View results

Respondent

36 Anonymous

17:08
Time to complete

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

IP1846

Your information

2. Name: *

ALEX MIRAS

3. Job title: *

PROFESSOR OF ENDOCRINOLOGY

4. Organisation: *

ULSTER UNIVERSITY

5. Email address: *

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

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

6055106

How NICE will use this information:

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

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

Yes I am familiar with the technology based on my work on the endobarrier, thermal DMR and now electrical DMR

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

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

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

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

No as it is still in the experimental/clinical trial phase

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

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [x] I have worked on medical devices that bypass or ablate the duodenal mucosa

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

The main indication is for the treatment of type 2 diabetes

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

Very innovative and provides an additional treatment modality for patients with diabetes. It is insulin independent and also causes weight loss.

16. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

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

It has the potential to be used as an adjunct to existing care.

Current management

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

Pharmacotherapy based on the NICE guidance. No endoscopic interventions are used.

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

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

    No

Potential patient benefits and impact on the health system

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

    Minimally invasive, mimics bariatric surgery but without the need for permanent surgery, appears to be safe as a day case, causes weight loss

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

    People with type 2 diabetes and obesity

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

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

    By improving glycaemic control it could reduce the burden and cost of T2DM complications like retinopathy, nephropathy and neuropathy on the NHS

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

    Endoscopy facilities and a skilled endoscopist

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

    yes, mainly for the endoscopist doing the procedure

Safety and efficacy of the procedure/technology

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

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

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

    Perforation, stenosis, anaesthetic complications, loss of efficacy with time. These are theoretical, with the available evidence so far being favourable for this specific technology

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

Glycaemic control
Weight Loss
Use/doses of glucose-lowering medications

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

Long term safety and efficacy

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

Yes, about its long term efficacy and safety

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

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

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

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

REGENT-1 Study abstract (abstract #46) titled "Duodenal Mucosal Regeneration Induced by Endoscopic Pulsed Electric Field Treatment Improves Glycemic Controls in Patient with Type II Diabetes – Interim Results from First-in-Human Study, oral presentation at Digestive Disease Week (DDW) from May 6 – 9, 2023

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

Yes, link: https://www.endogenex.com/clinical-studies/

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

n/a

Other considerations

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

10,000

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

Beneficial outcome measures.

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

HbA1c, weight, use of diabetes medications, IWQOL and other QoL measured used by NICE at 3, 12 months and then yearly thereafter

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

Adverse outcome measures.

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

early: bleeding, perforation, infection, anaesthetic complications
late: stenosis, collections, loss of efficacy

Further comments

36. 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.

37. Type of interest: *

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

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

I have received research funding from the National Institute for Health and care Research, Medical Research Council, Jon Moulton Charity Trust, Fractyl, Novo Nordisk, Fractyl and Randox.

I have received honoraria for educational events from Novo Nordisk, Astra Zeneca, Currax, Boehringer Ingelheim, Screen Health, Rhythm, Medtronic, Ethicon and GI dynamics.

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

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

- (●) I agree
- ( ) I disagree

Signature

40. Name: *

ALEX MIRAS

41. Date: *

26/09/2023

View results

Respondent

1 Anonymous

19:43
Time to complete

Your information

1. Name: *

allan john morris

2. Job title: *

consultant gastroenterologist

3. Organisation: *

Greater Glasgow and Clyde

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

British Society of Gastroenterology

6. Nominated/ratified by (if applicable):

BSG as above

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

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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?

   Yes ,Involved in pivotal study of DMR in type II diabetes mellitus (Revita) in 2020

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 currently using technology, may be used in 4-5 centres in UK,slow uptake in UK

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?

- (•) 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?

major variation in clinical practice,usual standard is drug therapy

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?

Likely additional treatment in carefully selected individuals

Current management

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

Diet, oral antidiabetic drugs and Insulin

18. 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

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

Improvement of HBA1C(diabetic control)
reduced hepatic fat/liver fibrosis(Nash)
Weight loss

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

21. 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?

likely highly selected group, difficult to deliver in scale for target population due to need for endoscopy/anaesthetic

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

Dietician, UGI endoscopy/sedation list,Imaging (fluoroscopy) for catheter deployment,post endoscopy day patient or IP ward

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

Definitely needs specific endoscopist and nursing specific training to safely use equipment

Safety and efficacy of the procedure/technology

24. 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

    anaesthesia complication
    Duodenal haemorrhage
    duodenal perforation
    pancreatitis

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

    Improved HBA1c
    hepatic steatosis/fibrosis(fibroscan/MRI)
    BMI

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

    No

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

    generalisability outwith careful dietetics support in clinical trial

28. 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

29. 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.

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

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

Other considerations

32. 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)?

very limited in comparison to target population, <1-3%, limited by endoscopist training and endoscopy facilities available for this indication

33. 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.

As stated

34. 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

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

no

Declarations of interests

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

36. Type of interest: *

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

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

consultancy fees: Fractyl 2020

38. 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

39. Name: *

    allan john morris

40. Date: *

    11/04/2023

View results

Respondent

28 Anonymous

14:02
Time to complete

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

IP1846 Endoscopic duodenal mucosal resurfacing for type 2 diabetes

Your information

2. Name: *

Bu'Hussain Hayee

3. Job title: *

Consultant Gastroenterologist

4. Organisation: *

King's College Hospital NHSFT

5. Email address: *

6. Professional organisation or society membership/affiliation: *

British Society of Gastroenterology

7. Nominated/ratified by (if applicable):

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

4631420

How NICE will use this information:

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

Yes. I have used it in the context of clinical trials leading up to the covid pandemic, but not since

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

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

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

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

This is not currently performed in the NHS outside of clinical trials. Always performed by physician Gastroenterologists/Endoscopists but patients are referred by diabetologists/metabolic medicine specialists.

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

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [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

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

yes

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

Total innovation, no predicate

16. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- (•) The first in a new class of procedure.

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

In addition to standard care

Current management

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

Medical management of type 2 diabetes: oral hypoglycaemics, insulin, GLP1 agonists
Surgical management of type 2 diabetes: gastric bypass

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

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

    no

Potential patient benefits and impact on the health system

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

    not well established in my view; reductions in HbA1C of 1% or thereabouts are helpful but not dramatic

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

    Those on insulin

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

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

    Unclear

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

    High cost: departments require access to endoscopy, general anaesthetic, endoscopist expertise, and fluoroscopy - which most outside of teaching hospitals will not

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

    Yes - but learning curve is not steep

Safety and efficacy of the procedure/technology

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

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

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

    Perforation; Bleeding; abdominal pain

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

Reduction in HbA1C, liver fat, body weight, requirement for insulin, stabilised control of diabetes without a change in medication

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

Uncertain from published literature on magnitude of effect and how applicable this would be to real world uptake

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

Literature is not conclusive at my last assessment

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

- ○ Most or all district general hospitals.
- ○ A minority of hospitals, but at least 10 in the UK.
- ◉ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

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

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

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

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

Other considerations

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

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

Beneficial outcome measures.

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

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

Adverse outcome measures.

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

nausea, vomiting, abdominal pain, bleeding, perforation, ineffective in end-points, stricture (theoretical)

Further comments

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

Uptake will be severely limited by cost of equipment required, the device itself is very high cose, and expertise; At present I am not certain cost-effectiveness is in favour of the device in terms of the magnitude of effect on T2DM

Declarations of interests

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

37. Type of interest: *

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

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

.

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

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

    - (●) I agree
    - ( ) I disagree

Signature

40. Name: *

    Bu'Hussain Hayee

41. Date: *

    27/08/1975

View results

Respondent

29 Anonymous

25:34
Time to complete

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

Interventional Procedures Programme Invitation to act as a professional expert Endoscopic duodenal mucosal resurfacing for type 2 diabetes (IP1846)

Your information

2. Name: *

Cormac Gerard Edward Magee

3. Job title: *

Gastroenterology Registrar (Consultant from October)

4. Organisation: *

University College London Hospitals

5. Email address: *

6. Professional organisation or society membership/affiliation: *

British Society of Gastroenterology

7. Nominated/ratified by (if applicable):

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

7080293

How NICE will use this information:

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

Very familiar. I was a sub-investigator on 2 of the early major clinical trials.

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

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

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

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

Have used, not currently using. It is not used currently in the NHS. I think if approved will likely be realtively small numbers at first but this will increase. I have been involved and will be involved both in the patient selection and perfoming the procedure,

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

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

13. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

Yes

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

Novel approach

16. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- (●) The first in a new class of procedure.

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

Could replace some standard care by getting patients off medications for diabetes.

Current management

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

Typically medical and lifestyle treatment. In patients with obesity, other treatments like surgery may be used but this procedure is not specifically for patients with obesity.

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

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

    No.

Potential patient benefits and impact on the health system

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

    Safe, effective treatment which can improve diabetes control, reduce need for medications including insulin. Reduced concerns re compliance, and reduce complications from Diabetes.

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

    Patients on insulin, or those about to start insulin,.

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

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

    Yes - new pathway of additional endoscopic treatment for diabetes. Improving outcomes and reducing complications would reduce number of hospital visits,.

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

    Performed in endoscopy - can be done where there is endoscopy available with fluoroscopy and anaesthetic support,

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

    Practitioners do need to be trained on the procedure. This can be done via lab initially then with a mentor for cases.

Safety and efficacy of the procedure/technology

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

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

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

Published adverse events - diarrhoea, abdominal pain, throat pain. Mild in nature. Hypoglycaemia related to procedure in one case which may have been related to procedure.
van Baar ACG, Holleman F, Crenier L, et al
Endoscopic duodenal mucosal resurfacing for the treatment of type 2 diabetes mellitus: one year results from the first international, open-label, prospective, multicentre study
Gut 2020;69:295-303.

In initial first in humans trial there were a small number of duodenal stenoses treated with balloon dilation but this has not happened since and likely this is due to changes in the technique. https://www.sciencedirect.com/science/article/pii/S105251571630126X?via%3Dihub

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

Improvement in HbA1c and reduction of medications

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

No concerns.

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

No.

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

- ( ) Most or all district general hospitals.
- ( ) A minority of hospitals, but at least 10 in the UK.
- (•) Fewer than 10 specialist centres in the UK.
- ( ) Cannot predict at present.

Abstracts and ongoing studies

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

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

https://www.fractyl.com/fractyl-health-reports-durable-improvement-in-glucose-control-weight-loss-and-insulin-reduction-in-t2d-patients-using-revita-in-open-label-phase-of-revitalize-1-pivotal-study-at-the-american-d/

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

Unaware of any current trials in the UK

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

n/a

Other considerations

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

hard to tell. Could be 5-10% of all patients witH T2DM.

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

Beneficial outcome measures.

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

Improvements in HbA1c, Improvements in cholesterol and weight. Reduction of medications.
Would need to audit any adverse events or procedure complications.

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

Adverse outcome measures.

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

Pain, device failure.

Further comments

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

None

Declarations of interests

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

37. Type of interest: *

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

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

n/a

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

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

- (●) I agree
- ( ) I disagree

Signature

40. Name: *

Cormac Magee

41. Date: *

31/08/2023

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1846 Endoscopic duodenal mucosal resurfacing for type 2 diabetes**

Your information

Name:	David Hopkins
Job title:	Consultant Physician and Diabetologist
Organisation:	King's College London/ Health & Community Services, Jersey
Email address:	
Professional organisation or society membership/affiliation:	Royal College of Physicians (London) Diabetes UK, ABCD
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	GMC 3242834

How NICE will use this information:

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

x ☐ 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 have gained specific experience of the Revita DMR technology as a clinical researcher. As principal investigator at King's College Hospital I led a research team participating in two clinical trails (Revita 1, open label and Revita 2 sham controlled blinded study). As a diabetologist, I selected patients for these studies and provided ongoing medical management post-procedure. I also directly observed the open label Revita procedures carried out my endoscopist colleague Professor Bu Hayee at King's. In addition to my clinical experience, I have studied the literature surrounding the technology and its scientific background in depth and contributed to the writing groups for the study manuscripts for both studies and contributed to the development of the ongoing Revitalise-1 study. I am not currently involved in any ongoing studies of the technology having moved my clinical base outside of the NHS to Jersey, though I remain linked academically to King's College London. At present the use of the technology in the UK is investigational but it has now entered routine clinical practice in Germany. Once launched in the UK I would anticipate uptake initially in tertiary centres with a strong track record in metabolic disease and gastroenterology/ endoscopy with subsequent spread to additional centres as experience of the technique grows. By the nature of the technology its use will be managed jointly by diabetologists and gastroenterologists working within a multidisciplinary team, with diabetologists managing patient selection and follow up and gastroenterologists supervising the procedure and immediate after care. Additional clinicians participating in the multidisciplinary team would include dietitians and diabetes specialist nurses to support dietary and lifestyle change to maximise the benefit of the technology.

	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 done clinical research on this procedure involving patients. I have published this research.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes, “endoscopic duodenal mucosal resurfacing for type 2 diabetes” is appropriate. The acronym “DMR” is often used for “duodenal mucosal resurfacing”. The DMR procedure is a novel approach to treating T2D which is typically addressed through lifestyle modifications (diet and exercise) or pharmacologic intervention (anti-diabetic medications or insulin). Currently, the Revita DMR System is the only CE Marked device to perform this procedure. The first in a new class of procedure.
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?	Lifestyle modifications (i.e., diet and exercise) is the first recommendation for preventing progression of T2D followed by pharmacological intervention (i.e., anti-diabetic medication or insulin). Currently, DMR is not intended to replace diet and exercise, but is intended to be used as an adjunct to diet and exercise. Past studies have demonstrated the DMR procedure’s ability to reduce HbA1c and aid in glycaemic control among patients with T2D.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	Since the Revita DMR System was first CE Marked in 2016 there have not been any substantial modifications to the procedure technique or device. Prior to 2016, the procedure involved the use of a dual catheter system, however the functionality of the 2 catheters were combined into the

	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	single catheter used today. Since CE Marking, only minor changes to improve procedure efficiency (i.e., catheter trackability, guidewire use, etc.) have been made. No guidance on the Revita DMR System or DMR procedure have been published to date. Clinical studies including RCT have been performed on patients using oral diabetes medications and insulin. Additional clinical studies of the Revita DMR System are on-going.

Current management

6	Please describe the current standard of care that is used in the NHS.	The NICE Guidance for the care and management of T2D in adults provides recommendations on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications. Individualized and ongoing nutritional advice should be received from a healthcare professional with specific expertise and competencies in nutrition. Adults with T2D should be encouraged to follow the same healthy eating advice as the general population. It is recommended to integrate dietary advice with a personalized diabetes management plan, including other aspects of lifestyle modification such as increasing physical activity and losing weight. The guidance recommends a differential approach to the choice of glycemic targets in patients with T2D based on their current stage of management. For adults whose T2D is managed either by lifestyle and diet, or lifestyle and diet combined with a single drug not associated with hypoglycemia, the glycemic target should be an HbA1c level of 6.5% (48 mmol/mol). For adults on a drug associated with hypoglycemia, the glycemic target should be an HbA1c level of 7.0% (53 mmol/mol). In adults with T2D, if HbA1c levels are not adequately controlled by a single drug and rise to 7.5% (58 mmol/mol) or higher, further reinforced advice about diet, lifestyle and adherence to drug treatment; support for the patient to aim for an HbA1c level of 7.0% (53 mmol/mol) and intensification of drug treatment are recommended. Special considerations on relaxing the target HbA1c level on a case-by-case basis should be considered for adults with T2D, with special attention for people who are older or more frail. NICE Guidance recommendations that the choice of drug treatments should be based on the person's individual clinical circumstances (e.g., comorbidities, contraindications, weight and risks from polypharmacy), the person's individual preferences and needs, the effectiveness of the drug treatments in terms of metabolic response and CV and renal protection, safety and tolerability of the drug treatment, monitoring requirements, the licensed indications or combinations available

		and cost. The first-line drug for adults with T2D is metformin. Based on the CV risk assessment if patients with T2D: 1) have chronic HF or established ASCVD, an SGLT-2 inhibitor with proven CV benefit in addition to metformin should be offered and 2) are at high risk of developing CVD, an SGLT-2 inhibitor with proven CV benefit in addition to metformin should be considered. However, before starting an SGLT-2 inhibitor, a patient should be checked for an increased risk of diabetic ketoacidosis (DKA). If further interventions are needed to control HbA1c, a DPP-4 inhibitor, pioglitazone, sulfonylurea (SU) or SGLT-2 inhibitor suitable for combination therapy should be added. If dual therapy with metformin and another oral drug has not continued to control HbA1c to below the person's individually agreed threshold for further intervention, triple therapy or starting insulin-based treatments should be considered. If triple therapy with metformin and 2 other oral drugs is not effective, not tolerated or contraindicated, one drug in triple therapy can be switched for a GLP-1 mimetic for adults with T2D who 1) have a BMI ≥35 kg/m2 or higher (should be adjusted accordingly for people from Black, Asian and other minority ethnic groups) and specific psychological or other medical problems associated with obesity or 2) have a BMI <35 kg/m2 and for whom insulin therapy would have significant occupational implications or weight loss would benefit other significant obesity-related comorbidities.
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?	Duodenal mucosal resurfacing is a unique treatment modality and there is no direct comparator technology in use in clinical practice in the United Kingdom. The closest comparator in the clinical pathway for type 2 diabetes is metabolic (bariatric) surgical procedures such as Roux-en-Y gastric bypass (RYGB); these procedures provided some of the initial inspiration into the mechanisms of action associated with the DMR procedure. Recommendations on bariatric surgery for people with early (<10-years from diagnosis) diabetes are summarized in the NICE Guidance on obesity with a recommendation that people with diabetes with a BMI ≥35 should be offered an expedited assessment for bariatric surgery. Short-term studies (1 to 2 years) show that patients with T2D who undergo bariatric surgery lose more weight and have better blood glucose control than those managed with conventional diabetes treatment regimes. Duodenal mucosal resurfacing is intended to mimic the benefits of bypassing the duodenum observed in subjects with T2D who receive RYGB, but in a way which may be safer (minimally invasive versus surgical procedure) and more accessible to a larger patient population (including patients with a lower BMI), thus making the DMR procedure more scalable in routine clinical practice.

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?	The primary benefit of DMR is improved glycaemic control through reduction in HbA1c which has been demonstrated in multiple studies. Additionally, DMR has the benefit of not relying on patient adherence to achieve its primary clinical benefit, unlike pharmacotherapy. DMR is also associated with a reduction in liver fat deposition in patients with type 2 diabetes and may thus impact on the natural history of hepatic steatosis and non-alcoholic fatty liver disease which is emerging as an important complication of type 2 diabetes with significant impact on public health. It is anticipated that DMR may have impact on other diabetes complications through improvements in insulin resistance and glycaemic control and this is supported by mechanistic data from clinical studies though in view of the relatively short history of the technology long-term endpoint data on efficacy at reducing complications are not yet available. Other potential benefits, which have yet to be confirmed through clinical studies, may be those benefits that come with a reduced HbA1c.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients whose diabetes is poorly controlled despite oral and/or injectable glucose lowering medications and/or long-acting insulin therapy are those who could benefit from using this procedure. Evidence from the clinical trial programme has indicated some subgorups who may be expected to have the best response to treatment particularly those with more marked insulin resistance, higher fasting glucose and relatively preserved insulin secretion
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?	Yes. Duodenal mucosal resurfacing has the potential to reduce HbA1c and help patients achieve glycaemic control while not relying on patient adherence to achieve its clinical benefit. In some cases DMR will enable a de-escalation of treatment with current research focusing on the potential to withdraw insulin. As an endoscopic procedure DRM is less invasive than RYGB surgery and may provide similar benefits in terms of impact on metabolic parameters. Furthermore, the procedure provides a minimally invasive alternative to RYGB.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The Revita DMR System has been designed to be used in a standard endoscopy suite enabled with fluoroscopy. No changes to the endoscopy suite are required to perform the DMR procedure.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, as DMR is a novel procedure, all endoscopy teams (typically composed of an endoscopist, and 2 assistants) require a specific short training to perform the DMR procedure.

Safety and efficacy of the procedure/technology

13 What are the potential harms of the procedure/technology?

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

Adverse events reported in the literature (if possible, please cite literature)

Anecdotal adverse events (known from experience)

Theoretical adverse events

The DMR procedure has demonstrated an excellent safety record in clinical trials. As an endoscopic procedure there are some generic risks that are associated with endoscopy such as potential for dental injury and some specific risks such as stricture formation following duodenal ablation but in practice these have been rare and the latte only observed with the early dual catheter system that has now been replced with refinement of the technology..

From clinical data, the follow rates of AEs have been observed:

Total number of patients: 174*	**Procedure-and Device-Related AEs**		**Only Procedure-related AEs**	
	# of Events**	**%(n/N) of Pts**	**# of Events****	**%(n/N) of Pts**
GI disorders	28	16.1%	92	52.9%
General disorders and administration site conditions	3	1.7%	12	6.9%
Injury, poisoning and procedural complications	2	1.1%	4	2.3%
Metabolism and nutrition disorders	1	0.6%	86***	49.4%
Nervous system disorders	1	0.6%	6	3.4%
Respiratory, thoracic and mediastinal disorders	3	1.7%	8	4.6%
Vascular disorders	1	0.6%	0	0.0%

*Single catheter only.

**Most events have been mild and transient in nature, only 12 (6.2%) procedure-related events (0 device-related) have been serious adverse events across all Revita DMR studies (n=5, range=0-11.8%).

***The events in this category are predominantly mild hypoglycaemic events, including many asymptomatic episodes identified by blood glucose testing. The majority of reported hypoglycemia cases in the Revita-procedure trials were reported 30 days or more post-procedure and most of them come from a single Brazilian study site in the Revita-2 study. A particular local factor was high use of sulfonylurea medication which carries a higher risk of hypoglycaemia than other oral agents. Overall, most hypoglycemia cases across the Revita-procedure studies have been mild with only one SAE of hypoglycemia reported (1/174; 0.6%).

		No additional (serious or non-serious) hypoglycemia events were reported for this subject for the remainder of the study.
14	Please list the key efficacy outcomes for this procedure/technology?	Glycaemic improvement measured by reduction in HbA1c. Change in requirement for additional dibetes treatments.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	To date studies have shown durability of glycaemic improvement out to 24 months, but it is unclear exactly how long the benefit will last beyond this. It is likely that the long-term benefit will be related to patient factors including lifestyle factors and weight management and it is anticipated that the benefits will be prolonged in those where effective lifestyle modification is achieved alongside the treatment.. As noted above, the safety record of the technology is excellent when used in appropriate patients. •
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	None
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. ~~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

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	All relevant literature including abstracs should be available in a comprehensive search. Initial open label date from the Revitalsie trial programme was presented at the American Diabetes Association Scientific Sessions in 2023 and the Abstract available in a supplement to the journa Diabetes. (https://diabetesjournals.org/diabetes/article/72/Supplement_1/824-P/150693/824-P-Glycemic-Improvement-Insulin-Reductions-and?searchresult=1)

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yes: 1. The Revitalize-1 Study is a prospective, randomized, double-blind, sham-controlled, multi-center pivotal study to evaluate the efficacy and safety of duodenal mucosal resurfacing using the Revita System in subjects with T2D on insulin therapy., 2. A real-world registry of subjects with T2D who are inadequately controlled on insulin therapy and receive the DMR procedure is underway and enrolling patients treated in routine clinical practice in Germany
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	According to NICE Guidance, in 2019 approximately 3.2 million adults in the UK had diabetes, about 90% of which accounted for T2D. Fractyl suspects that 20% of T2D individuals are on multiple agents and still inadequately controlled, and these individuals would be candidates for a DMR procedure.
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.	1. HbA1c – primary measure of impact on glucose control. Potential for use to assess impact at 6 months and over long-term (Current published data to 24 months) 2. Biometric parameters, Weight, BMI and blood pressure 3. Changes in Liver enzymes – 3 – 12 months post-procedure 4. Generic and diabetes specific quality of life measures (e.g EQ5D, SF 36, DSQoL) and treatment satisfactions measures (DTSQc) pre and 6 month post-procedure.

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: Early complications: measured from time of procedure to 24 hours post procedure. Late complications: measured 24 hours to 24 months post procedure.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	The DMR technology has been effectively studied in the developmental clinical trial programme to date and has now reached a level of maturity making it suitable for wider use in routine clinical practice. Further long-term data from real world registries will be helpful in determining its full potential in diabetes management.

NICE National Institute for Health and Care Excellence

Declarations of interests

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

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

No relevant conflicts of interest in last 12 months – my only current affiliation with a company in the med tech space is with My Sugar Watch (Jersey) whose interests are restricted to glucose sensing technology only.

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:	**David Hopkins**
Dated:	**9th October 2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1846 Endoscopic duodenal mucosal resurfacing for type 2 diabetes**

Your information

Name:	Rehan Haidry
Job title:	Consultant Gastroenterologist
Organisation:	University College London Hospitals / Cleveland Clinic London
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Society of Gastroenterology
Nominated/ratified by (if applicable):	British Society of Gastroenterology
Registration number (e.g. GMC, NMC, HCPC)	6028603

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.

☒ 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	Endoscopic duodenal mucosal resurfacing (DMR) is a novel minimally invasive endoscopic procedure, which selectively ablates the duodenal mucosa, this has been associated with durable improvements in insulin sensitivity and metabolic parameters in patient with type 2 diabetes (T2D). I have a good knowledge of the procedure, its risk/benefit, and potential role within T2D management as I have been involved in the procedural development, initial implementation in the clinical setting as well as evaluation of safety and efficacy of DMR in the context of multicentre international studies and as such I have been performing DMR since then. DMR is not widely used in the NHS, at present, it has been predominantly performed in tertiary academic centres by advanced upper GI interventional endoscopists with an interest in metabolic endoscopy and in close collaboration with diabetologist. Those endoscopists using the Revita DMR technology need to have advanced endoscopic skills including fluoroscopy as well as specific training in the hydrothermal ablation device including placement and handling of the catheter using a guidewire, which sometimes may be challenging in particular in the horizontal part of the duodenum. However, the training curve for expert upper GI endoscopist might be small with proficiency in about 15-20 cases. Patient selection and indication to appropriate intervention for diabetes management will be aided by MDT including a diabetologists to ensure that patients are aware of all the possible treatment

	procedure/technology, please indicate your experience with it.	options available to them and to get appropriate individualised care and follow-up. Within the gastroenterology community there is significant interest in metabolic and bariatric endoscopy and the use of the device, and this would lead to a rapid uptake across the country, including integration into advanced endoscopy training programmes.
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 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 (please comment) I have been actively involved in DMR research, evaluated Revita DMR safety and efficacy in the context of international multicentre study, published those results and acted as a primary supervisor to several doctoral student studying metabolic endoscopy. I am also actively involved in the development of devices and alternative technique for duodenal mucosal ablation.
3	Does the title adequately reflect the procedure? 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 title describes the procedure adequately, however, some evidence suggests that DMR improves glycaemic parameters as well as hepatic parameters and it is associated with a positive effect on multiple parameters of cardiovascular health, hence, duodenal mucosa ablation followed by mucosal regeneration could be used in several dysmetabolic conditions. Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

	Which of the following best describes the procedure (please choose one):	Definitely novel and of uncertain safety and efficacy. **The first in a new class of procedure.**
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?	Diabetes is a complex and chronic condition, there is no one treatment that is the most effective and often diabetes management involves a combination of several approaches and medications. Despite this glycaemic control remains suboptimal in several patients and new treatments including drugs, endoscopic and surgical interventions could complement current standard of care and need to be taken into account and used according to level of efficacy side-effects and of course patient preference. DMR has demonstrated a beneficial glycaemic and hepatic metabolic effects among patients with type 2 diabetes and it might be a valuable adjunct to be used in combination with current standard of care potentially reducing the need of other pharmacological interventions.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	During DMR development it has been noted that longer segment of duodenal ablation length had better outcome hence a complete DMR is now considered to be ≥ 9 cm. A novel catheter has been implemented as well. The novel catheter integrated submucosal lift and hydrothermal ablation functions. eliminating the need for catheter exchanges during the procedure and helped ensure that ablation was performed immediately after submucosal lift of the same segment of duodenum. DMR has also recently been combined with a glucagon-like peptide-1 receptor agonist (GLP-1RA), resulting in discontinuation of exogenous insulin treatment in 69% of patients with insulin dependent type 2 diabetes mellitus (T2DM) in the INSPIRE study.

Current management

6	Please describe the current standard of care that is used in the NHS.	Management of diabetes is complex and has to be individualised and tailored to the need and circumstances of each patient taking into account their preference and concomitant morbidity. Generally speaking, patient education, dietary and lifestyles measures are the foundation of the care together with oral drug treatment and insulin-based treatment have been the core or the

		treatment, however guidelines are now recommending considering to combine this intervention with bariatric surgery and GLP-1 mimetic for adults with type 2 diabetes and have high BMI.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	There is not an endoscopic procedure that selectively targeting the duodenal mucosa available on the NHS. Historically duodenal bypass liners have been used with good metabolic outcomes however there were abandoned due to implant-related adverse effect.

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?	DMR might offer a minimal invasive to promote improved metabolic response, this might offset the requirement of medication and insulin improving quality of life and potentially disease outcome.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patient with a poor glycaemic control despite oral and insulin treatment as an adjunct or substitute to drug therapy.
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?	Yes. Patients could be given an endoscopic option as a treatment for diabetes and dysmetabolic conditions as an alternative to bariatric surgery. In addition, this could be an alternative or complement to drug therapy. Compared to bariatric surgery, DMR is safer, quicker, more cost-effective and associated with shorter hospital stay (theoretically patients could be discharged the same day). It would also widen the access to diabetes treatments.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The procedure can be performed within an endoscopic unit that can perform fluoroscopic assisted advanced endoscopic procedures under general anaesthesia these are usually commonly practice in tertiary hospitals. Additional dedicated training will be needed to master hydrothermal device.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Endoscopist performing advanced endoscopic procedure would need to be trained to perform this procedure. Proficiency will be expected after about a few procedures. The adverse events that can occur in relation to the procedure are the same as those with any advanced endoscopist procedure, so endoscopists would already be trained on how to deal with these scenarios.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology?	Potential adverse events from DMR: - Abdominal discomfort - Cramping, pain

	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	- Diarrrhoea - Difficulty swallowing - Mucosal injury to gastrointestinal tract - Perforation - Sore throat - Stricture - Bleeding - Abscess formation - Hypoglycaemic events - Pancreatitis These are similar risks to any advanced endoscopic procedure within the upper GI tract (e.g. duodenoscopy, endoscopic ultrasound, stent placement). Specific risks unique to the device could include: - Allergic reaction to the device materials - Device dysfunction - Disarticulation of component from the device - Device/component lost in GI tract or wall - Puncture damage to surrounding structures (e.g. liver, pancreas A prospective, single-arm, open-label, multicentre study of DMR feasibility, safety, and efficacy in patients with type 2 diabetes (REVITA-1) documented no device or procedure related serious adverse events, unanticipated device effects, or hypoglycaemic events between 12 and 24 months post-DMR.

14	Please list the key efficacy outcomes for this procedure/technology?	Primary: Reduction in HbA1c Secondary: Reduction in use of diabetic medications, reduction in diabetes related co morbidities, reduction in dysmetabolic indicators
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	DMR has shown acceptable safety profile and efficacy, however in a recent study DMR has shown to be less effective in a Brazilian cohort, further study is ongoing to evaluate its effectives further.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The long-term effect and efficacy of the procedure remain unclear however so far a positive effect seems to persist with improvements in insulin sensitivity and multiple downstream metabolic parameters through 24 months post-treatment.
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. **A minority of hospitals, but at least 10 in the UK.** **(Any tertiary hospital performing advanced endoscopic procedure in the upper GI tract could perform the procedure).** Fewer than 10 specialist centres in the UK. Cannot predict at present.

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	n/a

	comprehensive reference list but it will help 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.	Evaluation of the Efficacy and Safety of Duodenal Mucosal Resurfacing Using the Revita® System in Subjects With Type 2 Diabetes on Insulin Therapy (REVITALIZE 1) Revitalize-1 is a prospective, randomized, double-blind, crossover, sham-controlled study that is expected to enroll more than 500 patients across 35 sites in the United States and Europe. Is enrolling patients whose type 2 diabetes is uncontrolled by long-acting insulin therapy. Revitalize-1 will assess the potential of DMR treatment to improve blood sugar control and help to eliminate patients' need for long-acting insulin. (NCT #04419779).
20	Please list any other data (published and/or unpublished) that you would like to share.	n/a

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)?	Potentially any patient with type 2 diabetes with suboptimal glycaemic despite oral and insulin therapy that no contraindications to the procedure might be evaluated.
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.	Beneficial outcome measures: - Reduction in HbA1c (blood test – 6 months, 1, 3, 5-years) - Reduction in NAFLD risk scores (e.g. FIB-4; blood tests – 6 months, 1, 3, 5 years) - Reduction in Hepatic fibrosis (e.g. Fibroscan; transient elastography – 6 months, 1, 3, 5-years) - Reduction in systolic/diastolic BP (BP reading – 6 months, 1, 3, 5 years) - Reduction in use of diabetic medications (no. of medications – 6 months, 1, 3, 5 years) - Reduction in use of blood pressure medications (no. of medications – 6 months, 1, 3, 5 years)

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: - Incidence of peri-procedural and 3-day risk of bleeding, perforation, infection, need for re-intervention (endoscopy), need for surgery, readmission, length of hospital stay, mortality. - Incidence of suboptimal glycaemic control (i.e. hypoglycaemia and hyperglycaemia) - Incidence of duodenal stenosis

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	n/a

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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.			

☒ 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:	**Rehan Haidry**
Dated:	**18/04/2024**