2020 exceptional surveillance of lung cancer: diagnosis and management (NICE guideline NG122) and colorectal cancer (NICE guideline NG151)

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Surveillance decision

We will not update the <u>NICE guidelines on lung cancer</u> and <u>colorectal cancer</u>.

Reason for the exceptional review

The purpose of this exceptional review was to examine any impact of <u>2 Streamline</u> <u>diagnostic accuracy studies of whole-body MRI for staging metastatic disease in non-</u> <u>small-cell lung cancer and colorectal cancer</u> on NICE's guidelines on lung cancer and colorectal cancer.

The studies were funded by the National Institute for Health Research (HTA 23660), and results have been published in the Lancet as 2 individual studies: the <u>Streamline L study</u> (lung cancer) and the <u>Streamline C study</u> (colorectal cancer).

Methods

The exceptional surveillance process consisted of:

- Considering the new evidence that triggered the exceptional review.
- Feedback from topic experts, including the NHS England national clinical director for cancer, and the NHS England national specialty advisor for imaging.
- Assessing the new evidence and topic expert feedback against current recommendations to determine whether or not to update the lung cancer and colorectal cancer guidelines.

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

For further details about the process and the possible update decisions that are available, see <u>ensuring that published guidelines are current and accurate in developing NICE</u> guidelines: the manual.

Information considered in this exceptional surveillance review

Streamline studies

Methods

The Streamline studies were multicentre, non-randomised, single-arm prospective trials across 16 hospitals in England comparing whole-body MRI (WB-MRI) staging with standard staging pathways in adults with histologically proven or suspected cancer. Two studies were conducted, one in non-small-cell lung cancer (NSCLC) (n=187) and one in colorectal cancer (n=299), but with the same intervention and outcomes.

All patients in both studies underwent WB-MRI staging (results withheld until all study arms were complete) followed by the standard staging pathway. A multidisciplinary team then decided on treatment, firstly based on the standard pathway alone, then on WB-MRI (plus any additional tests needed), and finally on all tests. The primary outcome was difference between WB-MRI and standard staging in per-patient sensitivity for identifying metastatic disease, against a consensus reference standard based on 12-month follow-up data. Secondary outcomes included per-patient specificity (correctly identifying those without metastatic disease), nature of treatment decisions, time taken to complete staging, number of tests required, and cost effectiveness.

Lung cancer outcomes

For the primary outcome, there was no significant difference in sensitivity for detecting metastatic disease between WB-MRI and standard staging pathways (50% versus 54%, difference=-4% [95% confidence interval (CI) -15 to 7; p=0.73]). For secondary outcomes, no significant differences were found between WB-MRI and standard staging for: specificity for metastatic disease (93% versus 95%, difference= -2% [95% CI -7 to 2; p=0.45]); agreement with the multidisciplinary team's final treatment decision (98% versus 99%, difference= -1% [95% CI -4 to 2; p value not stated]); or number of tests required (1 versus 1, difference=0 [95% CI -1 to 0; p value not stated]). However, median time taken for staging was significantly less with WB-MRI than standard staging (13 days versus 19 days, difference=6 days [95% CI 4 days to 8 days; p value not stated]), as were mean staging costs per patient (£317 [95% CI 273 to 671] versus £620 [95% CI 574 to 666]; p value not stated).

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Colorectal cancer outcomes

As with lung cancer, for the primary outcome, there was no significant difference in sensitivity for detecting metastatic between WB-MRI and standard staging pathways (67% versus 63%; difference=4% [95% CI -5 to 13; p=0.51]). For secondary outcomes, no significant differences were found between WB-MRI and standard staging for specificity for metastatic disease (95% versus 93%, difference=2% [95% CI -2 to 6; p=0.48]); or agreement with the multidisciplinary team's final treatment decision (96% versus 95%, difference=1% [95% CI -2 to 4; p value not stated]). However, median time taken for staging was significantly less with WB-MRI than standard staging (8 days versus 13 days, difference=5 days [95% CI 3 to 7 days; p value not stated]), as were median number of tests required (1 versus 2, difference=1 [95% CI 1 to 1; p value not stated]), and mean staging costs per patient (£216 [95% CI 211 to 221] versus £285 [95% CI 260 to 310]; p value not stated).

Patient preference for WB-MRI or conventional staging

A related <u>discrete choice study</u> recruited patients (n=138) from both Streamline studies to assess preferences for attributes associated with WB-MRI and standard staging. Patients preferred WB-MRI over standard staging for both lung cancer (probability 0.64) and colorectal cancer (probability 0.66) if it had equivalent accuracy, total scan number, and time to diagnosis.

Topic expert feedback

We contacted topic experts who were recruited to the NICE Centre for Guidelines Panel of Expert Advisers. We asked the experts if they believed that the Streamline studies affected current recommendations.

We received feedback from 10 topic experts: the NHS England national clinical director for cancer, the NHS England national specialty advisor for imaging, 3 radiologists (2 with lung specialism), 2 colorectal surgeons, a thoracic surgeon, a consultant respiratory physician specialising in lung cancer, and a thoracic oncologist. Eight experts stated that the new evidence did not indicate a need to change the guidelines, 1 stated there was possibly an impact (but would prefer further evaluation in real clinical practice), and 1 said the evidence had an impact.

General comments

Most experts raised issues relevant to both lung and colorectal cancer. Comments about the study findings included that: WB-MRI does not improve staging accuracy and a better use of resources may be to improve standard pathways; the benefit of the small improvement in staging speed for survival outcomes (which were not measured by the study) was unknown; and there may be a greater clinical need for WB-MRI in other tumours such as multiple myeloma (for which NICE recommends considering WB-MRI as first-line imaging). Limitations of the studies noted by the experts included that a computerised tomography (CT) scan is much quicker than MRI which the studies did not appear to account for, and there was substantial attrition in the studies possibly related to limited availability of WB-MRI. Wider issues noted by experts were the very limited capacity in the NHS for MRI (both equipment and trained staff), and significant intolerance of MRI in some patients.

Only 1 expert suggested there was an impact of the evidence, noting that using WB-MRI would reduce patient exposure to radiation (though radiation exposure was not assessed in the studies).

Lung cancer comments

Four of the 5 experts specialising in this area (2 thoracic radiologists, a thoracic surgeon, and a thoracic oncologist) agreed the guideline should not be updated. The fifth expert (a consultant respiratory physician specialising in lung cancer) thought there was possibly an impact. Comments relating to the study results included: 4 experts had concerns that lymph node staging was significantly worse with WB-MRI than the standard pathway; and 1 expert noted that the sensitivity in lung cancer for metastases below 1 cm in diameter was only 9% with WB-MRI (compared with 27% with the standard pathway, although the difference was not statistically significant). Two experts noted that the time saving with WB-MRI could be beneficial in lung cancer, but 1 of these stressed that they would want to see NHS real-world data first.

Comments relating to MRI more generally included that if MRI is the baseline scan, then it must also be used for later scans putting more pressure on limited MRI capacity (in lung cancer there may be 4 or 5 CT scans during 5-year follow up).

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Colorectal cancer comments

Among the 2 experts specialising in this area (both colorectal surgeons), 1 stated that it would be reasonable to continue existing staging strategies and the guideline should not be updated, though colorectal cancer units that are able to could move to WB-MRI. The other expert suggested there was an impact of the evidence, stating that advantages of WB-MRI included: more accurate staging for rectal cancer; more detailed assessment with MRI to identify people who would benefit from chemotherapy; and better surgery planning as MRI highlights organ involvement especially in stage T4.

Current guideline recommendations

Lung cancer

The <u>NICE guideline on lung cancer</u> currently recommends a multimodality staging pathway for lung cancer, which may include contrast-enhanced chest CT, ultrasound, positronemission tomography CT (PET-CT), endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA), endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA), and surgical staging. The guideline states, 'Do not routinely use MRI to assess the stage of the primary tumour (T-stage) in NSCLC'. But it recommends MRI in some circumstances, such as: assessing disease extent in superior sulcus tumours; confirming isolated distant metastases/synchronous tumours when considering treatment with curative intent; when treating stage 3 NSCLC with curative intent; suspected intracranial pathology; and suspected bone metastasis if X-ray is negative or inconclusive.

Colorectal cancer

The <u>NICE guideline on colorectal cancer</u> does not cover staging of colorectal cancer because practice was reported to be well established and consistent in this area, therefore it was not prioritised for inclusion in the guideline scope.

Equalities

No equalities issues were identified during the surveillance process.

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Overall decision

The NICE guideline on lung cancer currently recommends a staging pathway based on CT, PET-CT, ultrasound and biopsy. It states MRI should not be used routinely to stage the primary tumour, but may be used for other aspects of staging (though does not mention WB-MRI). The NICE guideline on colorectal cancer does not cover staging.

The new evidence suggests that for both lung and colorectal cancer, there is no difference between WB-MRI and standard staging pathways for detecting metastases or in making treatment decisions, though WB-MRI staging takes less time and has lower costs per patient. Topic experts had concerns about the study findings, such as whether they reflected real-world scenarios. They were also concerned about the current viability of WB-MRI for every patient with lung and colorectal cancer that needs staging, believing that improving standard staging pathways may be a better return on investment. Other key issues raised were that WB-MRI may not improve patient outcomes, and has some drawbacks compared with CT such as a lower resolution.

Given that WB-MRI can only match the accuracy of standard staging pathways, would require substantial investment to implement, and may not lead to improved patient outcomes, there is currently no impact of the new evidence on the guidelines. Further real-world findings may provide a clearer picture of the potential benefits of WB-MRI staging.

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