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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Prostate cancer: diagnosis and management (update)

This guideline will update the NICE guideline on Prostate cancer: diagnosis and management (CG175). To see which areas will be covered in this update, see the [proposed outline for the guideline](#).

The guideline will be developed using the methods and processes outlined in [Developing NICE guidelines: the manual](#).

This guideline will also be used to update the NICE [quality standard](#) for prostate cancer.

1 Why the update is needed

New evidence that could affect existing recommendations was identified through an exceptional surveillance review. Full details are set out in the [surveillance review decision](#).

Why the guideline is needed

Key facts and figures

Prostate cancer is the most common cancer in men, and the second most common cancer in the UK. In 2014 there were over 46,000 new diagnoses of prostate cancer, which accounts for 13% of all new cancers diagnosed. About 1 in 8 men will get prostate cancer at some point in their life.

1 Prostate cancer can also affect transgender women, as the prostate is usually
2 conserved after gender-confirming surgery, but it is not clear how common it
3 is in this population.

4
5 More than 50% of prostate cancer diagnoses in the UK each year are in men
6 aged 70 years and over (2012), and the incidence rate is highest in men aged
7 90 years and over (2012–2014). Out of every 10 prostate cancer cases, 4 are
8 only diagnosed at a late stage in England (2014) and Northern Ireland (2010–
9 2014). Incidence rates are projected to rise by 12% between 2014 and 2035
10 in the UK to 233 cases per 100,000 in 2035.

11
12 A total of 84% of men aged 60–69 years at diagnosis in 2010–2011 are
13 predicted to survive for 10 or more years after diagnosis. When diagnosed at
14 the earliest stage, virtually all men with prostate cancer survive 5 years or
15 more: this is compared to less than a third of men surviving 5 years or more
16 when diagnosed at the latest stage.

17
18 There were approximately 11,000 deaths from prostate cancer in 2014.
19 Mortality rates from prostate cancer are highest in men aged 90 years and
20 over (2012–2014). Over the past decade, mortality rates have decreased by
21 more than 13% in the UK. Mortality rates are projected to fall by 16% between
22 2014 and 2035 to 48 deaths per 100,000 men in 2035.

23
24 Prostate cancer mainly affects men aged 50 and over. Men of African family
25 origin are at higher risk of prostate cancer (lifetime risk of approximately 1 in
26 4). Prostate cancer is inversely associated with deprivation, with a higher
27 incidence of cases found in more affluent areas of the UK.

28
29 Costs for the inpatient treatment of prostate cancer are predicted to rise to
30 £320.6 million per year in 2020 (from £276.9 million per year in 2010).

31 32 **Current practice**

33 *Diagnosis and staging*

1 Initial findings from a urine sample, prostate-specific antigen (PSA) test and
2 digital rectal examination are used to decide if further tests may be needed. If
3 suspicion of prostate cancer is high, a person would then usually go onto have
4 a trans-rectal ultrasound guided biopsy (TRUS) to confirm the diagnosis.
5 However, because the location of the cancer is not known when the biopsy is
6 completed, TRUS biopsies can miss up to 1 in 5 cancers.

7 Since the last update of the prostate cancer guidance in 2014, new research
8 has been published on using imaging at initial diagnosis or imaging-based
9 assessment to improve diagnosis of prostate cancer. This has led to some
10 settings using multiparametric or functional MRI imaging to aid in the
11 diagnosis of prostate cancer.

12 *Treatment*

13 The treatment of prostate cancer varies, depending on a person's
14 circumstances. Factors that affect preferred treatment options include:

- 15 • a person's general health
- 16 • the type and size of the cancer
- 17 • the grade of the cancer
- 18 • whether the cancer has spread to other parts of a person's body
- 19 • a person's preference.

20 New evidence published since the publication of the 2014 guidance indicates
21 that developments in the following areas may change clinical practice:

- 22 • the use of multiparametric/functional MRI in the diagnosis and surveillance
23 of prostate cancer
- 24 • risk stratification and treatment of localised prostate cancer: active
25 surveillance, radical prostatectomy or radical radiotherapy
- 26 • use of docetaxel added to the standard treatment for hormone-sensitive
27 metastatic prostate cancer and hormone-sensitive locally-advanced
28 prostate cancer
- 29 • changes to the optimal dose and fractionation schedule of radiotherapy
30 treatment in men with localised prostate cancer.

1 Feedback from the NICE GP reference panel indicated that there is a lack of
2 clarity over follow-up for men who have undergone radical therapy for prostate
3 cancer.

4 **Policy, legislation, regulation and commissioning**

5 *MRI/imaging for diagnosis*

6 The [2016 National Prostate Cancer Audit \(NPCA\)](#) highlighted that new biopsy
7 methods are being introduced, but TRUS biopsy remains most commonly
8 used (92% of diagnoses). Multiparametric MRI is being used more frequently
9 in diagnosis, with 65% of men having MRI before they have a biopsy. NPCA
10 (2016) concluded that providers need to think about whether and when to use
11 MRI in the diagnostic pathway.

12 *Docetaxel*

13 NHS England (2016) released a [Clinical Commissioning Policy Statement on](#)
14 [Docetaxel in combination with androgen deprivation therapy \(ADT\) for the](#)
15 [treatment of hormone naïve metastatic prostate cancer](#). NHS England
16 reviewed the evidence and concluded that the survival benefit from starting
17 docetaxel at the same time (or within 12 weeks) as ADT was sufficient to fund
18 this treatment for men with hormone-naïve metastatic prostate cancer.

19 *Radiotherapy*

20 NHS England (2016) have recommended that stereotactic ablative body
21 radiotherapy (SABR) and proton beam therapy should not be routinely
22 commissioned for men with localised prostate cancer, based on the results of
23 recent clinical trials. This is not reflected by current recommendations.

24 **2 Who the guideline is for**

25 This guideline is for:

- 26 • healthcare professionals in the NHS
- 27 • commissioners and providers of prostate cancer services.

1 It may also be relevant for:

- 2 • voluntary organisations and patient support groups

3 Men with suspected or diagnosed prostate cancer, their families and carers
4 and the public will be able to use the guideline to find out more about what
5 NICE recommends, and help them make decisions.

6 NICE guidelines cover health and care in England. Decisions on how they
7 apply in other UK countries are made by ministers in the [Welsh Government](#),
8 [Scottish Government](#) and [Northern Ireland Executive](#).

9 ***Equality considerations***

10 NICE has carried out [an equality impact assessment](#) during scoping. The
11 assessment:

- 12 • lists equality issues identified, and how they have been addressed
13 • explains why any groups are excluded from the scope.

14 Following the equalities impact assessment, the following equalities issues
15 were identified as potentially requiring particular consideration: age, ethnicity,
16 transgender women and difficulty speaking or reading English.

17 **3 What the updated guideline will cover**

18 **3.1 Who is the focus?**

19 **Groups that will be covered**

- 20 • Men referred from primary care for investigation of possible prostate
21 cancer, in line with '[Referral guidelines for suspected cancer](#)'
22 • Men with a confirmed diagnosis of primary adenocarcinoma of the prostate,
23 or an agreed clinical diagnosis¹ if biopsy is inappropriate.

¹ Agreed clinical diagnosis on the basis of, for example, digital rectal examination, high PSA levels and known metastases.

1 **Groups that will not be covered**

- 2 • Asymptomatic men with an abnormal PSA level who are not referred for
3 subsequent investigation.
- 4 • Men with metastatic disease of different primary origin involving the
5 prostate.
- 6 • Men with rare malignant tumours of the prostate, such as small cell
7 carcinoma and rhabdomyosarcoma.

8 **3.2 Settings**

9 **Settings that will be covered**

- 10 • All settings where NHS-funded care is provided.

11 **3.3 Activities, services or aspects of care**

12 **Key areas that will be covered in this update**

13 We will look at evidence in the areas below when developing this update. We
14 will consider making new recommendations or updating existing
15 recommendations in these areas only.

- 16 1 Assessment, diagnosis and staging of prostate cancer
 - 17 - the role of multiparametric or functional MRI in the diagnosis of
18 prostate cancer.
- 19 2 Treatment of prostate cancer
 - 20 - the role of multiparametric or functional MRI in the active
21 surveillance of prostate cancer.
 - 22 - risk stratification and treatment of localised prostate cancer:
23 active surveillance, radical prostatectomy or radical radiotherapy.
 - 24 - the optimal dose and fractionation schedule of radical
25 radiotherapy in localised prostate cancer.
 - 26 - the use of docetaxel in hormone-sensitive locally-advanced
27 prostate cancer and hormone-sensitive metastatic prostate
28 cancer.
- 29 3 Follow-up
 - 30 - follow-up protocols after radical treatment of prostate cancer.

1 Note that guideline recommendations for medicines will normally fall within
2 licensed indications; exceptionally, and only if clearly supported by evidence,
3 use outside a licensed indication may be recommended. The guideline will
4 assume that prescribers will use a medicine's summary of product
5 characteristics to inform decisions made with individual patients.

6 **Proposed outline for the guideline**

7 The table below outlines all the areas that will be included in the guideline. It
8 sets out what NICE plans to do for each area in this update.

9

10

Area in the guideline	What NICE plans to do
1.1 Information and decision support	
Information Decision support	No review of the evidence: retain recommendations from the existing guideline.
1.2 Assessment	
Diagnosis <ul style="list-style-type: none"> • Biopsy • MRI for re-biopsy Staging	Review the evidence: update the existing recommendations related to the role of multiparametric or functional MRI in the diagnosis of prostate cancer. For all other areas in this section there will not be a review of the evidence: the recommendations from the existing guideline will be retained.
1.3 localised and locally-advanced prostate cancer	
Low risk prostate cancer <ul style="list-style-type: none"> • active surveillance • radical treatment 	Review the evidence for treatment options after risk stratification in localised prostate cancer only: update the existing recommendations as needed.
Intermediate and high risk prostate cancer <ul style="list-style-type: none"> • active surveillance • radical treatment • watchful waiting 	Review the evidence for treatment options after risk stratification in localised prostate cancer only: update the existing recommendations as needed.
Locally-advanced prostate cancer	Review the evidence for docetaxel in hormone-sensitive locally-advanced prostate cancer only: update the existing recommendations as needed For all other areas in this section there will not be a review of the evidence: the recommendations from the existing guideline will be retained.

Managing adverse effects of radical treatment <ul style="list-style-type: none"> • sexual dysfunction • urinary incontinence • radiation induced enteropathy 	No review of the evidence: retain the recommendations from the existing guideline.
Follow-up	Review the evidence for follow-up protocols after radical treatment: update the existing recommendations as needed.
Management of relapse after radical treatment	No review of the evidence: retain the recommendations from the existing guideline.
1.4 Men having hormone therapy	
Management of adverse effects of hormone therapy: <ul style="list-style-type: none"> • hot flushes • sexual dysfunction • osteoporosis • gynaecomastia • fatigue 	No review of the evidence: retain the recommendations from the existing guideline.
1.5 Metastatic prostate cancer	
Metastatic prostate cancer: <ul style="list-style-type: none"> • information and support • treatment • hormone relapsed metastatic prostate cancer • bone-targeted therapy • pelvic-targeted therapy 	Review the evidence for docetaxel in hormone-sensitive metastatic prostate cancer only: update the existing recommendations as needed For all other areas in this section there will not be a review of the evidence: the recommendations from the existing guideline will be retained.

1

2 Recommendations in areas that are being retained from the existing guideline
3 may be edited to ensure that they meet current editorial standards, and reflect
4 the current policy and practice context.

5 **Areas not covered by the guideline**

6 These areas will not be covered by the guideline.

7 1 Referral from primary care with suspected prostate cancer

8 - This is covered by the NICE guideline on [Suspected cancer: recognition and referral](#) (2015)

10 2 Screening for prostate cancer

1 - This is covered by the UK National Screening Committee.

2 **Related NICE guidance**

- 3 • [Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer](#) (publication date to be confirmed) NICE interventional
4 procedures guidance.
- 6 • [Pembrolizumab for treating prostate cancer \[ID866\]](#) (publication expected
7 August 2018) NICE technology appraisal guidance.
- 8 • [Use of a hydrogel perirectal spacer during radiotherapy for prostate cancer](#)
9 (publication date to be confirmed) NICE interventional procedures
10 guidance.
- 11 • [Abiraterone for treating newly diagnosed metastatic hormone-naive
12 prostate cancer \[ID945\]](#) (publication expected September 2018) NICE
13 technology appraisal guidance.
- 14 • [Suspected cancer](#) (2016) NICE quality standard QS124
- 15 • [Irreversible electroporation for treating prostate cancer](#) (2016) NICE
16 interventional procedures guidance 572
- 17 • [Radium-223 dichloride for treating hormone-relapsed prostate cancer with
18 bone metastases](#) (2016) NICE technology appraisal guidance 412
- 19 • [Degarelix for treating advanced hormone-dependent prostate cancer](#)
20 (2016) NICE technology appraisal guidance 404
- 21 • [Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with
22 Docetaxel](#) (2016) NICE technology appraisal guidance 391
- 23 • [Abiraterone for treating metastatic hormone-relapsed prostate cancer
24 before chemotherapy is indicated](#) (2016) NICE technology appraisal
25 guidance 387
- 26 • [Enzalutamide for treating metastatic hormone-relapsed prostate cancer
27 before chemotherapy is indicated](#) (2016) NICE technology appraisal
28 guidance 377
- 29 • [Diagnosing prostate cancer: PROGENSA PCA3 assay and Prostate Health
30 Index](#) (2015) NICE diagnostics guidance 17
- 31 • [Prostate cancer](#) (2015) NICE quality standard 91
- 32 • [Suspected cancer: recognition and referral](#) (2015) NICE guideline NG12

- 1 • [Enzalutamide for metastatic hormone-relapsed prostate cancer previously](#)
2 [treated with a docetaxel-containing regimen](#) (2014) NICE technology
3 appraisal guidance 316
- 4 • [Denosumab for the prevention of skeletal-related events in adults with bone](#)
5 [metastases from solid tumours](#) (2012) NICE technology appraisal guidance
6 265
- 7 • [Abiraterone for castration-resistant metastatic prostate cancer previously](#)
8 [treated with a docetaxel-containing regimen](#) (2012) NICE technology
9 appraisal guidance 259
- 10 • [Focal therapy using high-intensity focused ultrasound for localised prostate](#)
11 [cancer](#) (2012) NICE interventional procedures guidance 424
- 12 • [Focal therapy using cryoablation for localised prostate cancer](#) (2012) NICE
13 interventional procedures guidance 423
- 14 • [Transperineal template biopsy and mapping of the prostate](#) (2010) NICE
15 interventional procedures guidance 364
- 16 • [Intraoperative red blood cell salvage during radical prostatectomy or radical](#)
17 [cystectomy](#) (2008) NICE interventional procedures guidance 25
- 18 • [Laparoscopic radical prostatectomy](#) (2006) NICE interventional procedures
19 guidance 193
- 20 • [High dose rate brachytherapy in combination with external-beam](#)
21 [radiotherapy for localised prostate cancer](#) (2006) NICE interventional
22 procedures guidance 174
- 23 • [Docetaxel for the treatment of hormone-refractory metastatic prostate](#)
24 [cancer](#) (2006) NICE technology appraisal guidance 101
- 25 • [Cryotherapy as a primary treatment for prostate cancer](#) (2005) NICE
26 interventional procedures guidance 145
- 27 • [Low dose rate brachytherapy for localised prostate cancer](#) (2005) NICE
28 interventional procedures guidance 132
- 29 • [Cryotherapy for recurrent prostate cancer](#) (2005) NICE interventional
30 procedures guidance 119
- 31 • [High-intensity focused ultrasound for prostate cancer](#) (2005) NICE
32 interventional procedures guidance 118

- 1 • [Improving supportive and palliative care for adults with cancer](#) (2004) NICE
2 cancer service guideline 4
- 3 • [Improving outcomes in urological cancers](#) (2002) NICE cancer service
4 guideline 2

5 ***NICE guidance that will be updated by this guideline***

- 6 • [Prostate cancer: diagnosis and management](#) (2014) NICE guideline CG175

7 **NICE guidance about the experience of people using NHS services**

8 NICE has produced the following guidance on the experience of people using
9 the NHS. This guideline will not include additional recommendations on these
10 topics unless there are specific issues related to prostate cancer:

- 11 • [Medicines optimisation](#) (2015) NICE guideline NG5
- 12 • [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- 13 • [Service user experience in adult mental health](#) (2011) NICE guideline
14 CG136
- 15 • [Medicines adherence](#) (2009) NICE guideline CG76

16 **3.4 *Economic aspects***

17 We will take economic aspects into account when making recommendations.
18 For each review question (or key area in the scope) for which the evidence is
19 being reviewed, we will develop an economic plan that states whether
20 economic considerations are relevant, and if so whether this is an area that
21 should be prioritised for economic modelling and analysis. We will review the
22 economic evidence and carry out economic analyses, using an NHS and
23 personal social services (PSS) perspective, as appropriate.

24 **3.5 *Key issues and questions***

25 While writing the scope for this updated guideline, we have identified the
26 following key issues and draft questions related to them:

- 27 1 Assessment, diagnosis and staging of prostate cancer
- 28 1.1 Does multiparametric/functional MRI before TRUS biopsy increase
29 diagnostic yield of initial biopsy in men with suspected prostate cancer?

- 1 1.2 Can multiparametric/functional MRI, instead of TRUS biopsy,
2 exclude a diagnosis of clinically significant disease?
- 3 2 Treatment of prostate cancer
- 4 2.1 What is the clinical and cost- effectiveness of active surveillance
5 compared to radical prostatectomy or radical radiotherapy for men with
6 localised prostate cancer?
- 7 2.2 Can multiparametric/functional MRI, instead of TRUS biopsy,
8 exclude the clinically significant progression of prostate cancer in men
9 with low to intermediate risk (as defined in NICE CG175)?
- 10 2.3 What is the optimal dose and fractionation schedule for men with
11 localised prostate cancer (T1b–T3a N0 M0) who are treated with radical
12 radiotherapy?
- 13 2.4 What is the most clinically- and cost-effective scheduling of
14 docetaxel added to standard treatment for the treatment of hormone-
15 sensitive locally-advanced prostate cancer?
- 16 2.5 What is the most clinically- and cost-effective scheduling of
17 docetaxel added to standard treatment for the treatment of hormone-
18 sensitive metastatic prostate cancer?
- 19 3 Follow-up protocols for prostate cancer treatment
- 20 3.1 What is the most clinically- and cost-effective follow-up protocol for
21 men with prostate cancer who have had radical treatment?

22 **3.6 Main outcomes**

23 The main outcomes that will be considered when searching for and assessing
24 the evidence are:

- 25 1 all-cause mortality
- 26 2 prostate-cancer-specific mortality
- 27 3 treatment-related mortality
- 28 4 metastasis-free survival
- 29 5 health-related quality of life (for example: EORTC, EPIC instrument)
- 30 6 diagnosis-related morbidity
- 31 7 treatment-related morbidity
- 32 8 number of severe adverse events

- 1 9 number of dropouts because of adverse events
2 10 utility outcomes relevant to the use of MRI in diagnosis and
3 surveillance, including patient experience and resource use

4 **4 NICE quality standards and NICE Pathways**

5 **4.1 NICE quality standards**

6 **NICE quality standards that may need to be revised or updated when** 7 **this guideline is published**

- 8 • [Prostate cancer](#) (2015) NICE quality standard 91

9 **4.2 NICE Pathways**

10 When this guideline is published, the recommendations will be added to NICE
11 Pathways. NICE Pathways bring together all related NICE guidance and
12 associated products on a topic in an interactive flowchart. The existing
13 [prostate cancer flowchart](#) will be reviewed and amended to integrate the
14 updated recommendations.

15 **5 Further information**

This is the draft scope for consultation with registered stakeholders. The
consultation dates are 30 June to 14 July 2017.

The guideline is expected to be published in January 2019.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.

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