People referred with suspected prostate cancer

- Discuss PSA level, DRE findings, co-morbidities, risk factors, history of previous negative prostate biopsy
- Offer multiparametric MRI as the first-line investigation to people with suspected clinically localised prostate cancer. Report MRI results using a 5-point Likert scale.
- Do not routinely offer imaging to people who are not candidates for radical treatment.
- Consider omitting prostate biopsy for people whose multiparametric-MRI Likert score is 1 or 2, but only after discussing the risks and benefits with the person and reaching a shared decision.
- Give people information, support and adequate time to make a decision. Explain the risks and benefits of biopsy.
- Do not automatically offer prostate biopsy on the basis of serum PSA level alone.
- Do not offer prostate biopsy for confirmation if the clinical suspicion of cancer is high (a high PSA and evidence of bone metastases).

**Decision to proceed with biopsy**
Offer multiparametric-MRI influenced prostate biopsy to:
- people whose multiparametric-MRI Likert score is 3 or more,
- people who have lower scores and have opted for biopsy.

Only offer mapping transperineal template biopsy as part of a clinical trial.

**Positive initial biopsy**
- Offer prostate biopsy if the index of suspicion is still high.
- Discharge the person to primary care with advice for follow up if the level of suspicion is low.

**Negative initial biopsy**

- Advise there is still a risk that prostate cancer is present.
- Advise the risk is slightly higher if biopsy showed HGPIN, biopsy showed ASAP, abnormal DRE.
- If there is concern after negative biopsy, discuss in MDT meeting with a view to repeating biopsy.

**Use nomograms to aid decision making, and help predict biopsy results, pathological stage and risk of treatment failure. Clearly explain the reliability, validity and limitations of the prediction.**

**Positive rebiopsy**
- Offer isotope bone scans to asymptomatic people on watchful waiting at high risk of developing bone complications.
- Do not routinely offer isotope bone scans to people with low risk localised prostate cancer.
- Do not offer CT of the pelvis to people with low or intermediate risk localised disease.
- Do not offer PET for prostate cancer in routine clinical practice.

**Radical treatment intent**
- For people who have a raised PSA, Likert 1 or 2 and negative biopsy, repeat PSA at 3–6 months and:
  - offer repeat biopsy if there is strong suspicion of prostate cancer.
  - discharge the person to primary care if the level of suspicion is low.

**No radical treatment intent**
- If there is concern after negative biopsy, discuss in MDT meeting with a view to repeating biopsy.
- Offer isotope bone scans to asymptomatic people on watchful waiting at high risk of developing bone complications.
- Do not routinely offer isotope bone scans to people with low risk localised prostate cancer.
- Do not offer CT of the pelvis to people with low or intermediate risk localised disease.
- Do not offer PET for prostate cancer in routine clinical practice.
LOCALISED PROSTATE CANCER

Assign risk category to all newly diagnosed men with prostate cancer

- men about treatment options and their risks and benefits in an objective, unbiased manner and that there is limited evidence for some treatment options
- Give men with prostate cancer who are candidates for radical treatment the opportunity to discuss their treatment options with a specialist surgical oncologist and a specialist clinical oncologist.
- Before treatment for prostate cancer, warn men:
  - That it will result in an alteration of sexual experience and may result in loss of sexual function
  - About potential loss of ejaculation and fertility, and offer sperm storage, and
  - Of the likely effects of the treatment on their urinary function

Treatment
(See algorithm on treatments for localised prostate cancer)

Follow up
- Discuss the purpose, duration, frequency and location of follow-up with each person with localised and locally advanced prostate cancer, and if they wish, their partner or carers.
- Advise people with prostate cancer about potential longer-term adverse effects of treatment and when and how to report them.
- Check PSA levels for all people with prostate cancer who are having radical treatment no earlier than 6 weeks after treatment, at least every 6 months for the first 2 years, and then at least once a year after that.
- Do not routinely offer digital rectal examination to people with localised prostate cancer who are not on active surveillance while their PSA remains at baseline levels.
- After at least 6 months’ initial follow-up, consider a non-hospital based follow-up strategy for people with a stable PSA who have had no significant treatment complications, unless they are taking part in a clinical trial that needs formal clinic-based follow-up. Examples of possible follow-up strategies include:
  - supported self-management
  - shared care
  - telephone-based follow-up.
- Follow up people with prostate cancer who have chosen a watchful waiting regimen with no curative intent in primary care if protocols for this have been agreed between the local urological cancer MDT and the relevant primary care organisation(s). Measure their PSA at least once a year.
TREATMENT FOR LOCALISED PROSTATE CANCER

**Low risk localised prostate cancer**
- Consider using the following active surveillance protocol
  - Offer mpMRI at 3-6 months post biopsy for people who have not had a pre-biopsy MRI. If there is discordance with the original biopsy then offer MRI influenced biopsy.
  - Consider mpMRI in people who have been on active surveillance and have not had a multiparametric MRI before. If there is discordance with the original biopsy then offer MRI influenced biopsy.
  - Year 1 of active surveillance: every 3-4 months measure PSA* and monitor PSA kinetics; at 12 months perform DRE^; and at 12 - 18 months perform biparametric MRI.
  - Year 2 of active surveillance onwards: every 6 months measure PSA and monitor PSA kinetics; and every 12 months perform DRE.
  - If there is concern about clinical or PSA changes, re-assess with multiparametric-MRI and/or re-biopsy.
- The decision to move from active surveillance to radical treatment should be made in the light of the individual man’s personal preferences, comorbidities and life expectancy.
- For people with evidence of disease progression offer radical treatment.

**Intermediate risk localised prostate cancer**
- Offer as an option to radical treatment.
- Consider as an option.

**High risk localised prostate cancer**
- Offer.

**Radical prostatectomy or radical radiotherapy**

**Discuss the benefits and harms of each treatment option**

**HIFU and cryotherapy**
(Not recommended outside clinical trials)

**Active surveillance**
(Do not offer for high risk localised prostate cancer)

**High dose rate brachytherapy + EBRT**

**Radical prostatectomy**
- Commissioners of urology services should consider providing robotic surgery.
- Commissioners should ensure robotic systems are cost effective by basing them in centres where the number of radical prostatectomies exceeds 150 per year.

**Radical external beam radiotherapy**
- Offer planning and treatment techniques that optimise the dose to the tumour while minimising the risks of normal tissue damage.
- Offer 60 Gy in 20 fractions using image-guided intensity modulated radiation therapy (IMRT) unless clinically contraindicated.
- Offer those not suitable for hypofractionated radiotherapy conventional radiotherapy (74 Gy in 37 fractions).

**Radiotherapy + hormones**
(See algorithm on locally advanced prostate cancer)

**Chemotherapy**
Discuss the option of docetaxel chemotherapy with people with newly diagnosed non-metastatic prostate cancer who are starting ADT if they have high risk disease and no significant co-morbidities and come to a shared decision about whether they should have it.

*PSA monitoring may be carried out in primary care if there are agreed shared-care protocols and recall systems.

^DRE should be performed by a healthcare professional with expertise and confidence in performing DREs.

+ This may include PSA, doubling time and/or PSA velocity.
**BIOCHEMICAL RELAPSE**

**Post radical prostatectomy**
- Do not offer biopsy of the prostatic bed
- Offer radical radiotherapy to the prostatic bed to people with biochemical relapse after radical prostatectomy but with no known metastases

**Post radiotherapy**
Offer biopsy of the prostate only to people being considered for local salvage therapy in the context of a clinical trial.

**Imaging**
For people with evidence of biochemical relapse following radical treatment who are considering radical salvage therapy
- Do not offer routine MRI prior to salvage radiotherapy
- Offer isotope bone scan if symptoms or PSA trends are suggestive of metastases.

**Management**
- Biochemical relapse (a rising PSA) alone should not prompt an immediate change in treatment
- Biochemical relapse should trigger an estimate of PSA doubling time based on a minimum of 3 measurements over at least a six month period
- Consider people with biochemical relapse for entry into appropriate clinical trials
- Do not routinely offer hormonal therapy unless people have symptomatic local disease progression or any proven metastases or a PSA doubling time of less than 3 months.
**LOCALLY ADVANCED PROSTATE CANCER**

- Do not offer bisphosphonates for the prevention of bone metastases
- Do not offer HIFU and cryotherapy other than in the context of clinical trials

Discuss the benefits and harms of docetaxel chemotherapy with people with newly diagnosed non-metastatic prostate cancer who are starting ADT if they have high risk disease and no significant co-morbidities and come to a shared decision about whether they should have it

**Radiotherapy + hormones**

- Offer people with intermediate and high-risk localised disease a combination of radiotherapy and androgen deprivation therapy
- Offer people with intermediate and high-risk localised prostate cancer 6 months of androgen deprivation therapy given before, during or after radical external beam radiotherapy
- Consider pelvic radiotherapy in people with locally advanced prostate cancer who have a greater than 15% risk of pelvic lymph node involvement and who are to receive neoadjuvant hormonal therapy and radical radiotherapy

**Hormone therapy alone (no specific recommendations)**

Consider continuing androgen deprivation therapy for up to 3 years for people with high risk localised prostate cancer

**Radical prostatectomy**

- Do not offer adjuvant hormonal therapy, even to people with margin-positive disease, other than in the context of a clinical trial
- Do not offer immediate post-operative radiotherapy, even to people with margin-positive disease, other than in the context of a clinical trial
If no previous diagnosis of prostate cancer, do not offer prostate biopsy for histological confirmation if the clinical suspicion of prostate cancer is high (a high PSA value and evidence of bone metastases) and unless this is required as part of a clinical trial.

**people with hormone-naive metastatic prostate cancer**
- Offer bilateral orchidectomy as an alternative to continuous LHRHa therapy
- Do not offer combined androgen blockade as a first line treatment
- Offer anti-androgen monotherapy with bicalutamide (150mg) if willing to accept the adverse impact on overall survival and gynaecomastia
- Stop bicalutamide treatment and begin androgen withdrawal if bicalutamide monotherapy does not maintain satisfactory sexual function

**people with hormone-relapsed prostate cancer**
- Treatment options to be discussed with the urological cancer MDT. Seek oncology and/or specialist palliative care opinion as appropriate
- Offer spinal MRI to people shown to have extensive metastases in the spine if they develop any spinal-related symptoms
- Do not routinely offer spinal MRI to all people with known bone metastases

**Chemotherapy**
Offer docetaxel chemotherapy to people with newly diagnosed metastatic prostate cancer who do not have significant comorbidities.

**Corticosteroids**
Offer a corticosteroid such as dexamethasone (0.5mg daily) as third line hormonal therapy.

**Radioisotopes**
For guidance on treatments for people with bone metastases from prostate cancer, see the NICE technology appraisal on radium-223 dichloride.

**Bisphosphonates**
- Consider zoledronic acid for people with hormone-refractory metastatic prostate cancer to prevent or reduce skeletal-related events
- Consider bisphosphonates for pain relief for people with hormone refractory prostate cancer when other treatments have failed
- For guidance on treatments for people with bone metastases from prostate cancer, see TA412

**Relevant TA’s**
- For recommendations on the use of abiraterone see TA259 and TA387
- For recommendations on cabazitaxel see TA319
- For recommendations on Enzutlmidt see TA377 and TA316

**Chemotherapy**
For recommendations on the use of docetaxel see TA101
Complications of disease

Bone metastases
Consider zoledronic acid for people with hormone-refractory metastatic prostate cancer to prevent or reduce skeletal-related events

Urinary obstruction
For people with obstructive uropathy secondary to hormone relapsed prostate cancer:
- Offer decompression of the upper urinary tract by percutaneous nephrostomy or insertion of a double J stent
- Discuss the option of no intervention
# MANAGING COMPLICATIONS OF TREATMENT

## Urinary symptoms
- Offer people experiencing troublesome urinary symptoms before treatment a urological assessment
- Ensure people with troublesome urinary symptoms after treatment have access to specialist continence services
- Refer people with intractable stress incontinence to a specialist surgeon for consideration of an artificial urinary sphincter.
- Do not offer injection of bulking agents into the distal urinary sphincter to treat stress incontinence.

## Bowel symptoms*
- Ensure people with signs and symptoms of radiation induced enteropathy (RIE) are offered care from a team of professionals with expertise in RIE.
- Tell people there is a small increase in the risk of colorectal cancer after radical external beam radiotherapy for prostate cancer.
- Carry out full investigations, including flexible sigmoidoscopy, in people who have symptoms of RIE to exclude inflammatory bowel disease, for malignancy of the large bowel, and to ascertain the nature of the radiation injury.

## Sexual dysfunction
- Ensure people have early and ongoing access to specialist erectile dysfunction services.
- Offer phosphodiesterase type 5 (PDES) inhibitors to people who experience loss of erectile function.
- If PDES inhibitors fail to restore erectile function or are contraindicated, offer a choice of intraurethral inserts, penile injections, penile prosthesis, vacuum devices.

## Hot flushes
- Offer medroxyprogesterone (20mg a day), initially for 10 weeks. Evaluate the effect at the end of treatment.
- Consider cyproterone acetate or megestrol acetate (20mg twice a day for 4 weeks) if medroxyprogesterone is not effective or not tolerated.
- Tell people there is no good quality evidence for the use of complementary therapies.

## Endocrine
- Offer people starting long term bicalutamide monotherapy (>6 months) prophylactic radiotherapy to both breast buds within the first month of treatment. Choose a single fraction of 8 Gy using orthovoltage or electron beam radiotherapy.
- Consider tamoxifen if radiotherapy is unsuccessful in preventing gynaecomastia.

## Fatigue
- Tell people who are starting androgen deprivation therapy that fatigue is a recognised side-effect of this treatment.
- Offer people who are having androgen deprivation therapy supervised resistance and aerobic exercise at least twice a week for 12 weeks to reduce fatigue.

## Preventing osteoporosis
For people having androgen deprivation therapy:
- Consider assessing fracture risk in line with Osteoporosis Frailty Fracture Risk (NICE CG146)
- Do not routinely offer bisphosphonates to prevent osteoporosis.

## Managing osteoporosis
For people having androgen deprivation therapy:
- Offer bisphosphonates.
- Consider denosumab if bisphosphonates are contraindicated or not tolerated.

* The nature and treatment of radiation-induced enteropathy should be included in the training programmes for oncologists and gastroenterologists.
HORMONAL THERAPY FOR PROSTATE CANCER

Hormonal therapy

Locally advanced prostate cancer
See algorithm on locally advanced prostate cancer for recommendations on hormones combined with radiotherapy

Biochemically relapsed prostate cancer

Metastatic prostate cancer
See algorithm on metastatic prostate cancer

- Consider intermittent therapy for people having long term androgen deprivation therapy
- For men having intermittent androgen deprivation therapy measure PSA every 3 months and restart androgen deprivation therapy if PSA is 10ng/ml or above, or if there is symptomatic progression

See algorithm on complications of disease