View results

Respondent

24 Anonymous

58:21
Time to complete

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

IP782/2

Your information

2. Name: *

Edward V Wood

3. Job title: *

Consultant Orthopaedic Surgeon

4. Organisation: *

Countess of Chester Hospital NHS FT

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

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

4342931

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

Familiar with 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 use this technology/procedure regularly within my clinical practice and therefore have personal experience with it.

I am involved with the BOFAS Clinical practice committee and we run the BOFAS Registry. This is a National Registry capable of covering all foot and ankle surgical procedures. We include the ability to specifically record this procedure. I can therefore interrogate the registry to determine the usage of this procedure amongst those surgeons entering data.

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.
- [ ] I have had no involvement in research on this procedure.
- [x] See notes wrt BOFAS registry above.

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?

I consider it a minor variation.
The principles of open surgery are well established, this uses a variation of surgical technique to achieve the same goals: ie deformity correction using metatarsal & phalangeal osteotomies with internal fixation.
The difference being: the osteotomies are performed percutaneously.

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.
Likely to be a surgeon/patient preference decision.

Current management

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

As this is the newer technique, the more established practice in the NHS is with the use of open techniques to achieve metatarsal and phalangeal osteotomies to correct hallux valgus.
This is likely to vary from unit to unit, depending on surgeon preference and patient demand.

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?

Open surgery is the standard.
Minimal access techniques aim to achieve the same correction of deformity, using metatarsal and phalangeal osteotomies, but achieve these via percutaneous incisions, rather than a standard open approach.

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?

Lower pain post op.
Fewer wound healing complications.
Less residual swelling post op
Less joint stiffness

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

People at high risk of wound healing complications
Patient preference
Patients with pain management issues

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?

Less invasive treatment.
Likely higher daycare rate due to reduced pain post op.
Reduced swelling and pain improve short term PROMS.
Equipment / implant costs equivalent to standard open techniques

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

Intra-operative X-ray/image intensifier essential, although many use this in open surgery as well.
Specific machine/burr to perform osteotomy.

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

Yes.
I would advocate cadaveric course as an essential prior to undertaking 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

Loss of fixation - 5%
Recurrence early - 5%
Nerve injury - 5%
Non/mal union - 5%
Wound healing issues - lower than open techniques.
CRPS - lower than open techniques
Tendon damage - lower than open techniques

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

Patient PROMS
Return to activity
Lower pain scores

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

Learning curve: surgeons need to accommodate learning curve. Cadaveric instructional courses +/- dual surgeon operating initially +/- visitations. During this period, likely higher complication rate and slower surgical procedure

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

The learning curve and minimising it's impact.

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.

I'm answering this away from my desk and don't have these sources available to me. There is however abundant literature on this procedure including systematic reviews and meta-analyses that I shall be happy to give upon my return.

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

These are entered into the BOFAS Registry via the Adult Foot and Ankle pathway. This allows the collection of pre and post op PROMS with MOXFQ/EQ5D and Pain VAS. The registry can be interrogated to produce these outcomes.

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)?

Of the hallux valgus corrections undertaken in the UK each year, I would suggest 75% would be amenable to this or the standard open technique. For the more severe deformities other techniques may be utilised

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.

PROMS: MOXFQ/EQ5D/ VAS pain / complications
Collect via BOFAS registry

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:

Wound healing issues
Non/mal union
Recurrent deformity
CRPS
Tendon damage
DVT/PE

Further comments

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

This technique is already in use in a number of units, both NHS & independent sector.
If there is an increase in uptake there needs to be sufficient capacity for appropriate training, which, in my opinion should involve cadaveric workshops.
Both open and percutaneous/minimally invasive techniques have risk of complications.
The BOFAS Registry is already established and allows collection of PROMS on both open and minimally invasive techniques for hallux valgus correction.

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. *

Not applicable

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: *

Edward V Wood

41. Date: *

02/08/2023

View results

Respondent

9 Anonymous

26:11
Time to complete

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

Advice for Surgical correction of hallux valgus using minimal access techniques (IP782/2)

Your information

2. Name: *

Kaser Nazir

3. Job title: *

Consultant Podiatric Surgeon

4. Organisation: *

London Foot & Ankle Surgery Limited

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Royal College of Podiatry

7. Nominated/ratified by (if applicable):

20295

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

CH15007

How NICE will use this information:

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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 - I have used it for 5 years and perform approx 126 cases a year on average

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.

It is not widely used at the moment as it requires specific training and a steep learning curve to achieve consistent and repeatable outcomes.

It is more expensive than performing the scarf osteotomies, however it has specific advantages over the scarf osteotomy

- reduced swelling
- less joint stiffness
- less post op pain
- ability to correct a greater degree of deformity.

Podiatric Surgeons as well as Orthopaedic Surgeons with a special interest in foot surgery perform this procedure.

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.
- [ ] 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

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?

Fundamentally it's not a novel procedure as the same bone cuts are performed and fixation for stabilisation of osteotomy is performed as open technique. This is performed using minimal access and this less for tissue trauma.

I would agree with a minor variation from the fundamentals with a significant learning curve.

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?

I believe it could supersede the current standard of care (scarf akin or Lapidus) with some advantages but needs specific training. There will always be cases with clinical contraindications to minimal access namely osteopaenic bone and significant hyper mobility

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

The screw and burr technology has allowed better cutting tools and more stable fixation.

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

Yes - recent studies have 2 and 3 year follow ups that show at least that outcomes match the current gold standard scarf and akin procedure

20. Do you think the guidance needs updating?

Yes

Current management

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

Scarf and Akin procedure - open procedure with excellent repeatability and stability.

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?

Yes. Intramedullary devices but they have less advantages than the percutaneous osteotomy and fixation

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?

Less post Pain
Less swelling
Quicker weightbearing
Less chance of joint stiffness

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

All patients groups with
Moderate to severe hallux valgus deformity with good quality bone, non significant osteoarthritis of the 1st MTP joint and no severe hyper mobility

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.

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

No significant change. Needs a C arm or intro op fluoroscopy

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

Yes. Cadaver and hands on training for 25 cases is minimum to overcome
Learning curve

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

Nerve injury - less than 1%
Fracture
Screw misplacement
Screw irritation
Neuropraxia ans paraesthesia
Joint stiffness
Transfer pain
DVT
Joint stiffness
Recurrence
Hallux Varus

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

Early mobilisation

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

Delayed bone healing and prolonged swelling

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.

    David Gordons paper 200 cases
    Robbie Ray

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

    No

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)?

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.

    Outcome measures and complications data - essential proms

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:

    2 years

Further comments

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

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

None

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: *

Kaser Nazir

44. Date: *

18/07/2023

View results

Respondent

25 Anonymous

3385:33
Time to complete

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

Surgical correction of hallux valgus using minimal access techniques (IP782/2)

Your information

2. Name: *

Robbie Ray

3. Job title: *

Consultant Orthopaedic surgeon

4. Organisation: *

Kings College Hospital NHS Foundation trust (This work on behalf of British Orthopaedic Foot and Ankle Society)

(BOFAS)

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Orthopaedic Foot and Ankle Society (BOFAS)

7. Nominated/ratified by (if applicable):

British Orthopaedic Foot and Ankle Society (BOFAS)

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

GMC 6148167

How NICE will use this information:

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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 am familiar and experienced with the procedure and technology discussed. I was one of the first UK surgeons to gain formal fellowship training in the procedure between 2016-2017 in Sydney, Australia. Since 2019, I have completed over 200 procedures and will do this procedure most weeks. I collect patient reported outcome measures on all cases. My series of my first 50 cases with 12 months follow up has been published in peer reviewed publication.

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 currently use this procedure and the modern technology associated with it on a regular basis.

As a member of the BOFAS outcomes committee, I have reviewed the national foot and ankle registry and of 766 hallux valgus procedures logged 137 as logged as minimally invasive metatarsal osteotomies. This is an overall rate of 18%.
My personal opinion is that including unlogged procedures the rate of minimally invasive bunion correction is probably lower than 18% but I have no doubt that the rate of uptake is increasing. This is due to, firstly, a major increase in the published literature on these procedures showing learning curves, technical advances, radiological and clinical outcomes. recurrence rates and comparison to procedures. The second reason is that industry has developed newer technology such as specialised hardware and insertion aids known as jigs to potentially reduce the variability of the procedure due to surgeon and patient interest and are marketing and arranging training accordingly.

I believe this procedure may be being performed by podiatrists who practice surgery but I have no experience or knowledge of this.

Our speciality is the primary subspeciality of Trauma and Orthopaedics and as such we are the primary doctors who perform this procedure.

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.
- [ ] 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.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [x] Lewis TL, Ray R, Robinson P, Dearden PMC, Goff TJ, Gordon D, Lam P. Letter Regarding: Biomechanical Comparison of 2 Common Techniques of Minir

13. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) The title somewhat reflects the procedure but does encompass a wide variety of procedures and techniques. For instance the majority of modern lite

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?

A novel appproach compared to open surgery with new cutting tools, blades, fixation devices jigs etc. But this approach was developed for foot surgery many decades ago, has been used in Europe in some form since the late 1990s and has been used in the UK in its current form since around 2008.

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?

Evidence to date shows equivalence with the current standard of practice which is open hallux valgus surgery. Comparative trials have suggested that there may significantly be less pain in the early stages after surgery when compared to open techniques and significantly better range of movement but there is not enough evidence for either statement to come to a firm conclusion.
There is strong interest from both surgeons and patients for these techniques so I believe they will be used more and more in addition to standard techniques and in time may have the potential to replace the current standard of care but this will take time as the procedures involve a learning curve which is challenging for established surgeons due to new equipment, philosophies and technique and it will take time for adopters to teach this technique effectively in the NHS potentially leading to the technique becoming more commonly used by future generations of surgeons.

Current management

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

There is no enforced standard of care of hallux valgus surgery in the NHS. Due to the complex nature of the deformity a number of techniques are utilised. The most common, both in my experience and according to the national registry is open surgery with osteotomy which according to the registry is 50-70%, fusion of either the 1st MTP joint or 1st TMT joint is less than 10% and as mentioned earlier minimally invasive surgery is 18%

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?

There are no other competing novel techniques that are being used in significant enough number to warrant comparison with minimally invasive techniques. In my mind, the discussion is whether modern percutaneous surgery (minimal access techniques) now has enough evidence to show a similar safety and efficacy profile to the established open techniques and whether the guidance should be updated significantly to reflect this. I believe it is with the caveat (from multiple learning curve papers) that adequate training and experience is required to recreate the results published in the literature.

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?

The potential benefits are smaller scars with less ancillary trauma during surgery, less early post operative pain, possibly a better range of motion following surgery and possibly a lower recurrence rate of deformity at the medium term. Lower recurrence has not been shown in comparative trials but can be inferred from comparing the rates shown in series with longer follow up.
The only definite benefit over open surgery is smaller scars but in my experience there is certainly increasing patient and surgeon preference for percutaneous surgery which should be taken into account if results are similar between techniques

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

We have shown in two separate papers good results using percutaneous surgery in severe deformity which is the most challenging area of hallux valgus surgery. With smaller wounds and less infection risk, I believe patients with poor soft tissues or severe deformities would particularly benefit from percutaneous hallux valgus correction.

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?

    At the current time, hallux valgus surgery is generally already performed as a day case so although this is the expectation with minimally invavsive surgery, this is also the expectation with open hallux valgus surgery.
    PROMs are similar between open and minimally invasive techniques but this may well be due to ceiling effect as successful hallux valgus surgery brings PROMs into the realm of a normal foot.
    As per the title the surgery is certainly less invasive and as such may cause the patients less pain, less risk of readmission and less risk of infection but I believe the evidence for this statements is still weak

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

    These procedures require radiological guidance with a c-arm type x-ray machine. I believe this should also be the case with open hallux valgus surgery. Specialised equipment is required but this is now readily available and not significantly more expensive than the equipment required for standard open hallux valgus surgery

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

    There is a learning curve with percutaneous hallux valgus surgery as with any surgery. There is very little published evidence on the learning curve of standard of care open hallux valgus surgery but the few studies available show that it may be similar to minimally invasive techniques. The main difference is that surgeons who perform open surgery have significant experience from their training programme and fellowship so start practice with a good grounding in the technique. I personally train surgeons in minimally invasive techniques both as part of the minimally invasive foot and ankle society (MIFAS/GRECMIP) through an annual international course and through my own bespoke programme which I am fortunate to have funded through industry. This training involves a visitation to view procedures followed by a hands on day in a cadaveric lab practising techniques on saw bone and cadavers. This does not completely mitigate the learning curve but I believe instills basic principles and confidence in the techniques and my students have access to me as a preceptor to facilitate their learning through their learning curve. This is the closest I think established consultants can come to a formal training programme and fellowship training which I would hope would become the norm in the future.

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

    The most common adverse event as seen both in my experience and in the literature is medium term prominence of hardware requiring removal. Literature rates are 5-10% and seem higher than open surgery. Screw technology has advanced to mitigate this complication but it is still probably higher than open surgery.
    I have published extensively on the complication profile of this procedure and do not believe that complications other than metalwork removal are higher than in open surgery.
    There have been concerns of avascular necrosis of the metatarsal head or non union due to the large corrections in this procedure but these concerns have not been borne out in the literature.
    Recurrence and revision rates are low and possibly lower than in open surgery which is the current standard of care

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

    Clinical outcomes- Health Related Quality of Life measures (HRQOL) such as EQ5DLD, validated foot specific measures such as the MOXFQ, recurrence rate, complications
    Radiological measures- comparing correction of deformity and maintenance of this correction to other series and other procedures
    As mentioned above the recent literature is available to suggest these parameters are equivalent to the open standard of care procedures

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

The major concern with efficacy and safety would be widespread adoption of the techniques without adequate training. There is also no published evidence for the multiple recently introduced surgical jigs which may increase general uptake of the procedure.

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

As above. The technique has been shown to be effective and safe in multiple series but I believe strict guidance on training and experience is required to reliably reproduce these results in the majority of centres

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.

My papers are now published to date and available via literature search

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)?

I cannot give an indication of this from data available to me but I would expect thousands of patients in England would be eligible for this procedure each year in the UK.

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.

Beneficial outcome measures:
I believe all patients who have this procedure should have PROMS collected on the BOFAS national database on the general foot and ankle pathway allowing for external audit of results. The data set includes HRQOLs and foot specific validated measures.

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:

Clinical and radiographic follow up should follow current practice for open procedures but during the learning curve (first 50 cases) 12 months of radiographic and clinical follow up would be advised.

Adverse outcome measures:
Deep infection- 6 months
Recurrence- 12 months
Metalwork removal- 6 months

Further comments

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

no

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: *

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

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

Teaching contract with Marquardt UK- I am paid for my time to train surgeons in MIS techniques by Marquard UK. This includes surgeon visitations and cadaveric lab teaching. Marquardt UK also pay for the labs and all costs incurred through the teaching programme.

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: *

robbie ray

41. Date: *

02/08/2023

View results

Respondent

26 Anonymous

06:50
Time to complete

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

IP782/2

Your information

2. Name: *

Robert Clayton

3. Job title: *

Consultant Orthopaedic Foot and Ankle Surgeon

4. Organisation: *

NHS Fife

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Orthopaedic Foot and Ankle Society

7. Nominated/ratified by (if applicable):

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

4697600

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 been a consultant orthopaedic surgeon since 2010. My elective practice is now almost entirely confined to foot and ankle surgery. I have undertaken over 1000 hallux valgus correction operations. My primary procedure remains an open operation (most commonly a Scarf / Akin osteotomy). However I do also perform the Minimally Invasive Chevron / Akin (MICA) procedure. I have undergone specialist training on this technique.
The procedure was developed in continental Europe in the early 2000s and was introduced to the UK in the late 2000s. Initially Foot and Ankle specialists maintained a healthy scepticism and for several years the procedure was deemed experimental and controversial. However over the last ten years an increasing number of significant size publications, including some comparative studies, have been published which has led to more widespread adoption of the technique and general acceptance. It is now no longer viewed as particularly controversial but has instead become accepted as one of several reasonable strategies for surgical treatment of hallux valgus. The surgical techniques are being refined with time to increase reproducibility. Implants have been designed which are easier to reproducibly and reliably implant and which are contoured to reduce the rate of hardware prominence (and so reduce the rate of re-operation to remove fixation screws).
The next stage in evolution of the techniques is development of new jigs for increased accuracy of bone cuts. This is likely to lead to increased accuracy of the surgery and will in turn lead to a more widespread adoption of the technique. My own practice is likely to shift decisively for this reason.
Image intensifiers and surgical low speed high torque burrs are used in other orthopaedic subspecialties but it would be inappropriate for anyone other than consultant orthopaedic surgeons specialising in foot and ankle surgery to carry out this procedure. This should not be undertaken by non medically qualified surgical podiatrists.

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.

See answer to 10

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.
- [ ] I have had no involvement in research on this procedure.
- [x] I have had no involvement in research on this procedure other than marking papers presented at the BOFAS meeting.

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 comparison with the open techniques (such as Scarf osteotomy, Lapidus procedure etc) the use of minimal access incisions is a fairly major new concept. However the configuration of the bone cuts is a simple variation on the Chevron osteotomy which has been well established for decades. The MICA itself has been around for long enough, and sufficiently well studied, to no longer be considered "novel"

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?

It is already one of several well established treatment options for hallux valgus. As with so many other areas of surgery, eventually this type of minimal access surgery is likely to supersede the current open surgical techniques.

Current management

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

Open hallux valgus correction remains the current standard of care. Over 100 first metatarsal osteotomies have been described, many remain in current use. The Scarf / Akin osteotomy remains the commonest procedure in the UK

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?

NA

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?

Smaller incisions. Possibly reduced post-operative swelling. The proponents claim faster recovery but this remains unproven.

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

Any patient undergoing hallux valgus correction could potentially benefit.

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 is by its definition a less invasive treatment.

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

Intra-operative fluoroscopy is mandatory. Otherwise no different from other procedures.

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

Yes. It should not be undertaken without specialist training. It is not suitable for non medically-qualified podiatrists practicing surgery.

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 risk of requirement for metalwork removal. Higher rate of recurrence. Unsuitability for more advanced complex deformities (although this changes as the techniques develop)

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

Visual analogue pain scores, hallux valgus angle measured on x-ray, other patient reported outcome measures including MOX-FQ and SF-12

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

See above

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

See previous answers

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.

There are a lot of recent papers from London (led by Robbie Ray) and from Brighton (led by David Redfern) which are strongly supportive.

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

The BOFAS registry is rapidly growing in its scope and can be used for collection of outcome data for all surgical foot and ankle procedures. If use of a registry is to be encouraged then I would strongly recommend the BOFAS registry be selected. This would be consistent with the NICE recommendation for the Cartiva implant, which concluded that the BOFAS registry should be used to collate data.

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)?

Potentially up to 90% of patients undergoing hallux valgus correction. Visual Analogue Pain Scores.

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.

Visual Analogue Pain Scores.
Manchester – Oxford Foot Quotient (MOX-FQ)
Short Form 12 (SF-12)
Data should be collected pre-operatively and as a minimum at one year. Ideally at earlier time points such as 3 and 6 months as well.

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:

Re-operation for any reason. Removal of hardware. Revision Hallux valgus. Persistent pain. Infection. All but infection could occur at any time and should be monitored up to five years.

Further comments

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

No

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

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

I am a Director of the British Orthopaedic Foot and Ankle Society (BOFAS)
I have received payment for teaching from Stryker but not in relation to this type of surgery

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: *

Robert Clayton

41. Date: *

07/08/2023

View results

Respondent

1 Anonymous

17:22
Time to complete

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

IP782/2 Overview | Surgical correction of hallux valgus using minimal access techniques

Your information

2. Name: *

Colin Howie

3. Job title: *

Hon Prof Orthopaedics

4. Organisation: *

Edinburgh University

5. Email address: *

6. Professional organisation or society membership/affiliation: *

IPAC committee member

7. Nominated/ratified by (if applicable):

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

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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 am familiar with the technique and technologies together with the patient groups

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
    It is carried out by orthooaedic foot surgeons and operating podiatristsdo not look after these patients any more

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.
- [ ] 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

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?

In many ways this has become the 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?

N/A

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

There are many different descriptions of minor changes over the last 10 years. probably little material difference

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

Since previous publication there has been at least 1 RCT (showing no difference) and multipke meta analysis often coming to opposite views. There has also been a paper on learning curve. It does appear to take longer in theatre and involve more radiation.

Current management

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

A mix of open and minimally invasisve carried out as day case

21. 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?

Internal and external fixation have been used

Potential patient benefits and impact on the health system

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

Less wound problems and neuralgia. probably the same rehab

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

No

24. 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?

Possible less wound infections which can be a problem in open surgery

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

Image intensifier in theatre and longer theatre time

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

It does appear to require a learning curve

Safety and efficacy of the procedure/technology

27. 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

    Neurological damage infection non union pain diffficulty walking. Failure to maintain correction

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

    Better Manchester oxfrod foot score (MOFX); EQ5D; Intermetatarsal angle correction

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

    Benefits over standard treatment, open metatarsal correction.

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

    see above

31. 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

32. 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.

    Pub med search brings up relevant papers

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

    No

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

Other considerations

35. 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)?

36. 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 length of stay, wound infections 30 days. removal metalwork 1 year; return to normal gait/ shoes up to one year. Non union rate, reopertaion rate. Manchester oxford foot ankle scor

37. 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:

    See above

Further comments

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

    Oerative time and wound healing are key

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.

39. Type of interest: *

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

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

None

41. 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

42. Name: *

Colin R Howie

43. Date: *

13/01/2023