View results

Respondent

1 Anonymous

29:29
Time to complete

Your information

1. Name: *

Mark Ferguson

2. Job title: *

ENT Consultant (Rhinology, Facial Plastics and Anterior Skull Base Surgeon)

3. Organisation: *

Imperial College Healthcare NHS Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

ENT UK

6. Nominated/ratified by (if applicable):

ENT UK

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

GMC: 6064334

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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 run a monthly local anaesthetic interventional clinic and I have been offering cryotherapy (Clarifix) since Jan 2022. I do approx 2-3 case per month under LA (more than anyone else in London)

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.

    This is not widely offered currently but could be adopted relative swiftly. No other specialities use this. Patient are referred to Rhinology (either my clinic or colleagues' clinics in the sector) and then referred onto me for treatment.

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

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

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

Compared to the current established final treatment this is a far less invasive and cheaper option.

14. 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.

15. 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 could replace vidian neurectomy

Current management

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

Intranasal steroid sprays and ipratropium bromide sprays, if allergy tests are negative and rhinorrhoea persists then patients can be trial on amitriptyline and if they fail that then endoscopic vidian neurectomy.

17. 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

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

Resolution of symptoms without needing endoscopic sinus surgery

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

Refractory rhinitis, refractory rhinorrhoea

20. 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. It potentially offers a cheaper, cost effective treatment for these difficult to manage patients

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

It's ideal for the local anaethestic setting and so adoption of more "awake hubs"

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

Very staright forward to use once the "awake hub" is set up (with associated LA protocol)

Safety and efficacy of the procedure/technology

23. 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

    Failure to work
    Transient post-op headache
    Dry nose and eyes

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

    Improvement in symptoms (and I have been using improvement in NOSE score)

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

    Unproven in UK market

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

    Efficacy?

27. 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

28. 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.

    N/A

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

    N/A

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

    N/A

Other considerations

31. 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)?

    Unclear depends on what the ultimate inclusion criteria are. I see about 2-3 referrals a month from NWL sector for refractory rhinorrhoea.

32. 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.

    NOSE score before, then post-op at 6 weeks, 3/12, 6/12 and 1yr

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

    Adverse outcome measures.

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

Further comments

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

    N/A

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.

35. Type of interest: *

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

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

N/A

37. 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

38. Name: *

Mark Ferguson

39. Date: *

02/12/2022

View results

Respondent
2 Anonymous

34:32
Time to complete

Your information

1. Name: *

Samuel Leong

2. Job title: *

Consultant ENT Surgeon

3. Organisation: *

Liverpool Head and Neck Centre

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

GMC

6. Nominated/ratified by (if applicable):

ENTUK

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

6030970

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- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

Yes. I have seen the technology and procedure.

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.

The technology is indicated for some patients presenting with chronic rhinitis and/or post-nasal drip who have not responded to conventional topical treatment. Currently, some patients may be offered endoscopic vidian neurectomy which is a procedure that typically requires general anaesthetic and specific skill sets not readily available among general ENT surgeons. Where this is not available, most patients do not receive treatment for their symptoms or may get referred to a surgeon who may offer endoscopic vidian neurectomy.

The technology and required procedure is within the remit of appropriately trained ENT surgeons.

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

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

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

The technology is less invasive an can be done under local anaesthetic. The procedure can be repeated if necessary and is simple to learn.

The procedure targets peripheral nerves which potentially results in fewer complications.

14. 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.

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

As an addition to existing standard care

Current management

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

Topical nasal spray
Endoscopic vidian neurectomy

17. 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?

Endoscopic vidian neurectomy requires general anaesthesia. This procedure typically entails finding the vidian nerve after sphenopalatine artery ligation.

Potential patient benefits and impact on the health system

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

More patients have access to potentially effective treatment which is less invasive and can be undertaken under local anaesthetic.

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

Elderly patients who have concomitant medical problems and are not safe candidates for general anaesthetic

20. 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, improved patient pathways and reduced waiting lists. Patients can have this procedure in clinic rather than listed for the procedure.

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

No change. The procedure can be undertaken in ENT clinics or theatres.

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

No specific training required apart from standard familiarisation and on site support by the company.

Safety and efficacy of the procedure/technology

23. 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

Discomfort (minor pain)
Intermittent congestion
Bleeding of the nose
Headaches

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

Improved rhinitis, congestion
Improved SNOT-22 scores

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

Not aware

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

Not aware

27. 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

28. 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.

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

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

Other considerations

31. 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)?

    10,000

32. 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.

    Sustainment of clinic benefit at 6, 12 and 18 months

33. 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 - 3 months
late - 12 months

Further comments

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

Nil

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.

35. Type of interest: *

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

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

As above

37. 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

38. Name: *

Samuel C Leong

39. Date: *

17/12/2022

View results

Respondent

3 Anonymous

50:56
Time to complete

Your information

1. Name: *

Jonathan Joseph

2. Job title: *

Consultant Rhinologist and Facial Plastic Surgeon

3. Organisation: *

Royal National Ear, Nose and Throat Hospital, UCLH

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

ENTUK

6. Nominated/ratified by (if applicable):

N/A

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

GMC 6105465

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- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

   Are you familiar with the procedure/technology?

   I have read the published data on Clarifix and have started to use it in routine practice my rhinology clinics. I am aware of the scientific basis behind its method of action and indications for use.

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

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

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

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

    I have used the technology to perform cryotherapy of the posterior nasal nerve on 5 patients so far.
    There has been some uptake in the NHS. For example UCLH are trialling it in a small number of cases. Device cost is a barrier to uptake so it will require a strong business case.
    Cryotherapy is widely used in many specialties but this particular device is only for use in the nose.

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

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

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

This procedure is a major variation compared to the standard approach. The current options are medical management using nasal sprays or major surgery to divide the vidian nerve from which the posterior nasal nerve branches.

14. 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.

15. 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 does have the potential to replace standard surgical treatment for this problem. It should also reduce the reliance on nasal medication.

Current management

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

Medical treatment - nasal steroids and nasal ipratropium bromide spray.
Surgical treatment - endoscopic vidian neurectomy

17. 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

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

In many the medical options are not adequate to treat the disease.
Surgery is very invasive and his significant risks.
The device can provide a more effective treatment without exposing patients to the risks of surgery

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

Intractable rhinorrhoea is the main indication for this procedure. It must have a significant impact on quality of life to warrant undertaking the procedure.

20. 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 can certainly lead to reduction in symptoms. It has a prolonged effect so patients can be discharged from care with fewer hospital visits.
When compared to the standard surgical treatment this is far less invasive. It only takes 15-20 minutes to perform.

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

The procedure needs to be carried out in a procedure setting. This can either be an operating theatre or an enhanced outpatient clinic space with patient monitoring facilities.

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

There needs to be training on device use but this is very simple and would only take a few short sessions.

Safety and efficacy of the procedure/technology

23. 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 only adverse events reported are severe pain related to the temperature of the device. It is equivalent to the well known 'ice cream headache'. This can be resolved with re-injecting local anaesthetic in to the operated area.

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

Reduction in watery nasal discharge
Reduction in nasal congestion

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

The indications for use are not clearly stated so more specific criteria would be helpful.
We have no data yet for the UK and there is no data greater than 1 year post-procedure

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

Only related to its efficacy and cost

27. 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

28. 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.

    No

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

    No

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

    Nil available

Other considerations

31. 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)?

My estimate is that national a few hundred or 1000 people per year would be eligible

32. 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.

The most useful outcome measures will be subjective outcome questionnaires such as SNOT-22 and NOSE. It would also be helpful to have objective measures such as nasal inspiratory peak flow (NIPF) and acoustic rhinometry.

33. 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:

Pain scores in the first hour after the procedure
Pain scores in the first 2 weeks after the procedure
Crusting post-operatively

Further comments

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

It will take time to understand the indications which are better suited to this device with more certainty. The cost of the device is a barrier to this. However, there has been some use in private healthcare which may be a useful data resource.

Declarations of interests

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

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

Nil

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

    - (●) I agree
    - ( ) I disagree

Signature

38. Name: *

    Jonathan Joseph

39. Date: *

    03/01/2023

View results

Respondent

4 Anonymous

90:07
Time to complete

Your information

1. Name: *

Billy Derrick Siau

2. Job title: *

Consultant Rhinologist and ENT Surgeon

3. Organisation: *

Manchester Foundation Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

GMC, RCPSG

6. Nominated/ratified by (if applicable):

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

GMC 6064817

How NICE will use this information:

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- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

   Are you familiar with the procedure/technology?

   Yes.
   attended a few talks and conferences about Cryofix, seems to have good results for a far less invasive procedure that can be done under local anaesthesia.

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

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

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

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

    used it in NHS. In process of getting this approved for the Spire Manchester/Cheshire.
    This procedure is only undertaken by ENT surgeons particular rhinologist. don't see other specialties getting involved.
    it is a very simple device/ procedure, but costs may be a factor in NHS uptake as more than 1000 pounds per device.

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

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

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

This is a very innovative product which can change the way we manage this condition. Traditionally, intractable vasomotor rhinorrhoea was treated by Vidian neurectomy or posterior nasal nerve section. Both involves complex sinus surgery under GA and takes 1-2 hours surgical time with risk of complications. This device involves freezing the nasal nerves under local anaesthesia and takes 15 mins. it is inherently safer as the only significant risk being having an 'ice-cream' headache for a short while. The science behind it is similar to a Vivian/posterior nasal nerve section; but the nerves are frozen rather than resected.

14. 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.

15. 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 traditional procedure as much safer, quicker (15min vs 1-2 hrs) and can be done under local anaesthesia

Current management

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

Vasomotor rhinorrhoea is predominately treated with nasal sprays. Those who failed medical therapy are then considered for Vidian or posterior nasal nerve section via endoscopic approach under GA

17. 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

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

can be done under LA
time : 15 min vs 1-2 hours fr traditional procedure
safety : cryotherapy is inherently safer as no tissues resected

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

elderly pts not suitable for long GA
vasomotor rhinorrhoea also predominately affects the elderly, benefits in not subjecting themto a GA and an invasive procedure

20. 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, a far less invasive treatment that negates a GA. Has be done in the outpatient setting in some centres rather than an operating theatre. Cost savings can be achieved from not having GA, shorter procedure time, potentially bed-saving and a greatly improved safety profile.

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

can be done in operating theatre with existing sinus equipment. if in outpatient setting, will require 'stacker/screen', rigid endoscope, local anaesthesia and the Cryofix device.

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

minimal training as procedure is very straightforward and far simpler than traditional nerve section.
I attended a seminar and demonstration, practiced on a dummy model.

Safety and efficacy of the procedure/technology

23. 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 main adverse outcome is failure. the published success rate is 75% who 25% will fail. the only significant complication is an 'ice-cream' headache which settles down with some analgesia. similar to eating an ice-cream too quickly. There was one reported case of epistaxis which occurred a week post-procedure which may or may-not be related to the procedure. Ow, Randall A., et al. "Cryosurgical Ablation for Treatment of Rhinitis: Two-Year Results of a Prospective Multicenter Study." The Laryngoscope 131.9 (2021): 1952-1957.

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

    Total nasal symptom score is used pre and post-procedure to evaluate efficacy. Patient will report subjectively whether their rhinnorhoea improves post-operatively

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

    75% efficacy but I suppose no procedure offers 100%. May need repeat procedure in a few years.

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

    no

27. 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

28. 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.

    Ow, Randall A., et al. "Cryosurgical Ablation for Treatment of Rhinitis: Two-Year Results of a Prospective Multicenter Study." The Laryngoscope 131.9 (2021): 1952-1957.

    this is the main study that I have been reading.

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

    I am not aware

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

numbers performed to small to be published as yet. But so far seems very safe, no complications and 100% improvement rate.

Other considerations

31. 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)?

10 % of population suffers from chronic rhinitis. majority will be managed medically. a small proportion of these (10%) will need surgical intervention. Exact numbers difficult to estimate, but will be less than 1 % of general population

32. 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.

Total Nasal Symptom Score (rTNSS), Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) over 24 months

33. 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:

only reported significant complication is "ice-cream' headache which resolves in hours to days and treated with simple analgesia. these would have resolved when they attend their first follwo-up

Further comments

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

Realistically, this is 'quality of life" procedure to improve rhinorrhoea and nasal congestion and may not be a priority for the CCG in the present financial climate. in the short term, I see this mainly done in the private sector due to funding limitations.

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.

35. Type of interest: *

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

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

none

37. 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

38. Name: *

Billy Derrick Siau

39. Date: *

09/01/2023

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1928 Cryotherapy for Chronic Rhinitis**

Your information

Name:	Henry Sharp
Job title:	Consultant ENT Surgeon / Rhinologist and Nasal Plastic Surgeon
Organisation:	East Kent Hospitals Foundation University NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	ENT-UK, British Rhinological Society
Nominated/ratified by (if applicable):	Council of British Rhinological Society
Registration number (e.g. GMC, NMC, HCPC)	3494765

How NICE will use this information:

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	I am familiar with the technology on a theoretical level, and have assessed it on a personal basis based upon a personal literature search of relevant papers published in peer-reviewed literature. The issue that it seeks to resolve is an extremely common part of a specialist rhinologist's practice. The small amount of these patients who do not get improvement with standard treatment pathways would, in theory, be excellent candidates for this treatment. On first principles, it's anatomical basis and theory seems well thought out and a reasonable alternative to much more invasive alternative procedures currently in use. I have not personally used it on patients yet, but plan to in the next 3 months. I am aware that it is being used in both the NHS and Private sector in the UK, but as ever with new technology, barriers exist currently predominantly because of the cost of the single use instrumentation. It's implementation would be decided upon by specialist ENT practitioners, and no onward referral to other specialities would be necessary.

	procedure/technology, please indicate your experience with it.	
2	– 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 had no involvement in research on this procedure. Other (please comment)
3	Does the title adequately reflect the procedure? Yes How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Instrumentation new, but concept not new within current standard of care, but this only available in tertiary units (vidian neurectomy). Which of the following best describes the procedure (please choose one): New instrumentation and procedure based on current tertiary treatment.	
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It has the potential to replace vidian neurectomy, which is a much more invasive procedure performed under general anaesthetic with more potential side effects (particularly dry eye), and thus to offer treatment to a cohort of patients that do not respond to standard medical or conservative management on a much more non-invasive as well as equitable basis.

Current management

6	Please describe the current standard of care that is used in the NHS.	Medical management involves assessment for allergic triggers and advice on avoidance, and usually topical steroid medication or anticholinergic sprays or drops. Topical or systemic antihistamines may be prescribed. Desensitisation may be relevant in patients with significant defined allergy. If these don't work or if the patient has non-allergic rhinitis, current options are limited, with specialist Tertiary units offering vidian neurectomy for a small number of patients each year.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	A significant improvement in quality of life related to the issues caused by debilitating perennial rhinorrhoea and/or nasal congestion.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those pts who do not respond to standard conservative and/or medical treatment as outlined above.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	It has the potential to add a treatment option for a limited amount of patients who do not respond to standard treatments as outlined above. As such, it could lead to significantly improved outcomes in these patients (who have no alternative treatments at a local level at present), with a much less invasive treatment than currently on offer, and with a long term result which would significantly reduce burden in follow up both in primary and secondary care.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None, apart from purchasing the single use equipment for each patient.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Via appropriate company representatives and training courses.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	Adverse events reported in my literature search were: Transient discomfort for around 48 hrs post-procedure (1 in 10) Transient bleeding for up to 10 days post-procedure (1 in 100) Nose or sinus infection (1 in 100)

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Palatal numbness or dry eye (1 in 1000)
14	Please list the key efficacy outcomes for this procedure/technology?	Improved congestion and / or rhinorrhoea
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	None
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help	None that you will not have with a relevant literature search.

	us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	no
20	Please list any other data (published and/or unpublished) that you would like to share.	None that I am aware of

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	I would estimate around 20 per Consultant Specialist Rhinologist per year in the UK
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: SinoNasal Outcome Test (SNOT) 22 Mini RQLQ (Mini rhinoconjunctivitis quality of life questionnaire) Total Nasal Symptom Score (TNSS) A time period of up to 12 months post-op would be reasonable Adverse outcome measures: Patient reported

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	None

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Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

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

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

Print name:	**Henry Sharp**
Dated:	**21/12/2022**