NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **Low energy contact X-ray brachytherapy (the Papillon technique) for rectal cancer (IP1724/2)**

Your information

Name:	Dr Alexandra Stewart
Job title:	Consultant Clinical Oncologist
Organisation:	Royal Surrey County Hospital NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Radiologists, GEC ESTRO (Chair of GI GEC working group)
Nominated/ratified by (if applicable):	Royal College of Radiologists, GEC ESTRO
Registration number (e.g. GMC, NMC, HCPC)	4424011

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consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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 very familiar with the procedure/technology-contact X-Ray Brachytherapy (CXB). I have been using CXB since April 2014 and have treated over 500 patients. I led the GEC ESTRO guidelines for CXB and developed and participated in the OPERA trial. There are 4 sites in the UK that treat using CXB-Clatterbridge (Liverpool), Hull, Nottingham and Guildford. Several sites are preparing to deliver CXB including Swansea, Colchester, St Bartholomew's, London and the Royal Free Hospital. Further sites are interested in developing CXB. In all sites the Clinical Oncologists are leading the procedure, in some they are supported by Consultant Colorectal surgeons.

	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 or healthy volunteers. I have published this research.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. Does this have a multi-indication? 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 This is potentially a wider remit than other recommendations which were split for early and advanced rectal cancer, without specifics as to what these were and when they were assessed which added confusion to previous recommendations The machine used for CXB can be used in other areas of the body however, this recommendation is specifically regarding rectal cancer. This is an established treatment which has been is use for many years in the UK and has a wide range of publications supporting its use-both retrospective and prospective series and 2 randomised trials. However, its use is limited to a very small number of centres and therefore there are a number of centres in the country that won't be referring patients for it when it would be appropriate and for others patients may have long distances to travel to access treatment. It is under-utilised within the UK and a better strategy of treating centres and referral centres is required. Established practice and no longer new.
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?	This treatment should be standard of care for relevant cancers in centres where it currently isn't.

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?	There has been an updated treatment machine (the P+) since the last guidance was issued. There are small differences in applicator design and treatment delivery but the treating concept is the same. The evidence base has changed since the publication of the guidance for early rectal cancer. The OPERA trial has been published giving randomised evidence for the use of a CXB boost. The OPRA trial gives randomised evidence for the sequencing of radiotherapy and chemotherapy for rectal cancer. There are several publications using the Guildford database showing multi-centre prospective outcomes for different treatment cohorts such as short course radiotherapy or sole CXB treatment and post-operative patients.

Current management

6	Please describe the current standard of care that is used in the NHS.	The standard of care with the lowest risk of recurrence in surgically fit patients is surgical excision of the rectum. However organ preservation is offered in place of a permanent stoma or for patients with higher health risks from surgery. When organ preservation is offered in surgically fit patients the OPERA trial shows us that it should be chemoradiotherapy plus a CXB boost. In less fit patients the Lyon trial showed us that external beam radiotherapy and a CXB boost is safe and efficacious. In reirradiated or post operative patients, prospective series indicate that CXB should be considered. This is standard of care in the 4 centres using CXB and in some referring centres but use throughout the UK is inconsistent.

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?	HDR brachytherapy using a flexible silicone applicator with 8 channels can be used to deliver a localised brachytherapy boost. It is slightly less precise than CXB and delivers more dose to surrounding tissues than CXB. There is also not as much randomised evidence for the use of HDR brachytherapy. However, many sites have access to the HDR brachytherapy machine unlike the CXB machine.

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?	Patients may have a better quality of life without a permanent stoma and for less fit patients there will be health benefits to the avoidance of surgery. Patients value the opportunity to have a choice about the treatment that will suit them the best.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	This is most beneficial in patients with tumours 6cm or less from the anal verge and for elderly patients, especially those with co-morbidities.
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, the CXB technology has potential to avoid surgery in patients, published economic analysis has demonstrated that using CXB in place of surgery decreases the costs to the NHS.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	There need to be more CXB machines in the UK. I would recommend supra-networks with one machine serving several cancer centres. There should be a combined MDT for rectal cancers to be discussed so that CXB is considered in a larger variety of cases.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training is required for all the members of the team-in the radiotherapy department this is the clinical oncologists, the physicists and the radiographers. As part of the wider multi-disciplinary team the surgeons and radiologists need training and support for the assessment of response and surveillance.

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:	During or immediately after the procedure there may be pain and tenesmus but this is usually managed with over the counter remedies if anything. In the longer term, this procedure carries a risk of rectal bleeding, this is up to 30%. Approximately 8% of patients may require argon plasma coagulation to treat this. There may be a painless ulcer in the rectum which could take several months to heal. Bowel function appears to be the same for patients receiving an external beam radiotherapy boost compared to a CXB boost.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	The rate of organ preservation (stoma free survival), disease free survival, overall survival. Quality of life outcomes.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	I feel that the OPERA trial has shown us the efficacy and safety of this procedure. Patients that undergo organ preservation using radiotherapy may have a higher surgical toxicity if surgery is required than patients who have not have radiotherapy. This does not seem to be increased by CXB (as per OPERA) but is general to organ preservation using radiotherapy.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	There are groups who do not believe in the efficacy of CXB, however the OPERA trial shows proven efficacy.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. -more to cover the approx. 60 cancer centres in the UK about 20 machines would be required.

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	2 important publications: Baron D, Pace Loscos T, Schiappa R, Barbet N, Dost E, Ben Dhia S, Soltani S, Mineur L, Martel I, Horn S, Picardi C, Stewart A, Cotte E, Coquard R, Baudin G, Evesque L, Dhadda A, Sun Myint A, Gérard JP, Doyen J; ICONE group.. A phase III randomized trial on the addition of a contact x-ray brachytherapy boost to standard neoadjuvant chemo-radiotherapy for organ preservation in early rectal adenocarcinoma: 5 year results of the OPERA trial. Ann Onc 2025 36(2), 208-215

	comprehensive reference list but it will help us if you list any that you think are particularly important.	Stewart AJ, Van Limbergen EJ, Gerard J-P, Appelt AL, Verhaegen F, Berbee M, Vuong T, Brooker C, Rockall T, Sun Myint A. GEC ESTRO ACROP consensus recommendations for contact brachytherapy for rectal cancer. Clin Transl Radiat Oncol. 2020 33; 15-22 C Rao, A Stewart, AP Martin, B Collins, DM Pritchard, T Athanasiou, A Sun Myint. Contact X-ray brachytherapy as an adjunct to a watch and wait approach is an affordable alternative to standard surgical management of rectal cancer for patients with a partial clinical response to chemoradiotherapy. Clin Oncol. 2018 30(10):625-633.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	The TRESOR trial in France-currently recruiting. The CITRuS trial-completed recruitment, in follow up. The Guildford database-free to use, encouraged in all UK centres.
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)?	Rates of use in Guildford have increased nearly 700% comparing 2019 number to 2024. A continuing rise is unsustainable in one centre and it is important that more centres can deliver this. I would estimate that 20 centres across the country could treat about 50 patients per annum which would be economically viable and sustainable.
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: Local control, disease free survival, overall survival-at 3 years and 5 years. Quality of life-specifically with EORTC questionnaires, the CITRuS trial is assessing electronic delivery of PROMs and CITRuS 2 will assess automatic delivery of interventions to improve quality of life. Adverse outcome measures: Rate of rectal bleeding. Rate of local regrowth. Surgical complication rates. Surveillance should continue for 5 years.

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

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Further research is required. There is a new trial using immunotherapy in development, plus one comparing CXB with local excision. A PROMs trail (CITRuS2) is in development with a randomised trial (CITRuS3) to follow. The biggest challenge for these trials is funding which should be encouraged

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
Direct - financial	Honoraria for lecturing from Elekta 2025, 2024, 2019	**Aug 2019**	**Jan 2025**
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:	**Alexandra Stewart**
Dated:	**24/2/2025**

View results

Respondent

25 Anonymous

17:02
Time to complete

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

IP1724 Low-energy contact X-ray brachytherapy (the Papillon technique)

Your information

2. Name: *

Alexander Valdman

3. Job title: *

rediation oncologist

4. Organisation: *

Karolinska university hospital

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

ESTRO, ICONE, EPTN

7. Nominated/ratified by (if applicable):

prof. Sun Myint

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

?

How NICE will use this information:

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

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

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 inform ation 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. Completed the Papillon course in Clatterbridge
My institution is currently purchasing the equipment for Low-energy contact X-ray brachytherapy

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.

Planning to use as soon as the equipment is installed at out institution
Planning a separate clinical trial

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

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

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

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

well established procedure. Several decades of clinical practice

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?

yes. Many patients treated with upfront surgery could be subjected to this procedure

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

Procedure is largely unchanged

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

Yes. The Phase 3 randomized OPERA trial

20. Do you think the guidance needs updating?

yes

Current management

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

not a NNS person

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

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

no

Potential patient benefits and impact on the health system

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

avoiding major surgery and a stoma

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

young and fit patients who wish to avoid surgery

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

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

    Yes. The procedure is much less invasive compared to surgery. It is also significantly cheaper

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

    can be easily installed at any facility

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

    yes. Theoretical and practical training is needed

Safety and efficacy of the procedure/technology

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

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

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

    OPERA trial summarizes these. Proctitis, rectal bleedings. These are usually transient.

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

OPERA trial. 81% are free from surgery after 3 years of follow up. In patients with tumors less that 3 cm this number is impressive 97%

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

the procedure is very effective

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

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

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

Abstracts and ongoing studies

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

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

    OPERA trial

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

    OPAXX, TRESOR

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

Other considerations

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

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

    Beneficial outcome measures.

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

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

    Adverse outcome measures.

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

Further comments

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

    In Sweden, we are very keen on implementing this technology into clinical practice.

Declarations of interests

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

40. Type of interest: *

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

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

nothing to declare

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

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

- (•) I agree
- ( ) I disagree

Signature

43. Name: *

Alexander Valdman

44. Date: *

05/02/2024

View results

Respondent

70 Anonymous

13:15
Time to complete

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

Low energy contact X-ray brachytherapy (the Papillon technique) for rectal cancer (IP1724/2)

Your information

2. Name: *

Alexandra Gilbert

3. Job title: *

Associate Professor and Honorary Consultant in Clinical Oncology

4. Organisation: *

University of Leeds

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

FRCR

7. Nominated/ratified by (if applicable):

RCR

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

6149156

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

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

10. 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.

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

Are you familiar with the procedure/technology?

Yes. We will often refer our patients for this treatment.

12. 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.

Referral to others. Not currently available in our centre.

13. 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.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [x] Clinical trials in organ preservation.

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

Yes

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

Organ preservation isn't current standard of care. However, results from RCT STARTREC will be presented in May 2025 and this will change practice. Papillon is an alternative option rather than local excision.

17. 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.

18. 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.

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

No

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

Increased evidence of efficacy

21. Do you think the guidance needs updating?

Yes - to include RCT OPERA trial data.

Current management

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

Surgery for early rectal cancer.

23. 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?

HDR brachytherapy, local excision

Potential patient benefits and impact on the health system

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

No need for GA

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

Frailer patients and those wishing for organ preservation

26. 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

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

N/A in centres which already have this equipment

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

Yes

Safety and efficacy of the procedure/technology

29. 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

AEs are relatively minor. Mild GI symptoms and rectal bleeding

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

Improved Organ preservation rates

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

N/A

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

N/A

33. 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

34. 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.

    OPERA RCT

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

    OPERA - recently reported

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

Other considerations

37. 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)?

    early rectal cancer patients
    Frailer patients not suitable for surgery

38. 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.

    LRF
    Acute and late toxicity
    QOL - EORTC C30 and CR29

39. 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:

    Up to 2-3 years

Further comments

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

    Needs involvement of endoscopist as well as clinical oncologist at time of procedure which requires coordination.

Declarations of interests

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

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

n/a

43. 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

44. Name: *

Alexandra Gilbert

45. Date: *

09/02/2025

View results

Respondent

28 Anonymous

27:58
Time to complete

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

IP1724

Your information

2. Name: *

An-Sofie Verrijssen

3. Job title: *

Radiation Oncologist

4. Organisation: *

Catharina Hospital (Eindhoven, Netherlands)

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

ESTRO, ICONE

7. Nominated/ratified by (if applicable):

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

NA (Registered in the Netherlands)

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 informa tion 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 perform the procedure myself.

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

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

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

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

    It is used in our hospital for rectal cancer only.

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.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

Yes

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

I consider it a renaissance of a technique used in the past but now in the concept of organ preservation it can provide more patients with an organ preservation trajectory and is thereby innovative.

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 my opinion it would be an addition to existing standard care. There is not enough data on the use of CXB for locally advanced rectal cancer. In the Netherlands we are conducting the OPAXX trial which includes CXB as one of the treatment arms for patients (including some patients with locally advanced rectal cancer) with a near complete response after radiotherapy. In my opinion there is limited value of CXB in the setting of the very ugly tumors.

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

Not really. We hope to be able to use a slanted applicator in the future.

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

Yes, the OPERA trial has been published, but this did not include patients with locally advanced rectal cancer.

20. Do you think the guidance needs updating?

Yes.

Current management

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

I'm not quite sure as I don't live and work in the UK. In the Netherlands, standard of care for locally advanced rectal cancer is neoadjuvant chemoradiation followed by restaging after 6-8 weeks, followed by resection. In the case of a complete response, watch and wait can be offered.

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

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

No,

Potential patient benefits and impact on the health system

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

Increased local control, increased organ preservation

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

For patients with locally advanced rectal cancer: Patients with a good response after chemoradiation and normalization of pathological lymph nodes
For patients with early rectal cancer: Like OPERA trial

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

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

    Yes, if major surgery can be prevented.

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

    Very few as it concerns low energy x rays.

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

    Yes, the technique has to be taught and a certain level of experience is necessary

Safety and efficacy of the procedure/technology

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

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

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

    Rectal bleeding
    Proctitis
    Pain from ulcer

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

Clinical complete response, organ preservation rate

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

Treatment of T3-T4 tumors --> chance of long-term perforation of the rectal wall?

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

Not in my opinion

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

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

Abstracts and ongoing studies

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

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

    OPERA
    Publications by Gerard, Dhadda, Sun Myint, Stewart

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

    OPAXX (NL)

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

    I am currently keeping track of our treated patients in Eindhoven and plan to publish this data at a certain point

Other considerations

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

    Difficult to say, dependent on the number of centers who perform the intervention

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

    Beneficial outcome measures.

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

    Clinical complete response, organ preservation, quality of life

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

    Adverse outcome measures.

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

    Grade 3 complications (according to CTCAE)

Further comments

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

    none

Declarations of interests

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

40. Type of interest: *

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

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

none, other than the fact that I perform the procedure

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

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

- (●) I agree
- ( ) I disagree

Signature

43. Name: *

An-Sofie Verrijssen

44. Date: *

07/02/2024

View results

Respondent

23 Anonymous

94:30

Time to complete

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

IP1724 Low-energy contact X-ray brachytherapy (the Papillon technique) for locally advanced rectal cancer

Your information

2. Name: *

Chris Rao

3. Job title: *

Consultant Colorectal Surgeon

4. Organisation: *

North Cumbria Integrated Care NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

ACPGBI

7. Nominated/ratified by (if applicable):

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

GMC: 6148953

How NICE will use this information:

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

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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 informa tion about the procedure/technology and/or your experience.

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

    Are you familiar with the procedure/technology?

I manage patients with rectal cancer. I frequently refer patients for CXB. I then have primary responsibility for monitoring response and performing salvage surgery in patients who do not have a response/ have tumour regrowth.
In addition to my clinical interest in this technology I have for several years been investigating the clinical and cost-effectiveness of this technology relative to surgery and other organ preserving strategies

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

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

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

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

-I refer patients with rectal cancer every couple of weeks to the Clatterbridge Cancer Centre for treatment.
-I am aware that there are currently 5 UK centres with several other centres at an advanced stage of developing business plans
-Management of patients with rectal cancer is multi-disciplinary, the procedure is primarily undertaken by radiation (clinical) oncologists however in several centres this is in close collaboration/ joint procedure with surgeons. I am not familiar with the use of this technology in other tumour groups apparat from rectal cancer.
-I manage patients with rectal cancer. I frequently refer patients for CXB. I then have primary responsibility for monitoring response and performing salvage surgery in patients who do not have a response/ have tumour regrowth. We have a fairly large cohort of such patients in my institution.
-In addition to my clinical interest in this technology I have for several years been investigating the clinical and cost effectiveness of this technology relative to surgery and other organ preserving strategies. I have published extensively in this field.

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

I think locally advanced needs to be defined in terms of TMN staging as this means different things to different cancer clinicians. I also don't think it reflects all of the contexts where this technology can be used.

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?

Whilst organ preservation was controversial way to manage rectal cancer relatively recently, there is now an increasing acceptance that this is something that should be discussed with patients who have a clinical complete response or near clinical complete response. CXB is a very useful adjunct to an organ preservation approach improving but the rate and durability of a clinical complete response.

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?

Management of rectal cancer is becoming increasing individualised. For many patient groups it has the potential to replace current standard of care. It is of particular interest for patients with T2-3 low rectal cancers. Traditionally used for elderly, co-morbid and stoma averse, for small low rectal cancers it has the potential to move beyond traditional applications

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

Patient selection and follow-up has become better refined but the technology has remained largely constant

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

The OPERA randomised trial represents a significant change in the evidence base on CXB. Alongside the main trial surgical outcomes have also been published for salvage surgery and an economic analysis performed by HTW. The evidence supporting the safety and efficacy of organ persevering (watch and wait) approaches to managing rectal cancer has also become more comprehensive and compelling

20. Do you think the guidance needs updating?

Yes

Current management

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

The standard of care is neoadjuvant chemoradiotherapy for patient with threatened CRM/ high risk features such as T3b and above or EMVI or significant nodal disease followed by total mesorectal excision, or total mesorectal excision alone for patients with no high risk features. There is an acknowledgement however that rectal cancer care is become much more individualised with wider acceptance of organ preserving approaches and associated adjuncts and total neoadjuvant approaches. Patient choice is paramount.

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

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

HDR brachytherapy, lower dose intensity higher treatment volume more damage to collateral tissue, better for palliating larger tumours.
Local excision (TAMIS/TEMS/TEO) more widely available but needs GA and not technically feasible in many patients in whom CXB is feasible (very low, anterior tumours, above peritoneal reflection)

Potential patient benefits and impact on the health system

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

Avoidance of mortality and morbidity of surgery (very significant in elderly comorbid patients)
Avoidance of stoma
Better HRQoL

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

The elderly and patients with co-morbidities for whom TME surgery is particular high risk
Patients who are unwilling to have a stoma.

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

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

    -Equivalent survival and oncological outcomes
    -Avoids major surgery and stomas in some patients
    -As avoids lifelong stoma and major surgery in some patients very cost-effective, potentially dominant.

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

    To ensure equity of access there needs to be 5-6 new centres across the United Kingdom. Existing infrastructure and capacity sufficient to manage patient selection, follow-up and salvage surgery.

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

    The learning curve exists but is relatively short compared to other interventional procedures and would be supported by existing centres.

Safety and efficacy of the procedure/technology

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

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

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

    Rectal bleeding, fewer than 1 in 10, requiring hospitalisation and transfusion in fewer than 1 in 50 patients. Approximate based on reported date from OPERA and UK centre experience (Hull and Clatterbridge)

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

    20% absolute increase (25% relative increase) in clinical complete response rate. 10% absulture reduction (50% relative reduction) in regrowth rate. Resulting increase in avoidance of surgery and organ preservation. Approximate based on reported date from OPERA and comparison of UK centre experience (Hull and Clatterbridge) with published UK data sets eg OnCeRe.

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

    Not just CXB but all organ preservation approaches - effect on distant metastasis rate in patients who experience local tumour regrowth - Based on meta analysis from Kristof Buijko, data from IWW collaborative and Sao Paulo group. If exists likely to be very small effect but needs to be discussed with patients during informed consent for organ preservation approaches. Some people say CXB makes salvage surgery more challenging but I have not found this to be the case in my experience.

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

    See section 30

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

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

Abstracts and ongoing studies

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

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

Literature search and evidence appraisal by HTW
https://healthtechnology.wales/reports-guidance/low-energy-contact-x-ray-brachytherapy-cxb/

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

CITRUS trial - Alex Stewart Guildford
OPERA trial - Arthur Sun Myint Clatterbridge
ICONE group - Amandeep Dhadda Hull
IWW database/ OnCeRe database on organ preservation - Andrew Renehan Christie

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

Literature search and evidence appraisal by HTW
https://healthtechnology.wales/reports-guidance/low-energy-contact-x-ray-brachytherapy-cxb/

Other considerations

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

Approximately 800 per year depending on intervention - Rao C, Stewartz A, Martin AP, et al., 2018, Contact X-ray Brachytherapy as an Adjunct to a Watch and Wait Approach is an Affordable Alternative to Standard Surgical Management of Rectal Cancer for Patients with a Partial Clinical Response to Chemoradiotherapy, Clinical Oncology, Vol:30, ISSN:0936-6555, Pages:625-633

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

Beneficial outcome measures.

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

clinical complete response (0 - 1 year);
local regrowth (0 - 3 years);
organ preservation rate (0 - 3 years);
stoma free survival (0 -3 years);
absolute, cancer and disease free survival (0- 5 years);
metastatic disease (0- 5 years);
health-related quality of life (0 - 5 years) generic - EQ-5D, disease specific- EROTC colorectal modules, functional - Wexner/ Vaizey/ LARS score
decision regret (0 - 5 years)

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

Adverse outcome measures.

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

Early - Bleeding
Mid Failed Salvage Surgery/ R1 resection rate
Late - Metastatic disease

Further comments

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

HRQoL is poorly studied in the whole field of organ preservation in rectal cancer including for CXB and this should be a research priority

Declarations of interests

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

40. Type of interest: *

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

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

Direct - Financial, Consultant Colorectal and General Surgeon, North Cumbria Integrated Care NHS Foundation Trust, May 2022-ongoing
Direct - Financial, Specialist Registrar in general and colorectal surgery within the NHS, Oct 2014- April 2022
Direct - Financial, Consultant, Concentric Healthcare, April 2022-April 2023
Direct - Professional/Personal non-financial, Fellow/Member, Royal College of Surgeons, Nov 2019-October 2023
Direct - Professional/Personal non-financial, Member of Association of Coloproctology of Great Britain and Ireland, April 2018-ongoing
Direct - Financial, Grants from the Clatterbridge Cancer Charity and Honorarium from GEC-ESTRO
(European society of radiation oncology), Jan 2017-Oct 2019

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

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

- (●) I agree
- ( ) I disagree

Signature

43. Name: *

Chris Rao

44. Date: *

23/01/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1724 Low-energy contact X-ray brachytherapy (the Papillon technique) for locally advanced rectal cancer**

Your information

Name:	Dr Amandeep Singh Dhadda
Job title:	Consultant Clinical Oncologist
Organisation:	Hull University Teaching Hospitals NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	RCR
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4502472

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?	Experience of using contact brachytherapy since 2011 and have treated over 300 patients using this technique. Procedure is performed in 4 specialist centres currently although other sites have expressed interest in developing their own service on the background of the positive OPERA trial (Gerard et al 2023). Further centres due to open in Colchester, Swansea and London in 2025.

	– If your specialty is involved in patient selection or referral to another specialty for this 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 or healthy volunteers. 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. Standard of care for these patients would be pre-operative chemo/radiotherapy followed by surgery. Previously the procedure was considered in patients felt to be unfit for major resectional surgery. However, since publication of the OPERA trial data it should be considered a standard of care for fit operable patients with low/mid rectal cancers < 3cm who wish for a non-operative approach and organ preservation. Established practice and no longer new. Has been used in Liverpool for > 25 years.
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?	The definition of locally advanced needs to be clarified. In the OPERA trial patients were allowed to enter if they had T2-T3b N0/1 tumours. For tumours < 3cm that fit this criteria certainly based on OPERA there is a potential to replace surgery as standard of care for patients who wish for organ preservation.
5	Have there been any substantial modifications to the procedure technique or,	No

	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?	 Yes – we now have long term outcome data from a randomised controlled trial showing that this could be considered a standard of care for patients with tumours < 3cm.

Current management

6	Please describe the current standard of care that is used in the NHS.	Pre-operative radiotherapy + TME surgery
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?	Potential for organ preservation for more patients with tumours < 3cm. Better outcomes for patients who are suitable for this procedure and unfit for surgery.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Elderly patients who are unfit for surgery. Patients with co-morbidities who have a high risk of surgical morbidity/mortality Stoma averse patients who wish for organ preservation.
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
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Facilities already in place in the 4 current centres providing this technique.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	For new centres yes. There is a national training meeting run by Liverpool 2 x year.

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:	Proctitis, deterioration in bowel function, rectal bleeding. Theoretical risk of rectal stenosis/fistula (<1%). Have not seen personally and have treated > 300 patients.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Complete clinical response Organ preservation
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	We need Level 1 evidence for truly locally advanced fit rectal cancer patients who would not fit into the eligibility criteria for the OPERA trial.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above – more level 1 evidence required in locally advanced setting and for patients with tumours > 3cm
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK.

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	A phase III randomised trial on the addition of a contact X-ray brachytherapy boost to standard neoadjuvant chemo-radiotherapy for organ preservation in early **rectal** adenocarcinoma: 5 year results of the **OPERA** trial. Baron D et al. .Ann Oncol. 2024 Nov 10:S0923-7534(24)04904-4. doi: 10.1016/j.annonc.2024.10.827. Online ahead of print. Low energy contact X-ray brachytherapy for treatment of **rectal** cancer: a health technology appraisal by Health Technology Wales.

	comprehensive reference list but it will help us if you list any that you think are particularly important.	Bennett H et al. Colorectal Dis. 2024 May;26(5):1053-1058. doi: 10.1111/codi.16935. Epub 2024 Mar 11. The safety and efficacy of total mesorectal excision (TME) surgery following dose-escalation: Surgical outcomes from the organ preservation in early **rectal** adenocarcinoma (**OPERA**) trial, a European multicentre phase 3 randomised trial (NCT02505750). Sun Myint et al. Colorectal Dis. 2023 Nov;25(11):2160-2169. doi: 10.1111/codi.16773. Epub 2023 Oct 13. Neoadjuvant chemoradiotherapy with radiation dose escalation with contact x-ray brachytherapy boost or external beam radiotherapy boost for organ preservation in early cT2-cT3 **rectal** adenocarcinoma (**OPERA**): a phase 3, randomised controlled trial. Gerard JP et al. Lancet Gastroenterol Hepatol. 2023 Apr;8(4):356-367. doi: 10.1016/S2468-1253(22)00392-2. Epub 2023
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Guildford host a national database for this.
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)?	~ 100

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: Organ preservation at 2-3 years LARS score Adverse outcome measures: 3-5 years timescales although most will be evident within 12 months.

Further comments

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

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.			

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:	**Dr A S Dhadda**
Dated:	**28/01/2025**

View results

Respondent

27 Anonymous

74:02
Time to complete

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

IP1724

Your information

2. Name: *

Dr Craig Barrington

3. Job title: *

Consultant Clinical Oncologist

4. Organisation: *

South West Wales Cancer Centre

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

RCR

7. Nominated/ratified by (if applicable):

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

7130841

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 informa tion 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 refer 1-2 patients a month with Early Rectal Cancer for contact radiotherapy. This is either as the patients are unfit for surgery or want to avoid surgery.
I am also leading on bringing the service to Wales

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.

As above, I do refer for it regularly and I am helping to bring the treatment into Wales for our patients.
I am aware of the numbers referred into the 4 treating sites in England, since the OPERA trial, these numbers have increased. For me, will continue to do so not only with further evidence and longer follow up emerging but with an increased knowledge of the technology
Only used by Clinical Oncologists
As mentioned we refer regularly and currently follow the patients up locally

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

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

13. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

Yes and No, I would be more specific about what constitutes an early rectal cancer. For me T1-3b, N1 (local node <8mm). No EMVI, margin not threatened. Size of tumour is relevant and height from anal verge

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?

It is not novel, it has been in use for decades.
The major difference is avoiding surgery and the risks associated with surgery including the long term morbidity (stoma formation).
The follow up is also different for an organ preservation patient.

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?

Both
Will replace standard of care for many. It would be an addition for patients who have an endoscopic resection for a T1/2 tumour with high risk features.

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

Not known

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

Yes
Phase III RCT showing its benefit versus external beam RT boost (OPERA).
Further safety and cost effective/utility analysis have been published

20. Do you think the guidance needs updating?

yes

Current management

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

This does depend on where you live.
Note, Wales has access to dostarlimab for dMMR/MSI High stage II/III rectal cancers.
Surgery (TME) or polypectomy (TEMS/TAMIS) are the options with or without external beam radiotherapy.
Based on the previous NICE guidance some patients will have this treatment, either as they are not fit for surgery or they choose to avoid surgery

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

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

No

Potential patient benefits and impact on the health system

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

Avoiding surgery without oncological compromise
Cost saving
Reduced morbidity for the patient (risks from surgery/permanent stoma)

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

One would argue all
Older patients, where risks of surgery are greater
Younger patients, where living with a permanent stoma would be more devastating

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

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

yes
Less surgery, can only be beneficial as other patients can be treated quicker, also cost saving by avoiding surgery and long term stoma costs
Follow up pathway would change, more MRI and endoscopies with this route.

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

More centres delivering the treatment to enable equity of access.
Robust governance is needed to ensure adherence to agreed follow up protocols with MRI scans, sigmoidoscopies, CEA monitoring and digital rectal examinations

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

yes. Competence in rigid sigmoidoscopy is needed. Peer support from an established centre is critical.

Safety and efficacy of the procedure/technology

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

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

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

7% proctitis in OPERA trial
Typically very well tolerated
Personal experience is occasional bleeding (minor), no Grade 3/4 side effects

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

Organ Preservation approach for patients without oncological compromise (survival/local control)

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

Longer term outcomes from the OPERA trial needed to see long term sustainable outcomes

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

none known

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

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

Abstracts and ongoing studies

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

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

    Health Technology Wales have recently reviewed this topic and recommended it

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

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

Other considerations

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

Can only speak for Wales
80-120 per year as it stands
with the screening programme lowering in age and incidence of rectal cancer increasing, fair estimate of numbers for the Welsh population

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

Beneficial outcome measures.

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

Organ Preservation up to 5 years
PFS
OS
PROM/PREM

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

Adverse outcome measures.

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

Up to 3 years, capturing the same side effects as per OPERA

Further comments

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

Ideally would want to compare contact v surgery but this is a trial we would never be able to recruit into
Organ Preservation is favourable for most patients as long as oncological outcome is not compromised (for the majority). With contact radiotherapy this is achieved.
There needs to be greater access to the treatment and robust follow up needs to be ensured

Declarations of interests

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40. Type of interest: *

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

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

I am leading on bringing the treatment into Wales and have commissioned the HTW report

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

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

- (●) I agree
- ( ) I disagree

Signature

43. Name: *

Craig Barrington

44. Date: *

06/02/2024

View results

Respondent

67 Anonymous

302:22
Time to complete

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

IP1724/2

Your information

2. Name: *

Emma de Winton

3. Job title: *

Consultant Clinical Oncologist

4. Organisation: *

Royal United Hospitals Foundation Trusts Bath

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

RCR

7. Nominated/ratified by (if applicable):

Dr Rebecca Muirhead

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

4108029

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

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

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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

10. 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.

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

Are you familiar with the procedure/technology?

I am a consultant clinical oncologist specialising in Colorectal cancer for the last 17 years.
I have shared care for patients undergoing this treatment, supervising and managing external beam radiotherapy treatment locally and liasing with / referring to treating Centres for Papillon contact rectal brachytherapy where this treatment is indicated

12. 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 has been available and used for decades, but only available in a very limited number of sites in the UK.
There is an increasing unmet need (particularly in some regions) with an aging population and recent evidence of good outcomes in combination with external beam treatment)
It is undertaken by Clinical Oncologists
I have been involved in patient selection and referral to treating Centres for many years (see above)

13. 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.
- [x] I have treated patients within the OPERA trial (delivering the external beam chemoradiotherapy +/- boost treatments within the trial)

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

Yes

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

An important treatment option for patients with lack of equity of access to the procedure nationally at present. The alternative brachytherapy approach using interstitial radioisotopes is no longer used in the UK (as far as I am aware) and in this respect it is innovative despite being used for many decades

17. 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.

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

Yes in areas without access to Papillon contact brachytherapy in selected groups (below)
In selected patients wishing to pursue an organ preservation approach and in selected patients unfit for radical surgery this technique improves local control of rectal cancer significantly compared to external beam radiotherapy or chemoradiotherapy alone

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

The technology is simple and cheap. I am not aware of significant changes to modern applicators or KV machines
Improved imaging and localisation for delivery

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

Yes

21. Do you think the guidance needs updating?

Yes

Current management

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

Standard of care for rectal cancer is surgery with preoperative RT/CRT if risk factors for local recurrence. Or local excision for very early cancers /rectal polyps (with or without EBRT)
There has been increasing interest on organ preservation over the last decade with several randomised studies undertaken and a move to offering this to patients as an option.
Concern remains regarding longer term local control rates and metastatic relapse rates for more advanced cancers
Contact brachytherapy improves local control (in appropriate patients)

23. 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

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

In selected patients increased chance of local control and organ preservation

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

Patients with primary disease amendable to contact rectal brachytherapy
early stage cancers
elderly / frail patients unfit for surgery
patients wanting to pursue an organ preservation approach

26. 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

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

Support for service by CRC clinical team
Appropriate location within ODN and agreement by ODN
Appropriate space for KV machine and within existing radiotherapy department
Training for staff
Commissioning by CCG
Clinical Oncologist to lead service with appropriate time job planned to develop local protocols/ governance /referral pathways etc

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

See above

Safety and efficacy of the procedure/technology

29. 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

Ionizing radiation risks and radiation protection in line with IMER requirements
Acute toxicities are manageable (proctitis/ulceration/rectal bleeding/tensmus)
The most common late toxicity above those seen with EBRT is rectal bleeding (gd1-2)
Rectal Necrosis is the most significant. Deterioration in anorectal function and faecal incontinence
Theoretical risks of perforation/ stricture /fistulation

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

Increase in local control of in patients not undergoing surgery for rectal cancer (due to medical fitness or patient choice)

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

Well proven and well tolerated cost effective treatment
Using KV radiation in cancer patients where risks and benefits are well established and understood

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

No

33. 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

34. 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.

None aware of

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

UK Papillon Centre Contact XR data bases

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

N/A

Other considerations

37. 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 5% of target population

38. 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.

These are all well documented for previous trials
Clinical Complete response rate at 3 and 6 months
Local recurrence rates, locoregional recurrence rates, distant recurrence rates at 1,3, 5 and 10 years
PRO QOL measures with validated questionnaire at 3 months, 1 year, 3 years

39. 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:

These are all documented from previous trials
acute side effects at 2, 6 and 12 weeks
late side effect at 1 year and 3 years

Further comments

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

Main concern is adequate provision to meet need for increasing patient numbers and equity of access regionally across the UK

Declarations of interests

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41. Type of interest: *

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

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

N/A

43. 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

44. Name: *

Emma de Winton

45. Date: *

30/01/2025

View results

Respondent

26 Anonymous

50:48
Time to complete

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

IP1724 Jean Pierre GERARD

Your information

2. Name: *

jean pierre GERARD

3. Job title: *

professor

4. Organisation: *

centre Antoine Lacassagne

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

SFRO- ESTRO

7. Nominated/ratified by (if applicable):

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

06/9977

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 inform ation about the procedure/technology and/or your experience.

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

    Are you familiar with the procedure/technology?

    I am familiar with Papillon technique since 1973 in Lyon

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

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

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

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

    I used it 30 years in Lyon and 20 years in NIce

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

- [x] I have done bibliographic research on this procedure.
- [x] I have done research on this procedure in laboratory settings (e.g. device related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [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

In the OPERA trial (Lancet GH 2023) the Papillon technique is dedicated for EARLY rectal adenocarcinoma and in the Title it is for LARC (locally advanced rectal cancer). In France the HAS in 2008, following the Lyon R 96-02 randomized trial granted SMR (Service médical rendu) for rectal acncer T1-T2 and T3. In the last French Guidance (TNCD Sep 2023 -SNFGE) Papillon is recommended for tumor 3 cm or less. My suggestio would be to update the NICE guidelines for Rectal cancer in general because the most validated indication for Papillon technique is more for Early tumors than for LARC

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?

At present time 98% of rectal cancers are treated using radical surgery (usualy TME) and conservative approach is unfreqent . Papillon technique is a very innovative procedure/technique limited by the small number of available machines and the little experience of radiation oncologists to perform rigid rectoscopy and use of the Papillon machine

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?

Yes, following the OPERA trial Papillon has the potential to replace standard surgery in selected Tumours (T1T2 early T3) approximately 10-20% of rectal cancers M0 of the distal-middle rectum

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

NO but some technical improvement are possible with the present device

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

YES : The guidance (2019) was based on the Lyon R96-02 randomized trial.
Since March 2023 there is the OPERA randomized ytrial pubished in the Lancet GH

20. Do you think the guidance needs updating?

YES

Current management

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

SURGERY TME

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

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

YES HRDR Iridium brachytherapy

Potential patient benefits and impact on the health system

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

BETTER quality of life

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

Rectal cancer T1 T2 T3 of distam-middle rectum

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

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

YES Fewer hospital for surgery

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

Strong industrial company to produce on a large basis reliable Papillon + machine

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

YES TRAINING of radiation oncologist is crucial : Learning curve : 10 patients / 6 months FIRST learn to pracrice rigid rectoscopy in the KNEE-CHEST position with a clean an open rectal Cavity (and not lumen in the Gyne position)

Safety and efficacy of the procedure/technology

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

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

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

Few toxicity Mainly late rectal telangiectasia (moderate rectal blod spoting)

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

Efficacy : clinical complete response close to 90%
Organ (rectal) preservation close to 80%

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

SElection of patients : tumors above 3.5 cm Uncertain results
New trials are running : TRESOR IG ROuusy Paris

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

Some as always in science and medecine

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

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

Abstracts and ongoing studies

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

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

    OPERA Trial Neo adjuvant chemoradiotherapy JP Gerard, N Barbet, R Schiappa & al Lancet Gastro hepato 2023 doi 10.1016

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

    YES : TRESOR trial (France)
    OPAXX 5Netnerland G Beets)

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

    OPRA study J Garcia Aguilar (USA)
    STAR-TREC S Bach (UK)

Other considerations

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

In France : 10% of 8000 : 800 if early tumors are seleted

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

Beneficial outcome measures.

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

Training in France and UK
Practice of rigid rectoscopy in Knee-chest position
Assessement of clinical complete response

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

Adverse outcome measures.

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

Assessment of radiation lcer and telangiectasia

Further comments

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

Continue phase III trials as TRESOR, OPAXX, STAR-TREC
Go to FICARE meeting in 2024 (Sao Paulo) and to LUCARRE meeting in Nice 2025

Declarations of interests

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

40. Type of interest: *

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

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

My main bias is that i am using this technique since 1973 and I have made 2 positive randomized trials (Lyon R96-02 and OPERA) and I consider after these 2 trials that Papillon is a validated technique to preserve SAFELY and SIMPLY the rectum for selected early tumors as far as the technique is used properly

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

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

    - (●) I agree
    - ( ) I disagree

Signature

43. Name: *

    jean pierre GERARD

44. Date: *

    05/02/2024

View results

Respondent

22 Anonymous

91:27
Time to complete

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

Routine Review: IP1724 Low-energy contact X-ray brachytherapy (the Papillon technique) for locally advanced rectal cancer

Your information

2. Name: *

Michael Davies

3. Job title: *

Consultant Colorectal Surgeon

4. Organisation: *

Cardiff and Vale University Health Board

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Association of Coloproctology of Great Britain & Ireland

7. Nominated/ratified by (if applicable):

Association of Coloproctology of Great Britain & Ireland

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

3482845

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 informa tion about the procedure/technology and/or your experience.

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

    Are you familiar with the procedure/technology?

I am a Colorectal Surgeon with a specialist interest in Early Rectal Cancer. I run a Tertiary Referral Centre for management of Early Rectal Cancer. Contact Radiotherapy (Papillion Therapy) is one of e range of modalities that our unit uses for management of patients with Early Rectal Cancer. We therefore have long term experience with this treatment over many years (>15 years) with referral of multiple patients to a specialist unit (Clatterbridge / Guildford) for treatment and then local follow up and surveillance post treatment

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 treatment is used widely within the NHS for management of patients with Early Rectal Cancer. There is likely to be increasing uptake of this treatment now since the recent publication of the OPERA Trial in the Lancet (2023). This treatment is used by Colorectal Surgeons in combination with Clinical Oncologists for treatment of early rectal cancer.
Our unit has referred multiple patients over many (>15 years) to a specialist unit (Clatterbridge / Guildford) for treatment and then undertaken local follow up and surveillance post treatment.

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

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

13. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) Other

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

No. Currently the NICE IPG 659 refers only to locally advanced rectal cancer. Contact Radiotherapy (Papillion) is appropriate for early rectal cancer including stages cT2-3 for Organ Preservation as demonstrated by the OPERA Trial (Lancet 2023)

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?

This treatment is an important treatment option for patients with early rectal cancer, to enable organ preservation avoiding the quality of life impact and financial costs of resectional rectal surgery. It also provides a treatment option in patients who are too frail for major colorectal surgery

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?

As detailed above the data from the recently published OPERA trial indicates that this provides a new option for Organ Preservation in patients with Early Rectal Cancer (including cT2-T3). It therefore may be offered as an alternative option for treatment compared with the current standard of care (resectional surgery)

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

Expansion of its use in combination with Chemoradiotherapy based on evidence from the OPERA Trial (Lancet 2023)

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

Yes. Publication of the OPERA Trial (Lancet 2023)

20. Do you think the guidance needs updating?

Yes

Current management

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

For Early Rectal Cancer the current standard of care is rectal resectional surgery but local excision should be considered and discussed with patients (cT1-CT2N0M0). For cT3N0M0 rectal tumours the current standard of care is resectional rectal surgery.

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

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

No

Potential patient benefits and impact on the health system

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

Organ Preservation. Reduction in the number of patients who require rectal resectional surgery with the associated quality of life and financial impacts. In more frail patient this treatment provides an important option to avoid the significant risks of resectional rectal surgery and provides an option for treatment for patients who otherwise would not be able to receive treatment for early rectal cancer since they are too frail for resectional surgery.

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

Those patients with early rectal cancers cT2-CT3N0M0 which are less than 5cm in diameter and those patients who are too frail for resectional surgery or who wish to avoid the physical and quality of life impact of rectal cancer surgery.

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

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

Yes this technology definitely has the potential to change the current treatment pathway for early rectal cancer. There is a significant opportunity to improve outcomes for patients with less invasive treatment, organ preservation and avoidance of stomas. These outcomes are associated with significant quality of life and financial benefits.

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

Appropriate facilities for delivering intercavitary radiotherapy are required. These are already likely to exist in all Radiotherapy Units since they are likely to already be delivering intercavitary radiotherapy in the form of Brachytherapy. There are already a number of specialist units delivering this treatment around the UK but given the expansion of indications there may be insufficient capacity in existing units.

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

Yes specific training is required to deliver this treatment. Follow up by specialists with experience with patients treated with Contact Radiotherapy is also helpful

Safety and efficacy of the procedure/technology

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

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

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

Potential risk include:
1. Bleeding - up to 30% of patients but this usually settles spontaneously and only requires endoscopic treatment in a very small percentage of patients
2. Rectal ulceration at the sire of treatment occurs in 30% of patients. This will gradually heal over 3-6months and there are very few associated symptoms
4. Diarrhoea may occur if treatment is combined with external beam radiotherapy.
5. Pain may occasionally occur during the short period of the procedure but settles within a few minutes of treatment
6. Uncommon long term side effects are rectal stricture and fistula (<1%)
7. There are no recorded treatment related deaths associated with Papillion Treatment

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

Organ (Rectal) Preservation
Avoidance of stoma formation
Local and distant recurrence rates
5 year overall survival and disease free survival

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

Contact Radiotherapy (Papillion) is one of a series of treatment modalities which can be considered for use with patients with early rectal cancer. Uncertainty relates to the choice of this treatment (potentially in combination with external beam radiotherapy) over alternative treatments (patient selection)

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

Patient Selection.

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

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

Abstracts and ongoing studies

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

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

N/K

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

N/K

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

Please refer to the OPERA Trial (Lancet 2023)

Other considerations

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

This is still to be determined since there is current potential to significantly increase the numbers of patients for which with treatment is appropriate since publication of the OPERA Trial.

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

Beneficial outcome measures.

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

Organ (Rectal Preservation) rate
Stoma formation rate
Quality of Life (evaluated by appropriate tools e.g. EQ-5D-5L and EORTC QLQ-C30)
Local and Distant Recurrence Rate
Overall and Disease Free Survival

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

Adverse outcome measures.

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

Stoma formation rate
5 year+ Local and Distant Recurrence Rate
5 year+ Overall and Disease Free Survival

Further comments

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

There is a need to expand the availability and consideration of Papillion treatment as a treatment modality for patients with early rectal cancer. The current NICE IPG 659 guidance is outdated and refers to a too narrow patient group. Expansion of use including education and implementation needs to be considered

Declarations of interests

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

40. Type of interest: *

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

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

N.A

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

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

- (●) I agree
- ( ) I disagree

Signature

43. Name: *

Michael Davies

44. Date: *

20/01/2024

View results

Respondent

24 Anonymous

212:04
Time to complete

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

Simon Powell

Your information

2. Name: *

Simon Powell

3. Job title: *

Senior Clinical Research Fellow / Specialist Registrar in Colorectal Surgery

4. Organisation: *

University of Liverpool / Liverpool University Hospitals NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Royal College of Surgeons

7. Nominated/ratified by (if applicable):

Arthur Sun Myint

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

7457010

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 inform ation about the procedure/technology and/or your experience.

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

    Are you familiar with the procedure/technology?

I have recently undertaken a comprehensive systematic review exploring clinical and oncological outcomes of contact radiotherapy. As such, I have an intimate knowledge regarding outcomes from this procedure

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

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

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

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

Our MDT routinely refers people for contact radiotherapy

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

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

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

Yes

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

This procedure is long established, although is still considered non standard of care

16. Which of the following best describes the procedure:

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

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

In addition in appropriatley selected patients

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

Yes, addition of external beam chemoradiotherapy regimens

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

no

20. Do you think the guidance needs updating?

Yes

Current management

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

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

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

Potential patient benefits and impact on the health system

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

    Avoids major surgery, suitable for elderly/frail patients, increased organ presrvation

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

    Elderly, frail, stoma adverse

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

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

    Yes - cheaper than surgery

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

    Specialist centre with experts delivering therapy including specialist machines and capabilities for ongoing monitoring of therapy

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

    yes

Safety and efficacy of the procedure/technology

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

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

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

    proctits and rectal bleeding - both usually mild

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

Local regrowth, organ preservation , overall survival

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

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

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

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

Abstracts and ongoing studies

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

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

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

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

    I have written a systemaic review and meta-analysis consolidating outcomes from contact radiotherapy. This manuscript is soon to be published

Other considerations

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

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

    Beneficial outcome measures.

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

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

    Adverse outcome measures.

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

Further comments

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

    -

Declarations of interests

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

40. Type of interest: *

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

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

-

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

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

- (●) I agree
- ( ) I disagree

Signature

43. Name: *

Simon Powell

44. Date: *

02/02/2024

View results

Respondent

68 Anonymous

30:52
Time to complete

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

IP1724/2

Your information

2. Name: *

Richard Adams

3. Job title: *

Consultant Clinical Oncologist

4. Organisation: *

Velindre University NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

FRCR

7. Nominated/ratified by (if applicable):

approached by NICE

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

4094805

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

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

10. 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.

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

Are you familiar with the procedure/technology?

I am aware of the procedure/technology as a practising clinician with a specialist knowledge in rectal cancer and in radiotherapy delivery. I have referred patients for this treatment overseen by appropriate governance within the NHS for a number of years

12. 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 do not deliver the treatment myself and it is not available in my institution or region, I refer patients to a specialist UK centre after discussion in local MDT

13. 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 am assisting with the development of research in this area

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

No, the abstract is very limited in its scope and does not acknowledge recent phase III randomised control trial data - OPERA. The abstract references us in patients who have inoperable disease and does not define this broad group of patients or acknowledge the merits of treatment in those who decline surgery or which to approach their disease in a non operative manner if at all possible

16. 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 it self is not new or innovative. Recent RCT evidence is evidence and has been practice changing but knowledge is poorly disseminated and there are opportunities for current adoption of the high level evidence research findings as well as further research opportunities, which would be innovative

17. 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.

18. 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 current standard of care for a cohort of patients with scope for research in patients outside the current practice changing evidence base

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

Not to the equipment but yes to the use of this therapy in patients with T2/3 N0/X low rectal cancer as a potential definitive non operative procedure

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

safety has not changed and it is considered safe in specialist hands. There is new evidence on efficacy including phase III RCT data

21. Do you think the guidance needs updating?

Yes

Current management

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

Direct to surgery for low rectal cancer T2/3N0 or long course chemoradiotherapy followed by surgery. Most frequently with an abdominoperineal resection and permanent stoma bag

23. 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?

in a subgroup of patients Local excision via techniques such as Transanal endoscopic microsurgery is feasible

Potential patient benefits and impact on the health system

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

avoidance of major surgery. In those with low tumours avoidance of a permenant stoma bag, potential for more cost effective procedure

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

those with early low cancers who prefer not to have a stoma bag or are unfit for major surgery

26. 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 less time in hospital , less post operative complications, less morbidity, less costs in terms of stoma bags

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

    access to a papillon machine and an outpatient/theatre/endoscopy facility with adequate radiation protection for superficial xray therapy

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

    training is available within the UK and a number of additional clinical teams have been trained by the team in Clatterbridge over recent years

Safety and efficacy of the procedure/technology

29. 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

    Low anterior resection syndrome, including incontinence and urgency
    bleeding, infection

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

    complete clinical response to rectal cancer without need for operative intervention or the need for a permanent stoma

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

    stages of rectal cancer that can be treated beyond T2/3

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

    when to be used as opposed to Transanal endoscopic microsurgery, when external beam radiotherapy is not also required

33. 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

34. 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.

    The results of the OPERA trial have been published including long term outcomes as have the CONTEM1 trial results. I believe there is a meta-analysis of studies which is in manuscript stage

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

    OPERA most recently

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

    N/A

Other considerations

37. 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)?

    400+ England and Wales

38. 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.

    complete clinical response
    organ preservation
    salvage rates for relapse in patients fit for surgery
    PROMs
    LARS score

39. 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:

    stoma requirements
    salvage surgery in fit patients

Further comments

40. 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.

41. Type of interest: *

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

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

nil

43. 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

44. Name: *

Richard Adams

45. Date: *

01/02/2025