

Guideline for the Diagnosis of Breast Cancer

Version History

Version	Date Issued	Brief Summary of Change
2.0	May 2007	Approved by the Governance Committee
2.0	25.11.08	Discussed at the NSSG
2.1	5.12.08	Minor changes made following NSSG
2.1	5.12.08	Sent to Andrea Stevens for clarification re needle biopsy
2.2	09.12.08	With comments from AS and for final consultation to the Breast NSSG
2.2	22.12.08	Approved by the Breast NSSG and prepared for Governance procedure
3	21.01.09	Endorsed by the Guidelines Review Sub Group of the Governance Committee following minor amendments
3.1	19.06.12	Guideline up for review. Discussed at the NSSG on 12 th June. Phil Brookes Identified as author for review. Marion Circulated to Phil 18.6.12
3.2	29.06.12	Comments from Phil Brookes and Doreen Cox received and incorporated. Forwarded to KM as NER
3.3	08.08.12	Comments incorporated and sent to the NSSG with 2 week deadline for comments.
3.4	20.08.12	With LB comments
3.5	07.09.12	With comments from Phil Brookes, Adele Francis and Hamish Brown included – awaiting response from the CIU
4.0	14.03.13	With final comments from AJ and DC

1 Scope of the Guideline

This guidance has been produced to support the following:

- The assessment of women referred with suspected breast cancer
- Hormone receptor testing
- Herceptin (HER 2) testing

2 Guideline Background

- 2.1 In recent years, there have been a multitude of publications and guidelines produced by professional and healthcare groups describing the care and treatment individuals with breast cancer should receive.
- 2.2 There is a need to bring together these various themes and recommendations in a single document to ensure that up to date research, current thinking, and local expert opinion have been considered.

Guideline Statements

3 Initial Assessment (pre-operative)

- 3.1 All patients, regardless of route of referral should receive care within the context of a specialist team comprising surgeons, radiologists, breast physicians, specialist nursing and pathology staff.
- 3.2 Initial diagnostic tests should be carried out in one day (excepting where anticoagulant medication needs to be changed) and should include the following triple assessment:
- I. clinical examination
 - II. mammography and ultrasound including ultrasound assessment of the axilla where cancer is suspected clinically or on initial imaging
 - III. material for cytology / histology: core biopsy material should be obtained in all but exceptional circumstances
- 3.3 The diagnosis of cancer should be based on the review of all three assessments described in 3.2 above.
- 3.4 Additional tests:
- 3.3.1 where abnormal axillary nodes are seen, they should be further assessed with core biopsy (preferred) or fine needle aspiration cytology
 - 3.3.2 a specimen image should be available for review in pathology if the core biopsy is performed for micro-calcification
- 3.5 A breast care nurse or clinical nurse specialist should be available to the patient on the day of the triple assessment.

- 3.6 Results should be available within 5 working days, and for those diagnosed with a malignancy the breast care nurse or clinical nurse specialist should be present when results are discussed.

4 Histological and hormone testing – pre operative

- 4.1 FNA and core biopsy material should be sent for ER/PGR to the pathology department of the hospital where the surgery is carried out.
- 4.2 Heartlands Hospital and Queen Elizabeth Hospital carry out HER2 and FISH testing. All requests from outside of these hospitals should go to Heartlands Hospital who will distribute the cases between Queen Elizabeth Hospital and Heartlands Hospital.
- 4.3 The following testing should be carried out on the core biopsy material and be available to the MDT **at the treatment planning meeting**.
- a Hormone Receptor Status
Oestrogen receptor status of invasive carcinomas should be assessed by the local hospital on core biopsy. An established scoring system should be used, e.g. quick score or H-score. If the invasive carcinoma is oestrogen receptor negative or poor (e.g. q score of 3 or less, h-score of 50 or less), then **progesterone receptor status** should be measured. Neither oestrogen nor progesterone receptor status is mandatory for in-situ carcinomas. ER status on insitu carcinomas is used by BASO if the information is available. This information is also sometimes required for patients in clinical trials.
- b **HER 2** status for the following cases:
- new invasive carcinomas (not in-situ carcinomas or sarcomas)
 - recurrent carcinomas: the original carcinoma/tumour block **or (preferably)** excised metastasis/recurrence should be tested if the result is required for treatment planning

5 Histological and hormone testing – post operative

- 5.1 Following surgery 6 unstained 3um sections on coated slides should be prepared and haematoxylin and eosin (H&E) testing should be carried out. A copy of the original histology report should be sent with the specimen.
- 5.2 Following MDT discussion a repeat of the ER/PGR/HER2 (if negative on the core) from the excision specimen may be requested, which should be available at the patient's first oncology appointment.

- 5.5 If recurrent or metastatic tissue is excised, then this material is preferred (for histological assessment) to the primary tumour.
- 5.6 Fluorescent in-situ hybridisation (FISH) should be performed where the HER 2 is scored as grade 2.

6 Staging

- 6.1 Staging data for all breast cancers should be collected electronically and transferred to the West Midlands Cancer Intelligence Unit (WMCIU). For patients with breast cancer this should be done at the postoperative MDT. Both the NPI and TNM staging should be recorded on the patient database.
- 6.2 All Trusts
 - a. The Trust should send electronic extracts from their histopathology system regularly to the WMCIU.
 - b. The Trust should send imaging extracts for cancer patients electronically to the WMCIU regularly, or establish remote access for the WMCIU to their radiology information system and / or data warehouse.
 - c. Data extracts should be sent in line with the cancer registry dataset / cancer outcomes and services dataset guidance.
- 6.3 For those with **invasive cancer undergoing surgery**
 - a. MDTs record the full cancer registry dataset onto their MDT database at the time of discussion at the MDT meeting.
 - a. Staging extracts for all patients are sent to the WMCIU within 6 months of diagnosis.
- 6.4 For those with **invasive cancer not having surgery**
 - a. Clinical stage and biopsy data should be recorded on the MDT database.
 - b. Staging extracts for all patients are sent to the WMCIU within 6 months of diagnosis.

7 Performance Status

All patients should have their performance status recorded onto the MDT database at the MDT. This should be done using the WHO classification which will ensure it is in line with the cancer outcomes and services dataset guidance.

8 Clinical Trials

- 8.1 Wherever possible, patients who are eligible should be offered the opportunity to participate in National Institute for Health Research portfolio clinical trials and other well designed studies.

- 8.2 Where a study is only open at one Trust in the Network, patients should be referred for trial entry. A list of studies available at each Trust is available from the Pan Birmingham Cancer Research Network. Email: PBCRN@westmidlands.nhs.uk
- 8.3 Patients who have been recruited into a clinical trial will be followed up as defined in the protocol.

9. Patient Information and Counselling

- 9.1 A named key worker (usually the CNS) should be identified for each patient. All patients, and with their consent, their partners will be given access to appropriate written information during their investigation and treatment, and on diagnosis will be given the opportunity to discuss their management with a clinical nurse specialist who is a member of the relevant MDT. The patient should have a method of access to the breast team at all times, usually via the named CNS or key worker.
- 9.2 Access to psychological support will be available if required. All patients should undergo an holistic needs assessment and onward referral as required.

10 Bony Metastases

- 10.1 All patients diagnosed with a metastasis to **any bone** should receive information about the possibility of developing metastasis to the spine. This is essential to enable patients to report signs of spinal metastases early, thereby offering treatment options that may prevent damage to the spinal cord and unnecessary disability.
- 10.2 This information should be offered by a senior cancer clinician (for example a CNS or consultant). The patients should be advised about what to look for and what to do in the event that they have symptoms and/or signs of spinal metastases.
- 10.3 Patients should be provided with information about the symptoms and/or signs of spinal cord compression and what to do if they develop them. This discussion should be supported by written information in the form of the PBCN Patient Information on Cancer that has Spread to the Bone (Bone Metastases) and the Patient Alert Card. <http://www.birminghamcancer.nhs.uk/patients/leaflets/bone-cancer>

11. Palliative Care

Palliative care services will be made available to all patients as deemed appropriate by the MDT.

