View results

Respondent

4 Anonymous

50:20
Time to complete

Your information

1. Name: *

Andrew Metcalfe

2. Job title: *

Professor of Trauma and Orthopaedics & Consultant Orthopaedic Surgeon

3. Organisation: *

University of Warwick, University Hopsitals Coventry and Warwickshire

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

Royal College of Surgeons, British Orthopaedic Association

6. Nominated/ratified by (if applicable):

British Elbow and Shoulder Society (BESS)

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

6074794

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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 led a multi-centre randomised trial about the balloon (the START:REACTS trial, The Lancet, 2022) that was funded primarily by NIHR (although the manufacturer supplied some devices and some training costs), following the recommendation of the 2016 NICE IPG on the topic.

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.

    It was used 30,000 times in Europe between 2010 and 2022 according to Stryker press releases, but figures for the UK specifically (which started approx 2013) are not available as I understand.

    I do not use it in my practice (which is more focused on knee surgery) but I have a large research experience in the device having led START:REACTS and its associated sub-study

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.
- [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.
- [x] 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, I believe it is, and have seen nothing in the literature that suggests otherwise

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 innovative, it is a new approach to this challenging surgical problem

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 had the potential to, although the START:REACTS trial found that using the balloon was worse than not using the balloon (in an otherwise identical operation). It was less effective and more expensive.

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

No, the technique and stated indication appears to be materially unchanged

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

Yes.
There have been two new trials in 2022 (published within 24 hours of each other).

START:REACTS, The Lancet 2022 (for which I was lead author) found that outcomes were significantly worse in the balloon group compared to an otherwise identical operation (a Subacromial debridement) without the balloon. This was based on the primary outcome measure, the Oxford Shoulder Score (a commonly used PROM).The study was a UK double-blind multi-centre adaptive trial and stopped early (at 117 out of a planned 221) due to futility. Other outcomes were in the same direction, although mostly not significant. Health economic analysis demonstrated that the balloon group was less effective and more costly than standard care and is highly unlikely to be cost effective. The trial was funded by the NIHR EME programme but OrthoSpace/Stryker also funded some of the balloons and some training costs.

We have a (as yet unpublished) health economic analysis at 1 year. The 2-year dataset is currently being analysed.

The SPACE trial, Verma et al Journal of Bone and Joint Surgery 2022 was a company funded non-inferiority trial comparing the use of the balloon to partial rotator cuff repair. the latter is a procedure which is not widely used in the UK due to concerns about its effectiveness. The study found no differences in the main outcomes between the two treatments. There were some significant secondary outcomes such as range of movement but partial rotator cuff repair may be expected to cause some stiffness, so this it likely to explain their findings. It is hard to directly compare the two trials as the comparators were different, from different healthcare settings. That EQ5D utilities were not reported so we cannot compare these. The trial was funded by the manufacturer, and co-authors include company employees and share-holders.

Overall, I would conclude that there is very little evidence in either trial of any clinical benefit for the balloon, and some evidence (one trial of two, based in the UK and funded by NIHR) that it may worsen outcomes.

Current management

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

Debridement of the Subacromial space

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?

Not similar mode of action. Superior Capsular Reconstruction is an emerging technique but there is uncertainty about technique and benefit, it is only used in some centres.

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 was aiming to reduce pain, but I dont think it does

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

In our study, females did much worse then males (in males we saw no difference, in females results were substantially worse, approx 10 points on the Oxford Score), although this was a small subgroup analysis.

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?

    No, see efficacy statements above

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

    None

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

    It is easy to pick up and use with only a small amount of 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

    See question on efficacy, I believe it may be detrimental to patient outcomes.

    We have not observed a clear difference in safety profile at 1 year, I do not know the 2-year outcomes yet.

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

Pain, function, adverse events

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

See efficacy results above, I am certainly concerned about outcomes. Without NICE guidelines, use of the procedure is likely to continue in the UK, tis could result in harm to UK patients and is very unlikely to be beneficial.

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

As covered 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.

    We have 2 year data which is being analysed at present.

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

    Apart from the two 2022 trials, I believe there may be one in Holland ongoing, although we have not been able to find registration details.

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

    We have 2 year data and a 1-year within-trial health economic analysis which is being analysed at present.

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)?

    5,000(??)

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.

    Oxford Shoulder Score, WORC score, EQ5D

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:

    Early and late complications and re-operations, up to 5 years

Further comments

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

    I am happy to comment or provide data further as needed.

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

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

I am Chief Investigator of the START:REACTS trial, published in The Lancet in 2022. This was funded by NIHR EME (a NIHR & MRC partnership). To reduce treatment costs to trial sites, 23 InSpace devices were provided for free under an agreement with the manufacturers of the balloon (initially OrthoSpace, Israel and later Stryker, USA). OrthoSpace also funded some of the training centre costs of a study-related cadaveric course to train participating surgeons in the use of the balloon at the start of the study. The full independence of the trial team is protected by legal agreements.

I am Chief Investigator on one and co-investigators on another NIHR-funded trial of a robotic system made by Stryker (RACER-Knee and RACER-Hip, I lead RACER-Knee), for which Stryker also fund treatment costs and some imaging costs. As with the presented study, the full independence of the study team is protected by legal agreements.

I am Chief Investigator on two other unrelated NIHR-funded trials (METEOR2 and REPPORT).

I receive no personal funding that may represent a conflict of interest, and do not have a private practice.

I have been involved in NICE processes before, including as a member for the evidence review team for two related Health Technology Assessments (TA477, 04/10/17 and TA508, 07/03/18) and as a member of the NICE Joint Replacement (NG157) guideline development committee (published 2020).

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: *

    Andrew Metcalfe

42. Date: *

    07/02/2023

View results

Respondent

2 Anonymous

5845:13
Time to complete

Your information

1. Name: *

Neal Millar

2. Job title: *

Professor of Orthopaedic Surgery

3. Organisation: *

University of Glasgow

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

GMC

6. Nominated/ratified by (if applicable):

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

GMC 6026522

How NICE will use this information:

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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 have extensive experience with biodegradable spacers in the subacromial space and have been utilising them in my NHS practice for approximately 2 years. I use them in a wide variety of specialist cases.

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.

    Use in my NHS practice

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?

Novel approach to deal with massive cuff tears.

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 Standard of care.

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

There have been changes in surgical technique (such as sizing)

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

Yes, there have been two randomised controlled trials in this space in the last year each showing confounding results

Current management

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

Current standard of care for a massive cuff tear is either non operative and physiotherapy or operative in the from of a Reverse total shoulder arthroplasty

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?

NO

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?

Less invasive, quicker procedure
Quicker recovery and rehabilitation

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

>75 with con dominant medical issues that may preclude a total shoulder replacement

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?

Potentially fewer hospital visits
Less invasive treatment is the main attraction of this procedure
Outcomes at present have shown no vast improvement however the initial RCT had several flaws and was carried out during COVID with varying follow up

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

Day surgery unit capabilities

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

Yes, surgeons should have trained in cad lab or similar before implantation

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

Anterior escape of the balloon in the shoulder, causes pain ++
Inserting too large a balloon
Overfilling of device
No ensuring that it is appropriately sited to ensure taking shoulder through ROM

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

Pain (VAS)
Functional improvement (QUICKDASH scoring or equilavent upper limb functional patient reported outcome)

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

? improvement over placebo type surgery

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

As above...doe sit provide any benefit over placebo type shoulder surgery

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.

    Verma N, Srikumaran U, Roden CM, Rogusky EJ, Lapner P, Neill H, Abboud JA. (2022). InSpace implant compared with partial repair for treatment of full-thickness massive rotator cuff tears. J Bone Joint Surg Am. Advance online publication. doi. 10.2106/JBJS.21.00667.

    Srikumaran U, Roden C, ROGUSKY E, Lapner P, Abboud J, Verma N. Subacromial Balloon Spacer versus Partial Repair for Massive Rotator Cuff Tears: A Prospective, Randomized, Multi-center Trial. Orthopaedic Journal of Sports Medicine. 2021;9(7_suppl4).

    Metcalfe A, Parsons H, Parsons N, et al. . Subacromial balloon spacer for irreparable rotator cuff tears of the shoulder (START:REACTS): a group-sequential, double blind, multicentre randomised controlled trial. Lancet 2022

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)?

Of rotator cuff tear population approx 1-2%. I think this would be increased if this device was used to augment partial thickness rotator cuff tears which is ongoing in the US

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.

QuickDASH upper limb PROM 6 months and 1 year
SF-12 quality of life - 6 months and year

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:

Early, first 6 weeks...late either 6 or 12 months

Further comments

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

Further research is being undertaken to ascertain the role in partial (medialiased repairs) repairs which is probably where this prodcut will sit.

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

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

Lectured at Stryker surgeons course on the InSpace balloon and my use of it in my NHS practice.

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: *

    Professor Neal Millar

42. Date: *

    04/02/2023

View results

Respondent

1 Anonymous

06:53
Time to complete

Your information

1. Name: *

Stephen Gwilym

2. Job title: *

Consultant Surgeon

3. Organisation: *

Oxford university hospitals

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

BESS

6. Nominated/ratified by (if applicable):

BESS

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

4724821

How NICE will use this information:

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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?

   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.

    Not used but aware of use by others
    Involved in clinical trial of efficacy

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).
- [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?

- [x] 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?

novel

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.
- [x] 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?

replace

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?

yes

Current management

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

Used widely, without need for special permission

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?

No

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?

Small procedure

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

Massive coffee tears

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?

Less invasive treatment

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

Nil specific - operating theatre

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

No

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

    Infection

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

    Reduction in pain

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

    No proven efficacy in NHS

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

    Start:Reacts study

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.

    I was part of the DSMC for the start:reacts study

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.

    https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00652-3/fulltext

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)?

    1000s

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.

    Pain
    Function
    QoL

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
    Paoin
    Further surgery

Further comments

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

    Nil

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. *

nil

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: *

Stephen Gwilym

42. Date: *

27/01/2023

View results

Respondent

5 Anonymous

21:33
Time to complete

Your information

1. Name: *

Mt Steve Drew

2. Job title: *

Consultant trauma and Orthopaedic Surgeon

3. Organisation: *

University Hospitals Coventry and Warwickshire NHS Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

BESS (British Shoulder and Elbow Society) President Elect

6. Nominated/ratified by (if applicable):

7. 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

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. I performed 30 InSpace Balloon Procedures as a shoulder surgeon before being part of the team that undertook a randomised controlled clinic trial the results of which were published in the Lancet in May 2022

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.

    Previously used it extensively for patients with massive irreprable rotator cuff tears where they had failed non-operative treatment. The results of the randomised trial (Subacromial balloon spacer for irreparable rotator cuff tears of the shoulder (START:REACTS): a group-sequential, double-blind, multicentre randomised controlled trial) The Lancet VOLUME 399, ISSUE 10339, P1954-1963, MAY 21, 2022 however, informs us that the balloon should no longer be used for this indication.

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).
- [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.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

No longer appropriate due to results of trial which show a worse outcome for patients following insertion of the biodegradeable spacer than a debridement and decompression

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 was novel when introduced in 2011. Established practice throughout Europe for the management of irreparable tears based solely on a small number of cases series. Recent publication indicates it should no longer be used

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?

See 14 ; results of trial indicate should no longer be used

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

No but see answer to 16

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

Yes see results of trial published in Lancet in may 2022 ref see 10 above

Current management

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

Initially massive irreparable cuff tears are treated non-operatively with analgesia, injections and physiotherapy. If no improvement consider surgery of which biodegradable balloon spacer was 1 option; Should no longer be used.

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?

    Partial Rotator Cuff Repair
    Superior Capsular reconstruction
    Both have little evidence to support them!

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?

    Should no longer be used

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

    Should no longer be used

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?

    Should no longer be used

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

Should no longer be used

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

Should no longer be used

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

Infection
Significant pain post op
Worse outcome compared to debridement and decompression so shoul no longer be used

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

Should no longer be used see results of published trial

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

Should no longer be used see results of published trial

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

Should no longer be used see results of published trial

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.

See answer 10

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

See answer 10

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)?

Should no longer be used based on published trial outcome

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.

Should no longer be used based on published trial outcome

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:

Should no longer be used based on published trial outcome

Further comments

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

Should no longer be used based on published trial outcome

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
- [x] Indirect
- [ ] No interests to declare

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

I am a paid Educational Consultant for Stryker UK for arthroplasty work. Stryker also market the biodegradable balloon

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: *

    Mr Steve Drew

42. Date: *

    11/02/2023