NHS England

Guidelines for the Management of Prostate Cancer

West Midlands Expert Advisory Group for Urological Cancer

West Midlands Clinical Networks and Clinical Senate

Coversheet for Network Expert Advisory Group Agreed Documentation

This sheet is to accompany all documentation agreed by the West Midlands Strategic Clinical Network Expert Advisory Groups. This will assist the Clinical Network to endorse the documentation and request implementation.

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Authors		
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Approval Signatures:	**EAG Chair** 	**Network Clinical Director** 

Guidelines for the management of prostate cancer

This Guideline has been produced to support the following:

a) Management of patients presenting with suspected prostate cancer
b) Management of patients with Prostate Cancer

It is based on the NICE Guideline – Prostate cancer: diagnosis and management (2014) nice.org.uk/guidance/cg175 and Suspected cancer: recognition and referral (2015) nice.org.uk/guidance/ng12

1 Assessment in primary care

1.1 Male patients with lower urinary tract symptoms (LUTS) should have a digital rectal examination (DRE) and serum prostate-specific antigen (PSA) assay after counseling.

1.2 Prostate cancer should also be considered in men with:

erectile dysfunction
haematuria
lower back pain
weight loss, especially in the elderly
direct family history of prostate, breast or ovarian cancer

1.3 Urinary infection (UTI) should be excluded before PSA testing, especially in men with LUTS. The PSA test should be repeated one month after successful treatment of a UTI.

2 Referral from GPs

2.1 Patients with suspected urological cancer should be referred from GPs to local urology units according to the NICE referral guidelines.

2.2 Referrals deemed inappropriate by consultant urologists will be notified to the referring GP and to the relevant CCG according to agreed mechanisms within each Trust.

2.3 GPs will be notified of the diagnosis of cancer within 24 hours of discussion with the patient and will be informed of all aspects of the patients care.

3 Multi Disciplinary Teams (MDTs)

3.1 Each MDT will hold regular meetings. All patients with proven urological malignancy are discussed by the MDT. Normally this will be the local MDT in the first instance; overall responsibility for the patient's management rests with the local MDT until referral has been agreed.

4 Staging

4.1 For cancers diagnosed clinically or those that have not had surgery, clinical TNM stage is recorded on the National Prostate Cancer Audit database

5 Performance Status

5.1 All patients should have WHO performance status recorded at the MDT.

6 Patient Information and Counselling

6.1 At the point of initial assessment, presence of LUTS and degree of erectile function should be recorded.

6.2 This information should be offered by a CNS or consultant and should be supported by written information.

6.3 All patients, and with their consent, their partners will be given appropriate written information during investigation and treatment; on diagnosis they will have the opportunity to discuss their management with a CNS member of the relevant MDT. The patient should have access to the urology team at all times.

6.4 Access to psychological support will be available if required. All patients should be offered a holistic needs assessment at key points in the pathway.

6.5 All patients diagnosed with bone metastasis should receive information about the possibility and symptoms of spinal cord compression.

7 Patient information and support

7.1 All patients should be given access to appropriate written information during their investigation and treatment.

7.2 Patients should be offered a permanent record of their key consultations with their specialist team.

7.3 Patients should have a method of access to their MDT (Monday – Friday 9am – 5pm) and the contact details of their key worker at diagnosis or first referral (whichever occurs first).

8 Palliative care

8.1 Palliative care services will be available to all patients.

9 Clinical trials

9.1 Eligible patients should have the opportunity to participate in NIHR portfolio clinical trials and other well-designed studies.

10 Referral

10.1 Urgent Referral

10.1.1 Patients with the following symptoms should be referred urgently for a 2 week appointment:

- those with an abnormal prostate on DRE
- symptomatic patients with high PSA levels
- those with or without LUTS and in whom the prostate is normal on digital rectal examination but the age specific PSA is raised (see below) or rising.
- patients with a healthy life expectancy of les than 10 years do **not** require urgent referral for mildly elevated PSA.

If there is doubt about whether to refer an asymptomatic male with a borderline level of PSA, the PSA test should be repeated after 6 weeks. If the second test shows a further rise, the patient should be referred urgently.

11 Diagnosis and staging

11.1 Diagnosis should be confirmed by biopsy before initiation of treatment except in a clinical emergency, for example spinal cord compression.

11.2 A clinical diagnosis will occasionally be made on the basis of a palpable tumour, very high PSA or evidence of bone metastases.

11.3 Even with a clinical diagnosis of metastatic cancer, biopsy should be performed if trial entry is a possibility.

11.4 Multiparametric MRI will frequently be offered prior to biopsy to minimize clinical delays and optimize biopsy technique. Where this is not the case, imaging should be delayed for at least 6 weeks to prevent biopsy artefacts. MRI should be acquired and reported as per the PI RADS (v2) standard.

11.5 Patients with Gleason score ≥ 4+3 0r serum PSA ≥ 20mcg/l, who are considered for radical treatment, should undergo staging bone scan +/- CT.

11.6 Saturation transperineal template biopsy should be considered in patients with a negative TRUSS-guided transrectal biopsy but ongoing suspicion of cancer (e.g. very high or rising PSA, abnormal multiparametric MRI, clinical suspicion or histological evidence of HGPIN/ASAP). Where this is not available within the cancer unit, referral to an appropriate specialist centre is required.

11.6.1 The level of demand for saturation transperineal template biopsy suggests that each unit offering radical prostatectomy should be offering such a service.

12 Management of primary tumour: localised disease

12.1 Patients should be risk-stratified as per NICE guidance using table 1:

Table 1 Risk stratification criteria for men with localised prostate cancer. Men with clinical stage T3–T4 cancers have locally advanced disease (see page 8).

	PSA (ng/ml)		Gleason score		Clinical stage
Low risk	< 10	and	≤ 6	and	T1–T2a
Intermediate risk	10–20	or	7	or	T2b–T2c
High risk	> 20	or	8–10	or	T3–T4

12.2 There is no clear optimum treatment for localised prostate cancer. All four options below are acceptable for low and selected intermediate risk patients as per table 2. They offer different side-effects; treatment decisions are individual following discussion with the patient and the MDT.

Localised prostate cancer

Key:
✔ preferred treatment
◆ treatment option
✗ not recommended

Table 2 Treatment and management options for men with localised prostate cancer.

		Low risk	Intermediate risk	High risk
	Watchful waiting	◆	◆	◆
	Active surveillance	✔	◆	✗
Radical treatments	Prostatectomy	◆	✔	✔*
	Brachytherapy	◆	◆	✗
	Conformal radiotherapy†	◆	✔	✔*
	Cryotherapy	✗‡	✗‡	✗‡
	High-intensity focused ultrasound	✗‡	✗‡	✗‡

* Offer if there is a realistic prospect of long-term disease control
† Conformal radiotherapy should be given at a minimum dose of 74 Gy (at a maximum of 2 Gy per fraction)
‡ Unless as part of a clinical trial comparing use with established interventions

12.3 In patients with a life expectancy of 10 years or more, management options include:

a. radical prostatectomy
b. external beam radiotherapy (XRT) +/- hormone therapy
c. brachytherapy +/- hormone therapy
d. active surveillance (AS)

12.4 Unless there are specific contra-indications, all options should be discussed with the patient prior to formulating a management plan.

12.5 Active surveillance

12.5.1 Active surveillance is best suited to men with low-risk disease

12.5.2 Active surveillance protocol

PSA estimation (including doubling time (DT)) and DRE every 3-6 months.
Early MRI and rebiopsy after 12 months (TRUSS-guided or template).

12.5.3 Active surveillance - progression to treatment:

PSA DT of 2 years or less
Evidence of disease progression on PSA, DRE or rebiopsy

Prior to treatment, restaging may be appropriate

12.6 Radical prostatectomy

12.6.1 Radical prostatectomy must be performed at a prostatectomy centre.

12.6.2 Patients should be offered clinical trials such as RADICALS in case of high risk features post surgery. Upon biochemical relapse, if appropriate early salvage radiotherapy should be discussed.

12.7 Conformal radiotherapy

12.7.1 Patients suitable for radical radiotherapy should be treated using IMRT.

12.7.2 Neo-adjuvant androgen ablation should be given for intermediate/high risk disease

12.7.3 Duration of andjuvant hormone ablation is determined by the risk group.

12.8 Brachytherapy (Low dose rate)

12.8.1 Patients with a PSA < 10ng/ml or Gleason score of 3+3 or 3+4 benefit most from brachytherapy.

12.8.2 PSA should be <10ng/ml with prostate volume < 45cc. Staging MRI is essential for local staging as are urinary flow studies.

13 Patients with locally advanced disease

13.1 Patients with short life expectancy, significant co morbidities and minimal LUTS should be offered hormonal treatment or watchful waiting.

13.2 For other patients, radical treatment options should be discussed, including referral to a centre offering high dose-rate brachytherapy.

13.3 All patients should be offered at least 2 years of adjuvant androgen ablation (medical or surgical); oral anti-androgens may be considered.

13.4 Patients should be fully informed of their options prior to choosing.

13.5 Patients should be considered for available clinical trials.

14 Patients with a life expectancy of less than 10 years

14.1 Surveillance is advised for men with localised tumours; current data do not demonstrate superior survival following radiotherapy or total prostatectomy. Radical treatment could be considered for high-risk disease.

15. Follow up after radical treatment

15.1 Follow up should be with the primary treatment team until the patient's condition is stable.

15.2 Subsequent follow-up can be made with the primary treatment team, the referring team, or by GP according to the clinical situation and patient preference.

15.3 Clinical teams should actively pursue alternative models of follow-up outside the hospital, including PSA testing with telephone assessment or nurse-led clinics.

15.4 Most patients require follow up as below; those with a high risk of recurrence may require more frequent monitoring:

- 3, 6 and 12 months for the first year
- 6 monthly for the second and third year
- annually thereafter in line with Network follow up guidelines

15.5 Patients require the following at each follow-up review:

- clinical/symptomatic assessment
- serum PSA test
- assessment for erectile dysfunction and incontinence issues

15.6 The following should be observed for/actions should be taken:

15.6.1 After radical prostatectomy, a serum PSA level of more than 0.1mg/ml or three consecutive rises with ultrasensitive PSA, should prompt referral for salvage radiotherapy if appropriate.

15.6.2 After radiotherapy, a rising PSA level, rather than specific threshold value, is the most reliable sign of persistent or recurrent disease (biochemical relapse is usually defined as Nadir serum PSA value + 2ng/ml).

15.7 If a patient has bone pain or raised alkaline phosphatase, a bone scan is be indicated; if bone scan is normal, MRI/CT of the bones affected may be of value.

15.8 Follow-up for patients with advanced or metastatic disease

a. these patients require an individual approach to follow-up, with referral to palliative care teams as required.

16. Recurrent/progressive/metastatic disease

16.1 In the case of local recurrence after radical treatment, the patient should be discussed at MDT wih a view to appropriate referral.

16.2 Hormone ablation should be considered for all patients with metastatic disease and offered to those with symptoms. Hormone ablation should be considered in the absence of metastases when PSA >50 or rising rapidly.

16.3 Patients commencing hormone therapy should be offered a choice between medical or surgical androgen ablation.

16.4 LHRH (luteinizing hormone-releasing hormone) agonist flare can be blocked by an anti-androgen for 7 days before and after initiation of treatment.

16.5 Surgical castration or LHRH antagonists may be appropriate in patients at very high risk of flare complications

16.6 Patients with metastatic disease who experience a good response to Androgen Blockade Therapy (ABT) should be considered for intermittent hormone therapy, to be restarted when PSA>10 or increasing rapidly.

16.7 Neither high intensity focused ultrasound (HIFU) nor cryotherapy are appropriate outside of clinical trials, based on current evidence.

16.8 Metastatic bone pain that is resistant to hormone treatment should be treated with chemotherapy, radiotherapy or a bisphosphonate.

16.9 In hormone resistant metastatic disease docetaxel, abiraterone and enzalutamide are of benefit. The optimal sequence of these remains unproven

16.10 Early commencement of bisphosphonate therapy using zoledronate reduces skeletal related morbidity.

16.11 Consideration should be given to the use of denosumab as an alternative to zoledronic acid for patients requiring bone protecting agents.

16.12 In suspected cases of spinal cord compression (SCC), MRI should be performed. If SCC is confirmed, surgical decompression and stabilisation

at a specialist centre should be considered followed by radiotherapy to the surgical field. If unsuitable for surgery, palliative radiotherapy should be considered.

16.13 If obstructive uropathy from advanced prostate cancer is suspected USS or CT should be performed. If confirmed, decompression by nephrostomy or stents should be considered.

16.14 There are many new agents in clinical trials for prostate cancer; consideration should therefore always be given to clinical trial entry.