

National Institute for Health and Clinical Excellence

921 – Single-port laparoscopic nephrectomy Consultation Comments table

IPAC date: Thursday 8 September 2011

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Specialist Adviser	1	No comment	Please respond to all comments Thank you for your comment.
2	Consultee 2 NHS Professional	1	I have been asked to comment on this consultation on behalf of Kidney Cancer UK, a kidney cancer support group and registered charity. 1. Patient information: Cancer recurrence rates and survival. There is a lack of cancer patients in the single port studies and a lack of meaningful oncological follow up. I recommend that patient information and consent needs to clearly state that single port surgery is more difficult than conventional laparoscopy and that local cancer recurrence rates and survival are unknown.	Thank you for your comment. Section 1.2 states that clinicians should ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Section 1.5 of the guidance notes the lack of long-term follow-up for patients with malignant disease and this will be included in the 'Understanding NICE guidance' document for the procedure (NICE's information for patients).
3	Consultee 2 NHS Professional	1	2. Technical outcome: I recommend that the authors consider defining experienced laparoscopic surgeon as a surgeon who performs a minimum of 50 laparoscopic renal operations per year.	Thank you for your comment. Section 1.4 states that the procedure should only be carried out by experienced laparoscopic surgeons who have received specific training in the procedure. Interventional Procedures guidance does not normally specify a minimum number of operations,. The purpose of NICE's recommendation at section 1.2 that clinicians carrying out the procedure should inform the clinical governance leads in their trust, is to ensure that the trust is satisfied that the procedure is being carried out with the appropriate skill level, as local circumstances may vary .

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4	Consultee 1 Specialist Adviser	2.1	Please include partial nephrectomy and needle ablative therapy such as cryotherapy Aron M, Canes D, Desai MM et al. Transumbilical single-port laparoscopic partial Nephrectomy. BJU Int. 2009;103:516-21. Goel RK, Kaouk JH Single port access renal cryoablation (SPARC): a new approach. Eur Urol. 2008 Jun;53(6):1204-9.	Thank you for your comment. Section 2.1.1 of the guidance will be changed. The papers referenced by the consultee refer to procedures other than single-port laparoscopic nephrectomy and will not be included in the overview.
5	Consultee 1 Specialist Adviser	2.2	This is not necessarily true. One can perform single site nephrectomy using conventional trocars rather than any specially designed systems.	Thank you for your comment. Section 2.2.2 of the guidance will be changed.
6	Consultee 1 Specialist Adviser	2.3	Please also include reference and text pertaining to this reference, a seminal RCT Kurien A, Rajapurkar S, Sinha L et al. Standard Laparoscopic Donor Nephrectomy Versus Laparoendoscopic Single-Site Donor Nephrectomy: A Randomised Comparative Study. J Endourol. 2011;25:365-70	Thank you for your comment. The reference cited by the consultee was identified in the post consultation literature search and will be added to table 2 of the overview.
7	Consultee 2 NHS Professional	2.3	The majority of patients treated in these papers have benign disease. There is effectively no data on oncological outcomes. For cancer surgery, the relatively clumsy instruments (still in evolution) and the catching of instruments can result in sudden movements that may result in breach of the tumour capsule and tumour seeding. Therefore, I suggest that care must be taken with case selection so that, for example, exophytic tumours with thin overlying perinephric fat are excluded from the single port approach.	Thank you for your comment. Section 1.3 of the guidance states that patient selection is important when the procedure is being considered for the treatment of patients with malignant disease and notes the lack of long-term follow-up for patients with malignant disease. This will be mentioned in the 'Understanding NICE guidance' document for the procedure (NICE's information for patients).
8	Consultee 2 NHS Professional	2.3	In my view, patients with cancer need to be informed that there is no data on cancer outcomes and in particular local recurrence rates following single port nephrectomy.	Thank you for your comment. Section 1.2 of the guidance states that clinicians should ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information.

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9	Consultee 2 NHS Professional	2.4	The studies, including the RCT, contain small numbers of patients. Â Serious complications might be significantly more common with the single port approach and yet not be observed in such a small cohort of patients. Â Therefore considerable caution is still required.	Thank you for your comment.
10	Consultee 1 Specialist Adviser	2.5	The procedure has also been performed robotically: Rane A, Autorino R. Robotic natural orifice transluminal endoscopic surgery and laparoendoscopic single-site surgery: current status. Curr Opin Urol. 2011 Jan21(1):71-7.	Thank you for your comment. The cited paper is a review and is not therefore included in the overview.
11	Consultee 2 NHS Professional	2.5	I have performed over 700 laparoscopic nephrectomies and one single port nephrectomy. Â I would observe that a safe standardised operation (laparoscopic nephrectomy) becomes more difficult and clumsy when performed through a single port, with more limited options to deal rapidly with unexpected complications, particularly bleeding. Â Evidence suggests that surgical volume is important in determining outcome in difficult or complex operations and this was accepted when formulating IOG for urological pelvic cancer surgery.	Thank you for your comment. Section 1.4 of the guidance states that the procedure should only be carried out by experienced laparoscopic surgeons who have received specific training in the procedure. Interventional Procedures guidance does not usually specify a minimum number of operations. See also response to comment no. 3.
12	Consultee 2 NHS Professional	2.5	Â I would suggest that the guidelines need to take into account that the UK environment still allows surgeons to perform renal cancer surgery with no minimum numbers requirement from IOG. Â This increases the risk of introducing single port nephrectomy. Therefore, I recommend that the guidance restricts this procedure to surgeons performing a minimum of 50 laparoscopic renal operations per year.	Thank you for your comment. Section 1.4 states that the procedure should only be carried out by experienced laparoscopic surgeons who have received specific training in the procedure. Interventional Procedures guidance does not usually specify a minimum number of operations. See also response to comment no. 3.
13	Consultee 2 NHS Professional		Laparoscopic and robotic instrumentation is evolving rapidly. Â Instrumentation is likely to improve in the future and with it the safety of the surgery.	Thank you for your comment. Section 2.5.1 of the guidance states that the technology used for this procedure is evolving rapidly and these developments may influence its safety and efficacy.

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