

Guidelines for Management of Prostate Cancer

Date Approved by Network Governance	June 2012
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Date for Review	June 2015
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Changes Between Versions 2 and 3

The following sections have been updated:-

9. Referral
11. Management of primary tumour: localised disease
12. Patients with locally advanced disease
14. Follow up after radical treatment
15. Recurrent/Progressive/Metastatic Disease

1. Scope of the guideline

This Guidance has been produced to support the following:

- a) The management of patients presenting with symptoms suspicious of Prostate Cancer
- b) The management of patients found to have Prostate Cancer

2. Guideline background

- 2.1 This guideline is based on the referral guidelines for suspected cancer¹ (www.dh.gov.uk), Improving Outcomes in Urological Cancer – The Manual² (www.nice.org.uk) and the European Association of Urology (EAU) Clinical Guidelines³ (www.uroweb.org). The guideline has been written by the Pan Birmingham Urology Network Site Specific Group (NSSG) which consists of local urology teams based at University Hospital Birmingham NHS Foundation Trust (UHBFT), Sandwell and West Birmingham Hospitals NHS Trust (SWBH), Heart of England NHS Foundation Trust (HEFT) and Walsall Healthcare NHS Trust.
- 2.2 In line with the Improving Outcomes Guidance in Urological Cancer² the Pan Birmingham Cancer Network has two designated centres for the location of major pelvic surgery. All patients in the Network requiring a prostatectomy are referred to either Heart of England NHS Foundation Trust (HEFT) or University Hospital Birmingham NHS Foundation Trust (UHBFT). Within these cancer centres, surgery is carried out by Surgeons doing 5 or more radical procedures per year. A minimum of 50 radical procedures will be carried out at each of the centres per year.

Guideline statements

3. Referral from GPs

- 3.1 Patients with suspected urological cancer should be referred from GPs to local urology units according to the NICE referral guidelines¹ (see section 9 for details).
- 3.2 Referrals deemed inappropriate by consultant urologists will be notified to the referring GP and to the relevant PCT according to agreed protocols.
- 3.3 GPs will be notified of the diagnosis of cancer within 24 hours of the diagnosis being made, and will be kept informed of all aspects of the patients care.

4. Multi Disciplinary Teams (MDTs)

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

5. Staging

- 5.1 Staging data for 70% of all cancers (90% of stageable cancers) should be collected electronically and transferred to the West Midlands Cancer Intelligence Unit (WMCUI).
- 5.2 All Trusts
- a. The Trust is sending electronic extracts from their histopathology system regularly to the WMCUI
 - b. The Trust is sending imaging extracts for cancer patients electronically to the WMCUI regularly, or has established remote access for the WMCUI to their radiology information system
- 5.3 For cancers diagnosed clinically or those that have not had surgery
- a. Clinical TNM stage is recorded on the MDT database
- 5.4 For those with invasive cancer who have had surgery
- a. MDTs record the full cancer registry dataset onto their MDT database at the time of discussion at the MDT meeting and send extracts to the WMCUI on a regular basis

6. Performance Status

All patients should have their performance status recorded at the onto the MDT database at the MDT. This should be done using the WHO classification which will ensure it is in line with the cancer outcomes and services dataset guidance

7. Patient Information and Counselling

- 7.1 All patients diagnosed with a metastasis to **any bone**, or who have **myeloma**, should receive information about the possibility of developing metastasis to the spine. This is essential to enable patients to report signs of spinal metastases

early, thereby offering treatment options that may prevent damage to the spinal cord and unnecessary disability.

- 7.2 This information should be offered by a senior cancer clinician (for example a CNS or consultant). The patients should be advised about what to look for and what to do in the event that they have symptoms and/or signs of spinal metastases.
- 7.3 Patients should be provided with information about the symptoms and/or signs of spinal cord compression and what to do if they develop them. This discussion should be supported by written information in the form of the PBCN Patient Information on Cancer that has Spread to the Bone (Bone Metastases) and the Patient Alert Card.
- 7.4 All patients, and with their consent, their partners will be given access to appropriate written information during their investigation and treatment, and on diagnosis will be given the opportunity to discuss their management with a clinical nurse specialist who is a member of the relevant MDT. The patient should have a method of access to the urology team at all times.
- 7.5 Access to psychological support will be available if required. All patients should undergo a holistic needs assessment and onward referral as required.

8. Patient information and support

- 8.1 All patients should be given access to appropriate written information during their investigation and treatment.
- 8.2 At diagnosis and other stages of their pathway patients should be given the opportunity to undergo Holistic Needs Assessment with a clinical nurse specialist. As part of this assessment they will have further opportunities to discuss their diagnosis and treatment. Onward referral to other agencies and teams, including those offering psychological support, should be offered as required by the patient.
- 8.3 Patients should be offered a permanent record of their key consultations with their specialist team.
- 8.4 Patients should have a method of access to their multidisciplinary team (Monday – Friday 9.00 a.m. – 5.00 p.m.) and be given the contact details of their key worker at diagnosis or first referral (whichever occurs first).

9. Palliative care

- 9.1 Palliative care services will be made available to all patients as deemed appropriate by the MDT.

10. Clinical trials

- 10.1 Wherever possible, patients who are eligible should be offered the opportunity to participate in National Institute for Health Research portfolio clinical trials and other well designed studies.
- 10.2 Where a study is only open at one Trust in the Network, patients should be referred for trial entry. A list of studies available at each Trust is available from the Pan Birmingham Cancer Research Network. Email: Email: PBCRN@westmidlands.nhs.uk.
- 10.3 Patients who have been recruited into a clinical trial will be followed up as defined in the trial protocol.

11. Assessment in primary care

- 11.1 Patients presenting with symptoms suggesting prostate cancer should have a digital rectal examination (DRE) and prostate-specific antigen (PSA) test after counselling. Such symptoms may include frequency, nocturia, hesitancy and /or weak stream.
- 11.2 Prostate cancer is also a possibility in male patients with any of the following unexplained symptoms:
- a. erectile dysfunction
 - b. haematuria
 - c. lower back pain
 - d. weight loss, especially in the elderly
 - e. where there is a direct family history of prostate cancer
- 11.3 These patients should also be offered a DRE and PSA test.
- 11.4 Urinary infection should be excluded before PSA testing, **especially in men presenting with lower tract symptoms**. The PSA test should be postponed for at least one month after treatment of proven urinary infection.

12. Referral

12.1 Urgent Referral

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

- a. those with a hard irregular prostate (typical of a prostate carcinoma) on rectal examination
- b. symptomatic patients with high PSA levels (see table below in 9.2)
- c. those with or without lower urinary tract symptoms and in whom the prostate is normal on digital rectal examination but the age specific PSA is raised (see below) or rising¹. NB *Elderly patients (over 80yrs) or those with significant co-morbidity do not require urgent referral for mildly elevated PSA in the absence of symptoms*

12.2 Age specific PSA levels PSA are elevated when:

Age	PSA level
40 - 49	more than 2.0 ng/ml
50 - 59	more than 3.0 ng/ml
60 - 69	more than 4.0 ng/ml
70 - 80	more than 5.0 ng/ml

In patients over 80, age related PSA is not relevant. Patients should be referred for palliative treatment of prostate cancer if symptomatic.

If there is doubt about whether to refer an asymptomatic male with a borderline level of PSA, the PSA test should be repeated after an interval of 1 to 3 months. If the second test indicates that the PSA level is rising, the patient should be referred urgently

12.3 Routine Referral

Routine referrals should be made when the prostate is enlarged and the PSA is within the age-specific reference range

12.4 Other situations

- a. patients who request a PSA test in the absence of symptoms (PSA screening) should be offered appropriate counselling prior to having the test
- b. in those patients whose clinical state is compromised by other co-morbidities, a discussion with the patient or carers and/or a specialist in urological cancer may be more appropriate than an urgent referral
- c. appendix 2 shows the referral and diagnosis pathway

13. Diagnosis and staging

- 13.1 Diagnosis should be made by biopsy before initiation of treatment except in a clinical emergency, for example spinal cord compression.
- 13.2 Very rarely a clinical diagnosis will be made on the basis of a palpable tumour and a very high PSA and clinical evidence of bone metastases (high PSA alone could be gross BPH (Benign Prostatic Hyperplasia) and obstruction).
- 13.3 Biopsy should normally be performed at the same time as a trans-rectal ultrasound scan (TRUS).
- 13.4 Even when the clinical diagnosis of metastatic cancer is likely, a biopsy should be performed if subsequent trial entry a possibility, as virtually all trials require a biopsy confirmation of cancer for entry. Hence only the very old or frail should not be offered a biopsy.
- 13.5 Patients suitable for radical curative treatment (see section 11 below) require staging with MRI and bone scan only if the PSA exceeds 10 or Gleason score is 8 or more.
- 13.6 Patients who have a TRUS suspicious of capsular breach are also suitable for MRI.
- 13.7 Patients with a PSA between 10 and 20 normally undergo an MRI. In patients with a PSA greater than 20 there is a higher chance of distant metastases and they are less likely to be offered radical surgical treatment.
- 13.8 In cases where PSA is greater than 15 a bone scan is also required. Patients with higher Gleason score more than 8 with a low PSA also require a bone scan.
- 13.9 Patients with PSA of more than 20 who are unsuitable for surgical treatment should have an abdominal & pelvic CT to exclude/detect metastases.

14. Management of primary tumour: localised disease

- 14.1 There is at present no clear indication as to which treatment options are of most benefit for patients with localised prostate cancer. All four options below are acceptable treatment options. They do however offer different co-morbidities and therefore treatment decisions are made on an individual patient basis following discussion with the patient and the MDT.
- 14.2 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

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

14.4 Active surveillance

14.4.1 Patients who are on active surveillance are most likely to have a low risk prostate cancer with Gleason score of 3+3 or less and a PSA of less than 10, or a Gleason score of 3 or 4, a PSA of less than 15 and are aged over 70. They will have a less than 2% chance of prostate cancer death by 8 years post therapy.

14.4.2 Active surveillance is particularly suitable for a subgroup of men with low-risk

- a. localised prostate cancer who have clinical stage T1c, a Gleason score 3+3, a
- b. PSA density < 0.15 ng/ml/ml and who have cancer in less than 5% of their total number of biopsy cores with < 10mm of any core involved.

14.4.3 Active surveillance should not be offered to patients with localised high risk prostate cancer.

- a. PSA estimation (with particular observation of the doubling time (DT)⁴ and digital rectal examination every 3-6 months).
- b. Consideration should be given to the use of MRI ahead of rebiopsy for cases with a rising PSA on active monitoring.

Active surveillance treatment criteria:

- a. those with a PSA DT of 2 years or less (based on a minimum of three determinants over 6 months) should be considered for a radical intervention
- b. patients with evidence of disease progression on PSA or DRE should be re-discussed at the MDT and MRI and, if indicated, re-biopsy considered at 1 and 2 years
- c. if switching from active monitoring to treatment, MRI followed by rebiopsy will be indicated to confirm Gleason grade and TNM stage so that accurate current staging available for treatment

14.5 Men with localised prostate cancer who have chosen an active surveillance regimen and who have evidence of disease progression (that is, a rise in PSA or adverse findings on biopsy) should be offered radical treatment.

14.6 Radical prostatectomy

14.6.1 This will be performed at one of the specialist centres (University Hospitals Birmingham NHS Foundation Trust or Heart of England NHS Foundation Trust).

- a. patients should be offered a choice of open or laparoscopic prostatectomy unless there are specific contra-indications

14.6.2 Currently robot assisted surgery is not offered in this Network. Clinicians should follow the local commissioning process for Individual Funding applications where they believe there are exceptional circumstance to support referral to a centre offering robotic surgery .

14.6.3 Patients should be offered clinical trials such as RADICALS in case of high risk features post surgery for radiotherapy timing randomisation. Upon biochemical relapse if appropriate early salvage radiotherapy should be discussed. Clinical trial such as RADICALS- HT should be discussed.

14.7 Conformal radiotherapy

14.7.1 Patients suitable for radical radiotherapy should be given 74 Gy in 37 fractions using conformal radiotherapy and where possible and appropriate intensity modulated and/or image guided radiotherapy.

14.8 Neo-adjuvant hormonal manipulation with androgen ablation

14.8.1 This is normally given according to the pre-treatment Gleason score and PSA. A minimum of 3 months therapy pre-RT is required. Target window for completion of radiotherapy is between 3 and 6 months of commencement of therapy where no adjuvant therapy planned.

14.9 Brachytherapy

14.9.1 Patients with a PSA of less than 10 or Gleason score of 3+3 or 3+4 are likely to benefit most from brachytherapy.

14.9.2 Patients suitable for prostate low dose rate brachytherapy usually have stage cT1c–T2a N0, M0 prostate cancer with Gleason score of 3+3 or 3+4 with assessed on a sufficient number of random biopsies.

14.9.3 Initial PSA should be ideally 10 or less with prostate volume < than 40-45cc. it is essential to have staging MRI scan to evaluate the local staging and urinary flow studies performed to assess suitability.(5)

15. Patients with locally advanced disease

- 15.1 Patients with a short life expectancy, significant co morbidities and minimal urinary outflow obstruction should be considered for hormonal treatment or watchful waiting.
- 15.2 For all other patients radical curative external beam radiotherapy in combination with neoadjuvant, concurrent and adjuvant hormonal treatment should be discussed.
- 15.3 All patients should be offered at least 2-3 yrs of adjuvant hormonal treatment (10) - preferably androgen ablation (medical or surgical), however, oral anti-androgens may be considered according to the patient's tolerance. Survival and quality of life are the same but there are significant differences in the pattern of side effects.
- 15.4 Patients should be fully informed of their options prior to making the decision.
- 15.5 These patients should be considered for the STAMPED trial (Systemic Treatment for Advanced or Metastatic Prostate Cancer).

16. Patients with a life expectancy of less than 10 years

- 16.1 Surveillance is advised for patients with T1a tumours. For other localised tumours surveillance is still an option as some men have low rates of progression and current data do not clearly demonstrate superior survival following radiotherapy or total prostatectomy⁶.
- 16.2 The remainder of the patients should be discussed on a case by case basis.

17. Follow up after radical treatment

- 17.1 Follow up should be with the team that managed the primary treatment until the patients condition is considered stable.
- 17.2 Subsequent follow-up can be made with the primary treatment team, the referring team (if different) or by GP according to the clinical situation and patient preference. See appendices 1 -3 for supporting documentation for GP follow up.

- 17.3 Clinical teams should be actively pursuing alternative models of follow-up including PSA testing with telephone assessment or nurse led clinics.
- 17.4 Patients who have been recruited into a clinical trial will be followed up as per the trial protocol.
- 17.5 Most patients will require the following follow up, however it is recognised that *those with a high risk of recurrence may require more frequent monitoring*:
- at 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
- 17.6 All patients will require the following at each follow-up review:
- a clinical/ symptomatic assessment
 - a PSA test
 - assessment for erectile dysfunction and incontinence issues
 - no routine imaging is necessary
- 17.7 The following should be observed for/actions should be taken:
- after radical prostatectomy, a serum PSA level of more than 0.2mg/ml, or a rising PSA on ultrasensitive assay at lower absolute PSA levels can be associated with residual or recurrent disease. Patients with biochemical relapse should be considered entry into the clinical trial such as RADICALS if appropriate.
 - 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 PSA value +2). PSA often rises initially after RT due to recovery of androgen production and residual normal prostate. Patients should usually only be assessed for relapse if their PSA is at least 1.5 - 2 with an exponential rising trend.
 - if there is clinical suspicion of a recurrence (on PSA or DRE) patients should be considered for repeat TRUS biopsy and subsequently bone scan and/or CT of abdomen and pelvis. If there is evidence of local recurrence then Combined Endorectal and Phased-Array MRI may give local staging.
 - if there is an early rise in PSA (usually within 12 months) it is likely to be as a result of metastatic disease, a late rise in PSA (usually after 3 years) may indicate local recurrence (though emerging research may challenge this assumption). This may be considered when choosing imaging technique. Patients should be considered for radiotherapy as early as possible if they have high risk RRP (radical retropubic prostatectomy) histology and a rising PSA on ultrasensitive assay even if it is less than 0.2
 - detection of local recurrence by TRUS and biopsy is recommended if it will affect the treatment plan. In most cases TRUS and biopsy are not necessary

before second line therapy, especially as most patients with very low but rising PSA will have no obvious target lesion for biopsy.

- 17.8 If a patient has bone pain or a raised alkaline phosphatase, a bone scan may be indicated irrespective of the serum PSA level, and in those that bone scan does not help an MRI or CT of the bones affected may be of value.
- 17.9 Follow-up for patients with advanced or metastatic disease
 - a. these patients will require an individual approach to follow-up, with referral to palliative care teams as required. Appendix 1 shows the secondary care follow up and discharge pathway
 - b. consider for entry into STAMPEDE trial

18. Recurrent/progressive/metastatic disease

- 18.1 In the case of local recurrence or local progression after radical treatment consideration should be given to re-staging and treating with further radical therapy (radiotherapy or surgery).
- 18.2 Hormone manipulation should be considered for all patients with metastatic disease; and offered to all patients with symptoms of metastatic disease. Hormone manipulation should be considered when the PSA is very high (>50) or is rising rapidly⁶.
- 18.3 Patients commencing hormone therapy should be offered a choice between medical or surgical androgen ablation as first line therapy⁶.
- 18.4 LHRH (luteinizing hormone-releasing hormone) agonist flare should be blocked by use of an anti-androgen for at least three consecutive days before and for three days after the initiation of treatment⁶.
- 18.5 Patients with asymptomatic metastatic disease should no longer be offered deferred treatment except for exceptional cases (where the risks of pathological fracture are considered to be low and patients choose this option after being fully informed). Patients may be suitable for this where they have a low PSA and a long doubling time (greater than 3 years).
- 18.6 Patients with metastatic disease who experience a good response to Androgen Blockade Therapy (ABT) should be considered for intermittent hormone therapy with cessation of ABT, to be restarted when PSA>10 or symptoms occur.
- 18.7 Neither high intensity focused ultrasound nor cryotherapy are recommended as primary treatment by NICE (2008) unless part of a clinical trial and therefore are not commissioned at Pan Birmingham Cancer Network.

- 18.8 Metastatic bone pain that is resistant to hormone treatment should be treated with chemotherapy (see below), radiotherapy or a bisphosphonate.
- 18.9 There is evidence that early commencement of bisphosphonate therapy using zoledronic acid reduces the risk of a skeletal related morbidity⁸.
- 18.10 Consideration should be given to the use of denosumab as an alternative to zoledronic acid for patients requiring bone protecting agents.
- 18.11 In resistant cases patients can be referred to the MDT at UHBFT or HEFT for treatment with strontium 89 or samarium 153. Referral should be made promptly as these treatments are best considered before patients have very extensive disease due to problems with myelotoxicity if given late.
- 18.12 In hormone resistant metastatic disease docetaxel has been shown to be of benefit⁸
- 18.13 Patients relapsing post docetaxel may be considered for treatment with either cabazitaxel or abiraterone in line with the current West Midlands Cancer Drugs Fund policy.(available at:- <http://www.westmidlands.nhs.uk/WhatWeDo/WestMidlandsCancerDrugFund/CohortPoliciesDrugsConsideredbyCDFPanel.aspx>) or e-mail:- wm.cancerdrugs@nhs.net
- 18.14 In suspected cases of spinal cord compression an MRI should be performed. If spinal cord compression is confirmed surgical decompression and stabilisation at a specialist orthopaedic centre should be considered followed by radiotherapy to the surgical field (refer to MSCC pathway). If unsuitable for surgery, palliative radiotherapy should be considered.
- 18.15 If obstructive uropathy caused by advanced prostate cancer is suspected ultrasound or CT should be performed. If confirmed decompression by nephrostomy or stents should be considered.
- 18.16 The new radio-isotope Ra223 is set to be licenced for castrate refractory bony metastatic disease in 2012/3. Trial data suggests that this agent may significantly prolong survival and reduce clinical bone events in both chemotherapy exposed and chemo-naïve patients. Clinicians may consider this as a treatment option once supported by national or local commissioning policy.
- 18.17 There are many new agents in clinical trials for prostate cancer. Therefore , consideration should therefore always be given as to whether entry into a study may be appropriate.

Monitoring of the guideline

Adherence to the Network guidelines may from time to time be formally monitored.

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References

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Approval Signatures

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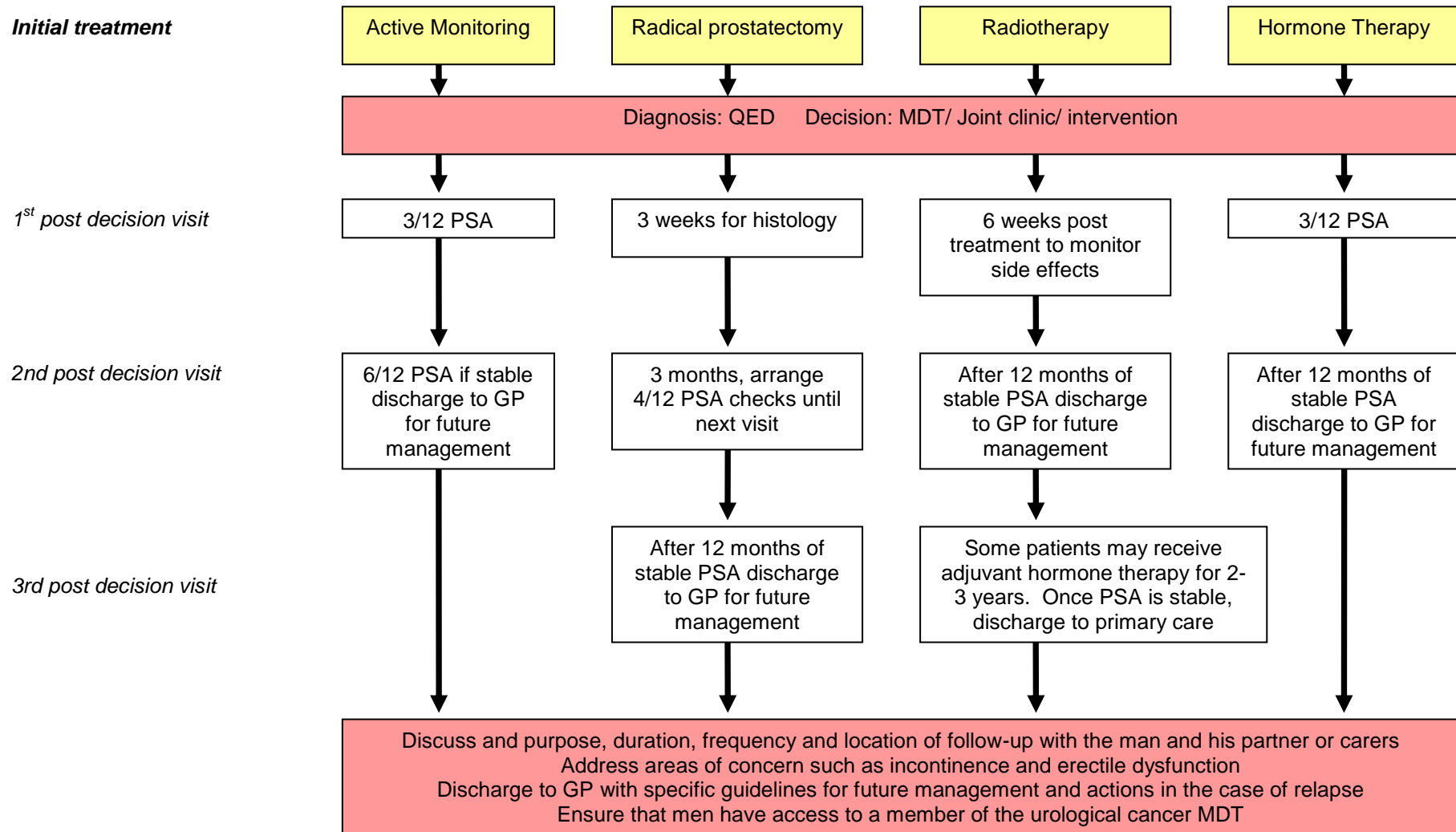
Name: Rupesh Bhatt

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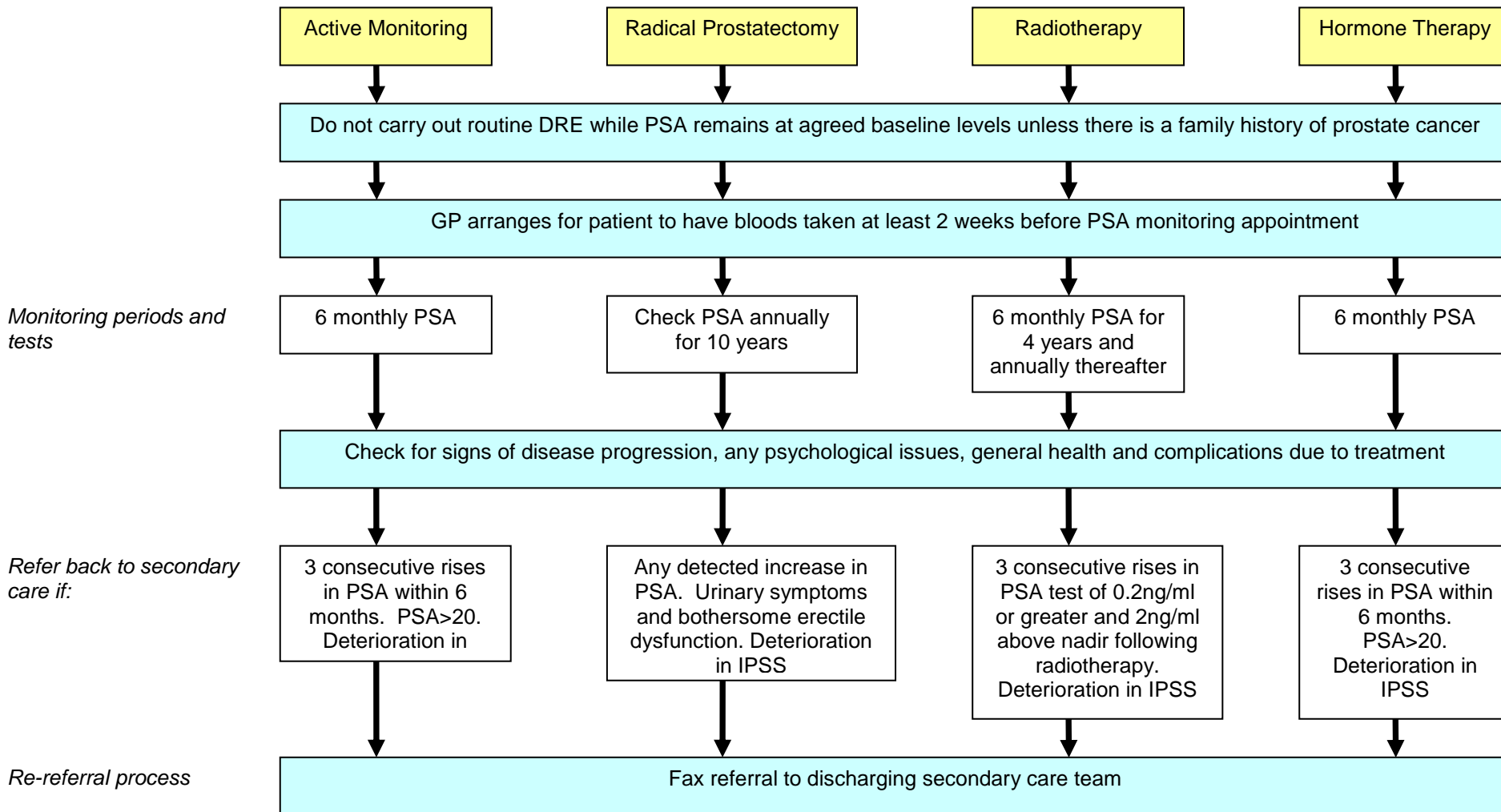
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Appendix 1 - Primary Care Discharge and Management protocol for Prostate Cancer

Secondary care follow up and discharge pathway

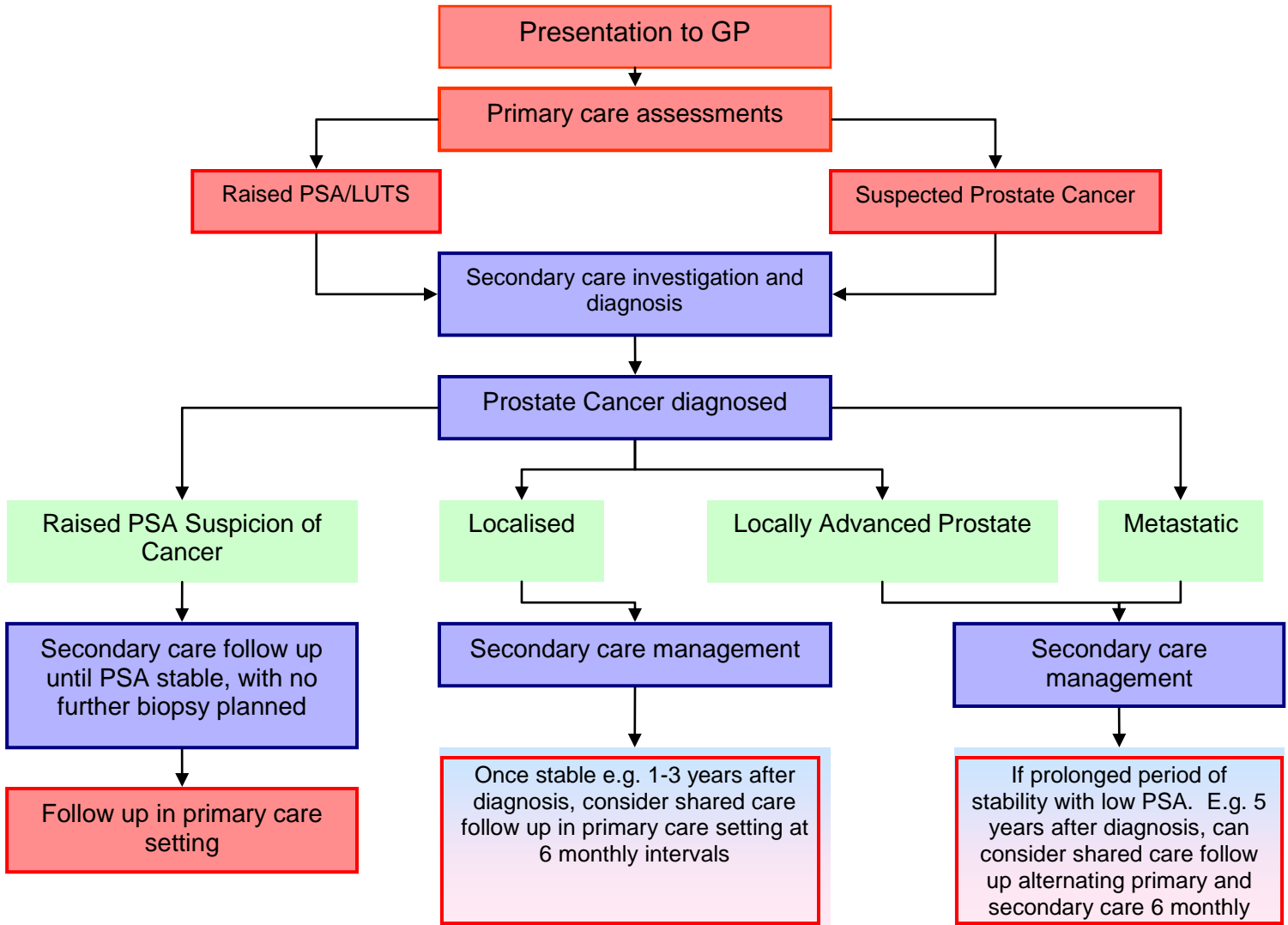


Appendix 2 Primary Care Management Pathway



Appendix 3

GENERIC Shared Care Protocol for Prostate Cancer (DRAFT)



Assessment in Primary Care –

Patients presenting with symptoms suggesting prostate cancer should have a DRE and a PSA test after counselling.

Symptoms may include frequency, nocturia, hesitancy and/or weak stream.

Patients with the following unexplained symptoms should also be offered a DRE and PSA test - **Erectile dysfunction, haematuria, lower back or bone pain, weight loss (especially in the elderly).**

Urinary infection should be excluded with an MSU, **especially in men presenting with LUTS**. Repeat PSA test should be done about a month after treatment of an infection.

Key

DRE – Digital Rectal Examination
PSA – Prostate - Specific Antigen
LUTS – Lower Urinary Tract Symptoms
Primary Care actions
Secondary Care actions

Age Specific PSA levels are elevated when-

40-49 > 2.0 ng/ml
 50-59 > 3.0 ng/ml
 60-69 > 4.0 ng/ml
 70-80 > 5.0 ng/ml
 80 + PSA not relevant in asymptomatic patients

Patients should be referred for palliative treatment of prostate cancer if symptomatic.

Referral –

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

- **hard irregular prostate on rectal examination,**
- **raised PSA levels (see below)**

If there is doubt about whether to refer an asymptomatic male with a borderline level PSA either with or without LUTS, the PSA test should be repeated after 1-3 months.

If the second test indicates that the PSA levels are rising, the patient should be referred urgently.

If the prostate is enlarged and the PSA is in the age specific reference range a routine referral should be made.

Other Situations –

Patients who request PSA in the absence of symptoms should be offered appropriate counselling prior to the test. For those whose clinical state is compromised by other co-morbidities, a discussion with the patient, carers and/or specialist in urological cancer may be more appropriate than an urgent referral.

