Kent and Medway Cancer Collaborative

The Management of Prostate Cancer

Pathway of Care

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1.0 Purpose of this document

To describe the process for ensuring that all Prostate Cancer cases diagnosed within the Kent & Medway Cancer Collaborative (KMCC) region are managed by the East and West Kent & Medway Urology Specialist Teams, achieving a coordinated seamless patient pathway in accordance with the best possible evidence based practice and to facilitate advancement in the specialty of prostate cancer management.

This document is the product of the KMCC Prostate Sub Group of the Urology Tumour Site Specific Group (TSSG) and has been agreed by the full Urology TSSG.

The KMCC Urology TSSG has agreed that the European Association of Urology (EAU) Guidelines for the management of Prostate Cancer should underpin KMCC guidance. The full EAU Guidelines can be found by following the links:

- Full Guidance
  http://www.uroweb.org/gls/pdf/08%20Prostate%20Cancer_LR%20March%2013th%202012.pdf
- Pocket Guidance
  http://www.uroweb.org/gls/pockets/english/07_Prostate_Cancer.pdf
- European Urology Article – Part 1
  http://www.uroweb.org/gls/EU/2011%20EAU%20Guidelines%20on%20Prostate%20Cancer%20part%20I%2059(1)61-71.pdf
- European Urology Article – Part 2
  http://www.uroweb.org/gls/EU/2011%20prior%20to%20print%20PC%20part%20II.pdf

A key feature of this document is to provide a quick reference guide to the management of patients with prostate cancer based on the EAU guidelines as well as to highlight any locally agreed interpretations of those guidelines for the purposes of clarification.

The NICE Guidance for Urological Cancers also underpins KMCC guidance, full details of the latest NICE Guidance can also be found via the following link:

https://www.nice.org.uk/guidance

2.0 Scope

This Standard Operating Procedure (SOP) applies to all cases and suspected cases of prostate cancer within the Kent & Medway area. The KMCC prostate cancer specification of care requires all Trusts within the area to adopt an agreed policy. The policy relates to the expected pathway of care / treatment regimes for patients diagnosed with prostate cancer.

The policy covers the following:

- Access
- Initial Assessment
- Investigations
- Urological oncology multidisciplinary meeting (MDM)
- Surgical and non-surgical treatment.
- Recurrent disease
- Follow up

3.0 General Principles

- In East Kent, there will be a single Urology Team, which will function at both Local and Specialist Levels and will be hosted on the Canterbury site of the East Kent Hospitals University Foundation Trust

- In West Kent:
  - All Specialist Urological Surgery will be undertaken at the Medway Foundation Trust
  - The Darent Valley Hospital and Medway Foundation Trust Urology Teams will function as a single Urology Team functioning at both Local and Specialist Levels
  - The Maidstone and Tunbridge Wells Urology Team will provide Local Level Urological Services at Maidstone for Mid Kent, BUT will undertake any Specialist Urological Surgery for their patients at Medway Foundation Trust in accordance with KMCC agreed clinical guidelines

- Any KMCC Secondary Care NHS urology prostate service or clinic must be provided or lead by a clinician who:
  - Is a member of the KMCC
  - Is a member of a recognised KMCC Urology MDT and attends MDMs at least to levels (2/3rd) specified in the Quality Measures
  - Is a member of the KMCC Urology TSSG and attends at least 75% of Urology TSSG meetings in any 2 year period

- Patients will be offered a Key Worker and should expect to receive clinical and supportive care of the highest standards at all stages along the Pathway of Care

- All patients should be considered for entry into an approved clinical trial

- Patients should be referred under the two-week rule according to the agreed referral criteria detailed below. These include the Prostate-specific Antigen (PSA) reference ranges recommended by the KMCC based on the Department of Health Prostate Cancer Risk Management Programme

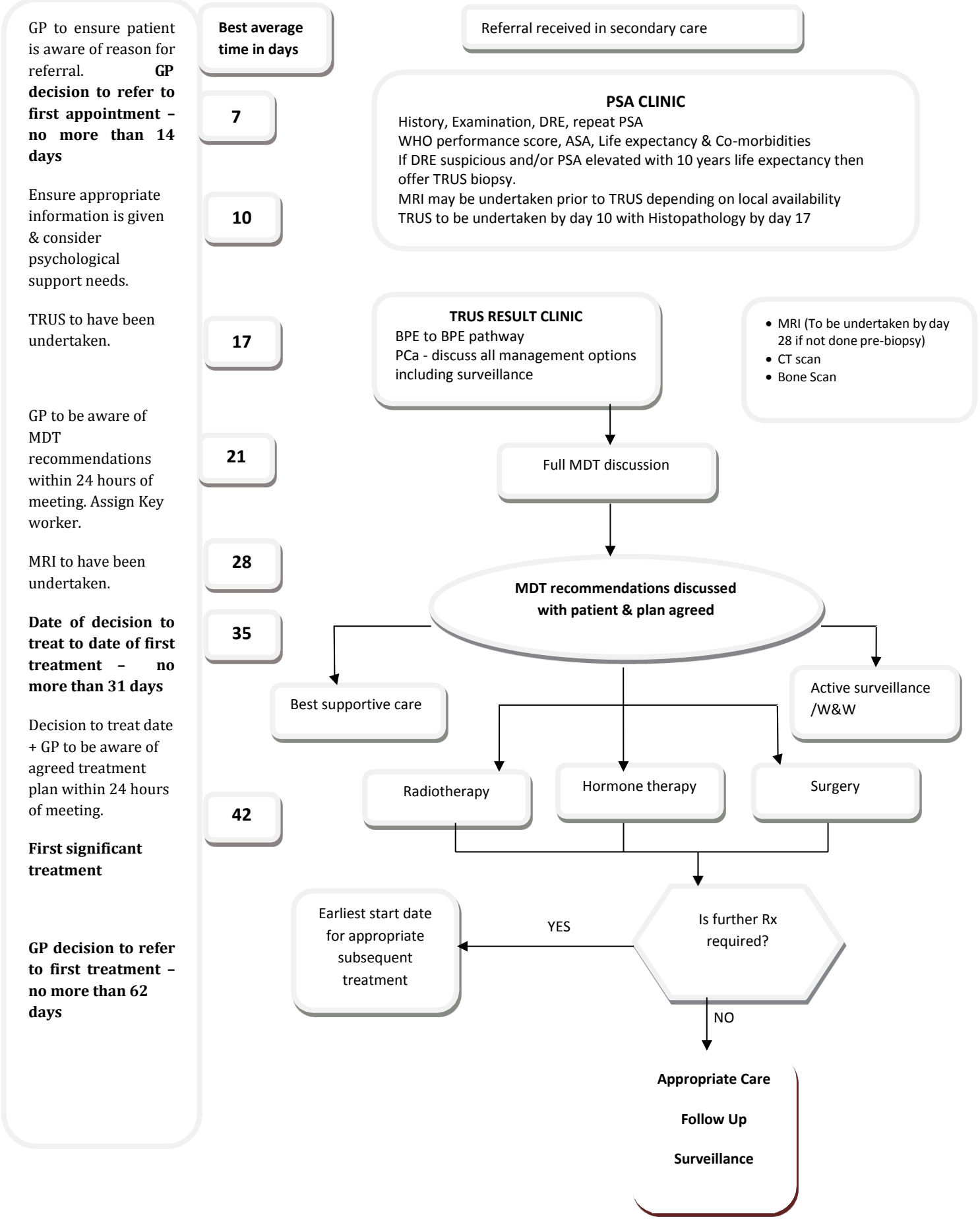
- Patients will be seen in a rapid access prostate assessment clinic and investigated as detailed below, which can have several outcomes. Transrectal ultrasound and biopsies of the prostate will be arranged for appropriate patients

- Patients after prostate biopsies will need to attend a results clinic. Ideally the histology should be available within 5 working days unless additional immunochemical staining is required. This should be reviewed by the multidisciplinary team before the patient attends so that the need for staging and appropriate treatments has already been discussed. Referral to the Specialist MDT should be made in appropriate cases from the local MDT

- As there are several different treatment options for localised prostate cancer or for locally advanced prostate cancer a full discussion should take place about these, after any necessary staging investigations have been carried out, involving the relevant specialists and the patient before a definitive decision is made

- This pathway will be revised by the Kent and Medway Specialist Urology Team as and when appropriate

4.0 Very High Level Overview of Prostate Cancer Pathway



5.0 Prostate Cancer Diagnostic and Staging Pathway

5.1 In Primary Care – a brief overview

Guidance for General Practitioners on the symptoms, diagnosis, referral, clinical management and surveillance for men with prostate cancer can be found in the Cancer Research UK publication:

Prostate Cancer Risk Management Programme - information for primary care
This can be located by following the link:

https://www.gov.uk/government/publications/prostate-cancer-risk-management-programme-psa-test-benefits-and-risks

"Quick Overview" Information Which May Be of Value to General Practitioners

Box 1

The Prostate Cancer Risk Management Programme recommends the following cut-off values are used for the PSA test:-

50-59 years greater than or equal to 3.0ug/L

60-69 years greater than or equal to 4.0ug/L

70 years and over greater than 5.0ug/L

Concentrations <3.0ug/L maybe significant in men <50 years but there is no recommended cut-off for younger men

Note: The threshold at which PSA concentrations should be considered significant, may be lower in Asian, and higher in Afro-Caribbean compared to the quoted Caucasian ranges

Box 2

Prostate Cancer is Suspected if:

1	The prostate is asymmetrical, firm hard, nodular or craggy
2	The PSA is above the age adjusted range with no history of UTI
3	The PSA remains above the age adjusted limits after treatment of a UTI
4	The patient is experiencing bone pain and the PSA ≥ 20 ug/L
5	There is evidence of haematopspermia in men aged ≥ 60 years *(It is useful to request an MSU, semen culture and PSA)*
6	There is an increasing PSA after previously negative biopsies
7	If anyone of the above is true then prostate cancer is suspected
8	If none of the above are true then manage according to benign pathways

Box 3 **EMERGENCY REFERRAL (STAT) IF:**
Acute or chronic urinary retention + uraemia
Ill with uraemia, anaemia and back pain
Suspected spinal cord compression

Box 4 **Benign Disease**	
1	**Normal PSA, benign DRE, no LUTs** • Unlikely to be cancer • Reassure and offer annual PSA check
2	**Normal PSA, benign DRE & LUTs** • Manage LUTs according to BPE pathways • Try alpha blocker if gland <50g • Add 5-alphreductase inhibitor if gland is >50g but double any subsequent PSA concentration – Refer to urology if alpha blockade fails – Symptoms are severe • Repeat PSA in 12 months is there is a positive family history
3	**Borderline or upper normal PSA** • If DRE is normal, manage LUTs as above **but** avoid 5-alpha reductase inhibitors • Offer repeat PSA in 6 weeks, 6 months, 12 months and then annually • Refer if a rising trend is seen at any stage
4	**UTI with normal PSA after treatment** • Any male with a UTI needs urological referral for FFR Rvol and U/S upper tracts

Box 5 **Suspected Cancer Referral – by the 2 Week Wait process**	
1	If any of the criteria (1-6) set out in Box 2 are true
2	The PSA is raised (with a life expectancy is > 10 years) without UTI or completion of treatment for UTI
3	**Use a 2 Week Wait Rapid Access Proforma to refer the patient to one of the appropriate urgent urology clinics**
4	**East Kent 01227 866300**
5	**Maidstone & Tunbridge Wells 01622 224015**
6	**Medway 01634 833912**
7	**Dartford 01322 428631**
8	A professional referral letter attached to the referral proforma indicating past medical history, current medication and any known allergies is greatly appreciated
9	Please attach the results such as MSU, FBC and Creatinine
10	Please make sure that the patient is aware that the reason an urgent 2 Week Wait appointment has been requested is that because there is at least a suspicion of cancer

5.2 In Secondary Care – a brief overview

*By **Day 7***

- **Urgent 2WW Urology Clinic**
  - (Repeat PSA if necessary)
  - If appropriate organise TRUS Bx for patients with good performance status (results to be available for MDT)
  - For patients with poor performance status TRUS Bx may not be necessary and should be referred directly to the MDT
  - Consider bone scan if clinically indicated and the patient has a good performance status (ideally this should be timed so that results are available for the MDT on day 15)

*By **Day 10***

- **TRUS Bx undertaken**

  ❖ *For consideration between 2WW Clinic visit and upon obtaining TRUS Bx results in the run up to the MDT:*

  - **Benign disease** ⇒ **To benign pathway**
  - **Low risk** ⇒ **MRI not routinely required**
  - **Medium/High Risk** ⇒ **Consider MRI if radical treatment is likely to be considered by the MDT**
  - **High Risk (**Gleason ≥ 4+3) ⇒ **Consider Bone Scan**

*By **Day 21***

- **MDT**

  Consider:

  ❖ **Watchful waiting**
  - PSA & symptom monitoring (for PSA 20-50 ug/L in men with poor performance status)

  ❖ **Active Surveillance**
  - PSA surveillance & re-biopsy strategies (for [1] small volume / well differentiated disease, [2] low risk early disease)

  ❖ **Curative Treatments (for Low, Medium & High Risk Disease)**
  - Radiotherapy (external beam/brachytherapy)
  - Radical prostatectomy (+/- radiotherapy)

  ❖ **Palliative Treatments**
  - Hormone/BSO
  - Radiotherapy
  - Chemotherapy
  - Stenting

*By **Day 31***

- **MRI undertaken (if indicated)**

*By **Day 35***

- **Treatment options discussed and treatment plan agreed with patient**

*By **Day 42***

- **Significant treatment (any modality) commenced**

Note: Further information for Primary and Secondary Care Clinicians can be found in Appendix 1

6.0 Imaging/Biopsy

6.1 Diagnosis

- **Transrectal Ultrasonography (TRUS)**

Unless clinical diagnosis is obvious and sufficient for management plan (unfit patients)
*(Guidelines agreed by the KMCC Diagnostics CCAG, Cellular Pathology CCAG & Urology TSSG)**

12 biopsies in 6 pots – minimum standard

Twelve biopsies are required for prostates 20g. More samples can be taken if clinically indicated. Eight to ten biopsies are an adequate sample of a small (10-20g) prostate.

Where MRI has been performed pre-biopsy, additional or targeted biopsies may be taken based on the MRI findings.

Repeat biopsies may be targeted based on MRI findings or a saturation/template biopsy strategy can be used.

Ideally each biopsy should be analysed and reported separately and therefore should be submitted in separate pots. The TSSG has agreed that 12 biopsies in 6 pots is acceptable. 2 cores are taken from each of the following zones: Right Base, Left Base, Right peripheral zone, Left peripheral zone, Right apex and Left apex.

The cores are placed in 6 clearly marked pots. Additional Central zone, anterior samples or seminal vesicle samples may be indicated. In larger glands more cores can be taken from appropriate areas.

Note: * Full KMCC imaging guidelines can be found in the agreed document located on the KMCC website on the following link: http://kmcc.nhs.uk/tumour-sites/sub-groups-or-cross-cutting-groups/diagnostics-group/

6.2 Staging

- **Multiparametric MRI Scan**
  - MRI Should be performed If Radical curative treatment is being considered
  - MRI may be performed pre-biopsy to
    - Allow targeted biopsies to be taken of abnormal areas eg anterior
    - Avoid haemorrhage artefact form MRI performed post-biopsy
    - Improve local staging
    - Avoid delays in the pathway
    - Reduce need for re-biopsies after a negative set of TRUS biopsies
- **CT Scan CAP**
  - CT CAP should be performed for N & M staging in
    - Any gleason 5 on biopsy
    - PSA >20
- **Bone Scan**
  - Nuclear medicine bone scan should be performed in
    - Any Gleason 5 on biopsy
    - PSA >20
    - bone pain

***Note:** Please see appendices 3 & 4

6.3 Surveillance

- Bone Scan
  - Not routinely indicated
  - May be of value in patients experiencing bone pain

7.0 Treatment

1. Patients must always be counselled on the full range of treatment options recommended as a result of an MDT discussion

2. Based on individual patient performance status, stage of disease, co-morbidity, diagnostic and staging investigations (and the patient's wishes) these will include:

    - Watchful waiting
    - Active surveillance
    - Brachytherapy
    - Radiotherapy
    - Radical surgery
        - Open surgery
        - Laparoscopically assisted surgery without robotic assistance
        - Laparoscopically assisted surgery with robotic assistance
    - Hormone therapy
    - Focal therapies (via UCL) as part of a trial
    - "Other" novel treatments – providing:
        - These are evidenced based
        - Fully discussed and sanctioned by the KMCC Urology TSSG

Note: Information on agreed oncology guidelines developed by the Urology Non-Surgical Oncology Group can be found at the following location on the KMCC website:

http://kmcc.nhs.uk/tumour-sites/tumour-site-specific-information/urology-tssg/

8.0 Follow Up After Treatment

8.1 Active surveillance – General Principles:

Offer active surveillance as an option to men with low-risk localised prostate cancer for whom radical prostatectomy or radical radiotherapy is suitable.
AS may be carried out in primary care if there are agreed shared-care protocols and recall systems.

Criteria for inclusion:

- Gleason Score 3+3 (Gleason 3+4 may be considered in selected cases after MDM discussion)
- PSA $\leq$ 10
- Max core length involved < 50%
- Total number of cores involved < 30%
- Clinically T1c and MRI shows organ confined disease

Follow up protocol:

Timing	Tests
At enrolment in AS	Multiparametric MRI if not previously performed
Year 1 of AS	Every 3 months: measure PSA Every 6 months: DRE At 12 months: prostate re-biopsy (template)
Years 2 onwards until AS ends	Every 6 months: measure PSA Every 12months: DRE Every 2 years mpMRI

If there is concern about clinical or PSA changes at any time during active surveillance, reassess with multiparametric MRI and/or rebiopsy.

Consider treatment after further MDM discussion if progressive PSA rise (PSADT <3yr), upgrading at repeat biopsy or MRI suggests progressive.

8.2 Follow up following any treatment with curative intent

The purpose of follow up/surveillance is to (if possible) detect recurrence at an early stage so that appropriate management offering the patient the best clinical outcome (and quality of life) can be initiated at the earliest opportunity. However, follow up and surveillance should both be evidenced based and take account of new ways of surveillance being piloted throughout the UK as well as taking in to account the views of patients on “survivorship” voiced at local and national events.

PSA measurement is a cornerstone of follow-up after curative treatment. PSA recurrence nearly always precedes clinical recurrence, in some cases by many years.

Follow-up/surveillance should always be tailored to individual patient needs and may therefore vary slightly from patient to patient. It may also be dependent on the type of treatment they have received and the time taken for the PSA to return to normal levels following that treatment. An idealised follow-up and surveillance programme is set out below:

Time Pre Treatment	PSA	Clinical Exam Including DRE
	✓	(✓)
Time Post treatment	PSA	Clinical Exam Including DRE
6/52	✓	+/-
3/12	✓	+/-
9/12	✓	+/-
12/12	✓	✓
18/12	✓	+/-
24/12	✓	✓

8.2.1 Following Radical Prostatectomy

- Two consecutive values of 0.4 ug/L or greater appear to represent an international consensus defining recurrent cancer
- Discuss referral to oncology if positive margins or extracapsular (pT3a or pT3b) disease for consideration of early radiotherapy within RADICALS trial

8.2.2 Following Radiotherapy

- Biochemical relapse is defined according to international guidelines. (1996 ASTRO guidance defines post radiotherapy relapse as a PSA >2.0 ug/L above the nadir)
- PSA concentrations fall slowly after radiation treatment when compared with PSA concentration following surgery. The optimal cut off value for PSA is controversial, and the interval before reaching the nadir PSA may take many months indeed in some cases 36 months or even longer
- Patients are typically reviewed in the oncology clinic 8 weeks following the completion of radiotherapy. A follow up plan will be agreed at that point, which may include PSA check at 6 monthly or annual intervals depending on risk stratification

8.2.3 When discharging to Primary Care

- **It is essential to define PSA parameters for relapse for GPs when discharging the patient to their care**

8.2.4 General

- Consider consultant led outpatient follow up until continence and potency are satisfactory and the PSA <0.1ug/L at this point transfer to nurse led follow up

8.2.5 Low risk patients

- At 24/12 discharge to Primary Care with the following request
  - Annual PSA check and refer back if PSA > 0.2 ug/L

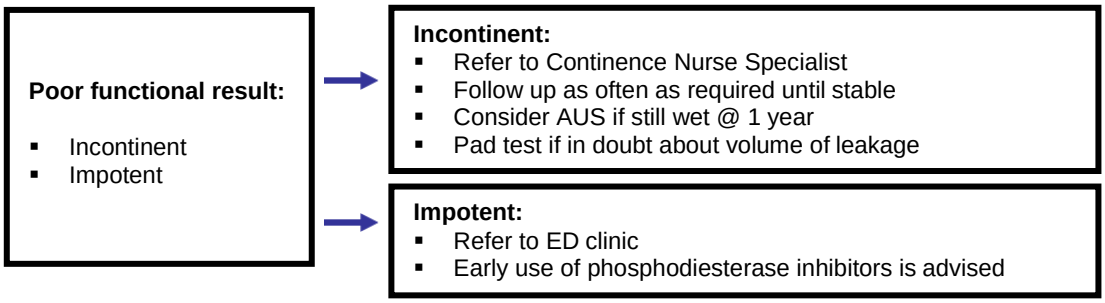
8.2.6 High risk patients

- Continue Secondary Care follow- up to 5 years
  - Annual PSA check and clinical assessment (if appropriate), MDT review if PSA >0.2 ug/L
  - Consider regular outpatient review for Gleeson grade 8-10 tumours where PSA assessments may not be as reliable

8.2.7 DRE following curative treatment

- The interpretation of DRE is notoriously difficult following curative treatments especially following radiotherapy, however a newly detected nodule should always ring alarm bells

8.2.8 Follow up functional results:



8.2.9 Back to normal activity monitoring

- Regardless of treatment modality, the interval between the date of surgery (or the date of completion of radiotherapy) to the date the patient was able to return to work/return to normal activity should be recorded. This metric is one of the Coalition Government's quality targets

8.2.10 Patients on hormone therapy in the absence of bone metastases

- 6/12 PSA & review in Primary Care. Refer back to MDT when PSA concentration rises as per pre-agreed parameters
- Patients on long term bicalutamide may be offered prophylactic breast bud irradiation to prevent gynaecomastia (NICE CG175) as surgery for gynaecomastia after any hormonal manipulation is only offered on an individual patient basis

8.2.11 Patients on hormone therapy in the presence of bone metastases & no symptoms

- Clinical review 3/12 - PSA and symptom assessment
- Nurse led holistic care should be encouraged

- This could be undertaken in Primary Care
- Patients should be referred back to Secondary care if the PSA rises as per pre-agreed parameters

8.2.12 Patient with relapsing metastatic disease

- Review in oncology clinic. Nurse led assessment may be appropriate
- Consider referral to community palliative care team if specialist palliative care needs

9.0 Management of recurrent disease/relapse

- MDT discussion required
- Refer to NOG Guidance: http://kmcc.nhs.uk/tumour-sites/tumour-site-specific-information/urology-tssg/

9.1 Management of PSA relapse following Radical Prostatectomy

- Consider:
  - Clinical trials (RADICALS)
  - Salvage radiotherapy
  - LHRH analogue s/Orchidectomy

} Early referral as soon as PSA >0.2 for consideration of clinical trial and salvage RT

9.2 Management of PSA relapse following radiotherapy

- Consider
  - Salvage radical prostatectomy in selected patients
  - Cryosurgery
  - Hormonal therapy

10.0 Data Collection

Collection of data at each stage of the pathway is the responsibility of the team looking after the patient at that time. The minimum dataset agreed by the TSSG will be a combination of those data items that meet national requirements, and additional items as agreed by the TSSG.

National data requirements will include:

- Cancer Waiting Times monitoring, including Going Further on Cancer Waits. The data items required will be as defined in ISB0147 at the time of referral and/or treatment. Details of the Cancer Waiting Times dataset are available from: http://www.datadictionary.nhs.uk/data_dictionary/messages/clinical_data_sets/data_sets/national_cancer_waiting_times_monitoring_data_set_fr.asp

  Cancer Waiting Times data will be submitted according to the timetable set out in the National Contract for Acute Services.

- The Cancer Outcomes and Services Dataset. The data items will be as defined in ISB1521, and any subsequent versions, at the time of diagnosis and/or treatment. The requirement will include those fields listed in the “Core” section of the dataset, and any additional tumour site specific sections, as

applicable. Details of the COSD are available from: http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd.aspx

Cancer Registration and Cancer Outcomes and Services (COSD) data will be submitted according to the timetable set out by National Cancer Registration Service (NCRS)

- Where applicable, teams will also collect additional data items as defined in any corresponding National Clinical Audit Support Programme (NCASP) audit dataset. Details of these datasets are available from: http://www.ic.nhs.uk/services/national-clinical-audit-support-programme-ncasp/cancer

  Data for NCASP audits will be submitted, where applicable, according to timetables as agreed by the TSSG, and within the overall submission deadlines for each audit

Submission of data to meet these national requirements will be the responsibility of each individual Trust. Note that these standards are subject to variation from time to time, and where these requirements change, the data items required to be collected by the team will also change in line with national requirements.

Local data requirements will include any additional data items as agreed by the TSSG. These must be selected to avoid overlap with any existing data items, and where possible must use standard coding as defined in the NHS Data Dictionary. Where possible and applicable, InfoFlex will be used for the collection and storage of data.

Additional areas of the COSD, relating to pathology, radiotherapy, SACT, diagnostic imaging and basic procedure details will feed into the dataset from other nationally mandated sources. It is the responsibility of each team to ensure that the whole of the relevant dataset is collected, and it is acknowledged that this may come from a variety of sources.

11.0 Audit

All KMCC Urology MDTs should undertake the following audits and which should be presented and discussed at the Urology TSSG at least annually:

1. TRUS to MRI time interval audit (proforma found in Appendix 4 – section 18.1)
2. Back to dryness & back to normal activity audit following radical treatment for prostate cancer by any modality (proforma found in Appendix 4 – section 18.2)
3. Incidence and severity of gastrointestinal disturbance following radical radiotherapy
4. Erectile Dysfunction audit (Proforma found in Appendix 4 – section 18.3)

Other audit programmes may be undertaken at the discretion of the Urology TSSG.

12.0 Erectile Dysfunction (ED)

Erectile dysfunction (ED) is a consequence of radical prostatectomy in approximately 50% of patients and 90% of patients receiving radiotherapy to the prostate.

Erectile dysfunction following radical surgery is immediate with gradual improvement, whereas there is progressive loss of erectile function following radiotherapy. These two indications therefore need to be considered separately.

12.1 Erectile dysfunction following radiotherapy

12.1.1 First line

PDE5 inhibitor

12.1.2 Second line

Intracavernosal injections

12.1.3 Third line

Vacuum devices

12.2 Erectile dysfunction following radical prostatectomy

- All patients should receive preoperative counselling
- In patients in whom ED is a concern, assess erectile function using the International Index of Erectile Function (IIEF) before and 3 months after radical prostatectomy
- Not all patients will want drug treatment for erectile dysfunction, but for those that do, start medication immediately (if necessary pre-operatively) using a PDE5 inhibitor. Early intervention is beneficial. Treatment should be initiated by the hospital Consultant
- The choice of PDE5 inhibitor should be made locally, based on side effect profile and financial implications (decisions will be affected by the likely increased availability of generic PDE5 inhibitors), however Tadalafil (Cialis®) has the advantage of a longer half life and a choice of the following dosing schedules:
  - Tadalafil 5mg orally once a day
  - Tadalafil 10-20mg orally twice a week

Patients who experience side effects on a twice weekly schedule may benefit from a change to daily dosing as the lower dose produces less side effects

- Patients should receive 3 monthly monitoring with the IIEF
- Patients should be offered a referral to an erectile dysfunction clinic if there is no return of erectile function 3 months after initiation of PDE5 inhibitor, and the following interventions may be considered:
  - Intracavernosal Injections
  - Vacuum Devices
  - Penile Prostheses

All NHS treatments require funding as per NICE guideline CG175 and Schedule 11 guidance.

12.3 Patients with a cardiac history

- Patients with a cardiac history on nitrates should be treated with alprostadil

- Patients who are not on nitrates and are able to walk a mile on a flat followed by a flight of stairs may be treated with a PDE5 inhibitor

13.0 Supportive and Palliative Care

Patients with prostate cancer should have access to an appropriate Clinical Nurse Specialist support at all points of the pathway regardless of Primary, Local and Specialist team borders. Local and Specialist Team Clinical Nurse Specialists will actively co-operate to ensure that there is continuity of care, engaging with Primary Care and Palliative Care colleagues when appropriate.

Patients may be referred to the Specialist and Palliative Care Team at any point along the pathway, whether by Primary, Local or Specialist Teams.

Open and frank discussions with patients should take place with patients at all stages of their journey so that patients are not confused about their prognosis or have unrealistic expectations of any of the forms of treatment offered to them.

Relatives and carers will need to be appropriately supported and given appropriate information. However, in accordance with the recommendations set out in the various 'Improving Outcomes Guidance', relatives and carers should not be given information different to that given to the patient.
The prime aim of palliative treatment is to alleviate symptoms.

Palliative care provision should be made available for all patients:

- Hospital Teams, including Clinical Nurse Specialists for urology patients
- Primary Health Care Teams would provide for palliative care at home
- General Practitioners should be informed within 24 hours of the diagnosis, treatment plan and medication – including any MDM revisions to the treatment plan and medication

The management of symptoms, psychological, social and spiritual issues, and the communication of the diagnosis and the any associated problems should be in the domain of all health care professionals.

Referral to specialist palliative care services should be considered when these issues have not been resolved and in particular for patients with:

- Complex symptom management issues, which are difficult to manage
- Difficulties in adjusting to the disease or progression
- Psychological and family issues – such as communication problems within the family
- Spiritual issues – such as the challenging of belief system/faith/cultural values as a result of the cancer

Consideration of specialist palliative care support should be given throughout the patient pathway, particularly:

- At the MDM
- When no active treatment is considered
- After active treatment
- At relapse
- In the terminal stages

14.0 Cellular Pathology

The KMCC Urology TSSG has agreed to formally adopt the Royal College of Pathologist's Urology Data Set/Guidelines:

All KMCC reporting pathologists follow The Royal College of Pathologists Histopathology Reporting on Cancers guidelines – a copy of which is available through the KMCC website:-

http://kmcc.nhs.uk/tumour-sites/sub-groups-or-cross-cutting-groups/pathology-group/

This therefore supersedes the KMCC Urology Pathology Data Set and Guidelines.

The Urology TSSG has also agreed that reporting pathologists should always stipulate which version of the TNM they are referring when issuing reports.

15.0 Appendix 1: PSA Clinic - Options for Clinicians to Consider *(with particular focus for the attention of junior medical staff)*

All patients	History	Examination
• **IPSS** • **Bother score** • **Free Flow Rate >150 ml** • **U/S residual urine volume**	• **Symptoms** – Urinary? – Metastatic? • **Co-morbidity & performance** – PMH & Medications *(Take note of Warfarin & Clopidogrel)* – Performance status FH, alcohol, smoking	• **General** – BMI, BP, Anaemia, Oedema • **Abdomen** – Exclude retention – DRE • **Neurology** – Leg power, reflexes

Process at clinic	
The clinician should consider: • The index of suspicion of prostate cancer as related to DRE findings, PSA and symptoms of metastatic disease • Can a clinical diagnosis be made and the likely clinical stage proposed • The performance status, co-morbidity and life expectancy • Will biopsy influence management? • Bladder outflow obstruction FFR and Rvol • Is admission indicated	Biopsy & treatment not required if: • Poor performance status, co-morbid, asymptomatic • GP agrees to monitor PSA & symptoms & will refer back if the PSA is >50 ug/L and rising Admission indicated • Obstructive uropathy/retention • Spinal cord compression/pain

Continued on next page

Process considerations – continued from previous page

Repeat PSA & Review (if)	? Early (if)	? Locally Advanced (if)	? Advanced (if)
• Borderline PSA with benign feeling gland • Suspicion of UTI **Actions to be considered:** • *Patient needs time to think* • Review in 4 weeks' time or by results and write • If PSA remains borderline – then consider TRUS (which can be organised with re-attendance and by patient agreement)	• PSA <20 ug/L • DRE normal, firm asymmetric or T2 nodule **Actions to be considered:** • Consider bone scan if there is bone pain (there may be a high grade tumour not elaborating PSA) • Letter to GP with copy to MDT coordinator • Pre-book TRUS/TURP and result clinic appointment • *Key worker?*	• PSA > 20 ug/L, no UTI & DRE =T3 malignant gland **Actions to be considered:** • Discuss diagnosis with patient • Discuss biopsy in men with good performance status • Consider bone scan and if test thought to be of value then discuss with patient – and book! • Consider initiating treatment (refer to latest urology TSSG/NOG guidelines but which may be: – Casodex 150mgs od – Cyproterone 100mgs tds) • Consider referral to oncology (ensuring copy is sent to GO & MDT coordinator) flagging up discussion at MDT when the life expectancy is > 10 years, no co-morbidities, ASA 1&2 and good WHO performance status • *Key worker?*	• PSA > 20 ug/L & DRE = malignant gland • Symptoms of metastases **Actions to be considered:** • Consider initiating treatment (refer to latest urology TSSG/NOG guidelines but which may be: – Casodex 50mgs od as lead into LHRH – Pain relief – Alpha blocker) • FBC, ECr, LFT & Ca. • Consider bone scan and if test thought to be of value then discuss with patient – and book! • Consider referral to oncology (ensuring copy is sent to GP & MDT coordinator) flagging up discussion at MDT to be timed with bone scan results • *Key worker?*
Poor performance status and co-morbid patients may not require Bx but do need to be discussed at MDT	Poor performance status and co-morbid patients may not require Bx but do need to be discussed at MDT		

16.0 Appendix 2: Decision Making Options for Clinicians to Consider Based on Results

NEGATIVE – NOT CANCER	POSITIVE HISTOLOGY	ATYPIA, PIN or UNCERTAIN

• **3 month post Bx baseline PSA check by GP**
  – **If < referral PSA GP may check annually**
  – **If > referral PSA consider early re-Bx**
• **GP to refer back, stat, if PSA rises at a later stage**
• **Manage LUTs and other conditions**
	Categorise:
	• **Small Volume Well Differentiated (LOW RISK)**
	  – Presenting PSA <10 ug/L
	  – <10% of one single core only
	  – Gleason score = 3+3
	• **Significant Early T2 (MEDIUM RISK)**
	  – Presenting PSA <15 ug?l
	  – >50% of core positive
	  – Core length <50% involvement
	  – Gleason score = 3+3, 3+4, 4+3
	• **Probable Locally Advanced T3 (HIGH RISK)**
	  – Presenting PSA <15 ug/L
	  – > 50% of cores positive or bilateral disease
	  – >50% involvement of any single core
	  – Or any Gleason score ≥ 8
		MDT Review:
		• Consider early re-biopsy
		• Consider post biopsy PDA and then 3 monthly monitoring
		• Consider planned re-biopsy strategy

LOW RISK	MEDIUM RISK	HIGH RISK
• **Active surveillance** • **Watchful waiting** • **Brachytherapy** • **Radical external beam radiotherapy** • **Radical prostatectomy** • **Trials?**	• Active surveillance (selected cases) • Watchful waiting (advanced age/co-morbidity) • Brachytherapy • Brachytherapy + EBXRT • Radical external beam radiotherapy • Radical prostatectomy • Trials?	• Watchful waiting (advanced age/co-morbidity) • Brachytherapy + EBXRT + adjuvant hormone treatment • Radical external beam radiotherapy + adjuvant hormone treatment • Radical prostatectomy • Hormone treatment alone (where radiotherapy or surgery is contraindicated) • Trials?

17.0 Appendix 3: MRI

Traditionally MRI has been performed on patients with positive prostate biopsies, but delayed until 6 weeks following TRUS biopsy. This is to minimise the effects of haemorrhage artefact, which hamper the interpretation, most often leading to overcalling of capsular involvement. A 6 week gap can contribute significantly to 62 day target breaches.

From the radiological point of view, it is ideal to perform MRI prior to biopsy, as localisation of tumour is much more accurate, and staging more reliable. This does result in all patients getting an MRI, but the apparent disadvantage of this is negated by NICE guidance which calls for MRI on all patients with negative biopsy in order to detect missed lesions.

East Kent and Maidstone have changed to MRI prior to biopsy in all patients. The remaining sites use a combination.

MRI prostate should be audited against biopsy results. If MRI is performed after biopsy, the proforma set out in Appendix 4 should be used.

18.0 Appendix 4: Audit proformas

18.1 KMCC MRI Prostate Audit

Hospital	
Patient Number	
Date of Biopsies	
Date of MRI	
Haemorrhage Artefact	1 2 3
Radiological Stage	
Repeat MRI Recommended	Y/N
Surgical pathological stage (if surgery)	
Comments	

Key:

Haemorrhage Artefact

1 Minor

2 Significant but still allowing diagnosis

3 Significant preventing diagnosis

18.2 Continence Audit

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ICIQ Incontinence Questionnaire

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

PLEASE TICK THE APPROPRIATE ANSWER THAT BEST DESCRIBES HOW YOU FEEL FOR EACH QUESTION.

1. Are you : Female ☐ Male ☐

2. How often do you leak urine?

☐ 0 Never
☐ 1 About once a week or less often
☐ 2 Two or three times a week
☐ 3 About once a day
☐ 4 Several times a day
☐ 5 All the time

3. We would like to know how much urine you think leaks. How much urine do you usually leak (whether you wear protection or not)?

☐ 0 None
☐ 1 A small amount
☐ 2 A moderate amount
☐ 3 A large amount

4. Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
NOT AT ALL A GREAT DEAL

5. When does urine leak?
(Please tick all that apply to you)

☐ Never – urine does not leak
☐ Leaks before you can get to the toilet
☐ Leaks when you cough or sneeze
☐ Leaks when you are asleep
☐ Leaks when you are physically active/exercising
☐ Leaks when you have finished urinating and are dressed
☐ Leaks for no obvious reason
☐ Leaks all the time

Thank you very much for answering these questions.

ICIQ score: sum scores 2+3+4

☐

The Sexual Health Inventory for Men (SHIM) or IIEF-5

Over the past 6 months,

1.How did you rate your confidence that you could get & keep an erection?		Very low 1	Low 2	Moderate 3	High 4	Very high 5
2.When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	No sexual Activity 0	Almost Never or never 1	A few Times 2	Sometimes 3	Most times 4	Almost always or always 5
3.During sexual intercourse, how often were you able to maintain your erection after you had penetrated your partner?	Did not Attempt Intercourse 0	Almost Never or never 1	A few Times 2	Sometimes 3	Most times 4	Almost always or Always 5
4.During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	Did not Attempt Intercourse 0	Extremely Difficult 1	Very difficult 2	Difficult 3	Slightly difficult 4	Not difficult 5
5.When you attempted sexual intercourse, how often was it satisfactory to you?	Did not attempt Intercourse 0	Almost Never or never 1	A few Times 2	Sometimes 3	Most times 4	Almost always or Always 5

The IIEF-5 is administered as a screening instrument for the presence & severity of ED in conjunction with the clinical assessment. The score is the sum of the responses to the five items, so that overall score may range from 1 to 25. A score of 20 or higher indicates a normal degree of erectile functioning. Low scores (10 or less) indicate moderate to severe ED.

19.0 Personnel and Contact Information

A comprehensive, up to date list of MDM contact details can be found on the KMCC website via the following link: http://kmcc.nhs.uk/tumour-sites/terms-of-reference/

20.0 Glossary

Acronyms in common usage throughout KMCC documentation

CAT	Clinical Advisory Team
CCAG	Cross Cutting Advisory Group
CYP	Children & Young People (in relation to the IOG)
DCCG	Diagnostic Cross Cutting Group
DOG	Disease Orientated Group (NSSG/TSSG/TWG)
DVH	Darent Valley Hospital
EK	East Kent
EKHUFT	East Kent Hospitals University Foundation Trust
EAU	European Association of Urology
HOP	High Level Operational Policy
PSA	Prostate-specific Antigen
TRUS	Transrectal Ultrasonography
IOSC	Improving Outcomes: A Strategy for Cancer
K&C	Kent & Canterbury Hospital, Canterbury, (EKHUFT)
KMCN	Kent & Medway Cancer Network
KMCC	Kent & Medway Cancer Collaborative
KMCRN	Kent & Medway Cancer Research Network
MFT	Medway Foundation Trust
MTW	Maidstone & Tunbridge Wells NHS Trust
NCIN	National Cancer Intelligence Network
NOG	Non-Surgical Oncology Group (Permanent oncologist sub group of the TSSGs with a specific responsibility for chemo/rad pathways and advice to the TSSG, KMCC and geographical locations on new drugs)
O&Q Group	Operational & Quality Group (KMCC interface with Trust Cancer Lead Clinicians, Lead Nurses and Lead Managers to oversee the implementation of TSSG agreed policies and which has delegated authority from the KMCC CEO Board to carry out this function)
PoC	Pathway of Care
Provider Board	KMCC CEO Cancer Board (Trust CEOs and Core KMCC Team chaired by EK CEO)
QEQM	Queen Elizabeth the Queen Mother Hospital, Margate (EKHUFT)
QoL	Quality of life
RAT	Research and Trial Group (Permanent sub-group of the TSSGs with a specific responsibility for taking forward the clinical trials agenda)
TSSG	Tumour Site Specific Group
QVH	Queen Victoria Foundation Trust Hospital East Grinstead
WHH	William Harvey Hospital, Ashford (EKHUFT)
WK	West Kent

21.0 Document Administration

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Co-author(s)	The Prostate Sub Group (May 2016): H.Evans, A.Henderson, B.Hernden, S.Madaan, P.Reddy, H.Taylor S.Madaan, I.Morrison
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			C.Tsatsaklas
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