



Clinical Commissioning Policy Proposition: Robotic Assisted Surgery for Kidney Cancer

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1 Executive Summary

Policy Statement

NHS England proposes to not routinely commission robotic assisted surgery (RAS) for the treatment of kidney cancer in accordance with the criteria outlined in this document.

In creating this policy proposition NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

The policy proposition aims to confirm NHS England's commissioning approach to robotic assisted surgery for the treatment of kidney cancer.

Most people have two kidneys which are located on either side of the body, just underneath the ribcage. The main role performed by a kidney is the filtering out of waste products from the blood, as well as the production of urine. Usually, only one of the kidneys is affected by cancer.

In 2013, kidney cancer was the eighth most common cancer affecting adults in the United Kingdom (UK), representing approximately 3% of all cancer cases (Public Health England, 2015). There are many different types of kidney cancer, however Renal Cell Carcinoma (RCC) is the most common and accounts for approximately 90% of all renal cancers. Typically kidney cancer affects more men than women and is more common with increasing age. The main risk factors for kidney cancer include smoking and being overweight. In addition, people with kidney disease who have experienced long-term kidney dialysis are at an increased risk of developing kidney cancer (Cancer Research UK, 2016).

The rate of new diagnoses (incidence) of kidney cancer has risen significantly in England since 2011 and in 2013 there were 8,562 new diagnoses in England (Public Health England, 2015). The overall survival outlook for kidney cancer is that 70% of people diagnosed survive for 1 year and almost 60% survive for five years or more (Cancer Research UK, 2016). Treatment is easier and survival rates are better where kidney cancer is diagnosed at an earlier stage.

Treatment options for kidney cancer are determined by both the size and spread of the cancer, however surgery is the mainstay option. Unlike most other cancers, chemotherapy is not usually effective in treating kidney cancer; however radiotherapy treatments are available.

Kidney cancer can be surgically treated using a nephrectomy procedure, which is the removal of the kidney. There are three types of nephrectomy (simple, radical and partial) and procedures can be carried out in three different ways (open, laparoscopic or robotic assisted laparoscopic).

Robotic surgery requires expensive equipment, which represents a capital cost as well as the cost of consumables. Currently providers are reimbursed for robotic

assisted surgery through the national prices, with a separate additional payment for the cost of the robotic consumables.

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of robotic assisted surgery to treat kidney cancer.

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2 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission robotic assisted surgery (RAS) for the treatment of kidney cancer.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether RAS for the treatment of kidney cancer will be routinely commissioned is planned to be made by NHS England by May 2016 following a recommendation from the Clinical Priorities Advisory Group.

3 Proposed Intervention and Clinical Indication

Renal cell carcinoma is the eighth most common cancer in the United Kingdom (UK) (Public Health England, 2015). It is more common in men than women and typically affects adults over the age of 50.

The mainstay treatment for kidney cancer is surgical removal, or partial removal, of the kidney (nephrectomy or partial nephrectomy). Unlike most other cancers, chemotherapy isn't generally very effective at treating kidney cancer, however radiotherapy techniques are available.

Robotic Assisted Surgery (RAS) is a form of minimally invasive surgery that is increasingly used in a number of complex surgical procedures internationally. Within England, this technique has developed primarily within the field of urological cancer treatment and, alongside laparoscopic techniques, has been replacing traditional open surgical procedures.

In the treatment of kidney cancer, RAS is mainly used to perform partial nephrectomy procedures. Traditionally such procedures have been undertaken using open methods or standard laparoscopic methods. RAS for partial nephrectomy has only recently been developed, however it is of increasing use.

4 Definitions

There are three types of nephrectomy:

- **Partial nephrectomy** is defined as the removal of part of the kidney and is used to treat small accessible tumours which have not metastasised. It is sometimes called nephron-sparing surgery.
- **Simple nephrectomy** which involves the removal of the whole kidney. It is mainly used to treat benign renal disease.
- **Radical nephrectomy** which involves removal of the whole kidney, the adrenal gland, local lymph nodes and surrounding tissue. It is used to treat renal cancer confined to the kidney but unsuitable for partial nephrectomy, and sometimes for more advanced renal cancer.

Nephrectomy can be carried out in three different ways:

- **Open nephrectomy** is where the kidney is removed through a large incision. The procedure is carried out under direct vision.
- **Laparoscopic nephrectomy** is where the surgeon inserts a laparoscope and other surgical instruments through small incisions in the abdominal wall, and uses them to remove the kidney.
- **Robot-assisted laparoscopic nephrectomy** is a variant on the laparoscopic approach.

5 Aims and Objectives

This policy proposition considered: RAS for the treatment of kidney cancer.

The objectives were to: Establish whether RAS should be routinely commissioned to treat kidney cancer, and if so, to identify any appropriate commissioning criteria.

6 Epidemiology and Needs Assessment

Renal cell carcinoma represents 2-3% of all cancers. Worldwide its incidence is increasing annually by approximately 2%. In the UK there were over 11,000 new cases in 2013, with around 4,300 patients dying of kidney cancer, making it the eighth most common malignancy in the UK.

Renal cell carcinoma is the most common form of kidney cancer, accounting for 90% of all renal malignancies. There is a 1.5:1 predominance in men over women, with peak incidence occurring between 60 and 70 years of age (Public Health England, 2015).

In 2012 and 2013 there were 1,970 partial nephrectomies for malignancy recorded on the British Association of Urological Surgeons (BAUS) audit (about 14% of all nephrectomies). Of these, 18% were recoded as being robotically-assisted..

The BAUS audit data also demonstrated:

- That there was no significant difference in the age of patients undergoing RAS partial nephrectomy compared to the laparoscopic or open approach with 54% of robotically-assisted procedures occurring were in those aged 50-69 (24% 50-59; 29% 60-69); and
- That there is a trend towards the increased use of RAS for partial nephrectomy in the UK. In 2012, 13 trusts recorded robot-assisted partial nephrectomies for malignancy with a median of 6 procedures, a minimum of one and a maximum of 22. In 2013, 18 trusts recorded robot-assisted partial nephrectomies for malignancy with a median of 12 procedures, a minimum of one and a maximum of 37.

In the absence of a clinical commissioning policy, the number of RAS partial nephrectomies performed in the UK would be expected to increase by 10% per annum.

7 Evidence Base

There is a lack of compelling evidence that robot-assisted approaches for the treatment of kidney cancer (either by radical or partial nephrectomy) are associated

with lower mortality or morbidity, lower recurrence risk, longer survival or any durable patient advantage when compared to laparoscopic or open approaches as demonstrated through results from three systematic reviews of controlled studies (Zhang et al. 2013, Wu et al. 2014, MacLennan et al. 2012).

In addition to the consideration of an evidence review, a study of audit data (held by the British Association of Urology Surgeons, BAUS) was undertaken, which indicated that the use of RAS in partial nephrectomies may offer promise. However, the data for RAS partial nephrectomy does not clearly show a benefit over standard approaches such that a positive commissioning statement can be produced. This is because of confounding data within the literature and unpublished yet promising data in national audits.

There was limited evidence of some clinical advantages from robot-assisted nephrectomy/partial nephrectomy when compared with laparoscopic procedures. These include: shorter warm ischaemia time, reduced blood loss, lower re-admission rates and a reduced need for secondary procedures (Zhang et al. 2013, MacLennan et al. 2012, Kalifeh et al. 2013). However, these could be the result of confounding and patient selection within the studies. There is limited evidence that shorter warm ischaemic time in robotic surgery leads to better long term preservation of overall renal function compared with standard laparoscopy.

The technical difficulty of laparoscopic partial nephrectomy may limit its use in complex renal lesions. There is limited evidence that robotic partial nephrectomy may allow more complex lesions to be treated using nephron sparing surgery (Volpe et al 2014), and thereby offering the long term benefits of nephron sparing surgery to more patients.

There was limited evidence of some clinical advantages from robot-assisted nephrectomy when compared with open procedures. These include: reduced blood loss and shorter inpatient stay. In some series the robot-assisted operations took longer to perform, although other series report shorter operative time using the robotic approach compared to standard laparoscopy (Kim et al 2015) There were also fewer complications after robot-assisted procedures (Wu et al. 2013, Wu et al 2015).

There was no clear evidence of improved safety associated with robotic approaches, though some studies do indicate that RAS procedures are associated with lower complications (Wu et al.2013). However this was not consistently reported.

There was some evidence that robotic partial nephrectomy is more expensive than conventional alternatives. This was found to be largely because of the cost of buying and maintaining the machine, but also because of differences in the cost of consumables. Shorter operations and reduced lengths of in-patient stay were not found to offset the higher cost of the procedure (Mir et al.2011, Laydner et al. 2013).

There was no evidence about the relationship between hospital volume and clinical outcome and only very limited evidence about the relationship between surgeon experience and clinical outcome (Khalief et al. 2013).

Positive margin rates, requirement for blood transfusion and median length of stay were compared for two arrangements of centres. Firstly in two groups of less than 20 or 20 or more procedures; secondly in three groups of less than 20, 20-39 and 40 or more procedures. There was insufficient evidence of a difference in outcomes by surgical volume when split into three groups. When split into two groups there was a shorter median length of stay in centres which did 20 or more procedures, at 3 days compared to 4 days ($p < 0.001$).

Review of BAUS audit data

NHS England also reviewed audit data supplied by BAUS. Targeted interrogation and analysis of this data indicated that the technique may offer patient advantages, such as reduced blood loss and length of stay, and may possibly reduce post-operative complications, where the technique issued to perform partial nephrectomy procedures.

There were 363 RAS partial nephrectomies recorded on the BAUS database for 2012 and 2013, representing approximately 18% of all partial nephrectomies recorded on the database. Of these, 91% required no blood transfusion, with 8% missing data. This compares to 83% in the open group (p -value for open vs robotic < 0.001) with 12% missing data. A sensitivity analysis indicates that if missing data

is unbiased then the statistical significance remains ($p < 0.001$).

The 30-day mortality rate in all groups was negligible and no comparisons could be made. The median length of stay for the RAS group was 3 days, 4 days for the laparoscopic group and 5 days for the open group (p -value for open vs robotic < 0.001 ; p -value for laparoscopic vs robotic < 0.001).

It is established that nephron sparing (i.e., partial nephrectomy) surgical approaches result in better preservation of overall renal function compared with total nephrectomy (MacLennan et al 2012). In the long term this may result in significantly less chance of chronic renal deterioration, which may ultimately lead to dialysis dependence in some patients.

8 Proposed Criteria for Commissioning

Robotic assisted surgical techniques to treat kidney cancer will not be routinely commissioned.

9 Proposed Patient Pathway

There is no change to the patient pathway as a result of this policy proposition. The policy proposition clarifies the routinely commissioned surgical techniques for the treatment of kidney cancer.

10 Proposed Governance Arrangements

Not applicable.

11 Proposed Mechanism for Funding

Not applicable.

12 Proposed Audit Requirements

Not applicable.

13 Documents That Have Informed This Policy Proposition

None.

14 Date of Review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by May 2016).

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