

# Prostate cancer: diagnosis and management

Clinical guideline

Published: 8 January 2014

[nice.org.uk/guidance/cg175](https://www.nice.org.uk/guidance/cg175)

## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

## Contents

Introduction .....	5
Drug recommendations.....	6
Patient-centred care .....	7
Key priorities for implementation .....	8
Information and decision support for men with prostate cancer, their partners and carers .....	8
Assessment.....	8
Localised and locally advanced prostate cancer.....	8
<b>1 Recommendations .....</b>	<b>11</b>
1.1 Information and decision support for men with prostate cancer, their partners and carers .....	11
1.2 Assessment .....	13
1.3 Localised and locally advanced prostate cancer .....	15
1.4 Men having hormone therapy .....	23
1.5 Metastatic prostate cancer .....	25
<b>2 Research recommendations .....</b>	<b>29</b>
2.1 Prognostic indicators .....	29
2.2 Androgen deprivation therapy and/or brachytherapy added to radiotherapy for men with intermediate- and high-risk localised non-metastatic prostate cancer .....	29
2.3 Local salvage therapies in men with biochemical relapse after radiotherapy.....	30
2.4 Bisphosphonates and denosumab to treat osteoporosis .....	30
2.5 Duration of exercise to combat fatigue in men having androgen deprivation therapy .....	30
<b>3 Other information.....</b>	<b>32</b>
3.1 Scope and how this guideline was developed.....	32
3.2 Related NICE guidance.....	32
<b>4 The Guideline Development Group, National Collaborating Centre and NICE project team.....</b>	<b>35</b>
4.1 Guideline Development Group .....	35
4.2 National Collaborating Centre for Cancer .....	36
4.3 NICE project team.....	37

Changes after publication.....	39
About this guideline .....	40
Update information.....	40
Strength of recommendations.....	42
Other versions of this guideline .....	44
Implementation .....	44
Your responsibility.....	44
Copyright.....	44

This guideline replaces CG58 and TA194.

This guideline is the basis of QS91.

## Introduction

This guideline updates and replaces 'Prostate cancer' (NICE clinical guideline 58). The recommendations are labelled according to when they were originally published (see [About this guideline](#) for details).

Prostate cancer is the most common cancer in men and makes up 26% of all male cancer diagnoses in the UK. In 2008, 34,335 men were diagnosed with prostate cancer and there were 9376 deaths from prostate cancer in England, Wales and Northern Ireland. This figure increased to 9632 deaths in 2010.

Prostate cancer is predominantly a disease of older men (aged 65–79 years) but around 25% of cases occur in men younger than 65. There is also higher incidence of and mortality from prostate cancer in men of black African-Caribbean family origin compared with white Caucasian men.

Prostate cancer is usually diagnosed after a blood test in primary care has shown elevated prostate-specific antigen (PSA) levels. The introduction of PSA testing has significantly reduced the number of men presenting with metastatic cancer since the 1980s. Most prostate cancers are now either localised or locally advanced at diagnosis, with no evidence of spread beyond the pelvis.

A number of treatments are available for localised disease, including: active surveillance, radical prostatectomy, external beam radiotherapy and brachytherapy. Hormone therapy (androgen deprivation or anti-androgens) is the usual primary treatment for metastatic prostate cancer, but is also increasingly being used for men with locally advanced, non-metastatic disease.

This updated guidance includes several treatments that have been licensed for the management of hormone-relapsed metastatic prostate cancer since the publication of NICE clinical guideline 58 (2008). It also aims to reduce the uncertainty and variations in practice that remain in some areas of prostate cancer diagnosis and management. Updated recommendations are provided on:

- pre-biopsy imaging
- management after an initial negative biopsy

- imaging for T and N staging
- groups for whom active surveillance is suitable and a protocol for active surveillance
- the most effective radical prostatectomy method
- the combination of external beam radiotherapy and brachytherapy in non-metastatic prostate cancer
- management of radiation-induced enteropathy
- the combination of hormone therapy and external beam radiotherapy in non-metastatic prostate cancer
- intermittent compared with continuous hormone therapy for men having long-term hormone therapy
- management of side effects resulting from long-term androgen deprivation therapy.

This guideline covers the care of men referred to secondary care with suspected or diagnosed prostate cancer, including follow-up in primary care for men with diagnosed prostate cancer. The guideline does not cover men with an abnormal PSA (prostate-specific antigen) level detected in primary care who have no symptoms and are not referred for subsequent investigation.

An update of [Referral for suspected cancer](#) (NICE clinical guideline 27) is in development. For more information see [clinical guidelines in development](#) on the NICE website.

## *Drug recommendations*

The guideline assumes that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some drugs for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information. Where recommendations have been made for the use of drugs outside their licensed indications ('off-label use'), these drugs are marked with a footnote in the recommendations.

## Patient-centred care

This guideline offers best practice advice on the care of men referred to secondary care with suspected or diagnosed prostate cancer, including follow-up in primary care for men with diagnosed prostate cancer.

Patients and healthcare professionals have rights and responsibilities as set out in the [NHS Constitution for England](#) – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the [Department of Health's advice on consent](#). If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) and the supplementary [code of practice on deprivation of liberty safeguards](#).

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in [Patient experience in adult NHS services](#).

## Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in [section 1](#).

### *Information and decision support for men with prostate cancer, their partners and carers*

#### Decision support

- Discuss all relevant management options recommended in this guideline with men with prostate cancer and their partners or carers, irrespective of whether they are available through local services. [2008]

#### Assessment

#### Diagnosis

##### *Magnetic resonance imaging for rebiopsy*

- Consider multiparametric MRI (using T2- and diffusion-weighted imaging) for men with a negative transrectal ultrasound 10–12 core biopsy to determine whether another biopsy is needed. [new 2014]

#### Staging

- Consider multiparametric MRI, or CT if MRI is contraindicated, for men with histologically proven prostate cancer if knowledge of the T or N stage could affect management. [new 2014]

### *Localised and locally advanced prostate cancer*

#### Low-risk localised prostate cancer

##### *Active surveillance*

- Offer active surveillance (in line with the following recommendation) as an option to men with low-risk localised prostate cancer for whom radical prostatectomy or radical radiotherapy is suitable. [new 2014]
- Consider using the protocol in table 2 for men who have chosen active surveillance. [new 2014]



**Table 2 Protocol for active surveillance**

Timing	Tests <sup>1</sup>
At enrolment in active surveillance	Multiparametric MRI if not previously performed
Year 1 of active surveillance	Every 3–4 months: measure PSA <sup>2</sup> Throughout active surveillance: monitor PSA kinetics <sup>3</sup> Every 6–12 months: DRE <sup>4</sup> At 12 months: prostate rebiopsy
Years 2–4 of active surveillance	Every 3–6 months: measure PSA <sup>2</sup> Throughout active surveillance: monitor PSA kinetics <sup>3</sup> Every 6–12 months: DRE <sup>4</sup>
Year 5 and every year thereafter until active surveillance ends	Every 6 months: measure PSA <sup>2</sup> Throughout active surveillance: monitor PSA kinetics <sup>3</sup> Every 12 months: DRE <sup>4</sup>
<p><sup>1</sup> If there is concern about clinical or PSA (prostate-specific antigen) changes at any time during active surveillance, reassess with multiparametric MRI and/or rebiopsy.</p> <p><sup>2</sup> May be carried out in primary care if there are agreed shared-care protocols and recall systems.</p> <p><sup>3</sup> May include PSA doubling time and velocity.</p> <p><sup>4</sup> Should be performed by a healthcare professional with expertise and confidence in performing DRE (digital rectal examination).</p>	

## Intermediate- and high-risk localised prostate cancer

### Active surveillance

- Consider active surveillance (in line with the recommendation above) for men with intermediate-risk localised prostate cancer who do not wish to have immediate radical prostatectomy or radical radiotherapy. [new 2014]

## ***Radical treatment***

- Offer men with intermediate- and high-risk localised prostate cancer a combination of radical radiotherapy and androgen deprivation therapy, rather than radical radiotherapy or androgen deprivation therapy alone. [new 2014]

## **Managing adverse effects of radical treatment**

### ***Sexual dysfunction***

- Ensure that men have early and ongoing access to specialist erectile dysfunction services. [2008, amended 2014]

### ***Radiation-induced enteropathy***

- Ensure that men with signs or symptoms of radiation-induced enteropathy are offered care from a team of professionals with expertise in radiation-induced enteropathy (who may include oncologists, gastroenterologists, bowel surgeons, dietitians and specialist nurses). [new 2014]

## **Men having hormone therapy**

- Consider intermittent therapy for men having long-term androgen deprivation therapy (not in the adjuvant setting), and include discussion with the man, and his partner, family or carers if he wishes, about:
  - the rationale for intermittent therapy and
  - the limited evidence for reduction in side effects from intermittent therapy and
  - the effect of intermittent therapy on progression of prostate cancer. [new 2014]

## 1 Recommendations

The following guidance is based on the best available evidence. The [full guideline](#) gives details of the methods and the evidence used to develop the guidance.

The recommendations apply to men referred to secondary care with suspected or diagnosed prostate cancer, including follow-up in primary care for men with diagnosed prostate cancer. The recommendations do not apply to men with an abnormal PSA (prostate-specific antigen) level detected in primary care who have no symptoms and are not referred for subsequent investigation.

The wording used in the recommendations in this guideline (for example, words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation). See [About this guideline](#) for details.

### 1.1 *Information and decision support for men with prostate cancer, their partners and carers*

#### Information

- 1.1.1 Follow the recommendations on communication and patient-centred care in the NICE cancer service guidance [Improving outcomes in urological cancers](#) and [Improving supportive and palliative care for adults with cancer](#) throughout the patient journey. [2008]
- 1.1.2 Offer men with prostate cancer individualised information tailored to their own needs. This information should be given by a healthcare professional (for example, a consultant or specialist nurse) and may be supported by written and visual media (for example, slide sets or DVDs). [2008]
- 1.1.3 Offer men with prostate cancer advice on how to access information and support from websites, local and national cancer information services, and from cancer support groups. [2008]
- 1.1.4 Before choosing or recommending information resources for men with prostate cancer, check that their content is clear, reliable and up to date. Seek feedback from men with prostate cancer and their carers to identify the highest quality information resources. [2008]

## Decision support

- 1.1.5 Ascertain the extent to which the man wishes to be involved in decision-making and ensure that he has sufficient information to do so. [2008]
- 1.1.6 Use a validated, up-to-date decision aid<sup>[1]</sup> in all urological cancer multidisciplinary teams (MDTs). Healthcare professionals trained in its use should offer it to men with localised prostate cancer when making treatment decisions. [2008]
- 1.1.7 Nomograms may be used by healthcare professionals in partnership with men with prostate cancer to:
- aid decision-making
  - help predict biopsy results
  - help predict pathological stage
  - help predict risk of treatment failure. [2008]
- 1.1.8 When nomograms are used, clearly explain the reliability, validity and limitations of the prediction. [2008]
- 1.1.9 Discuss all relevant management options recommended in this guideline with men with prostate cancer and their partners or carers, irrespective of whether they are available through local services. [2008]
- 1.1.10 Tell men:
- about treatment options and their risks and benefits<sup>[1]</sup> in an objective, unbiased manner and
  - that there is limited evidence for some treatment options. [new 2014]
- 1.1.11 Ensure that mechanisms are in place to allow men with prostate cancer and their primary care providers to gain access to specialist services throughout the course of their disease. [2008]

- 1.1.12 Adequately inform men with prostate cancer and their partners or carers about the effects of prostate cancer and the treatment options on their sexual function, physical appearance, continence and other aspects of masculinity. Support men and their partners or carers in making treatment decisions, taking into account the effects on quality of life as well as survival. [2008]
- 1.1.13 Offer men with prostate cancer and their partners or carers the opportunity to talk to a healthcare professional experienced in dealing with psychosexual issues at any stage of the illness and its treatment. [2008]

## 1.2 Assessment

### Diagnosis

#### *Biopsy*

- 1.2.1 To help men decide whether to have a prostate biopsy, discuss with them their prostate-specific antigen (PSA) level, digital rectal examination (DRE) findings (including an estimate of prostate size) and comorbidities, together with their risk factors (including increasing age and black African-Caribbean family origin) and any history of a previous negative prostate biopsy. Do not automatically offer a prostate biopsy on the basis of serum PSA level alone. [2008]
- 1.2.2 Give men and their partners or carers information, support and adequate time to decide whether or not they wish to undergo prostate biopsy. Include an explanation of the risks (including the increased chance of having to live with the diagnosis of clinically insignificant prostate cancer) and benefits of prostate biopsy. [2008]
- 1.2.3 If the clinical suspicion of prostate cancer is high, because of a high PSA value and evidence of bone metastases (identified by a positive isotope bone scan or sclerotic metastases on plain radiographs), do not offer prostate biopsy for histological confirmation, unless this is required as part of a clinical trial. [2008]
- 1.2.4 Carry out prostate biopsy following the procedure recommended by the Prostate Cancer Risk Management Programme in [Undertaking a transrectal ultrasound guided biopsy of the prostate](#). [2008]

1.2.5 A core member of the urological cancer MDT should review the risk factors of all men who have had a negative first prostate biopsy, and discuss with the man that:

- there is still a risk that prostate cancer is present and
- the risk is slightly higher if any of the following risk factors are present:
  - the biopsy showed high-grade prostatic intra-epithelial neoplasia (HGPIN)
  - the biopsy showed atypical small acinar proliferation (ASAP)
  - abnormal digital rectal examination. [new 2014]

### ***Magnetic resonance imaging for rebiopsy***

1.2.6 Consider multiparametric MRI (using T2- and diffusion-weighted imaging) for men with a negative transrectal ultrasound 10–12 core biopsy to determine whether another biopsy is needed. [new 2014]

1.2.7 Do not offer another biopsy if the multiparametric MRI (using T2- and diffusion-weighted imaging) is negative, unless any of the risk factors listed in recommendation 1.2.5 are present. [new 2014]

### **Staging**

1.2.8 Determine the provisional treatment intent (radical or non-radical) before decisions on imaging are made. [2008]

1.2.9 Do not routinely offer imaging to men who are not candidates for radical treatment. [2008]

1.2.10 Offer isotope bone scans when hormonal therapy is being deferred through watchful waiting to asymptomatic men who are at high risk of developing bone complications. [2008]

1.2.11 Consider multiparametric MRI, or CT if MRI is contraindicated, for men with histologically proven prostate cancer if knowledge of the T or N stage could affect management. [new 2014]

- 1.2.12 Urological cancer MDTs should assign a risk category (see table 1) to all newly diagnosed men with localised prostate cancer. [2008]

**Table 1 Risk stratification for men with localised prostate cancer**

Level of risk	PSA		Gleason score		Clinical stage
Low risk	<10 ng/ml	and	≤6	and	T1–T2a
Intermediate risk	10–20 ng/ml	or	7	or	T2b
High risk <sup>1</sup>	>20 ng/ml	or	8–10	or	≥T2c
<sup>1</sup> High-risk localised prostate cancer is also included in the definition of locally advanced prostate cancer.					

- 1.2.13 Do not offer CT of the pelvis to men with low- or intermediate-risk localised prostate cancer (see table 1). [2008]
- 1.2.14 Do not routinely offer isotope bone scans to men with low-risk localised prostate cancer. [2008]
- 1.2.15 Do not offer positron emission tomography imaging for prostate cancer in routine clinical practice. [2008]

### 1.3 *Localised and locally advanced prostate cancer*

- 1.3.1 Prior to radical treatment, warn men and, if they wish, their partner, that radical treatment for prostate cancer will result in an alteration of sexual experience, and may result in loss of sexual function. [2008, amended 2014]
- 1.3.2 Warn men and, if they wish, their partner, about the potential loss of ejaculation and fertility associated with radical treatment for prostate cancer. Offer sperm storage. [2008, amended 2014]
- 1.3.3 Warn men undergoing radical treatment for prostate cancer of the likely effects of the treatment on their urinary function. [2008, amended 2014]
- 1.3.4 Offer men experiencing troublesome urinary symptoms before treatment a urological assessment. [2008]

- 1.3.5 Given the range of treatment modalities and their serious side effects, men with prostate cancer who are candidates for radical treatment should have the opportunity to discuss their treatment options with a specialist surgical oncologist and a specialist clinical oncologist. [2008]
- 1.3.6 Tell men that there is a small increase in the risk of colorectal cancer after radical external beam radiotherapy for prostate cancer. [new 2014]

## Low-risk localised prostate cancer

### *Active surveillance*

- 1.3.7 Offer active surveillance (in line with recommendation 1.3.8) as an option to men with low-risk localised prostate cancer for whom radical prostatectomy or radical radiotherapy is suitable. [new 2014]
- 1.3.8 Consider using the protocol in table 2 for men who have chosen active surveillance. [new 2014]

**Table 2 Protocol for active surveillance**

Timing	Tests <sup>1</sup>
At enrolment in active surveillance	Multiparametric MRI if not previously performed
Year 1 of active surveillance	Every 3–4 months: measure PSA <sup>2</sup> Throughout active surveillance: monitor PSA kinetics <sup>3</sup> Every 6–12 months: DRE <sup>4</sup> At 12 months: prostate rebiopsy
Years 2–4 of active surveillance	Every 3–6 months: measure PSA <sup>2</sup> Throughout active surveillance: monitor PSA kinetics <sup>3</sup> Every 6–12 months: DRE <sup>4</sup>



<p>Year 5 and every year thereafter until active surveillance ends</p>	<p>Every 6 months: measure PSA<sup>2</sup>                      Throughout active surveillance: monitor PSA kinetics<sup>3</sup>                      Every 12 months: DRE<sup>4</sup></p>
<p><sup>1</sup> If there is concern about clinical or PSA changes at any time during active surveillance, reassess with multiparametric MRI and/or rebiopsy.  <sup>2</sup> May be carried out in primary care if there are agreed shared-care protocols and recall systems.  <sup>3</sup> May include PSA doubling time and velocity.  <sup>4</sup> Should be performed by a healthcare professional with expertise and confidence in performing DRE.</p>	

1.3.9 The decision to proceed from an active surveillance regimen to radical treatment should be made in the light of the individual man's personal preferences, comorbidities and life expectancy. [2008]

### **Radical treatment**

1.3.10 Offer radical treatment to men with localised prostate cancer who have chosen an active surveillance regimen and who have evidence of disease progression. [2008, amended 2014]

## **Intermediate- and high-risk localised prostate cancer**

### **Active surveillance**

1.3.11 Consider active surveillance (in line with recommendation 1.3.8) for men with intermediate-risk localised prostate cancer who do not wish to have immediate radical prostatectomy or radical radiotherapy. [new 2014]

1.3.12 Do not offer active surveillance to men with high-risk localised prostate cancer. [2014]

### **Radical treatment**

1.3.13 Offer radical prostatectomy or radical radiotherapy to men with intermediate-risk localised prostate cancer. [2008]

- 1.3.14 Offer radical prostatectomy or radical radiotherapy to men with high-risk localised prostate cancer when there is a realistic prospect of long-term disease control. [2008]
- 1.3.15 Commissioners of urology services should consider providing robotic surgery to treat localised prostate cancer. [new 2014]
- 1.3.16 Commissioners should ensure that robotic systems for the surgical treatment of localised prostate cancer are cost effective by basing them in centres that are expected to perform at least 150 robot-assisted laparoscopic radical prostatectomies per year. [new 2014]
- 1.3.17 Offer men undergoing radical external beam radiotherapy for localised prostate cancer a minimum dose of 74 Gy to the prostate at no more than 2 Gy per fraction. [2008]
- 1.3.18 For men with localised prostate cancer<sup>[2]</sup> receiving radical external beam radiotherapy with curative intent, offer planned treatment techniques that optimise the dose to the tumour while minimising the risks of normal tissue damage. [2008]
- 1.3.19 Offer men with intermediate- and high-risk localised prostate cancer a combination of radical radiotherapy and androgen deprivation therapy, rather than radical radiotherapy or androgen deprivation therapy alone. [new 2014]
- 1.3.20 Offer men with intermediate- and high-risk localised prostate cancer 6 months of androgen deprivation therapy before, during or after radical external beam radiotherapy. [new 2014]
- 1.3.21 Consider continuing androgen deprivation therapy for up to 3 years for men with high-risk localised prostate cancer and discuss the benefits and risks of this option with them. [new 2014]
- 1.3.22 Consider high-dose rate brachytherapy in combination with external beam radiotherapy for men with intermediate- and high-risk localised prostate cancer. [new 2014]

- 1.3.23 Do not offer brachytherapy alone to men with high-risk localised prostate cancer. [2008]
- 1.3.24 Do not offer high-intensity focused ultrasound and cryotherapy to men with localised prostate cancer other than in the context of controlled clinical trials comparing their use with established interventions<sup>[3]</sup>. [2008]

### ***Watchful waiting***

- 1.3.25 A member of the urological cancer MDT should review men with localised prostate cancer who have chosen a watchful waiting regimen and who have evidence of significant disease progression (that is, rapidly rising PSA level or bone pain). [2008]

### **Locally advanced prostate cancer**

- 1.3.26 Clinical oncologists should consider pelvic radiotherapy in men with locally advanced prostate cancer who have a higher than 15% risk of pelvic lymph node involvement<sup>[4]</sup> and who are to receive neoadjuvant hormonal therapy and radical radiotherapy. [2008]
- 1.3.27 Do not offer immediate post-operative radiotherapy after radical prostatectomy, even to men with margin-positive disease, other than in the context of a clinical trial. [2008]
- 1.3.28 Do not offer adjuvant hormonal therapy in addition to radical prostatectomy, even to men with margin-positive disease, other than in the context of a clinical trial. [2008]
- 1.3.29 Do not offer high-intensity focused ultrasound and cryotherapy to men with locally advanced prostate cancer other than in the context of controlled clinical trials comparing their use with established interventions<sup>[3]</sup>. [2008]
- 1.3.30 Do not offer bisphosphonates for the prevention of bone metastases in men with prostate cancer. [2008]

## Managing adverse effects of radical treatment

### *Sexual dysfunction*

- 1.3.31 Ensure that men have early and ongoing access to specialist erectile dysfunction services. [2008, amended 2014]
- 1.3.32 Offer men with prostate cancer who experience loss of erectile function phosphodiesterase type 5 (PDE5) inhibitors to improve their chance of spontaneous erections. [2008]
- 1.3.33 If PDE5 inhibitors fail to restore erectile function or are contraindicated, offer men vacuum devices, intraurethral inserts or penile injections, or penile prostheses as an alternative. [2008]

### *Urinary incontinence*

- 1.3.34 Ensure that men with troublesome urinary symptoms after treatment have access to specialist continence services for assessment, diagnosis and conservative treatment. This may include coping strategies, along with pelvic floor muscle re-education, bladder retraining and pharmacotherapy. [2008]
- 1.3.35 Refer men with intractable stress incontinence to a specialist surgeon for consideration of an artificial urinary sphincter. [2008]
- 1.3.36 Do not offer injection of bulking agents into the distal urinary sphincter to treat stress incontinence. [2008]

### *Radiation-induced enteropathy*

- 1.3.37 Ensure that men with signs or symptoms of radiation-induced enteropathy are offered care from a team of professionals with expertise in radiation-induced enteropathy (who may include oncologists, gastroenterologists, bowel surgeons, dietitians and specialist nurses). [new 2014]
- 1.3.38 The nature and treatment of radiation-induced enteropathy should be included in the training programmes for oncologists and gastroenterologists. [2014]

- 1.3.39 Carry out full investigations, including flexible sigmoidoscopy, in men who have symptoms of radiation-induced enteropathy to exclude inflammatory bowel disease or malignancy of the large bowel and to ascertain the nature of the radiation injury. Use caution when performing anterior wall rectal biopsy after brachytherapy because of the risk of fistulation. [2014]

## Follow-up

- 1.3.40 Discuss the purpose, duration, frequency and location of follow-up with each man with localised prostate cancer<sup>[2]</sup>, and if he wishes, his partner or carers. [2008]
- 1.3.41 Clearly advise men with prostate cancer about potential longer-term adverse effects of treatment and when and how to report them. [2008]
- 1.3.42 Men with prostate cancer who have chosen a watchful waiting regimen with no curative intent should normally be followed up in primary care in accordance with protocols agreed by the local urological cancer MDT and the relevant primary care organisation(s). Their PSA should be measured at least once a year. [2008]
- 1.3.43 Check PSA levels for all men with prostate cancer who are having radical treatment at the earliest 6 weeks following treatment, at least every 6 months for the first 2 years and then at least once a year thereafter. [2008]
- 1.3.44 Do not routinely offer DRE to men with localised prostate cancer while the PSA remains at baseline levels. [2008]
- 1.3.45 After at least 2 years, offer follow-up outside hospital (for example, in primary care) by telephone or secure electronic communications to men with a stable PSA who have had no significant treatment complications, unless they are taking part in a clinical trial that requires formal clinic-based follow-up. Direct access to the urological cancer MDT should be offered and explained. [2008]

## *Managing relapse after radical treatment*

- 1.3.46 Analyse serial PSA levels after radical treatment using the same assay technique. [2008]

- 1.3.47 Do not offer biopsy of the prostatic bed to men with prostate cancer who have had a radical prostatectomy. [2008]
- 1.3.48 Offer biopsy of the prostate after radiotherapy only to men with prostate cancer who are being considered for local salvage therapy in the context of a clinical trial. [2008]
- 1.3.49 For men with evidence of biochemical relapse following radical treatment and who are considering radical salvage therapy:
- do not offer routine MRI scanning prior to salvage radiotherapy in men with prostate cancer
  - offer an isotope bone scan if symptoms or PSA trends are suggestive of metastases. [2008]
- 1.3.50 Biochemical relapse (a rising PSA) alone should not necessarily prompt an immediate change in treatment. [2008]
- 1.3.51 Biochemical relapse should trigger an estimate of PSA doubling time, based on a minimum of 3 measurements over at least a 6-month period. [2008]
- 1.3.52 Offer men with biochemical relapse after radical prostatectomy, with no known metastases, radical radiotherapy to the prostatic bed. [2008]
- 1.3.53 Men with biochemical relapse should be considered for entry to appropriate clinical trials. [2008]
- 1.3.54 Do not routinely offer hormonal therapy to men with prostate cancer who have a biochemical relapse unless they have:
- symptomatic local disease progression, or
  - any proven metastases, or
  - a PSA doubling time of less than 3 months. [2008]

## 1.4 *Men having hormone therapy*

- 1.4.1 Consider intermittent therapy for men having long-term androgen deprivation therapy (not in the adjuvant setting), and include discussion with the man, and his partner, family or carers if he wishes, about:
- the rationale for intermittent therapy and
  - the limited evidence for reduction in side effects from intermittent therapy and
  - the effect of intermittent therapy on progression of prostate cancer. [new 2014]
- 1.4.2 For men who are having intermittent androgen deprivation therapy:
- measure PSA every 3 months and
  - restart androgen deprivation therapy if PSA is 10 ng/ml or above, or if there is symptomatic progression. [new 2014]

## Managing adverse effects of hormone therapy

### *Hot flushes*

- 1.4.3 Offer medroxyprogesterone<sup>[5]</sup> (20 mg per day), initially for 10 weeks, to manage troublesome hot flushes caused by long-term androgen suppression and evaluate the effect at the end of the treatment period. [new 2014]
- 1.4.4 Consider cyproterone acetate (50 mg twice a day for 4 weeks) to treat troublesome hot flushes if medroxyprogesterone is not effective or not tolerated. [new 2014]
- 1.4.5 Tell men that there is no good-quality evidence for the use of complementary therapies to treat troublesome hot flushes. [new 2014]

### *Sexual dysfunction*

- 1.4.6 Before starting androgen deprivation therapy, tell men and, if they wish, their partner, that long-term androgen deprivation will cause a reduction in libido and possible loss of sexual function. [new 2014]

- 1.4.7 Advise men and, if they wish, their partner, about the potential loss of ejaculation and fertility associated with long-term androgen deprivation and offer sperm storage. [new 2014]
- 1.4.8 Ensure that men starting androgen deprivation therapy have access to specialist erectile dysfunction services. [new 2014]
- 1.4.9 Consider referring men who are having long-term androgen deprivation therapy, and their partners, for psychosexual counselling. [new 2014]
- 1.4.10 Offer PDE5 inhibitors to men having long-term androgen deprivation therapy who experience loss of erectile function. [new 2014]
- 1.4.11 If PDE5 inhibitors fail to restore erectile function or are contraindicated, offer a choice of:
- intraurethral inserts
  - penile injections
  - penile prostheses
  - vacuum devices. [new 2014]

### ***Osteoporosis***

- 1.4.12 Do not routinely offer bisphosphonates to prevent osteoporosis in men with prostate cancer having androgen deprivation therapy. [2008]
- 1.4.13 Consider assessing fracture risk in men with prostate cancer who are having androgen deprivation therapy, in line with [Osteoporosis](#) (NICE clinical guideline 146). [new 2014]
- 1.4.14 Offer bisphosphonates to men who are having androgen deprivation therapy and have osteoporosis. [new 2014]
- 1.4.15 Consider denosumab for men who are having androgen deprivation therapy and have osteoporosis if bisphosphonates are contraindicated or not tolerated. [new 2014]



## ***Gynaecomastia***

- 1.4.16 For men starting long-term bicalutamide monotherapy (longer than 6 months), offer 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. [2008]
- 1.4.17 If radiotherapy is unsuccessful in preventing gynaecomastia, weekly tamoxifen<sup>[6]</sup> should be considered. [2008]

## ***Fatigue***

- 1.4.18 Tell men who are starting androgen deprivation therapy that fatigue is a recognised side effect of this therapy and not necessarily a result of prostate cancer. [new 2014]
- 1.4.19 Offer men who are starting or having androgen deprivation therapy supervised resistance and aerobic exercise at least twice a week for 12 weeks to reduce fatigue and improve quality of life. [new 2014]

## ***1.5 Metastatic prostate cancer***

### **Information and support**

- 1.5.1 Offer men with metastatic prostate cancer tailored information and access to specialist urology and palliative care teams to address the specific needs of men with metastatic prostate cancer. Offer them the opportunity to discuss any significant changes in their disease status or symptoms as these occur. [2008]
- 1.5.2 Integrate palliative interventions at any stage into coordinated care, and facilitate any transitions between care settings as smoothly as possible. [2008]
- 1.5.3 Discuss personal preferences for palliative care as early as possible with men with metastatic prostate cancer, their partners and carers. Tailor treatment/care plans accordingly and identify the preferred place of care. [2008]
- 1.5.4 Ensure that palliative care is available when needed and is not limited to the end of life. It should not be restricted to being associated with hospice care. [2008]

- 1.5.5 Offer a regular assessment of needs to men with metastatic prostate cancer. [2008]

## Treatment

- 1.5.6 Offer bilateral orchidectomy to all men with metastatic prostate cancer as an alternative to continuous luteinising hormone-releasing hormone agonist therapy. [2008]
- 1.5.7 Do not offer combined androgen blockade as a first-line treatment for men with metastatic prostate cancer. [2008]
- 1.5.8 For men with metastatic prostate cancer who are willing to accept the adverse impact on overall survival and gynaecomastia in the hope of retaining sexual function, offer anti-androgen monotherapy with bicalutamide<sup>[7]</sup> (150 mg). [2008]
- 1.5.9 Begin androgen deprivation therapy and stop bicalutamide treatment in men with metastatic prostate cancer who are taking bicalutamide monotherapy and who do not maintain satisfactory sexual function. [2008]

## Hormone-relapsed metastatic prostate cancer

Recommendations in this section marked with an asterisk are from [Docetaxel for the treatment of hormone-refractory metastatic prostate cancer](#) (NICE technology appraisal guidance 101).

- 1.5.10 When men with prostate cancer develop biochemical evidence of hormone-relapsed disease, their treatment options should be discussed by the urological cancer MDT with a view to seeking an oncologist and/or specialist palliative care opinion, as appropriate. [2008]
- 1.5.11 Docetaxel is recommended, within its licensed indications, as a treatment option for men with hormone-refractory prostate cancer only if their Karnofsky performance-status score is 60% or more. [2008]\*
- 1.5.12 It is recommended that treatment with docetaxel should be stopped:
- at the completion of planned treatment of up to 10 cycles, or
  - if severe adverse events occur, or

- in the presence of progression of disease as evidenced by clinical or laboratory criteria, or by imaging studies. [2008]\*
- 1.5.13 Repeat cycles of treatment with docetaxel are not recommended if the disease recurs after completion of the planned course of chemotherapy. [2008]\*
- 1.5.14 Offer a corticosteroid such as dexamethasone (0.5 mg daily) as third-line hormonal therapy after androgen deprivation therapy and anti-androgen therapy to men with hormone-relapsed prostate cancer. [2008]
- 1.5.15 Offer spinal MRI to men with hormone-relapsed prostate cancer shown to have extensive metastases in the spine (for example, on a bone scan) if they develop any spinal-related symptoms. [2008]
- 1.5.16 Do not routinely offer spinal MRI to all men with hormone-relapsed prostate cancer and known bone metastases. [2008]

### **Bone-targeted therapies**

- 1.5.17 Do not offer bisphosphonates to prevent or reduce the complications of bone metastases in men with hormone-relapsed prostate cancer. [2008]
- 1.5.18 Bisphosphonates for pain relief may be considered for men with hormone-relapsed prostate cancer when other treatments (including analgesics and palliative radiotherapy) have failed. Choose the oral or intravenous route of administration according to convenience, tolerability and cost. [2008]
- 1.5.19 Strontium-89 should be considered for men with hormone-relapsed prostate cancer and painful bone metastases, especially those men who are unlikely to receive myelosuppressive chemotherapy. [2008]

### **Pelvic-targeted therapies**

- 1.5.20 Offer decompression of the upper urinary tract by percutaneous nephrostomy or by insertion of a double J stent to men with obstructive uropathy secondary to hormone-relapsed prostate cancer. [2008]

1.5.21 The option of no intervention should also be discussed with men with obstructive uropathy secondary to hormone-relapsed prostate cancer and remains a choice for some. [2008]

---

<sup>[1]</sup> A decision aid for men with localised prostate cancer is available from [NHS Shared decision making](#).

<sup>[2]</sup> This may also apply to some men with locally advanced prostate cancer.

<sup>[3]</sup> NICE interventional procedure guidance [118](#), [119](#) and [145](#) evaluated the safety and efficacy of cryotherapy and high-intensity focused ultrasound for the treatment of prostate cancer. NICE clinical guidelines provide guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS. As there was a lack of evidence on quality of life benefits and long-term survival, these interventions are not recommended in this guideline.

<sup>[4]</sup> Estimated using the Roach formula; %LN risk =  $2/3 \text{ PSA} + (10 \times [\text{Gleason score} - 6])$

<sup>[5]</sup> At the time of publication (January 2014), medroxyprogesterone did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[6]</sup> At the time of publication (January 2014), tamoxifen did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[7]</sup> At the time of publication (January 2014), bicalutamide did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

## 2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline.

### 2.1 *Prognostic indicators*

Further research is required into the identification of prognostic indicators in order to differentiate effectively between men who may die with prostate cancer and those who might die from prostate cancer. [2008]

#### Why this is important

The greatest uncertainties in managing prostate cancer are around the identification of which cancers are of clinical significance and over the choice of radical treatment, and in which settings they are appropriate. With the diagnosis of prostate cancer being made more frequently in asymptomatic men, it is of growing importance to know which of these men are likely to benefit from aggressive treatment.

### 2.2 *Androgen deprivation therapy and/or brachytherapy added to radiotherapy for men with intermediate- and high-risk localised non-metastatic prostate cancer*

Does the addition of androgen deprivation therapy and/or brachytherapy to high-dose external beam radiotherapy improve outcomes for men with intermediate- and high-risk localised non-metastatic prostate cancer? Outcomes of interest are biochemical disease-free survival, metastasis-free survival, overall survival, side effects and quality of life. [new 2014]

#### Why this is important

There is insufficient evidence on the effectiveness of adding androgen deprivation therapy or brachytherapy, or both, to external beam radiotherapy (using current optimal techniques) in men with intermediate- and high-risk localised non-metastatic prostate cancer.

Randomised controlled trials should compare the effectiveness of the following:

- external beam radiotherapy combined with androgen deprivation therapy

- external beam radiotherapy combined with brachytherapy
- external beam radiotherapy combined with androgen deprivation therapy and brachytherapy
- external beam radiotherapy alone.

### 2.3 *Local salvage therapies in men with biochemical relapse after radiotherapy*

Clinical trials should be set up to examine the effect of local salvage therapies on survival and quality of life in men with biochemical relapse after radiotherapy. [2008]

#### **Why this is important**

Salvage local therapies after radiotherapy include radical prostatectomy, cryotherapy and high-intensity focused ultrasound, but little evidence exists to support their use, and there may be a higher risk of incontinence, impotence and rectal damage than when used as primary treatment.

### 2.4 *Bisphosphonates and denosumab to treat osteoporosis*

What is the clinical and cost effectiveness of standard care with bisphosphonates compared with denosumab to treat osteoporosis caused by long-term androgen deprivation therapy? Outcomes of interest are bone mineral density, fracture risk, tolerability and skeletal-related events. [new 2014]

#### **Why this is important**

Men having long-term androgen deprivation therapy for prostate cancer have an increased fracture risk. [Osteoporosis](#) (NICE clinical guideline 146) recommends that fracture risk be assessed when starting long-term androgen deprivation therapy but the effectiveness of interventions such as bisphosphonates and denosumab in men with an increased fracture risk is not known.

### 2.5 *Duration of exercise to combat fatigue in men having androgen deprivation therapy*

Does a longer (more than 12 weeks) programme of supervised aerobic resistance exercise reduce fatigue more effectively than a 12-week programme in men having androgen deprivation therapy? Outcomes of interest are measures of fatigue, aerobic capacity, cardiovascular function and quality of life. [new 2014]

### **Why this is important**

A 12-week programme of supervised aerobic resistance exercise given for 12 weeks has been shown to improve quality of life and reduce side effects for men having androgen deprivation therapy for prostate cancer. It is not clear whether continuing the exercise programme beyond 12 weeks will result in further improvements.

## 3 Other information

### 3.1 *Scope and how this guideline was developed*

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

#### Groups that will be covered

- Men referred from primary care for investigation of possible prostate cancer, in line with [Referral guidelines for suspected cancer](#) (NICE clinical guideline 27).
- Men with a biopsy-proven diagnosis of primary adenocarcinoma of the prostate, or an agreed clinical diagnosis<sup>[a]</sup> if biopsy is inappropriate.
- Consideration will be given to men of African-Caribbean family origin.

#### Groups that will not be covered

- Asymptomatic men with an abnormal PSA level detected in primary care who are not referred for subsequent investigation.
- Men with metastatic disease of different primary origin involving the prostate.
- Men with rare malignant tumours of the prostate, such as small cell carcinoma and rhabdomyosarcoma.

#### How this guideline was developed

NICE commissioned the National Collaborating Centre for Cancer to develop this guideline. The Centre established a Guideline Development Group (see [section 4](#)), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in [The guidelines manual](#).

### 3.2 *Related NICE guidance*

Details are correct at the time of publication (January 2014). Further information is available on the [NICE website](#).



## Published

### General

- [Patient experience in adult NHS services](#). NICE clinical guidance 138 (2012).
- [Medicines adherence](#). NICE clinical guideline 76 (2009).

### Condition-specific

- [Opioids in palliative care](#). NICE clinical guideline 140 (2012).
- [Osteoporosis fragility fracture](#). NICE clinical guideline 146 (2012).
- [Bone metastases from solid tumours – denosumab](#). NICE technology appraisal guidance 265 (2012).
- [Prostate cancer \(metastatic, castration resistant\) – abiraterone \(following cytotoxic therapy\)](#). NICE technology appraisal guidance 259 (2012).
- [Prostate cancer – cabazitaxel](#). NICE technology appraisal guidance 255 (2012).
- [Focal therapy using cryoablation for localised stage prostate cancer](#). NICE interventional procedure guidance 423 (2012).
- [Focal therapy using high-intensity focused ultrasound \(HIFU\) for localised prostate cancer](#). NICE interventional procedure guidance 424 (2012).
- [Metastatic spinal cord compression](#). NICE clinical guideline 75 (2008).
- [Intraoperative red blood cell salvage during radical prostatectomy or radical cystectomy](#). NICE interventional procedure guidance 258 (2008).
- [Laparoscopic radical prostatectomy](#). NICE interventional procedure guidance 193 (2006).
- [High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer](#). NICE interventional procedure guidance 174 (2006).
- [Cryotherapy as a primary treatment for prostate cancer](#). NICE interventional procedure guidance 145 (2005).
- [Low dose rate brachytherapy for localised prostate cancer](#). NICE interventional procedure guidance 132 (2005).

- [Referral guidelines for suspected cancer](#). NICE clinical guideline 27 (2005).
- [Cryotherapy for recurrent prostate cancer](#). NICE interventional procedure guidance 119 (2005).
- [High-intensity focused ultrasound for prostate cancer](#). NICE interventional procedure guidance 118 (2005).
- [Improving supportive and palliative care for adults with cancer](#). NICE cancer service guidance (2004).
- [Transurethral electrovaporisation of the prostate](#). NICE interventional procedure guidance 14 (2003).
- [Improving outcomes in urological cancers](#). NICE cancer service guidance (2002).

## Under development

NICE is developing the following guidance (details available from the [NICE website](#)):

- Prostate cancer (hormone relapsed, metastatic) – enzalutamide (after docetaxel). NICE technology appraisal guidance. Publication expected February 2014.
- Prostate cancer (hormone relapsed, bone metastases) – radium-223 dichloride. NICE technology appraisal guidance. Publication expected February 2014.
- Prostate cancer (metastatic, hormone relapsed) – sipuleucel-T (first line). NICE technology appraisal guidance. Publication expected February 2014.
- Prostate cancer (advanced, hormone dependent) – degarelix depot. NICE technology appraisal guidance. Publication expected May 2014.
- Suspected cancer. NICE clinical guideline. Publication date to be confirmed.

---

<sup>[8]</sup> Agreed clinical diagnosis on the basis of, for example, digital rectal examination, high PSA levels and known metastases.

## 4 The Guideline Development Group, National Collaborating Centre and NICE project team

### 4.1 *Guideline Development Group*

The Guideline Development Group members listed are those for the 2014 update. For the composition of the previous Guideline Development Group, see the [full guideline](#).

#### **Hugh Butcher**

Patient and carer member

#### **Sarah Cant**

Patient and carer member, Head of Policy and Campaigns, Prostate Cancer UK

#### **Sean Duffy**

GDG Chair (until March 2013), Yorkshire Cancer Network

#### **John Graham**

GDG Chair (from March 2013), Consultant Lead Clinical Oncologist, Taunton and Somerset NHS Trust

#### **Peter Hoskin**

Consultant Oncologist, Mount Vernon Cancer Centre

#### **Nicola James**

Nurse Consultant, Chesterfield Royal Hospital, Derbyshire

#### **Peter Kirkbride**

GDG Lead Clinician, Medical Director, Clatterbridge Cancer Centre, Merseyside

#### **Howard Kynaston**

Professor of Urological Surgery, Cardiff University

#### **Brian McGlynn**

Nurse Consultant Urology Oncology, The Ayr Hospital, Ayr

#### **David Neal**

Professor of Surgical Oncology, University of Cambridge

**Kathleen Nuttall**

Director, Lancashire and South Cumbria Cancer Network

**Jon Oxley**

Consultant in Cellular Pathology, Southmead Hospital, Bristol

**Jonathan Richenberg**

Consultant Uroradiologist, Brighton and Sussex University Hospital NHS Trust

## **4.2 *National Collaborating Centre for Cancer***

**John Graham**

Director

**Andrew Champion**

Centre Manager

**Angela Bennett**

Assistant Centre Manager

**Victoria Titshall**

Project Manager (until December 2012)

**Jenny Stock**

Project Manager (from December 2012)

**Nathan Bromham**

Senior Researcher

**Kimberley Cann**

Researcher

**Mia Schmidt-Hansen**

Researcher

**Jennifer Hilgart**

Researcher

**Elise Hasler**

Information Specialist

**Stephanie Arnold**

Information Specialist

**Sabine Berendse**

Information Specialist

**Bernadette Coles**

Site Librarian, Cancer Research Wales Library

**Matthew Prettyjohns**

Health Economist

### **4.3 *NICE project team***

**Nicole Elliott**

Guideline Lead (until July 2013)

**Sharon Summers-Ma**

Guideline Lead (from August 2013)

**Mark Baker**

Clinical Adviser

**Katie Perryman Ford**

Guideline Commissioning Manager (from June 2013)

**Claire Ruiz**

Guideline Commissioning Manager (until May 2013)

**Carl Dawood**

Guideline Coordinator (until August 2013)

**Anthony Gildea**

Guideline Coordinator (from September 2013)

**Steven Barnes**

Technical Lead (from January 2013)

**Toni Tan**

Technical Lead (until December 2012)

**Prashanth Kandaswamy**

Health Economist (until April 2013)

**Bhash Naidoo**

Health Economist (from May 2013)

**Judy McBride**

Editor

## Changes after publication

**November 2015:** Amended recommendation 1.4.4 by adding the dose of cyproterone acetate for managing hot flushes, and removing reference to megestrol acetate because it is not available in the UK at the dose needed.

## About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions.

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

This guideline was developed by the National Collaborating Centre for Cancer. The Collaborating Centre worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in [The guidelines manual](#).

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

## *Update information*

This guideline updates and replaces NICE clinical guideline 58 (published February 2008).



Recommendations are marked as [new 2014], [2014], [2008] or [2008, amended 2014]:

- [new 2014] indicates that the evidence has been reviewed and the recommendation has been added or updated
- [2014] indicates that the evidence has been reviewed but no change has been made to the recommended action
- [2008] indicates that the evidence has not been reviewed since 2008
- [2008, amended 2014] indicates that the evidence has not been reviewed since 2008, but changes have been made to the recommendation wording that change the meaning (see below).

## Recommendations from NICE clinical guideline 58 that have been amended

Recommendations are labelled [2008, amended 2014] if the evidence has not been reviewed since 2008 but changes have been made to the recommendation wording that change the meaning.

Recommendation in NICE clinical guideline 58	Recommendation in current guideline	Reason for change
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 level or adverse findings on biopsy) should be offered radical treatment. [1.3.9]	Offer radical treatment to men with localised prostate cancer who have chosen an active surveillance regimen and who have evidence of disease progression. [1.3.10] [2008, amended 2014]	The text 'that is, a rise in PSA level or adverse findings on biopsy' has been deleted because it is now inconsistent with the protocol recommended for active surveillance.

<p>Prior to treatment, men and their partners should be warned that treatment for prostate cancer will result in an alteration of sexual experience, and may result in loss of sexual function. [1.4.6]</p>	<p>Prior to radical treatment, warn men and, if they wish, their partner, that radical treatment for prostate cancer will result in an alteration of sexual experience, and may result in loss of sexual function. [1.3.1] [2008, amended 2014]</p>	<p>The original wording has been amended to clarify that partners are covered by the recommendation only if the man wishes this to be the case. Wording has also been amended to clarify this recommendation relates to radical treatment.</p>
<p>Men and their partners should be warned about the potential loss of ejaculation and fertility associated with treatment for prostate cancer. Sperm storage should be offered. [1.4.7]</p>	<p>Warn men and, if they wish, their partner, about the potential loss of ejaculation and fertility associated with radical treatment for prostate cancer. Offer sperm storage. [1.3.2] [2008, amended 2014]</p>	<p>The original wording has been amended to clarify that partners are covered by the recommendation only if the man wishes this to be the case. Wording has also been amended to clarify this recommendation relates to radical treatment.</p>
<p>Men undergoing treatment for prostate cancer should be warned of the likely effects of the treatment on their urinary function. [1.4.12]</p>	<p>Warn men undergoing radical treatment for prostate cancer of the likely effects of the treatment on their urinary function. [1.3.3] [2008, amended 2014]</p>	<p>Wording has also been amended to clarify this recommendation relates to radical treatment.</p>
<p>Healthcare professionals should ensure that men and their partners have early and ongoing access to specialist erectile dysfunction services. [1.4.8]</p>	<p>Ensure that men have early and ongoing access to specialist erectile dysfunction services. [1.3.31] [2008, amended 2014]</p>	<p>The text 'and their partners' has been deleted as this only applies to the man.</p>

## Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most

patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also [Patient-centred care](#)).

## **Interventions that must (or must not) be used**

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

## **Interventions that should (or should not) be used – a 'strong' recommendation**

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

## **Interventions that could be used**

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

## **Recommendation wording in guideline updates**

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations ending [2008] (see [Update information](#) above for details about how recommendations are labelled). In particular, for recommendations labelled [2008] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

## *Other versions of this guideline*

The full guideline 'Prostate cancer: diagnosis and treatment' contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Cancer.

The recommendations from this guideline have been incorporated into a [NICE Pathway](#).

We have produced [information for the public](#) about this guideline.

## *Implementation*

[Implementation tools and resources](#) to help you put the guideline into practice are also available.

## *Your responsibility*

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

## *Copyright*

© National Institute for Health and Care Excellence 2014. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

ISBN: 978-1-4731-0404-4

## Accreditation

