NICE National Institute for Health and Care Excellence

2023 exceptional surveillance of prostate cancer: diagnosis and management (NICE guideline NG131)

Surveillance report
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Surveillance decision

We will not update recommendations 1.2.16, 1.2.17 and recommendation 1.3.54 related to isotope bone scans in NICE's guideline on prostate cancer.

Reasons for the decision

This exceptional review was triggered by the 2021 update committee, who flagged that the 2008 recommendations on isotope bone scans may be out of line with practice, and that there are new emerging technologies such as the gallium-68-prostate specific membrane antigen positron emission tomography-CT (gallium-68-PSMA-PET-CT) scans.

A survey of topic experts suggests that the current recommendations are appropriate and align with current practice. Although there is a suggestion to change the 'strength' of the recommendation from 'offer' to 'consider' isotope bone scans in asymptomatic people who are at high risk of developing bone complications but are undergoing 'watchful waiting' instead of hormonal therapy (recommendation 1.2.17), there is no evidence to support a change at this time. We will continue monitoring the evidence base for new technologies such as gallium-68-PSMA-PET-CT and other PET-CT scans.

Reason for the exceptional review

As the recommendations on isotope bone scans have not been updated since 2008, the 2021 update committee was concerned that they may no longer be aligned with current practice. Moreover, they were aware of new technologies, such as the gallium-68-PSMA-PET-CT are emerging. In addition, there was a potential gap in recommendations for people at intermediate (Cambridge Prognostic Group [CPG] 3) and higher risks (CPG 4 and CPG 5) because the guideline did not specify whether isotope bone scans should be offered.

Methods

The exceptional surveillance process consisted of:

- Considering the new evidence and information that triggered the exceptional review.

- Feedback from topic experts. The topic experts provided feedback on the current NICE guideline recommendations on isotope bone scans, and the current NHS practice of using isotope bone scans to detect bone metastases in patients with newly diagnosed prostate cancer.
- Considering the evidence used to develop the guideline in 2008, and in the 2014 and 2019 updates.
- Assessing the new evidence and information from topic experts' feedback against current recommendations to determine whether to update sections of the guideline, or the whole guideline.

We decided that full updated literature searches were not needed because the information we had from topic experts was enough to establish whether an update to the guideline recommendations was needed.

Information considered in this exceptional surveillance review

Two studies provided by the 2021 update committee were evaluated.

The first study (Kandaswamy et al. 2017) was a retrospective analysis of isotope bone scan results of 2,720 patients registered in a UK prostate cancer database between 2002 to 2015. Patients were stratified into low-, intermediate- and high-risk groups based on the D'Amico classification. The positivity (percentage of people with positive results) of isotope bone scan results were reported. This study showed that none of the patients classified at 'low' or 'intermediate' risk (Gleason 3+4 pattern) had a positive isotope bone scan. In contrast, 15% of the 'high' risk patients had a positive scan, while 1% of those in the intermediate (Gleason 4+3) had a positive scan.

This study had some limitations due to its design and would not be sufficient on its own to support a change of recommendations. However, it suggested that a positive isotope bone scan is very unlikely for patients with 'low' risk prostate cancer.

The other study (Hofman et al. 2020) was an Australian multicentre randomised controlled trial (RCT) of 302 patients allocated to either CT and isotope bone scan as a first line diagnosis and staging strategy, or PSMA-PET-CT as a first line strategy. All participants in this study had features of 'high risk', histopathologically confirmed prostate cancer and

were being considered for radical prostatectomy or radiotherapy with curative intent. Within 14 days of the first line imaging, participants crossed over to receive the second line imaging. The results of the first line imaging were available when the second line imaging was reported.

In this cohort of participants, about 30% had a pelvic nodal or distant metastatic disease. The study reported that PSMA-PET-CT had a 27% (95% confidence interval [CI] 23 to 31) greater accuracy than that of the conventional imaging strategy of isotope bone scan and CT (92% [95% CI 88 to 95] versus 65% [95% CI 60 to 69], p<0.001). They recorded whether these imaging strategies resulted in a change in classification or management strategy, but it was not possible to evaluate the impact on patient outcomes as management strategies were informed by the results of both scanning strategies compared.

Although this study suggests that PSMA-PET-CT scans may be more useful in detecting metastases than the conventional strategy, there is no evidence that it results in better patient outcomes.

Topic expert feedback

Seven topic experts with a special interest in prostate cancer diagnosis completed an online survey: 2 general practitioner and academic researchers, 2 uroradiologists, 1 urological surgeon, 1 histopathologist and 1 nuclear medicine researcher.

On the questions around whether there are any issues with current recommendations on isotope bone scans, 3 experts declined to comment because they are not currently involved in this stage of patient care. The other topic experts thought that the current recommendation of not routinely offering isotope bone scans to people on CPG1 and CPG 2 (recommendation 1.2.16) are appropriate and widely implemented. However, 1 expert noted that in their practice, exceptions are made (to offer scans) to people in lower risk categories if they present with high prostate specific antigen (PSA) levels (such as above 10 ng/mL).

One topic expert suggested rephrasing recommendation 1.2.17 from 'offer' to 'consider'. The topic expert was of the view that for asymptomatic patients undergoing 'watchful waiting' (hormonal therapy differed) who are at high risk of developing bone complications, other types of scans may be more useful in guiding clinical decisions.

The topic experts indicated that isotope bone scans 'are the poorest modality for detecting metastases' compared to other newer imaging modalities such as MRI and PET-CT scans. Although it is routinely offered to people at higher risks (CPG 4 or CPG 5 or grade 3 and above), some well-resourced centres have replaced it to different extents with gallium-68-PSMA-PET-CT scans, if these technologies are available. In contrast, some less well-resourced centres may only be able to use gallium-68-PSMA-PET-CT scans routinely for patients at the highest risks (for example, Gleason pattern 5 on biopsy). In others, these technologies are not available.

Experts highlighted some equality issues arising from geographical variations in the availability of gallium-68-PSMA-PET-CT scans, which may have affected the local patient pathways.

One topic expert also noted that since the start of the pandemic, more prostate cancer patients from deprived areas are presenting at a later stage. Another topic expert noted that Black African people are at risk of poorer outcomes.

Information considered when developing the guideline

In the 2014 and 2019 updates, isotope bone scans were not considered.

There was very little evidence found in the evidence review for the original guideline published in 2008.

Other relevant NICE guidance

There is currently no other guidance in this area.

Equalities

See topic expert feedback for equality issues identified.

An equalities and health inequalities assessment was completed during this surveillance review. See appendix A for details.

Overall decision

We will not update the recommendations related to isotope bone scans in the NICE guideline on prostate cancer. Topic expert feedback suggested that the current recommendations are appropriate and align with current practice, and do not signal a need to update the guideline at this time.

There was a suggestion to change the 'strength' of recommendation from 'offer' to 'consider' isotope bone scans in asymptomatic people who are at high risk of developing bone complications but are undergoing 'watchful waiting' instead of hormonal therapy (recommendation 1.2.17). However, there is currently no evidence to support a change at this time.

We will continue monitoring the evidence base for the new technologies such as gallium-68-PSMA-PET-CT and other types of PET-CT scans.

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