NICE National Institute for Health and Care Excellence

2021 exceptional surveillance of prostate cancer: diagnosis and management (NICE guideline NG131)

Surveillance report

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Surveillance decision

Risk stratification

We propose to update recommendation 1.2.16 on risk stratification in the NICE guideline on prostate cancer and to consider the impact of any changes to risk stratification on treatment recommendations. There is evidence that newer 5-tier risk stratification models, particularly those from the Cambridge Prognostic Group (CPG), perform better than the 3-tier model currently recommended in the NICE guideline, and that using the old model may result in harm to the patient because of over and under treatment. There is also new evidence that might inform treatment recommendations using the CPG risk stratification model.

Prostate cancer biopsy

We propose not to update the recommendations on prostate cancer biopsy. There was new evidence of prostate cancer biopsy showing a shift towards local anaesthetic transperineal biopsy and that transperineal biopsies may reduce rates of sepsis compared to transrectal biopsy, albeit possibly at the risk of increased urinary retention. However, following discussion with clinicians and the diagnostics assessment team within NICE it was decided that the diagnostics assessment process would be the most appropriate way to assess the clinical and cost-effectiveness of specific transperineal prostate cancer biopsy devices. As such, the topic will be considered for guidance development within the diagnostics assessment programme.

Related interventional procedures guidance

We propose to make an editorial amendment that will make reference to NICE's interventional procedures guidance on focal therapy using high-intensity focused ultrasound for localised prostate cancer and focal therapy using cryoablation for localised prostate cancer. This is in response to feedback from a clinician in August 2020 that the 2019 update of the NICE guideline made no reference to these 2 relevant procedures.

Exceptional surveillance review summary

There were 3 independent intelligence triggers for this exceptional review. Each is discussed in turn.

Risk stratification

Reason for considering this area

In January 2020, a clinician drew NICE's attention to Predicting prostate cancer death with different pretreatment risk stratification tools: a head-to-head comparison in a nationwide cohort study and suggested that the 3 criteria model for risk stratification used in recommendation 1.2.16 of the NICE guideline could be out of date.

Methods

To review this recommendation, we took the following approach:

- Considered the evidence used to develop the guideline.
- Considered inhouse NICE intelligence on how the guideline was updated in 2019.
- Obtained feedback from topic experts.
- Assessed the new evidence and intelligence against the current recommendations.

Full updated literature searches were not needed because the information we had obtained was enough to establish whether an update to the guideline was needed.

For further information see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Information considered when developing the original guideline

Currently, recommendation 1.2.16 in the NICE guideline provides a table of risk stratification for people with localised prostate cancer. This model stratifies people into low, intermediate and high risk based on 3 criteria: prostate-specific antigen, Gleason

score and clinical stage. The subsequent treatment recommendations based on this risk stratification, particularly around active surveillance, were based on longitudinal studies and committee consensus. Review of the 2008 stratification model was not within scope of the 2019 update.

New evidence and intelligence

The nationwide cohort study provides evidence on newer risk stratification models. This study included 154,811 Swedish men and compared 9 pre-treatment risk classification tools for predicting prostate cancer death, including the risk stratification model used in the NICE guideline. The study found that the following tools performed better than the NICE risk stratification model:

- Cambridge Prognostic Group (CPG).
- Cancer of the Prostate Risk Assessment (CAPRA).
- Memorial Sloan Kettering Cancer Centre (MSKCC).

The CPG model was highlighted as important to UK practice as this is a UK developed model. Table 1 shows how the CPG 5-tier model equates to the 3-tier NICE model.

Table 1 Risk stratification using NICE and CPG

CPG	NICE
CPG1 low risk	low risk
CPG2 favourable intermediate risk	intermediate risk
CPG3 unfavourable intermediate risk	intermediate risk
CPG4 high risk	high risk
CPG5 very high risk	high risk

Incorrect risk stratification can lead to under and over treatment and thus represent harm to a patient. As such this evidence could be used to inform recommendation 1.2.16. However, this study does not show evidence of how to change treatment options on the basis of newer risk stratification models. Without changing treatment options, men could simply be classified differently but still be over or under treated.

Three clinical experts were contacted and responded to say that an update of the guideline could be considered but cautioned that there is still insufficient evidence on how to adapt treatments based on the 5-tier CPG criteria.

Subsequently, the enquirer submitted 4 studies to provide further evidence.

- The 5-tier CPG classification was used to stratify follow-up in active surveillance in UK (n=3,659) and Swedish (n=27,942) cohorts of patients (Gnanapragasam et al. 2019). In the UK cohort, the 10-year prostate cancer mortality was 2.3% in CPG1, 1.5%/3.5% in treated/untreated CPG2, and 1.9%/8.6% in treated/untreated CPG3. In the Swedish cohort, the 10-year prostate cancer mortality was 1.0% in CPG1, 2.2%/2.7% in treated/untreated CPG2, and 6.1%/12.5% in treated/untreated CPG3.
- The 5-tier CPG classification was validated in 2 cohorts of patients from Singapore (n=2,550) and Sweden (n=72,337) respectively (Gnanapragasam et al. 2018). The study found that the CPG model was superior in predicting prostate cancer mortality across different treatment groups, compared with the 3-tier model.
- A UK consensus statement (Merriel et al. 2019) was developed on current best practice of active surveillance. The statement was based on a systematic review of national and international guidelines, data from a freedom of information request to UK urology departments about active surveillance current practice, and interviews of men with localised prostate cancer. The review found significant variation in the practice of active surveillance, and interviews found that men have clear information and support needs. An expert reference group subsequently agreed 30 consensus statements of best practice of active surveillance.
- The UK National Prostate Cancer Audit database (Parry et al. 2020) was analysed between 2014 and 2017 using the CPG tool to risk stratify 61,999 men. Men in CPG3 were significantly more likely to receive radical treatment than men in CPG2 (66.3% versus 48.4%; adjusted risk ratio [RR] 1.44; 95% confidence interval [CI] 1.36 to 1.53). Radically treated men in CPG3 were also significantly more likely to receive radiotherapy than men in CPG2 (59.2% versus 43.9%; adjusted RR, 1.18; 95% CI 1.10 to 1.26). There was no significant difference in radical treatment rates between CPG4 and CPG5 (78.8% versus 73.3%), although more men in CPG5 received radiotherapy than in CPG4 (79.9% versus 59.1%, adjusted RR 1.26; 95% CI 1.12 to 1.40). The authors noted that there was currently potential overtreatment associated with CPG2, and differences in use of radiotherapy between CPG4 and CPG5, which supports the 5-tier system over the traditional 3-tiered risk stratification system.

- The National Prostate Cancer Audit (NPCA) used the CPG for risk stratification of prostate cancer in a report that published in February 2021 and found an impact on the 'over treatment' indicator used to monitor the use of radical treatment for lower risk patients. As such, the proportion of men potentially 'over-treated' increased from 4% of men in the low risk group (previous 3-tier model) to 10% in CPG1 (CPG 5-tier model). The report concluded that the 5-tier CPG criteria is likely to improve the quality of care as more providers are identified as outliers.

Three clinical experts were contacted again with the updated evidence base and 2 responded to say that an update of the guideline on the basis of risk stratification was now warranted. One clinical expert did not reply.

Conclusions

Five studies indicated that active surveillance may not be appropriate in patients with unfavourable intermediate prostate cancer, and that there may be over treatment of favourable intermediate risk and lower risk patients. The fact that the NPCA is now moving to use the 5-tier CPG criteria also means that the NICE guideline will be out of step with key UK auditing and system improvement measures.

Currently, recommendation 1.2.16 in the NICE guideline provides a table of risk stratification for people with localised prostate cancer and stratifies people into low, intermediate and high risk based on 3 criteria: prostate-specific antigen, Gleason score and clinical stage. Treatment is then stratified on the basis of this 3-tier model. For example, recommendation 1.3.12 suggests considering active surveillance (in line with recommendation 1.3.9) for people who choose not to have immediate radical treatment with intermediate risk localised prostate cancer. As this recommendation is based on the 3-tier risk stratification it does not differentiate between favourable intermediate risk (CPG2) and unfavourable intermediate risk (CPG3), unlike the CPG criteria.

As such, we believe that this new evidence is a sufficient basis for an expert committee to consider the impact on risk stratification (recommendation 1.2.16) and the subsequent treatment recommendations.

Prostate cancer biopsy

Reason for considering this area

In January 2020, a meeting held by the National Clinical Audit and Patient Outcomes Programme (NCAPQP) highlighted the NPCA: prostate biopsy short report and questioned if the recommendations on prostate cancer biopsy in the section on assessment and diagnosis in the NICE guideline needed to be updated.

Methods

To review this section of the guideline, we took the following approach:

- Considered the evidence used to develop the guideline.
- Considered inhouse NICE intelligence on how the guideline was updated in 2019.
- Obtained feedback from topic experts
- Assessed the new evidence and intelligence against the current recommendations.

Full updated literature searches were not needed because the information we had obtained was enough to establish whether an update to the guideline was needed.

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Information considered when developing the original guideline

The NICE guideline currently makes several recommendations on prostate biopsy in the section on assessment and diagnosis but does not recommend 1 type of biopsy over another; notably it does not specify whether local anaesthetic transperineal biopsy is preferred to transrectal ultrasound guided biopsy. The committee did not see any evidence that allowed them to clearly differentiate between transperineal (non-mapping) and transrectal biopsy, so it agreed to refer to 'prostate biopsy' throughout the recommendations.

The committee also made recommendation 1.2.5 which states: Do not offer mapping transperineal template biopsy as part of an initial assessment, unless as part of a clinical

trial. Note that mapping transperineal template biopsy is distinct from local anaesthetic transperineal biopsy and typically involves general anaesthesia and more core biopsies being performed. The committee made this recommendation as they considered that mapping transperineal template biopsy is too resource intensive to be used as an initial assessment as it requires general anaesthetic and extensive histological analysis. The committee recognised that this technique could be allowed as part of a clinical trial because it is often used as the benchmark or gold standard test in those trials.

New evidence and intelligence

The NPCA: prostate biopsy short report was published in December 2019 and found that:

- during the past 3 years the number of men undergoing transperineal biopsy has nearly doubled (from 14% to 25%)
- if all biopsies were performed by transperineal biopsy, 3.6 fewer men would be readmitted because of sepsis and 10.6 more men would be readmitted because of urinary retention per 1,000 biopsies, with no difference in 30-day mortality
- there is a shift in contemporary practice in some hospitals to undertaking transperineal biopsies under local anaesthetic using mapping technology, which may reduce the risk of urinary retention, but data are not yet available. However, there is a need for longer-term data on complications to assess the merits of both transperineal and transrectal biopsy methods.

Three clinical experts were contacted and agreed this was an important study and indicated that there was a shift to peritoneal biopsy in some centres. However, 1 expert highlighted that different diagnostic devices may have differing effectiveness and cost-effectiveness. As such, the diagnostic assessment programme within NICE may be better placed to assess the different transperineal biopsy devices.

Conclusions

After considering the available information, it was decided that the diagnostics assessment programme is likely to be the most appropriate way to assess the clinical and cost-effectiveness of specific transperineal prostate cancer biopsy devices. As such, no update to the NICE guideline is currently proposed as the topic will be considered for guidance development within the diagnostics assessment programme.

Related interventional procedures guidelines

Reason for considering this area

In August 2020, a clinician contacted NICE noting that the 2019 update of the NICE guideline made no reference to the relevant NICE interventional procedures guidance on focal therapy using high-intensity focused ultrasound for localised prostate cancer and focal therapy using cryoablation for localised prostate cancer.

Methods

We reviewed the relevance of the interventional procedures guidance to the NICE guideline and considered the editorial approach that may be appropriate to reference them.

New information

Recommendation 1.3.26 currently states: Do not offer high-intensity focused ultrasound and cryotherapy to people with localised prostate cancer, other than in the context of controlled clinical trials comparing their use with established interventions.

This recommendation includes a footnote: The guideline currently states the NICE interventional procedures guidance IPG118, IPG119 and IPG145 evaluated the safety and efficacy of cryotherapy and high-intensity focused ultrasound for the treatment of prostate cancer. NICE guidelines provide guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS. Because there was a lack of evidence on quality-of-life benefits and long-term survival, these interventions are not recommended in this guideline.

Conclusions

NICE's interventional procedures guidance on focal therapy using high-intensity focused ultrasound for localised prostate cancer and focal therapy using cryoablation for localised prostate cancer have been published since the guideline was updated. As these procedures are relevant to the NICE guideline, we will add a reference to them.

Equalities

No equalities issues were identified during the surveillance process.

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