

National Institute for Health and Clinical Excellence

400/1 – Cryotherapy for the treatment of liver metastases

Comments table

IPAC date: Friday 15 October 2010

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Specialist Adviser	1	There is no one now in the UK using cryotherapy to treat primary or secondary liver tumours and hasnt been for nearly 10 years. This is old fashioned treatment that has been superceded by RFA and microwave	Please respond to all comments Thank you for your comment. The IP programme established that the procedure is being used in the UK before proceeding to develop guidance on this topic.
2	Consultee 2 NHS Professional	1	At Sothampton we have substantial experience with the use of modern cryoablation devices in the treatment of renal tumours.A considerable amount of your quoted literature dates from experience in the 1990s with older devices and technology.There is however still some reticence about cryoablation in the liver due to persistent if intermittent reports of cryoshock and post-procedural haemorrhage, particularly in relation to the open procedure. Case series and audits-if sanctioned- should be closely followed to make an early determination about the safety of this procedure.	Thank you for your comment. Section 1.3 of the guidance stipulates that any clinician wishing to undertake this procedure should 'Audit and review clinical outcomes of all patients having cryotherapy for liver metastases'. NICE will consider reviewing this guidance (as with guidance on any topic) if substantive new safety concerns are brought to NICE's attention.

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3	Consultee 3 Registrar, Royal College of Physicians	1	In responding to this consultation, I would like to submit joint comments on behalf of the NCRI/RCP/RCR/ACP/JCCO. We are aware that the Health Technology Assessment Programme have commissioned a systematic review of ablation therapies which includes cryotherapy. Â This has been awarded to a research group run from Southampton and includes members of the NCRI Clinical Studies Group. We believe that it would be inappropriate for NICE to perform an evaluation of cryotherapy prior to this review being available. Â Therefore, we would very strongly recommend that the work be deferred until 2011 when the review will be available.	Thank you for your comment. NICE was aware of this HTA-commissioned systematic review. The Committee considered this comment and decided not to delay developing guidance. The HTA-commissioned review would be used to inform any future review of the IP guidance by NICE.
4	Consultee 1 Specialist Adviser	2.1	There are no indications for cryotherapy for this condition	Thank you for your comment.
5	Consultee 2 NHS Professional	2.1	Agreed. Combined treatment modalities continues to confound decisions about safety and treatment efficacy of a number of ablation modalities.	Thank you for your comment.
6	Consultee 1 Specialist Adviser	2.2	cryotherapy should be abandoned	Thank you for your comment. Please see response to comment no. 1.
7	Consultee 2 NHS Professional	2.2	Agreed however percutaneous procedures are also carried out under GA or intravenous anaesthesia for the purposes of improved outcomes.	Thank you for your comment. Section 2.2.3 of the guidance will be changed.
8	Consultee 1 Specialist Adviser	2.3	There are no data or evidence to support the continued use of cryotherapy	Thank you for your comment.
9	Consultee 2 NHS Professional	2.3	Agreed.	Thank you for your comment.
10	Consultee 1 Specialist Adviser	2.4	cryotherapy is dangerous	Thank you for your comment. The safety outcomes described in section 2.4 are those published in the literature. Section 1.1 of the guidance states that 'Current evidence on the safety of cryotherapy for the treatment of liver metastases appears adequate in the context of treating patients whose condition has such a poor prognosis.'

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11	Consultee 2 NHS Professional	2.4	Again there is scope here to sanction a few centres and prospectively monitor/request reporting of any adverse events. Patients need to offered alternative ablation therapies by these centres such as microwave ablation. There is a significant but not verified understanding in this community that the percutaneous procedure with thinner probes is substantially safer than the older open, large probe procedures reported in your literature survey. - Â Apologies....I note you have made this point below.	Please respond to all comments Thank you for your comment. A new section on the expertise required for patient selection and treatment will be added to section 1 of the guidance.

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