 10 and 20 years post procedure.

38. 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:

Complications to be audited would include bleeding, infection, VTE, need for further surgery (broken down in to arthroplasty and non-arthroplasty)

Further comments

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

If I can be involved in any capacity I would be delighted to assist

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.

40. Type of interest: *

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

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

I have been a faculty member for educational events run and funded by Joint Operations, the UK distributor for Chondrogide, one of the most widely used chondral scaffolds in the UK.

42. 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

43. Name: *

    Nick Howells

44. Date: *

    29/10/2023

View results

Respondent

59 Anonymous

28:24
Time to complete

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

Microstructural scaffold (patch) insertion without autologous cell implantation for repairing symptomatic chondral knee defects

Your information

2. Name: *

Stuart Roy

3. Job title: *

Consultant Trauma and Orthopaedic Surgeon

4. Organisation: *

Cwm Taf University Health Board

5. Email address: *

6. Professional organisation or society membership/affiliation: *

Biological Knee Society

7. Nominated/ratified by (if applicable):

Mr James Murray

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

3657254

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?

    I have used the technology in select patients for over 15 years

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 its use amongst knee surgeons in the UK and further afield.
    I believe it has had some use in Foot and Ankle surgery also

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?

I have been using it for over 15 years so it is not a new technique. It is a variation on other techniques (ACI/MACI).

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 as above.

Current management

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

There are a variety of techniques used in knee surgery for symptomatic chondral lesions. Indications for the various techniques vary depending on size of the lesion, site of the lesion in the knee, concomitant issues (malalignment/ instability for instance) and age of the patient. There isn't one technique that is used for all lesions.

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?

As above. ACI involves harvesting cartilage and then culturing a matrix rich in chondrocytes which is introduced into the lesion with a second procedure and held in place with a periosteal graft.

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?

Symptomatic relief for lesions which are too big for the simpler marrow stimulation techniques we use.

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

As above. Select patients with symptomatic lesions too big for simpler techniques.

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?

Evidence for symptomatic relief but not aware that is has been proven to slow progress of degenerative joint disease.

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

none

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

not really. It is a straight forward procedure in my opinion

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

    Only the normal risks of any surgical procedure - infection/ DVT/etc
    Risk of not working and implant becoming loose - not seen in any of my patients

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

    Pain relief
    Improved appearance of lesion/s on follow-up MRI
    Return to normal activities

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

    Risk of not working - not experienced this myself

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

    NO

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.

    Systematic Review and Meta-Analysis of the Clinical Evidence on the Use of Autologous Matrix-Induced Chondrogenesis (AMIC) in the Knee
    Cartilage 2019:1-15

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

    Not aware

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)?

one or two patients at most in my practice

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.

pain score - VAS
KOOS score
Tegner activity score

All measured pre-op, 3 months and a year

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:

Infection / DVT / Ongoing pain
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 *

I find it a simple technique for the correct patient. Strict selection of patients key as for all interventions

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. *

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: *

Stuart Roy

41. Date: *

18/01/2024