<table>
<thead>
<tr>
<th>Contents</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>03</td>
</tr>
<tr>
<td>2. Referral Pathways from Primary and Secondary Care</td>
<td>04</td>
</tr>
<tr>
<td>3. Fast-Track Pathway for Suspected Renal Cancer</td>
<td>05</td>
</tr>
<tr>
<td>4. Renal Cancer MDT Referral Notes</td>
<td>05</td>
</tr>
<tr>
<td>5. Renal Cancer MDT checklist</td>
<td>09</td>
</tr>
<tr>
<td>6. Renal Cancer MDT Review – Imaging Outcomes</td>
<td>10</td>
</tr>
<tr>
<td>7. Guidelines for the Use of MRI contrast in Renal Cancer</td>
<td>11</td>
</tr>
<tr>
<td>8. Renal Mass Biopsy Guidelines</td>
<td>12</td>
</tr>
<tr>
<td>9. Surgical Pathways for Unilateral Tumours in patients with normal renal function (eGFR&gt;60)</td>
<td>15</td>
</tr>
<tr>
<td>10. Surgical Pathways for Bilateral tumours, tumours in solitary functioning kidneys and patients with impaired renal function</td>
<td>16</td>
</tr>
<tr>
<td>11. Protocol for patients wih ≤ CKD 3 for NSS / nephrectomy</td>
<td>17</td>
</tr>
<tr>
<td>12. Post nephrectomy follow-up schedule for RCC</td>
<td>18</td>
</tr>
<tr>
<td>13. Kidney cancer guidelines for referral and follow up of patients considered for ablation of a small tumour</td>
<td>19</td>
</tr>
<tr>
<td>14. Kidney cancer Oncological pathways</td>
<td>22</td>
</tr>
<tr>
<td>15. Quality Performance Indicators and Outcomes</td>
<td>24</td>
</tr>
<tr>
<td>16. Clinical Trials</td>
<td>32</td>
</tr>
</tbody>
</table>
1. Introduction

These guidelines are intended to direct the treatment of patients with Renal cancer. They have been developed by Royal Free London NHS Foundation Trust in conjunction with all trusts with London Cancer. The guidelines should be read and used in conjunction with other guidelines covering the investigation and surgical management of Renal cancer.
Referral Pathways from Primary and Secondary Care

It is recognised that the classical presentation of renal malignancy (loin pain / haematuria / mass) occurs only in a minority of cases. The commonest presentation is now as an incidental finding on imaging which may have been requested as part of an inpatient or outpatient by primary or secondary care.
Fast-Track Pathway For Suspected Renal Cancers

Suspected renal tumour
(e.g. finding on USS / MRI / single-phase CT)
These patients should have the following investigations before MDT referral, unless there is a very good reason

Triple phase (renal mass) CT

Unless:
• Young (<40), pregnant or contrast allergy – needs renal mass MRI protocol
• Renal failure – needs non-contrast renal MRI (with diffusion) +/- contrast USS

Must be reviewed by local consultant radiologist with experience in renal CT – they will decide if this needs SMDT referral

AML
AML pathway

Suspicious lesion
i.e. Solid lesion or cysts that are Bosniak 2 or higher

Awaiting possibility of same-day CT slots at RFH

Chest CT for Bosniak 3/4 cysts + solid lesions
Non-contrast CT chest if renal failure
CT chest not required for Bosniak 2 cysts

Refer for review at Central Renal SMDT
With all relevant images and reports
Cases will not be reviewed without the external reports

Other benign lesion
e.g. Bosniak 1/2 cyst, column of Bertin

Not for SMDT

Addendum to report
Document benign nature of lesion

See "Guidelines for the Use of MRI contrast in renal cancer" for advice regarding renal failure and use of MRI contrast agents

June 20, 2014
Renal Pathway Notes

1) There must be at least 2 locally-nominated renal radiologists at each site.
2) The local renal radiologist decides which cases come to MDT.
3) If there is any uncertainty or temporary lack of local cover (e.g. sudden leave), the cases may be reviewed centrally.
4) For now, if there is doubt whether a case falls into the fast-track pathway, it may be discussed at the local MDT first, but all attempts should be made not to delay the pathway. e.g. the renal radiologist should be consulted.
5) All reports and previous relevant imaging are required for MDT review as otherwise vital information may be omitted leading to an incorrect MDT decision. Examples:
   - External imaging on CD / film was reviewed at local hospital and this is discussed on the local report. The central radiologist would not be aware of this without the local report.
   - Previous CTs/ultrasounds/MRIs would help to establish rate of lesion growth.
6) For now Bosniak 3 lesions will have a CT chest. We will audit whether this is needed in the future as a recent paper showed no metastases in these lesions:

Questions:

1) Who will review images from each site at the MDT (some local, some central?)
   a. What hospitals are included? Which hospitals can project images into MDT?
   b. Can we stipulate that all sites have to present their local imaging and clinical history?
2) Is all biopsy tissue going to be reviewed centrally?

CT protocols

Triple-phase renal mass protocol CT:
Full dose (not low dose) non-contrast images of kidneys.
Post contrast images of kidneys at 35 sec and of abdomen / pelvis at 90 sec.

CT urogram for upper tract TCC:
   a) Low dose CT kidneys only.
   b) Give 100 ml iv contrast and scan abdomen / pelvis at 80 sec.
      Then give 10 mg frusemide and get patient to walk around or roll 360 degrees (please ensure this is done well as it affects bladder assessment).
   c) Rescan abdomen / pelvis at 10 mins.

Renal cancer follow-up protocols:
- Post-surgical vs post-ablation vs post-systemic therapy
(Should they all be the same, unless part of specific trial?)
- How often and what should we scan (i.e. when to include the chest and pelvis)?
- Effect of stage and grade of tumour?
AML assessment:
- Should the initial assessment CT be triple-phase?
- What size can we ignore?

MRI protocols

Renal mass protocol MRI:
- Axial and coronal T2 BLADE SFOV kidneys (3 mm) - cover kidneys only.
- Diffusion kidneys (as for prostate, including ADC and b1400).
- Sagittal in / out-of-phase precontrast kidneys (3 mm).
- Coronal T1 TSE FS precontrast kidneys (3 mm).
- Axial VIBE SFOV kidneys 0s, 45s, 90s, 180s (3 mm)
- Coronal T1 TSE FS postcontrast kidneys (3 mm).
- Sagittal in / out-of-phase postcontrast kidneys (4 mm).

(Can every site do these (e.g. b values)? What are the minimum sequences?)

MRI urogram protocols:
- See our protocols inc indications below:

MR urogram (with contrast):

Indication:
TCC staging, haematuria.
This scan must always be discussed with a uroradiologist before being accepted.
Always question why they are not having a CT urogram, as that is more sensitive. One acceptable reason is iodinated contrast allergy.
GFR must be over 40.

Technique:
Full bladder. Administer buscopan before the exam.
  - Axial and coronal T2 BLADE SFOV kidneys to bladder (3mm) – in 2-3 blocks. Reduce FOV (does not need subcutaneous fat to be on there!)
  - Coronal heavily T2-weighted sequence (like MRCP) – cover kidneys to bladder. Administer 10 mg iv frusemide and 10 ml iv contrast.
  - Axial VIBE SFOV kidneys to bladder 0s, 45s, 90s, 180s (3 mm). Get the patient to walk around the room & then roll them through 360° whilst on the scan table.
  - 3D acquisition as for renal angio
    - Kidneys only at 8 minutes
    - Kidneys to bladder (will be around 10 minutes)
MR urogram (without contrast):

Indication:
TCC staging, haematuria.

This scan must always be discussed with a uroradiologist before being accepted. The radiologist will also decide if the patient should have 10 mg iv frusemide, 10 minutes prior to the scan (no need for frusemide if baggy PC system).

Always question why they are not having a CT urogram, as that is more sensitive. One acceptable reason is low GFR (=< 40, hence not suitable for contrast).

Technique:
Full bladder. Administer 10 mg iv frusemide and buscopan before the exam.
Axial and coronal T2 BLADE SFOV kidneys to bladder (3mm) – in 2-3 blocks.
Coronal heavily T2-weighted sequence (like MRCP) – cover kidneys to bladder.

To Be Decided

1) AML Pathway
2) Discuss what we have read:
   a. Bosniak:
      i. Good paper re what constitutes each stage
      ii. Malignancy and metastasis rates + follow-up protocols
   b. Cancer:
      i. Metastatic rates for different cancer stages / grades / tumour types
   c. Renal cancer follow-up protocols
   d. Evidence for MRI protocols
Checklist for new case discussion at Renal SMDT

For Local MDT co-ordinators

- **Renal mass CT or renal mass MRI performed**
  Should not be referred with ultrasound only, unless there is a very good reason

- **CT / MRI reviewed by local renal radiologist**
  Local renal radiologist must agree that case is suitable for MDT

- **If Bosniak 3 / 4 cyst or solid lesion, needs urgent CT chest locally**
  If this will delay referral by a week, discuss with RFH MDT co-ordinator (? RFH slot available)

- **All relevant imaging sent by IEP to The Royal Free**
  Including current and previous imaging of kidneys and CTs/MRIs of the body

- **All imaging reports for the scans sent to RFH**
  Either via IEP (if your PACS allows this) or via email to RFH MDT co-ordinator
Renal Cancer MDT Review – Imaging Outcomes

Review at central Renal MDT
With all relevant images AND reports

- Definite primary tumour or Bosniak 3/4 cyst
  - Consideration for definitive treatment

- Bosniak 2f cyst
  - "2f Pathway"
    1) Lesion documented on central database (including reasons why lesion called 2f)
    2) 5-year imaging follow-up locally
    3) Nurse-led telephone clinic review suggested
    4) Referral back to MDT if any change in imaging

- Equivocal enhancement of lesion
  Examples:
  • Too small to assess
  • 15-20 HU enhancement
  - Consider local USS if still equivocal:
    1) MRI
    2) Contrast USS (refer to sites which can perform this)

- Consideration for biopsy
  - Indications:
    1) Uncertainty re nature of lesion (e.g. lymphoma, metastasis, lipid-poor AML)
    2) Prior to systemic therapy (i.e. metastatic)
    3) Prior to ablative therapy
    4) Prior to lesion surveillance (e.g. Small masses, lipid-poor AML, oncocyctoma)

- Possible renal vein / IVC involvement
  - Consider:
    1) CT venogram
    2) IVC MRI (with gated sequences)

- ? Upper tract TCC
  - CT urogram + cystoscopy

June 27, 2014
Guidelines for the Use of MRI contrast in renal cancer

These guidelines are based on ESUR\(^1\) and RANZCR\(^2\) guidelines, following consultation with The Nephrology Unit at The Royal Free Hospital (many thanks to Dr. Robin Woolfson). Newer agents are believed to be more stable and less prone to cause NSF, but we have taken a slightly more cautious approach, especially in extremely low eGFR / haemodialysis / peritoneal dialysis.

Always use the lowest possible contrast dose and avoid high-risk agents if possible (even if not contraindicated).

**MRI requiring iv contrast**
(eg for renal mass characterisation, in lieu of triple-phase renal CT)

**Unstable renal function?**

- YES
  - Consider Risks vs Benefits of Contrast
    - Consider other imaging modalities
    - Consider postponing until renal function stabilised / improved
    - Use low-risk agent, if contrast MRI required
  - Formal measurement of creatinine / eGFR
    - eGFR > 60: Proceed with MRI contrast
    - eGFR 30 - 60: Try to avoid high-risk agents
    - eGFR 15-29: High-risk agents contraindicated
    - eGFR < 15: No contrast
    - Haemodialysis: No contrast
    - Peritoneal dialysis: No contrast

- NO
  - Risk Factors for Chronic Kidney Disease (CKD)?
    - 1. Known renal disease / dialysis
    - 2. Family history of renal disease
    - 3. Age of 60 or over
    - 4. Diabetes mellitus
    - 5. Vascular disease (MI / stroke)
    - 6. Hypertension
    - 7. BMI of 30 or over
    - 8. Smoker

- Proceed with iv contrast
  - Use lowest dose and lowest risk agent

**Risk of NSF**

<table>
<thead>
<tr>
<th>Risk of NSF</th>
<th>Trade Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Omniscan</td>
<td>gadodiamide</td>
</tr>
<tr>
<td></td>
<td>Magnevist</td>
<td>gadopentetate</td>
</tr>
<tr>
<td></td>
<td>Optimark</td>
<td>gadoversetamide</td>
</tr>
<tr>
<td>Medium</td>
<td>Primovist</td>
<td>gadoxetate</td>
</tr>
<tr>
<td></td>
<td>Ablavar</td>
<td>gadofosveset</td>
</tr>
<tr>
<td></td>
<td>MultiHance</td>
<td>gadobenate</td>
</tr>
<tr>
<td>Low</td>
<td>Dotarem</td>
<td>gadoterate</td>
</tr>
<tr>
<td></td>
<td>Gadovist</td>
<td>gadobutrol</td>
</tr>
<tr>
<td></td>
<td>ProHance</td>
<td>gadoteridol</td>
</tr>
</tbody>
</table>

**REFERENCES:**
2) http://www.ranzcr.edu.au/component/docman/doc_download/553-revised-college-guidelines-for-gadolinium-containing-mri-contrast-agents-
Renal Mass Biopsy Guidelines

The most up-to-date recommendations are the EAU 2013 renal cancer guidelines. The network guidelines are based on this document.

Indications

1) When there is uncertainty regarding the nature of a renal lesion, especially if suspicion of:
   a. Lymphoma
   b. Metastasis

2) To obtain tissue (in order to select optimal systemic therapy) in cases of metastatic disease.

3) Prior to ablative therapy
   a. At a separate sitting
   b. Or at the start of the ablation procedure

4) To select patients with small renal masses for surveillance approaches
   a. Suspected lipid-poor AML
   b. Suspected oncocytoma
   c. Other lesions that are for active surveillance

Preparation

1) All patients should have recent routine bloods including FBC, U&Es and clotting screen (INR and APTT).

2) If Hb < 10 or biopsy at high risk of bleed (e.g. very vascular lesion, anti-clotting therapy), needs Group & Save.
   a) If Hb < 8, consider preprocedure transfusion.

3) If on anti-coagulation / anti-platelet therapy, this will need to be stopped pre-procedure.
   a) Always consult the team that instituted the therapy (e.g. cardiologist, stroke physician) or the haematology team regarding cessation.
   b) Aspirin - stopped for 7 days.
   c) Clopidogrel - stopped for 10 days.
      i) If on combination aspirin / clopidogrel therapy, aspirin therapy may need to be continued.
         (1) Higher risk should be explained to the patient.
         (2) Consider delaying biopsy if combination therapy is for a limited period (e.g. 6 months / 1 year).
   d) LMWH - omitted the night before and the day of the procedure.
   e) Warfarin – bridging plan from haematology team.
   f) Newer anticoagulants (e.g. rivaroxaban) – haematology review.
Technique

1) If the lesion cannot be confidently identified on ultrasound (especially if the lesion is endophytic), then CT guidance should be used.
   a. Prebiopsy, contrast injection should be strongly considered to help target enhancing regions of the lesion.

2) Core biopsies should be obtained rather than FNA.
   a. A co-axial needle should be used (thought to reduce risk of seeding).
   b. The biopsy needle should be at least 18G.
   c. At least 2 samples should be taken.

3) Non-necrotic (i.e. enhancing) areas of the tumour should be targeted – most often, the periphery of the lesion is the best site on larger tumours.
   a. If there is any concern regarding adequate sampling, the co-axial needle may be repositioned and further samples taken (i.e. multiple sites as well as multiple biopsies).

4) If samples are to be used for cytogenetic studies or tissue banking, they most likely cannot be fixed in formalin.
   a. See below.

Histological Analysis
(Thanks to Drs. A Bates & S El Sheikh)

1) All the material received will be histologically examined and initial H&E sections cut. Immunohistochemistry will be undertaken as a panel at the pathologist’s discretion.
   a) Appropriate clinical information should be provided on the pathology request form.

2) Samples showing necrotic tissue only will be examined at multiple levels before the final report is issued as inadequate biopsy.

3) Fuhrman grading to be attempted, particularly as high grade (3-4) versus low grade (1-2), with the limitation of sampling error highlighted.

4) Oncocytic tumours may be present in the form of hybrids (particularly hybrid oncocytoma-chromophobe carcinoma).
   a) The distinction between the two tumours on biopsy may be evident on H&E supported by immunohistochemistry but tumour heterogeneity is a caveat that must be recognised.

5) Cytogenetic studies or tissue banking require fresh tissue in the majority of cases and cores taken for this purpose cannot be fixed in formalin.
   a) The problems anticipated are related to the rapid freezing and facilities required and the possible erroneous sampling (for example a core of benign renal tissue or an entirely necrotic core).
   b) Protocols must be in place before this is attempted.

6) Normal parenchyma present may be further assessed by special stains if renal function is compromised.
References

1)  http://www.uroweb.org/gls/pdf/10_Renal_Cell_Carcinoma_LR.pdf

Surgical Pathways for Unilateral Tumours in patients with normal renal function (eGFR>60)

General Principles:

1) The patient should be involved in the discussion and decision on treatment options

2) Minimally invasive surgical approaches (laparoscopic +/- robotic assistance) should be performed if technically possible.

3) Nephron sparing surgery should be attempted where possible without compromising oncological safety.

4) Clinically or radiologically suspicious lymph nodes & adrenals should be excised

5) Any appropriate open clinical trials should be discussed with the patient.

Treatment Options by Stage

<table>
<thead>
<tr>
<th>T1a</th>
<th>T1b</th>
<th>T2</th>
<th>T3a-c/T4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveillance consider initial biopsy</td>
<td>NSS</td>
<td>NSS</td>
<td>Nx Multidisciplinary surgical team and facilities if required</td>
</tr>
<tr>
<td>NSS</td>
<td>Nx Ablation</td>
<td>Nx</td>
<td></td>
</tr>
<tr>
<td>Ablation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NSS = nephron sparing surgery
Nx = nephrectomy
Ablation = RFA or Cryo
Surgical Pathways for bilateral tumours, tumours in solitary functioning kidneys and patients with impaired renal function.

General Principles

1) The patient should be involved in the discussion and decision on treatment options including the risk of cancer related mortality against the risks of surgery and renal replacement therapy.

2) The aim of treatment is to achieve oncological cure whilst maintaining as much renal function as possible.

3) These are complex cases which may require a multimodality (ablative & surgical) and multidisciplinary approach (surgical/radiological/nephrological)

4) Additional investigations (differential renal function/biopsy) may be required to best inform treatment decisions

5) Treatment pathways need to be decided on a case by case basis

6) The protocol for Renal Surgery in patients with CKD should be followed
Post nephrectomy follow up schedule for RCC

<table>
<thead>
<tr>
<th>MAYO-Leibovich score</th>
<th>6 weeks post op F/U</th>
<th>6 months</th>
<th>6-24 months</th>
<th>Annually years 2-5</th>
<th>5-10 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk 0-2 RR: 7.5%@ 10 yrs RN/PN</td>
<td>Operative site and gen wellbeing and Feedback Bloods BP, Urine Dip GFR</td>
<td>CT CAP Bloods BP, Urine Dip GFR</td>
<td>US KUB CXR Bloods BP, Urine Dip GFR-annual</td>
<td>US KUB CXR Bloods BP, Urine Dip GFR</td>
<td>Discharge after 5 yrs</td>
</tr>
<tr>
<td>Intermediate risk 3-5 RR: 36%@ 10 yrs All treatments</td>
<td>Operative site and gen wellbeing and Feedback Bloods BP, Urine Dip GFR</td>
<td>CT CAP Bloods BP, Urine Dip GFR</td>
<td>CT CAP Bloods BP, Urine Dip GFR Every 6 months</td>
<td>US KUB CXR Bloods BP, Urine Dip GFR every yr.</td>
<td>US KUB CXR Bloods BP, Urine Dip GFR yrly</td>
</tr>
<tr>
<td>High risk &gt;6 RR: 76%@ 10 yrs All treatments</td>
<td>Operative site and gen wellbeing, Feedback and any trial enrolment discussion Bloods BP, Urine Dip GFR</td>
<td>CT CAP Bloods BP, Urine Dip GFR</td>
<td>CT CAP Bloods BP, Urine Dip GFR Every 6 months</td>
<td>CT CAP Bloods BP, Urine Dip GFR</td>
<td>CT and US/CXR Alternate yrs Bloods BP, Urine Dip GFR every yr</td>
</tr>
</tbody>
</table>

- Individually tailored follow up for Bilateral and Familial disease
- The metastatic risk may differ with histology other than clear cell
Kidney Cancer guidelines for referral and follow up of patients considered for ablation of a small renal tumour.

Background

- Different expert societies have guidelines surrounding ablation of small renal masses.
- In the UK, the National Institute for Health and Clinical Excellence has also issued guidelines.
- Recommendations must be made for the referral of patients for ablation, the type of ablation offered and follow up after ablation in the London Cancer Renal Cancer Pathway.

Methods

- Expert society and national guidelines have been reviewed and summarized below.
- More comprehend excerpts from the guidelines for each society are given in the appendices; AUA (appendix 1), EAU 2010 update (appendix 2), BAUS (appendix 3), NICE – radiofrequency ablation & cryoablation (appendix 4).

Results

Pre-ablation biopsy

<table>
<thead>
<tr>
<th>Society</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUA</td>
<td>Recommended before ablation</td>
</tr>
<tr>
<td>EAU</td>
<td>Recommended before ablation</td>
</tr>
<tr>
<td>BAUS</td>
<td>Not specified</td>
</tr>
<tr>
<td>NICE</td>
<td>Not specified, but noted that interpretation of data difficult without definitive histology</td>
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</table>

Referral for ablation

<table>
<thead>
<tr>
<th>Society</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUA</td>
<td>'substantial comorbidities'</td>
</tr>
<tr>
<td>EAU</td>
<td>Small, incidentally found renal cortical lesions in elderly patient, patients with a genetic predisposition for developing multiple tumours, those with bilateral tumours, and patients with a solitary kidney who are at high risk of complete loss of renal function following NSS... Small tumours and/or significant comorbidity who are unfit for surgery.</td>
</tr>
<tr>
<td>BAUS</td>
<td>Stage T1 or T2 disease</td>
</tr>
<tr>
<td></td>
<td>Life expectancy &gt;1</td>
</tr>
<tr>
<td></td>
<td>Genetic predisposition to multiple tumours</td>
</tr>
<tr>
<td></td>
<td>A solitary kidney</td>
</tr>
<tr>
<td></td>
<td>Bilateral tumours</td>
</tr>
<tr>
<td>NICE</td>
<td>Not specified</td>
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</tbody>
</table>
**Type of ablation & follow-up**

<table>
<thead>
<tr>
<th></th>
<th>AUA</th>
<th>EAU</th>
<th>BAUS</th>
<th>NICE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not specified</td>
<td>Cryoablation, as less risk of local recurrence</td>
<td>Not specified</td>
<td>Less risk of local recurrence with cryoablation, but slightly increased risk of haemorrhage</td>
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**Follow up after ablation**

<table>
<thead>
<tr>
<th></th>
<th>AUA</th>
<th>EAU</th>
<th>BAUS</th>
<th>NICE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CT or MR @ 3 &amp; 6 months, then yearly. CXR yearly if low risk RCC or oncocytoma</td>
<td>Intermediate risk – CT @ 6 month, 2 &amp; 5 years. CXR &amp; US @ 1, 3 &amp; 4 years. High risk – CT @ 6 months and the yearly</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
</tbody>
</table>

**Considerations**

Given the paucity of long term data on ablative techniques, entry into national & international registries and clinical trials should be encouraged

Most studies require a biopsy proven malignancy to be an inclusion criterion

**Recommendations**

- **Biopsy**
  - A percutaneous renal biopsy should be undertaken before ablation to confirm the diagnosis of malignancy
  - This should be performed sufficiently in advance of the ablation so that an inconclusive biopsy may be repeated
  - Histological diagnosis of an oncocytoma will require further discussion at the MDT given that oncocytoma and RCC may coexist

- **Indications**
  - Nephron sparing surgery should be considered as first line intervention for stage T1a renal tumours
  - Ablation should be considered more favourably if:
    - The patient does not wish to undergo surgery
    - The patient is deemed unfit / high risk for surgery
    - There is a solitary kidney or poor renal function
• There are bilateral tumours or a genetic predisposition to multiple tumours
  – The tumour must be deemed suitable for ablation by at least two interventional consultants.
  – Chronological age is not necessarily an indication for ablation
  – The MDT must record the suggested order of interventional options on the information available (for instance: surgery first, ablation second & surveillance third). However, the final decision on the type of intervention offered must be made in the renal cancer MDT clinic with consensus between the surgeon and interventional oncologist

• Type of ablation
  – Percutaneous cryoablation should be offered in the first instance
  – Radiofrequency ablation may be offered if there is an increased risk of bleeding at the time of the procedure

• Follow up
  – A contrast enhanced CT of the kidneys will be performed at 3, 6 and 12 months and then yearly after ablation
  – Where the renal function is poor or there is a contrast allergy, a contrast enhanced MRI of the kidneys may be performed
  – A non-contrast CT scan of the chest will be performed yearly to exclude metastatic disease
Kidney Cancer Oncological Pathways

Commencing first line therapy in fit patients with metastatic/advanced renal cancer

MSKCC poor risk disease

MSKCC intermediate risk disease

MSKCC good risk disease

Targeted therapy

Disease progression

Observation

Symptomatic

Asymptomatic

Multiple organ involvement

Multiple sites in single organ

Single site in single organ

il-2 metasectomy RFA/cyberknife

Pazopanib or sunitinib

Axitinib or Everolimus

Everolimus

STAR or PDL-1 study

ZEBRA or Meteor

ZEBRA or AZTEC

Standard targeted therapy

Clinical trial strategy

Non clear cell disease

Clinical trial references
RECORD 1
RECORD 3
COMPARZ
AXIS
INTROSECT
GOLD

Sequencing of systemic therapy

Powles et al. BJ C 2010
The role of nephrectomy in metastatic disease

<table>
<thead>
<tr>
<th>MSKCC risk</th>
<th>Tumour burden from primary</th>
<th>Role of Nephrectomy¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good</td>
<td>Low</td>
<td>Indicated</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Indicated</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Low</td>
<td>Questionable</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Indicated</td>
</tr>
<tr>
<td>Poor</td>
<td>Low</td>
<td>Not recommended</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Questionable</td>
</tr>
</tbody>
</table>

¹ If primary is symptomatic then nephrectomy may be indicated

* Clinical trial include SURTIME and CARMENA

Bex A et al
Expert Rev Anticancer Ther.
1 INTRODUCTION AND GENERAL COMMENTS

In our previous paper "Update on outcomes December 2013" we presented our outcomes for the first 9 months of 2013 against our quality performance indicators. This paper outlines progress made over the course of the first quarter of 2014 in measuring and reporting on our kidney cancer outcomes.

Our aspiration is to provide World Class Surgical and Oncological care. Measuring and improving outcomes is a key element of our plan for delivery of the specialist renal cancer surgical service and leading improvement in renal cancer across London Cancer. The Quality performance indicators have been reviewed and amended to benchmark the centre against world leading international centres in terms of surgical and oncological outcomes.

Robotically assisted nephrectomy and partial nephrectomy were introduced in March 2014 with 15 cases being performed in a 4 week period.

Prior to 2013, measurement of activity and outcomes was largely ad hoc, retrospective and therefore of doubtful accuracy and limited use in driving improvement. Although the data outlined in this summary are incomplete, the establishment of a process for prospective collection of surgical outcome data and a process for aligning data collection with the patient pathway is a significant achievement. While we recognise that the process needs to be strengthened to ensure all patient data are captured, we feel that we now have a robust process in place for capture of this data and production of reports that can inform service improvement.

2 DATA SOURCES

The main data sources used to compile this report are:

- Prospective collection of surgical outcome data (submitted to national BAUS Nephrectomy Audit). The process for this data collection is outlined in figure 1. Data capture is now reviewed on a weekly basis at the Renal Cancer Surgical Planning meeting and any missing data collected at this point so it is anticipated that there will be minimal missing data in the future
- Cerner reports for process measures (e.g. LoS, time from referral etc.)
- Manual reports from renal cancer team (e.g. date of MDT from MDT co-ordinator)
- Patient satisfaction survey. Telephone follow up is currently underway as the postal survey yielded a low response rate
- Morbidity and mortality meetings for details of major complications
3 ACTIVITY

3.1 Volume of Cases

From 1 January 2013 to date, we have carried out 133 nephrectomies and partial nephrectomies. The case load continues to grow (figure 2). And the projected figure for 2014 given the activity in the first quarter of 2014 is shown.

Figure 2. Growth in Renal Surgery Case Load 2013 and projected load 2014
3.2 Referral Map

The geographical origin of the patients referred for surgery is summarised in figure 3.

Figure 3. Map of Nephrectomy Referrals
Performance against our quality performance indicators is summarised in figure 4. Data for survival measures are not yet available so these indicators are currently shown in grey. Green, amber or red ratings have been assigned to each indicator. Targets will be reviewed on an annual basis to ensure they reflect best contemporary standards.

The source of the data and period measured are referenced in the “COMMENTS” column.
**Figure 4. Performance Against Quality Performance Indicators**

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>DESCRIPTION</th>
<th>EXCLUSIONS</th>
<th>TARGET</th>
<th>OUTCOME</th>
<th>COMMENTS</th>
</tr>
</thead>
</table>
| 1 | Time from referral received to first treatment < 62 days | Numerator = number of patients who receive first treatment within 62 days of entry to the pathway  
Denominator = all patients | Patients who refuse treatment  
Patients who die before treatment  
Patients unfit / unsuitable for treatment | 85% | 88% | A few waiters over 62 days might be excluded, data source Open Exeter (Oct12 - Sep13) |
| 2 | TNM Staging | Numerator = number of patients diagnosed with renal cell cancer who were clinically TNM staged before first treatment  
Denominator = all patients | | 100% | 99% | Process to be established to capture TNM staging at first MDT discussion and submission to BAUS audit |
| 3 | Patient Satisfaction | Numerator = number of patients rating their overall satisfaction with the service as good, very good or excellent in the annual patient satisfaction survey  
Denominator = all patients surveyed | Patients who do not return survey | 75% | 100% | 795 return rate for patient experience survey of sMDT clinic and in-patient stay |
| 4 | Nephron Sparing Surgery in T1a Disease | Numerator = number of patients with T1aN0M0 tumours undergoing nephron sparing surgery as first treatment | Patients who refuse treatment  
Patients who receive RFA/cryotherapy  
Patients receiving supportive care only | 40% | 57% | BAUS |
<table>
<thead>
<tr>
<th>MEASURE</th>
<th>DESCRIPTION</th>
<th>EXCLUSIONS</th>
<th>TARGET</th>
<th>OUTCOME</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Denominator = number of patients with T1aN0M0 tumours undergoing surgery as first treatment</td>
<td>Patients receiving active surveillance Patients who died before treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Reoperation within 30 days</td>
<td>Numerator = Number of patients undergoing second surgical procedure within 30 days of primary surgery Denominator = Number of patients undergoing surgery as first treatment</td>
<td></td>
<td></td>
<td>2 splenectomy, 1 completion nephrectomy</td>
</tr>
<tr>
<td>6</td>
<td>30 Day Mortality After Surgery or Ablation</td>
<td>Numerator = Number of patients who undergo minimally invasive or operative treatment as first treatment who die within 30 days Denominator = All patients who undergo minimally invasive or operative treatment as first treatment</td>
<td>Emergency surgery</td>
<td>&lt; 5% 0</td>
<td>Data source - Cerner (subject to DOD being recorded on Cerner) Jan-Sep13, M&amp;M data Jan-Sep 13</td>
</tr>
<tr>
<td>7</td>
<td>Proportion of patients undergoing minimal access rather than open surgery</td>
<td>Numerator = number of patients undergoing surgery as first treatment who have minimal access surgery Denominator = number of patients undergoing surgery as first treatment</td>
<td>Emergency surgery</td>
<td>65% 82%</td>
<td>Data source - BAUS</td>
</tr>
<tr>
<td>8</td>
<td>Proportion of patients requiring perioperative or postoperative renal replacement therapy</td>
<td>Numerator = number of patients requiring perioperative or postoperative renal replacement therapy Denominator = all patients undergoing surgery</td>
<td>Patients on renal replacement therapy pre-operatively</td>
<td>&lt;5% 3%</td>
<td>Data source –BAUS / VitalData</td>
</tr>
<tr>
<td>MEASURE</td>
<td>DESCRIPTION</td>
<td>EXCLUSIONS</td>
<td>TARGET</td>
<td>OUTCOME</td>
<td>COMMENTS</td>
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<td>----------</td>
</tr>
<tr>
<td>9</td>
<td>Number of surgeons carrying out fewer than 20 nephrectomies or partial nephrectomies per annum (open / laparoscopic / robotic)</td>
<td></td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Mean change in eGFR following partial nephrectomy (laparoscopic or robotic) at 6 months</td>
<td>Patients on renal replacement therapy pre-operatively</td>
<td>10%</td>
<td>7.4%</td>
<td>BAUS, eGFR on Cerner. NB Small numbers in current data set.</td>
</tr>
<tr>
<td>11</td>
<td>TRIFECTA rate in partial nephrectomy T1a tumours</td>
<td></td>
<td>60%</td>
<td>76%</td>
<td>Data source - BAUS for procedure type, ischaemic time, margins, complications, Cerner for LOS, RENAL score not recorded Jan - Sep 2013</td>
</tr>
<tr>
<td>12</td>
<td>Clinical trials</td>
<td></td>
<td>7.5%</td>
<td></td>
<td>NCRI benchmark Data not yet available</td>
</tr>
<tr>
<td>MEASURE</td>
<td>DESCRIPTION</td>
<td>EXCLUSIONS</td>
<td>TARGET</td>
<td>OUTCOME</td>
<td>COMMENTS</td>
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<tr>
<td>13</td>
<td>Oncology Clinical trials % of patients who receive a systemic therapy who are enrolled in clinical trials. This includes 1st, 2nd, 3rd line and beyond.</td>
<td>Numerator = number of systemic therapies given within the context of a clinical trials in the population. Denominator = number of new systemic therapies started in the population.</td>
<td>50%</td>
<td>-</td>
<td>Data not yet available</td>
</tr>
<tr>
<td>14</td>
<td>2 Year Survival Metastatic Kidney Cancer from the time of starting systemic therapy</td>
<td>Numerator = number of patients with metastatic cancer at diagnosis for whom at least 2 years have elapsed since diagnosis who are alive 2 years after diagnosis Denominator = number of patients with metastatic cancer at diagnosis for whom at least 2 years have elapsed since diagnosis.</td>
<td>50%</td>
<td>-</td>
<td>Data not yet available</td>
</tr>
<tr>
<td>15</td>
<td>MSKCC Score</td>
<td>Numerator = number of patients with biopsy proven metastatic renal cell cancer who are assigned an MSKCC score prior to starting therapy. Denominator = all patients with biopsy proven Renal cell cancer starting systemic therapy.</td>
<td>100%</td>
<td>-</td>
<td>Data not yet available</td>
</tr>
<tr>
<td>16</td>
<td>1 Year Survival T1 Kidney Cancer (includes surveillance, ablation and surgery)</td>
<td>Numerator = number of patients with T1 cancer at diagnosis for whom at least one year has elapsed since diagnosis who are alive one year after diagnosis Denominator = all patients with T1 cancer at diagnosis for whom at least one year has elapsed since diagnosis.</td>
<td>97%</td>
<td>-</td>
<td>Data not yet available</td>
</tr>
</tbody>
</table>
Clinical Trials

Key Principles

- Potential recruitment into suitable trials to be discussed with all patients
- Explanation of clinical trials included in patient information
- All patients to be approached regarding biobanking of urine, serum and tissue
- sMDT discussion and output to identify potential patients for current open clinical trials