

National Institute for Health and Care Excellence

IP1540 / Robot-assisted kidney transplant

IPAC date: 8 February 2018

Co m. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional Consultant Surgeon	General	<p>I strongly believe that there is no need for Robotics in Transplantation. Techniques (open or Laparoscopic) currently available give excellent results. Competent and skilled surgeons must be able to perform the surgery without the use of a robot. The cost involved and the higher complications rate with the robotic surgery (published data) makes this exercise unwarranted.</p> <div data-bbox="853 903 1491 1310" style="background-color: black; width: 100%; height: 100%; min-height: 250px;"></div>	<p>Thank you for your comment.</p> <p>The Interventional Procedures (IP) programme at NICE assesses the safety and efficacy of new interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition.</p> <p>In this instance, in patients for whom conventional open kidney transplant surgery is suitable, the recommendation was that " this procedure should only be used in the context of research." And for patients with obesity who would not otherwise be able to have a kidney transplant, the recommendation was that " this procedure</p>

				<p>should only be used with special arrangements for clinical governance, consent, and audit or research.”</p> <p>Cost-effectiveness is not part of the remit of the IP Programme either.</p>
2	<p>Consultee 2 Professional Organisation British Association of Urological Surgeons</p> <p>BAUS's comments were prepared with input from [REDACTED]</p>	1.4	<p>There is data from Europe and the USA that robotic renal transplantation can be safely performed in a high volume robotic surgery centre. These reports are based on case series from surgeons who already perform complex robotic surgery. Data from the USA suggest it would be a useful method for patients with high BMI. BAUS would encourage joint operating between experienced robotic surgeons (often urologists) and transplant surgeons as this complementary expertise minimises intraoperative problems.</p> <p>Three units in the UK (Royal Free, Guy's and Oxford) have done small numbers (2-8) cases. Newcastle plans to start later this year. Surgeons from the Royal Free have submitted an abstract to British Transplantation Society for presentation in March detailing their experience on their first 8 cases. They conclude that RAKT is a technically challenging procedure with a steep learning curve, resulting in longer implantation and operative times. Close co-operation between transplant surgeons, urologists and anaesthetists, specialist training and mentorship in robotic surgery, and the use of intracorporeal ice for graft cooling allows safe</p>	<p>Thank you for your comment.</p> <p>The committee considered this comment but decided not to change the guidance.</p> <p>The Interventional Procedures (IP) programme at NICE assesses the safety and efficacy of new interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition.</p> <p>In this instance, in patients for whom conventional open kidney transplant surgery is suitable, the recommendation was that “ this procedure should only be used in the context of research.” And for patients with obesity who would not otherwise be able to have a kidney transplant, the recommendation was that “ this procedure should only be used with special</p>

			<p>progress through this learning curve. This results in equivalent graft outcomes - even in initial cases - to those from OKT.</p> <p>"Whereas case for the safety of robotic renal transplant surgery under certain circumstances has been made, the case for its utility has yet to be proven.</p> <p>Under those circumstances it is too early for NICE to recommend robotic renal TX as a recognised modality in UK, other than to suggest that this procedure should only be performed by a robotic surgeon who performs high volume robotic surgery in a high volume robotic centre. There should be governance mechanism in place to record the outcomes.</p> <p>"</p>	<p>arrangements for clinical governance, consent, and audit or research."</p> <p>Section 3.8 of the guidance states: " The committee was told that there is a substantial learning curve for surgeons wishing to do this procedure ."</p>
3	<p>Consultee 3 NHS Professional British Transplantation Society</p>	General	<p>"</p> <p>The British Transplantation Society (BTS) welcomes the opportunity to comment on these draft recommendations.</p> <p>We offer the following comments:</p> <p>Generic comments:</p> <p>The BTS suggests that the cost effectiveness of robotic-transplant surgery remains unproven and, as such, must be clinically and financially justified prior to use outside the research arena.</p>	<p>Thank you for your comment.</p> <p>Cost-effectiveness is not part of the remit of the IP Programme.</p>
4	<p>Consultee 3 NHS Professional British Transplantation Society</p>	3.6	<p>Section 3.5: Replace "harvested"™ with "retrieved"™ to be consistent with current descriptors for organ retrieval.</p>	<p>Thank you for your comment.</p> <p>Section 3.6 has been changed to:</p>

				<p>“ Most of the evidence came from studies in which kidneys were <u>retrieved</u> from living donors.”</p>
5	<p>Consultee 3 NHS Professional British Transplantation Society</p>	<p>1.1 and 1.2</p>	<p>Draft recommendations: The pre-condition of obesity must be qualified because open kidney transplant is technically possible in all patients but may not be appropriate on grounds of safety. We suggest that recommendations 1.1 and 1.2 are reworded to reflect this, as follows: 1.1 Current evidence on the safety and efficacy of robot-assisted kidney transplant is limited in quantity and quality. For patients with obesity who would not otherwise be able to have a kidney transplant without considerable risk of morbidity, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. In patients for whom conventional open kidney transplant surgery is suitable, this procedure should only be used in the context of research. 1.2 Clinicians wishing to perform robot-assisted kidney transplant in people with obesity who would not otherwise be able to have a kidney transplant without considerable risk of morbidity should: • Inform the clinical governance leads in their NHS trusts. NICE interventional procedures consultation document, December 2017 IPCD “ Robot-assisted kidney transplant Page 3 of 6 Issue date: [month year] © NICE 2017. All rights reserved. Subject to Notice of rights.</p>	<p>Thank you for your comment.</p> <p>Sections 1.1 and 1.2 of the guidance have been changed as follows:</p> <p>“1.1 Current evidence on the safety and efficacy of robot-assisted kidney transplant is limited in quantity and quality. For patients with obesity who would not otherwise be able to have a kidney transplant without an unacceptable risk of morbidity, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. In patients for whom conventional open kidney transplant surgery is suitable, this procedure should only be used in the context of research.</p> <p>1.2 Clinicians wishing to do robot-assisted kidney transplant in people with obesity who would not otherwise be able to have a kidney transplant without an unacceptable risk of morbidity should:</p> <ul style="list-style-type: none"> • Inform the clinical governance leads in their NHS trust. • Ensure that patients understand the uncertainty about the procedure’s safety and efficacy and provide them with clear written information to

		<p>â€¢ Ensure that patients understand the uncertainty about the procedureâ€™s safety and efficacy and provide them with clear written information to support shared decision-making. In addition, the use of NICEâ€™s information for the public [[URL to be added at publication]] is recommended.</p> <p>Submitted by: ██████████ ██████████, British Transplantation Society On behalf of the Council and Executive "</p>	<p>support shared decision-making. In addition, the use of NICE’s information for the public is recommended.</p> <ul style="list-style-type: none"> • Report details about all patients having robot-assisted kidney transplantation to NHS Blood and Transplant and review clinical outcomes locally. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion)."
--	--	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

"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."