

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

SCOPE

Clinical guideline title: Prostate cancer: diagnosis and treatment

Quality standard title: Prostate cancer

1 Introduction

1.1 *Clinical guidelines*

Clinical guidelines are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. They are based on the best available evidence.

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider.

This is an update of '[Prostate cancer: diagnosis and treatment](#)', NICE clinical guideline 58 (2008). See section 3.3.1 for details of which sections will be updated. We will also carry out an editorial review of all recommendations to ensure that they comply with NICE's duties under equalities legislation.

This update is being undertaken as part of the guideline review cycle.

1.2 *Quality standards*

Quality standards are a set of specific, concise quality statements and measures that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions.

For this clinical guideline a NICE quality standard will be produced during the guideline development process, after the development of the clinical guideline recommendations.

This scope defines the areas of care for which specific quality statements and measures will (and will not) be developed.

The guideline and quality standard development processes are described in detail on the NICE website (see section 7).

2 Need for guidance

2.1 *Epidemiology*

Cancer research UK statistics suggest that:

- a) Prostate cancer is the most common cancer in men and makes up 24% of cancer diagnoses in men in the UK.
- b) Prostate cancer is predominantly a disease of older men but around 25% of cases occur in men younger than 65 years.
- c) The incidence and mortality rate of prostate cancer is higher in men of black African-Caribbean family origin compared white Caucasian men.
- d) In 2008, 34,335 men were diagnosed with prostate cancer and there were 9376 deaths from prostate cancer in England, Wales and Northern Ireland.

2.2 *Current practice*

- a) Most prostate cancer is diagnosed following a blood test in primary care showing elevated prostate-specific antigen (PSA) levels.
- b) Presentation with metastatic disease is much less common than it was in the 1980s, before the introduction of PSA testing. At diagnosis most prostate cancers are either localised or locally advanced with no evidence of spread beyond the pelvis.
- c) A number of treatments are available for localised disease, including active surveillance, radical prostatectomy, radical radiotherapy and brachytherapy.

- d) Hormonal therapy (testosterone suppression) is being used increasingly for men with locally advanced non-metastatic disease.
- e) A number of new treatments have been licensed for the management of castrate-resistant metastatic prostate cancer¹ since the publication of NICE clinical guideline 58 (2008).

3 Clinical guideline

3.1 Population

3.1.1 Groups that will be covered

- a) Men referred from primary care for investigation of possible prostate cancer, in line with 'Referral guidelines for suspected cancer' (NICE clinical guideline 27).
- b) Men with a biopsy-proven diagnosis of primary adenocarcinoma of the prostate, or an agreed clinical diagnosis² if biopsy is inappropriate.
- c) Consideration will be given to men of African-Caribbean family origin.

3.1.2 Groups that will not be covered

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

¹Since the 2008 guideline the term hormone-refractory prostate cancer has been replaced with castrate-resistant metastatic prostate cancer by healthcare professionals as it is more clinically accurate. However, due to its negative connotations for men with the disease the alternative terminology 'hormone relapsed prostate cancer' will be proposed at the GDG, as this remains an accurate description and would be acceptable to patient groups.

²Agreed clinical diagnosis on the basis of, for example, digital rectal examination, high PSA levels and known metastases.

3.2 Healthcare settings

- a) All settings in which NHS care is received– excluding population-based and opportunistic screening.

3.3 Management

3.3.1 Key issues covered by the update

- a) Optimal diagnostic strategy in patients referred to secondary care with suspected prostate cancer, including:
- i) Initial transrectal ultrasoundbiopsy.
 - ii) If initial biopsy is negative, subsequent investigation (including multiparametric magnetic resonance imaging, 3D ultrasound, and template biopsy) or surveillance.
- b) Magnetic resonance imaging in the staging of prostate cancer.
- c) Active surveillance including:
- i) Eligibility.
 - ii) Protocol.
- d) The following methods of radical prostatectomy:
- retropubic
 - transperineal
 - laparoscopic
 - robot-assisted laparoscopic.
- e) High dose rate brachytherapy in combination with external beam radiotherapy for localised and locally advanced non-metastatic prostate cancer.
- f) Combination low dose rate brachytherapy and external beam radiotherapy for localised and locally advanced non-metastatic prostate cancer.

- g) Combinations of hormones plus external beam radiotherapy for localised or locally advanced non-metastatic prostate cancer.
- h) Intermittent hormone therapy for men receiving long-term hormonal therapy for prostate cancer.
- i) Interventions for radiation bowel toxicity after radical radiotherapy.
- j) Identifying and managing late effects of long-term androgen suppression.

3.3.2 Key issues covered by NICE clinical guideline 58 for which the evidence will not be reviewed

- a) Communication and support.
- b) Imaging other than in 3.3.1a) and 3.3.1b).
- c) Nomograms.
- d) Watchful waiting.
- e) Radiotherapy other than covered in 3.3.1e), 3.3.1f) and 3.3.1g).
- f) High-intensity focused ultrasound and cryotherapy.
- g) Follow-up.
- h) Managing adverse effects of treatment, other than covered in 3.3.1i) and 3.3.1j).
- i) Managing relapse after radical treatment.
- j) Bisphosphonates in the treatment of prostate cancer.
- k) Adjuvant hormonal therapy after radical prostatectomy.
- l) Hormone-refractory prostate cancer.
- m) Palliative care.

3.3.3 Key issues that will not be covered

- a) Referral from primary care with suspected prostate cancer (this will be covered by the update to the 'Referral for suspected cancer' guideline).
- b) Screening for prostate cancer.
- c) Cabazitaxel and abiraterone for castrate-resistant metastatic prostate cancer (these are the subject of ongoing NICE technology appraisals).

3.4 Main outcomes

- a) Overall survival (at 5 years, 10 years, and median survival).
- b) Disease-free survival.
- c) Biochemical disease-free survival.
- d) Diagnosis-related morbidity.
- e) Diagnosis-related mortality.
- f) Treatment-related morbidity.
- g) Treatment-related mortality.
- h) Number and severity of adverse events.
- i) Health-related quality of life.

3.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see section 7).

4 Quality standard

Information on the NICE quality standards development process is available on the NICE website, see section 7.

4.1 Areas of care

The areas of care of a patient's pathway used to inform the development of the quality statements are set out in section 4.1.1. The content of the quality standard statements may change during the process and may differ after consultation with stakeholders.

4.1.1 Areas of care that will be considered

- a) Patient information and decision-making, for example counselling and pre-treatment decision-making.
- b) Multidisciplinary team.
- c) Prostate biopsy methods.
- d) Imaging.
- e) Watchful waiting and active surveillance.
- f) Radical treatment of localised prostate cancer:
 - surgery
 - radiotherapy
 - brachytherapy.
- g) Radical treatment of locally advanced prostate cancer with combined hormones and radiotherapy.
- h) Access to specialist services for complications of treatment, for example, sexual dysfunction, incontinence, bowel problems.
- i) Management of biochemical failure following radical local treatment.

- j) Hormonal therapy.
- k) Management of castrate-resistant metastatic prostate cancer.
- l) Metastatic spinal cord compression in men with prostate cancer.
- m) Follow-up after radical treatment for prostate cancer.
- n) Supportive and palliative care.

4.1.2 Areas of care that will not be considered

- a) Screening for prostate cancer.
- b) Referral from primary care with suspected prostate cancer.

4.2 Economic aspects

Developers will take into account both clinical and cost effectiveness when prioritising the quality statements to be included in the quality standard. The economic evidence will be considered, and the cost and commissioning impact of implementing the quality standard will be assessed.

5 Status

5.1 Scope

This is the final scope.

5.2 Timings

The development of the guideline recommendations and the quality standard will begin in February 2012.

6 Related NICE guidance

6.1.1 NICE guidance that will be incorporated in or updated by the clinical guideline

This guideline will update the following NICE guidance:

- [Prostate cancer](#). NICE clinical guideline 58 (2008).

This guideline will incorporate the following NICE guidance (subject to review):

- [Docetaxel for the treatment of hormone-refractory metastatic prostate cancer](#). NICE technology appraisal guidance 101 (2006).

6.2 Related NICE guidance

Published

- [Denosumab for the treatment of therapy-induced bone loss in non-metastatic prostate cancer](#) (terminated appraisal). NICE technology appraisal 194 (2010).
- [Medicines adherence](#). NICE clinical guideline 76 (2009).
- [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 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).
- [Transperineal electrovaporisation of the prostate](#). NICE interventional procedure guidance 14 (2003).
- [Improving outcomes in urological cancers](#). NICE cancer service guidance (2002).

- [Service user experience in adult mental health](#). NICE clinical guideline. NICE clinical guideline 136 (2011).

NICE guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- Focal therapy using cryoablation for localised stage prostate cancer. NICE interventional procedure guidance. Publication expected Winter 2011/12.
- Prostate cancer –cabazitaxel. NICE technology appraisal. Publication expected February 2012.
- Focal therapy using high-intensity focused ultrasound (HIFU) for localised prostate cancer. NICE interventional procedure guidance. Publication expected Spring 2012.
- Opioids in palliative care. NICE clinical guideline. Publication expected May 2012.
- Prostate cancer (metastatic, castration resistant) –abiraterone (following cytotoxic therapy). NICE technology appraisal. Publication expected May 2012.
- Bone metastases from solid tumours –denosumab. NICE technology appraisal. Publication expected June 2012.
- Prostate cancer (metastatic, castrate-resistant, not treated with chemotherapy) - abiraterone acetate (with prednisolone). NICE technology appraisal. Publication expected July 2013.
- Patient experience in adult NHS services. NICE clinical guideline. Publication date to be confirmed.
- Prostate cancer (hormone refractory) –atrasentan. NICE technology appraisal. Suspended.
- Prostate cancer (prevention) –dutasteride. NICE technology appraisal. Suspended.
- Prostate cancer – intensity modulated radiotherapy. NICE technology guideline. Suspended.

7 Further information

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'
- 'The guidelines manual'
- 'Developing NICE quality standards: interim process guide'.

These are available from the NICE website

(www.nice.org.uk/GuidelinesManual

and www.nice.org.uk/aboutnice/qualitystandards). Information on the progress of the guideline and quality standards is also available from the NICE website (www.nice.org.uk).