East Midlands Strategic Clinical Networks

East Midlands Breast
Expert Clinical Advisory Group (ECAG)

Management and Clinical Guidelines for the Investigation and Treatment of Breast Cancer

Version 2.2

Status:	**Final**
Ratified by:	**Dr Samreen Ahmed ECAG Lead & Members on 23rd March 2015**
Inclusions:	**June 2010 – TYA Pathway** **June 2012 – Chemotherapy Algorithms** **January 2013 – Minimum Risk Stratified Pathway** **March 2015 – ABS Consensus Statement**
Review date:	**March 2017**

Contents

Clinical and Referral Guidelines
(Demonstrating Compliance with Measure 13-1C-104b)

The East Midlands Breast ECAG has agreed that the referral guidelines for Breast Cancer are those contained in the NICE Guidance which can be downloaded from www.nice.org/CG027 The Network Teams have also adopted the Going Further on Cancer Waits: Symptomatic Breast Two Week Wait Standard and will be fully compliant by December 2009.

- **The point of contact for Referral for Suspected Cancer** has been agreed in each Trust as follows:

Trust	Named Contact	Telephone/Email
Kettering General Hospital	▪ Trudi Vanni	01536 493303 trudivanni@nhs.net
Northampton General Hospital	▪ 2ww Office	01604 544235
University Hospital Leicester	▪ Rosey Spence ▪ 2ww Office	0116 250 2543
Derby Hospitals	▪ 2ww Office	01332 788395
Burton	▪ Patient Access Centre	01283 593200
King's Mill	▪ Choose and Book team (2WW office)	01623 676007
Nottingham University Hospitals	▪ 2ww Office	0115 8405801 twoweekwaitoffice@nuh.nhs.uk
United Lincolnshire Hospitals	▪ Julie Miller Appointments Team Leader	01522 573738 Fax:- 01522 573351 2WeekWaitTeamLincoln@ulh.nhs.uk

Measure 13-1C-106b: The Guideline for onward referral to another MDT either within or out with the Network is on page 6.

Measure 13-1C-104b: The East Midlands Cancer Network Breast ECAG Pathology Guidelines were agreed as:

The Pathology Reporting of Breast Disease: NHSBSP Publication No 58 (Jan 2005).

This is a joint document incorporating the third edition of the NHS Breast Screening Programme's *Guidelines for Pathology Reporting in Breast Cancer Screening* and the second edition of the Royal College of Pathologists' *Minimum Dataset for Breast Cancer Histopathology.*

http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp58.html
Measure 13-1C-104b: The East Midlands Breast ECAG adopted as the Breast Network Imaging Guidelines:

The NHSBSP Clinical Guidelines for Quality Assurance Guidelines for Breast Cancer Screening Radiology Publication No 59 (2005)

http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp59.pdf

and

The Royal College of Radiologists: Recommendations for Cross Sectional Imaging in Cancer Management (RCR (06)1)
www.rcr.ac.uk/publications.aspx?PageID=310

The Standards for communication of critical, urgent and unexpected significant radiological findings

www.rcr.ac.uk/publications.aspx?PageID=310

Non-surgical oncology guidelines will be reviewed by the Oncology Subgroup.

Follow Up Guidelines were agreed as:

The Follow Up Guidance for the EMCN Breast ECAG is as in the publication of NICE Guidance (CG80 – February 2009).
http://www.guidance.nice.org.uk/CG80

Prior to this the Trusts had been compliant with the previous agreed guidance, namely follow up for 2-3 years after completion of treatment, with the exception of high risk patients and those in clinical trials where follow up was tailored to individual risk or the trial protocol.

High risk and trials patients will continue to be dealt with on an individual basis.

Follow Up at Patient Request remains open access via the key worker – usually the Breast Care Clinical Nurse Specialist or the team secretary.

Genetics services are provided within the East Midlands and follow:
Familial Breast Cancer: The classification of women at risk of familial breast cancer in primary secondary and tertiary care (Oct 2006: National Collaborating Centre for Primary Care).

East Midlands Cancer Network Breast ECAG Agreed
Referral Guidelines to other MDTs
(Demonstrating Compliance with Measures 13-1C-106b)

All new breast cancer patients must be discussed at a breast MDT. This will, in the first instance, almost always be in the Trust receiving the first referral. This is for the purpose of this guideline 'the *First MDT*'.

Referrals from first MDT to second MDT within or out with the East Midlands Cancer Network by reason of referral as follows:

1. Further consideration of a complex case

(E.g. borderline decision for surgery due to extensive co-morbidity, rare tumour, diagnostic uncertainty, etc.)
All cases in this category must be discussed by the second MDT. The second MDT decisions would usually supersede the decisions of the first MDT. The second MDT will take lead responsibility in this case

2. Second opinion requested by patient or first MDT

All such cases will be discussed at the second MDT. The two sets of views will be considered in the decision making with the patient.

3. Referral to another specialist for further tests/treatment

Many staff participate in more than one MDT. It is not therefore necessary to discuss straightforward cases again at a second MDT (e.g. radiotherapy, uncomplicated surgery, etc.). However these patients may be discussed if the clinician receiving the referral feels it would be of advantage or it is second MDT policy.

Lead responsibility will remain with the first MDT.

4. Communication and waiting times

Good and rapid communication between the MDTs involved is vital. The MDT co-ordinator for each breast MDT should have a list of all fax numbers for MDT co-ordinators across the network(s). Referrals should be faxed in the first instance.

1. Introduction

The management of breast cancer will be the same regardless of whether the diagnosis is made in a screening or symptomatic setting.

Management of breast cancer will be organised and performed to National Standards laid out in current Professional and Governmental Guidelines.

These are laid out in Documents produced by the Association of Breast Surgery at BASO, the National Institute of Clinical Excellence, and the Royal Colleges of Pathology and Radiology.

These Guidelines are supported by Cancer Network (E Midlands) and Trust produced documents that outline local and regional variations in practice and are appropriate to individual staff groups and infrastructure differences in individual localities.

Quality Assurance will be outlined and measured by a Programme of Local, Regional and National Audit processes.

The Administration of the Breast Multi- Disciplinary Team is described in a separate Document – The Local Breast Cancer Multi-Disciplinary Meeting Operational Policy.

All Trusts within the East Midlands Clinical Network are expected to follow this guideline. The Trusts within the East Midlands Clinical Network are:

- Burton Hospitals NHS Foundation Trust (BHFT)
- Derby Hospitals NHS Foundation Trust (RDH)
- Kettering General Hospital NHS Foundation Trust (KGH)
- Northampton General Hospital NHS Trust (NGH)
- Nottingham University Hospitals (NUH)
- Sherwood Forest Hospitals NHS Foundation Trust (SFHT)
- United Lincolnshire Hospitals NHS Trust (ULHT)
- University Hospitals of Leicester NHS Trust (UHLT)

2. Multidisciplinary Care

The breast multidisciplinary team (MDT)

Breast cancer care should be provided by breast specialists in each discipline and that multidisciplinary teams form the basis for best practice. The constituent members of the Breast Team are conveniently divided into two separate but inter-dependent groups.

a) Breast Diagnostic Team

As most patients do not have breast malignancy, the role of the breast clinic is both to diagnose breast cancer and to treat and reassure patients with benign breast disorders. The key component members of this group are:

- Breast Specialist Clinician normally a Consultant Surgeon with an interest in breast disease and their team which may include Associate Specialists, Breast Clinicians, Staff Grade Surgeons and Specialist Trainees.
- Specialist Breast Radiologist, Breast Radiographers and Breast Radiographic Assistants
- Pathologist (Cytopathologist and/or Histopathologist) and Laboratory Support Staff
- Breast Care Nurse
- Nurse Practitioner
- Clinic Staff
- Administrative Staff
- Dedicated MDT Co-ordinator

b) Breast Cancer Treatment Team

This will include members of the Diagnostic Team as well as the following:

- Clinical Oncologist
- Medical Oncologist
- Plastic and Reconstructive Surgeon and/or Oncoplastic Breast Surgeon
- Medical Geneticist
- Data Management Personnel
- Cancer Specialist and Research Nurse
- Lymphoedema specialist
- Medical Prosthetist
- Clinical Psychologist
- Palliative Care Team

The core and extended team members for each local MDT are listed in the Local Breast Cancer Multi-Disciplinary Team Operational Policy.

Multidisciplinary team meetings

Consultants and other team members within the breast unit must have contractual time for attendance at the multidisciplinary team meeting. The MDT meeting is by definition a fixed clinical commitment. For medical staff, all MDT related activity should be recognised in the job plan: this includes the time involved in preparation, the meeting itself and post-meeting administration. It is essential for trainees within breast surgery and its related disciplines to attend the MDT meeting.

A record of attendance should be kept, and trainees should record attendance in their logbook. The conclusions of patient discussion should be recorded in the case notes. Everyone involved in the NBSS should attend MDTM's containing screening assessment cases on a regular basis.

A designated member of the clerical team (MDT Co-ordinator) should have the responsibility to co-ordinate this process. This may be shared with a secretarial or data management function. This is an important, responsible role and appropriate time should be available to discharge this effectively.

Video-conferencing facilities should be available to permit discussion between units, if required.

At least one Multi – Disciplinary Team Meeting will be held each week.

Patients are discussed at up to 3 Stages in the management of care.

a) Diagnostic

This is where new cases are discussed. Discussion is considered for all cases where a needle biopsy has been carried out. The imaging and pathology (core biopsy / fine needle aspiration) results should be available. The correlation of results of triple assessment should be reviewed. All patients diagnosed with breast cancer should be discussed prior to instigation of therapy whether surgery, neo-adjuvant or primary medical therapy. Results of all required prognostic and predictive factors (including ER status and ideally HER2 status) should be available for this discussion.

b) Treatment planning

This is also known as the 'post-operative results' MDT, whereby the pathology results of definitive treatment (usually surgery) are discussed and appropriate adjuvant treatment options decided. Results of all required prognostic and predictive factors (ER, HER2) must be available for this discussion.

c) Re-presentation

This is where a previously treated patient re-presents with symptoms. A common instance of this might be the re-presentation of a patient with suspicious symptoms and a diagnosis of metastatic disease.

3. Diagnosis

All breast referrals will be seen within 2 weeks from GP referral. Cases will be managed, by routine, in a one-stop clinic style with imaging and biopsy performed on the same day where appropriate according to local written protocols.

Wherever possible, a non-operative breast cancer diagnosis should be achieved by triple assessment, (clinical and radiological assessment followed by core biopsy and/or fine needle aspiration). Whilst core biopsy is preferable due to the additional information it can provide, there may be circumstances where a fine needle aspiration is appropriate or only possible.

A non-operative diagnosis should be possible in the vast majority of invasive breast cancers, with a minimum standard of achieving this in at least 90% of cases and a target of more than 95%. The majority of non-invasive breast cancers will be screen-detected and impalpable, making a non-operative diagnosis potentially more difficult. The minimum standard for non-operative diagnosis is at least 85% of cases for non-invasive cancers with a target of more than 90%.

Diagnostic excisions

Diagnostic excision biopsy is now relatively unusual, with the advent of triple assessment and also the increasing use of vacuum assisted biopsy for difficult cases. However, some breast lesions may still require diagnostic excision, if the core biopsy or FNA is not benign. Hence lesions graded as B3/4 or C3/4 may still need to be removed for definitive histology. Such lesions are more likely to emanate from the NHSBSP than the symptomatic clinic. To minimize patient anxiety, an operation for diagnostic purposes should be within two weeks of the decision to operate. For patients having surgical removal of a pathologically proven benign lesion the 18 week target waiting time will apply.

All diagnostic biopsy specimens should be weighed. More than 90% of diagnostic biopsies for impalpable lesions, which subsequently prove to be benign, should weigh less than 20 g in line with the current Quality Assurance Guidelines for Surgeons in Breast Cancer Screening. Any benign diagnostic resection specimen weighing more than 40 g will be discussed at the post operative MDT Meeting and any mitigating reasons recorded, and if a screening case, also discussed at the next Quality Assurance visit to that unit.

Frozen sections with immediate pathological reporting at surgical breast biopsy should not be performed except in very unusual circumstances and the reasons documented.

4. Treatment Planning and Patient Communication

Each breast MDT must have written guidelines for the treatment of breast cancer, which have been formulated and agreed by the local breast multidisciplinary team. The treatment of patients should usually follow these guidelines, although it is accepted that there may be reasonable exceptions. The reasons for not following guidelines should be discussed at the MDT meeting and documented. There should be continuity of care as far as possible with regards care under a named specialist team.

Following confirmation of a breast cancer diagnosis and appropriate MDT discussion to plan management, the results should be discussed with the patient. Patients should be encouraged to bring a partner or friend with them when the results are being discussed. The person conducting the consultation should be a member of the Breast MDT and the breast care nurse should be present. It should take place in an appropriate environment with adequate privacy. The follow up arrangements should be clear and the patient must

know how to access the breast care nurse and other relevant components of their care plan.

Patients must be given adequate time, information and support in order to make a fully informed decision concerning their treatment. This must include discussion of suitable treatment options with the surgeon in liaison with the breast care nurse. The treatment options offered should have been agreed at a MDT meeting and patient refusal of the recommended treatment options should be recorded.

Close communication must be maintained between surgeons and oncologists to plan primary treatment and to facilitate subsequent adjuvant therapy. A care plan for each patient must be drawn up. It must take account of factors predictive of both survival and of local or regional recurrence, the age and general health of the patient, the social circumstances and patient preferences. Treatment planning should allow adequate time for discussion of oncoplastic/reconstructive surgical options for those women who wish to consider it.

Breast cancer at diagnosis is classified broadly into three clinical categories:

a) Operable Primary Breast Cancer

The majority of breast cancer cases, presenting symptomatically or diagnosed through breast screening, will fall into this category. Surgery will usually be the first treatment.

Neoadjuvant endocrine treatment may be appropriate in some instances to downstage bulky disease to facilitate breast conserving surgery in post menopausal women with ER positive breast cancers.

Preoperative systemic therapy can be offered to patients with early invasive breast cancer who are considering breast conserving surgery that is not advisable at presentation. However, the increased risk of local recurrence with breast conserving surgery and radiotherapy rather than mastectomy after systemic therapy should be discussed with and written information on this provided to the patient. (NICE CG80)

Where neoadjuvant therapy is given with the aim of facilitating breast conserving surgery this will be according to written local protocols.

b) Locally advanced Primary Breast Cancer

The management of locally advanced primary breast cancer will be multidisciplinary and will initially require a core biopsy and staging investigations. In some patients medical treatment, (hormonal/chemotherapy) and/or radiation therapy may be the most appropriate initial treatment.

The management of locally advanced primary breast cancer will be according to written local protocols.

Offer local treatment by mastectomy (or, in exceptional cases, breast conserving surgery) followed by radiotherapy to patients with locally advanced or inflammatory breast cancer who have been treated with chemotherapy. (NICE CG80)

c) Metastatic breast cancer

Following the symptomatic presentation of distant metastases, average life expectancy is approximately 2 years, with virtually all patients eventually dying from breast cancer. The aim of treatment is to palliate symptoms and to maintain the highest possible quality of life. The management of patients with metastatic breast cancer should be multidisciplinary. Although the majority of patient care is likely to be delivered by oncologists and the palliative care team some surgeons with established experience in this field may continue to be involved in the multidisciplinary team. In addition all breast surgeons need to be involved with the local control of the disease.

The management of metastatic breast cancer will be according to written local protocols. Guidance around systemic therapies is available on the East Midlands Cancer Network website. http://www.eastmidlandscancernetwork.nhs.uk/Library/AdvBreast.pdf

Recurrent breast cancer

A multidisciplinary approach is needed in the management of patients with recurrent breast cancer. All patients presenting with recurrent breast cancer will be restaged prior to definitive management. A significant proportion of patients presenting with 'local recurrence' will have systemic relapse as well. Those patients with widespread disease should be managed by systemic therapy if possible.

The management of recurrent breast cancer will be according to written local protocols.

5. Organisation of Breast Cancer Surgical Services

Personnel

Surgical treatment of patients with breast cancer will be carried out by surgeons with a special interest and training in breast disease. Each surgeon is involved in the NHS BSP and will maintain a surgical caseload of at least 10 screen-detected cancers per year, averaged over a three year period. Each surgeon can demonstrate an annual surgical workload of at least 30 treated breast cancers. Breast surgeons work in breast teams, which have the necessary expertise and facilities for a multidisciplinary approach.

Waiting times for surgical treatment

When a decision has been reached to offer surgical treatment, patients will be offered a date for operation rather than be placed on a waiting list. Reconstruction procedures will require logistical planning but should not lead to unnecessary delay. All diagnostic and therapeutic operations are urgent.

The NHS Cancer Plan states that patients should have a maximum wait of 31 days from 'decision to treat' to first treatment. In 2002, this standard was extended to a maximum 62 days wait from urgent GP referral to first treatment. A similar 62 days wait target now applies to screen detected breast cancers, from December 2008, following publication of the Cancer Reform Strategy. Staffing levels must be appropriate to achieve this.

The 'decision to treat' is taken as the date on which the patient is informed by the treating clinician that they require treatment. As previously stated, an operation for diagnostic purposes should be carried out within two weeks of the decision to operate.

Pre-operative investigations

A pre-operative search for occult metastases by radiological investigations such as CT scan, bone scan, liver ultrasound and chest x-ray does not yield useful information in patients with operable primary breast cancer. These investigations will not normally be carried out unless the patient is symptomatic or high-risk of metastases disease. The patient will normally have a full blood count, liver function tests and routine biochemistry and any abnormalities will be investigated appropriately.

6. Surgery for Invasive Breast Cancer

Treat patients with early invasive breast cancer, irrespective of age, with surgery and appropriate systemic therapy, rather than endocrine therapy alone, unless significant co - morbidity precludes surgery (NICE CG80)

Type of breast surgical procedure

Long term follow up of randomised clinical trials have reported similar survival rates for women treated by mastectomy or breast conservation surgery. However all of these studies had selection criteria and indeed the vast majority of patients in these studies presented with tumours <2.5 cms.

Accurate pre-operative assessment of the size and extent of the tumour is essential for deciding whether breast conservation surgery is an alternative option to mastectomy. Routine methods for assessing the extent of disease in the breast are clinical examination, mammography and ultrasound. In some cases the true extent of disease is underestimated, particularly with invasive lobular cancer. The decision to offer MRI will be discussed at the MDT meeting and be according to written local protocols.

Consider Offering MRI of the breast to patients with invasive breast cancer:

- *if there is discrepancy regarding the extent of disease from clinical examination, mammography and ultrasound assessment for planning treatment*
- *if breast density precludes accurate mammographic assessment*
- *to assess the tumour size if breast conserving surgery is being considered for invasive lobular cancer. (NICE CG 80)*
- *occult on mammogram*

Whilst many women may be suitable for breast conservation surgery, various factors (e g biological, patient choice) may lead to some women being advised or choosing to have a mastectomy for their disease.

Wherever possible, patients should be offered an informed choice between breast conservation surgery and mastectomy.

This includes patients with Paget's disease of the nipple that has been assessed as localised.

Offer breast conserving surgery with removal of the nipple-areolar complex as an alternative to mastectomy for patients with Paget's disease of the nipple that has been assessed as localised. Offer oncoplastic repair techniques to maximise cosmesis. (NICE CG80)

Patients choosing or advised to have mastectomy for invasive breast cancer should have the opportunity to discuss whether breast reconstruction is appropriate and feasible. The reasons for not offering choice and/or breast reconstruction to a patient should be documented in the patient's case notes.

Discuss immediate breast reconstruction with all patients who are being advised to have a mastectomy, and offer it except where significant co- morbidity or (the need for) adjuvant therapy may preclude this option. All appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally. (NICE CG80)

Margins of excision

Patients undergoing breast conservation surgery should routinely have malignant tumours excised with microscopically clear radial margins. Close margins at the chest wall (deep margin) or near the skin may be less important so long as an entire cylinder of tissue from the skin to the chest wall has been received. If for any reason, an entire cylinder has not been taken, the pathologist must be informed so that the relevant non-radial margin can also be examined. Where breast tissue is to be moved at the time of surgery (e g oncoplastic techniques) particular consideration must be given to ensuring that further excision of involved margins can be easily carried out.

Histologically involved margins lead to an excessively high risk of local recurrence, even if adjuvant radiotherapy is given. Approximately one in four patients with later local recurrence will succumb to their disease, who otherwise would not have died of breast cancer if they had not developed a local recurrence. There are no data to support a specific margin of excision. There are no randomised trials of margins of excision. NICE have recommended a minimum margin of 2 mm but there is no Level 1 evidence to support this.

Each MDT should have local written guidelines regarding acceptable margin width and individual cases should be discussed at the treatment MDT meeting. If, after MDT meeting discussion, the margin of excision is deemed to be inadequate then further surgery to obtain clear margins should be recommended.

Specimen radiography and handling

Intra-operative specimen radiography is mandatory for impalpable lesions requiring radiological localisation, and should be for all wide local excision procedures. Dedicated equipment (e g, digital specimen radiography cabinet) should be available so that a radiograph can be taken of the specimen and reported to or by the surgeon within 20 minutes. Interpretation of specimen radiographs must be clearly recorded. If this is done by the operating surgeon, the result must be confirmed by the radiologist at the subsequent multidisciplinary team meeting. Radiologists would be unwilling to report/comment on specimens imaged outside the standards and techniques they are required to work to. If a specimen radiograph is performed, this should be available to the reporting pathologist.

The surgeon should orientate and mark the specimen prior to delivery to the pathologist (and radiologist). Each breast unit should have a written protocol for specimen orientation and the handling of pathological specimens.

Surgical Cavities in breast conservation surgery

Consistent and accurate localisation of the tumour resection bed after breast conservation is important if the full benefits of Intensity modulated radiotherapy (IMRT) and further radiotherapy advances are to be obtained. The marking of the tumour bed is especially important when oncoplastic techniques are used to improve the cosmetic outcome. The insertion of markers, such as surgical clips or gold seeds, in the tumour bed by the operating surgeon provides a way of visualising the tumour bed.

7. Axillary Node Management in Invasive Cancer

The presence of axillary node metastases is a powerful prognostic determinant in primary operable breast cancer and its assessment requires histological examination of excised axillary lymph nodes. Appropriate management of the axilla is also important in the

prevention of uncontrolled axillary relapse. Axillary relapse is defined as relapse in the axilla itself and does not include supraclavicular node recurrence.

Some patients with invasive breast cancer may be diagnosed with axillary disease prior to definitive surgery. The use of pre-operative axillary assessment with ultrasound and appropriate fine needle aspiration (or core biopsy if feasible) can yield a diagnosis of involved nodes in some cases.

Pre-treatment ultrasound evaluation of the axilla should be performed for all patients being investigated for breast cancer and, if morphologically abnormal lymph nodes are identified, ultrasound-guided needle sampling should be offered. (NICE CG80)

If a positive non-operative diagnosis of axillary nodal metastasis is made in a patient with early breast cancer, it will proceed to an axillary clearance.

If an axillary clearance is carried out all axillary lymph nodes should be removed unless there are specific reasons or unit policies not to do this. In the latter cases the anatomical level of dissection should be specified in the operation note. The number of nodes retrieved from axillary node clearance histology specimens will be both surgeon and pathologist dependent. However, for a full axillary clearance at least 10 nodes should be retrieved in >90% of cases. This should exclude cases where neo-adjuvant therapy (ie chemotherapy, endocrine therapy or radiotherapy) has been given and as a result there may be significant fibrosis due to the neo-adjuvant therapy.

Ideally, all patients with early invasive breast cancer should have axillary staging and if positive for metastasis, treatment for axillary disease. If an axillary staging procedure is not to be carried out the reasons for this should be discussed at the MDT meeting and documented in the patient's case notes.

Minimal surgery, rather than lymph node clearance, should be performed to stage the axilla for patients with early invasive breast cancer and no evidence of lymph node involvement on ultrasound or a negative ultrasound-guided needle biopsy. Sentinel node biopsy (SLNB) has become a standard approach for axillary staging. This technique provides accurate assessment of the axilla, with few false negatives and a significant reduction in surgical morbidity, especially lymphoedema. The combined technique (blue dye and radio-isotope) is the most sensitive method used. Two lymph nodes are desirable and surgeons should be able to achieve minimum standards with a >90% sentinel node identification rates and <10% false negative rates over a minimum 30 case audit series. If there is technical failure of SNB, then axillary sampling (usually 4 nodes) should be employed.

Where the sentinel node is positive (macrometastasis), further axillary treatment (axillary dissection or radiotherapy) as well as adjuvant systemic therapy is recommended. The EORTC-AMAROS trial compares axillary clearance versus radiotherapy and showed a 5 year axillary recurrence rate of 0.54% for axillary dissection versus 1.03% for radiotherapy; this was not statistically significant. The lymphoedema rate was higher in the surgical arm. The ACOS-OG Z0011 trial compares axillary clearance versus

observation only and showed that the outcome for women with one or two involved sentinel nodes was not significantly different between the two groups. The decision to carry out a completion (full) axillary clearance or to give axillary radiotherapy if the sentinel node is positive will be discussed at the MDT meeting and with the patient, be according to local written guidelines, and be documented in the patient's case notes.

The results of the above trials raise concerns regarding potential overtreatment of the axilla leading to avoidable long term morbidity. Micrometastases should be regarded as node positive for planning of systemic adjuvant treatments. Options for the local management of the axilla where micrometastases are found:

- no further treatment
- axillary radiotherapy or
- axillary lymph node dissection (ALND).

Where the sentinel lymph node shows only a micrometastasis and the patient is receiving some form of systemic treatment it may be most appropriate to treat only the lower axilla with radiotherapy as part of tangential fields to the breast or chest wall rather than giving radiotherapy to the whole axilla or carrying out an axillary node clearance. This should be discussed at the MDT meeting and with the patient, be according to local written guidelines, and be documented in the patient's case notes.

Entrance into the POSNOC study would be encouraged http://www.ncri.org.uk/

Follow the link below for the Association of Breast Surgeons (ABS) Consensus Statement 2015 Document on further guidance of the management of the axilla.
http://www.associationofbreastsurgery.org.uk/media/48727/axilla_abs_consensus_statement_16_3_15.pdf

Do not offer further axillary treatment to patients found to have only isolated tumour cells in their sentinel lymph nodes. These patients should be regarded as lymph node-negative. (NICE CG 80)

8. Surgical Management of Ductal Carcinoma In Situ

Ductal carcinoma in situ (DCIS) is a malignant precursor of invasive breast cancer. The aim of surgery is to achieve complete excision of the in situ tumour and to minimise local recurrence. The grade of the tumour and clear resection margins are important factors in the management of DCIS.

Tumour multifocality is not uncommon and can lead to high local failure rates. Approximately 50% of local relapses after treatment for DCIS are invasive and not in situ. The indications for mastectomy are uncertain but extensive micro calcification on the pre-operative mammogram is a risk factor for local recurrence after conservation surgery. High recurrence rates occur with larger tumours (>40mm diameter) and

mastectomy could be considered for such cases. While mammographic findings do not always correspond to pathological size the mammographic size is more commonly an underestimate of the final histological size.

If mastectomy is being considered for the treatment of DCIS on the basis of multifocality, then, ideally, at least two areas of the breast should be biopsied to confirm this.

There have been randomised trials of adjuvant radiotherapy after breast conservation for DCIS. In the EORTC study clear margins (>1 mm) were associated with a local recurrence rate of 15% at 5 years compared to 36% in patients with close or involved margins (<1 mm or frankly involved), regardless of the use of radiotherapy. Likewise, low grade DCIS is associated with a low risk of recurrence.

Patients undergoing breast conserving surgery should routinely have the DCIS excised with microscopically clear radial margins. Close margins at the chest wall or near the skin may be less important. Where breast tissue is to be moved at the time of surgery (eg oncoplastic techniques) particular consideration must be given to ensuring that further excision of involved margins can be easily carried out without a patient per se being committed to a mastectomy.

Local written protocols for intra-operative specimen radiography and specimen handling and the marking of surgical cavities following breast conservation surgery should be followed as for invasive cancer (see section 5).

There are no data to support a specific margin of excision. Each MDT should have local written guidelines regarding acceptable margin width for DCIS.

Individual cases will be discussed at the treatment MDT meeting. If, after MDT meeting discussion, the margin of excision is deemed to be inadequate then further surgery to obtain clear margins should be recommended.

For all patients treated with breast conserving surgery for DCIS a minimum of 2 mm radial margin of excision is recommended with pathological examination to NHSBSP reporting standards. Re-excision should be considered if the margin is less than 2 mm, after discussion of the risks and benefits with the patient. (NICE CG80).

Lymph node staging is not normally required for patients with a non-operative diagnosis of DCIS alone. However, some patients may be at high risk of an occult invasive carcinoma being found at subsequent pathological examination. These would include patients undergoing surgery for an extensive area of microcalcification, a palpable mass, high grade disease or where micro-invasion or frank invasion is suspected on the non-operative biopsies. In such cases SNB should be considered. Axillary clearance is contra-indicated in the treatment of patients with a non-operative diagnosis of DCIS alone.

Do not perform SLNB routinely in patients with a preoperative diagnosis of DCIS who are having breast conserving surgery, unless they are considered to be at a high risk of

invasive disease. Offer SLNB to all patients who are having a mastectomy for DCIS. (NICE CG80).

The decision to carry out an axillary staging procedure will be discussed at the MDT meeting and with the patient, according to local written guidelines, and will be documented in the patient's case notes.

The management of screen detected non-invasive breast cancer (and atypical hyperplasias) is the subject of a national audit, the Sloane Project. This will report in due course

9. Surgery for Lobular In Situ Neoplasia

Lobular in situ neoplasia, LISN, (to include lobular carcinoma in situ or LCIS and Atypical Lobular Hyperplasia or ALH) is often an incidental finding and is usually occult. Classical LISN may not be a local malignant precursor lesion, but it does confer an increased future risk, approximately seven-fold, of invasive breast cancer in both breasts. The risk of developing breast cancer is approximately 1% per year.

Discuss all legions at MDT particularly if there is discordant imaging and pathology, further sampling should be indicated.

It is suggested that breast lesions containing Classical LISN should be excised for definitive diagnosis, as some patients may have a co-existing invasive malignancy. The limited data available on LISN suggests that clear resection margins are not required following surgery for LISN alone. A policy of surveillance after excision biopsy is appropriate. Pleomorphic LCIS should be managed as DCIS. Non Pleomorphic LCIS with necrosis should be excised.

10. Breast Reconstruction

All patients, in whom mastectomy is a treatment option, should have the opportunity to receive advice on breast reconstructive surgery. Not all patients will be physically fit for or wish to consider reconstruction. If this is not available within the breast unit, the breast team should have a recognised line of referral to a breast or plastic surgeon with particular expertise in breast reconstruction. Timely access for patients considering reconstruction is essential in order that they are not discouraged by the process.

For patients, who express an interest in breast reconstruction, discussions should take place on the ideal timing of the reconstruction. This should include the risks and benefits of immediate versus delayed techniques. Ideally breast units should have clinicians with oncoplastic expertise and/or breast surgeons who work with plastic and reconstructive surgeons with an established interest in breast reconstruction, who can provide this

service. Where units offer breast reconstruction, adequate facilities, including theatre time and outpatient clinic time to counsel patients prior to surgery should be available. Facilities should be available for revisional surgery.

Further guidance has been published by the Association of Breast Surgery at BASO, the British Association of Plastic, Reconstructive and Aesthetic Surgeons and the Training Interface Group in Breast Surgery: Oncoplastic Breast Reconstruction Guidelines for Best Practice (November 2012).

For patients undergoing mastectomy without immediate reconstruction, a service should be provided to supply and fit breast prostheses.

Discuss immediate breast reconstruction with all patients who are being advised to have a mastectomy, and offer it except where significant co- morbidity or (the need for) adjuvant therapy may preclude this option. All appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally. (NICE CG80)

11. Peri and Post Operative Care

Peri-operative and follow up care

Patients will be supported by a breast care nurse, who is a member of the breast team.

They have established links with outpatient, ward and community nurses to assist in continuity of care. Following mastectomy (without immediate breast reconstruction), the fitting and supply of breast prostheses will be explained to patients. Patients will be informed about the range of services available to them and be provided with literature to include details of follow up treatment and local self help support groups.

All patients with breast cancer should be assigned to a named breast care nurse specialist who will support them throughout diagnosis, treatment and follow-up. NICE CG80

Communication with General Practitioners

The breast team ensure that primary care practitioners (GPs) receive communications that give them a clear and rapid understanding of the diagnosis, care plan, and toxicity profile of any proposed treatment. It is the responsibility of clinical trialists to ensure that GPs are fully briefed about any trial for which the patient is entered and the potential side effects.

Treatment multidisciplinary team meeting

All patients with breast cancer have their cases discussed after definitive surgery in the ‘post-operative results’ section of the MDT meeting.

The post-operative pathology results include all required predictive and prognostic markers (ER, HER2) and must be available to allow adequate discussion.

NICE CG80

Assess oestrogen receptor (ER) status of all invasive breast cancers, using immunohistochemistry with a standardised and qualitatively assured methodology, and report the results quantitatively.

Do not routinely assess progesterone receptor status of tumours in patients with invasive breast cancer.

Test human epidermal growth receptor 2 (HER2) status of all invasive breast cancers, using a standardised and qualitatively assured methodology.

Ensure that the results of ER and HER2 assessments are available and recorded at the multidisciplinary team meeting when guidance about systemic treatment is made.

Decisions about the need for further surgical treatment and/or adjuvant treatments should be discussed and the decisions recorded in the patient's case notes. An Oncologist should be present for this section of the meeting.

NICE CG 80

Consider adjuvant therapy for all patients with early invasive breast cancer after surgery at the multidisciplinary team meeting and ensure that decisions are recorded. (NICE CG80)

12. Adjuvant Treatments

Written local breast cancer treatment guidelines should identify which patients should be considered for adjuvant treatments. All patients should be discussed at the 'post-operative results' MDT meeting and a plan for any further treatment and follow up documented in the patient's case notes.

Adjuvant systemic treatments have been shown to reduce the risk of recurrence and to improve overall survival. Adjuvant treatments should not be decided upon based on relative risk reduction calculations. The use of adjuvant treatments should be decided after a calculation has been made of an individual patient's absolute risk of recurrence and the absolute benefit of a proposed treatment either alone or in combination with another treatment.

Oncotype Dx^{R} is a test which genomically profiles the resected invasive tumour, giving prognostic and predictive information. Tumours are divided into low, intermediate or high risk of recurrence. There is also prediction of the proportional benefit from adjuvant chemotherapy. NICE recommendation is for its use in HER2 negative, HR positive, node

negative patients in refining risk of recurrence and recommendation of adjuvant chemotherapy.

NICE CG80

Decisions about adjuvant therapy should be made based on assessment of the prognostic and predictive factors, the potential benefits and side effects of the treatment. Decisions should be made following discussion of these factors with the patient.

Consider using Adjuvant! Online or Predict to support estimations of individual prognosis and the absolute benefit of adjuvant treatment for patients with early invasive breast cancer.

Local written adjuvant treatment guidelines should include the following areas taking into account the listed published NICE guidance:

a) Radiotherapy

- Breast radiotherapy for invasive breast cancer
- Chest wall radiotherapy post mastectomy for invasive breast cancer
- Axillary radiotherapy for invasive breast cancer
- Breast irradiation for patients with ductal carcinoma in situ (DCIS)
- Axillary radiotherapy for patients with ductal carcinoma in situ (DCIS)

NICE CG80

Start adjuvant radiotherapy as soon as clinically possible within 31 days of completion of surgery or as soon as possible following completion of systemic chemotherapy in patients with early breast cancer having treatment.

Radiotherapy after breast conserving surgery:
Patients with early invasive breast cancer who have had breast conserving surgery with clear margins should have breast radiotherapy.
Offer adjuvant radiotherapy to patients with intermediate/high grade DCIS following adequate breast conserving surgery and consider/discuss with them the potential benefits and risks.

Radiotherapy after mastectomy:
Offer adjuvant chest wall radiotherapy to patients with early invasive breast cancer who have had a mastectomy and are at a high risk of local recurrence. Risk factors for local recurrence include nodal involvement, Grade 3 tumours, vascular invasion and large tumours at presentation (>5 cm=T3). Any nodal involvement as the only risk factor should be an indication for postmastectomy radiotherapy. The potential benefits from postoperative radiotherapy should be considered at the MDT.

Do not offer radiotherapy following mastectomy to patients with early invasive breast cancer who are at low risk of local recurrence

Dose fractionation
Use external beam radiotherapy giving 40 Gy in 15 fractions over 3 weeks as standard practice for patients with early invasive breast cancer after breast conserving surgery or mastectomy. 50 Gy in 25 fractions over 5 weeks may still be used and considered following radiotherapy for DCIS, for postoperative nodal irradiation and in patients with other medical factors where the lower dose per fraction is considered to be important.

Breast boost
Offer an external beam boost to the site of local excision to patients with early invasive breast cancer and a high risk of local recurrence, following breast conserving surgery with clear margins and whole breast radiotherapy.

If an external beam boost to the site of local excision following breast conserving surgery is being considered in patients with early invasive breast cancer, inform the patient of the side effects associated with this intervention, including poor cosmesis, particularly in women with larger breasts.

Radiotherapy to nodal areas
Do not offer adjuvant radiotherapy to the axilla or supraclavicular fossa to patients with early breast cancer who have been shown to be histologically lymph node-negative.

Do not offer adjuvant radiotherapy to the axilla after ALND for early breast cancer.

Offer adjuvant radiotherapy to the supraclavicular fossa to patients with early breast cancer with four or more involved axillary lymph nodes.

Radiotherapy to the axilla (plus or minus RT to SCF) may be given to patients with 1-3 macroscopically involved axillary nodes demonstrated at sentinel lymph node biopsy as an alternative option to treatment with axillary node clearance.

Do not offer adjuvant radiotherapy to the internal mammary chain as routine treatment to patients with early breast cancer who have had breast surgery. Radiotherapy to the internal mammary nodes should be considered if patients have been found to have involved internal mammary nodes.

b) Endocrine therapy

All patients with ER positive invasive breast carcinoma can potentially benefit from hormonal therapy. Hormonal therapy reduces the hazard ratio of death from breast cancer by approximately 30%. This effect is independent of progesterone receptor status, patient age and concomitant chemotherapy use. A decision whether or not to use endocrine therapy should be based on an assessment of the absolute benefit and the risks or side effects of treatment. Treatment regimes are described in the East Midlands Network Guidelines

NICE CG80

Ovarian suppression (OS)/ablation for early ER positive invasive breast cancer:

Offer adjuvant ovarian ablation/suppression in addition to tamoxifen to premenopausal women with ER-positive early invasive breast cancer who have been offered chemotherapy but have chosen not to have it.

The results of the SOFT trial show added benefit for the addition of Ovarian Suppression with LHRH agonist in women who regain menstruation following adjuvant chemotherapy. OS should be offered in addition to tamoxifen.

Aromatase inhibitors for early invasive breast cancer:

Postmenopausal women with ER-positive early invasive breast cancer who are not considered to be at low risk should be offered an aromatase inhibitor, either anastrozole or letrozole, as their initial adjuvant therapy. Offer tamoxifen if an aromatase inhibitor is not tolerated or contraindicated.

Offer an aromatase inhibitor, either exemestane or anastrozole, instead of tamoxifen to postmenopausal women with ER-positive early invasive breast cancer who are not low risk and who have been treated with tamoxifen for 2–3 years.

Offer additional treatment with the aromatase inhibitor letrozole for 3-4 years to postmenopausal women with lymph node-positive ER-positive early invasive breast cancer who have been treated with tamoxifen for 5 years.

For premenopausal women the duration of treatment with tamoxifen for up to 10 years, should be considered. For postmenopausal who are intolerant to aromatase inhibitors, tamoxifen should be recommended for 10 years (Results of ATLAS and ATTOM).

The aromatase inhibitors anastrozole, exemestane and letrozole, within their licensed indications, are recommended as options for the adjuvant treatment of early ER-positive invasive breast cancer in postmenopausal women. The choice of treatment should be made after discussion between the responsible clinician and the woman about the risks and benefits of each option. Factors to consider when making the choice include whether the woman has received tamoxifen before, the licensed indications and side-effect profiles of the individual drugs and, in particular, the assessed risk of recurrence. There is currently no evidence to support adjuvant AI use beyond 5 years.

Tamoxifen for ductal carcinoma in situ
Do not offer adjuvant tamoxifen after breast conserving surgery to patients with DCIS.

The Early Breast Cancer Trialists' Collaborative Group (EBCTCG) Oxford Overview shows that women with ER negative invasive tumours derive no benefit from hormonal therapy (Level 1 evidence). Endocrine treatment should not normally commence until the oestrogen receptor status has been determined.

Bone monitoring, by dual energy x-ray absorptiometry (DEXA) scanning, should be available for patients taking aromatase inhibitors. Treatment for drug induced bone loss, such as calcium supplementation and bisphosphonates where necessary, is available. See East Midlands Network Guidelines

NICE CG80

Assessment and treatment of bone loss:

Patients with early invasive breast cancer should have a baseline dual energy X-ray absorptiometry (DEXA) scan to assess bone mineral density if they

- *are starting adjuvant aromatase inhibitor treatment*
- *have treatment-induced menopause*
- *are starting ovarian ablation/suppression therapy.*

Do not offer a DEXA scan to patients with early invasive breast cancer who are receiving tamoxifen alone, regardless of pretreatment menopausal status.

Offer bisphosphonates to patients identified by algorithms 1 and 2 in 'Guidance for the management of breast cancer treatment-induced bone loss: a consensus position statement from a UK expert group' (2008) (see appendix 2 of the full guideline, available from www.nice.org.uk/CG80FullGuideline).

c) Chemotherapy

Adjuvant chemotherapy prolongs disease-free and overall survival in patients with early breast cancer, especially in premenopausal women with ER negative tumours. The efficacy of chemotherapy is greater in younger patients. Efficacy of chemotherapy is seen in both ER positive and negative breast cancer. However in ER positive disease treated by endocrine therapy the additional absolute benefit of chemotherapy will be calculated (Adjuvant online/Predict). This is particularly the case where the risk of recurrence is low, ER expression is high &/or the patient is of older age where they are competing causes of mortality.

NICE CG80

Start adjuvant chemotherapy within 31 days of completion of surgery or as soon as clinically possible in patients with early breast cancer having treatment.

Offer taxanes to patients with lymph node-positive breast cancer, triple negative breast cancer and HER2+ breast cancer as part of an adjuvant chemotherapy regimen.

d) Targeted therapy

Trastuzumab (Herceptin) is a monoclonal antibody to the HER2 receptor protein. In HER2 positive women, adjuvant trastuzumab (when combined with chemotherapy) approximately halves the risk of disease recurrence and death.

HER2 testing is available for all new patients with invasive breast cancer; the test results must be available for discussion at the 'post operative results' MDT meeting. Trastuzumab should be offered to all HER2+ patients according to NICE guidance Cardiac monitoring, both pre-treatment and during treatment should be available, as trastuzumab can lead to cardiac toxicity.

NICE CG80
Offer trastuzumab, given at 3-week intervals for 1 year or until disease recurrence (whichever is the shorter period), as an adjuvant treatment to women with HER2-positive early invasive breast cancer following surgery, chemotherapy, and radiotherapy when applicable.

Assess cardiac function before starting treatment with trastuzumab. Do not offer trastuzumab treatment to women who have any of the following:

- *a left ventricular ejection fraction (LVEF) of 55% or less*
- *a history of documented congestive heart failure*
- *high-risk uncontrolled arrhythmias; angina pectoris requiring medication*
- *clinically significant valvular disease*
- *evidence of transmural infarction on electrocardiograph (ECG*
- *poorly controlled hypertension.*

Repeat cardiac functional assessments at 4 and 8 months (NCRI guidance). If the LVEF drops by 10 percentage (ejection) points or more from baseline and to below 50% then trastuzumab treatment should be suspended. Restart trastuzumab therapy only after further cardiac assessment and a fully informed discussion of the risks and benefits with the woman. Patients who have required cardiotropic drugs should have an echocardiogram on completion of trastuzamab treatment.

13. Complications of Local Treatment and Menopausal Symptoms

Lymphoedema

All patients with early breast cancer should be informed about the risk of developing lymphoedema and given relevant written information before treatment with surgery and radiotherapy. This includes advice on how to prevent infection or trauma that may cause or exacerbate lymphoedema. Patients with early breast cancer who develop lymphoedema should have rapid access to a specialist lymphoedema service.

Inform all patients with early breast cancer about the risk of developing lymphoedema and give them relevant written information before treatment with surgery and radiotherapy.

Give advice on how to prevent infection or trauma that may cause or exacerbate lymphoedema to patients treated for early breast cancer.

Ensure that all patients with early breast cancer who develop lymphoedema have rapid access to a specialist lymphoedema service. (NICE CG80)

Arm mobility

Breast units should have written local guidelines agreed with the physiotherapy department for postoperative physiotherapy regimens. Breast cancer patients with pre-existing shoulder conditions should be identified preoperatively as this may inform further decisions on treatment. Instructions are given, on functional exercises, which should start the day after surgery, to all breast cancer patients undergoing axillary surgery. This will include relevant written information from a member of the breast or physiotherapy team. Referrals to the physiotherapy department are made if patients report a persistent reduction in arm and shoulder mobility after breast cancer treatment.

All breast units should have written local guidelines agreed with the physiotherapy department for postoperative physiotherapy regimens.

Identify breast cancer patients with pre-existing shoulder conditions preoperatively as this may inform further decisions on treatment.

Give instructions on functional exercises, which should start the day after surgery, to all breast cancer patients undergoing axillary surgery. This should include relevant written information from a member of the breast or physiotherapy team.

Refer patients to the physiotherapy department if they report a persistent reduction in arm and shoulder mobility after breast cancer treatment.

(NICE CG80)

Menopausal symptoms

Hormone replacement therapy (HRT) should be discontinued in women who are diagnosed with breast cancer. HRT (including oestrogen/progestogen combination) should not be offered routinely to women with menopausal symptoms and a history of breast cancer. HRT may, in exceptional cases, be offered to women with severe menopausal symptoms and with whom the associated risks have been discussed.

Discontinue hormone replacement therapy (HRT) in women who are diagnosed with breast cancer.

Do not offer HRT (including oestrogen/progestogen combination) routinely to women with menopausal symptoms and a history of breast cancer. HRT may, in exceptional cases, be offered to women with severe menopausal symptoms and with whom the associated risks have been discussed. (NICE CG80)

Information and counselling should be offered to all women about the possibility of early menopause and menopausal symptoms associated with breast cancer treatment.

Local written information regarding menopausal symptoms in breast cancer patients should be available taking into account the listed published NICE guidance:

Offer information and counselling for all women about the possibility of early menopause and menopausal symptoms associated with breast cancer treatment.

Tibolone or progestogens are not recommended for women with menopausal symptoms who have breast cancer.

The selective serotonin re-uptake inhibitor antidepressants paroxetine and fluoxetine may be offered to women with breast cancer for relieving menopausal symptoms, particularly hot flushes, but not to those taking tamoxifen as there is drug interaction.

Clonidine, venlafaxine and gabapentin should only be offered to treat hot flushes in women with breast cancer after they have been fully informed of the significant side effects. (NICE CG80)

14. Follow Up (Refer to EM Minimum Risk Stratified Pathway)

Each breast unit should have written local guidelines for the follow up of patients treated for breast cancer.

a) Clinical Follow Up

There is no firm evidence that early detection of local or systemic recurrence improves survival. However many breast cancer patients seek reassurance that they are free of recurrence and that any such recurrence will be detected at the earliest opportunity.

Patients on continuing active treatment should be followed up until such treatment has been completed.

If a GP detects a possible recurrence, the patient should be referred back to the breast unit. Mechanisms to facilitate this should be made known to both GPs and patients.

Patients diagnosed and treated for breast cancer will have ongoing requirements to meet their psychosocial needs, surveillance of ongoing treatment effects, monitoring of primary treatment morbidity and monitoring of recurrence rates. All these aspects of care should be provided for in whatever local follow up regime is implemented.

Data about long-term follow up is essential in monitoring clinical outcomes locally, regionally and nationally. Data collection must be reliable and functioning.

NICE CG80
After completion of adjuvant treatment (including chemotherapy, and/or radiotherapy where indicated) for early breast cancer, discuss with patients where they would like follow-up to be undertaken. They may choose to receive follow-up care in primary, secondary, or shared care. Patients treated for breast cancer should have an agreed, written care plan, which should be recorded by a named healthcare professional (or professionals), a copy sent to the GP and a personal copy given to the patient. This plan should include:

- *designated named healthcare professionals*
- *dates for review of any adjuvant therapy*
- *details of surveillance mammography*
- *signs and symptoms to look for and seek advice on*
- *contact details for immediate referral to specialist care, and*
- *contact details for support services, for example support for patients with lymphoedema.*

b) Imaging Follow Up

The ideal frequency for mammographic follow up is not established and current practice is variable. Current UK guidelines from the Royal College of Radiologists suggest routine mammography every 1 to 2 years for up to 10 years after diagnosis.

Annual mammography should be offered to all patients treated for DCIS and Invasive disease until the patient commences NHS Breast Screening and for 5 years as a minimum when the patient has reached the age of eligibility for NHS breast screening.

Mammography of the ipsi-lateral soft tissues should not be offered after mastectomy. Ultrasound and MRI should not be offered for routine post-treatment surveillance in patients who have been treated for invasive breast cancer or DCIS.

NICE CG80

Offer annual mammography to all patients with early breast cancer, including DCIS, until they enter the NHSBSP/BTWSP. Patients diagnosed with early breast cancer that are already eligible for screening should have annual mammography for 5 years.

On reaching the NHSBSP/BTWSP screening age or after 5 years of annual mammography follow-up we recommend the NHSBSP/BTWSP stratify screening frequency in line with patient risk category.

Do not offer mammography of the ipsilateral soft tissues after mastectomy.

Do not offer ultrasound or MRI for routine post-treatment surveillance in patients who have been treated for invasive breast cancer or DCIS.

15. Minimum Data Set, Data Collection, National Quality Assurance and Audit Schedules

These are as agreed at the ECAG on 06.06.2014. Each unit participates in and will continue to participate in all relevant national quality assurance and audit.

Appendix 1 – Local Guidelines

The appendices attached below are local Guidelines created by the Breast Multi-Disciplinary Team Hospital Teams.

REQUIRED LOCAL GUIDELINES / PROTOCOLS
(These should be updated and agreed on annual basis)

MDT Operational policy

Clinic guidelines – triple assessment

Breast cancer treatment guidelines:
- neoadjuvant treatment to downstage tumours
- locally advanced breast cancer
- metastatic breast cancer
- recurrent breast cancer

MRI

Specimen handling / specimen x-ray

Margins – invasive and DCIS

Axillary node management

Adjuvant treatment guidelines:
- radiotherapy
- endocrine therapy inc bone monitoring (East Midlands)
- chemotherapy
- Targeted treatments

Physiotherapy – arm movements

Follow up – clinical / imaging / data collection

Appendix 2 – Teenage and Young Adult Operational Framework

The NICE Improving Outcomes Guidance for Children/Young People with Cancer details the requirements to provide age appropriate facilities/age appropriate care for both children/young people and young adults. The Teenage and Young Adult Pathway is being finalised but the text below sets out the working practices for the Teenage and Young Adult Psychosocial Multi-disciplinary meeting across the East Midlands in accordance with the Improving Outcomes Guidance. Whilst breast cancer is not common in this age group it does occur and the ECAG wishes to ensure that both site specific care and psychosocial care are provided to the highest standard in IOG compliant services.

For the remainder of this section the Teenage and Young Adult Psychosocial Multi-disciplinary team will be referred to as TYA MDT. This document will be used in conjunction with Teenage and Young Adult referral pathway documents.

Purpose

The TYA MDT brings together a range of knowledge, expertise and experience to ensure the treatment plan received from the Site-Specific MDT incorporates within it the psychosocial aspects of the patients care; in turn developing a holistic and individual treatment plan for the teenager/young adult. The TYA MDT ensures all teenage/young adult cancer patients have access to age appropriate care/facilities that meets their needs across the region.

Aims of the TYA MDT

1. To review all TYA patients (aged 13-24) with a new cancer diagnosis and where significant changes have taken place i.e. transfer, relapse, palliative care, triggers relating to psychosocial needs and review of outcomes
2. To provide a multi-professional forum for discussion of psychosocial considerations for each patient throughout their period of care and rehabilitation
3. To agree the patients treatment/care plan with the site-specific MDT, to coordinate age appropriate specialist, medical, nursing and psychosocial care, ensuring that treatment plans are compatible with national age-specific treatment guidance and / or research protocols
4. To ensure a clear plan of action has been agreed relating to the patients care and documented and filed in case notes
5. To act as a focus for clinical audit aimed at enhancing age appropriate clinical practice wherever the young person is being cared for
6. To ensure that the location for treatment is identified and that alternatives where available are discussed and offered to the patient
7. To offer multi-professional support to the clinical team caring for TYA patient
8. To ensure a key worker is allocated to the patient (inpatient and outpatient)

9. To collate data on TYA cancer registration and submit to the Cancer Intelligence Service.

10. To maintain and improve team working

11. To agree a unified approach between paediatric and adult cancer teams for TYA cancers

Referral Criteria

All patients diagnosed with cancer between the ages of 13-24, living within the East Midlands*, to be discussed at TYA MDT and relevant adult Site-Specific MDT or Children's MDT.

** East Midlands region as part of the East Midlands Cancer Network boundaries.*

All referrals to the TYA MDT will need to be made via the referral form. The following referral routes have been identified:

1. Site Specific MDTs (i.e. MDT Coordinator) – adults 18-24 years
2. Surgeon at Biopsy stage of the pathway
3. Children's Integrated Cancer Service 13-18 years
4. Trusts/Departments
5. Via Pathology Department
6. Via Alert System

Responsibility for making the referral will lie with MDT Coordinators, Consultants, CNSs. Practitioners referring the patient will be advised to join the TYA MDT for discussion of their patient.

All referral forms accompanied by relevant information relating to the patient i.e. Holistic Assessment, treatment information etc. will either be faxed to the Principle Treatment Centre. Referrers will need to ensure that any electronic copy submitted is via an nhs.net email account and marked in the subject box as 'Confidential information for TYA MDT'. All referrals will be picked up by the TYA MDT Coordinator or in his/her absence by the chair of the TYA MDT.

Notification to the TYA MDT should occur once a cancer diagnosis is confirmed or in some cases (to avoid the delay in treatment) where a cancer diagnosis seems likely (normally at the Site Specific MDT). Disease Specific Pathways will incorporate referral routes to the TYA MDT and these should be followed when referring to the TYA MDT.

Cancer Centre Managers will have notification of TYA MDT dates and referrals will need to be submitted to the TYA MDT Coordinator at least two working days prior to the

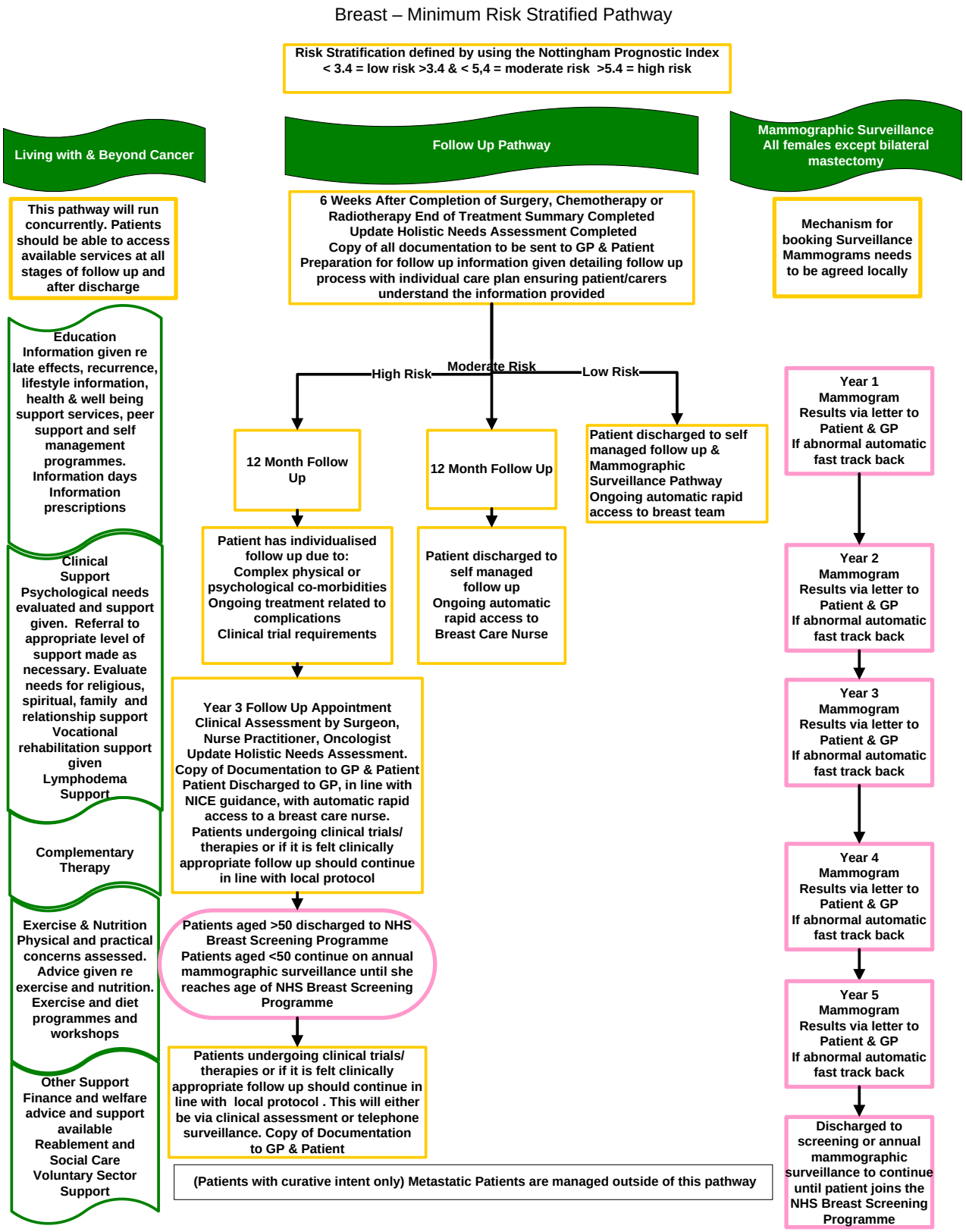
meeting. Where required (urgent/emergency cases) telephone referrals will be accepted or referral forms submitted on the day of the TYA MDT.

Upon receiving the referral form, the TYA MDT Coordinator will distribute a letter/email*/* to the referring person confirming TYA MDT date and inviting the referring person or deputy to join the TYA MDT and the process for this.

All notifications to TYA MDT will be recorded (via agreed arrangements) and submitted to the TYA Cancer Registry via the TYA MDT Coordinator.

Patients to be discussed at the TYA MDT will be notified by their key worker that their case is being discussed as well as the reason for and timing of the MDT discussion. Patients are informed about the outcome of the MDT meeting at the time of their next contact with their key worker. Outcomes of and recommendations made at the MDT will be communicated directly to the GP within 24 hours of the MDT.

Appendix 3 – Minimum Risk Stratified Pathway and Guidelines



Guidelines for the Implementation of Risk Stratified Pathways

A risk stratified follow up pathway enables the creation of an efficient service that is tailored to meet the individual needs of patients living with and beyond cancer. It promotes the development of effective sign posting not only to internal information and services but also to external and voluntary organisations for patients and relatives. It should also support the promotion of self-management and effective coping skills. The following is a guide to support you through the implementation process:

- Ensure process is clinically led with input from all surgeons, oncologists, cancer nurse specialists (CNS) and any other health professionals involved in the follow up pathway
- Ensure all members of clinical team have a full understanding and agree with of the main components of the risk stratified follow up pathway
- Meeting of all stakeholders - successful implementation requires total buy-in and support from everyone including clinical teams, managers and commissioning teams. The pathway acts as a clear guide to what is needed to guarantee success. A meeting also gives an opportunity to make key decisions at a local level based on the available capacity and competencies of the provider. The model also offers the chance for providers to look at new models of delivering follow up for example telephone appointments, remote testing and shared care with GPs where necessary
- Clear communication between health professionals is essential to reduce duplication and omissions which may disadvantage the patients on their follow up journey
- Pathway should be used to facilitate access to educational programmes including self-management and coping strategies for symptoms and personal health and wellbeing together with wider patient support and exercise groups
- Ensure patients are fully appraised of scheduling and significance of surveillance tests. Patient also need to agree with the CNS or Consultant how and when results will be notified and how 'bad' news with be communicated
- Use of Holistic Needs Assessment (HNA) will ensure the focus is on the patient not just the illness or treatment. It will identify the patient needs and can be shared with other health professionals where necessary in different stages of the patient's journey. The HNA assists individuals to identify issues and concerns which are dominating their lives and emphasises areas where support and education programmes may be beneficial. It will also define existing support.
- Self-management programmes need to be developed either in acute trusts or the community to enable patients to access services and be sign posted to all available programmes including those provided by the voluntary sector.
- Ensure signposting in place to enable patients to seek advice and insight from other cancer peer support networks offered by groups and charities in addition to other health information and advisory services to patients and carers
- Process for rapid access to secondary health care team needs to be agreed and mechanisms in place to ensure patients can contact clinical team when pathway implemented. Patients should have clear written instructions with contact

telephone numbers and working hours for clinical teams This should also include how to access help and advice out of hours

Appendix 4 – Chemotherapy Treatment Guidelines

Chemotherapy Treatment guidelines for Breast which have been ratified by Breast Oncologists can be found at:

http://www.eastmidlandscancernetwork.nhs.uk/_HealthProfessionals-Chemotherapy-Oncology-BreastCancer.aspx

Appendix 5 – Teenage and Young Adult Pathway