NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Robot-assisted kidney transplant

A kidney transplant is an effective treatment for people who have end-stage kidney failure. A robot-assisted kidney transplant is a 'keyhole' technique in which the surgeon uses a robot to assist with transplanting the kidney. The aim is to use smaller cuts (the largest being about 7 cm) and decrease blood loss during surgery, and to reduce recovery time. It may also allow kidney transplantation in some patients with obesity in whom conventional transplant surgery would not be considered.

The National Institute for Health and Care Excellence (NICE) is looking at robot-assisted kidney transplant. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the <u>Interventional Procedures Programme process</u> guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of

IPCD – Robot-assisted kidney transplant

Page 1 of 6

Issue date: [month year]

discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 22 January 2018

Target date for publication of guidance: April 2018

1 **Draft recommendations**

- 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, 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 do robot-assisted kidney transplant in people with obesity who would not otherwise be able to have a kidney transplant should:
 - Inform the clinical governance leads in their NHS trusts.

IPCD – Robot-assisted kidney transplant

Page 2 of 6

Issue date: [month year]

- Ensure that patients understand the uncertainty about the
 procedure's safety and efficacy and provide them with clear
 written information to support shared decision-making. In
 addition, the use of NICE's information for the public [[URL
 to be added at publication]] is recommended.
- Clinicians should report details about all patients having robot-assisted kidney transplantation to <u>NHS Blood and</u> <u>Transplant</u> and review clinical outcomes locally.
- 1.3 Further research should include studies comparing robot-assisted kidney transplant with open surgery. This should collect data on patient selection, warm ischaemia times, the need for conversion to open surgery, graft function, and long-term graft and patient survival.
- 1.4 The procedure should only be done by teams of surgeons with experience in both transplant surgery and robotic surgery.

2 The condition, current treatments and procedure

The condition

2.1 End-stage renal disease results when kidney function is insufficient to maintain health without either dialysis or a kidney transplant.

This is typically when the glomerular filtration rate is less than 15 ml/min/1.73 m². End-stage renal disease may be caused by a number of conditions, most commonly diabetes mellitus.

Current treatments

2.2 The treatments for end-stage renal disease include conservative treatment, dialysis and kidney transplant. Kidney transplant is

IPCD - Robot-assisted kidney transplant

Page 3 of 6

Issue date: [month year]

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- considered the treatment of choice for many patients but is not always possible.
- 2.3 Kidney transplant, using a kidney from either a deceased or living donor, is usually done by open surgery through an incision in the left or right lower abdomen providing a retroperitoneal approach to the iliac fossa.

The procedure

- 2.4 Robot-assisted kidney transplants may result in decreased blood loss, shorter recovery time, fewer wound complications and improved cosmetic results compared with conventional open surgery.
- 2.5 With the patient under general anaesthesia and placed in a supine position, a periumbilical incision of about 7 cm is made to insert a hand-assist device. Subsequently, 4 or 5 small incisions (0.5 to 1 cm) are made to insert robotic arms and instruments into the abdomen. After the ports and the hand-assist device are placed, the patient is usually moved to the Trendelenburg position. The external iliac vessels are prepared and the bladder is filled with normal saline to facilitate its dissection. The graft kidney is put into the peritoneum and the renal vein and artery are anastomosed to the external iliac vessels using the robot. After completion of vascular anastomoses, a ureteroneocystostomy is performed robotically. The patient's wounds are closed in a standard manner. Intra-operative Doppler imaging may be used to assess graft vascular flow.
- 2.6 Modifications of the techniques used for robot-assisted kidney transplant have been described.

IPCD – Robot-assisted kidney transplant

Page 4 of 6

Issue date: [month year]

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 2 comparative studies, 6 case series, data provided by the ERUS RAKT registry, and safety data from 2 conference abstracts. These are presented in table 2 of the interventional procedures overview [add URL]. Other relevant literature is in appendix A of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: patient survival, graft survival and renal function.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: blood loss, warm ischaemia time, conversion to open surgery, arterial thrombosis, loss of renal function, infection and graft rejection.

Committee comments

- 3.4 Most of the evidence was from studies in patients with obesity who might otherwise be ineligible for conventional transplant surgery and this underpinned recommendation 1.1.
- 3.5 Most of the evidence came from studies in which kidneys were harvested from living donors.

- 3.6 The committee was advised that the placement of the transplant kidney within the peritoneum may increase risk of torsion of the kidney and make biopsy difficult. However, a technique to fix the kidney in an extra-peritoneal pouch has been developed, with the aim of preventing vascular torsion and allowing biopsy.
- 3.7 The committee was informed that there was a significant learning curve for surgeons wishing to undertake this procedure.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
December, 2017