A06/S(HSS)b

2013/14 NHS STANDARD CONTRACT
FOR EX-VIVO PARTIAL NEPHRECTOMY SERVICE (ADULT)

PARTICULARS, SCHEDULE 2 – THE SERVICES,
A - SERVICE SPECIFICATION

Service Specification No.	A06/S(HSS)b
Service	Ex-vivo partial nephrectomy service (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Oncologic outcomes

Patients with T1-2 organ confined renal tumours have a good overall prognosis with five year survival rates of between 80-95%. The oncologic outcomes for patients with tumours in solitary kidneys managed with conventional open partial nephrectomy are similar to the general population. Patients who undergo an ex-vivo partial nephrectomy (EPN) have larger more complex tumours which one would expect to have a poorer prognosis.

There is a paucity of data regarding the oncologic outcomes after EPN. To date 13 patients have been treated at Oxford Radcliffe Hospitals NHS Trust with an overall survival rate of 76.9%, a cancer specific survival rate of 92% and a recurrence free survival rate of 72.7% at median follow-up of 29 months. Other centres across the world have reported: Mickisch - recurrence free survival rate of 94% in 36 cases with a median follow up of 2.8 years; Nozaki et al – 100% recurrence free survival in seven patients with a median follow up of 11. 4 months; Kulisa et al - 36.4 % disease free survival in 11 patients with a mean follow up of 37.8 months.

Patients not managed with an EPN will usually be treated with a radical nephrectomy and dialysis There is no randomized controlled trial data comparing the outcomes of EPN and radical nephrectomy plus haemodialysis. Reinberg et al reported that 9/11 (82%) patients managed with haemodialysis died of cancer, compared with 1/12 (8%) patients who received a kidney transplant following renal cancer surgery, this despite comparable stages of renal cell carcinoma and Wilms' tumour in the two groups. Black et al treated six patients with bilateral tumours and reported a five year

survival rate of 44%.

Renal preservation

Patients treated with an EPN have an excellent chance of being dialysis free following their treatment. Out of the 10 surviving patients treated in Oxford 10/10 patients are dialysis free (100%). Dialysis free rates were equally high in the hands of others; Mickish 94%, Nozaki et al 100% and Kulisa et al 81%.

As stated earlier there is no randomized control trial comparing health outcomes for EPN and radical nephrectomy plus haemodialysis, however parallels can be drawn from the end stage renal failure population. Data from the UK Renal Registry in 2007 showed that the incident one-year survival for patients with end stage renal failure who had just commenced renal replacement therapy was 86%. The age-adjusted survival (adjusted to age 60) of prevalent dialysis patients in 2007 was 89%. The standardised mortality ratio of patients on dialysis is significantly lowered following kidney transplantation. One can infer that renal preservation in the setting of EPN is also likely to demonstrate similar if not greater survival benefits as EPN patients are not on immunosuppression.

2. Scope

2.1 Aims and objectives of service

In the United Kingdom (UK) up to 40 patients per year become dialysis dependent having under gone renal cancer surgery. Ex-vivo partial nephrectomy and renal auto-transplantation (EPN) is an operation that can be used to treat complex cancers in patients with a single kidney not suitable for other nephron sparing approaches. EPN offers suitable patients the possibility of cancer cure and avoidance of a life on dialysis.

The overall aim of the service is to provide patients with complex renal tumours in solitary kidneys or bilateral disease not suitable for conventional treatments, the possibility of cancer cure and avoidance of dialysis. Between 1997 and 2007, approximately 300 patients in the UK developed end stage renal failure requiring renal replacement therapy as a direct consequence of renal cancer surgery (data from the UK renal register). A proportion of these patients may have avoided dialysis had they had the option of an EPN. We anticipate that 50% of the patients with complex T1-2 tumours may be suitable for an EPN. National commissioning of ex-vivo partial nephrectomy now means that up to 20 potentially salvageable patients will be no longer be rendered anephric and dialysis dependent. It is expected that the EPN service will result in significant quality of life and cost benefits to the health service in England.

2.2 Service description/care pathway

As a single centre for the national service, the provider must ensure adequate clinical staffing levels to meet the national caseload for this service.

Key components of the service will include:

Initial assessment and evaluation

The initial assessment entails each patient being seen by a consultant urological surgeon, a cancer nurse specialist, a renal physician and a transplant surgeon independently. These appointments will ensure patients are fully evaluated for their suitability for an EPN and are fully informed regarding the risks and benefits of their treatment options (EPN or radical nephrectomy plus haemodialysis).

Patients will require additional radiological investigations as part of this evaluation. If suitable for surgery, patients will have a full pre-operative work-up.

All cases will be reviewed in the specialist uro-oncology multi-disciplinary team (MDT) as per Improving Outcomes Guidance (IOG). The core members include consultant urological surgeon (renal cancer specialist), medical oncologist, radiologist, pathologist and clinical nurse specialist.

Surgery & post-operative recovery

Patients will be admitted on the day of surgery and the surgery will be conducted by a team of surgeons (urology and transplant), in most cases the surgery will take eight hours.

Post-operatively patients will go to intensive care followed by the high dependency unit on the dedicated transplant ward. Post-operative care will be managed by the urology consultant in conjunction with the transplant and renal teams. The average length of stay is 21 days following surgery. Some patients may require dialysis following surgery.

Follow up

Patients will be reviewed in the specialist renal cancer clinic at months 1, 3, 6, 9 and 12. They will have surveillance imaging prior to their outpatient appointments at months 3, 6 and 12. After one year, patients will be referred back to their local urological surgeon with a recommended surveillance protocol.

Risk management

Care delivered by the ex-vivo partial nephrectomy service must be of a nature and quality to meet the care standards, specification and agreement for the service. It is the trust's responsibility to notify the commissioner on an exceptional basis should there be any breaches of the care standards. Where there are breaches any consequences will be deemed as being the trust's responsibility.

Patients must be managed in line with the specification and care standards. Any deviation from these which has not been approved by NHS England is at the trust's risk both clinically and financially. It is the trust's responsibility to inform the commissioners of any such non-approved deviations on an exceptional basis.

Where a patient's presentation challenges the assumptions that underpin the specification, service standards and contractual arrangements it is the trust's responsibility to inform the commissioners on an exceptional basis, prior to any treatment (except for emergency treatment) so that the implications of the patient's requirements can be considered. This does not affect situations where the Individual Funding Application process applies.

Service model and care pathways

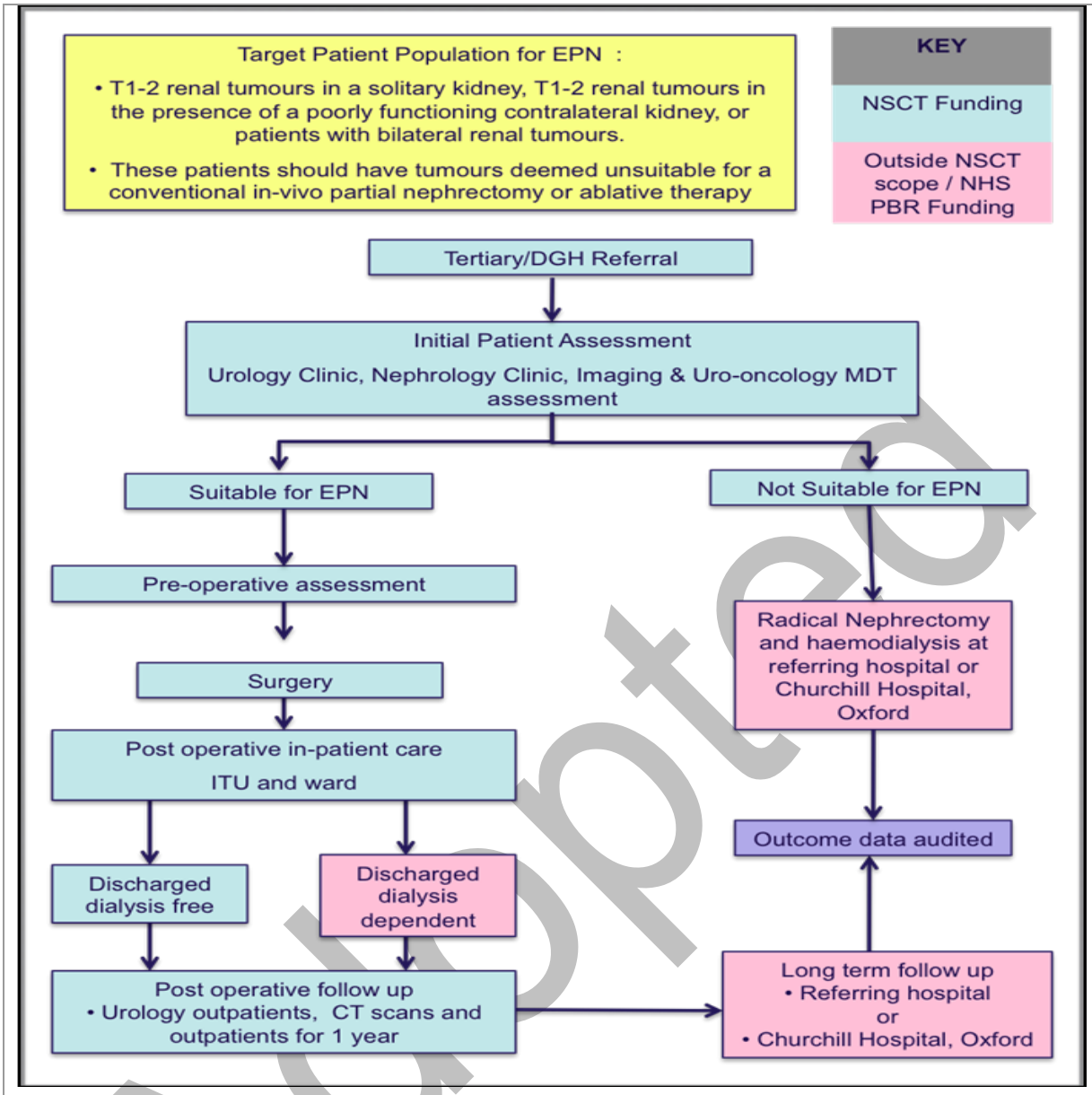
Every patient referred for an EPN must be seen by a consultant urological surgeon in conjunction with a cancer nurse specialist after which their case will be reviewed in an uro-oncology MDT as per IOG guidelines. All patients must also see a renal physician prior to surgery for an independent medical opinion and an opportunity to discuss the principles of renal replacement therapy. This is to ensure that all patients are fully informed regarding the risks and benefits of their treatment options (EPN and radical nephrectomy plus haemodialysis).

Post-operatively patients must be managed jointly by the urology and transplant teams with input from the renal team as required.

All inpatients must be discussed at the weekly urology and transplant departmental meetings, to ensure optimal care and patient safety.

Upon discharge patients must be followed up in the nationally designated service for one year as per protocol with regular cross-sectional imaging with the recommendation of having longer term beyond one year conducted at their local hospital.

All patients that have received an EPN are invited to join the Friends of Renal Oncology Group (FROG) which is a dedicated renal cancer patient support group based in Oxford. This is a patient run support group, which has very close links with the urology and oncology units in Oxford. There are patients within the FROG membership who have previously under gone successful EPN.



Days/hours of operation

The service is open to referrals at all times**.**

Discharge criteria & planning including any transition arrangements

Upon discharge, patients will be followed up in an outpatient setting at months: 1, 3, 6, 9 and 12. They will have a surveillance scan prior to their outpatient visits at months 3, 6 and 12.

After one year, patients will be referred back to their local urological surgeon and with a recommended surveillance protocol.

2.3 Population covered

This service covers patients registered with an English General Practitioner or normally resident in England plus patients resident in the European Union and eligible for treatment in the NHS under reciprocal arrangements. Patients from Scotland, Wales and Northern Ireland are not part of this commissioned service and the Trust must have separate arrangements in place for reimbursement of treatment of patients from the devolved administrations.

2.4 Any acceptance and exclusion criteria

Patients will be referred by their local urological surgeon or tertiary referral centre. There will be no restriction according to culture, disability, gender or age. Patients are less likely to be suitable the older they get because of co-morbidity, however they will be assessed according to their co-morbidities and not their age. The Oxford Radcliffe Hospitals NHS Trust ensure that staff attend mandatory training on equality and diversity and that facilities are provided for appropriate disabled access for patients, family and carers. When required, the service will use translators and ensure that printed information is available in multiple languages.

The EPN service is reserved for patients with complex T1-2 organ confined renal cell carcinomas in solitary kidneys or T1-2 tumours in the presence of a poorly functioning contralateral kidney or bilateral renal cancers not suitable for an in-vivo partial nephrectomy/ablative therapy where conventional treatment options such as radical nephrectomy would render patients anephric and dialysis dependent.

Exclusion criteria

All patients referred to the provider will be assessed on an individual basis regarding their suitability for an EPN. The decision to offer an EPN will be determined by a number of factors including tumour characteristics and patient fitness. EPN is a significant undertaking as these patients need to have sufficient performance status to tolerate the surgery and the potential complications associated with it. A proportion of patients are not suitable for EPN for this reason.

Response time & detail and prioritisation

All newly referred patients will be seen in the dedicated renal cancer clinic as soon as possible to ensure compliance with nationally set cancer targets.

2.5 Interdependencies with other services

The Oxford Radcliffe Hospitals NHS Trust has integrated urology, renal and transplant services which are essential as the success of this complex surgery is dependent upon a multi-disciplinary team approach with support and expertise from urological surgeons, transplant surgeons, nephrologists, oncologists, anaesthetists and cancer nurse specialists.

Patient referrals will be welcomed from urological surgeons across England. Patients who go on to receive an EPN will be followed up for one year where after they will be followed up by their local hospital. The provider will continue to monitor patient outcomes via their referring urological surgeons.

Relevant networks and screening programmes

There are 28 uro-oncology cancer networks across England, within which are a number tertiary renal cancer centres. Hospitals within these networks will provide referrals for the EPN service.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

The nationally designated ex-vivo partial nephrectomy service will be fully integrated into the trust's corporate and clinical governance arrangements. The commissioners and service will conduct a formal Joint Service Review at least every six months.

4. Key Service Outcomes

Quality Performance Indicator	Threshold	Method of measurement	Consequence of breach	Report Due
30 day post-operative survival	80%	Regular outpatient follow up	Inform NHS CB	6 monthly
Overall survival (1 year)	75%	Regular outpatient follow up	Inform NHS CB	Annually
Recurrence free survival (1 year)	65%	Regular outpatient follow up	Inform NHS CB	Annually
Dialysis free rate in surviving patients (1 year)	70%	Regular outpatient follow up	Inform NHS CB	Annually

5. Location of Provider Premises

Oxford University Hospitals NHS Trust