National Cancer Control Programme

DRAFT

Diagnosis and staging of patients with breast cancer

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HSE National Clinical Guideline:
Diagnosis and staging of patients with Breast Cancer

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Disclaimer

This guideline ("the Guideline") was developed by a multidisciplinary Guideline Development Group ("the Group") and is based upon the best clinical evidence available together with the clinical expertise of the Group members. The Guideline supersedes all previous Health Service Executive (HSE), National Cancer Control Programme (NCCP), and National Clinical Effectiveness Committee (NCEC) guidelines for the diagnosis and staging of patients with breast cancer. The NCCP is part of the HSE and any reference in this disclaimer to the NCCP is intended to include the HSE. Please note, the Guideline is for guidance purposes only. The appropriate application and correct use of the Guideline is the responsibility of each health professional. The Group's expectation is that health professionals will use clinical knowledge and judgment in applying the principles and recommendations contained in this guideline. These recommendations may not be appropriate in all circumstances and it may be necessary to deviate from this guideline. Clinical judgment in such a decision must be clearly documented. Care options should be discussed with the patient, his/her significant other(s), and the multidisciplinary team on a case-by-case basis as necessary. The NCCP accepts no liability nor shall it be liable, whether arising directly or indirectly, to the user or any other third party for any claims, loss or damage resulting from any use of the Guideline.

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1 Background

1.1 Purpose

The purpose of this National Clinical Guideline is to provide evidence based recommendations on the diagnosis and staging of patients with breast cancer through the integration of the best research evidence with clinical expertise, patient values and experiences. This guideline aims to address areas of care with new and emerging evidence, reduce variation in practice, and improve patient experience and service delivery.

1.2 Mandate

The National Cancer Strategy 2017-2026 (Department of Health, 2017) states that: "The NCCP will develop further guidelines for cancer care in line with National Clinical Effectiveness Committee (NCEC) standards" (recommendation 37).

1.3 Scope

The scope of the guideline is to provide clinical recommendations on the diagnosis and staging of patients with breast cancer.

1.4 Target audience

This guideline is intended for all health professionals involved in the diagnosis and staging of patients with breast cancer. This guideline is also relevant to those involved in clinical governance, in both primary and secondary care, to help ensure that arrangements are in place to deliver appropriate care for the population covered by this guideline.

Whilst the guideline is focused on clinical care, it is expected to be of interest to patients with breast cancer and their significant others. An accompanying Plain Language Summary of this guideline is available which outlines what is covered in this guideline along with a suggested list of questions you may want to ask your healthcare professionals (see Appendix V).

While the CEO, General Manager and the Clinical Lead of the cancer centre/hospital have corporate responsibility for the implementation of the recommendations in this guideline, each member of the multidisciplinary team is responsible for the implementation of the individual guideline recommendations relevant to their discipline.

1.5 Target population

- Adults (18 years or older) patients with suspected breast cancer who are undergoing diagnosis.
- Adults (18 years or older) patients with newly diagnosed breast cancer who are undergoing staging.

2 Summary of changes from the 2015 Guideline

This Guideline retains some clinical questions addressed in the radiology section of the National Clinical Guideline: Diagnosis, staging and treatment of patients with breast cancer (Department of Health, 2015). An updated literature search was carried out for each question. The updated evidence base is presented in the text. The updated evidence has resulted in some changes to the original recommendations and the inclusion of new good practice points and practical considerations regarding patient care.

The updated guideline and recommendations follow an amended GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. Further detail on the grading of recommendations in this guideline is available in Appendix III.

A full list of the abbreviations and a glossary of terms used in this guideline can be found in Sections 7 and 8.

3 Standard Practice

The following recommendations from the National Clinical Guideline: Diagnosis, staging and treatment of patients with breast cancer (2015) are now considered standard practice.

For all patients being investigated for invasive breast cancer, pre-treatment ultrasound evaluation of the axilla should be performed and, if morphologically abnormal lymph nodes are identified, ultrasound-guided needle sampling should be offered. **(2015: recommendation 2.2.1.1)**

Ultrasound guided lymph node sampling (fine needle aspiration/core needle biopsy) is recommended in patients with breast cancer where ultrasound demonstrates lymph nodes of cortical thickness of ≥3mm or if the node demonstrates abnormal morphological features. **(2015: recommendation 2.2.2.1)**

Good Practice Point*

When breast cancer is suspected, diagnosis in the breast clinic is made by triple assessment (clinical assessment, breast imaging and tissue sampling [core biopsy and/or fine needle aspiration cytology]). The timing of these tests will be determined by the degree of clinical concern.

minor update to **2015 good practice point

The original 2015 guideline is available upon request.

4 National Clinical Guideline

4.1 Practical considerations regarding patient care applicable across all recommendations in this guideline

All patients diagnosed with breast cancer should have access to a Breast Care Clinical Nurse Specialist (CNS) to address any concerns they have in relation to their diagnosis, imaging and the timeframe within which they can expect their results.

Information regarding the benefits and harms of radiological imaging should be shared with patients to achieve informed decision-making.

All patients should be clearly informed of when their imaging results will be available and how their results will be communicated.

The psychosocial needs of all patients should be acknowledged, with referral to the Psycho-Oncology MDT if necessary, as there can be a significant impact on their mental health and emotional wellbeing following a cancer diagnosis.

4.2 Clinical questions, evidence statements and recommendations

4.2.1 Clinical question 1: In symptomatic patients with suspected breast cancer, with a normal ultrasound and mammogram, which subgroups will benefit from MRI?

Early and accurate detection is essential in the management of breast cancer.

Breast Magnetic Resonance Imaging (MRI) is a valuable diagnostic tool but it is not a first-line test and is generally reserved for specific situations where additional imaging is deemed necessary. This question addresses which symptomatic patients would benefit from MRI, following normal mammogram and ultrasound.

Evidence Summary

A systematic review (Hadadi et al., 2021), network meta-analysis (Filipe et al., 2020), and prospective multicentre study (Boisserie-Lacroix et al., 2021) addressed this question. The overall quality of the body of evidence was moderate.

Nipple discharge

According to the NCCP National Breast Cancer GP Referral Guideline (2021), unilateral bloody nipple discharge and unilateral spontaneous serous nipple discharge warrant referral to a Symptomatic Breast Clinic (SBD).

There was insufficient evidence in the previous National Clinical Guideline: Diagnosis, staging and treatment of patients with breast cancer (2015), on the benefit of MRI for women with normal ultrasound and mammography to recommend its routine use in the context of clinically suspicious nipple discharge. Following a recent update of the literature, we identified new evidence to address this question.

A network meta-analysis, conducted by Filipe et al. (2020) compared the diagnostic efficacy of various imaging modalities in patients with pathologic nipple discharge and sought to determine the best diagnostic strategy to assess the risk of breast cancer. Sensitivity for the detection of malignancy was highest for MRI (83%) compared to ultrasound (50%) and mammography (22%). Specificity was highest for mammography (93%), MRI (76%) and ultrasound (69%). Diagnostic accuracy was 77% for MRI, 76% for mammography and 65% for ultrasound. Pooled data for MRI, when ultrasound and mammography were negative, indicated a sensitivity of 76%, specificity of 84% and a diagnostic accuracy of 83% (Table 1).

Table 1: Diagnostic efficacy of imaging modalities (compilation of data extracted from Filipe et al., 2020)

	Sensitivity	Specificity	Positive predictive value (PPV)	Negative predictive value (NPV)	Diagnostic accuracy
Ultrasound	50%	69%	31%	83%	65%
Mammography	22%	93%	46%	80%	76%
MRI	83%	76%	40%	96%	77%
Pooled data (detection of breast cancer - pathological nipple discharge with normal ultrasound and/or mammography)					
MRI	76%	84%	37%	97%	83%

A prospective multicentre study, carried out by Boisserie-Lacroix et al. (2021) evaluated the diagnostic accuracy of MRI in identifying lesions requiring excision for patients with suspicious nipple discharge but normal mammography and ultrasound. MRI detected a lesion requiring excision in 46 participants (45%) with unexplained discharge. The sensitivity, specificity, NPV, and PPV of breast MRI were 96% (95% confidence interval [CI], 85.75–99.49; 85% (95% CI, 72.9–93.4); 96% (95% CI, 85.75–99.49), and 85% (95% CI, 72.9–93.4), respectively. Papillomas (benign or with atypia) were found in 39% and malignant lesions in 8% of all pathologic discharges. There were two cases of false-negative MRI (two papillomas with negative MRI). No significant correlation between bloody discharge and lesions requiring excision was observed (p=0.15). The performance of MRI for the detection of a malignant lesion was as follows: sensitivity 100%, specificity 51%, NPV 100%, and PPV 15%, based on one-year follow-up.

Paget's disease of the nipple

Paget's disease of the nipple is a malignant condition that affects the nipple/areola complex from where it may spread to the surrounding skin. Patients present with a thickened, reddened, weeping or crusted area on the nipple. Nipple discharge and ulceration may sometimes occur, and there may be an associated palpable breast lump.

Following a literature review, no new relevant evidence was identified to add to the previous National Clinical Guideline: Diagnosis, staging and treatment of patients with breast cancer (2015). The 2015 recommendation has been re-endorsed. MRI continues to play an important role where there is a suspicion of breast cancer in patients with Paget's disease.

Breast density

Current best practice stipulates that in patients with a persistent clinically suspicious finding with no correlate on mammogram and ultrasound, that a clinically-guided core biopsy should be considered in the first instance.

Breast density is defined according to the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS; Table 2).

Table 2: BI-RADS 5th edition

A	Almost entirely fatty	10% of women
B	Scattered fibroglandular tissue	40% of women
C	Heterogeneous fibroglandular tissue	40% of women
D	Extreme fibroglandular tissue	10% of women

In patients with dense breast tissue (breast density C or D), mammograms may be less sensitive. This section addresses the role of MRI in this setting.

Hadadi et al. (2021) conducted a systematic review and meta-analysis of screening and symptomatic populations, to compare the diagnostic performance of mammography alone versus mammography combined with adjunctive imaging modalities, including MRI in women with non-dense (A or B) and dense breasts (C or D).

In studies comparing the diagnostic accuracy between mammography alone and adjunctive MRI in dense breasts, the weighted-average sensitivities were 36% and 82%, respectively, and the weighted-average specificities were 93.4% and 80%, respectively. In women with non-dense breasts, the weighted-average sensitivity of mammography alone (44%) was lower than that of adjunctive MRI (92%), and the specificity of mammography alone was higher (97%) than that of adjunctive MRI (91%).

In four MRI studies, the cancer detection rate was significantly higher when using MRI as an adjunct to mammography (pooled relative risk [RR]=2.16; 95% CI, 1.81-2.58; I^2 = 0%; p<0.00001) in women with dense breasts. In three MRI studies, the cancer detection rate was also higher when using adjunctive MRI compared to mammography alone (pooled RR=1.78; 95% CI, 1.14-2.77; I^2 = 47%; p=0.01) in women with non-dense breasts.

Three studies that used MRI as an adjunct imaging modality to mammography showed the largest increase in recall rate, compared with ultrasound. Based on the overall estimate, the use of MRI significantly increased the recall rate in women with dense breasts, and the pooled recall rate was increased by 171% (RR=2.71; 95% CI, 1.73-4.25; I^2 = 87%; p<0.0001). In two MRI studies, the recall rate was also significantly higher than for mammography alone among women with non-dense breasts (RR=3.01; 95% CI, 1.68- 5.39; I^2 = 79%; p=0.0002). The authors acknowledged that the sampled MRI studies mainly focused on women at a high risk of breast cancer and that this patient selection bias may be responsible for the increased false positives and recall rates attributed to MRI.

There is agreement across international guidelines for the use of MRI if there is discrepancy between conventional imaging and clinical/physical examination or if breast density precludes accurate assessment (European Society of Medical Oncologists [ESMO], 2023, 2019; Royal College of Radiologists [RCR], 2019; National Institute for Health and Care Excellence [NICE], 2024; European Society of Breast Imaging [EUSOBI], 2015).

Benefits and Harms

Using MRI can help identify cancers that are not detected on conventional imaging (mammography and/or ultrasound). Mammography has reduced sensitivity in women with increased breast density. However, MRI may result in false positive and/or false negative results and the need for subsequent imaging and biopsies. Not all patients can have MRI, including but not limited to patients who are pregnant, claustrophobic, those who have certain implantable devices or an allergy to MRI contrast.

Preferences and values

The multidisciplinary Guideline Development Group (GDG), including patient representatives, recognise that knowledge and understanding are important patient values. It is essential for patients to be well informed regarding the need for accurate imaging to diagnose breast cancer. The justification for what imaging modality is used should be clearly communicated.

The GDG believes that informed patients will recognise that MRI is not a first-line test but may be beneficial in some patients. It is important that patients are afforded the opportunity to ask questions about the benefits and harms of MRI. This should help reassure patients that they are receiving the best level of care based on current evidence.

Open communication around timelines; when the scan may be scheduled; when results will be available and how they will be communicated is important in managing patients' expectations.

Resources, capacity, equity and other considerations

There was no relevant cost-effectiveness literature found to address this clinical question.

The following resources, capacity, equity and other considerations were discussed by the GDG:

- The use of breast MRI results in increased need for resources, including additional imaging, image-guided biopsy and histopathology.
- It was acknowledged that there are capacity constraints/resource limitations in all cancer centres nationally, including:
    - Access to MRI scanners (for breast MRI and MR-guided breast biopsies)

- Access to radiography staff
- Access to radiologists with a specialist interest in breast imaging
- Access to biopsy following MRI.

Recommendation 1.1
For patients with persistent, clinically concerning, unilateral nipple discharge, in whom conventional imaging (mammogram & ultrasound) has not identified a cause, MRI may be considered following multidisciplinary discussion.

Quality of Evidence: Moderate **Grade of recommendation: Weak**

Recommendation 1.2*
For patients with Paget's disease of the nipple, in whom conventional imaging is normal, MRI may be considered following multidisciplinary discussion.

Quality of Evidence: Moderate **Grade of recommendation: Weak**

minor update to **2015: recommendation 2.2.6.1*

Good practice points

A Breast MR service should include access to MR-guided breast biopsies.

In patients with a persistent clinically suspicious examination (S4, S5)* and normal imaging (mammography and ultrasound), clinically guided core biopsy should be considered.

*Clinical exam
S4 – findings moderately suspicious of malignancy
S5 – findings highly suspicious of malignancy

4.2.2 Clinical question 2: In patients with biopsy proven breast cancer, what is the role of breast MRI in preoperative staging?

Evidence Summary

A review of the literature was conducted and the following studies were appraised to address this question - four systematic reviews and meta-analyses (Eisen et al., 2023; Canelo-Aybar et al., 2021; Houssami et al., 2017; Fancellu et al., 2015), two randomised controlled trials (RCTs) (Mota et al., 2023; Gonzalez et al., 2014, 2021), a prospective observational study (Sardanelli et al., 2022) and a retrospective review (Moloney et al., 2020).

The quality of the evidence was moderate but represents the best current evidence. The evidence covered in-situ disease, invasive disease (including lobular cancer), and addressed a range of patient variables (e.g. age, breast density, menopausal status). This reflects everyday practice and the spectrum of the disease.

Use of MRI in invasive and in-situ breast cancer

A systematic review and meta-analysis by Eisen et al. (2023) comparing patients newly diagnosed with breast cancer, with and without preoperative MRI, indicated benefits for the use of MRI. While there were a large number of studies included in this analysis, the evidence was of low-moderate quality, with a high risk of bias in the RCTs. It reported that the use of MRI resulted in decreased rates of reoperation (odds ratio [OR] = 0.73; 95% CI 0.63-0.85; $p < 0.0001$; 14.4% vs 18.7%), re-excisions (OR = 0.63; 95% CI 0.45-0.89; 6.9% vs 10.5%), and recurrence (hazard ratio[HR] = 0.77; 95% CI 0.65-0.90; $p = 0.001$; 8.2% vs 10.5%), as well as increased detection of synchronous contralateral breast cancer (HR = 2.52; 95% CI 1.75-3.62; $p < 0.00001$) and lower rates of metachronous breast cancer (HR = 0.71; 95% CI 0.59-0.85; $p = 0.0003$).

The recent Breast-MRI trial (Mota et al., 2023) evaluated survival and surgical outcomes of preoperative MRI for conservative breast cancer surgery and found that MRI increased mastectomy rates by 8%. After a median follow-up time of 6 years, there was no influence on local recurrence-free survival (HR = 0.72; 95% CI 0.12-4.28; $p = 0.7$; 99.2% MRI group vs 98.9% control group) or overall survival (HR = 1.37; 95% CI 0.59–3.19; $p = 0.8$; 95.3% vs 96.3%). No difference was found in reoperation rates, 22 (8.7%) in the MRI group versus 23 (8.7%) in the control group (RR = 1.002; 95% CI 0.57–1.75; $p = 0.85$).

Sardanelli et al. (2022) investigated whether preoperative MRI could inform surgical planning but at the same time cause overtreatment by increasing the mastectomy rate, in a prospective study of 5,896 patients. The overall mastectomy rate was higher in the MRI group compared to the no-MRI group (36.3% vs 18%). Following MRI, an additional 11.6% of women converted from planned conservative surgery to mastectomy; while 0.3% converted from planned mastectomy to conserving surgery.

Factors associated with increased mastectomy rates included pre-operative breast MRI for local staging, increased breast density, invasive histology at biopsy, high familial risk, premenopausal status, lesion diameter ≥20mm, and planned mastectomy on conventional imaging. Reoperation for close/positive margins was lower in the MRI group than in the no-MRI group ($p<0.001$) – factors associated with increased re-excision rates increased breast density, invasive lobular histology and lesion diameter ≥20mm. This finding was consistent with the results from previous RCTs (POMB trial [Gonzalez et al., 2014]; IRCIS trial [Ballyguier et al., 2019]).

The following secondary clinical endpoints - rate of breast recurrence and distant metastases – from the Sardanelli study will be evaluated at a 5-year follow-up.

Use of MRI in ductal carcinoma in-situ (DCIS)

Canelo-Aybar et al. (2021) assessed the impact of preoperative breast MRI on surgical outcomes, treatment change and loco-regional recurrence in the management of DCIS. Pooled estimation showed approximately 17% of initial surgical decisions may change to a more extensive resection or mastectomy when MRI was used. However, they found low to very low evidence to suggest an improvement in surgical outcomes or risk of local recurrence. The authors noted concerns in relation to risk of bias and certainty of the evidence.

Fancellu et al. (2015) examined the effects of MRI on surgical treatment and found no associated improvement in outcomes as a result of preoperative MRI. MRI significantly increased the odds of having a mastectomy as initial surgery ($p = 0.012$) – the odds of having breast conserving surgery were much higher for women who did not have an MRI ($p = 0.004$). There were no significant differences in the proportion of women with positive margins following breast conserving surgery in the MRI vs the no-MRI groups ($p = 0.716$), nor the need for reoperation for positive margins ($p = 0.844$). The overall mastectomy rate (initial mastectomy plus mastectomy for positive margins after breast conserving surgery) did not significantly differ according to whether or not an MRI was performed ($p = 0.881$).

Use of MRI in invasive breast cancer

Houssami et al. (2017) examined the association between preoperative MRI and surgical outcomes and found evidence that MRI was significantly associated with increased odds of receiving a mastectomy as treatment ($p < 0.001$). There was no statistical evidence that MRI had an effect on the odds of re-excision or positive margins in those who received breast conserving surgery. Preoperative MRI significantly increased the odds of receiving contralateral prophylactic mastectomy ($p = 0.003$). Subgroup analysis of patients with invasive lobular cancer revealed no association between preoperative MRI and the odds of receiving a mastectomy ($p = 0.988$) or re-excision surgery ($p = 0.192$).

The POMB trial (Gonzalez et al., 2014) examined whether preoperative breast MRI would affect primary surgical management and reduce re-excision/re-operation procedures in patients with newly diagnosed breast cancer. A total of 440 patients, aged 56 years or less, were randomised to either preoperative MRI (220) or conventional imaging (220; control). The results found that in the MRI group, patients primarily scheduled for BCS showed a significantly higher rate of conversion to mastectomy as final treatment; 30 of 153 (20%) compared with 13 of 132 (10%) in the control group ($p = 0.0024$), however the final numbers of mastectomies did not differ between the two groups. The overall breast reoperation rate in the MRI group was significantly lower than in the control group ($p < 0.001$).

A 10 year update of the POMB trial (Gonzalez et al., 2021) demonstrated that disease-free survival (DFS) rates were 85.5% and 80% for the MRI and control groups respectively ($p = 0.099$). Overall survival (OS) rates after 10 years were 90.9% and 88.6% in the MRI and control groups respectively ($p = 0.427$). Preoperative breast MRI as an adjunct to conventional imaging resulted in slightly, but non-significantly, improved DFS and OS.

Benefits and Harms

Using preoperative breast MRI can help accurately map the extent of the disease and plan surgical treatment in some patients. MRI may result in a decrease in positive margins at initial resection and need for further surgery, following initial BCS.

Like all tests, breast MRI is not perfect. It may detect additional findings that are not clinically significant and lead to further investigations, including additional biopsies, with potential delays in treatment. The mastectomy rates are higher in patients who undergo breast MRI for preoperative staging, without any proven survival benefit. MRI can also have false negative results and patients may still require re-excision, post initial surgery.

Not all patients are suitable for MRI, including but not limited to patients who are pregnant, claustrophobic, or those who have certain implantable devices or a contrast allergy.

Preferences and values

The multidisciplinary GDG, including patient representatives, recognise that knowledge and understanding are important patient values. It is essential for patients to be well informed regarding the need for accurate imaging to diagnose breast cancer. The justification for what imaging modality is used, following discussion at the Breast Cancer tumour conference, should be clearly communicated to patients.

The GDG believes that informed patients will recognise that MRI is not a first-line test but may be beneficial in some patients. It is important that patients are afforded the opportunity to ask questions about the benefits and harms of MRI. This should

help reassure patients that they are receiving the best level of care based on current evidence.

Open communication around timelines; when the scan may be scheduled; when results will be available and how they will be communicated is important in managing patient's expectations.

Resources, capacity, equity and other considerations

There was no relevant cost-effectiveness literature found to address this clinical question.

The following resources, capacity, equity and other considerations were discussed by the GDG:

- It was acknowledged that there are capacity constraints/resource limitations in all cancer centres nationally, including:
    - Access to MRI scanners (for breast MRI and MR-guided breast biopsies)
    - Access to radiography staff
    - Access to radiologists with a specialist interest in breast imaging
    - Access to biopsy following MRI.

The current recommendations aim to ensure that the use of breast MRI for preoperative staging in patients with biopsy proven breast cancer is in line with current best practice.

Recommendation 2.1*

In patients with biopsy proven breast cancer, breast MRI in preoperative staging is not routinely recommended.

Quality of Evidence: Moderate **Grade of recommendation: Strong**

update to **2015: recommendation 2.2.4.1*

Recommendation 2.2**

In patients with biopsy proven breast cancer, breast MRI in preoperative staging should be considered in patients where there is discordance regarding the extent of the disease (following clinical examination and initial radiological evaluation) and/or where breast density precludes accurate size assessment, following multidisciplinary discussion.

Quality of Evidence: Moderate **Grade of recommendation: Weak**

update to **2015: recommendation 2.2.4.2

Good practice points

A Breast MR service should include access to MR-guided breast biopsies.

All patients with biopsy proven breast cancer should be discussed at the Breast multidisciplinary team meeting/tumour conference, where the need for breast MRI can be considered. The ensuing decision of whether to conduct MRI should be made in consultation with the patient and must take into account the balance of benefits and risks and patient preferences.

Practical considerations regarding patient care

Body habitus and mobility issues should be taken into account when discussing imaging options such as MRI with patients.

Other factors which may affect the diagnostic quality of MRI include artefact, movement and background parenchymal enhancement.

4.2.3 Clinical question 3: In patients with breast cancer, what subgroups should have staging investigations performed to detect distant metastases?

The prevalence of metastatic disease at the time of breast cancer diagnosis is generally low, especially in early-stage breast cancer. However, as the stage of breast cancer increases, the likelihood of metastases also increases. Therefore, staging investigations become more important in higher-stage breast cancer to accurately identify the presence or absence of distant metastatic disease.

The goal of staging is to detect the presence of distant metastatic disease. This information is crucial for determining the prognosis of the patient and for selecting the appropriate treatment approach. If distant metastases are identified, it indicates a more advanced stage of the disease and may require more aggressive treatment strategies. On the other hand, if no distant metastases are detected, it indicates a lower stage of the disease and may guide treatment decisions towards less aggressive approaches.

An updated literature review was conducted to address new or emerging evidence in the context of staging investigations for breast cancer to detect distant metastases, to determine which subgroups of patients should undergo staging investigations. A number of retrospective studies addressing this topic were identified.

Evidence Summary

The updated literature review identified eight retrospective studies, mostly single-institution, which have inherent selection bias (Rusch et al., 2016; Soares et al., 2018; Bychkovsky et al., 2016; Dull et al., 2017; Srour et al., 2021; Thavorn et al., 2016; McCartan et al., 2016; Piatek et al., 2017). The studies had a mixed population of stages and presentations and a variety of imaging modalities were used. Most studies also had a relatively small sample size.

Stage I and II

There is consensus across the literature that asymptomatic patients with stage I or II disease should not be routinely considered for radiological staging investigations to evaluate for distant metastases due to the low prevalence of metastatic disease and rate of incidental findings of uncertain significance encountered (e.g. false positives).

Rusch et al. (2016) demonstrated a diagnosis of distant metastases in 2/896 (0.2%) asymptomatic patients, as a result of routine staging. They estimated that approximately 3,000 unnecessary diagnostic staging procedures were performed in their patient cohort. They conclude that there was no argument justifying radiological staging in asymptomatic stage I or II breast cancer.

Soares et al. (2018) reviewed 685 stage I and II patients (91% of the overall cohort) who underwent staging imaging and revealed that distant metastases were detected in 32 (4.7%). Disease stage ($p < 0.001$) and pathological lymph node involvement ($p < 0.001$) were identified as risk factors for metastatic disease.

Low rates of distant metastases in stage I-II breast cancer have also been confirmed regardless of age or biomarker status (Bychkovsky et al. 2016). In clinical stage II asymptomatic patients with breast cancer, where 46.2% were ≤50 years, the rate of detection of distant metastasis based on baseline staging imaging was 2.1% (5/237) with no evidence that patients with more aggressive pathological subtypes should have different staging evaluations. Detection rates among ER/PR-positive patients, HER2+ patients, and patients with triple-negative breast cancer were 2.2%, 1.9% and 2.1%, respectively.

Routine staging imaging in asymptomatic patients is more likely to detect incidental findings than metastatic disease. Incidental findings are described by the American College of Radiology as findings that are unrelated to the clinical indication for which the imaging examination is being performed, in other words an abnormality that is not suspected to be breast-cancer related. As these findings are frequent, they can lead to additional diagnostic investigations across all stages with cost implications.

Dull et al. (2017) conducted a review of patients with stage I-II asymptomatic breast cancer. Of the 2,062 patients with stage I, 227 (11%) received staging, with 51 pulmonary nodules identified. Of the 1,259 patients with stage II, 436 (36.2%) received staging, with 133 pulmonary nodules identified. A large percentage of patients were found to have incidental pulmonary nodules (stage I 22.5%; stage II 29.2%), but only 9 patients (1.3%) ultimately developed pulmonary metastases.

In a cohort of stage I-III patients with invasive breast cancer undergoing neoadjuvant chemotherapy, Srour et al. (2021) compared incidental findings seen on preoperative staging with future distant recurrence. They found that the incidental findings were unlikely to be indicative of sites for future metastasis. Of the 262 patients who underwent staging imaging, 146 patients had reported incidental findings (n = 222). At a median follow-up of 3.7 years, 43 (15.6%) patients had a distant recurrence, however only 5 (1.9%) of these patients had distant metastasis in the same organ that was initially thought to be an incidental finding.

Similarly, existing international guidelines at the time of publication (National Comprehensive Cancer Network [NCCN], 2024; ESMO, 2019; RCR, 2019; NICE, 2016) do not recommend routine staging for the detection of distant metastasis in patients with early breast cancer in the absence of signs or symptoms.

Stage III and IV

The vast majority of studies support staging investigations in stage III and IV patients.

Evidence from a systematic review (Brennan & Houssami, 2012) was used in the original National Clinical Guideline: Diagnosis, staging and treatment of patients with breast cancer (2015). This study confirmed a higher prevalence of distant metastases in more advanced breast cancer presentations (stage III; inflammatory cancer; extensive lymph node involvement), justify systematic staging in this group.

In an Irish study by McCartan et al. (2016), all patients with clinical stage III or IV disease were staged for distant metastases, as well as 7.2% of patients with stage I and 52.1% with stage II. The presence of axillary nodal metastases and planned neoadjuvant chemotherapy were the most common indications for staging. Of the 631 patients who underwent staging, 69 (10.9%) had distant metastases at presentation. The risk of distant metastases showed a clear correlation with increased clinical stage. No patient with clinical stage I disease had distant metastases. Staging diagnosed distant metastasis in 18 of 240 (7.5%) patients with clinical stage II disease, 38 of 334 (11.4%) patients with clinical stage III disease and confirmed clinical suspicion in all 13 patients with clinical stage IV disease ($p < 0.001$). Further radiological investigations were required in 50 of the 631 patients to clarify indeterminate radiological findings.

Piatek et al. (2017) evaluated the value of staging in patients with clinical stage III breast cancer. The percentage of patients found to have indeterminate disease on routine staging imaging studies was greater than the percentage of patients found to have true metastatic disease (18.3% vs. 5%). Despite a total of 628 scans performed, treatment was altered in only 5.8% of patients.

International guidelines are also in agreement that patients with advanced stage disease should be considered for staging for distant metastases due to the higher prevalence of metastatic disease in these cohorts.

This review reconfirms the recommendations in the previous guideline.

Benefits and Harms

The benefit of staging is the detection of distant metastases in patients most likely to have metastases, which enables appropriate treatment planning.

Staging imaging exposes patients to ionising radiation. Radiation dose varies with imaging modality. The Health Information and Quality Authority (HIQA) sets out the diagnostic reference levels for medical exposure to ionising radiation (HIQA, 2023). Increased exposure to radiation can cause greater harm in young people, pregnant women and patients with an underlying predisposition to cancer.

The potential adverse effects of staging imaging is the detection of incidental findings that may require further workup including invasive procedures and related complications, which may result in delays to therapy. False-positive tests can result in unnecessary anxiety while false-negative tests give patients false reassurance.

Adherence to guideline recommendations will ensure the best use of resources and the avoidance of unnecessary staging investigations that can delay treatment.

Preferences and Values

The multidisciplinary GDG, including patient representatives recognise that knowledge and understanding are important patient values. It is essential for patients to be well informed regarding the need for staging to detect distant metastases. The justification for why a patient is or is not having radiological staging investigations should be clearly communicated.

The GDG believes that informed patients will recognise that staging investigations are not required in all patients with breast cancer. It is important that patients are afforded the opportunity to ask questions about the benefits and harms of particular investigations. This should help reassure patients that they are receiving the best level of care based on current evidence.

Open communication around timelines; when the scan may be scheduled; when results will be available and how they will be communicated is important in managing patient's expectations.

Resources, capacity, equity and other considerations

Thavorn et al. (2016) conducted a retrospective population-based cohort study to estimate and describe the cost of unnecessary imaging in women with stage I or II breast cancer where the incidence of radiologically evident metastases is 0.2-1.2% among this cohort. Of the 26,547 women diagnosed, 22,803 (85.9%) received at least one imaging test (i.e. bone scan, CT, MRI, ultrasonography, radiography, PET). Those with stage I disease (n = 13,724) received a mean of 3.2 ± 1.8 imaging tests and those with stage II (n = 12,823) disease received a mean of 4 ± 1.9 imaging tests. In total, over 83,000 imaging tests were performed at a substantial cost to the health care system and not taking into account clinic visits, follow-up tests and referrals to specialists.

The significant cost and resource implications of staging investigations for radiology services was acknowledged by the GDG.

Recommendation 3.1*
In newly diagnosed asymptomatic patients with stage I and II breast cancer, imaging for metastatic disease is not routinely recommended.

Quality of Evidence: Moderate **Grade of recommendation: Strong**

*update to ***2015: recommendation 2.2.7.2***

Recommendation 3.2**
In newly diagnosed asymptomatic patients with stage III and IV breast cancer, imaging for metastatic disease is recommended.

Quality of Evidence: Moderate **Grade of recommendation: Strong**

update to ***2015: recommendation 2.2.7.3*

Recommendation 3.3***
In patients diagnosed with breast cancer, where there is a significant clinical concern for metastatic disease, appropriate imaging should be considered, regardless of tumour stage.

Quality of Evidence: Moderate **Grade of recommendation: Weak**

update to ***2015: recommendation 2.2.7.1

Good practice points

All newly diagnosed breast cancers should be discussed by the multidisciplinary team (MDT) who may consider staging imaging in some patients who fall outside of the above recommendations, taking into account patient preferences and values.

4.2.4 Clinical question 4: In patients with breast cancer who are being staged, what investigations should be performed?

Staging investigations help determine the extent of the disease, including the presence or absence of distant metastases and are important to influence treatment decisions.

A comprehensive literature review was conducted to identify any updated evidence regarding staging imaging for breast cancer.

Evidence Summary

Contrast-enhanced CT-TAP vs contrast enhanced CT-TAP with bone scan
The review identified one prospective (Bruckmann et al., 2021) and three retrospective studies (McCartan et al., 2016; James et al., 2020; Bansal et al., 2018) that addressed whether contrast enhanced CT-TAP or contrast enhanced CT-TAP with bone scan should be performed in patients with breast cancer who are recommended for staging. The quality of the evidence is moderate to low with risk of bias due to the retrospective nature of most of the studies.

A prospective study conducted by Bruckmann et al. (2021) on 154 patients with newly diagnosed breast cancer compared the diagnostic performance of various imaging modalities for the detection of bone metastases. Bone metastases were found in 7/154 patients (4.5%), all detected by MRI. Contrast enhanced CT detected 5/7 patients, resulting in a sensitivity of 71.4% (CI: 35.9–91.8) and a specificity of 98.6% (CI: 95.2–99.6). Bone scintigraphy detected 2/7 patients, resulting in a sensitivity of 28.6% (CI: 8.2–64.1) and a specificity of 99.4% (CI: 96.4–99.9). A statistically significant superiority was shown for contrast enhanced CT in comparison to bone scintigraphy ($p = 0.039$, difference 19.5%, CI: 0.01–0.38).

A retrospective review by McCartan et al. (2016) on patients with newly diagnosed invasive breast cancer in Ireland evaluated the additional diagnostic yield of bone scan when added to contrast enhanced CT-TAP. The study identified breast cancer metastasis in 69 (10.9%) patients with bone metastases in 58 of these patients. True positive results were identified in 52/58 patients with bone metastases on contrast enhanced CT-TAP (sensitivity 91%; specificity 98%) and 53/58 imaged with bone scan (sensitivity 94%; specificity 95%). There were five false-negative contrast enhanced CT findings among a total of 631 patients (0.8%), compared with three false-negative bone scans (0.5%). Further radiological investigations were required following the contrast enhanced CT-TAP and bone scan in 50 (7.9%) of the 631 patients to clarify indeterminate radiological findings, most commonly MRI (27 of 50; 4.3%). The authors suggested that inclusion of the proximal femur in the CT scanning range could have reduced the false-negative rate for contrast enhanced CT-TAP from 0.8% to 0.5% by identifying the two patients with isolated long bone

metastases to the proximal femur, albeit for a marginal clinical gain. Of patients who ultimately did not have distant metastases, only 1.4% required an invasive biopsy to fully characterise indeterminate findings on the contrast enhanced CT-TAP or bone scan, indicating that current staging protocols enable definitive conclusions to be drawn for the majority of patients imaged. They concluded that contrast enhanced CT-TAP is a satisfactory stand-alone investigation and advised that the inclusion of the proximal femur as routine practice in this protocol would maximise the diagnostic yield. Bone scan can be reserved for patients with indeterminate findings on contrast enhanced CT or to determine extent of bone metastases identified on contrast enhanced CT.

Similarly, James et al. (2020) concluded that the value of bone scans in the screening for asymptomatic bone metastases in early breast cancer is limited. If the patient also has a contrast enhanced CT-TAP, the usefulness of bone scans may be very limited. In such situations, bone scans may be reserved for further characterisation of findings from a contrast enhanced CT-TAP or the assessment of bone symptoms not explained by the contrast enhanced CT-TAP findings. Such selective use of bone scans may result in significant cost savings without compromising the identification of metastases and ongoing treatment of early breast cancer. In their study, bone scans in combination with contrast enhanced CT-TAP as a staging investigation led to the diagnosis of two bone metastases, giving an overall yield of 1% (95% CI, -0.65, 2.71). The overall false-positive rate was 1.5% (95% CI, -0.45, 3.54). Of the two bone metastases observed by bone scan, one of them was also evident on the corresponding contrast enhanced CT-TAP imaging.

Bansal et al. (2018) conducted a retrospective study of 105 patients with locally advanced breast cancer, in the UK, comparing bone scan and contrast enhanced CT-TAP to evaluate their use in staging or management. Thirty-three (31.4%) patients had concordant normal results on contrast enhanced CT and bone scan. A further 33 patients had inconclusive findings, on either contrast enhanced CT, bone scan, or both. The remaining 39 patients (37.1%) had metastasis based on contrast enhanced CT-TAP findings. Of these 39 patients, 21 (20%) had concordant metastasis within the bones and CT picked up non-bone metastases in 12/21 (lung, liver, brain). The remaining 18 patients had non-bone metastases on CT with either negative bone scan (14 patients) or inconclusive bone scan (4 patients). Bone scans diagnosed peripheral osseous metastases in 5/105 (4.7%) which were either skull or extremity metastasis not covered on contrast enhanced CT-TAP field of view. However, all of these 5 patients had other metastatic lesions within either axial skeleton or soft tissues on contrast enhanced CT-TAP. CT and bone scan had equivocal findings in 28 (27.5%) and 13 (12.3%) patients, respectively. Equivocal CT findings were further evaluated with either abdominal US, contrast enhanced MRI, or interval follow-up with CT. Equivocal bone scans, which remained indeterminate after correlation with CT, were further evaluated with plain films or MRI. They

concluded that routine bone scan in asymptomatic patients with breast cancer can be omitted and used only as a problem solving tool in symptomatic patients. These studies showed that for patients diagnosed with breast cancer, contrast enhanced CT-TAP (to include supraclavicular fossa and proximal femora) is a satisfactory stand-alone investigation for systemic staging.

There is also agreement across international guidelines for the use of contrast enhanced CT when staging is required (NCCN, 2024; ESMO, 2019; RCR, 2019). The Royal College of Radiologists (UK) recommends contrast enhanced CT-TAP as the modality of choice and does not recommend a bone scan in the absence of bone symptoms.

Contrast enhanced CT-TAP vs PET-CT

A further review was conducted to address whether contrast enhanced CT-TAP or PET-CT should be performed on those who are recommended for staging. This identified two prospective studies (Bhoriwal et al., 2021; Kamal et al., 2022), and two retrospective studies (Ko et al., 2020; Jacene et al., 2020). The quality of the evidence was moderate, due to heterogeneity among the studies regarding patient selection and disease stage.

A prospective study by Bhoriwal et al. (2021) comparing ^{18}FDG PET-CT with contrast enhanced CT and Tc99m bone scan (conventional imaging) for staging locally advanced breast cancer demonstrated that overall PET-CT detected distant metastases in more patients compared to conventional imaging. Liver lesions were detected in a higher number of patients (17.8% vs 8.2%) as well as lung metastases (19.2% vs 10.8%) on PET compared to CT scans, which changed the management in 30% of patients. Similarly, a study by Kamal et al. (2022) reported that detection rates for metastases were slightly higher in combined PET-CT – pulmonary and visceral metastases (16% vs 14%; p = 0.99) and bony metastases (32% vs 28%; p = 0.83). While the performance of PET-CT was higher than CT for the detection of distant metastases, this was not statistically significant.

Jacene et al. (2020) identified 47 discordant interpretation of imaging findings by PET-CT and contrast enhanced CT among 41 of 81 patients (50.6%). Thirty of 47 (63.8%) discordant results related to the presence or absence of distant metastases due to inflammatory breast cancer. The largest category of discordance was regarding distant metastases detected on imaging (n = 21 findings in 21/81 patients, 25.9%) and nine equivocal discordant findings were interpreted as possible distant metastases from inflammatory breast cancer. The rate of upstaging to stage IV disease in patients who underwent PET-CT was 16%. Similarly, Ko et al. (2020) identified an overall upstaging rate of 14% (27/196) for distant metastases in patients with stage IIa-IIIc breast cancer who underwent PET-CT, with a positive predictive value (PPV) of 73% (when confirmed by histology).

Significantly more patients with false positive results were identified in those undergoing contrast enhanced CT-TAP and full body bone scan (22.1%; 51/231) versus PET-CT imaging (11.1%; 33/298; p = 0.0009), most commonly noted in younger patients (<45yrs; Hyland et al., 2020).

International guidelines (NCCN, 2024; RCR, 2022; ESMO, 2019; NICE, 2017) currently recommend PET-CT for problem-solving when the results from other imaging modalities are indeterminate.

Benefit and Harm

The benefit of staging imaging is the detection of distant metastases in patients most likely to have metastases, which enables appropriate treatment planning.

Staging imaging exposes patients to ionising radiation. Radiation dose varies with imaging modality. The Health Information and Quality Authority (HIQA) sets out the diagnostic reference levels for medical exposure to ionising radiation (HIQA, 2023). Increased exposure to radiation can cause greater harm in young people, pregnant women and patients with an underlying predisposition to cancer.

The benefits of whole body PET-CT compared with contrast enhanced CT-TAP include a higher sensitivity for the detection of metastases, the ability to analyse metabolic activity and the ability for whole body radiological imaging to be performed. All the studies show that PET-CT is sensitive for detecting distant metastases and can provide additional information in the setting of equivocal conventional staging imaging.

The potential harms of whole body PET-CT and bone scan compared with contrast enhanced CT-TAP include the long time spent in the scanner/department and the inconvenience associated with having to travel long distances due to the limited availability of PET-CT and bone scan. Patients also need to avoid close contact with babies, young children and pregnant women for a number of hours following a PET-CT and bone scan, due to radioactivity.

The potential adverse effects of staging imaging are the detection of incidental findings that may require further workup including invasive procedures and related complications, which may result in delays to therapy. False-positive tests can result in unnecessary anxiety while false-negative tests give patients false reassurance.

Adherence to guideline recommendations will ensure the best use of resources and the avoidance of unnecessary staging investigations that can delay treatment.

Preferences and Values

The multidisciplinary GDG, including patient representatives, recognise that knowledge and understanding are important patient values. It is essential for patients

to be well informed regarding the need for staging to detect distant metastases. The justification for which imaging modality is used should be clearly communicated.

The GDG believes that informed patients will recognise that bone scan and PET-CT are not first-line tests but may be beneficial in some patients. It is important that patients are afforded the opportunity to ask questions about the benefits and harms of the different imaging modalities. This should help reassure patients that they are receiving the best level of care based on current evidence.

Open communication around timelines; when the scan may be scheduled; when results will be available and how they will be communicated is important in managing patient's expectations.

Resources, capacity, equity and other considerations

There was no relevant cost-effectiveness literature found to address this clinical question.

The following resources, capacity, equity and other considerations were discussed by the GDG:

- Contrast enhanced CT-TAP alone (rather than contrast enhanced CT-TAP plus bone scan) will result in time, resource and capacity savings, as well as a reduction in radiation dose to the patient.

These recommendations apply to patients with newly diagnosed breast cancer requiring staging investigations.

Change to the recommendations in the 2015 guideline.

Recommendation 4.1

In patients with newly diagnosed breast cancer who require staging, contrast-enhanced computed tomography thorax, abdomen and pelvis (CT-TAP) is recommended. The scanning range should include supraclavicular fossa and proximal femur.

Quality of Evidence: Moderate **Grade of recommendation: Strong**

update to **2015: recommendation 2.2.8.1*

Recommendation 4.2
In patients with newly diagnosed breast cancer who require staging, bone scan is not routinely recommended. However, it may be considered in addition to contrast enhanced CT-TAP if there are signs or symptoms of bone metastases.

Quality of Evidence: Moderate **Grade of recommendation: Strong**

Recommendation 4.3**
In patients with newly diagnosed breast cancer who require staging, PET-CT should be considered where findings on standard staging imaging are equivocal.

Quality of Evidence: Moderate **Grade of recommendation: Weak**

update to **2015: recommendation 2.2.8.2

Good practice points

All patients with newly diagnosed breast cancer should be discussed by the multidisciplinary team (MDT) who may consider staging imaging in some patients who fall outside of the above recommendations, taking into account patient preferences and values.

5 Methodology

5.1 List of clinical questions

Clinical question 1

In symptomatic patients with suspected breast cancer, with a normal ultrasound and mammogram, which subgroups will benefit from MRI?

Population	Symptomatic patients with suspected breast cancer (normal ultrasound & mammogram)
Intervention	MRI
Control	No MRI
Outcome	To determine diagnosis - Sensitivity, specificity, diagnostic yield, positive predictive value, negative predictive value

Clinical question 2

In patients with biopsy proven breast cancer, what is the role of breast MRI in preoperative staging?

Population	Patients with biopsy proven breast cancer
Intervention	MRI
Control	No MRI
Outcome	Survival Rate of mastectomy Re-operation/re-excision

Clinical question 3

In patients with breast cancer, what subgroups should have staging investigations performed to detect distant metastases?

Population	Patients with breast cancer
Intervention	Staging investigations to detect metastases
Control	
Outcome	To detect distant metastasis - What subgroups

Clinical question 4

In patients with breast cancer who are being staged, what investigations should be performed?

Population	Patients with breast cancer (where staging is required)
Intervention	Contrast-enhanced CT-TAP alone
Control	Contrast-enhanced CT-TAP with bone scan
Outcome	To detect distant metastasis

Population	Patients with breast cancer (where staging is required)
Intervention	Contrast-enhanced CT-TAP alone
Control	PET-CT
Outcome	To detect distant metastasis

5.2 Describe and document the evidence search

The clinical questions outlined above were used to conduct literature searches of primary literature. A systematic literature review protocol was developed for the guideline development process by the HSE librarians in conjunction with the NCCP and is available upon request. The literature search strategies for each key question are available upon request.

5.3 Describe the method of screening and evidence appraisal

An evidence methodologist and two senior research officers screened the literature searches independently to identify relevant primary papers. Any disagreements on primary paper inclusion were agreed through discussion.

All primary papers deemed suitable for inclusion were appraised using validated checklists developed by the Scottish Intercollegiate Guideline Network (SIGN).

There were three main points considered when appraising the research evidence:

- Are the results valid? (internal validity)
- What are the results? (statistical and clinical significance)
- Are the results applicable/generalisable to the patient/population of the guideline? (external validity)

The GDG assigned each recommendation a quality of evidence and grade of recommendation. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach provides an explicit system for rating the quality of evidence and whether the recommendation is strong or weak (Guyatt et al., 2008). Further details are available in Appendix III.

5.4 Resource implications

Any potential barriers or resource implications of implementing the recommendations were identified by the guideline development group during meetings to discuss and agree the clinical recommendations. These are documented under ‘Resources, capacity, equity and other considerations’ for each clinical question in Section 4 National Clinical Guideline.

5.5 Consultation

5.5.1 National review

The draft guideline was signed-off by the GDG before going to national stakeholder review.

It was placed on the NCCP website and circulated to relevant organisations and individuals for comment between 5th July and 16th August 2024.

Stakeholders were asked to comment on the comprehensiveness of evidence used to form the recommendations. Stakeholders were required to submit feedback with supporting evidence on a form provided along with a completed conflict of interest form.

5.5.2 International review

The draft guideline was also submitted for international expert review. The GDG nominated the following experts to provide feedback on the draft guideline:

- …
- …
- …

The reviewers were chosen by the GDG based on their in-depth knowledge of the subject area and guideline development processes. The review followed the same procedure as the National Review.

All feedback received was reviewed by the GDG. Suggested amendments and supporting evidence were reviewed and consensus reached to accept or reject the amendments. All modifications were documented and the report is available upon request.

5.6 National implementation plan

An implementation plan was developed based on the NCEC Implementation guide (DoH, 2018). It outlines the actions required to implement each recommendation, who has lead responsibility for delivering the action, the timeframe for completion and the expected outcomes of implementation (see Appendix IV National Implementation Plan).

This National Clinical Guideline including the implementation plan should be reviewed by the multidisciplinary team and senior management in the cancer centre/hospital as it outlines the actions required to implement the recommendations.

The CEO, General Manager and Clinical Lead of each cancer centre/hospital have corporate responsibility for the implementation of the National Clinical Guideline and to ensure that all relevant staff are appropriately supported to implement the guideline.

The National Clinical Guideline will be circulated and disseminated through the professional networks who participated in developing and reviewing this document.

5.7 Governance and approval

The guideline was submitted to the NCCP Executive Management Team on …….. for approval.

A full list of the members can be found in Appendix II: Membership of NCCP Executive Management Team.

5.8 Communication and dissemination plan

This National Clinical Guideline is available on the HSE National Central Repository.

A Communication and Dissemination Plan was developed by the GDG to raise awareness of the development of this guideline, to ensure effective communication and collaboration with all key stakeholders throughout the various stages of guideline development process and to maintain momentum for the widespread adoption of the guideline.

In conjunction with the HSE Communications Division, key stakeholders were identified and a list of strategies was developed to inform them of the new guideline. The implementation of the guideline will also be supported by communication, training and education. Details of the Communication and Dissemination Plan are available upon request.

5.9 Sustainability

5.9.1 Plan for national monitoring and audit

5.9.1.1 Monitoring

Each cancer centre/hospital should implement a systematic process of gathering information and tracking over time to achieve the objectives of this guideline.

The Breast Cancer Tumour Conference in each cancer centre/hospital should monitor the implementation of recommendations specific to their practice.

5.9.1.2 Audit

It is important that implementation of this National Clinical Guideline is audited to ensure that this guideline positively impacts patient care. Each cancer centre/hospital should audit implementation of this guideline at least annually.

A number of metrics were discussed by the GDG which could be used by cancer centres/hospitals to audit their compliance with the recommendations and assess any discrepancies between the guideline and clinical practice.

5.10 Review/update

This guideline was issued in …… 2024 and will be considered for review by the NCCP in three years.

Surveillance of the literature base will be carried out periodically by the NCCP. Any updates to the guideline in the interim period where new evidence emerges or as a result of three year review will be noted in the guidelines section of the NCCP websites.

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7 Abbreviations

CI	Confidence interval
CNS	Clinical nurse specialist
CT	Computed tomography
CT-TAP	Computed tomography – thorax, abdomen, pelvis
ER	Estrogen receptor
ESMO	European Society of Medical Oncology
EUSOBI	European Society of Breast Imaging
GDG	Guideline development group
GP	General Practitioner
HER2	Human epidermal growth factor receptor 2
HR	Hazard ratio
HSE	Health Service Executive
I^2	Heterogeneity
MDT	Multidisciplinary team
MR	Magnetic resonance
MRI	Magnetic resonance imaging
NCCN	National Comprehensive Cancer Network
NCCP	National Cancer Control Programme
NCEC	National Clinical Effectiveness Committee
NICE	National Institute for Health and Care Excellence
NPV	Negative predictive value
OR	Odds ratio
p	p-value
PET	Positron emission tomography
PPV	Positive predictive value
PR	Progesterone receptor

RCR Royal College of Radiologists

RCT Randomised controlled trial

RR Relative risk

SBD Symptomatic breast disease

8 Glossary of Terms

Benefits and Harms
Benefits refer to improved quality of life and reductions in mortality and morbidity. There are physical risks of harm such as exposure to radiation and there are also emotional and psychological risks of harm such as anxiety and depression.

Body habitus
Describes the physical characteristics of an individual and includes such considerations as physique, general bearing, and body build.

Breast density
A term used to describe the amount of dense tissue compared to the amount of fatty tissue in the breast on a mammogram. Dense breast tissue has more fibrous and glandular tissue than fat. There are different levels of breast density, ranging from little or no dense tissue to very dense tissue. The more density, the harder it may be to find tumours or other changes on a mammogram.

Confidence intervals
Confidence intervals indicate the consistency, or variability of a result. If a study has 95% confidence interval calculated, the means that if the study was repeated multiple times with samples from the whole population and the confidence intervals were calculated for each of those repeated studies, then the true value would lie within the calculated confidence intervals 95% of the time.

Incidental findings
Findings that are unrelated to the clinical indication for which the imaging examination is being performed, in other words an abnormality that is not suspected to be breast-cancer related.

Good practice points
Good practice points are based on the clinical expertise of the Guideline Development Group.

Hazard ratio
A measure of how often a particular event happens in one group compared to how often it happens in another group, over time.

Negative predictive value
In the context of cancer investigations this describes the proportion of patients with a normal test result who do not have cancer.

Odds ratio
An odds ratio (OR) is a measure of association between an exposure and an outcome. The OR represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure. Odds ratio can be expressed as <1 indicating that the intervention group had more favourable outcome than the control group, >1 indicating worse outcome for the intervention group, and 1 indicating no difference between groups.

p-value
The p-value is related to the significance level. If the critical alpha value is 0.05, then the p-value must be smaller than 0.05 for the test to have a statistically significant result. If the p-value is greater than the critical alpha value, then the test does not have a statistically significant result.

Positive predictive value
In the context of cancer investigations this describes the proportion of patients with an abnormal test result who do have cancer.

Practical considerations regarding patient care
These are statements developed with the patient Guideline Development Group members on issues that were important to them with regards to their own experience of the diagnosis and staging of their cancer.

Preferences and values
The patient preferences and values statements were developed by the multidisciplinary Guideline Development Group including patient representatives. Patient members were given priority during guideline meetings to discuss preferences and values.

The Guideline Development Group tried to identify what an informed patient and their families would prefer. The value statements refer to what the Guideline Development Group believe are the values that are driving patient and family preferences.

Relative risk
A measure of the risk of a certain event happening in one group compared to the risk of the same event happening in another group. A relative risk of 1 means there is no difference between two groups in terms of their risk of cancer, based on whether or not they were exposed to a certain substance or factor, or how they responded to two treatments being compared. A relative risk >1 or <1 usually means that being exposed to a certain substance or factor either increases or decreases the risk of cancer, or that the treatments being compared do not have the same effects.

Sensitivity
Sensitivity describes how well a test can detect a specific disease or condition in people who actually have the disease or condition.

Specificity
When referring to a medical test, specificity refers to the percentage of people who test negative for a specific disease among a group of people who do not have the disease.

Staging
Performing tests to learn the extent of the cancer within the body, especially whether the disease has spread from where it first formed to other parts of the body.

Tumour conference
Previous known as multidisciplinary team (MDT) meetings.

A tumour conference involves a group of people from different healthcare disciplines, who meet together at a given time (whether physically in one place, or by video or tele-conferencing) to discuss a given patient and who are each able to contribute independently to the discussion on diagnosis and to make recommendations on patient management. It provides a forum for multidisciplinary teams to regularly convene and discuss the diagnosis and management of cancer patients.

9 Appendix

Appendix I Members of the Guideline Development Group

A conflict of interest form was signed by all members of the GDG. No conflicts of interest were declared.

Name	Title/position	Role on guideline group
Chairs of the Guideline Development Group		
Prof Deirdre Duke	Consultant Radiologist, Beaumont Breast Centre, Beaumont Hospital	Co-chair, writing member
Dr Eve O'Toole	Head of Evidence & Quality Hub, NCCP	Co-chair, writing member
Patient representatives		
Ms Kathleen O'Connor	Patient Representative	Writing member
Ms Aisling Dempsey	Patient Representative	Writing member
Radiology		
Ronan McDermott	Consultant Radiologist, St James's Hospital	Writing member
Dr Laura Sweeney	Consultant Radiologist, University Hospital Waterford	Writing member
Dr Emma Griffin	Specialist Registrar (Radiology), Beaumont Hospital	Writing member
Dr James Diedrich	Specialist Registrar (Radiology), Tallaght Hospital	Writing member
Dr Alexandra Booth	Specialist Registrar (Radiology), Northern Ireland Medical and Dental Training Agency	Contributor
Dr Katherine O'Boyle	Specialist Registrar (Radiology), Northern Ireland Medical and Dental Training Agency	Contributor
Nursing		
Ms Maeve Stenson	Advanced Nurse Practitioner, St James's Hospital	Writing member
Library		
Ms Linda Halton	HSE Librarian	Information services
NCCP		
Ms Deirdre Love	Evidence Methodologist, NCCP	Project manager, senior researcher, writing member
Dr Niamh Kilgallen	Senior Research Officer	Writing member
Mr Peter Dennan	Clerical Officer	Administrative support

Appendix II Membership of NCCP Executive Management Team

Name	Role and position

Sign-off by Chair of Approval Governance Group

National Clinical Guideline: Diagnosis and staging of patients with breast cancer was formally ratified and recorded in the minutes of the Approval Governance Group on …….

Name: (print)	
Title:	
Signature: **(e-signatures accepted)**	

Appendix III Grading the recommendations in this guideline

The Guideline Development Group assigned each recommendation a quality of evidence and grade of recommendation. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach provides an explicit system for rating the quality of evidence and whether the recommendation is strong or weak (Guyatt et al., 2008).

Quality of evidence

It is recognised that in guideline development that just assessing the level of evidence does not take into account the methodological quality of each individual study or the quality of the body of evidence as a whole (Harbour and Miller, 2001). The Guideline Development Group used an amended GRADE system which considers the following factors when classifying the quality of evidence; high, moderate or low (Guyatt et al., 2008):

- Study design
- Study design limitations
- Consistency of results
- Directness of the evidence
- Imprecision of results
- Reporting bias

Table i: Quality of evidence adapted from GRADE working group 2013

High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Grade of recommendation

There are two grades of recommendation: strong or weak. These reflects the balance of the following items:

- The quality of the body of evidence
- The balance between benefit and harm to patient
- Patient preferences and values
- Resources/cost

Table ii: Grade of recommendation adapted from GRADE working group 2013

Strong	A strong recommendation is one for which the Guideline Development Group is confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention). Strong recommendations are not necessarily high priority recommendations. A strong recommendation implies that most or all individuals will be best served by the recommended course of action.
Weak	A weak recommendation is one for which the desirable effects probably outweighs the undesirable effects (weak recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists. A weak recommendation implies that not all individuals will be best served by the recommended course of action. There is a need to consider more carefully than usual the individual patient's circumstances, preferences, and values. When there are weak recommendations caregivers need to allocate more time to shared decision-making, making sure that they clearly and comprehensively explain the potential benefits and harms to a patient.

Appendix IV National Implementation Plan

National Clinical Guideline: Diagnosis and staging of patients with breast cancer
Date National Clinical Guideline approved:
Expected date of full implementation:
Lead responsibility for national implementation: Hospital/Cancer Centre; Breast Cancer Tumour Conference

Implementation action	Implementation barriers / enablers	List of tasks to implement the action	Lead responsibility for delivery of the action	Expected completion date	Expected outcomes
Dissemination to all breast cancer centres via CEO/hospital manager/clinical leads	Enabler: Notice re updated guideline to be prepared by the NCCP for dissemination.	Disseminate guideline	National Director NCCP CEO/hospital manager and clinical leads in all cancer centres	On publication of the guideline	All healthcare staff involved in the diagnosis and staging of patients with breast cancer will be aware of the publication of a new guideline and recommendations.
Need for increased radiology resources, including additional imaging (MRI scanners), image-guided biopsy, histopathology, and	Barrier: Structural factors (e.g. budget constraints). Organisational factors (e.g. lack of radiology resources - access to imaging equipment and staff).	Secure funding through the HSE service planning process for equipment and access to	Health Regions NCCP as per National Cancer Strategy		All patients with breast cancer will have equal access to the appropriate diagnostic equipment and staff.

Implementation action	Implementation barriers / enablers	List of tasks to implement the action	Lead responsibility for delivery of the action	Expected completion date	Expected outcomes
radiology staff (radiologists with a specialist interest in breast imaging).	Enabler: - National Cancer Strategy recommendation 14: *The NCCP, working with the other Directorates in the HSE and with the Department of Health, will develop a rolling capital investment plan, to be reviewed annually, with the aim of ensuring that cancer facilities meet requirements.* - National Cancer Strategy recommendation 16: *The NCCP will ensure that consultant appointments for radiology, endoscopy and histopathology, where necessary, are made in conjunction with appointments in other disciplines such as surgery and medical oncology.* - National Cancer Strategy recommendation 50: *The NCCP, aided by a cross sector group, will draw up a comprehensive workforce plan for cancer services.*	imaging capacity. Secure funding through the HSE service planning process for further staffing.	recommendation 14, 16, 50.		Accurate diagnosis and timely staging.

Implementation action	Implementation barriers / enablers	List of tasks to implement the action	Lead responsibility for delivery of the action	Expected completion date	Expected outcomes
	This will include an interim assessment of staffing needs at medical, nursing and health & social care professional levels by mid-2018.				

Appendix V Plain Language Summary

Summary of National Clinical Guideline

This National Clinical Guideline contains evidence-based recommendations.

For patients with symptoms of breast cancer, it covers:

- which patients should get further scans to determine if they have cancer
- what type of imaging investigations should be considered

For patients with confirmed breast cancer, it covers:

- which patients should be considered for imaging investigations to determine if their cancer has spread to other parts of the body
- what type of imaging investigations should be considered

This guideline does not cover patients who are experiencing signs or symptoms related to their cancer.

The recommendations describe which imaging tests (MRI, contrast enhanced CT-TAP, bone scan, PET-CT) may be used. Not all patients will need nor decide to have imaging tests - this is a joint decision with their doctor. Ask your doctor or any member of your treating team if you want to know what your cancer stage is, this is information which should be made available to you.

What does this guideline mean for you?

Questions you may want to ask your healthcare professionals?

- Who will arrange my investigation scan?
- Is it safe?
- What happens during my scan?
- When will I get the results and who will give them to me?
- What happens next?
- Will this impact my day-to-day life?
- Who do I contact if something doesn't feel right or I am feeling unwell?

Understanding the language

Medical Term	Plain language explanation
Biopsy	The removal of cells or tissues for examination by a pathologist.
Image guided biopsy	Imaging technology is used to enables the safe insertion of needles into hard-to-reach places in the body, such as the lungs, kidneys, liver, lymph nodes, and the bones.
Bone scan	An imaging scan that uses a radioactive substance to visualise the bones, showing cell activity in the bone.

CT-TAP	An imaging scan that uses a combination of X-rays and computer technology to produce images of the inside of the body.
MRI	An imaging scan that uses magnets and radio waves to take detailed pictures (2D/3D) of the body's organs, muscles, soft tissues, and structures. It does not use radiation. It is sometimes used to clarify queries on other scan.
PET-CT	An imaging scan of the full body using a small amount of radioactive substance. It can help to identify if and to where the cancer has spread.
Staging	An assessment of the size of a cancer and whether it has spread to other parts of the body. This assessment helps the doctor decide the best treatment.
Stage I	The cancer is small (<2cm) and is only in the breast. It is also known as early stage breast cancer.
Stage II	The cancer is small (2-5cm) and is either in the breast or in a few axillary lymph nodes or both. It is also known as an early stage breast cancer.
Stage III	The cancer is larger (>5cm) and has spread from the breast to a greater number of lymph nodes close to the breast or to the chest wall. It is also known as locally advanced breast cancer.
Stage IV	The cancer has spread to another part of the body. It is also known as advanced cancer or metastatic breast cancer.
Metastatic cancer/distant metastases	Cancer that spreads from to other parts of the body.