

View results

Respondent

34

Anonymous

77:02

Time to complete

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

Image-guided percutaneous laser ablation for primary and secondary liver tumours (IP1972)

Your information

2. Name: *

Edward W Johnston

3. Job title: *

Academic Consultant in Interventional Radiology

4. Organisation: *

Royal Marsden Hospital

5. Email address: *

6. Professional organisation or society membership/affiliation: *

British Society of Interventional Radiology

7. Nominated/ratified by (if applicable):

BSIR

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

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How NICE will use this information:

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

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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

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

I agree

I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

I do not personally use laser ablation, and uptake in the UK has been very limited.
I have attended lectures on laser ablation at international meetings.
I have performed hundreds of ablation procedures using other energies (mainly microwave, but also radiofrequency, cryoablation, irreversible electroporation and ethanol.

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 have never used it. UCLH used to perform laser ablations, but not for primary or secondary liver cancer, and I don't think they have an active program any longer.

To the best of my knowledge, this procedure is not used in the NHS. Uptake is likely to be slow, as microwave is very effective (backed by positive level I trials vs. surgery) and is still undergoing considerable improvements. Laser ablation has also been around since the 1980s, so it is unlikely there will be a sudden influx of papers.

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

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure.
- All the above in microwave liver ablation, but not laser ablation.

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?

It is still a thermal ablation procedure that uses electromagnetic radiation (of higher frequency than RF and microwave). However prospective trials are broadly lacking, especially recently. Conceptually it could be useful for higher risk cases where ablative margins are critical (e.g., adjacent to vulnerable structures). The need for satisfactory margins means suitable lesions may be small/duration could be long in the case of multi applicator ablations.

16. Which of the following best describes the procedure:

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

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

I don't think there is any chance of it replacing RF and microwave any time soon - the evidence is too strong, complications are low and technologies are emerging which reduce local recurrence at a considerable rate.

Current management

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

Surgery
Thermal ablation - specifically microwave and radio frequency.

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

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

Other ablation procedures - microwave, radio frequency, irreversible electroporation.

Histotripsy is being explored in early phase clinical trials (extracorporeal technology).

Stereotactic ablative radiotherapy is another ablative tool that can be used in the liver and is usually provided by clinical (radiation) oncologists.

Potential patient benefits and impact on the health system

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

Tighter ablation margins with the potential for more predictable ablation zones, which might lower complications. However complications are already low with competing technologies (around 5%), and much lower than surgery (around 30%).

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

Not immediately apparent. The indications need to be defined through more research.

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

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

Not based upon current limited data.

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

- Teams with experience in performing the procedure.
- Multidisciplinary team discussion for patient recruitment including Interventional Radiologists, Hepatobiliary Surgeons and Oncologists.
- Teams with experience of running clinical trials.

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

All ablative procedures have a learning curve, and it is important that the learning curve is ascended prior to defining ultimate safety and efficacy. The literature has quoted 30 - 100 cases to become an expert with microwave liver ablation.

Safety and efficacy of the procedure/technology

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

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

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

Theory:

Needles are thinner for laser ablation than for microwave and RFA, so it could theoretically be safer. The ablation zone is also tighter which may reduce collateral damage to non target structures. However this might mean more needles are needed for a satisfactory ablation zone especially for larger tumours.

Evidence:

One randomised trial versus radiofrequency ablation:

Di Costanzo GG et al. Radiofrequency ablation versus laser ablation for the treatment of small hepatocellular carcinoma in cirrhosis: a randomized trial. *J Gastroenterol Hepatol*. 2015 Mar;30(3):559-65. doi: 10.1111/jgh.12791. PMID: 25251043.

...quoted very similar rates of minor complications (32 vs 35%) although a statistical comparison was not seemingly performed.

Another study:

Puls R et al., Laser ablation of liver metastases from colorectal cancer with MR thermometry: 5-year survival. *J Vasc Interv Radiol*. 2009 Feb;20(2):225-34. doi: 10.1016/j.jvir.2008.10.018. Epub 2008 Dec 24. PMID: 19109037.

In a series of 87 patients undergoing thermal ablation of colorectal liver metastases, quoted major complications in 4% per session and 8% per patient (Major complications included large pleural effusion, large subcapsular hematoma, abscess, large pneumothorax, pleuritis with fever, intrahepatic hemorrhage, and biloma). Minor complications (e.g. self limiting pleural effusion and liver haematoma) were seen in 50% of patients.

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

As in the SIO/DATECAN document (Puijk RS et al. Consensus Guidelines for the Definition of Time-to-Event End Points in Image-guided Tumor Ablation: Results of the SIO and DATECAN Initiative. *Radiology*. 2021 Dec;301(3):533-540. doi: 10.1148/radiol.2021203715. Epub 2021 Sep 28. PMID: 34581627.)

Safety (complication rates)

Unablated tumour/local recurrence rates

Local tumour progression free survival

Overall survival

Thereafter, and if the evidence builds, quality of life outcomes.

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

The safety data suggests laser ablation has a similar safety profile to RF/microwave. However there is less global experience with it, and the learning curve might change this as/if experience grows globally.

Studies are largely retrospective, and do not report robust oncological outcomes including sufficient follow up (at least 2 years) for local tumour progression free survival.

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

Uncertainty about most aspects - safety, learning curve and efficacy need definition.

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

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

Abstracts and ongoing studies

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

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

I am not aware of any important abstracts in preparation.

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

Not to my knowledge.

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

1. Vogl TJ, Dommermuth A, Heinle B, Nour-Eldin NE, Lehnert T, Eichler K, Zangos S, Bechstein WO, Naguib NN. Colorectal cancer liver metastases: long-term survival and progression-free survival after thermal ablation using magnetic resonance-guided laser-induced interstitial thermotherapy in 594 patients: analysis of prognostic factors. *Invest Radiol.* 2014 Jan;49(1):48-56. doi: 10.1097/RLI.0b013e3182a6094e. PMID: 24056114.
2. Orlacchio A, Bolacchi F, Chegai F, Bergamini A, Costanzo E, Del Giudice C, Angelico M, Simonetti G. Comparative evaluation of percutaneous laser and radiofrequency ablation in patients with HCC smaller than 4 cm. *Radiol Med.* 2014 May;119(5):298-308. doi: 10.1007/s11547-013-0339-y. Epub 2013 Nov 26. PMID: 24277510.
3. Pacella CM, Bizzarri G, Magnolfi F, Cecconi P, Caspani B, Anelli V, Bianchini A, Valle D, Pacella S, Manenti G, Rossi Z. Laser thermal ablation in the treatment of small hepatocellular carcinoma: results in 74 patients. *Radiology.* 2001 Dec;221(3):712-20. doi: 10.1148/radiol.2213001501. PMID: 11719667.

Other considerations

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

Now microwave is gaining the evidence, I do not see much of a scope for this procedure outside of a clinical trial.

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

Beneficial outcome measures.

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

As per SIO/datecan quoted earlier.

Follow-up must have at least 2 years of imaging (ideally MRI) for assessment of local tumour progression.

Shady W et al. Percutaneous Radiofrequency Ablation of Colorectal Cancer Liver Metastases: Factors Affecting Outcomes--A 10-year Experience at a Single Center. Radiology. 2016 Feb;278(2):601-11. doi: 10.1148/radiol.2015142489. Epub 2015 Aug 12. PMID: 26267832; PMCID: PMC4734163.

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

Adverse outcome measures.

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

Most complications are early in ablation procedures (first 6 weeks).

They should be recorded using an objective scoring system e.g. CTCAE, Society of Interventional Radiology or Clavien-Dindo.

Further comments

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

I am not aware of a UK expert that is using this technology. Implementation could therefore be difficult but happy to explore this if you think it is worthy of further study.

Data suggest metastases less than 2cm have better outcomes.

It is uncertain whether those that have been shrunk to 2cm with chemotherapy are suitable (there may be stray cells in the 'footprint' of the initial tumour). This does apply with microwave too, but could limit the scope if local tumour progression is higher in initially larger pretreated metastases.

Declarations of interests

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

37. Type of interest: *

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

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

I have attended courses in tumour ablation in the following technologies, run by the following companies:

RFA of the spine (OncoV), 2023

Cryotherapy (Boston Scientific), 2023

Electrochemotherapy (IGEA medical), 2023

The companies covered the costs of running the course (transport and subsistence).

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

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

I agree

I disagree

Signature

40. Name: *

Edward W Johnston

41. Date: *

21/09/2023



Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Robert Colliver"/>
Job title:	<input type="text" value="Consultant Interventional Radiologist"/>
Organisation:	<input type="text" value="The Royal United Hospital, Bath"/>
Email address:	<input type="text" value=""/>
Professional organisation or society membership/affiliation:	<input type="text" value="British Society of Interventional Radiologists (BSIR)"/>
Nominated/ratified by (if applicable):	<input type="text" value="BSIR"/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="GMC 7014893"/>

How NICE will use this information:

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

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

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see [our privacy notice](#).

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

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

<p>1 Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none">- 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?	<p>I have a good understanding of the thermal ablation in the liver and other organs having been on many courses and having done my own research into the area. I also undertook some cases of thermal ablation as a trainee but am not currently undertaking liver ablations. The difference here is the way the energy is delivered, laser rather than microwave or radiofrequency.</p> <p>No</p> <p>Not widely used</p> <p>Not in the same format in this country</p>
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	<p>- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.</p>	
2	<p>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have done bibliographic research on this procedure.</p> <p>I have done research on this procedure in laboratory settings (e.g. device-related research).</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers.</p> <p>I have published this research.</p> <p>I have had no involvement in research on this procedure.</p> <p>Other (please comment)</p>
3	<p>Does the title adequately reflect the procedure?</p> <p>Is the proposed indication appropriate? If not, please explain.</p> <p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>YES</p> <p>yes</p> <p>Established practice and no longer new.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. (WHEN COMPARED WITH MICROWAVE ABLATION OF LIVER TUMOURS)</p> <p>Definitely novel and of uncertain safety and efficacy.</p> <p>The first in a new class of procedure.</p>

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?	In addition to standard care on the whole although it would be first choice in some cases displacing some more established treatments, usually other forms of thermal ablation (microwave/RFA) but unlikely to replace liver resection or SABR.
5	<p>Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?</p> <p>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?</p>	<p>The method of delivering energy to the tumour is different. Laser is used in other areas of the body to cause coagulation/cell death (such as EVLA for varicose veins) so the concept is not completely new.</p> <p>No</p>

Current management

6	Please describe the current standard of care that is used in the NHS.	Thermal ablation for liver tumours in the UK usually consists of microwave or radiofrequency ablation. There are various other ways to treat liver tumours; resection, SABR, chemotherapy, chemoembolization, SIRT etc but thermal ablation is the most similar.
7	<p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p>	<p>Microwave and radiofrequency ablation is very similar.</p> <p>This approach may enable a smaller tract and therefore be less invasive with potentially less risk. The ablation zone maybe larger, particularly than RFA. This treatment may be cheaper. There is however more risk of heat sink (which may mean the tumour is incompletely killed) compared with microwave ablation so the anatomy of the area being treated is important.</p>

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?	Less risk to patient (bleeding and infection), cheaper. Possibly less painful.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Similar cohort to other forms of thermal ablation.
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?	No hugely but could be a good alternative for some patients but broadly the results will be very similar to other forms of ablation. Slightly less invasive.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Minimal if already undertaking thermal ablation. (CT scanner/US machine/Anaesthetist etc)
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes but this would be minimal for an operator skilled in other forms of thermal ablation.

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:	Non target cell damage (10% very significant 1%), bleeding (1%), infection(1%), pain (5%) and incomplete treatment (5%).
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	<p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	Thought to be almost identical to microwave ablation.
14	Please list the key efficacy outcomes for this procedure/technology?	Complete death of tumour
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Unknown 'heat sink' effect from nearby blood vessels taking the heat away.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	no
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	<p>Most or all district general hospitals.</p> <p>A minority of hospitals, but at least 10 in the UK.</p> <p>Fewer than 10 specialist centres in the UK.</p> <p>Cannot predict at present.</p>

Abstracts and ongoing studies

18	<p>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).</p> <p>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent</p>	
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	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	
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)?	Estimate: 1,000
22	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - 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 	<p>Beneficial outcome measures:</p> <p>Complete tumour treatment on serial imaging over 2 years.</p> <p>Tumour recurrence at the site of treatment over 2 years.</p> <p>Length of hospital stay</p> <p>Mobility post procedure</p> <p>Pain score</p> <p>Adverse outcome measures:</p>

	procedure timescales over which these should be measured:	Bleeding (short term(days to weeks)) Infection (6 weeks) Pain (2 weeks) Non target organ damage (2 months)
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Further comments

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

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

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

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

Print name:	<input type="text" value="Robert Colliver"/>
Dated:	<input type="text" value="19/09/2023"/>

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Wing Yan Liu"/>
Job title:	<input type="text" value="Consultant Interventional Radiologist"/>
Organisation:	<input type="text" value="University Hospitals Coventry and Warwickshire"/>
Email address:	<input type="text" value=""/>
Professional organisation or society membership/affiliation:	<input type="text" value="MBChB, MRCS, FRCR"/>
Nominated/ratified by (if applicable):	<input type="text" value="British Society of Interventional Radiology"/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="6100966"/>

How NICE will use this information:

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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

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<p>1 Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none">- 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?	<p>I performed percutaneous ablation on primary liver cancer and liver metastases regularly. I am familiar with radiofrequency, microwave, cryoablation and irreversible electroporation</p> <p>I have no personal experience with laser ablation.</p> <p>The technology is not widely used in NHS organisations. I expect the speed of uptake to be low due to the existing and more widely used technology for the same purpose.</p> <p>Possibly some HPB surgeons.</p>
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	<p>- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.</p>	<p>I am member of the HPB MDT where treatment options for patients with liver cancers are discussed, which include percutaneous liver ablation.</p>
2	<p>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have done bibliographic research on this procedure.</p> <p>I have done research on this procedure in laboratory settings (e.g. device-related research).</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers.</p> <p>I have published this research.</p> <p>I have had no involvement in research on this procedure.</p> <p>Other (please comment)</p> <p>I have performed literature search on this procedure</p>
3	<p>Does the title adequately reflect the procedure?</p> <p>Is the proposed indication appropriate? If not, please explain.</p> <p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>Yes</p> <p>Yes</p> <p>Established practice and no longer new.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p> <p>Definitely novel and of uncertain safety and efficacy.</p> <p>The first in a new class of procedure.</p>

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?	Addition to existing standard care
5	<p>Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?</p> <p>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?</p>	<p>No</p> <p>No. The number of publication remains small for laser ablation in liver.</p>

Current management

6	Please describe the current standard of care that is used in the NHS.	<p>For hepatocellular carcinoma (HCC), treatment strategy follow the Barcelona Clinic Liver Cancer guidance, where ablation is the first treatment option for single HCC of <2cm or 3 or less HCCs of <3cm which is not suitable for liver transplant.</p> <p>For liver metastases, ablation is offered to patients with lesions <3cm who are unfit or unsuitable for liver resection or resection is higher risk such as those who have had previous liver resection.</p>
7	<p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p>	<p>Radiofrequency and microwave ablation are most common technology used to treat liver tumours <3cm. Laser ablation is a known technology but infrequently used.</p> <p>Irreversible electroporation is a relatively new non-thermal ablation technology which is used to treat lesions close to major blood vessels or bile ducts. This is currently used in the context of research in NHS.</p>

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	The needles used in laser ablation is much thinner than the microwave or radiofrequency ablation probes, therefore risk of injury to liver structures is theoretically smaller. It is suggested that laser ablation is cheaper than microwave ablation when less than 3 needles are used.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	In liver lesion in a difficult to access location, e.g. percutaneous approach carries high risk of vascular or biliary injury.
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?	Potentially useful addition to existing pathway. Lower risk of complication in selective cases.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Increased procedure time during early stage New equipment
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. Training on case selection Training for operator – the approach in needle placement to treat a lesion with laser is different from microwave or radiofrequency Training for staffs – different set up of equipment

Safety and efficacy of the procedure/technology

<p>13</p>	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>Under or over treatment</p> <p>Potential increases risk of complication due to need of multiple needles to treat a liver lesion which could otherwise be treated with a single probe in microwave and radiofrequency.</p> <p>Adverse events:</p> <p>Bleeding, infection, pain</p> <p>Thermal injury – biliary stricture, vascular injury, visceral perforation, pneumothorax</p> <p>Reduced liver function</p>
<p>14</p>	<p>Please list the key efficacy outcomes for this procedure/technology?</p>	<p>Technical success</p> <p>Clinical success – residual disease</p> <p>Time to recurrence</p> <p>Progression free survival</p> <p>Overall survival</p>
<p>15</p>	<p>Please list any uncertainties or concerns about the efficacy and safety of this procedure/?</p>	<p>Lack of literature on this technology</p>
<p>16</p>	<p>Is there controversy, or important uncertainty, about any aspect of the procedure/technology?</p>	<p>Cost effectiveness of laser ablation as compared to other form of ablation</p>
<p>17</p>	<p>If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):</p>	<p>Most or all district general hospitals.</p> <p>A minority of hospitals, but at least 10 in the UK.</p> <p>Fewer than 10 specialist centres in the UK.</p> <p>Cannot predict at present.</p>

Abstracts and ongoing studies

18	<p>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).</p> <p>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.</p>	<p>Luerken L, Haimerl M, Doppler M, Uller W, Beyer LP, Stroszczynski C, Einspieler I. Update on Percutaneous Local Ablative Procedures for the Treatment of Hepatocellular Carcinoma. <i>Rofo</i>. 2022 Oct;194(10):1075-1086. English, German. doi: 10.1055/a-1768-0954. Epub 2022 May 11. PMID: 35545102.</p> <p>Kovács A, Iezzi R, Cellini F, Lancellotta V, Bischoff P, Carchesio F, Tagliaferri L, Kovács G, Gambacorta MA. Critical review of multidisciplinary non-surgical local interventional ablation techniques in primary or secondary liver malignancies. <i>J Contemp Brachytherapy</i>. 2019 Dec;11(6):589-600. doi: 10.5114/jcb.2019.90466. Epub 2019 Dec 8. PMID: 31969919; PMCID: PMC6964346.</p> <p>Sartori S, Tombesi P, Di Vece F, Bianchi L, Ambrosio R. Percutaneous Laser Ablation of Liver Metastases from Neuroendocrine Neoplasm. A Retrospective Study for Safety and Effectiveness. <i>Cardiovasc Intervent Radiol</i>. 2019 Nov;42(11):1571-1578. doi: 10.1007/s00270-019-02308-4. Epub 2019 Aug 13. PMID: 31410534.</p>
19	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	No
20	<p>Please list any other data (published and/or unpublished) that you would like to share.</p>	None

Other considerations

21	<p>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)?</p>	10-20% of patients suitable for percutaneous liver ablation
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<p>22</p>	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - 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: 	<p>Beneficial outcome measures:</p> <p>Technical success</p> <p>Cross over rate</p> <p>Clinical success – residual disease</p> <p>Time to recurrence</p> <p>Progression free survival</p> <p>Overall survival</p> <p>Adverse outcome measures:</p> <p>Vascular injury (immediate/early)</p> <p>Biliary complication (immediate/early/late)</p> <p>Other internal organ complication (immediate/early)</p> <p>Reduced liver function or liver failure (intermediate/late)</p> <p>Readmission for complication (30 days)</p> <p>Death (30 days)</p>
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Further comments

<p>23</p>	<p>If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.</p>	<p>There are little evidence and lack of clinical trial to proof the efficacy and benefit of laser ablation as compared to its competing technologies, e.g. radiofrequency and microwave.</p> <p>Other new technology such as irreversible electroporation which has a more distinct benefit of treating liver lesions close to important liver structures are being actively studied, making it even more difficult to outline the role of laser ablation.</p>
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Declarations of interests

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

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

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

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

Print name:	<input type="text" value="Wing Yan Liu"/>
Dated:	<input type="text" value="10/10/2023"/>