

# National Institute for Health and Clinical Excellence

## 344/2 – Laparoscopic cryotherapy for renal cancer Consultation Comments table

IPAC date: Friday 13 May 2011

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	1	In the absence of a uk clinical trial (comparing the various ablative techniques) any comparison will be restricted to matched series which I suspect will be short on numbers and it will difficult to draw any firm conclusions.	Thank you for your comment.
2	Consultee 2 Galilmedical Healthcare Other	1	We agree that the current evidence on the efficacy and safety of laparoscopic cryotherapy for renal cancer is adequate to support the use of this procedure provided under normal arrangements. Â Our company, in conjunction with the Department of Epidemiology at the University of Aarhus (Denmark) is working to create an online Renal Cryotherapy Registry. Â The registry design is based upon the EuCAP prostate registry that has been recognised by the EAU-RF (European Association of Urology Research Foundation). Â EuCAP will become fully available in April/May 2011 and the renal registry early in 2012.	Thank you for your comment.

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3	Consultee 1 NHS Professional	<b>2.1</b>	Most of the tumours suitable for nephron sparing treatment are now detected incidentally and not with symptoms. In cases where the diagnosis is not clear the role of biopsy should be discussed. In all cases treated with lap cryo a peri treatment biopsy is mandatory to allow the interpretation of follow up data. A third of all small renal masses will be benign and this clearly needs to be determined.	Thank you for your comment. Section 2.5.2 states that: <i>The Committee was advised that the diagnosis of malignancy is typically made by imaging and that histology is generally not available to confirm the diagnosis. This contrasts with treatment by any kind of nephrectomy which provides tissue for histological diagnosis.</i> The Committee did not consider they could make recommendations about the use of biopsy, however a reference to biopsy will be added to section 2.2.1 of the guidance.
4	Consultee 2 Galilmedical Healthcare Other	<b>2.1</b>	We agree and wish to make no further comment.	Thank you for your comment.
5	Consultee 1 NHS Professional	<b>2.2</b>	This is a very superficial of the procedure. This needs to be expanded to include: Probe numbers, Temperature probes, laparoscopic ultrasound monitoring of the ice ball etc.	Thank you for your comment. This section of the guidance is intended to be a summary description of the procedure, and will not be changed.
6	Consultee 2 Galilmedical Healthcare Other	<b>2.2</b>	We agree and wish to make no further comment.	Thank you for your comment.
7	Consultee 1 NHS Professional	<b>2.3</b>	This summarises the available data nicely.	Thank you for your comment.
8	Consultee 2 Galilmedical Healthcare Other	<b>2.3</b>	We agree and would also like to propose the following paper as offering further evidence as to the safety and efficacy of renal cryotherapy, especially appertaining to the preservation of renal function. Cadeddu et al., 2010 (journal of Endourology V24, No5 Pp 769-774): The Importance of Nephron-Sparing Focal Therapy: Renal Function Preservation	Thank you for your comment. The paper referred to by the consultee is a review article by Lucas SM and Cadeddu JA (2010). All the relevant studies referred to in this review have been included in the overview.
9	Consultee 1 NHS Professional	<b>2.4</b>	Fine	Thank you for your comment.

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10	Consultee 2 Galilmedical Healthcare Other	<b>2.4</b>	The haemorrhage rates as quoted in section 2.4.1 do not accurately represent the haemorrhage rates of the current technology being used in the majority of U.K. sites. We therefore do not agree that this particular reference accurately reflects the haemorrhage rates for the procedure. We agree and wish to make no further comment on the subsequent statements (2.4.2-2.4.6)	Thank you for your comment. The haemorrhage rates reported are those in the published literature. The overview provides more information about individual studies.
11	Consultee 1 NHS Professional	<b>2.5</b>	If you biopsy at the time of treatment this would allow follow up data to be analysed for malignant and benign lesions	Thank you for your comment. Section 2.5.2 states that: <i>The Committee was advised that the diagnosis of malignancy is typically made by imaging and that histology is generally not available to confirm the diagnosis. This contrasts with treatment by any kind of nephrectomy which provides tissue for histological diagnosis.</i> The Committee did not consider they could make recommendations about the use of biopsy, however a reference to biopsy will be added to section 2.2.1 of the guidance.
12	Consultee 2 Galilmedical Healthcare Other	<b>2.5</b>	While we agree with this statement, the histological diagnosis for nephrectomy is made as well after the surgical procedure has been completed. We would like to submit the following information that we consider to be worthy of inclusion as evidence of good practice in the biopsy proven treatment of renal tumours with cryotherapy. Following the reference to a papers that has not been currently cited Guazzoni et al., 2010 (renal Cancer): 53 patients have been followed-up for more than 5 years. 44 presented biopsy proven RCCs. All patients were cancer-free at 5 years and more.	Thank you for your comment. The overview provides more information about individual studies. Guazzoni 2010 was identified in the post consultation literature search and will be included in the appendix of the overview.
13	Consultee 1 NHS Professional	<b>General</b>	I am a consultant Urologist who provides a laparoscopic service (for South wales)for cryotherapy. I have presented my short term data on safety within Wales at a Welsh urologist meeting and am collecting lonh term oncological follow up data.	Thank you for your comment.

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*