



# Breast Cancer Clinical Guidelines

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## **INTRODUCTION**

### **Terms of Reference**

**This document provides regional guidelines for the management of breast cancer and is designed to complement existing national guidelines e.g. National Institute for Health and Care Excellence (NICE) and Association of Breast Surgery (ABS). This guideline does not override the individual responsibility of healthcare professionals in making decisions appropriate to the circumstances of the individual patient. It is not anticipated that the guidelines will cover all clinical situations in all patients, but where unusual circumstances exist, it is expected that such treatments would be discussed in the appropriate MDT.**

**These guidelines take into account NICE clinical guidelines, CG80 (NICE February 2009, April 2012) CG81 (June 2014) and CG164 (June 2013), and have been reviewed and revised, following TSSG discussion, in April 2015.**

**The guidelines will be reviewed on an annual basis. Where new treatments are introduced between revisions they will be added as an addendum to the current guideline.**

### **Facts and Figures**

- More than 40,000 breast cancers are diagnosed each year in the UK (1)
- Breast cancer causes around 13,000 deaths per annum the UK (1)
- One woman in 9 will develop breast cancer at some time during her lifetime.
- Eight of ten breast cancers occur after the menopause.
- Screening may reduce the chance of dying from breast cancer. It provides women with more choices in the planning of their surgical treatment.
- Nine out of ten breast lumps are not cancer.
- The number of deaths from breast cancer in England peaked in the late 1980's and since then has been falling faster than in any other country (2)
- Between five and ten per cent of women with breast cancer have an inherited predisposition.

### **Public Health and Prevention**

Environmental factors including obesity (BMI>32), moderate amounts of alcohol, nulliparity, and hormone replacement therapy have been associated with an increased risk of developing breast cancer. Caffeine, dairy products and smoking are not known to cause breast cancer. In 88,000 women in the Nurses' Health Study, there was an inverse association between breast cancer risk and the intake of low-fat dairy products. A healthy lifestyle involving regular physical activity, avoidance of high calorie diets and promotion of breastfeeding can lead to prevention of some cases of breast cancer.

## SCREENING

### General Population Screening

The National Breast Screening programme is well established. The aim of the screening programme is to produce a 30% reduction in mortality from breast cancer. The screening programme has an independent national quality assurance programme, run regionally by the Quality Assurance Reference Centre (QARC).

- All women aged 50 to 70 are currently invited for three yearly mammographic screening. The programme is being expanded to the age group 47 to 73 over the next few years
- Women over 70 are informed that they may request mammography although they are not routinely invited in the national screening programme. (Some age 71-73 will be called as part of the expansion)
- The chance of finding a cancer by mammography screening is 1 in 200 as outlined below:

Screened	200
All clear	186
Recall for assessment	14
Needle biopsy	5
Cancer	1

There are separate screening recommendations for women previously treated with radiotherapy for Hodgkin's Disease

## Management of Patients with a Family History indicating increased risk of Breast Cancer

<https://www.gov.uk/government/collections/breast-screening-professional-guidance>

<https://www.nice.org.uk/guidance/cg164>

NICE guidance on familial breast cancer stratifies women into three groups: near population risk, raised risk and high risk.

Patients with a Family History of Breast Cancer will be managed in accordance with guidelines issued by NICE and by the NHSBSP.

Risk	Breast cancer risk category		
	Near population risk	Moderate risk	High risk <sup>1</sup>
Lifetime from age 20	Less than 17%	Greater than 17% but less than 30%	30% or greater
Between ages 40 and 50	Less than 3%	3–8%	Greater than 8%
Site of Management	In Primary Care Reassurance, advice on avoiding risk factors.	In Secondary Care Breast Unit	In Tertiary Care Specialist Genetics Referral

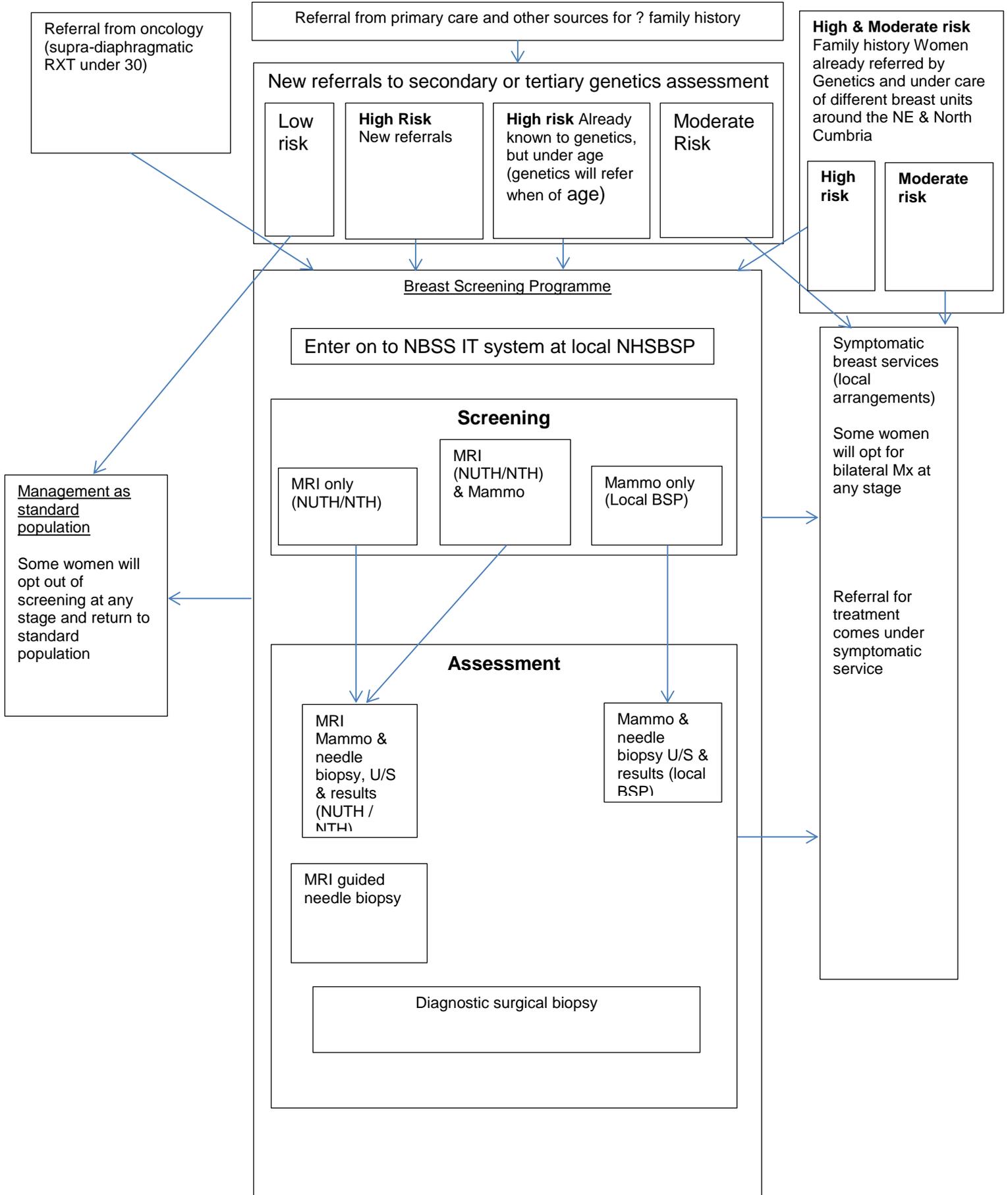
<sup>1</sup> This group includes known *BRCA1*, *BRCA2* and *TP53* mutations and rare conditions that carry an increased risk of breast cancer such as Peutz-Jegher syndrome (*STK11*), Cowden (*PTEN*) and familial diffuse gastric cancer (E-Cadherin).

## Chemoprophylaxis for Women at High Risk of Breast Cancer

NICE (CG184) states that postmenopausal women with a uterus with no personal history, but at high risk of breast cancer women due to a family history, should be offered either tamoxifen or raloxifene for 5 years to unless they have a past history of, or may be at increased risk of, thromboembolic disease or endometrial cancer.

However, these guidelines also acknowledge that neither agent currently has a UK marketing authorisation for this indication and that prescribers should follow relevant professional guidance, taking full responsibility for the decision and that informed consent should be obtained and documented.

# Pathway(s) for High Risk Women – in the North East and North Cumbria



## Protocols for the surveillance of women at higher risk of developing breast cancer

Risk	Ages	Surveillance Protocol	Frequency	Notes
BRCA1 or BRCA2 carrier or Not tested, equivalent high risk	20-29	n/a	Annual	Review MRI annually on basis of background density
	30-39	MRI	Annual	
	40-49	MRI + Mammography	Annual	
	50+	Mammography ± MRI	Annual	
TP53 Li-Fraumeni	20+	MRI	Annual	No mammography
A-T Homozygotes	25+	MRI	Annual	No mammography
A-T Heterozygotes	40-49	Mammography	18 monthly	Routine screening from 50
	50+	Mammography	Routine screening (3 yearly)	
Supradiaphragmatic radiotherapy: irradiated below age 30	30-39	MRI	Annual	Surveillance commences at 30, or 8 years after first irradiation, whichever is the later. Review MRI annually on basis of background density. Confirmation of history of radiotherapy must be obtained
	40-49	MRI ± Mammography	Annual	
	50+	Mammography ± MRI	Annual	

Taken from: NHSBSP Publication No 74

**Proforma for Referral of Patients to Clinical Genetics Service**

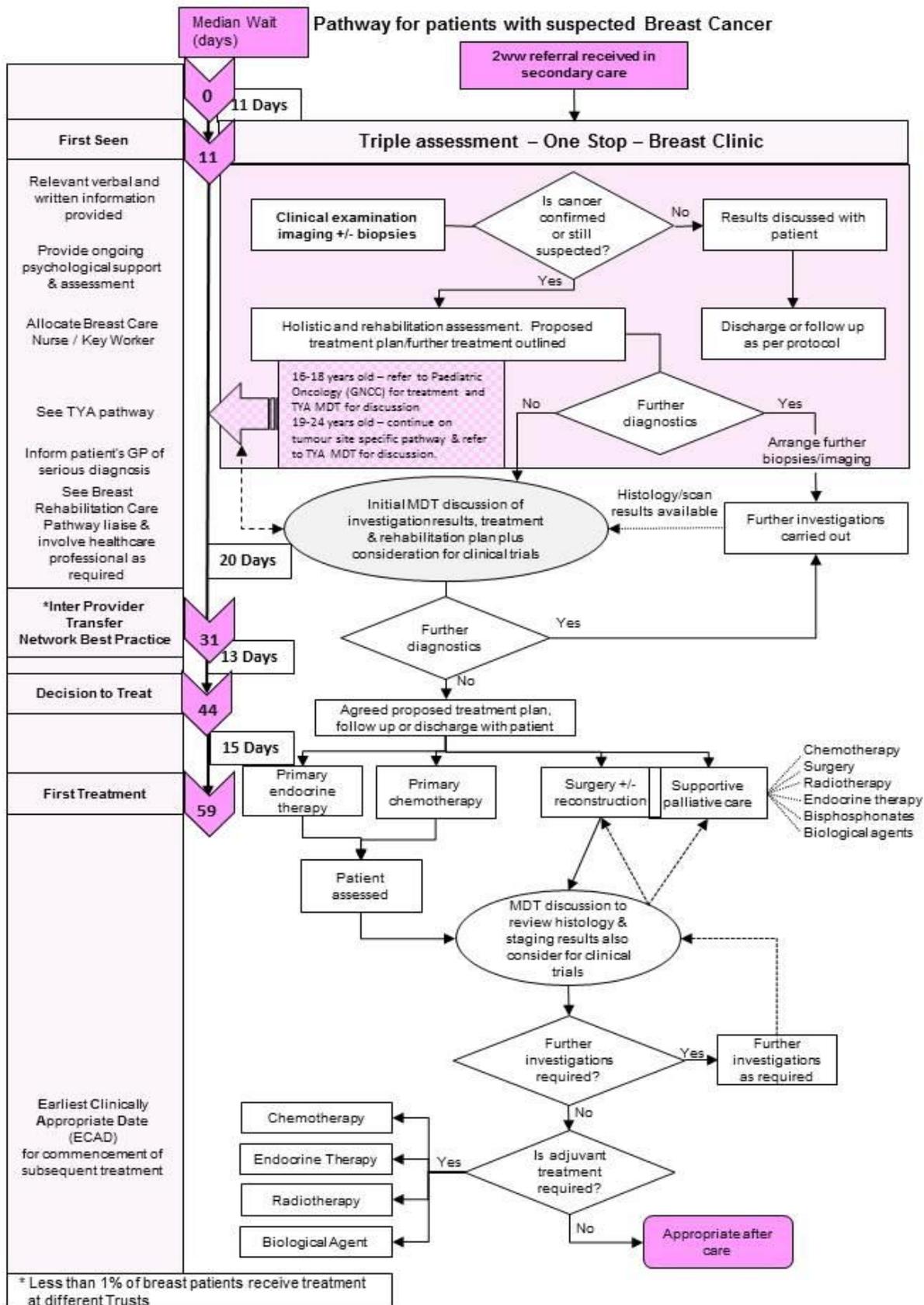
The Newcastle upon Tyne Hospitals 

NHS Foundation Trust  
Institute of Human Genetics

**FAMILY HISTORY BREAST SCREENING REFERRAL**

Section A: To be completed by Referrer			
Name		Genetics Reference no:	
DOB			
Address		NHS no	
		GP	
Telephone Number:			
Section B: To be completed by Genetics			
Risk assessment and any relevant family history			
Has patient had breast cancer		Yes / No	
If yes give details			
Has patient had oophrectomy		Yes / No / Unknown	
Risk category	Age	Surveillance Protocol*	Please tick
Supradiaphragmatic radiotherapy irradiated Below age 30	30-39	MRI Annually	
	40-49	MRI + mammography annually	
	50-70	Mammography annually +/- MRI	
BRCA1/2 or not tested equivalent risk	30-39	MRI Annually	
	40-49	MRI + mammography annually	
	50-70	Mammography annually +/- MRI	
Known TP 53 (Li Fraumeni)	20-70	MRI- annually	
>30% probability of TP53 carrier	20-49	MRI- annually	
	50-70	3 yearly -NHSBSP	
A-T Homozygote	25+	MRI	
AT Heterozygote	40-49	Mammography – 18/12	
	50-70	3 yearly -NHSBSP	
High Risk- Non BSP	40-59	Mammography- annually	
	60-70	3 yearly -NHSBSP	
Moderate Risk	40-49	Mammography- annually	
	50-70	3 yearly -NHSBSP	
Signed:		Role	
		Hospital	
Name		Date	
Section C: To be completed by Screening service			
Referral accepted for high risk Screening <input type="checkbox"/> Referral rejected for high risk screening <input type="checkbox"/>			
Reason for rejection			
Form not completed		<input type="checkbox"/> Does not meet criteria <input type="checkbox"/>	
Radiologist signature		Date _____	

\* Surveillance protocols based on agreed guidelines – May 2014



## **CRITERIA FOR URGENT BREAST CLINIC REFERRAL (UNDER 2 WEEK RULE)**

**Symptoms and warning signs that are suspicious and warrant urgent investigation:**

- **Lump**
  - any new discrete lump
  - new lump in pre-existing nodularity
  - asymmetrical nodularity that persists at review after menstruation
  
- **Pain**
  - if associated with a lump
  - unilateral persistent pain in post-menopausal women
  
- **Other potential signs of cancer**
  - ulceration
  - skin nodule
  - skin distortion
  - breast abscess or inflammation not settling after one course of antibiotics
  - nipple discharge especially if age >50, or bloodstained
  - nipple eczema unresponsive to topical steroids
  - recent (<3month) nipple inversion
  
- **Physical Examination**
  - An appropriate examination should be performed prior to referral
  - The aspiration of a lump in a patient with a history of multiple cysts should only be performed by a General Practitioner who has the necessary skills. Aspiration of solid lumps should not be attempted as it may affect imaging and delay diagnosis or even lead to mis-diagnosis.

### **Priority for Referral**

Following the Government's Health Service Circular (HSC 242/98), all patients with symptoms deemed to be suspicious by their GP will, if the letter is faxed or e-mailed, be seen within 14 days of the decision for referral (3). The guidance for the GPs determining which symptoms are suspicious is outlined in the booklet by Austoker et al (4). Such referrals must be considered as urgent and offered the next available appointment by the local breast clinic. The guidance for GPs should be directed by the Hospital and must be clear and easy to follow; an example of the recommended guidance is listed in Appendix 1.

### **Two weeks for all breast clinic referrals**

In line with new targets all referrals to symptomatic breast clinics will be seen within 2 weeks from the end of 2009.

## Referral Pathways

CCG Referral Pathways Area	Pop*	Trust	Designated MDT	Named MDT Lead/ Contact/Tel/Fax	Screening Centres
South Tees	276	North Tees & Hartlepool NHS FT	University Hospital of North Tees	Mr.Matei Dordea T:01642 617617 Mobile: 07956063472  Matei.dordea@nth.nhs.uk	Yes
Hambleton, Richmondshire & Whitby	153				
Hartlepool & Stockton	288				
Newcastle	249	Newcastle Upon Tyne Hospitals NHS FT	Royal Victoria Infirmary	S Nicholson T:0191 2823748 F:0191 2325278	Yes
Northumberland	316	Northumbria Health Care NHS FT	Wansbeck General Hospital  joint with  North Tyneside General Hospital	Ms A Townend T: 0191 293 2543 / 293 2522	
North Tyneside	203				
Gateshead South Tyneside	249 149	Gateshead Health NHS FT	Queen Elizabeth Hospital	Mr A Redman T:0191 4820000 F:0191 4820360	Yes
Sunderland Easington	278 93				
North Durham	248	County Durham and Darlington NHS FT	University Hospital of North Durham	Mr C Hennessy 0191 3332333 F:0191 594406	
Durham Dales, Easington & Sedgefield (excl Easington)	182				
Darlington	106		Darlington Memorial Hospital		
North Cumbria	318	North Cumbria University Hospital NHS Trust	Cumberland Infirmary	Mr Ioannis Michalakis T: 01228 814229 F:01228 634001	Yes

## **EAG Guidelines for Teenage and Young Adults**

### **Teenage and Young Adults Peer Review Measures Topic (Functions of the Network Site Specific Groups for TYA)**

#### **1. Teenage and Young Adult Pathway for initial Management**

The EAG has received the document named 'NCA Teenage and Young Adult Cancer Pathway Guidance Paper' and agrees to follow the generic TYA Pathway with any site specific variations to be documented. Please see Appendix 1 for pathway.

#### **2. Teenage and Young Adult Pathway for Follow up on completion of first line treatment**

Patients aged 19-24 years will adopt the site specific adult follow up pathway on completion of first line treatment. It is acknowledged by both the CYPCG and EAGs across NCA that further work is required to develop these pathways for this age group and partly in response a TYA working group has been established to take this work forward.

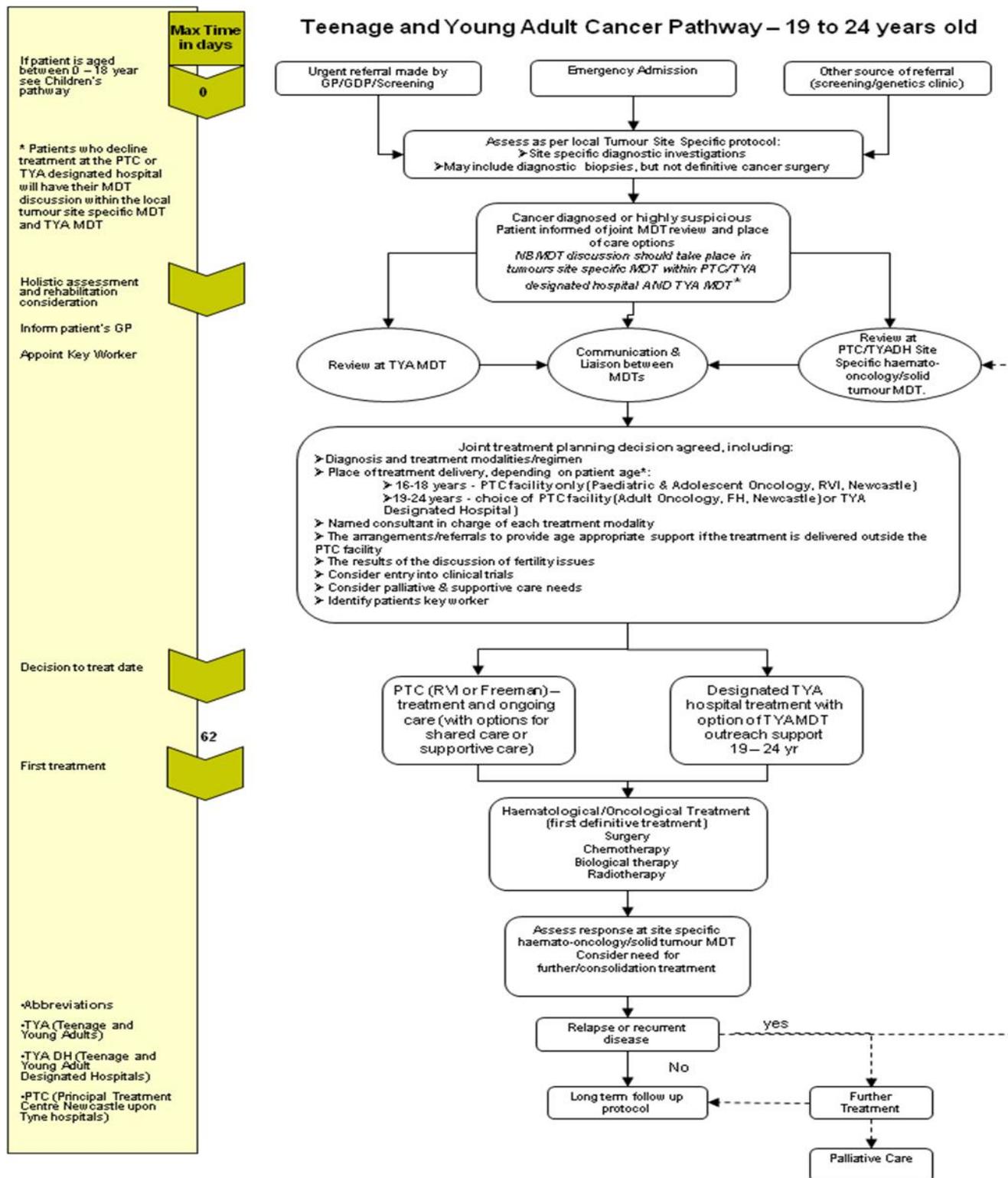
If advice is required regarding the follow up care of a 19-24 year old patient, then the Lead TYA Clinician at the designated hospital or PTC should be contacted. Please see Appendix 2 for contact details.

Patients age 16-18 years will continue to adopt the paediatric and adolescent follow up protocol of the PTC and all advice should be sought direct from the On Call Paediatric Oncologist at Royal Victoria Infirmary 0191 2336161. Paediatric Follow Up Protocols can be found on the CCLG website (2005 second edition) with the exception of trial specific protocols which can be requested via the Children's Trial Co-ordinator based at the RVI.

#### **3. Pathways for cases involving Specialised NHS services (Only Gynae and Sarcoma)**

The Gynae EAG and SAG reviewed and agreed the Specialised NHS Service pathway for patient's age 16-24 years. This is attached in Appendix 3.

# Appendix 1 – Teenage and Young Adult Pathway for initial Management



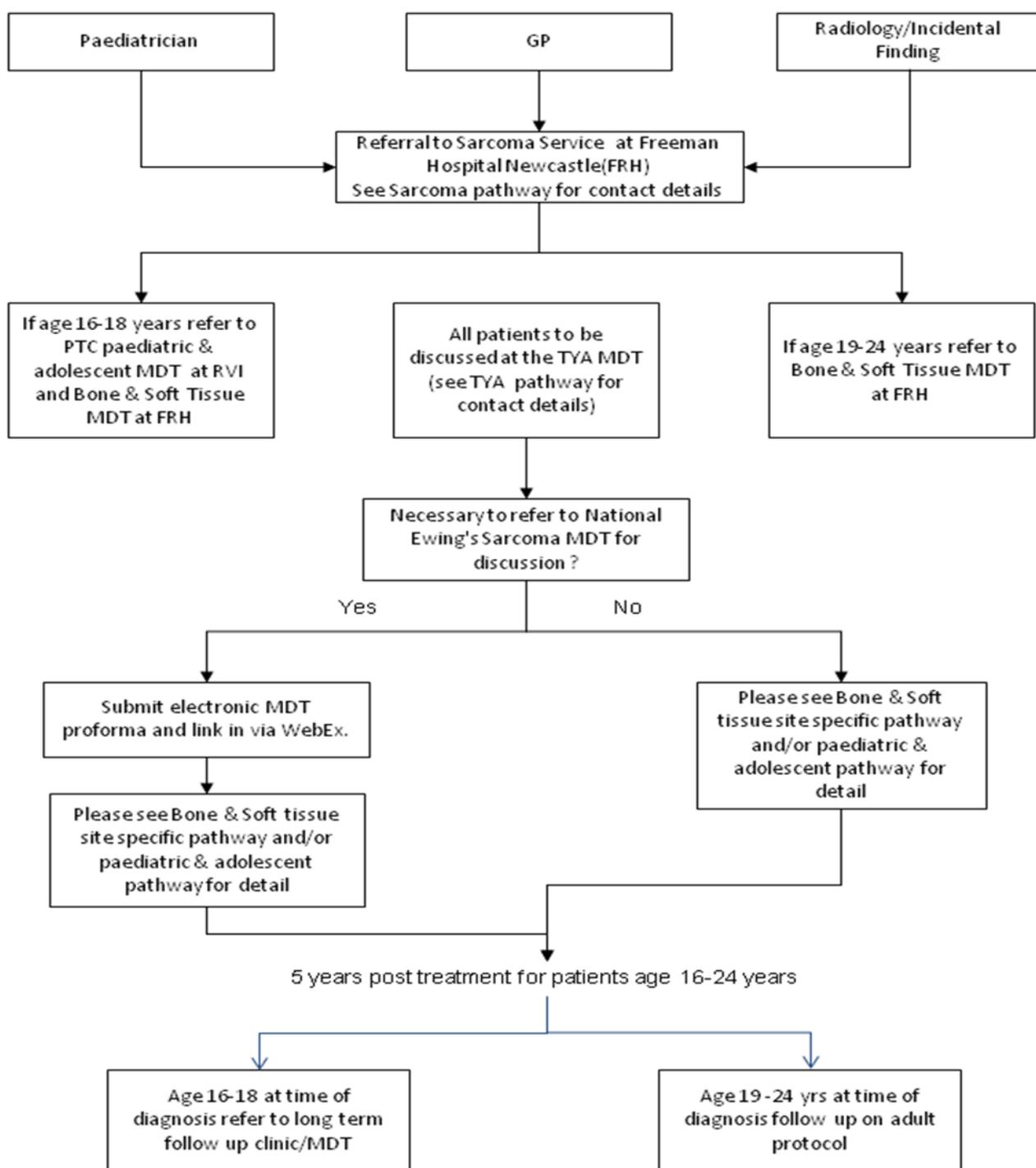
TYA Cancer Ideal Pathway Map version 1.7  
 ELTH/KJ/ST and acknowledgement to Wessex Cancer Network

## Appendix 2 – Contact Details

List of designated MDTs at Principal Treatment Centre and TYA Designated Hospitals (19 - 24 years)				
Name of NHS Trust and designated hospital site	Name of MDT	TYA Lead Clinician	TYA Lead Nurse	Contact Number
Principal Treatment Centre	All MDTs:	Dr Emma Lethbridge	David Short david.short@nuth.nhs.uk	0191 2448858 (Dect48858)
	Breast			
	Colorectal			
	Gynaecology (diagnostic)			
	Haematology			
	Head & Neck			
	Lung			
	Neurooncology (Brain/Spinal, Pituitary, Skull Base)			
	Sarcoma			
	Specialist Skin			
	Specialist pancreatic			
	Supra T-cell Lymphoma			
	Teenage and Young Adult MDT			
	Testicular			
Thyroid				
Specialist Upper GI				
Specialist Urology				
Gateshead Health NHS Foundation Trust - at Queen Elizabeth Hospital	Specialist Gynaecology	Ms Christine Ang	Rachael Mugnai rachaelmugnai@ghnt.nhs.uk	0191 4456148
City Hospitals Sunderland NHS Foundation Trust - at Sunderland Royal Hospital	Haematology	Dr Scott Marshall	Faye Laverick faye.armstrong@chsft.nhs.uk	0191 5656256
	Specialist Urology (testicular only)			
North Tees and Hartlepool NHS Foundation Trust - at University Hospital of North Tees	All MDTs:	Dr Padmaja Lokireddy	Kat Dawson katherine.dawson@nth.nhs.uk	01642 617617 ext 24697
	Haematology			
	Local Urology			
	Thyroid			
	Breast			
	Colorectal			
	Lung			
	Local Upper GI			
South Tees Hospital NHS Foundation Trust - at James Cook University Hospital	All MDTs:	Dr Dianne Plewis	Jill Linton jill.linton@stees.nhs.uk	01642 854381
	Specialist Gynaecology			
	Breast			
	Colorectal			
	Haematology			
	Head & Neck			
	Lung			
	Neurooncology			
	Specialist Skin			
	Thyroid			
	Specialist Upper GI			
Specialist Urology				

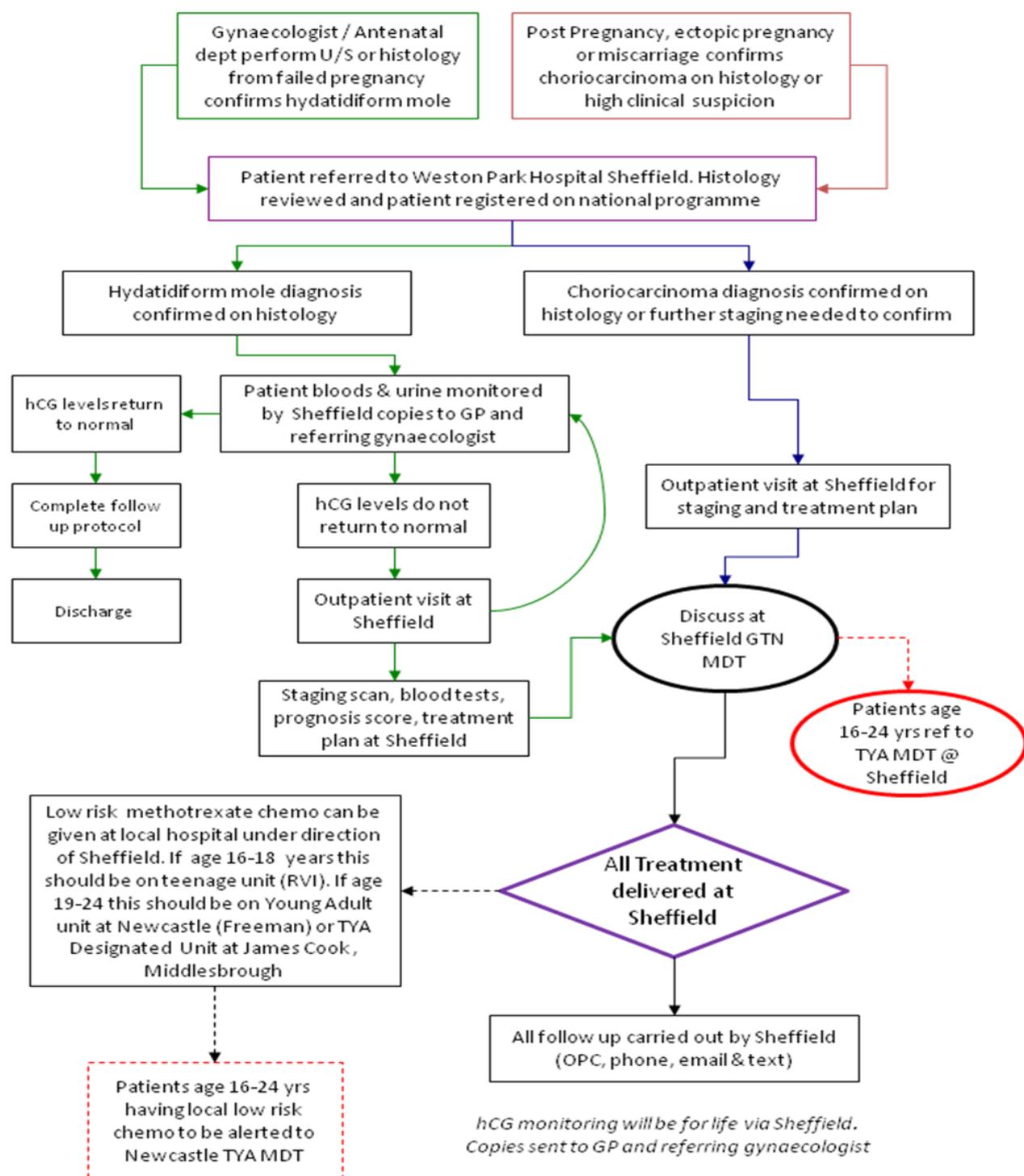
## Appendix 3 – NHS Specialised Services Pathway

### NHS Specialised Services - Referral Pathway for Primary Malignant Bone Cancer for patients age 16-24 years within the North of England



## NHS Specialised Services

Referral Pathway for Hydatidiform Mole / Gestational Trophoblastic Neoplasm / Choriocarcinoma  
Weston Park Hospital, Sheffield



Choriocarcinoma Pathway  
Toni Hunt NECN Version 0.4 Aug 2012

## HOSPITAL INVESTIGATION AND ASSESSMENT OF BREAST CANCER <sup>(5,6)</sup>

Triple assessment increases the accuracy and reduces overall cost of diagnosis when compared with selective use of the component tests. The three tests when used in experienced hands can result in a positive predictive value of 99% (7), thus minimising the need for open biopsy (8). This reduces surgical time and minimises anxiety induced by delay. At least 90% of women with breast cancer should be diagnosed pre-operatively.

Triple assessment comprising clinical examination, imaging (mammography /ultrasound) and biopsy, is recommended for women with suspected breast cancer at a single visit.

- Biopsy by needle core biopsy and/or FNA. Needle core biopsy is the investigation of choice where malignancy is suspected.
- Local anaesthetic may be appropriate for some patients.
- All facilities and staff needed to provide this service should be in close proximity to the diagnostic clinic.
- The results of triple assessment should be given to the patient within five working days.

The following investigations are recommended for different breast symptoms once clinical examination has taken place:

**Breast Lump:** Triple assessment:

**Breast Pain:** Unilateral persistent mastalgia without palpable abnormality: clinical examination only.

Localised areas of painful nodularity: mammography (if > 35 years old) and/or ultrasound

All focal lesions: FNA

**Nipple discharge:** clinical examination and imaging as indicated.

**Nipple retraction:** clinical examination and imaging as indicated.

**Change in skin contour:** triple assessment

When a diagnosis of cancer is made, the only other routine investigations recommended prior to surgery are a chest x-ray, full blood count and biochemistry (bone & liver).

See further information on perioperative staging later.

## COMMUNICATING THE DIAGNOSIS

### Informing the Patient

- The patient should be informed of the diagnosis by a Consultant or an appropriately experienced member of the MDT <sup>(9)</sup>.
- Facilities should be available for the patient to be informed of the diagnosis during a private uninterrupted consultation.
- A trained breast CNS should be available during the consultation and should be available to provide additional counselling as required <sup>(10)</sup>.
- Opportunity to contact the breast CNS for further counselling, support and information (confidential phone numbers, address and key worker contact cards etc) should be offered and follow up arrangements agreed before the patients leaves.
- Patients should be given time, information and support to make a fully informed decisions about their treatment. This should include discussion with the surgeon, in liaison with the breast CNS, of suitable treatment options. The offered options and the decisions for therapy as indicated by the discussions held at the multi-disciplinary team (MDT) should be recorded in the patient record <sup>(11, 12)</sup>.
- The patients informational needs will be constantly assessed. Details of available therapy should not necessarily be discussed at the diagnostic visit, especially if in the “one-stop” setting. Where necessary, arrangements should be made for a subsequent “treatment planning” visits.
- Patients should be given the opportunity for a close friend or relative to be present during the consultations and the subsequent journey home.
- Written information regarding breast cancer treatments should be available and offered to all patients <sup>(13)</sup>.
- A prognosis should not be offered before adequate staging information is available.

### Informing the Primary Care Team

- The GP should be informed of the diagnosis on the same day as the patient or by noon the day following, preferably by fax, using a serious diagnosis proforma.
- The general practitioner should be made aware of the information which has been given to the patient and, if possible, an outline of the planned treatment.
- If the diagnosis is made as in inpatient, the Primary Care Team should be informed prior to discharge from hospital
- Hospital nursing staff should ensure that relevant community nurses are also informed
- Major alterations to the management plan should be communicated to the General Practitioner by telephone, fax or letter within one working day. Similarly, if alterations are made by the general practitioner, these should be communicated to the hospital within two working days. A patient held record, where available, would be a supplementary means of such communication.

## CANCER WAITING TIMES TARGETS

The National Cancer Waiting Times system allows NHS providers to record data derived from patient care activity. This data can be used to:

- monitor cancer waiting times targets
- plan service improvements

As a patient moves through the stages of their treatment pathway data on referrals, treatments and diagnosis are derived from care records locally (decisions on how to collect these data from local systems are made locally).

After collection, the cancer waiting times data can be queried by NHS organisations, cancer networks and the Department of Health to provide reports and feedback on the progress towards meeting these targets.

Please see link below to the latest version of information for Cancer Waiting Times.

<https://digital.nhs.uk/services/systems-and-service-delivery/screening-services/cancer-waiting-times>

The addendum can also be found here:

<https://digital.nhs.uk/binaries/content/assets/website-assets/services/cancer-waiting-times/addendum-to-national-cancer-waiting-times-monitoring-data-guidance-v9.0.pdf>

# **GUIDELINES FOR SYMPTOMATIC BREAST IMAGING**

## **Based on:**

- Association of Breast Clinicians Best Practice Diagnostic Guidelines 2011
- Royal College of Radiologists Breast Imaging Guidelines

## **General Principles**

### **1. Patients 40 years and over**

Mammography is the imaging technique of choice. Target breast ultrasound provides useful additional information and may be used as a primary examination where physical examination suggests a benign process such as a cyst, if the woman has not had mammograms in the past 12 months. Unless there is clinical concern, a mammogram should not need to be repeated within two years. Ultrasound is NOT a suitable screening technique and should not be used in the absence of clinical or mammographic abnormality.

### **2. Patients under 40 years**

Many patients attending breast clinics are under 35 years and do NOT require imaging as part of their diagnostic assessment. There is a low incidence of breast cancer in this age group. In patients in this age group with significant focal problems targeted ultrasound is the imaging technique of first choice. Ultrasound is not indicated in the absence of a significant clinical symptom as it is not a screening tool. When malignancy is suspected either clinically or on ultrasound then mammography should be performed.

## **Symptom-Specific Imaging**

### **Discrete Lump**

>= 40 years	Mammography + ultrasound
< 40 years	Ultrasound (+ mammography for P4/5 or U4/5 lesions).  If P2/3 and U2 a core biopsy should confirm benignity and mammography not needed. If P3 and U1 consider mammography. (Best practice Guidelines P15).

### **Criteria for safe avoidance of unnecessary biopsy in females <25 years with solid breast masses**

Solid breast masses in young women are a common problem in breast clinics and the majority of these are fibroadenomata. Carcinoma, Phylloides and Papilloma are uncommon under 30 years and rare under 25 years thus the cut-off for targeted biopsy is considered to be 25 years.

If biopsy is NOT being performed then the following criteria should be met:

1. Clinical features:

- <25 years
- Mass not rapidly enlarging
- Smooth discrete mobile mass on palpation
- No risk factors for malignancy

2. Ultrasound features U2:

- Homogenous isoechoic or hypoechoic mass < 30mm
- Ovoid shape and parallel to skin surface
- Smooth or gently lobulated contour without microlobulations.
- Thin pseudocapsule
- No acoustic shadowing or calcifications

Reference: Clinical Radiology 65(2010)218-222

## **Lumpiness or "Asymmetric Nodularity"**

P1/P2 and $\geq$ 40 years	Mammography (opportunistic screen)
P1/P2 and <40 years	Ultrasound for clinically benign asymmetry (P2). If ultrasound U1 or U2 mammography is not indicated. (Best Practice guidelines p15).
P3 and $\geq$ 40 years	Mammography + ultrasound
P3 and <40years	Ultrasound. Proceed to mammography if indicated on ultrasound (i.e. score U3-U5) (Best Practice guidelines P15)
P4/P5 any age	Mammography and ultrasound

## **Nipple Discharge – No Lump**

Age appropriate imaging for spontaneous single duct or serosanguinous discharge i.e. under 40 ultrasound; 40 and over mammography + ultrasound

Routine imaging is not indicated in multi-duct or bilateral discharge.

## **Breast pain**

Bilateral or cyclical breast pain, ANY AGE, imaging not indicated.

Unilateral breast pain in patients:

>=40 years                      Mammography (opportunistic screen)

<40 years                        DO NOT REQUIRE ROUTINE IMAGING

The risk of finding a breast cancer on imaging in a woman with breast pain and normal clinical examination is no greater than the risk of finding breast cancer in an asymptomatic woman having a screening mammogram.

## **Suspected Breast Sepsis**

Ultrasound +/- ultrasound guided drainage is indicated in the acute phase. Patients >=40 years should have routine mammography once acute phase has settled. Localised tenderness is a focal clinical sign so should be imaged as appropriate for age i.e. 40 and over mammography, under 40 ultrasound (Best Practice guidelines p19).

## **Presumed Fat Necrosis**

If clinically benign (P1/P2) and imaging consistent with fat necrosis U2 (+/-M1/M2) then biopsy is not required. If there is ANY doubt either clinically or radiologically then biopsy should be performed

## **Intracystic Papillary Lesions**

If lesion is clearly seen on ultrasound then biopsy should be carried out and CLIP inserted as biopsy might render lesion difficult to see at a later date.

## **Skin Lesions, eg Sebaceous Cysts and Non-Suspicious Nipple Eczema**

Imaging not indicated

## **Gynaecomastia**

Gynaecomastia affects one third of all males in their lifetimes and is the commonest cause of a breast "lump" or discrete sub-areolar swelling in a male patient.

Carcinoma of the male breast is very rare and is extremely uncommon in men less than 50 years. It accounts for <1% breast cancers and <0.2% cancers in men.

In clinically suspected gynaecomastia with no suspicious features imaging is not indicated under age 50. If >=50, ultrasound is the imaging of choice.

Unifocal lumps in the male breast should undergo ultrasound of the breast and then guided core biopsy to avoid missing diagnosis of breast cancer or lymphoma. If the biopsy is positive then mammogram and axillary ultrasound is indicated.

## **Imaging of the Axilla**

Every patient with suspected breast malignancy should have ultrasound of the ipsilateral axilla.

If an abnormal node is seen (ultrasound criteria) then needle biopsy should be carried out. Positive pre-operative node biopsy identifies those patients unsuitable for SNB.

Ultrasound criteria for lymph node sampling are:

Cortex  $\geq$  as per local criteria  
Focal cortical bulge  
Short axis ratio  $>0.5$   
Loss of fatty hilum

i.e. score of N3 or higher

**IF HAEMATOLOGICAL MALIGNANCY IS SUSPECTED FNA IS INAPPROPRIATE. CORE BIOPSY OR EXCISION BIOPSY SHOULD BE CARRIED OUT.**

## **Needle Biopsy**

Needle core biopsy is preferred to FNAC for most solid/suspicious lesions and should be performed under image guidance wherever possible to achieve greatest accuracy and reduce the need for repeat procedures.

Free hand biopsy may be appropriate for cases of palpable locally advanced breast cancer and cases where imaging is normal but there is a suspicious localised clinical finding.

## **Indications for MRI Scanning**

**To diagnose or exclude breast cancer when triple assessment is inconclusive**

- Clinical/imaging discordance.
- Metastatic carcinoma in axillary lymph nodes with normal mammography and ultrasound.
- Conventional imaging difficult to interpret due to previous treatment or surgery.

**To assess the extent of newly diagnosed breast cancer**

- Clinico/radiological non-correlation of lesion size.
- Lobular carcinoma if conservative surgery planned to affected breast.
- Occult carcinoma to exclude multi-focality and to size accurately if patient wants conservative surgery.

### **To monitor response to neoadjuvant chemotherapy**

- Pre treatment to delineate size and extent of tumour.
- Post 2 cycles of chemotherapy to assess response.
- Post treatment if conservative surgery planned.

### **Breast implants**

Ultrasound examination to be undertaken first. If conclusive of rupture, no further imaging needed.

MRI is indicated when there is a clinical suspicion of rupture and ultrasound is normal. when there is a double lumen implant, MRI is the investigation of choice.

### **Breast reconstruction**

To investigate possible recurrence when mammography and ultrasound unhelpful.

**ALL MRI REQUESTS SHOULD BE DISCUSSED AT THE MDM AND MANAGEMENT DECISION AGREED**

## **NCA GUIDELINES FOR PATHOLOGY REPORTING**

Following the diagnosis of breast cancer a tumour should be staged according to the pT and pN categories of TNM classification (see appendix 1). The breast multidisciplinary team must include a pathologist or pathologists with a special interest and expertise in breast pathology and cytology, with designated time for breast cancer work. The pathology services must be organised according to the NHSBSP guidelines and include the RCPATH minimum dataset - *link to both sets of guidelines as follows:-*

<http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp58.html>  
<http://www.cancerscreening.nhs.uk/breastscreen/publications/qa-08.html>

### **Histopathology Standards:**

Histopathology procedures and reporting should be as described in the NHSBSP document "Pathology Reporting in Breast Cancer Screening". The recording of the data for symptomatic patients must be same as that for the screening patients.

Histopathology departments and surgeons must have access to specimen radiography. Specimen radiograph must accompany the specimen.

Histopathology laboratories should work towards nationally defined accreditation standards. It is desirable that Pathologists reporting breast cancer routinely should participate in the EQA National scheme.

It is the responsibility of the operating surgeon to ensure that the specimen is orientated and marked for the pathologist as agreed locally. Ideally nodal levels should be labelled and sent separately. There should be agreement between surgeons and pathologists in each unit on how specimens are oriented and labelled and considering the requirement for a specimen X-ray where appropriate.

## **REFERRAL GUIDELINES BETWEEN MDTs WITHIN AND OUTSIDE THE NCA**

All the constituent MDT's within the North of England Cancer Network recognise that referral to another MDT, or specialist centre for specific treatment might be required in certain cases. Examples of such referrals are: specialist pathological review in unusual cases, referral to another team if treatment not available locally, i.e., certain types of breast reconstruction or radiosurgery for brain metastases, patient request for relocation of their care.

When a local MDT or cancer team feels that such referral is indicated then the following are agreed:

- The MDT will follow the pathology guidelines regarding specialist MDT referral.
- The MDT or cancer team will provide all data to the receiving MDT including radiology, pathology and clinical information.
- The clinician in charge of the patient or a responsible member of their team will write a formal referral letter to the receiving team.
- The patient and their GP will be informed of the reason for their referral onto another MDT or specialist centre by the referring team.

On return of the patient the specialist MDT team will be expected:

- To provide written information regarding the treatment delivered.
- Indicate the need for any follow up by the referring team, or agreement of continuing shared care.
- To inform patient and their GP of transfer of care back to referring team if appropriate.

## SURGICAL TREATMENT OF BREAST CANCER

- Surgical treatment of breast cancer, especially reconstructive surgery, should be carried out by surgeons with a special interest and training in breast disease (see the BASO 1998 guidelines for recommendations for Surgical Training). Breast surgeons must work in Breast Units that provide necessary expertise and facilities for multidisciplinary approach <sup>(14)</sup>.
- In patients where breast conserving surgery is considered unwise and mastectomy is to be carried out, or where a patient requests mastectomy but with minimal cosmetic disruption, an opportunity should be provided before mastectomy for the patient to discuss the possibilities for breast reconstruction with an oncoplastic surgeon if this is oncologically appropriate. If reconstruction is needed and the MDT concerned do not have the relevant expertise the patient will be referred to another MDT within the Network
- Multidisciplinary case review and planning (MDM) should be the standard for all patients with newly diagnosed breast cancer <sup>(15)</sup>. Patients with recurrent or metastatic disease should be discussed where uncontrolled local disease is present, or at the discretion of MDT members.
- Consultants and other core members of the multidisciplinary team within the breast unit should have contractual time for attendance at multidisciplinary meetings in a planned programmed activity.
- The conclusions of the MDM should be recorded in all the patient records, irrespective of the number of hospitals that the patients attend for the management of their breast cancer. This should be supported by the appropriate clerical requirements. The MDM should be minuted with an attendance record; the minutes should be made available to all core members of the MDM
- The number of therapeutic procedures should be recorded. **90%** of patients having conservation surgery should have **three or fewer therapeutic** operations.
- It is the responsibility of the operating surgeon to ensure that the specimen is orientated and marked for the pathologist as agreed locally. Ideally nodal levels should be labelled and sent separately. . As a minimum the apical node should be marked in an axillary clearance specimen. There should be agreement between surgeons and pathologists in each unit on how specimens are oriented and labelled and considering the requirement for a specimen X-ray where appropriate.
- A diagnostic or therapeutic axillary procedure should be performed in all patients with an invasive cancer unless the MDT has specifically advised against this.
- 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 lymph node biopsy (SLNB) is the preferred technique. When performing SLNB the aim should be to sample no more than 4 nodes. SLNB should only be performed by a team that is validated in the use of the technique, as identified in the New Start training programme.

## Management of In situ breast cancer

### 1) Ductal carcinoma in situ (DCIS)

Up to 20% of screen detected cancers fall into this group but nearly 40% of DCIS lesions diagnosed currently in the UK present (often as incidental findings) in symptomatic clinics. DCIS is a direct precursor of invasive breast cancer. Fine needle aspiration is inadequate for distinguishing DCIS from invasive cancer. A core biopsy is necessary for cases with microcalcifications with mammographic appearance of DCIS. Vacuum assisted devices are also available e.g. mammotome which increase accuracy by providing larger volumes of tissue for analysis.

The risk of recurrence following surgery is influenced by grade, size, patient's age and resection margin. These factors form part of the Van Nuy's prognostic index which is often used as a guide for the need for radiotherapy after breast conserving surgery despite the fact that it has not been possible to validate this using data from any of the large randomised DCIS trials. While disease at, or very close to, the resection margin is the greatest predictor of recurrence after breast conserving surgery for DCIS once clear margins have been obtained the patient's age would appear to be the most important factor with young (<35) patients being most at risk.

#### Surgical management:

- *Multifocal or extensive (>40mm) DCIS:* simple mastectomy. In highly selected patients there may be a role for therapeutic mammoplasty in some larger DCIS lesions. Axillary staging with SLNB should be advised in those patients undergoing mastectomy. Reconstruction should be offered to all patients requiring or choosing mastectomy for DCIS.
- *Small (<40mm), non-central, unifocal lesions:* taking into consideration the patient body habitus and with regard to the resulting cosmetic appearances, the aim is complete local excision.
- *Margins:* remain a contentious issue and there are no clear guidelines available. The Surgical guidelines for the management of breast cancer (Association of Breast Surgery at BASO 2009) state: "Units should have local guidelines regarding acceptable margin width for DCIS 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". The international evidence, such as it is, seems to point to a margin of 2mm as being adequate but because margin width is but one variable other factors such as age, DCIS grade and lesion size should be considered by the MDT before recommending repeat excision when the margin is >1mm.

Follow-up specimen radiographs should be carried out to confirm complete excision of all suspicious calcifications, particularly if they are extensive or approach the edge of the surgical specimen.

### **Adjuvant treatment for DCIS:**

- Optimum adjuvant treatment of DCIS is still uncertain. The ultimate goal is to identify lesions that are more likely to recur locally, and thus, might be better treated with further adjuvant therapies. Over treatment of lesions unlikely to recur should be avoided particularly in older (>60) patients with significant co-morbidity. Adjuvant radiotherapy significantly reduces the risk of recurrence following breast conserving surgery for DCIS but has little or no influence on overall survival.

### **Adjuvant Tamoxifen for DCIS:**

- The UKCCCR DCIS trial showed no significant benefit from Tamoxifen<sup>(16)</sup>. The (US) NSABP B24 suggested a small reduction in the risk of recurrence (9.3% vs 6%, absolute benefit 3.3%) although this was in patients without rigorous control of excision margins. No survival advantage was demonstrated.
- The current evidence **does not** support the use of adjuvant endocrine therapy for DCIS outside a clinical trial. However patients who entered the IBISII trial were randomised between tamoxifen and Arimidex (anastrozole). IBIS II has now closed to recruitment.

### **Lobular carcinoma in situ (LCIS)**

This is an uncommon condition, invisible on mammography and often detected co-incidentally during histological evaluation of breast tissue. It acts as a marker for increased risk of developing either ductal or lobular breast cancer in the future which is 5-10 times the standard population risk. Invasive cancers may occur either in the ipsilateral or contralateral breast. Invasive cancers are likely to be visible on mammography thus annual mammographic screening for 5 years or until the patient enters the NHS BSP (whichever is later) is recommended.

Recent recommendations point out that **pleomorphic LCIS** should be treated in the same manner as DCIS and clear margins of excision are required.

**Radiotherapy for non-invasive lesions is discussed in the main Radiotherapy section of this guideline.**

## **SURGICAL TREATMENT OF INVASIVE BREAST CANCER**

### **Small unifocal invasive cancers with no palpable nodes.**

- Surgery may be wide local excision or total mastectomy, according to patients' preference, and the size and location of the primary tumour. Co-morbidities may restrict the treatment choices available to the patient and must be considered in treatment planning.
- The maximum size of cancers undergoing breast conserving surgery cannot precisely be regulated, however patient habitus, resulting cosmetic appearances and adequacy of resection margins should be taken into account. For the majority of patients a primary cancer greater than 4cm will probably not be best managed by breast conserving surgery. In those patients undergoing breast conserving surgery the margins must be clearly marked, preferably by a method agreed by the surgeon, radiologist and pathologist.
- There are good data from randomised controlled trials supporting the view that surgical margin status is a strong predictor of long term local recurrence rates<sup>(17)</sup>, although the trend towards smaller resection margins does not appear to confer a higher local recurrence rate, especially if adjuvant therapy is planned<sup>(18,19)</sup>.
- Resection margins remain a contentious issue in invasive breast cancer as well as in the treatment of DCIS. The Surgical guidelines for the management of breast cancer (Association of Breast Surgery at BASO 2009) state: For patients undergoing breast conserving surgery "All patients should have their tumours removed with no evidence of disease at the microscopic RADIAL margins and fulfilling the requirements of local guidelines. If, after MDT meeting discussion, the margin of excision is deemed to be inadequate then further surgery to obtain clear margins should be recommended". The ABS Guidelines also state "Close margins at the chest wall or near the skin may be less important" NICE have previously recommended a minimum radial margin of 2mm, although there are no data to substantiate this. As in the management of DCIS, many other factors need to be considered by the MDT such as patient age and co-morbidity, tumour grade and size and the use of systemic adjuvant therapies which in themselves reduce the risk of local recurrence. Local recurrence risk clearly needs to be stratified – for example a 1mm margin may be perfectly adequate in a 65 year old with a small (<10mm) low grade, ER+ cancer but inadequate in a 35 year old with a larger, high grade ER- cancer
- The indication for diagnostic vs. therapeutic axillary surgery should be discussed in the MDT meeting prior to operation. In rare cases of invasive cancer, there will be a recommendation for no axillary surgery, e.g. in a patient with advanced disease undergoing mastectomy for local control and those >80 with radiologically negative axillae who are fit for surgery but in whom chemotherapy will not be recommended.

## **Axillary Sentinel Lymph Node Biopsy**

All patients with invasive early breast cancer should have a preoperative ultrasound examination of the axilla and subsequent ultrasound guided nodal biopsy when indicated.

Sentinel Lymph Node Biopsy (SLNB) is the standard of care for staging the axilla in patients without pre-operative evidence of nodal disease.

The use and timing of SLNB in patients with locally advanced or inflammatory breast cancer is unclear and requires MDT discussion.

SLNB using radiolabelled nanocolloid is safe in pregnant women as the dose to the uterus is minimal. Blue dye should not, however, be used because of the risk of staining of fetal tissues.

A negative SLNB should identify those patients without axillary node involvement, thus obviating the need for ALND with its greater risk of morbidity. The risk of arm morbidity, particularly lymphoedema, is significantly lower after SLNB than ALND. A recent systemic review, performed by the ASCO expert guidelines panel, included 69 eligible trials of SLNB in early stage breast cancer, representing 8059 patients<sup>(18)</sup>. The SLN was identified using radiocolloid, blue dye, or both. Overall, 95 percent had a SLN successfully identified. The false negative rate overall was 7.3 percent.

## **Management of the Patient with Tumour-Positive SLNB**

Further axillary treatment is no longer considered mandatory in all cases of tumour-positive sentinel nodes. In its Consensus Statement<sup>62</sup> of March 2015, the Association of Breast Surgery (ABS) recommends:

### **Isolated Tumour Cells and/or Micrometastases**

No further axillary treatment is required in addition to breast conserving surgery or mastectomy.

### **For 1-2 Sentinel Nodes with Macrometastases**

Further axillary treatment is no longer mandatory in patients who meet these criteria:

- Receiving breast conservation with whole breast radiotherapy
- Post-menopausal
- Have T1, Grade 1 or 2, ER Positive and HER2 Negative tumours.

Further axillary treatment is recommended in this group of patients who meet these criteria:

- Are undergoing mastectomy
- Or who have tumours with one or more of the following features: T3, Grade 3, ER Negative or HER2 Positive.

*These patients could also be entered into the POSNOC or equivalent clinical trial.*

Radiotherapy to the axilla is a valid alternative treatment to axillary lymph node dissection in patients with a low burden of axillary disease.

The ABS Group did not reach consensus on the management of patients with one or more of the following features:

- Pre-menopausal status

- T2 tumours
- Lymphovascular invasion
- Extra-nodal spread

These cases will require individual MDT decisions

### **3 or More Sentinel Nodes with Macrometastases**

Patients should usually be recommended to have further axillary surgical treatment.

The preferred technique is axillary lymph node dissection (ALND) because it gives additional staging information. Where further surgery is deemed inappropriate following MDT discussion, radiotherapy to the lymph node drainage areas may be considered.

**Level of Dissection** — ALND extent can be defined by either the number of axillary LNs resected or their anatomic location. Axillary LNs are divided into three levels based upon their relationship to the pectoralis minor muscle:

- Level I — inferior and lateral to the pectoralis minor muscle
- Level II — posterior to the pectoralis minor and below the axillary vein
- Level III (infraclavicular) — medial to the pectoralis minor and against the chest wall.

Dissection of the axilla to Level III is unlikely to be of additional benefit over dissection of Levels I and II unless the patient has gross disease at the apex of the axilla and does carry an increased risk of lymphoedema and shoulder dysfunction.

The possibility of breast reconstruction should be discussed. The data in studies are inconclusive as to the perceived benefits from reconstructive surgery following mastectomy or breast conserving surgery <sup>(20)</sup>.

### **Larger tumours or with palpable nodes**

- Mastectomy and axillary node clearance to level 2 or 3 is currently the standard treatment in patients with proven axillary node disease.
- In patients in whom axillary ultrasound is negative' sentinel node biopsy is an acceptable alternative to axillary dissection.
- The possibility of immediate or delayed breast reconstruction should be discussed unless this is deemed inappropriate by the MDT, usually on the basis of risk of inadequate excision in the case of immediate reconstruction or risk of recurrence and/or death in the case of delayed reconstruction.
- If considered of doubtful operability, or where downstaging to enable breast conservation is desired, patients may be eligible for pre-operative systemic treatment with either chemo- or hormone therapy. Where possible this should be in a clinical trial.
- The Clinical Trials units at NCCC and JCUH have a portfolio of clinical trials including neoadjuvant treatment of breast cancer. Further information may be

obtained from Dr Verrill (0191 256 3603) Dr Humphreys (01642 282404) or the UKCRN website

### **Complications of Surgery:**

1. Breast conserving surgery. Patients should be warned that the cosmetic results may not be ideal but all surgeons should employ Level I oncoplastic techniques to minimise the risk of poor cosmesis. The primary aim of therapy is to remove the cancer with a low risk of recurrent disease. Level II oncoplastic techniques, such as reduction mammoplasty, may allow larger tumours to be removed whilst preserving the breast in suitable ladies. Similarly, central breast tumours may be considered for breast conserving surgery. The axillary incision can lead to tethering of the axillary skin leading to restrictive movement in the shoulder. All patients prior to breast cancer surgery should be seen pre-operatively by the Physiotherapist and instructed in the post operative exercises; this should continue post-operatively. Damage to the intercosto-brachial nerve results in hypoesthesia in the upper inner arm which may not fully recover. All patients should be warned of lymphoedema and facilities should exist for treatment of this condition at Cancer Unit level.
2. Mastectomy. Patients should be warned of the likely cosmetic appearance following this surgery; this should include practical information about the timing and type of prosthesis available. A small number of patients with large breasts or who are obese may require scar revision subsequently.
3. All types of surgery. Axillary seroma formation, wound haematoma and infection are possibilities and should be explained.
4. Lymphoedema: is a swelling of the arm due to poor lymphatic drainage, which can be caused by surgery, radiotherapy, lymphatic obstruction from tumour, trauma or infection. Venous obstruction can also cause a similar clinical picture. Acute lymphoedema should therefore trigger appropriate investigations or if a recurrence is suspected.

Lymphoedema is common in patients who have had an axillary dissection (2–10%). The combination of axillary irradiation therapy with axillary dissection increases the risk of arm oedema to 13–18%, with some studies putting the risk in this case as high as 38%. Axillary recurrence following adequate axillary surgery is so infrequent (0–2%) that routine axillary radiotherapy is not generally indicated.

Lymphoedema can affect quality of life and activities of daily living, depending on severity. It can lead to reduced movement due to arm weight, pain, cosmetic disfigurement, reduced wound healing, and cellulitis.

Prior to axillary surgery patients should be informed of the risk of lymphoedema and given appropriate preventative advice. Information should be reinforced throughout the patient's journey and on discharge from the CNS caseload. This should include: avoidance of venepuncture, injections or blood pressure recording on the affected side, as well as wearing gloves for gardening,

moisturising the arm daily with a bland emollient to keep the skin in good condition, avoiding insect bites and heat, and being vigilant for signs of infection.

Any signs of infection in the “at risk” arm should be treated promptly with antibiotics as per guidelines - British Lymphology Society (BLS) Guidelines for the use of antibiotics in lymphoedema – available at [www.thebls.com](http://www.thebls.com)

Patients should be taught specific exercises following surgery, which will help to reduce the risk of lymphoedema developing. Prevention of lymphoedema must be highlighted and reinforced throughout the patient journey and supported with written advice.

Treatment of lymphoedema involves skin care, exercises, simple lymph massage and wearing a lymphoedema sleeve, or sometimes compression bandaging. Where appropriate patients should be referred into a specialist service for MLD – Manual Lymph Drainage, a specialised massage to reduce limb size, improve the condition of the skin, and soften sub-cutaneous tissues. All patients should be able to access a local lymphoedema clinic.

## **Cosmetic Breast Reconstruction:**

In the presence of both invasive and non-invasive cancer, immediate reconstruction **must** be discussed in the MDT meeting prior to the procedure.

*Immediate* reconstruction following mastectomy is suitable for patients not likely to require adjuvant radiotherapy:

- Patients with small tumours with likely clear margins and negative nodes who request a mastectomy
- DCIS
- Small but centrally placed lesions
- Prophylactic mastectomy

*Delayed* breast reconstruction is suitable for the following categories of patients:

- Patients who were at high risk of local recurrence but have been disease free for a period of time, generally regarded as 2 to 5 years

*To minimise the risk of loco-regional recurrence* in patients undergoing reconstruction, patients should be advised against reconstruction according to the following criteria:

- High local recurrence risk such as with extensive lymph node involvement
- Extensive skin infiltration
- Disease attached to the chest wall
- Active cancer at any site

## **Pre and Peri-operative Staging**

### **Minimum**

- Full blood count and liver biochemistry should be the minimum baseline investigation for proven invasive breast cancer and should be performed before surgery in all patients.

### **For Higher Risk Cancers**

Gerber et al. studied the frequency of distant metastases in a series of more than 1000 patients with early breast cancer<sup>(21)</sup>. Approximately 3% of patients were found to have metastases. The overwhelming majority of patients had one of the following risk factors:

- Primary tumour > 5cm
- 4 or more involved axillary nodes

It is recommended that patients meeting these criteria should have additional staging in the form of a CT scan of chest and abdomen and bone scan.

Less than 1 in 800 patients without a risk factor have metastases and these patients should not be fully staged unless there is clinical suspicion.

Patients undergoing neoadjuvant therapy with either chemotherapy or hormones should be fully staged before treatment if they have a tumour > 5cm in diameter or palpable axillary lymphadenopathy.

## **RADIOTHERAPY FOR BREAST CANCER**

### **Adjuvant Radiotherapy for Invasive Breast Cancer**

(For non- invasive breast cancer, see below)

#### **Introduction**

**Ideally should begin within 6 weeks of completion of surgery or chemotherapy dependant on wound healing, shoulder mobility and the timing of chemotherapy. Delays of >8 weeks may be detrimental.**

A recent meta-analysis of 15 000 patients confirmed that delay in starting radiotherapy was associated with a significant increase in local relapse rate. This increase was seen when radiotherapy was delayed beyond 8 weeks following surgery corresponding to an increase in local recurrence rate from 5.8% to 9.1% at 5 years (22).

Anthracycline, capecitabine and taxane chemotherapy are radiosensitizers, therefore a gap of at least 3 weeks is recommended before commencing adjuvant radiotherapy. CMF has been given concurrently with radiotherapy. However, the incidence of acute radiotherapy side effects is increased although there is no evidence of an increase in long term side effects

Adjuvant breast radiotherapy after breast conserving surgery is considered standard therapy(23). The EBCCTG radiotherapy overview (24) found that:-

1.  $\frac{3}{4}$  of local recurrence occurred in the first 5 years.
2. Local recurrence was reduced by  $\frac{2}{3}$  by radiotherapy after wide local excision in node negative (reduced from 30% to 10%) and node positive breast cancers (reduced from 45% to 15%) at 15 years.
3. There was a 5% survival benefit from radiotherapy in node negative and 7% in node positive breast cancer after breast conserving surgery at 15 years.
4. Local recurrence was reduced by  $\frac{2}{3}$  by radiotherapy after mastectomy in node negative (reduced from 8% to 3%) and node positive breast cancers (reduced from 30% to 8%) at 15 years. Survival benefit of 5% was seen only in node positive breast cancer after mastectomy.
5. There was an excess mortality from heart disease (rate ratio 1.27, SE 0.07,  $2p=0.0001$ ) and lung cancer (rate ratio 1.78, SE 0.22,  $2p=0.0004$ ).

#### **Post Breast Conserving Surgery**

No subgroup of tumours has been identified which does not benefit from lower local recurrence rates following radiotherapy. However, elderly patients with good prognostic features are at low risk of recurrence. According to the CALGB trial in patients aged >70 with T1N0 ER+ve breast cancer, the five year recurrence rate following breast conserving surgery was 4% without radiotherapy versus 1% with radiotherapy(25). Similar data is available from the PRIME II trial.

In women deemed to be at very low risk of local recurrence, for example patients  $\geq 70$  years out of a research study and  $\geq 60$  years in study with T1N0 oestrogen receptor positive (ER+), progesterone receptor positive (PR+), human epidermal growth factor receptor negative (HER2-), Grade 1–2 tumours AND who are willing to take adjuvant

endocrine therapy for a minimum of five years AND have regular mammograms for ten years. The balance between toxicity from breast radiotherapy and 5 years of endocrine treatment needs to be considered in the treatment decision.

## **Post Mastectomy**

### **High Risk**

The following patients should be offered adjuvant chest wall radiotherapy post-mastectomy:

- All T3 (>5cm) breast cancers
- All T4 breast cancers (involving chest wall or skin)
- Breast cancers with 4 or more positive lymph nodes in the axilla.
- Margin<1mm
- Indications for axillary and/or supraclavicular fossa radiotherapy (see below)

### **Intermediate risk**

Relative indications for adjuvant chest wall radiotherapy post-mastectomy include 2 or more of the following factors: age<40 years, grade 3, 1-3 nodes or lymphovascular invasion (LVI).

Locoregional failure rates following mastectomy without RT are 5 to 15 percent for women with 1 to 3 positive nodes. This question was addressed in the SUPREMO Trial and results are currently awaited. Standard treatment is to offer chest wall radiotherapy if radiotherapy to lymph nodes is planned. In selected good prognosis patients, T1, G1-2, ER+, HER2-, no LVI, who have had ANC clearance, radiotherapy may be omitted.

## **Indications for radiotherapy to lymph node drainage areas**

### **Axilla**

Positive node(s) in patients who have not had an axillary node dissection and don't wish to have further surgery or enter a clinical trial.

### **Supraclavicular fossa**

Four or more positive nodes

Apical node involved

SCF node involvement

### **Internal mammary chain**

The UK consensus statement on Postoperative radiotherapy for breast cancer has recommended the following:

- Internal mammary chain (IMC) radiotherapy should be considered in patients at high risk of recurrence (that is, T4 and/or N2–3 disease).
- IMC radiotherapy should be considered in patients at intermediate risk of recurrence (that is, 1–3 axillary macrometastases and central/medial disease, who have been recommended locoregional irradiation).
- IMC radiotherapy should be given using techniques which minimise doses to organs-at-risk. Every centre should have a breath-hold technique available for patients undergoing IMC radiotherapy.
- The following dose constraints are recommended for IMC radiotherapy: heart V17 Gray (Gy) <10%, ipsilateral lung V17Gy <35%, mean contralateral breast

dose <3.5 Gy; in patients at intermediate risk of recurrence, a mean heart dose <6 Gy is considered a reasonable objective.

The above recommendation is based on the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) meta-analysis of outcomes in women treated with/without post-mastectomy locoregional radiotherapy including the supraclavicular fossa, axilla and IMC (8% reduction in breast cancer mortality at 20 years in patients with 1–3 positive lymph nodes), MA20 and EORTC internal mammary–medial supraclavicular (IM–MS) trials (3–5% disease-free survival benefit); and a Danish internal mammary node study (3.7% overall survival benefit with increased benefit in N2 disease, and in N1 disease with central/medial tumour location).

Treatment of the IMC is not currently standard practice in the UK, although it is being adopted in a number of centres, and the recommendation will be addressed in new NICE clinical guidelines. Currently our recommendation is that IMC radiotherapy is offered to patients with visible IMC nodal tissue on staging CT scan (performed in patients with high risk disease) and selected patients at high risk of local relapse in the IMC, following discussion in the MDT and with the patient, taking into account risks of long-term toxicity.

### **Axillary management of sentinel lymph node-positive disease**

#### **Further local treatment for the malignant sentinel lymph node (SLN) in individuals with early invasive breast cancer:**

- **Sentinel nodes with isolated tumour cells and/or micrometastases** – no further axillary treatment is required in addition to breast-conserving surgery or mastectomy.
- **1–2 sentinel nodes with macrometastases** – further axillary treatment is no longer mandatory in breast conservation with whole-breast radiotherapy in patients who are postmenopausal and have T1, Grade 1 or 2, oestrogen receptor positive (ER+) and human epidermal growth factor receptor negative (HER2-) tumours. *These patients could also be entered into the POSNOC or equivalent clinical trial.*

Standard treatment, outside a clinical trial is to offer further axillary treatment, In these good prognosis patients radiotherapy may be limited to level 1 and 2 nodes (as defined by the ESTRO Nodal Atlas).

- **Three or more sentinel nodes with macrometastases** – patients should usually be recommended to have further axillary treatment. In this case treatment could be either be further surgical clearance or radiotherapy to level 1-4 nodes.
- **Further axillary treatment** should usually be recommended for patients undergoing mastectomy or with tumours with one or more of the following features: T3, Grade 3, ER- or HER2+. *These patients could also be entered into the POSNOC or equivalent clinical trial.*
- No consensus exists on the management of the axilla for patients with one or more of the following features: premenopausal status, T2 tumours, lymphovascular invasion or extranodal spread. Outside a clinical trial, standard treatment with radiotherapy is offered.

## **Radiotherapy after neoadjuvant chemotherapy and surgery**

The management of patients following neoadjuvant systemic therapy is changing as more effective systemic therapy becomes available. There is little clinical trials evidence to guide practice and recommendations are based on review of international guidelines and St Gallen consensus recommendations.

### **cN0 at diagnosis**

After sentinel node biopsy

- ypN0 Radiotherapy to conserved breast  
Radiotherapy to chest wall if indicated based on pretreatment size, tumour characteristics and response to chemotherapy. Consider radiotherapy to levels 1-4 nodes in high risk patients.  
If cT4 at diagnosis RT to chest wall/breast + levels 1-4 nodes
- ypN1 Axillary node clearance, followed by locoregional RT

### **cN1 at diagnosis**

Axillary node clearance followed by locoregional RT.

If an excellent clinical response is demonstrated to neoadjuvant chemotherapy and axilla is US/FNA -, sentinel node biopsy is sometimes considered. In this case:

- ypN0/ypN1mic on 3 sentinel nodes RT to cw/b + L1-4. Where the initial presenting tumour was T1-2, N1 and a complete pathological CR is observed omission of nodal radiotherapy may be considered.
- ypN1macro proceed to axillary node clearance followed by locoregional RT

## **Patients unsuitable for surgery**

A small group of patients are unsuitable for primary surgery resulting from medical incapacity, infirmity or where there is high risk from general anaesthetic (preferably as assessed by the anaesthetist). Hormone therapy is the mainstay of treatment provided the tumour is hormone receptor positive. In one study of 113 patients, hormonal therapy with Tamoxifen provided local control for a median time of 2.5 to 3 years (27). Letrozole has been proven to be superior compared to tamoxifen in terms of time to progression (28). Radiotherapy may be considered appropriate if the tumour is ER – ve, or upon progression on hormonal therapy. Some patients with fungating, bleeding or painful tumours who require a faster response can also be offered primary radiotherapy.

NECN recommendation for palliative radiotherapy for locally advanced breast cancer:-  
Dose 40 Gy in 15 fractions over 3 weeks by tangential fields.

### **Alternative fractionation:-**

In patients felt to be too frail, or unwilling to attend, for three weeks of treatment alternative dose/fractionation may be considered:

Dose 26Gy in 5 fractions over one week as delivered in the Fast Forward trial.

Dose 32Gy in 4 fractions delivered once a week over 4 weeks. There is no published data on this fractionation regime but it has been used previously at the NCCT in a limited number of frail patients who would not be able to cope with daily travel.

### **Tumour bed boost**

A breast boost is not routinely recommended but should be considered in those at above average risk of local recurrence in the region of the tumour bed. It has been demonstrated in an EORTC trial to reduce local recurrence rates following breast conserving surgery in selected patients (29). All patients in the EORTC trial had microscopically complete excision margins. The greatest benefit was seen in those <40 years old (10% vs 20%), a modest benefit in those between 40 and 50 (5% vs 10%) and no benefit in women over 50 years old (3% vs 4%). However, cosmetic appearance was poorer after boost. At 3 years, 86% of patients in the no-boost group had an excellent or good result, compared to 71% in the boost group ( $p = 0.0001$ ). A 2007 update of the EORTC trial (J Clin Oncol 2007 25-22:3259-67) no longer suggests a statistically significant interaction by age group, but the absolute reduction at 10 years was largest in the under 40s.

In line with the most recent UK Consensus Statement the recommendations for boost to tumour bed are:

- All patients under the age of 40 years
- Consider in all patients under the age of 50 years. May reasonably be omitted in G1-2, ER+, Her2- tumours.
- Consider over the age of 50 with higher risk features, especially grade 3 and/or extensive intraduct component, involved margins not amenable to further surgery.

The dose given to boost tumour bed is 13.35Gy in 5 fractions.

## **Adjuvant Radiotherapy for Ductal Carcinoma In Situ**

RT significantly reduces the odds of in-breast recurrence but does not change the odds of distant recurrence or mortality, and therefore should be discussed with each patient carefully. The benefit of RT for DCIS was shown in a 2009 meta-analysis of RT compared with no further treatment following lumpectomy. Compared with lumpectomy alone, RT results in a reduction in the risk of all ipsilateral breast events of approximately 50%. However, treating all women who undergo breast-conserving surgery for DCIS with adjuvant RT may be overtreatment for some. The majority of cases of DCIS do not recur when treated with excision alone, and there may be subgroups of patients with DCIS in whom the risk of local recurrence is so low that RT may be of no benefit.

### **Adjuvant radiotherapy is currently recommended in the following patients following breast conserving surgery:**

High grade ductal carcinoma in situ  
Pleomorphic lobular carcinoma in situ  
DCIS with comedo necrosis

**Radiotherapy is not recommended after mastectomy for DCIS**

## **ENDOCRINE THERAPY FOR INVASIVE BREAST CANCER**

Always consider the current NCRN trial portfolio when considering anti endocrine therapies.

All ER +ve and / or PR +ve patients should be offered endocrine treatment unless there is a contraindication to its use.

### **POSTMENOPAUSAL WOMEN**

**Post-menopausal defined as age over 55 or amenorrhea for at least 12 months (in absence of chemotherapy, tamoxifen or ovarian suppression.)**

For women considered at low enough clinicopathological risk not to require chemotherapy, commence AI alone for 5 years.

After 5 years of treatment if patient is tolerating well, continuation for a further 5 years can be considered, but this should be after discussion with clinician, weighing up small benefit against potential side effects.

For women requiring chemotherapy, ( or where chemotherapy was considered but not administered for reasons including co-morbidity, patient's choice, etc.), commence an AI after chemotherapy for 5 years.

After 5 years of treatment, continuation of treatment for a further 5 years should be discussed on a case to case basis. If the patient is tolerating treatment it seems reasonable to continue for a further 5 years.

Tamoxifen should be offered if AI is not tolerated or contraindicated.

### **PREMENOPAUSAL WOMEN**

For women considered at low enough clinicopathological risk not to require chemotherapy, commence tamoxifen alone for 5 years.

After 5 years recommend a further 5 years of treatment with tamoxifen if tolerating well or still premenopausal.

In patients whom are thought to have become postmenopausal after 5 years of tamoxifen, a switch to an AI for 5 years can be considered. (It can be difficult to establish whether a patient has become postmenopausal and this should only be considered in patients > 55 years, or with care in patients who have chemotherapy induced amenorrhea. FSH and oestradiol can be measured but biochemical proof of post-menopausal status can be difficult to interpret whilst on tamoxifen.)

For women requiring chemotherapy, (or where chemotherapy was considered but not administered for reasons including co-morbidity, patients choice, etc.), Tamoxifen should be offered for an initial 5 years, followed by a further 5 years of endocrine treatment. It is reasonable to consider switching to an AI after 5 years if confident patient has become postmenopausal.

In patients who cannot tolerate tamoxifen/ tamoxifen is contraindicated, then an AI with LHRH analogue or oophorectomy should be considered.

## **OVARIAN SUPPRESSION**

In patients < 35 years and high risk disease, the use of ovarian suppression and an AI or tamoxifen should be considered. Ovarian suppression should be with monthly GnRH agonist. The additional benefit needs to be weighed against the additional toxicity associated with this treatment.

Patients undergoing OS need assessment of bone health.

## **MALE PATIENTS**

Tamoxifen should be offered for 5 years. In male pts unable to tolerate tamoxifen the use of an AI with a GnRH analogue can be considered.

## **SIDE EFFECTS OF ENDOCRINE TREATMENT**

Side effects of endocrine treatment can be considerable. If a patient is not tolerating an AI consider switching to an alternative AI, e.g. From Letrozole to exemestane. If AI still not tolerated consider switch to tamoxifen.

Please see attached guidance for General Practitioners and Specialist Nurses on management of hot flushes.

For patients that have ER+ve breast cancer we would recommend avoiding use of HRT and the Mirena coil, however appreciate in some circumstances this will need to be discussed on a case to case basis with the patient.

## **MANAGEMENT OF HOT FLUSHES IN PATIENTS RECEIVING HORMONE THERAPY FOR EARLY BREAST CANCER**

### Guidance for General Practitioners and Specialist Nurses

Optimal management of symptoms will enhance quality of life and improve treatment compliance allowing patient to benefit fully from treatment. The severity of symptoms is defined by the patient perception and the impact on daily living.

After initiation of hormone therapy symptoms are frequently more prominent and many patients experience a significant improvement after 2-3 months without intervention.

### Natural remedies.

There is no convincing evidence from clinical trials that the following are beneficial however a placebo effect may be observed in up to 50% of cases

- Oil of Evening Primrose
- Vitamin E
- Black Cohosh (avoid – liver damage reported)
- Red clover
- Phyto estrogens

Many other products are recommended in non-medical literature which are ineffective, expensive and some cases hazardous.

There is evidence to support the role of

- Acupuncture
- Relaxation/meditation
- Cognitive behaviour therapy
- Weight loss
- Smoking cessation
- Avoiding caffeine, alcohol and spicy foods
- Regular gentle exercise

### Therapeutic Options

- Venlafaxine 37.5mg daily initially. Increase to 75mg daily if required. There is no evidence that higher doses are more effective. This is the most commonly used intervention and well tolerated. May reduce the effect of tamoxifen as is a weak inhibitor of the enzyme which metabolises tamoxifen to active metabolites.
- Clonidine 0.1mg daily. Use may be limited by dizziness due to hypotensive effect.
- Gabapentin 300mg daily gradually increasing to 900mg daily if required.
- Oxybutinin 2.5mg daily increasing to b.d. if required.

Hormone therapy duration is commonly in excess of five years and vasomotor symptoms vary in severity and frequency during this time. It is recommended that prescription medications be used for max three months then reassess symptoms after a month without intervention.

### Modification of Hormone Treatment

All hormone therapy use to reduce the risk of breast cancer recurrence are associated with hot flushes due to the anti-oestrogen mechanism of action. There is no evidence that one agent is better tolerated in this respect.

Some post-menopausal patients report an improvement following a change in their hormone therapy e.g. switch from letrozole to exemestane. Premenopausal patients taking tamoxifen may be switched to an aromatase inhibitor but only in conjunction with Zoladex 3.6mg monthly with inherent impact on bone health. This should only be undertaken by supervising Oncologist.

The benefit of hormone therapy varies considerably from patient to patient. Post-menopausal patient with small, low grade node negative cancer may have minimal benefit and exploration of the risk benefit ratio may result in selected patients electing to discontinue treatment. This decision should be made following consultation with supervising Surgeon or Oncologist.

Patients may seek further advice from the following websites:

<https://www.breastcancercare.org.uk/information-support/facing-breast-cancer/going-through-treatment-breast-cancer/side-effects/menopausal-symptoms-after-treatment#managing%20menopausal%20symptoms>

<http://www.cancerresearchuk.org/about-cancer/coping/physically/sex-hormone-symptoms/women-coping-with-hormone-symptoms/hot-flushes-and-sweats>

## Endocrine Therapy For Metastatic Disease

Where possible, a patient presenting with new metastatic disease should undergo biopsy of one of the metastatic deposits. This will allow histological confirmation and will also permit assessment of Hormone Receptor and HER2 status of the metastatic disease since this may not be concordant with the status of the original primary tumour.

Endocrine therapy should be considered as first-line treatment for the majority of patients with hormone receptor positive disease, particularly where disease is confined to the bone. Where there is significant visceral disease chemotherapy, followed by endocrine therapy is likely to be the preferred option.

### Pre-menopausal

- Tamoxifen is the first line hormonal therapy of choice for patients with ER-Positive metastatic breast cancer (who are not already taking adjuvant tamoxifen). Those patients who have not previously taken Tamoxifen or who have completed a 5 year course more than one year before are suitable for consideration of Tamoxifen.
- In women already taking Tamoxifen, consider ovarian suppression +/- an aromatase inhibitor.

### Post-menopausal

- Aromatase inhibitors are the treatment of choice for post-menopausal women with ER-Positive breast cancer<sup>(38)</sup>. A change from a non-steroidal to a steroidal AI may give benefit in women who have previously received both a non-steroidal aromatase inhibitor and Tamoxifen.
- Progestogens may be considered in both pre and post-menopausal women when antioestrogens have failed.

### **Hormone replacement therapy (HRT)**

It is advised that every patient diagnosed with breast cancer should cease HRT. There are newer forms now becoming available which may be sufficiently selective to confer a reduced risk to patients with respect to recurrence of their breast cancer. There is currently an NCRN study looking at this.

## **NCA Breast Guidelines**

### **Neo-adjuvant chemotherapy**

There is no proven survival advantage to the use of neo-adjuvant chemotherapy (NAC) over adjuvant therapy. It does however offer certain advantages. Patients in whom NAC should be seriously considered include:

- Inflammatory cancer
- Locally advanced disease
- Larger tumours which with downstaging may become suitable for breast conserving surgery

NAC could also be considered in patients with significant family history in order to allow completion of genetic testing and so allow the patient to make a more informed surgical choice.

Patients with triple negative breast cancer and those with her 2 positive disease (particularly >2cm and/or node positive) are highly likely to be considered for adjuvant chemotherapy therapy. In these groups particular consideration should be given to NAC, ideally in the context of a clinical trial.

For ER positive patients neo-adjuvant hormonal therapy could also be considered.

### **Regimes**

Combination chemotherapy with an anthracycline and a taxane for between 6-8 cycles should be standard. For patients with Her 2 positive disease anti-Her 2 therapies should be included in neo-adjuvant treatment, as per current NICE guidelines.

### **Pre-chemotherapy procedures**

- Imaging
  - Radiological assessment of tumour size and axilla should be made as per local practices
- Core biopsy
  - Diagnosis must be established and ER, PR and Her 2 status ascertained
- Marker clip placement within the primary
  - All patients
- CT staging
  - T3 disease and/or positive axillary nodes

### **Management of the axilla**

- All patients should have their axilla evaluated clinically and radiologically pre NAC
- Suspicious lymph nodes should be biopsied
- In clinically node negative patients, sentinel node biopsy should be performed and this can be done either pre or post NAC
- Biopsy proven malignant nodes pre NAC should be removed post NAC
- Whether a full axillary clearance can be safely avoided in an axilla which was positive prior to NAC and now clinically negative remains controversial

## **Post -surgery treatment**

- Herceptin
  - Her 2 positive patients should complete a total of 18 cycles of Herceptin (including those given in the neo-adjuvant setting)
- Hormones
  - All ER positive patients should be offered adjuvant hormone therapy
- Radiotherapy
  - Patients should be referred to consider radiotherapy as per guidelines
- Further chemotherapy
  - Recent published data has suggested that patients with Her 2 negative disease who fail to achieve a complete pathological response post NAC have an improved survival with the use of adjuvant capecitabine.(1) The effect is particularly marked in the triple negative population. Although this is data from a single trial, this strategy could be considered for individual patients.

## **Adjuvant chemotherapy**

Adjuvant chemotherapy should start at the earliest clinically appropriate date, ideally within 8 weeks of definitive surgery. Beyond 12 weeks the value of adjuvant chemotherapy is highly questionable.

All patients should be discussed at MDT with an oncologist. The decision to refer for chemotherapy should be based upon the pathological information and the patients age and fitness. Electronic tools such as NHS predict can be used to estimate the benefit of adjuvant therapy and aid in decision making.

### **Choice of Adjuvant Chemotherapy Regimen:**

Choice of individual regimen requires an assessment of the risks and benefits for that patient. Adaptations to standard regimes may be required in individual patients.

- Consider entry into a clinical trial
- Standard treatment would be 6 cycles of an anthracycline containing regime eg.
  - EC
  - FEC (75)
  - FEC-T
- Not all patients are suitable for an anthracycline and require anthracycline sparing regime eg.
  - TC \*4 cycles
- All Her 2 positive patients receiving chemotherapy should be offered adjuvant Herceptin (assuming appropriate cardiac function)
  - 18 cycles in total
  - Outside of a clinical trial Herceptin should not be used in combination with an anthracycline
  - It can be used in combination with a taxane
- There is good phase 2 data that for patients with smaller Her 2 positive tumours (<3cm) which are node negative, less aggressive chemotherapy can still result in excellent 5 ys survival (2)
  - Weekly paclitaxel (80mg/m<sup>2</sup> for 12 weeks continuously) in combination with Herceptin can be considered in this group – particularly T1N0

## References

1. Norikazu Masuda, Soo-Jung Lee, Shoichiro Ohtani et al. Adjuvant capecitabine for breast cancer after preoperative chemotherapy: N Engl J Med 2017; 376:2147-2159
2. Sara M. Tolaney, William T. Barry, Chau T. Dang et al. Adjuvant paclitaxel and trastuzumab for node-negative, HER2 positive breast cancer. N Engl J Med 2015; 372:134-141

## **BISPHOSPHONATES FOR BONY SECONDARIES**

Bisphosphonate therapy prevents skeletal complications from osteolytic bone involvement by inhibiting osteoclasts. In the seminal paper by Hortobagyi in 1996, the median time to the occurrence of the first skeletal complication was greater when IV pamidronate 90 mg was delivered 4 weekly compared to the placebo group (13.1 vs. 7.0 months,  $P=0.005$ )<sup>(53)</sup>. In 2001, Zoledronic acid (4 mg) via 15-minute intravenous infusion was published to be as effective and well tolerated as 90 mg of pamidronate given over 2 hours in the treatment of bone metastases in patients with metastatic breast cancer<sup>(54)</sup>. Similar results are available for oral clodronate and ibandronate<sup>(55)</sup>. Upper GI adverse events were higher with oral ibandronate and it should be stressed to the patient that she should drink a full glass of liquid with the tablet and remain upright for at least ½ an hour after taking the tablet.

### **Serious complications from bisphosphonates**

An association has been noted between bisphosphonate therapy and development of the renal impairment due to a number of different mechanisms, including collapsing focal glomerulosclerosis. Because of the potential for renal toxicity, ASCO guidelines recommend that creatinine be monitored prior to each dose<sup>(56)</sup>. An increase of >44 micromol/L in serum creatinine, or an absolute level of >124 micromol/L among patients with normal baseline values should prompt temporary discontinuation. If renal function returns to baseline, therapy can be restarted cautiously.

Osteonecrosis of the jaw is an uncommon complication affecting usually the mandible. In one study, the incidence of ONJ was 1.5 percent among patients treated with these agents for 4 to 12 months, rising to 7.7 percent after treatment for 37 to 48 months.

The following variables were predictive for the development of osteonecrosis (or avascular necrosis) of the jaw:

- Dental extraction
- Sequential therapy with pamidronate/zoledronic acid
- Longer follow-up time
- Older age at diagnosis

Conservative debridement of necrotic bone, pain control, infection management, use of antimicrobial oral rinses, and withdrawal of bisphosphonates are preferable to aggressive surgical measures for treating this condition. The NCA recommends stopping bisphosphonates 3 weeks prior to and for 3 weeks after any dental procedure for patients on bisphosphonates.

## BREAST CANCER FOLLOW UP

Although there is no evidence that routine follow up by a specialist increases long term survival, it is believed that many women welcome the reassurance of regular review whether this is by specialist or by GP. A recent randomised controlled trial suggested that an improved quality of life occurred when patients had access to a breast CNS for one year following surgery <sup>(57, 58)</sup>.

### The purpose of follow up is:

1. To identify salvageable local recurrence. The incidence of local recurrence after conservative surgery and radiotherapy is reported to be about 10% @ 5 years, rising at 1% per year<sup>(16)</sup>.
2. To detect and manage treatment-related toxicity.
3. To screen for new primary tumours.
4. Patient psychosocial support.
5. To assess treatment outcomes/audit.
6. Teaching of Trainees in all disciplines.

*There is no evidence for the use of tumour markers in the follow up of asymptomatic patients and these are not recommended.*

### **North of England Cancer Network follow up protocol for patients treated in the adjuvant setting (complies with NICE guidance) This can be seen in full at appendix 6**

After completion of definitive treatment (includes surgery, radiotherapy, chemotherapy and herceptin if appropriate)

- Low/moderate risk (T1-2, N0, M0)
- 6 monthly clinical review year 1 with the consultant/breast care nurse (BCN) where they will decide together which form of follow-up best meets their needs
- At year 1 an aftercare appointment with the breast care nurse is booked and the patient is transferred to the stratified follow up pathway, no further follow up appointments are offered This appointment should take place within the three months following the end of treatment and feature:
  - o A review of the holistic needs assessment and additional information or signposting given as required.
  - o A clear re-entry pathway to services should be reiterated to patients at this point.
  - o The completion of the treatment summary clearly stating the method of follow up and sent to the patient and their GP.
  - o discussion regarding the next available health and wellbeing event
  - o a telephone contact within the nursing team who can address any concerns
  - o Booking of annual mammograms for 5 years
- Screening appointments and results will be sent annually to patients and their GP enabling remote surveillance monitoring.
- At the end of 5 years from transfer onto follow-up, the individual will be reviewed in a virtual MDT and a letter outlining any ongoing needs sent to the GP .
  
- High risk (T3-4, N1, M0-1)
- After active treatment including herceptin
- 6 monthly clinical reviews year 1 and 2
- Annual clinical review years 3,4,5.

- Review up to and including year 3 is carried out by either the surgical team or oncology team according to local practice. Follow up may be within nurse-led clinics.
- Annual mammograms for 5 years.

In ER and/or PR positive, node positive patients whose initial treatment was Tamoxifen, a discussion about extended adjuvant endocrine therapy should take place after 5 years. This discussion will be led by either the breast team or oncology team. Such patients should continue annual clinical review until this is completed. This may be in a nurse-led clinic.

- If under 50 after 5 years continue 2 yearly mammograms until screening age.
- In younger patients with dense breast tissue MRI scans may be used following discussion at the MDT.
- Annual clinical exam can be continued until 50 if patient prefers.

Follow up can be by a surgeon, oncologist or appropriately trained specialist breast care nurse. The professional carrying out the follow up will be clearly stated on the patient's follow up care plan, so that both the patient and their GP are aware who is taking responsibility for this part of their care. This professional will also be responsible for arranging and monitoring the breast imaging required during the active follow up period.

At each follow up visit the patient will be assessed not just for evidence of breast cancer recurrence, but also for any problems associated with the cancer treatments they have received. This will include the following:

Assessment of cosmesis following surgery and radiotherapy.

- This should include a discussion of any body image problems and the patient's satisfaction with the outcome. Where follow up is not being carried out by an oncoplastic surgeon, referral on to such a team may be required should the patient wish.

Examination for evidence of lymphoedema in those patients who have undergone axillary surgery.

- Immediate referral to a specialist in the treatment of lymphoedema should be made for assessment and treatment if lymphoedema is detected.

Assessment of any side effects caused by systemic therapy.

- This should include advise about the management of any reported symptoms and if necessary referral on to appropriate treatment or support services.
- Monitoring of bone densitometry measurements in patients receiving aromatase inhibitors.

The patient should have the name and contact number of their specialist breast care nurse or key worker, who can be contacted for advice in case of any concerns or new symptoms. Each MDT should have an agreed pathway for early patient review if deemed appropriate following contact by the patient. The following symptoms should precipitate early clinical review:

- New lumps or changes in treated or other breast
- Palpable axillary or supraclavicular fossa lymph nodes
- New and persistent changes in the skin at site of surgery
- Any swelling of arm or hand raising the concern of lymphoedema
- Any new or persistent changes in general health that are unexplained and last for more than a few weeks e.g. shortness of breath or cough, persistent aches or pains

***Clinical trial follow up requirements take precedence over these guidelines.***

## **Patient information**

- 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.

**The NCA written care plan proforma is shown in appendix 3**

## **THE BREAST CARE CLINICAL NURSE SPECIALIST (CNS)**

The CNS is part of the multidisciplinary team and should be available for any patients undergoing treatment for breast cancer if they so wish. Patients should be aware of the CNS availability when attending a breast clinic.

- The CNS should be present at the time of diagnosis when any options for treatment are discussed.
- A suitable room with adequate privacy should be available at this time. The patient may be emotionally shocked and may not be able to assimilate the information given, the presence of a companion such as a partner or friend is encouraged.
- The CNS will initiate a plan of care and arrange further contact with the patient/family as needed, ensuring the patient is aware of how to contact the CNS.
- The CNS will assess each patient's need for information and advice regarding their condition. This may include treatment choices, arm care and mobility, prosthetics, bra advice and treatment options as well as body image and psychosexual issues. The information may be written and/or verbal as desired by the patient.
- Support must be available both pre-and postoperatively and on subsequent outpatient visits to the hospital when patients may be receiving their results and further treatment may be discussed. The CNS should ensure a suitably trained nurse fits mastectomy patients with a temporary prosthesis prior to hospital discharge.
- The CNS will assess the patient for signs of anxiety and depression and refer to other health care professionals as appropriate.
- The CNS will establish links with the primary health care team (PHCT) and other relevant health care professionals to foster collaborative working and improve the patient journey.

- There must be an agreed programme of continuing education for the CNS, including IPR, nursing research and evidence of professional development plans. The CNS needs to be involved in the education of nursing staff on breast disease, both formally and informally, in the hospital setting and elsewhere.
- Ideally breast units need at least 2 CNSs to provide cross cover and it is mandatory that a CNS attends each multidisciplinary team meeting and is a core member of that team.
- The CNS is responsible for ensuring the details of the patient's key worker are recorded in the medical notes.

## PALLIATIVE CARE

1. The median survival of a patient with metastatic breast cancer is 24 months, with between 5 and 20% of patients surviving over 5 years depending on site of metastases. Therefore provision must be made for management of symptoms attributed to secondaries. The hospital team must have access to expertise in palliative care, in order to provide good symptom management advice during OP clinics when necessary, and in order to offer the best possible palliative care to in-patients. Palliative care services should work in liaison with the breast care team and the patient's primary care team.
2. Lymphoedema treatment clinics use a combination of compression, massage and exercise to reduce and control lymphoedema, emphasising the importance of self-management to patients. This is a specialist treatment, and the swollen limb needs careful monitoring to avoid or treat skin damage, thrombosis and cellulitis, whilst monitoring for recurrent disease. Breast cancer units should have access to a local lymphoedema service. The lymphoedema service for breast cancer patients should be fully funded by the NHS, even if it does not take place on NHS premises.

The involvement of palliative care teams in the Hospital and the community should be sought (BASO Guidelines).

### **Palliative care provision:**

Palliative care for breast cancer patients should be available as part of the NHS provision for their care: NCA cancer guidelines should specify this component of treatment, which can be purchased by PCTs via charities (eg local Hospices) or via Trusts. It is not acceptable to assume that a palliative care service funded by charitable means will have the capacity to respond to the needs of all patients referred by practitioners in the NHS. Breast Cancer Units should calculate their potential use of palliative care services, and include these costs in their negotiations with PCTs (see below)<sup>(59, 60)</sup>.

The ideal provision of palliative care services might include:

- CNS in palliative care: ideally, available to attend the breast clinic for symptom management advice, patient and carer support. The palliative care nurse is thus introduced by and integrated as part of the breast care team.
- CNS in palliative care: available for ward consultations for in-patients with palliative care needs.
- CNS in palliative care: in community, for home visits to continue symptom review and psychological support, where needed.
- Consultant in palliative medicine: available to see breast cancer patients with more complex symptoms, either in combined breast clinic or via the consultant's own OP clinic.
- Consultant in palliative medicine: availability to see patients with advanced disease on hospital wards or in their own homes, act as a resource to clinical nurse specialists, offer informal advice to breast care team.
- Attendance at breast cancer MDT, or liaison with breast care team following MDT, to discuss appropriate referrals.

Network wide guidelines exist for the management of certain core symptoms and situations in palliative care. These have been incorporated into a small A5 sized booklet and are distributed across the alliance. They are also available on the Northern Cancer Alliance website where other guidelines and links will be available at: [www.northerncanceralliance.nhs.uk](http://www.northerncanceralliance.nhs.uk)

**We also feel it can be helpful to give an explanation of some of the different terms often encountered when ‘palliative care’ is discussed.**

### **Supportive Care**

- “Umbrella” term for all services which help patient and family to cope with the condition and its treatment – from pre-diagnosis, through diagnosis and treatment, to cure, continuing illness or death and into bereavement
- Aims to help patient maximise benefits of treatment and to live as well as possible with the effects of the disease
- Should be given equal priority alongside diagnosis and treatment.

### **Supportive care includes:**

- |                         |                                    |
|-------------------------|------------------------------------|
| ▪ Self help and support | ▪ Social support                   |
| ▪ User involvement      | ▪ Rehabilitation                   |
| ▪ Information giving    | ▪ Complementary therapies          |
| ▪ Psychological support | ▪ Spiritual support                |
| ▪ Symptom control       | ▪ End of life and bereavement care |

### **Palliative Care**

- Part of, and embraces many elements of, supportive care.

Defined (NICE 2004) thus: *“the active holistic care of patients with advanced progressive illness. Management of pain and other symptoms and provision of psychological, social and spiritual support is paramount. The goal of palliative care is achievement of the best quality of life for patients and their families. Many aspects of palliative care are also applicable earlier in the course of the illness in conjunction with other treatments”.*

### **Key features of palliative care**

- Affirm life and regard dying as a normal process.
- Provide relief from pain and other distressing symptoms.
- Integrate the psychological and spiritual aspects of patient care.
- Offer a support system to help patients live as actively as possible until death.
- Offer a support system to help the family cope during the patient’s illness and in their own bereavement.

**General Palliative Care** is that care delivered by health professionals whose main role is not working with palliative care patients but who necessarily come across these patients in their work. This care is therefore delivered by a majority of healthcare professionals.

**Specialist Palliative Care** is delivered by professionals for whom the majority of their working role is in managing patients with palliative care needs. These

professionals would therefore manage, or be advising in the care of, patients and their families whose needs are more complex, challenging, time consuming and refractory to usual input, and where this demand exceeds that which can reasonably be expected to be delivered by a professional whose main role is in another discipline.

### **End of Life Care**

- An approach that enables the supportive and palliative care needs of both patient and family to be identified and met throughout the last phase of life and into bereavement.

### **Key features of end of life care**

- Anticipation and management of deterioration in the patient's condition
- Advance care planning in accordance with patient preferences
- Patient choice about place of care and death
- Effective co-ordination of care across all teams and providers of care (in statutory, voluntary and independent sectors) who are involved in the care of patient and family

### **Care of the Dying**

- Care of the patient and family in the last hours and days of life.
- Incorporates four key domains of care, physical, psychological, social and spiritual
- Supports the family through this phase and into bereavement.

### **References**

- *Department of Health (2007) Operating Framework 2007/08: PCT baseline review of services for end of life care*
- *National Council for Palliative Care Palliative Care Explained*  
<http://www.ncpc.org.uk>
- *National Institute for Clinical Excellence (2004) Improving supportive and palliative care for adults with cancer. The Manual. London*

## CLINICAL TRIALS

The Cancer Reform Strategy states that “in order to ensure that we build for the future of cancer services there is a need for increased support for research”. This statement underpins the need for promoting research to fill the gaps in the evidence and spreading good practice.

The NCA Research Networks will work with the Service Network to promote integration of research into routine practice.

Both NCA Research Networks will be meeting the performance based working proposals for the National Cancer Research Network (NCRN). This includes maintaining overall accrual and improving accrual into randomised controlled studies, (RCT's) with the aim being to provide as wide reaching a portfolio as possible across the NCA. There is a need to ensure that the Networks portfolios are inclusive of trials for all disease groups and that there is an expansion of pre-malignancy and non-cancer screening trials. Both Networks believe it is important that patients within the NCA have equity of access to trials open.

- New initiatives to strengthen research into prevention of cancer are underway The Research Networks will work with key stake holders and the Primary Care Research Networks to ensure that patients in the North East and Cumbria have access to these trials .
- The CRS states that there is funding for screening trials and the Research Networks will support the setting up and coordination of screening trials
- The NCRN has an important role in identifying potential new therapies and making sure that clinical trials are undertaken in a timely manner. NCRN engages with Industry and NICE with the aim of maximising the impact of NCRN trials on subsequent NHS Practice There will be further investment over the next 10 years into researching cures and treatments of the future. The Research Networks will ensure they maintain a wide reaching balanced portfolio and promote industry trials
- Access to high quality information is a prerequisite for patients to be able to participate in decision making about their care and this includes research trials. All staff need to be aware of research portfolios so they can ensure they provide patients with relevant information
- Reducing inequalities in equity of access to cancer trials.
- Promoting research proposals on cancer in equalities – encouraging more trials which include older people and ensuring that children and young adults are treated at centers where a complete portfolio of relevant trials is supported
- NCRI will help fund research on data collected by the National Cancer Intelligence network (NCIN) , facilitating a more informed analysis of cancer services
- To ensure research is incorporated in World Class Commissioning for cancer
- To work more closely with our Patient and Carer Group, particularly in relation to equity of access for patients to clinical trials. We hope they will be able to help us provide a patients perspective and help support us raise awareness.

The Cancer Reform Strategy supports the need for promoting integration of research into routine practice and the NCA Research Networks are keen to advance this concept.

## **AUDIT**

Data on patients in the NHSBSP are collected as part of QA for the programme.

- Audit data should be collected on all patients with breast cancer.
- Measures should include basic demographics, treatment and outcomes.
- Individual Trusts retain the responsibility for data collection required to demonstrate adherence to prevalent cancer standards.
- Funding for collection of “BASO” data is not available from the NCA.

A network-wide audit will be agreed annually and the results discussed at the March EAG meeting.

## **PATIENT SUPPORT GROUPS**

### **Breast Cancer Care**

Chester House  
1-3 Brixton Road  
London  
SW9 6DE  
[www.breastcancercare.org.uk](http://www.breastcancercare.org.uk)

### **Cancer Research UK**

P.O. Box 1561  
Oxford  
OX4 9GE  
[www.cancerresearchuk.org](http://www.cancerresearchuk.org)

### **Cancer Relief Macmillan Fund**

15-19 Britten St,  
London  
SW3 3TZ  
Tel: 0171 351 7811  
[www.macmillan.org.uk](http://www.macmillan.org.uk)

### **Cancerlink**

17 Britannia St,  
London  
WC1X 9JN  
Tel: 0171 833 2451  
[www.cancerlink.org](http://www.cancerlink.org)

### **Institute of Cancer Research**

123 Old Brompton Road  
London  
SW7 3RP  
[www.icr.ac.uk](http://www.icr.ac.uk)

### **Maggies (general enquires)**

The Gatehouse  
10 Dumbarton Road  
Glasgow  
G11 6PA  
[www.maggiescentres.org](http://www.maggiescentres.org)

### **Maggies Newcastle**

Freeman Hospital  
Melville Grove  
Newcastle Upon Tyne  
NE7 7NU

## BIBLIOGRAPHY

- 1 <http://www.cancerresearchuk.org/aboutcancer/statistics>
- 2 Peto et al Lancet, 355: 1822, 2000
- 3 Breast Cancer Waiting Times – Achieving the Two Week Target. NHS Executive, 1998; HSC 1998/242.
- 4 Austoker, J et al. Guidelines for referral of patients with breast problems. NHSBSP, Sheffield, 1999
- 5 The Royal College of Radiologists, Quality Assurance Guidelines for Radiologists, NHSBSP Screening Publications, 1990.
- 6 The NHS Breast Screening Programme and the Royal College of Pathologists. Guidance on Breast Pathology Services. NHSBSP Publications, 1996.
- 7 Layfield LJ, Glasgow BJ, Cramer H. Fine needle aspiration in the management of breast masses. Pathol-Annu 1989; 24: 23-62.
- 8 Galea M, Blamey RW. Diagnosis by teamwork: an approach to conservatism. Br Med Bull 1991; 47: 295-304.
- 9 National Cancer Alliance. “Patient-Centred Cancer Services”? What Patients Say. The National Cancer Alliance, 1996.
- 10 McArdle JMC, George WD, McArdle CS et al. Psychological support for patients undergoing breast cancer surgery: a randomised study. BMJ 1996; 312: 813-7.
- 11 Fallowfield LJ, Hall A, Maguire P et al. A question of choice: results of a prospective 3-year follow-up study of women with breast cancer. The Breast 1994; 3: 202-208.
- 12 Wolberg WH, Tanner MA, Romsaas EP et al. Factors influencing options in primary breast cancer treatment. J Clin Oncol 1987; 5: 68-74.
- 13 Griffiths M, Leek C. Patient education needs: Opinions of oncology nurses and their patients. Oncol Nurs Forum 1995; 22: 139-143. The NHS Breast Screening Programme and the Royal College of Pathologists. Guidance on Breast Pathology Services. NHSBSP Publications, 1996.
- 14 Gillis CR, Hole DJ. Survival outcome of care by specialist surgeons in breast cancer: a study of 3786 patients in the west of Scotland. BMJ 1996; 312: 145-148.
- 15 Lee-Feldstein A, Anton-Culver H, Feldstein PJ. Treatment differences and other prognostic factors related to breast cancer survival. Delivery stems and medical outcomes. JAMA 1994; 271: 1163-1168.
- 16 UK coordinating Committee on cancer Research(UKCCCR) Ductal Carcinoma in situ (DCIS) Working Party on behalf of DCIS trialists in the UK, Australia, and New Zealand Radiotherapy and tamoxifen in women with completely excised ductal carcinoma in situ of the breast in the UK, Australia, and New Zealand: randomized controlled trial. The Lancet 2003; 362:95-102

- 17 Smitt MC, Nowels KW, Zdeblick MJ et al. The importance of the lumpectomy surgical margin status in long term results of breast conservation. *Cancer* 1995; 76: 250-267.
- 18 Assersohn L, Powles TJ, Ashley S et al. Local relapse in primary breast cancer patients with unexcised positive margins after lumpectomy, radiotherapy and chemoendocrine therapy. *Annals of Oncology* 1999; 10: 1451-1455.
- 19 Kim T; Giuliano AE; Lyman GH Lymphatic mapping and sentinel lymph node biopsy in early-stage breast carcinoma: a metaanalysis. *Cancer*. 2006 Jan 1;106(1):4-16.
- 20 Filiberti A, Tamburini M, Murru L et al. Psychological effects and esthetic results of breast reconstruction after mastectomy. *Tumori* 1986; 72: 585-588.
- 21 Bernd Gerber, Eva Seitz, Heiner Müller, Annette Krause, Toralf Reimer, Günther Kundt and Klaus Friese. Perioperative Screening for Metastatic Disease is not Indicated in Patients with Primary Breast Cancer and no Clinical Signs of Tumor Spread. *Breast Cancer Research & Treatment*, 2003, 82:29-37.
- 22 Huang J, Barbero L, Brouwers M, Browman G, Mackillop WJ. Does delay in starting treatment affect the outcomes of radiotherapy? A systematic review. *J Clin Oncol* 2003;3:555–63.
- 23 National Institutes of Health Consensus Development Conference Statement: adjuvant therapy for breast cancer, November 1-3, 2000. [Eifel P](#), [Axelson JA](#), [Costa J](#), [Crowley J](#), [Curran WJ](#), [Deshler A](#), [Fulton S](#), [Hendricks CB](#), [Kemeny M](#), [Kornblith AB](#), [Louis TA](#), [Markman M](#), [Mayer R](#), Roter D *J Natl Cancer Inst* 2001; 93:979-89.
- 24 Clarke M, Collins R, Darby S, Davies C, Elphinstone P, Evans E, Godwin J, Gray R, Hicks C, James S, MacKinnon E, McGale P, McHugh T, Peto R, Taylor C, Wang Y; Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Effects of radiotherapy and of differences in the extent of surgery for early breast cancer on local recurrence and 15-year survival: an overview of the randomised trials. *Lancet*. 2005 Dec 17;366(9503):2087-106. Review.
- 25 Hughes KS, Schnaper LA, Berry D, Cirrincione C, McCormick B, Shank B, Wheeler J, Champion LA, Smith TJ, Smith BL, Shapiro C, Muss HB, Winer E, Hudis C, Wood W, Sugarbaker D, Henderson IC, Norton L; Cancer and Leukemia Group B; Radiation Therapy Oncology Group; Eastern Cooperative Oncology Group. Lumpectomy plus tamoxifen with or without irradiation in women 70 years of age or older with early breast cancer. *N Engl J Med*. 2004 Sep 2;351(10):971-7.
- 26 Landau DB, Laing RW. An audit of indications and techniques for supraclavicular fossa irradiation in early breast cancer in the United Kingdom. *Clin Oncol (R Coll Radiol)*. 2000;12(3):172-8.
- 27 JM, Preece PE, Dewar JA et al. Long-term follow-up of elderly patients with locoregional breast cancer treated with tamoxifen only. *Br J Surg* 1991;78:213–217.
- 28 Mouridsen H, Gershanovich M, Sun Yet al Superior efficacy of letrozole (Femara\*) vs tamoxifen as first-line therapy for postmenopausal women with advanced breast cancer Results of a phase III study of the International Letrozole Breast Cancer Group *JChn Oncol* 2001, 19(10) 2596-606
- 29 Bartelink H, Horiot JC, Poortmans P, Struikmans H, Van den Bogaert W, Barillot I, Fourquet A, Borger J, Jager J, Hoogenraad W, Collette L, Pierart M; European

- Organization for Research and Treatment of Cancer Radiotherapy and Breast Cancer Groups. Recurrence rates after treatment of breast cancer with standard radiotherapy with or without additional radiation. *N Engl J Med*. 2001 Nov 8;345(19):1378-87.
- 30 Lingos TI, Recht A, Vicini F, Abner A, Silver B, Harris JR. Radiation pneumonitis in breast cancer patients treated with conservative surgery and radiation therapy. *Int J Radiat Oncol Biol Phys* 1991;21:355–60.
  - 31 Schoepel S, LaVigne ML, Fraas BA, Herman JS, Cornell RG, Lichter AS. Radiation pneumonitis after treatment with tangential breast fields: a dose volume analysis (Abstr). Proceedings of ESTRO, Den Haag, The Netherlands: 1988.
  - 32 Maher Committee. Management of Adverse Effects Following Breast Radiotherapy. London, 1995; Royal College of Radiologists.
  - 33 Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. *Lancet*. 2005 May 14-20;365(9472):1687-717.
  - 34 Early Breast Cancer Trialists' Collaborative Group. Tamoxifen for early breast cancer: an overview of the randomised trials. *Lancet* 1998; 351: 1451-1467.
  - 35 Goss PE, Ingle JN, Martino S, Robert NJ, Muss HB, Piccart MJ, Castiglione M, Tu D, Shepherd LE, Pritchard KI, Livingston RB, Davidson NE, Norton L, Perez EA, Abrams JS, Therasse P, Palmer MJ, Pater JL. A randomized trial of Letrozole in postmenopausal women after five years of Tamoxifen therapy for early-stage breast cancer. *N Engl J Med* 2003; 349: 1793-1802
  - 36 Jonat W, Gnant M, Boccardo F, Kaufmann M, Rubagotti A, Zuna I, Greenwood M, Jakesz R. Effectiveness of switching from adjuvant tamoxifen to anastrozole in postmenopausal women with hormone-sensitive early-stage breast cancer: a meta-analysis. *Lancet Oncol*. 2006 Dec;7(12):991-6. Erratum in: *Lancet Oncol*. 2007 Jan;8(1):6.
  - 37 Quella SK, Loprinzi CL, Sloan J et al. Pilot evaluation of venlafaxine for the treatment of hot flashes in men undergoing androgen ablation therapy for prostate cancer. *Journal of Urology* 1999; 162: 98-102.
  - 38 Henning Mouridsen, Mikhail Gershanovich, Yan Sun, Ramón Pérez-Carrión, Corrado Boni, Alain Monnier, Justus Apffelstaedt, Robert Smith, Harm P. Smeets, Fritz Jaenicke, Anna Pluzanska, Magdolna Dank, Dominique Becquart, Poonamalle P. Bapsy, Eeva Salminen, Ray Snyder, Hilary Chaudri-Ross, Raquel Lang, Peter Wyld, Ajay Bhatnagar. Phase III Study of Letrozole Versus Tamoxifen as First-Line Therapy of Advanced Breast Cancer in Postmenopausal Women: Analysis of Survival and Update of Efficacy From the International Letrozole Breast Cancer Group. *JCO* 2003; 21(11): 2101-2109.
  - 39 Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials Early Breast Cancer Trialists' Collaborative Group (EBCTCG) *The Lancet* 2005; 365:1687-1717
  - 40 Goldhirsch, J. H. Glick, R. D. Gelber, A. S. Coates, B. Thürlimann, H.-J. Senn and Panel Members. Meeting Highlights: International Expert Consensus on the Primary Therapy of Early Breast Cancer 2005. *Annals of Oncology* 2005 16(10):1569-1583;

- 41 Jones SE, Durie BG, Salmon SE: Combination chemotherapy with adriamycin and cyclophosphamide for advanced breast cancer. *Cancer* 36:90-97, 1975
- 42 Roché H, Fumoleau P, Spielmann M, Canon JL, Delozier T, Serin D, Symann M, Kerbrat P, Soulié P, Eichler F, Viens P, Monnier A, Vindevoghel A, Campone M, Goudier MJ, Bonnetterre J, Ferrero JM, Martin AL, Genève J, Asselain B. Sequential adjuvant epirubicin-based and docetaxel chemotherapy for node-positive breast cancer patients: the FNCLCC PACS 01 Trial. *J Clin Oncol*. 2006 Dec 20;24(36):5664-71. Epub 2006 Nov 20.
- 43 Cardiac Function, Cardiotoxicity and Chemotherapy. *Clinical Oncology* 13:S230, 2001.
- 44 Jones SE, Savin MA, Holmes FA, O'Shaughnessy JA, Blum JL, Vukelja S, McIntyre KJ, Pippin JE, Bordelon JH, Kirby R, Sandbach J, Hyman WJ, Khandelwal P, Negron AG, Richards DA, Anthony SP, Mennel RG, Boehm KA, Meyer WG, Asmar L. Phase III trial comparing doxorubicin plus cyclophosphamide with docetaxel plus cyclophosphamide as adjuvant therapy for operable breast cancer. *J Clin Oncol*. 2006 Dec 1;24(34):5381-7. Erratum in: *J Clin Oncol*. 2007 May 1;25(13):1819.
- 45 Romond EH; Perez EA; Bryant J; Suman VJ; Geyer CE Jr; Davidson NE; Tan-Chiu E; Martino S; Paik S; Kaufman PA; Swain SM; Pisansky TM; Fehrenbacher L; Kutteh LA; Vogel VG; Visscher DW; Yothers G; Jenkins RB; Brown AM; Dakhil SR; Mamounas EP; Lingle WL; Klein PM; Ingle JN; Wolmark N Trastuzumab plus adjuvant chemotherapy for operable HER2-positive breast cancer. *N Engl J Med* 2005 Oct 20;353(16):1673-84.
- 46 Perez, EA, Romond, EH, Suman, VJ, et al. Updated results of the combined analysis of NCCTG N9831 and NSABP B-31 adjuvant chemotherapy with/without trastuzumab in patients with HER2-positive breast cancer (abstract). *J Clin Oncol* 2007; 25:6s.
- 47 Smith I; Procter M; Gelber RD; Guillaume S; Feyereislova A; Dowsett M; Goldhirsch A; Untch M; Mariani G; Baselga J; Kaufmann M; Cameron D; Bell R; Bergh J; Coleman R; Wardley A; Harbeck N; Lopez RI; Mallmann P; Gelmon K; Wilcken N; Wist E; Sanchez Rovira P; Piccart-Gebhart MJ 2-year follow-up of trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer: a randomised controlled trial. *Lancet*. 2007 Jan 6;369(9555):29-36.
- 48 Joensuu H; Kellokumpu-Lehtinen PL; Bono P; Alanko T; Kataja V; Asola R; Utriainen T; Kokko R; Hemminki A; Tarkkanen M; Turpeenniemi-Hujanen T; Jyrkkio S; Flander M; Helle L; Ingalsuo S; Johansson K; Jaaskelainen AS; Pajunen M; Rauhala M; Kaleva-Kerola J; Salminen T; Leinonen M; Elomaa I; Isola J Adjuvant docetaxel or vinorelbine with or without trastuzumab for breast cancer. *N Engl J Med*. 2006 Feb 23;354(8):809-20.
- 49 Bria E; Cuppone F; Fornier M; Nistico C; Carlini P; Milella M; Sperduti I; Terzoli E; Cognetti F; Giannarelli D Cardiotoxicity and incidence of brain metastases after adjuvant trastuzumab for early breast cancer: the dark side of the moon? A meta-analysis of the randomized trials. *Breast Cancer Res Treat*. 2007 Jul 19;.
- 50 Verrill, MW, Lee, J, Cameron, DA, et al. Anglo-Ceptic IV: First results of a UK National Cancer research Network randomized phase III Pharmacogenetic trial of weekly compared to 3 weekly paclitaxel in patients with locally advanced or metastatic breast cancer (abstract). *J Clin Oncol* 2007; 25:33s.
- 51 Freyer G, Delozier T, Lichinister M, et al. Phase II study of oral vinorelbine in first-line advanced breast cancer chemotherapy. *J Clin Oncol* (2003) 21:35–40.

- 52 Seidman AD, O'Shaughnessy J, Misset JL Single-agent capecitabine: a reference treatment for taxane-pretreated metastatic breast cancer? *Oncologist*. 2002;7 Suppl 6:20-8.
- 53 Hortobagyi GN; Theriault RL; Porter L; Blayney D; Lipton A; Sinoff C; Wheeler H; Simeone JF; Seaman J; Knight RD Efficacy of pamidronate in reducing skeletal complications in patients with breast cancer and lytic bone metastases. Protocol 19 Aredia Breast Cancer Study Group. *N Engl J Med* 1996 Dec 12;335(24):1785-91.
- 54 Rosen LS; Gordon D; Kaminski M; Howell A; Belch A; Mackey J; Apffelstaedt J; Hussein M; Coleman RE; Reitsma DJ; Seaman JJ; Chen BL; Ambros Y Zoledronic acid versus pamidronate in the treatment of skeletal metastases in patients with breast cancer or osteolytic lesions of multiple myeloma: a phase III, double-blind, comparative trial. *Cancer J* 2001 Sep-Oct;7(5):377-87.
- 55 Body JJ; Diel IJ; Lichinitzer M; Lazarev A; Pecherstorfer M; Bell R; Tripathy D; Bergstrom B Oral ibandronate reduces the risk of skeletal complications in breast cancer patients with metastatic bone disease: results from two randomised, placebo-controlled phase III studies. *Br J Cancer* 2004 Mar 22;90(6):1133-7.
- 56 Hillner BE; Ingle JN; Chlebowski RT; Gralow J; Yee GC; Janjan NA; Cauley JA; Blumenstein BA; Albain KS; Lipton A; Brown S American Society of Clinical Oncology 2003 update on the role of bisphosphonates and bone health issues in women with breast cancer. *J Clin Oncol* 2003 Nov 1;21(21):4042-57.
- 57 Grunfeld E, Yudkin P, Adewuyi-Dalton R. Follow-up in breast cancer: quality of life unaffected by general practice follow-up. *BMJ* 1995; 311: 54.
- 58 Grunfeld E, Yudkin P, Vessey MP et al. Evaluating primary care follow-up of breast cancer: Methods and preliminary results of three studies. *Annals of Oncology* 1995; 6: s47-s52.
- 59 Palliative and Terminal Care Health Needs Assessment, I Higginson, 1997.
- 60 Palliative Care 2000: Commissioning through partnership. National Council for Hospice and Palliative Care Services, 1999.
- 61 Davies, C, Pan, H, Godwin, J, Gray, R, Arriagada, R, Raina, V, Abraham, M, Alencar, VH, Badran, A, Bonfill, X, Bradbury, J, Clarke, M, Collins, R, Davis, SR, Delmestri, A, Forbes, JF, Haddad, P, Hou, MF, Inbar, M, Khaled, H, Kielanowska, J, Kwan, WH, Mathew, BS, Mittra, I, Muller, B, Nicolucci, A, Peralta, O, Pernas, F, Petruzella, L, Pienkowski, T, Radhika, R, Rajan, B, Rubach, MT, Tort, S, Urrutia, G, Valentini, M, Wang, Y & Peto, R (2013) Long-term effects of continuing adjuvant tamoxifen to 10 years versus stopping at 5 years after diagnosis of oestrogen receptor-positive breast cancer: ATLAS, a randomised trial. *Lancet*, 381, 805-816.
- 62 Association of Breast Surgery (2015). Association of Breast Surgery Consensus Statement. Management of the Malignant Axilla in Early Breast Cancer. URL: [http://www.associationofbreastsurgery.org.uk/media/48727/axilla\\_abs\\_consensus\\_statement\\_16\\_3\\_15.pdf](http://www.associationofbreastsurgery.org.uk/media/48727/axilla_abs_consensus_statement_16_3_15.pdf) [Accessed 06/04/2015]
- 63 National Institute for Health and Care Excellence (NICE) (2013). NICE Diagnostic Guideline DG10. Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management:

MammaPrint, Oncotype DX, IHC4 and Mammostrat. URL:  
<https://www.nice.org.uk/guidance/dg10/resources/gene-expression-profiling-and-expanded-immunohistochemistry-tests-for-guiding-adjuvant-chemotherapy-decisions-in-early-breast-cancer-management-mammaprint-oncotype-dx-ihc4-and-mammostrat-1053623071429> [Accessed 06/04/2015]

## Appendix 1 – TNM Staging of Breast Cancer

Staging of breast cancer

<b>Primary tumor (T)</b>	
<b>Tx</b>	Primary tumor cannot be assessed.
<b>T0</b>	No primary found.
<b>Tis</b>	In-situ ductal, lobular or Paget disease of the nipple only.
<b>T1</b>	T1mic: Microinvasion not larger than 0.1 cm in greatest dimension T1a: Tumor larger than 0.1 cm but not larger than 0.5 cm in greatest dimension T1b: Tumor larger than 0.5 cm but not larger than 1.0 cm in greatest dimension T1c: Tumor larger than 1.0 cm but not larger than 2.0 cm in greatest dimension
<b>T2</b>	Tumor larger than 2.0 cm but not larger than 5.0 cm in greatest dimension
<b>T3</b>	Tumor larger than 5.0 cm in greatest dimension
<b>T4</b>	T4a: Extension to chest wall, not including pectoralis muscle T4b: Edema (including peau d'orange) or ulceration of the skin of the breast, or satellite skin nodules confined to the same breast T4c: Both T4a and T4b T4d: Inflammatory carcinoma

<b>Pathologic classification (pN)</b>	
<b>pNX</b>	Regional lymph nodes cannot be assessed (e.g., not removed for pathologic study or previously removed)
<b>pN0</b>	No regional lymph node metastasis histologically, or only isolated tumor cells (ITC) (Note: ITCs are defined as single tumor cells or small cell clusters not larger than 0.2 mm)
<b>pN1</b>	pN1mi: Micrometastasis (larger than 0.2 mm but not larger than 2.0 mm) pN1a: Metastasis in one to three axillary lymph nodes pN1b: Metastasis in internal mammary nodes with microscopic disease detected by SLN dissection but not clinically apparent** pN1c: Metastasis in one to three axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by SLN dissection but not clinically apparent.
<b>pN2</b>	pN2a: Metastasis in four to nine axillary lymph nodes (at least one tumor deposit larger than 2.0 mm) pN2b: Metastasis in clinically apparent* internal mammary lymph nodes in the absence of axillary lymph node metastasis
<b>pN3</b>	pN3a: Metastasis in ten or more axillary lymph nodes (at least one tumor deposit larger than 2.0 mm); or, metastasis to the infraclavicular lymph nodes pN3b: Metastasis in clinically apparent* ipsilateral internal mammary lymph nodes in the presence of one or more positive axillary lymph

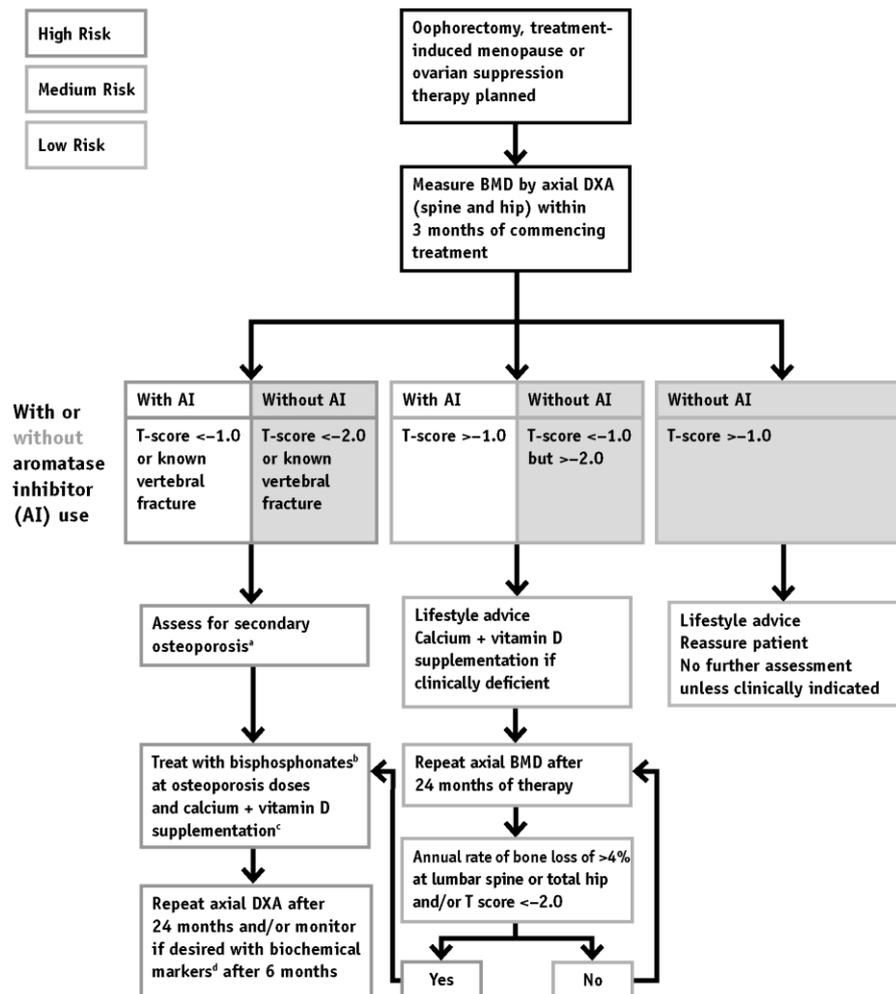
	node(s); or, in more than three axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent** pN3c: Metastasis in ipsilateral supraclavicular lymph nodes
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<b>AJCC Stage Groupings</b>	
<b>Stage 0</b>	Tis, N0, M0
<b>Stage I</b>	T1, N0, M0
<b>Stage IIA</b>	T0, N1, M0 , T1*, N1, M0 , T2, N0, M0
<b>Stage IIB</b>	T2, N1, M0, T3, N0, M0
<b>Stage IIIA</b>	T0, N2, M0, T1, N2, M0, T2, N2, M0, T3, N1, M0, T3, N2, M0
<b>Stage IIIB</b>	T4, N0, M0, T4, N1, M0, T4, N2, M0
<b>Stage IIIC</b>	Any T, N3, M0
<b>Stage IV</b>	Any T, Any N, M1

## Appendix 2 – Algorithms for Management of Breast Cancer Treatment-Induced Bone Loss

### Guidance for the management of breast cancer treatment-induced bone loss

**Algorithm 1:** Adjuvant treatment associated with ovarian suppression/failure with or without concomitant aromatase inhibitor use in women who experience premature menopause



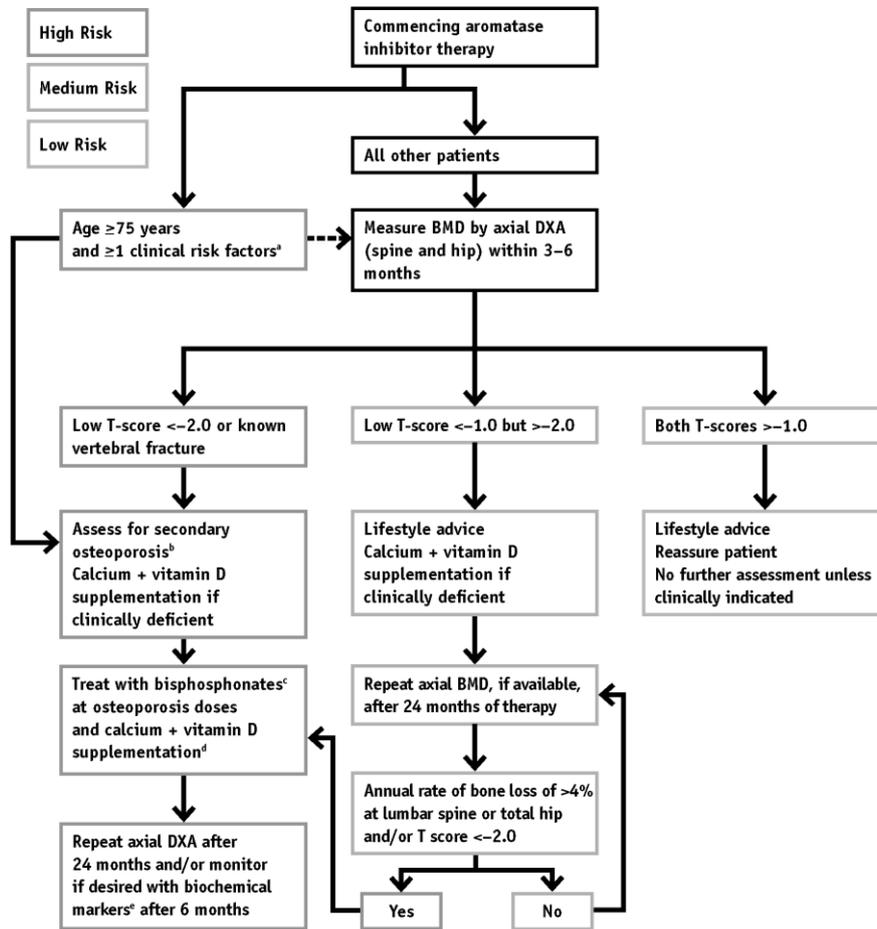
<sup>a</sup> ESR, FBC, bone and liver function (calcium, phosphate, alkaline phosphatase, albumin, AST /  $\gamma$ GT), serum creatinine, endomysial antibodies, serum thyroid-stimulating hormone

<sup>b</sup> Alendronate 70 mg per week, risedronate 35 mg per week, ibandronate (150 mg po monthly or 3 mg iv 3-monthly), zoledronic acid 4 mg iv 6-monthly

<sup>c</sup> To be given as  $\geq 1$  g of calcium +  $\geq 800$  IU of vitamin D

<sup>d</sup> Biochemical markers such as serum C-terminal telopeptide of type I collagen or urinary N-telopeptide of type I collagen

Algorithm 2: Postmenopausal adjuvant treatment with aromatase inhibitors



- a** Previous low-trauma fracture after age 50, parental history of hip fracture, alcohol intake of  $\geq 4$  units/day, diseases associated with secondary osteoporosis, prior corticosteroids for  $>6$  months, low BMI ( $<22$ )
- b** ESR, FBC, bone and liver function (calcium, phosphate, alkaline phosphatase, albumin, AST /  $\gamma$ GT), serum creatinine, endomysial antibodies, serum thyroid stimulating hormone
- c** Alendronate 70 mg per week, risedronate 35 mg per week, ibandronate (150 mg po monthly or 3 mg iv 3-monthly), zoledronic acid 4 mg iv 6-monthly
- d** To be given as  $\geq 1$  g of calcium +  $\geq 800$  IU of vitamin D
- e** Biochemical markers such as serum C-terminal telopeptide of type I collagen or urinary N-telopeptide of type I collagen

## **Appendix 3 - Follow-Up Care After Treatment For Breast Cancer**

This leaflet will explain your follow-up care. It is possible to transfer your follow-up care after your treatment has finished, please advise us if you wish to do so.

### **Follow-up appointments**

You will be followed up in the clinic regularly for five years. During the first year, your appointments will be variable depending on your treatment. After the first year or when you finish treatment your appointments will be yearly. This appointment will include an examination by your team which will be your surgical, oncology or nurse team, a review of your medication and an opportunity to discuss any worries or concerns. If you have no further problems your care will be transferred to your general practitioner after five years of treatment.

If you are taking part in a clinical trial, or are under fifty years of age, your follow-up may be longer than five years.

### **Endocrine therapy/medication**

If you are pre-menopausal you will usually be prescribed Tamoxifen tablets for five years. If you are post-menopausal you may be prescribed a different endocrine drug, i.e an aromatase inhibitor drug. Not everyone is suitable for this type of therapy and this will be discussed with you.

If you are prescribed an aromatase inhibitor drug i.e Anastrozole, Letrozole, Exemestane, (a type of hormone treatment sometimes used to treat post menopausal women with breast cancer) you will need to have a DEXA scan (a scan to check your bone mineral density) as these drugs can cause a reduction in bone thickness. This scan will be arranged by your hospital team or GP when you first start this medication and then may be repeated at two years and five years if necessary. You will be advised if you need further scans.

Your medication will be reviewed at your appointment but if you have any problems with your medication in between your appointment then contact your breast care nurse or GP.

### **Mammogram follow-up**

An x-ray of your breasts (mammogram) will be carried out each year for five years. Your hospital team will arrange this. The breast unit will inform you of the results by letter within three weeks. After five years you will be offered mammograms on the National Breast Screening Programme every three years. Once you are over seventy years old you are still entitled to have a mammogram but you will have to organise this yourself by contacting your local breast screening unit or GP.

Occasionally you may be offered other forms of radiology testing for example ultrasound or MRI, you will be advised if you require these tests.

If you are under fifty you may be discharged after 5 years or you may be reviewed yearly till you are fifty. Your hospital team will discuss this with you.

**What symptoms do I need to look for between my appointments?**

If you notice any of the following symptoms then you should contact your breast care nurse, GP or hospital team for advice:

- If you develop any swelling in your arm/hand and are concerned you are developing lymphoedema
- Recent changes in the area of your surgery including rashes or spots that don't go away
- New lumps at the site of your surgery
- New lumps in your armpits or neck
- New lumps or changes in the other breast or armpit

**Any new or persistent changes in your general health that is unexplained and last for more than a few weeks, for example:**

- Any new persistent shortness of breath or cough
- Any new persistent neck or back pains
- Any new persistent aches or pains

**These symptoms may not be related to your previous breast problem but should be checked out if they are persistent.**

**Concern between appointments**

If you have any other concerns or problems between your follow-up appointments contact your breast care nurse/key worker who will give you advice and if necessary bring your hospital appointment forward

**Your breast care nurse/key worker is.....**

**Contact number .....**

# NCA CHEMOTHERAPY TREATMENT ALGORITHM FOR BREAST

*“Quality and safety for every patient every time”*

## Document Control

Prepared By	Issue Date	Approved By	Review Date	Version	Contributors	Comments/ Amendment
EAG		Chemotherapy group	May 2014	1.1	Network Pharmacists	

For more information regarding this document, please contact:

**EAG Chair:**

## INTRODUCTION

The 2011 Peer Review Chemotherapy Measures require each Network Site Specific group (EAG) to agree in consultation with the Network Chemotherapy Group (NCG) a set of site specific chemotherapy treatment algorithms for the Network.

### *Peer Review Definitions*

#### ***Chemotherapy treatment algorithm***

A guideline which specifies the acceptable ranges of regimen options for named steps on the patient pathway. Treatment algorithms are cancer site-specific. Thus, the treatment algorithm for the Breast EAG includes a statement of the range of regimens agreed as acceptable

#### ***Chemotherapy***

The term 'chemotherapy' refers to the use of those cytotoxic agents commonly understood and accepted as being covered by this term and includes other agents such as, biological therapy and small molecule tyrosine kinase inhibitors used for the systemic treatment of cancer.

In NCA Treatment Algorithms are included in each EAG's Clinical Guidelines which can be found under the tumour specific page of the guidelines section of the website, e.g. for Breast Cancer at:

[http://www.northerncanceralliance.nhs.uk/advisory\\_group/breast-expert-advisory-group/](http://www.northerncanceralliance.nhs.uk/advisory_group/breast-expert-advisory-group/)

## SUPPORTING DOCUMENTS

As new regimens are approved by NICE / NECDAG protocols for use of the new treatment will be uploaded to the chemotherapy site specific pages. The EAG will be asked to update their algorithm with each new treatment approval.

The availability of the Cancer Drug Fund (CDF) has increased the number of treatments potentially available to patients. CDF funded drugs may not be included in the EAG clinical guidelines due to the dynamic nature of CDF funding (i.e. treatments can be removed as well as added).

Any deviation from the algorithm should be recorded by the local Trust clinical chemotherapy service and brought to the NCG for discussion. The Alliance Policy on managing deviations from approved protocols/ algorithms is on the website:

[http://www.northerncanceralliance.nhs.uk/advisory\\_group/chemotherapy-expert-advisory-group/](http://www.northerncanceralliance.nhs.uk/advisory_group/chemotherapy-expert-advisory-group/)

## **LIST OF APPROVED REGIMENS**

The NCA website provides the most up to date list of approved regimens and should be regularly checked. Appendix One below summarises the Breast regimens on the website.

## BREAST ALGORITHM (Extracted from clinical guidelines)

# CHEMOTHERAPY FOR INVASIVE BREAST CANCER

### ***Adjuvant Chemotherapy***

Chemotherapy should start within 31 days of the completion of surgery, or earliest clinically appropriate date. Hormone treatments should be interrupted or delayed until chemotherapy is complete.

Anthracycline containing polychemotherapy (e.g. FAC) reduces the annual risk of death by 38% for women under age 50, and by 20% for women aged 50 to 69<sup>(39)</sup>. The absolute benefit would be proportional to the individuals' risk of recurrence and this can be estimated using the adjuvantonline tool available at [www.adjuvantonline.com](http://www.adjuvantonline.com). This tool is to be used by health professionals familiar with the issues in the adjuvant treatment of breast cancer. The intention is that this tool be used to provide information that will then be helpful in shared decision making by the patient and the health professional.

For women < 70 years old, the St Gallen Consensus statement recommends that:

- All women with Node positive breast cancer and all women with Receptor negative breast cancer should be offered chemotherapy and so should be referred for an oncology opinion<sup>(40)</sup>.

Some women, for example those age >35 with T1, N0, ER+ve Grade 1, HER2 -ve tumours are unlikely to benefit from chemotherapy and do not need to be referred.

HER2 positive breast cancer is a feature which increases (up to double) the risk of recurrence. All patients with HER2 positive breast cancer with tumour size >1cm should be referred to the medical/clinical oncologist for discussion of adjuvant chemotherapy followed by Herceptin (Trastuzumab).

### **Choice of Adjuvant Chemotherapy Regimen:**

*Choice of individual regimen requires an assessment of the risks and benefits for the individual patients.*

*Always consider entry to the NCRN adjuvant trials portfolio.*

Node –negative patients who are suitable for adjuvant chemotherapy should receive an anthracycline containing regimen. Appropriate regimens are:

- **EC X 6 (Epirubicin 90mg/m<sup>2</sup> Cyclophosphamide 600mg/m<sup>2</sup>)**
- **FEC X 6 (5FU 600mg/m<sup>2</sup> Epi 75mg/m<sup>2</sup> Cyclo 600mg/m<sup>2</sup>)**

Dose intensity should be maintained using secondary prophylaxis with G-CSF in event of neutropenic sepsis. Dose reductions are accepted both from the outset and in response to toxicity depending on performance status and clinical judgement of the treating physician.

In patients wishing to minimise the risk of alopecia, or who have a contra-indication to anthracyclines, **classical CMF** would be an alternative.

A taxane containing regimen should be considered in all node-positive patients and offered where clinically appropriate. The regimen of choice is **FEC-T (Docetaxel). TC (Docetaxel + Cyclophosphamide)** is an accepted alternative in patients with cardiac co-morbidity.

A network-wide audit of FEC-T chemotherapy has shown rates of neutropenic sepsis rates in excess of 20% in unsupported patients. **The use of primary prophylaxis with GCSF is therefore recommended with this regimen.**

### **Cardiac Monitoring & Anthracyclines** <sup>(43)</sup>

Transient ECG changes can occur during anthracycline therapy and are not in themselves an indication to discontinue treatment. There is, therefore, no absolute need for an ECG at baseline although it may be a useful marker of cardiac disease.

There is a risk of cardiomyopathy in patients with increasing cumulative exposure to anthracyclines and patients with any of the following risk factors should have a baseline assessment of LVEF by either echocardiogram or MUGA scan.

- Age above 65
- Hypertension requiring medication
- Heart failure
- Left ventricular hypertrophy
- Medistinal irradiation
- Myocardial Infarction
- Planned cumulative doxorubicin dose > 360 mg/m<sup>2</sup> or epirubicin dose > 600 mg/m<sup>2</sup>
  - In these patients repeat assessment during chemotherapy is recommended
- Any other identified cardiac risk factor

### **Adjuvant Trastuzumab (Herceptin)**

20 percent of breast cancers overexpress HER2, a cell surface tyrosine kinase receptor. The addition of Herceptin to adjuvant chemotherapy is recommended for women with HER2-overexpressing tumors that are >1 cm or N+.

Two North American Cooperative Group trials were initially designed as parallel clinical trials. In NSABP trial B-31, 1736 women with HER2-positive, node-positive (N+) breast cancer received AC x 4 followed by Paclitaxel (175 mg/m<sup>2</sup> over 3 hours) x 4; they were randomly assigned to no further therapy (group NSABP-1) or weekly trastuzumab (initial loading dose 4 mg/kg, then 2 mg/kg weekly for one year, NSABP-2), beginning with the first dose of paclitaxel <sup>(39)</sup>. The North Central Cancer Treatment Group (NCCTG)-coordinated Intergroup trial N-9831 tested the value of

adding trastuzumab to sequential AC and paclitaxel. Combined analysis of both trials confirm a 49 percent reduction in the risk of disease recurrence and a 37 percent reduction in the risk of death (four-year OS 93 versus 89 percent)<sup>(45)</sup>. Similar figures were reported for the HERA trial<sup>(46)</sup>.

In the FinHer trial<sup>(47)</sup>, women with N+ or high-risk node-negative breast cancer were randomly assigned to three courses of docetaxel or vinorelbine followed by FEC x 3. The 232 women with HER2-positive breast cancer were randomly assigned to receive nine weekly trastuzumab infusions after completing chemotherapy. DFS was significantly better among those who received trastuzumab (89 versus 78 percent,  $p = 0.01$ ), similar in magnitude as other studies using one year of Herceptin.

There was a higher incidence of cardiac toxicity in the patients that received adjuvant Herceptin. A recent meta-analysis of five randomised control trials of adjuvant Herceptin found a 7.2% increased risk of significant drop in cardiac function and 1.61% increased risk of symptomatic NYHA grade 3-4 heart failure following one year of Herceptin<sup>(48)</sup>.

## **Management of cardiac events in trastuzumab-treated patients**

### **1. Baseline cardiac assessment prior to cytotoxic chemotherapy**

- Medical history & physical examination including BP measurement
  - To detect pre-existing cardiac disease and risk factors.
  - 12-lead electrocardiogram (ECG), with echocardiogram if abnormal
- LVEF measurement using Echo or radionucleotide multiple-uptake gated acquisition (MUGA) scan.

### **2. Interventions at baseline**

- Referral to a cardiologist
  - recommended for patients with significant cardiac co-morbidity.
- Modification of planned chemotherapy regimen
  - In patients with low or borderline LVEF
  - Prophylactic ACE inhibitor therapy may also be considered.
- Initiation of ACE inhibitors to control hypertension
  - Hypertension is a potent modifiable risk factor for the development of heart failure during Trastuzumab treatment.
  - Blood pressure above 140/85 mmHg should be treated with an ACE inhibitor, with primary care supervision of dose and renal function
- Lifestyle recommendations
  - Smoking cessation, healthy diet & alcohol intake, optimising weight

### **3. Management of cardiac function during trastuzumab**

- Assessment of LVEF prior to starting trastuzumab treatment
  - LVEF should be assessed after chemotherapy and before Trastuzumab. Patients with an LVEF  $\geq$  institution LLN should start Trastuzumab.
  - Patients with LVEF  $<$  institutional LLN should not start Trastuzumab but should be started on an ACE inhibitor and referred to a cardiologist.

Repeat assessment of cardiac function should take place after 3 months.

- Sharp falls in LVEF ( $> 0.10$ ) during cytotoxic chemotherapy may indicate increased susceptibility to cardiac dysfunction on Trastuzumab. Prophylactic ACE inhibitor therapy may be considered for such patients.
- Routine LVEF monitoring is recommended after 4 and 8 months.
  - Assessment at the end of treatment is recommended for patients requiring cardiovascular intervention during treatment.
  - Additional testing is required in patients who have LV
- **Patients developing signs and symptoms of heart failure should have their trastuzumab treatment interrupted**, receive an ACE inhibitor and be referred to a cardiologist.<sup>33,44,45</sup>
- If the LVEF falls to  $\leq 0.40$ , (representing biologically important LV systolic dysfunction) trastuzumab should be interrupted the patient should receive an ACE inhibitor and be referred to a cardiologist for treatment.<sup>33,44,45</sup>
- After Trastuzumab interruption and appropriate medical therapy, LVEF should be re-checked after 6–8 weeks. Trastuzumab may be re-initiated if the LVEF is restored to a level above the LLN.
- If the LVEF falls to below the LLN but  $> 0.40$ , trastuzumab may be continued, but an ACE inhibitor should be initiated.
  - If the patient is already on an ACE inhibitor, they should be referred to a cardiologist.
  - LVEF assessment should be repeated after 6–8 weeks.
- If the LVEF falls by 0.10 points or more but remains above the LLN, trastuzumab may be continued. Intervention with an ACE inhibitor is recommended in an attempt to reduce the risk of further LVEF decline of symptomatic CHF.
  - LVEF Monitoring should be repeated after 6–8 weeks.

### Traffic light system

Navigation through these guidelines may be facilitated by the adoption of a traffic light system.

- A green light indicates LVEF above the LLN, no signs or symptoms of CHF and any trastuzumab-related LVEF fall being  $< 0.10$ .
- An amber light indicates LVEF between the LLN and 0.40, with no signs or symptoms of CHF, or a trastuzumab-related LVEF reduction of 0.1 or more.
- A red light indicates LVEF  $\leq 0.40$  or symptoms and signs of cardiac failure.

Prior to chemotherapy, green indicates go. Red or amber indicates careful consideration of decision to start chemotherapy, with consideration of non-anthracycline-containing regimens. Both amber and red are indications for the initiation of ACE inhibitors, and referral to cardiology for the optimisation of cardiac function.

Post chemotherapy, green indicates go. Amber indicates defer until green. Red indicates that it is unlikely to be safe to start trastuzumab. Both amber and red are indications for the initiation of ACE inhibitors and referral to cardiology for the optimisation of cardiac function. It is recommended that LVEF is reassessed after 3

months, and that trastuzumab is not commenced unless LVEF is within normal limits at that point.

During trastuzumab, green is an indication to continue treatment. Amber is also an indication to continue chemotherapy, but patients should also be taking an ACE inhibitor. Patients who drop into the amber range while on an ACE inhibitor should be referred for a cardiology opinion. Red is an indication to interrupt trastuzumab, start on an ACE inhibitor (not already taking one) and refer for a cardiology opinion.

Patients whose trastuzumab is interrupted (i.e. red light) should not restart until LVEF is within the normal range (i.e. green light).

## **Neo-Adjuvant Chemotherapy**

For patients with locally advanced disease or tumours where downstaging might facilitate conservative surgery, including inflammatory breast cancers, neo-adjuvant therapy, ideally in the context of a clinical trial should be considered.

The diagnosis must be established by core biopsy and ER, PR and HER-2 status should be ascertained.

If T3 or node positive, staging investigation including a CT scan of thorax and abdomen ± bone scan should take place before the commencement of neoadjuvant chemotherapy.

FEC or EC for 4-6 cycles is the off trial standard treatment. There are no data on the benefits of post surgical chemotherapy in patients who have received neoadjuvant treatment, although sequences of chemotherapy (eg. Anthracycline followed by taxane) appear to be superior to anthracycline only combinations in this setting.

Patients who are ER positive should routinely be offered Tamoxifen after surgery.

In ER negative patients post surgical treatment should be discussed carefully on a case by case basis and may include Taxane monotherapy.

## **Chemotherapy in Metastatic Disease**

Chemotherapy should be offered as first-line treatment for patients with advanced breast cancer whose disease is imminently life-threatening or requires early relief of symptoms because of significant visceral involvement, providing they have had an opportunity to discuss the likely side effects and are prepared to accept them. The alternative of endocrine therapy should always be considered in hormone receptor positive patients.

This should always be discussed with the appropriate breast oncologist, taking into account the patient's wishes, prevailing NICE guidance and available clinical trial options. The following sequence of drugs may be considered in patients with metastatic disease, bearing in mind previous exposure in the adjuvant setting:-

1. Anthracycline
2. Taxane, 3 weekly docetaxel being the treatment of choice in the younger, fitter patient, weekly taxol being an alternative in others.
3. Capecitabine or Vinorelbine
4. Vinorelbine or Capecitabine
5. Others
6. Platinum-containing regimes for metastatic breast cancer

All suitable patients should be offered treatment within a clinical trial. Where none exists, a platinum-containing regime can be considered particularly in patients who have triple negative disease. If a taxane has not yet been used, the combination of carboplatin and paclitaxel should be considered. In the event of taxane therapy already being used, the combination of choice is gemcitabine and carboplatin. As many patients in this setting are heavily pretreated, a weekly schedule is recommended. The same regime may be considered in patients who are not triple negative, after exhausting all other available therapies, only after a frank discussion about risks and likely response rates.

In all patients receiving palliative chemotherapy consideration should be given to criteria for assessing treatment response including method of assessment and assessment interval.

Patients should have adequate baseline assessment at a time that allows for realistic on-treatment documentation of response.

### **Trastuzumab in metastatic disease**

In HER2 positive patients who relapse after completing adjuvant Trastuzumab, this may be reintroduced, where clinically appropriate, in the metastatic setting. For the best response rates Trastuzumab should be used in combination with chemotherapy, usually a taxane though vinorelbine may be an alternative in some patients.

It is recognised that, in a very small number of patients who would be suitable for trastuzumab, chemotherapy is not always appropriate, or may even be refused by the patient. In this setting single agent trastuzumab may be considered.

Treatment is not recommended beyond tumour progression with the exception of those patients responding to Trastuzumab in non-CNS sites and who relapse in brain and where the intention is to give radiotherapy. In this instance Trastuzumab should continue until either un-treatable CNS progression or progression in a systemic site.

**Further information on chemotherapy and its side effects and dose adjustments in organ failure can be found at:**

<http://www.bccancer.bc.ca/HPI/DrugDatabase/default.htm>

## **APPROVED LIST OF REGIMENS FOR BREAST**

Approved regimens for breast cancers are those that have been released on to the Two Network Chemotherapy E-prescribing systems\* and include those regimens that are either NICE approved, NHS England Baseline funding approved or approved on National Cancer Drugs Fund.

\*Note: One Trust is not part of Network Chemotherapy E prescribing systems and must therefore ensure the regimens it releases onto its electronic system are consistent with those released onto the Newcastle and Tee's Chemocare Networks.

## Appendix 5, Association of Breast Surgery Consensus Statement

### Association of Breast Surgery Consensus Statement

#### Management of the Malignant Axilla in Early Breast Cancer

The following summary statement has been agreed by the Trustees of the Association of Breast Surgery (ABS) following the ABS Multidisciplinary Consensus Meeting on the further management of the malignant axillary node, held in London on 26<sup>th</sup> January 2015. This should be read in conjunction with the 'Summary of Proceedings' of the meeting and the speaker presentations, both of which will be available on the ABS website. A review and full update of the ABS guidelines on the management of the axilla is under consideration and will be published shortly.

#### Further local treatment for the malignant sentinel lymph node in patients with early invasive breast cancer

##### Isolated tumour cells and micrometastases:

If the sentinel node(s) shows isolated tumour cells and/or micrometastases no further axillary treatment is required in addition to breast conserving surgery or mastectomy.

##### 1-2 sentinel nodes with macrometastases:

Further axillary treatment is no longer mandatory in patients who are receiving breast conservation with whole breast radiotherapy, that are post menopausal and have T1, grade 1 or 2, ER positive and HER2 negative tumours.

*These patients could also be entered into the POSNOC or equivalent clinical trial.*

Further axillary treatment should usually be recommended for patients undergoing mastectomy, or with tumours with one or more of the following features: T3, grade 3, oestrogen receptor negative or HER2 positive.

*These patients could also be entered into the POSNOC or equivalent clinical trial.*

No consensus was reached on the management of patients with one or more of the following features: premenopausal status, T2 tumours, lymphovascular invasion or extranodal spread.

##### 3 or more sentinel nodes with macrometastases:

Patients should usually be recommended to have further axillary treatment.



## **Axillary Treatment**

Radiotherapy to the axilla is a valid alternative treatment to axillary lymph node dissection in patients with a low burden of axillary disease.

## **Pre-operative Axillary Staging**

All patients with invasive early breast cancer should have a preoperative ultrasound examination of the axilla and subsequent ultrasound guided nodal biopsy when indicated.

## **Adjuvant Treatment Planning**

The total number of involved axillary nodes is no longer considered to be essential information to decide on the most appropriate systemic treatment. The choice of systemic treatment should be based on the prediction of response rather than the perceived prognosis.

Consensus was not reached on the importance of the total number of involved axillary nodes as essential information for post mastectomy radiotherapy decision making.

Please refer to the summary of proceedings of the meeting.

## **Management of the malignant axillary node diagnosed pre-operatively by ultrasound guided FNA or core biopsy**

There was considerable discussion regarding the management of the pre-operatively diagnosed positive axillary node where patients are planned to undergo breast conservation surgery with whole breast radiotherapy, and where pre-operative information indicates a likely good prognosis and low axillary nodal burden (T1 tumour, grade 1-2, ER positive and postmenopausal status).

However consensus was not reached as to whether sentinel node biopsy should be considered as the next step in such patients. Although there was support for this option, it was apparent that appropriate processes and protocols will be required before further guidelines are agreed.

The ABS Trustees aim to develop appropriate guidelines on this issue as soon as possible.

***Association of Breast Surgery Trustees 16<sup>th</sup> March 2015***



# **Northern Cancer Alliance**

## **Follow up guidelines for low risk breast cancer**

**2017/2018**

**Developed by the Breast Care Nursing  
Department at QE Hospital Gateshead and  
adopted by the Northern Cancer Alliance**

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## **INTRODUCTION**

This document provides regional guidelines to Breast teams for the management of follow up for breast cancer patients. It is designed to complement existing national guidelines e.g. National Institute for Health and Care Excellence (NICE) and NCA breast cancer guidelines. This guideline does not override the individual responsibility of healthcare professionals in making decisions appropriate to the circumstances of the individual patient.

It is not anticipated that the guidelines will cover all clinical situations in all patients, but where unusual circumstances exist, it is expected that such treatments would be discussed in the appropriate MDT.

These guidelines were developed by the Breast Care Nurse (BCM) at Queen Elizabeth Hospital, Gateshead and take into account NICE clinical guidelines, CG80 (NICE February 2009, April 2012) CG81 (June 2014) and CG164 (June 2013),

The guidelines will be reviewed on an annual basis. Where new treatments are introduced between revisions they will be added as an addendum to the current guideline.

## **BACKGROUND**

There are more than 40,000 breast cancers are diagnosed each year in the UK with one woman in 9 developing breast cancer at some time during her lifetime. Between five and ten per cent of women with breast cancer have an inherited predisposition whilst eight of ten breast cancers occur after the menopause. The number of deaths from breast cancer in England peaked in the late 1980's and since then has been falling faster than in any other country. Therefore there are more people living with and beyond breast cancer in England than ever before.

In July 2015 an Independent Cancer Taskforce published a report outlining 96 recommendations for improving cancer care and outcomes by 2020. Achieving World Class Cancer Outcomes - A Strategy for England 2015-20 set out six priority areas for action covering the whole patient journey of which number four is living with and beyond cancer. The aim of which is to ensure that by 2020 every person with

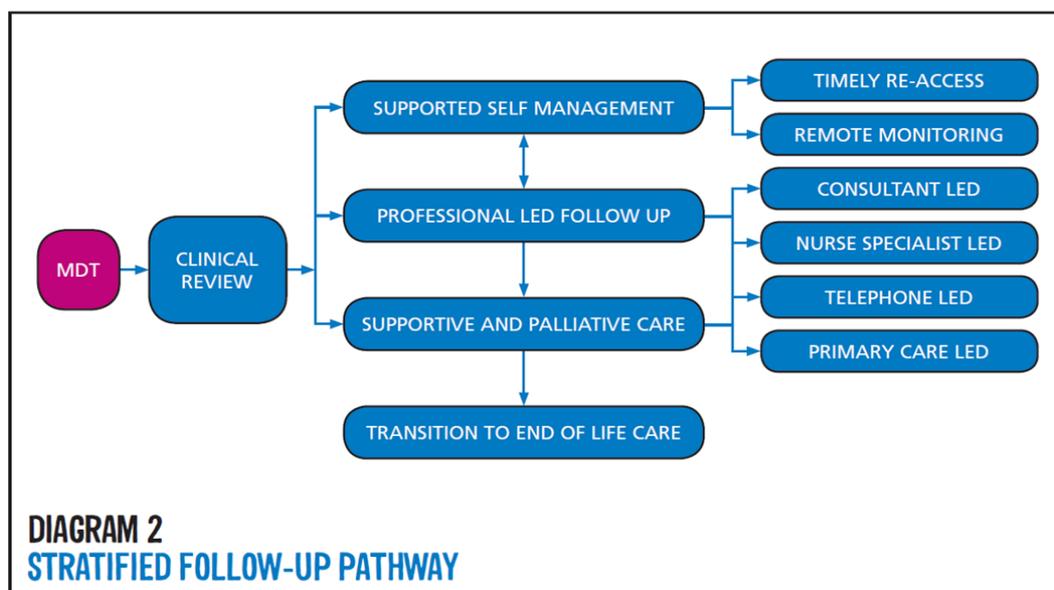
cancer will have access to elements of the Recovery Package, and stratified pathways of follow-up care.

The NHS Operational and Planning Guidance 18/19 secured this vision placing requirements on Cancer Alliances to roll out stratified follow up pathways for breast, colorectal and prostate pathways across their footprint.

Although there is no evidence that routine follow up by a specialist increases long term survival, it is believed that many women welcome the reassurance of regular review whether this is by specialist or by GP. A recent randomised controlled trial suggested that an improved quality of life occurred when patients had access to a breast CNS for one year following surgery (57, 58).his suggested that 75% of breast cancer patients are low risk and could be assigned to the self-management pathway.

Supported directed access offers a more effective approach to after-care than traditional medical models of follow-up which has the potential to reduce costs and improve patient satisfaction. Evidence for this model is based on the work undertaken by the National Cancer Survivorship Initiative in 2011 which has been emulated in other parts of the country such as Bath Breast Service and Northern Ireland. The Northern Cancer Alliance model builds on this and can be seen below.

## STRATIFIED FOLLOW UP PATHWAYS



Following clinical assessment of their needs, low risk patients can be supported to manage their own follow-up, with back up from the clinical team as needed. This is designed for eligible patients who have had treatment for primary breast cancer. Under this system patients will no longer have routine follow up appointments; instead they are educated and encouraged to contact the breast care nurses when they have a new concern or problem regarding their breast cancer. Surveillance imaging will be arranged by referral letter to breast screening.

The aim of this follow up is to allow patients to manage their own health and avoid unnecessary hospital visits and the anxiety that many women feel when they have to attend routine follow up appointments. It will give patients access to the breast clinics when they need it.

The patients follow up plan will be discussed with the patient when they attend the consultant's clinic for their histology results and written information about the plan will be given to the patient by the BCNs. (appendix 4).

## **ELIGIBILITY CRITERIA**

Patients who are classified as **low risk** of developing further problems following treatment for breast cancer, as identified at MDT, are eligible for stratified follow up. Shown at pathway appendix 4 and summarised below this includes:

- Patients whose surgical treatment is complete
- Patients who have not received chemotherapy and or Herceptin
- Patients who are not under the oncologist care
- Patient's on primary endocrine therapy

Patients who may not be suitable for stratified follow up are classified as **high risk** this includes:

- Patients who have received chemotherapy
- Patients on Herceptin
- Metastatic patients

- Patients who are under oncology care
- Patients on primary endocrine therapy (this will need to be a clinical decision)
- Patients where there is a concern re. compliance
- Patients requiring MRI as surveillance
- Male patients
- Patients still undergoing surgical treatment (e.g. reconstruction)
- Those where there is clinical concern

## PROCESS

### Existing Patients

All existing low risk patients who are over a year post surgery on the five year follow up pathways will be encouraged to transfer into the new follow up pathway. Existing patients who have been on the follow up pathway for **less than two years** will follow the process for new patients. Existing patients who have been on the follow up pathway for **over two years** can be discharged by the clinician with the discharge information booklet at (Appendix 1). For patients in this group who need more support a further appointment with the BCN can be arranged where the BCN can discuss the discharge plan in more detail. (Appendix 5)

### New patients

After surgery is completed new patients will attend the surgical clinic and be reviewed by the team. The clinician will discuss the follow up plan with the patient as per the eligibility criteria and MDT discussion. If the patient is suitable for low risk follow up as identified at the MDT, an appointment will be made to see the surgical team again in 6 months. At this appointment the patient will be referred to the breast care nurse clinic for their final review at one year after surgery (pathway appendix 6).

At the appointment with the BCN, which should take place within the three months following the end of treatment there will be:

- A review of the holistic needs assessment (Appendix 2)

- A comprehensive information booklet be given to the patient which advises them of their about their planned follow up, access back into the service and support services available (appendix 1)
- Completion of the treatment summary clearly stating the method of follow up and sent to the patient and their GP. (appendix 3)
- Information supplied regarding the next available health and wellbeing event
- Confirmation of booking of annual mammograms for 5 years and how results will be received

## **CLINICAL RESPONSIBILITIES AND ROLES**

### **Stratification**

The breast team / consultant is responsible for identifying patients suitable for low risk follow up at the MDT. The decision should be made based on clinical judgement and discussion with the patient, then recorded on the post-surgery MDT Performa and filed in the patients notes.

### **Discharge Consultation**

The Breast Care Nurse Specialists will manage the early discharge consultation. They will ensure that the patient is provided with written information (appendix 1) a treatment summary has been completed and a copy has been sent/given to the patient and sent to the GP (appendix 2). A holistic needs assessment will also be carried out and action taken as necessary. A copy will be placed in the patient's notes (appendix 3). All surveillance and scans should be in place and patients are aware of how results will be received.

### **Surveillance and Scans**

#### ***Mammograms***

When the patient is selected to go on to low risk follow up, the clinician will forward a referral letter to the breast screening secretaries (as pathway in appendix 7). The patient will receive a yearly mammogram for 5 years or until they reach screening age. At this point patients will receive 3 yearly mammograms via the screening programme.

### **DEXA scans**

The clinician will book the patients first DEXA scan and blood tests when an aromatase inhibitor is prescribed and copy the letter to the osteoporosis team. Subsequent DEXA scans/treatments will be organised by the osteoporosis team. (Pathway appendix 8).

### **Re- access to Breast Services**

Patients will receive verbal and written information about how to re access the service if they have a problem or concern at the consultation appointment with the BCN. Patients should contact their breast care nurse via telephone who will give them verbal advice or arrange a clinic appointment for the BCN clinic /follow up clinic/symptomatic clinic (Pathway appendix 9)

Patients can also re-access the service via their GP.

### **Discharge from service**

All patients on this pathway will be discharged back to the GPs care at 5 years and will have to re-access the service via their GP. Written information will be given to the patient/GP on the patient's treatment summary to advise them regarding this date.

## **ADVICE**

### **Endocrine therapy**

Patients, who are having problems/side effects from endocrine therapy, will be advised to contact their breast care nurse who will give verbal advice or refer to the appropriate consultants follow up clinic.

### **Prosthesis service**

Patients will have direct access to the prosthetic service and will be given information on how to access the service by their BCN at their final appointment.

### **Lymphoedema**

Patients can access the lymphoedema service directly via their Breast Care Nurse. Clinicians can refer to the lymphoedema clinic by sending a written referral to the Breast Care Nurse Specialists.

### **Patient who would like to consider reconstruction**

If a patient would like to consider breast reconstruction they then can contact their breast care nurse who will arrange for them to attend for a discussion on their options of breast reconstruction. The patient will then be added to the consultant's clinic if they wish to discuss further or proceed with reconstruction.

### **Psychological support**

Patients can continue to contact their breast care nurse if they need psychological support/ advice. All BCNs have access to the psychology service at Bensham if required.

### **Support services**

All patients will receive an information package from their BCN which will give them contact details of local support services and signpost them to available services.



# Information booklet for follow-up care after treatment for breast cancer

# Information booklet for follow-up care after treatment for breast cancer

**Your Breast Care Nurse is:** \_\_\_\_\_  
**Contact tel no:** \_\_\_\_\_

## Follow up plan

This booklet will inform you of your planned follow up care after treatment for breast cancer. Once you have completed treatment you will not need to attend the follow up clinic regularly but you will remain under our care for the next five years. This means that you will not have to attend regular hospital appointments; instead you can quickly gain access to the breast care team and hospital when you need to. After five years or when you reach screening age your care will be transferred to your GP.

## Treatment summary

When you visit the clinic for the final time you will receive a treatment summary. The Treatment Summary gives information about your diagnosis and treatment as well as how your follow up care will be organised. This includes:

- the dates of your future mammograms, if needed
- the dates you started and should complete your anti-cancer medication
- the dates of bone density (DEXA) scans if applicable to you
- further help and support
- How to contact the breast care team

## What about mammograms in the future?

After breast cancer you have a small increased risk of developing a further cancer in the same breast (recurrence) or a new cancer in the other breast. Mammograms (breast x rays) can detect breast cancer before it is able to be felt, either by you or a health care professional. For the majority of women, mammograms are the recommended way of checking for breast cancer. Our current recommendations are that you should have annual mammograms for five years following your diagnosis, or until you reach the age at which the National Breast Screening Programme starts. These mammograms will be organised by the surgical team. For a small number of women mammography may not be appropriate and if this is the case, we will discuss the other options with you.

## Results of mammograms

After your mammogram, you will receive your results letter within two weeks. If you do not receive your results within one month of having your mammogram, please contact us on 0191 4452554.

Sometimes, after having treatment for breast cancer, mammograms are not as easy to read; therefore we may recall you so we can carry out further assessment or investigations. We will contact you by letter if this is the case.

## The NHS Breast Screening Programme

A screening invitation is sent every three years to all women between the ages of 50 and 70 years. If you have recently undergone treatment for breast cancer and receive an invitation to attend for a screening mammogram during the 5 years when you are under our care, please cancel the appointment with the NHS Breast Screening Unit, telling them that you are receiving regular mammograms at the hospital after treatment for breast cancer.

## After your annual mammograms

**If you are aged over 50 years:** after five years of follow up at the hospital you will be invited and should attend the National Breast Screening Programme and receive mammograms every three years through your local screening service.

**If you are aged under 50 years:** we will recommend that you continue with annual mammograms until you are invited for routine screening. You will then be offered mammograms every three years through your local NHS Breast Screening service.

**If you are aged 70 years or over:** you may not be automatically called for routine screening. However you can continue to receive three yearly mammograms under the NHS Breast Screening Programme by requesting an appointment and it is recommended that you do this. Please contact your local NHS Breast Screening Unit on 0191 4452554 or your GP to arrange this.

## Your cancer medication - endocrine therapy

Patients with hormone sensitive cancers are usually prescribed anti- hormone tablets, also known as endocrine therapy. Anti-hormone therapy will include Tamoxifen, Letrozole, Arimidex and Exemestane. You will usually be on these tablets for five to ten years, although some patients may be advised to continue with their tablets for a longer period of time. Your treatment Summary will confirm the date you started your hormone medication and the date you will complete five – 10 years of hormone therapy.

You will not have to pay for tablets as you are entitled to free prescriptions for five years. A medical exemption certificate is available from your GP surgery, hospital pharmacy or local chemist.

## **Possible side effects of hormone medication**

You may experience side effects that are particular to the drug you are taking.

For example, as a result of taking tamoxifen the lining of your womb may become thicker which can then cause vaginal discharge/bleeding. This is common and not usually serious. However, if your periods have stopped and you experience unexpected vaginal bleeding please contact your GP. You may need to be referred to a gynaecologist. Contact your breast care nurse if you need advice.

There is some research that suggests some drugs – including the antidepressants paroxetine (Seroxat®) and fluoxetine (Prozac®) – may cause tamoxifen to be less effective, but this isn't certain. If you are prescribed these whilst you are taking tamoxifen please contact your GP as you may need to change your antidepressant medication. Aromatase inhibitors such as Letrozole can sometimes cause joint stiffness and pain, as well as vaginal dryness which some women find uncomfortable. If you are experiencing side effects of medication please contact your breast care nurse who will be able to offer further support and advice.

## **DEXA scans and bone health**

When you are taking an aromatase inhibitor such as Letrozole, Arimidex or Exemestane, we will recommend you have DEXA scans (a scan to check your bone mineral density as these drugs can cause a reduction in the density of your bone mineral) These scans can tell us if you are developing bone thinning which could lead to a condition called osteoporosis. These scans will be organised by the osteoporosis team. You will also need to attend the osteoporosis clinic. Regular exercise such as walking as well as a diet high in calcium will help to maintain bone health.

## **Possible side effects of treatment**

All treatments (surgery, chemotherapy, and radiotherapy and hormone therapy) have the possibility of some side effects and some of these can last longer than others. Not everyone will experience side effects and some patients may experience more difficulty with them than others. Below are some of the common side effects you may experience:

- breast discomfort or tenderness
- menopausal related side effects
- Fatigue (tiredness) – this is very common after treatment for breast cancer but will usually improve over time.
- Lymphoedema – swelling to the side of your surgery, breast, arm, chest wall which is caused by a build-up of lymph fluid in the tissues. This builds up as a result of damage to the lymph system because of surgery or radiotherapy to the lymph nodes.

If you have concerns about any of these side effects please contact your breast care nurse/GP

## What can I do about hot flushes?

Some ladies experience hot flushes as a result of treatment for breast cancer. Coping with cancer provide a service based at the Queen Elizabeth Hospital and at South Tyneside Hospital to help relieve these symptoms with the use of acupuncture. If you are interested in finding out more about this, your breast care nurse can provide you with written information. Coping with cancer can be contacted on 0191 280 5610.

## What symptoms do I need to look for?

It is important to know that survival rates for breast cancer are improving all the time and that modern breast cancer treatment is usually very successful. However, breast cancer can sometimes return. There is no maximum time span as to when breast cancer can return but for most people the risk reduces over time. It is important that you are aware of what to look out for and what to do if you become concerned about anything.

Breast cancer can return:

- in the treated breast (local recurrence)
- in the nearby area under your arm, above your collarbone or neck area (regional recurrence)
- in the other breast or
- elsewhere in the body (distant recurrence also known as metastatic breast cancer or secondary breast cancer)

Everyone has aches and pain, but when you have had breast cancer, you may be more aware of them and may be concerned that any pain is related to cancer. Included below is a summary of symptoms that you may want to report to either your breast care nurse or your GP. If you experience any of these symptoms it does not necessarily mean that your cancer has returned as they can be caused by many other common conditions, but it may mean that you should get them checked out by the breast team.

Getting a recurrence or a new cancer can be frightening, but it is important to remember that if breast cancer returns, it can usually be treated

## Summary of symptoms you may want to report:

Please contact us if you experience

- a lump or a swelling in your breast, in the skin after a mastectomy, above your collarbone, in the neck area, or under your arm
- any skin changes including dimpling, puckering, redness or raised spots on your breast or mastectomy scar
- nipple discharge
- if you develop lymphoedema (arm swelling on the side you have had surgery)

Or if you experience:

- any new persistent shortness of breath or a cough
- any new persistent aches or pains in any part of your body
- persistent headaches/dizziness

## **Breast awareness**

Being breast aware is an important part of caring for your body. It means getting to know how your breasts look and feel, so you know what is normal for you. You can then feel more confident about noticing any changes.

We know that after having treatment for breast cancer it can take some time (up to two years) to become familiar with your treated breast. However, the better we know our bodies, the quicker we notice what is normal or not normal for us. If something feels not normal for you, please contact your breast care nurse.

There is no right or wrong way to get to know your breasts. Try to get used to the way your breasts look and feel. You can do this around once a month, in the bath or shower, when using soap or body lotion. There is really no need to change your everyday routine. You can find leaflets and websites which may be helpful.

Your breast care nurse can recommend you to some if you wish. You know better than anyone how your breasts look and feel normally, so if you notice a change, contact your breast care nurse.

## **Younger women**

Younger women may have different needs at the end of treatment such as:

- The impact of treatment upon your fertility
- Becoming pregnant after treatment
- Issues related to body image and sexuality and how this may impact upon relationships
- Advice about contraception.

Your Breast care nurse may be able to advise you on this. You can also discuss your fertility needs with your oncologist.

There are various support groups available locally and on social media specifically for younger women. Breast Cancer Care provides services specifically for younger women with breast cancer. These include:

- Volunteer peer supporters – younger women with personal experience of breast cancer trained in one to one support
- Telephone support groups
- A help line – Tel 0808 800 6000
- Younger women's forum- [breastcancer.org.uk](http://breastcancer.org.uk)

- Internet chat rooms
- Accurate up to date written information

## **Contraception**

Even though you may not be having regular periods, you may still be able to get pregnant. Effective contraception is important. You may be advised to avoid hormone based contraception such as the pill/ mirena coil.

## **Breast Reconstruction**

If you have had a mastectomy and decided or were advised against immediate breast reconstruction but change your mind at a later date, please contact us via your breast care nurse to discuss delayed reconstruction. In some cases surgery can be offered to correct unequal breast sizes and your breast care nurse can refer you back to clinic if you wish to discuss this further. It is natural for breasts (treated and untreated) to change over time.

## **How do I arrange to get new breast prosthesis?**

If you need a new prosthesis, please contact the breast care nurse secretary on (0191 4453746) and she will arrange an appointment with our prosthetic fitter. If you just want a replacement and not a fitting please inform the secretary of the name and code of your prosthesis and she will arrange for this to be ordered for you and can be collected from the breast screening unit reception at your convenience.

## **Feelings and emotions:**

Everyone will have different feelings when they no longer need to see their medical team regularly. Some people feel relieved that they can start to get their lives back to normal, others may be concerned about what can happen in the future and anxious about losing contact with the hospital where they received their treatment. Most people worry about the cancer coming back at times. This is very normal and usually these anxieties lessen with time.

Realising that there is a problem and getting help is the most important thing you can do. While it is normal to feel low from time to time, sometimes you may find the way you are feeling is interfering with your enjoyment of life. If you are finding it difficult to cope your Breast Care Nurse/GP may be able to arrange an appointment for counselling. It may also help to contact a local or national support organisation such as Breast Cancer Care or Macmillan Cancer Support. Their contact details can be found at the back of this booklet.

## **Who do I contact if I have a concern?**

Once you have been discharged from the clinic you should contact your breast care nurse by telephone about any new symptoms that you are concerned about or other issues you may have. The aim of the telephone service is to provide helpful advice and allow you to have rapid access back to the breast team as required. When you reach 5 years following treatment your care will be transferred back to your GP and you would need to be re-referred into the breast service.

If your breast care nurse advises you that you need to be seen back in one of our clinics because of any symptoms you are experiencing, we will ensure that you are offered an appointment within 72 hours of contacting us. However if you decline this appointment then you will be offered the next available appointment. If necessary, further investigations may be organised and an out-patient appointment arranged to receive the results. Sometimes, verbal advice may replace the need for an outpatient appointment and may be supported by a written letter to you and your GP. We hope that this enhances and promotes your ability to care for yourself once treatment has been completed and enables you to benefit from the team's expertise as required.

## **Life after treatment /Health and well being**

### **Diet/exercise**

There is a lot of research being done to find out how diet may affect the risk of cancer developing. Some research has shown that being overweight and not eating enough fruit and vegetables could increase your risk of cancer.

Eating a balanced diet is one of the best choices you can make for your overall health. Keeping to a healthy weight will help you maintain or regain your strength and have more energy. Regular exercise is also important. More and more research is showing that exercise can reduce the risk of breast cancer coming back (recurrence) if you've been diagnosed, as well as reducing the risk of developing breast cancer if you've never been diagnosed. Exercise can also help you maintain a healthy weight, ease treatment side effects and boost your energy. All these steps can also reduce the risk of new cancer, heart disease, stroke and diabetes.

Making changes to your diet is not always easy. It may be more difficult if you are coping with a cancer diagnosis and having treatment. You could make changes gradually so that it is easier to eat differently. Many people find making this positive choice helps give them back a sense of control. It can also help you feel that you're doing the best for your health. Thinking about what and how much alcohol you drink is part of this too. Eating well and keeping to a healthy weight will help you maintain or regain your strength, have more energy, and have an increased sense of well-being.

## **Local Support services**

If you are worried about something to do with your breast cancer, or the treatment that you have had for it, please contact your breast care nurse. They would rather see you with something that

turns out to be nothing, than for you to be at home worrying. They are there to help you, so please call if you have any questions or concerns.

### **Cancer information centre**

If you are experiencing housing, employment, immigration, financial or welfare benefits issues, you can get help by contacting cancer information centre at the Queen Elizabeth Hospital on 0191 445 2979 or the cancer information centre in City Hospitals Sunderland telephone, Deborah Spraggon, Macmillan cancer support manager on 0191 05410122.

If there are other issues which concern you, that are not offered here, please discuss them with your breast care nurse, who may be able to advise you on where to get help and support and information if you need it.

### **Macmillan nurses**

Macmillan nurses give supportive care and advice to patients with cancer. This includes emotional, financial and practical support. A Macmillan nurse can be contacted via your GP, District nurse, Breast care nurse or Oncologist.

You can contact the Macmillan support line direct on 0808 808 0000 (Monday to Friday 9am-8pm). Or visit [be.macmillan.org.uk](http://be.macmillan.org.uk)

### **Marie Curie Centre**

Offers specialist nursing and medical care  
Tel 0191 2737931

### **Breast cancer care**

Breast cancer care is an organisation that offers practical advice and information. They also provide discussion forums, a confidential helpline chat and one to one support

Tel 0808 8006000 [Info@breastcancercare.org.uk](mailto:Info@breastcancercare.org.uk)

Free booklet available on moving forward for people living with and beyond breast cancer (contact Breast Cancer Care)

### **Cancer connections (South Tyneside)**

Offers emotional, financial and practical support including counselling and complementary therapies. Tel 0191 4565081.

### **FACT (Fighting All Cancers Together)**

FACT is a local charity based in Gateshead that offers support, advice and practical help to cancer patients and their families. Tel 0191 4420833. [www.fact-cancersupport.co.uk](http://www.fact-cancersupport.co.uk)

### **Maggie's (Freeman Hospital)**

Offers practical, emotional and social support to people with any form of cancer and their families. You can drop in to the centre Monday – Friday 9am-5pm. Maggie's have a rolling programme of support events or tel 01912336600. [newcastle@maggiescentres.org](mailto:newcastle@maggiescentres.org)

### **Coping with cancer**

Offers help and support as well complimentary therapies. Tel 0191 2805610.

### **CANCERBACUP**

London. Tel 0800 181 199.

[www.londonline.co.uk](http://www.londonline.co.uk)

### **CANCERLINK**

London Tel 0808 808 0000.

[www.cancerlinkfoundation.org.uk](http://www.cancerlinkfoundation.org.uk)

### **Breakthrough Breast Cancer**

London 0207 557 6600.

[www.breakthrough.org.uk](http://www.breakthrough.org.uk)

## **Data Protection**

Any personal information is kept confidential. There may be occasions where your information needs to be shared with other care professionals to ensure you receive the best care possible.

In order to assist us to improve the services available your information may be used for clinical audit, research, teaching and anonymised for National NHS Reviews. Further information is available in the leaflet Disclosure of Confidential Information IL137, via Gateshead Health NHS Foundation Trust website or the PALS Service.

**This leaflet can be made available in other languages and formats upon request**



## Appendix 3

### Holistic assessment for breast patients

#### Patient details:

This self-assessment is **optional**; however it may help us to understand the concerns and feelings you have. It will also help us identify any information and support you may need in the future.

If any of the problems below have caused you concern and you wish to discuss them with a health care professional please tick the box.

#### **Social**

Coping with dependants

Work hobbies/leisure activities

Finances

Parking/travel

Support

#### **Psychological/Emotional**

Anxiety

Depression

Fear

Body image issues

Emotional support

Stress

#### **Action**

#### **Physical**

Difficulties communicating

Sleep

Pain

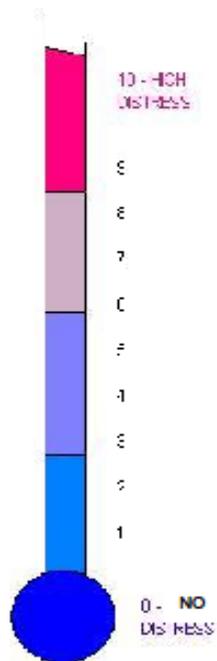
Menopausal symptoms

Tiredness/fatigue

Breast Care Nurse

Date

Or you can use the NCA Holistic Needs Assessment tool shown below:



Identify the number (0-10) that best describes how much distress has been experienced over recent weeks, if '0' is no distress and '10' is high levels of distress or anxiety.

This screening tool is aimed to encourage professionals and patients to explore current problems and issues that may be affecting patients' physical, psychological, social and spiritual well-being.

The outcome (including patient score) of this assessment is to be documented in the patients ongoing record with an agreed plan of care and referral on for symptom control, rehabilitation, social, spiritual or psychological care where necessary.

**Social Concerns**

- o Coping with dependants
- o Work/School
- o Hobbies/Leisure activities
- o Housing
- o Finances
- o Travel
- o Carer
- o Relationships

**Emotional Wellbeing**

- o Sadness
- o Fears
- o Worries / Anxieties
- o Anger
- o Alcohol/smoking/other drugs
- o Unable to express feelings
- o Feeling isolated
- o Loss of dignity
- o Forgetful/confused
- o Stress

**Spiritual / Religious Concerns**

- o Questioning values and beliefs
- o Sense of meaning
- o Issues relating to dying and death

**Rest / Activity**

- o Sleep
- o Fatigue
- o Tiredness

**My appearance / Body image**

- o Skin Dry / Itchy / wound healing
- o Swollen (limbs/abdomen)
- o Weight Changes – loss or gain
- o Sexual Problems

**Reduced Independence**

- o Bathing / Dressing
- o Getting Around

**Toileting Difficulties**

- o Constipation
- o Diarrhoea
- o Stoma
- o Changes in passing urine

**Physical Symptoms**

- o Difficulties in Communicating
- o Breathing
- o Pain
- o Temperature
- o Change in sensation: hands/feet

**Eating Difficulties**

- o Indigestion
- o Sores /painful mouth
- o Nausea
- o Taste changes
- o Swallowing difficulties
- o Change in appetite

**Any other factors**

**How do you cope at the moment?**

**What support do you have?**

**Do you have someone to talk to?**

**Would you like a copy of this assessment?**

**Are you happy for us to share this information with the people involved in your care?**

## Follow-up care by your surgeon following treatment for breast cancer

This leaflet will explain your follow up plan in the surgical clinic. It is possible to transfer your follow up care to your GP. If you wish to transfer your care to your GP then please inform your surgeon.

### Follow up appointments

You will be seen in the follow up clinic in six to twelve months after your results appointment. This appointment will include an examination by your surgeon or their team, a review of your medication and an opportunity to discuss any questions or concerns. After a year you will not be given any further appointments but will remain under our care for five years. If you have any questions or concerns you will need to contact your breast care nurse who will arrange an appointment for you to be reviewed. After five years your care will be transferred back to your GP.

### Endocrine therapy/medication

- If you are pre-menopausal you will usually be prescribed Tamoxifen tablets for five to ten years.
- If you are post-menopausal you may be prescribed a different endocrine drug i.e. an aromatase inhibitor drug. Not everyone is suitable for this type of therapy and this will be discussed with you.
- If you are prescribed an aromatase inhibitor drug i.e. (Anastrozole, Letrozole, Exemestane) which are drugs that are a type of hormone treatment sometimes used to treat post-menopausal women with breast cancer, you will need to have a DEXA scan (a scan to check your bone mineral density as these drugs can cause a reduction in the density of your bone mineral). This scan will be arranged by your consultant. Your consultant will also arrange for you to have a blood test and refer you to the osteoporosis nurse specialist at the Queen Elizabeth Hospital. You will then receive an appointment to see the osteoporosis specialist nurse in the clinic who will do an assessment of your risk of osteoporosis.
- The DEXA scan will be repeated in two years and five years, and will be organised by the osteoporosis team.
- Your medication will be reviewed at your appointments but if you have any questions before your appointment then please contact your Breast Care Nurse.

## Mammogram follow- up

An x ray of your breasts (mammogram) will be carried out each year for five years. Your surgeon or their team will arrange this. The breast-screening unit will inform you of the results by letter within three weeks. After five years you will be offered mammograms on the National Breast Screening programme every three years. **This leaflet can be made available in other languages and formats upon request**

Once you are over 70 years old you are still entitled to have a mammogram but you will have to organise this yourself by contacting your local breast screening unit.

If you are under 50 years old you will continue with a yearly follow up and mammograms until you reach the age of 50. At 50 you will be offered mammograms on the National Breast Screening programme every three years.

## What symptoms do I need to look for between my appointments?

If you notice any of the following symptoms you should contact your Breast Care Nurse for advice:

- If you develop any swelling to your arm/hand and are concerned you are developing lymphoedema
- Recent changes in the area of your surgery including rashes or spots that don't go away
- New lumps at the site of your surgery
- New lumps in your armpits or neck
- New lumps or changes in the other breast or armpit

Any new or persistent changes in your general health that is unexplained and last for more than a few weeks, for example:

- Any new persistent shortness of breath, or cough
- Any new persistent neck or back pains
- Any new persistent aches or pains

**These symptoms may not be related to your previous breast problem but should be checked out if they are persistent.**

## Concerns between appointments

If you have any other concerns or questions please contact your Breast Care Nurse/Key Worker who will give you advice and if necessary arrange an appointment in the clinic for you.

**Your Breast Care Nurse/Key Worker is** \_\_\_\_\_

**Contact Number – 0191 4820000 ask for bleep number**\_\_\_\_\_

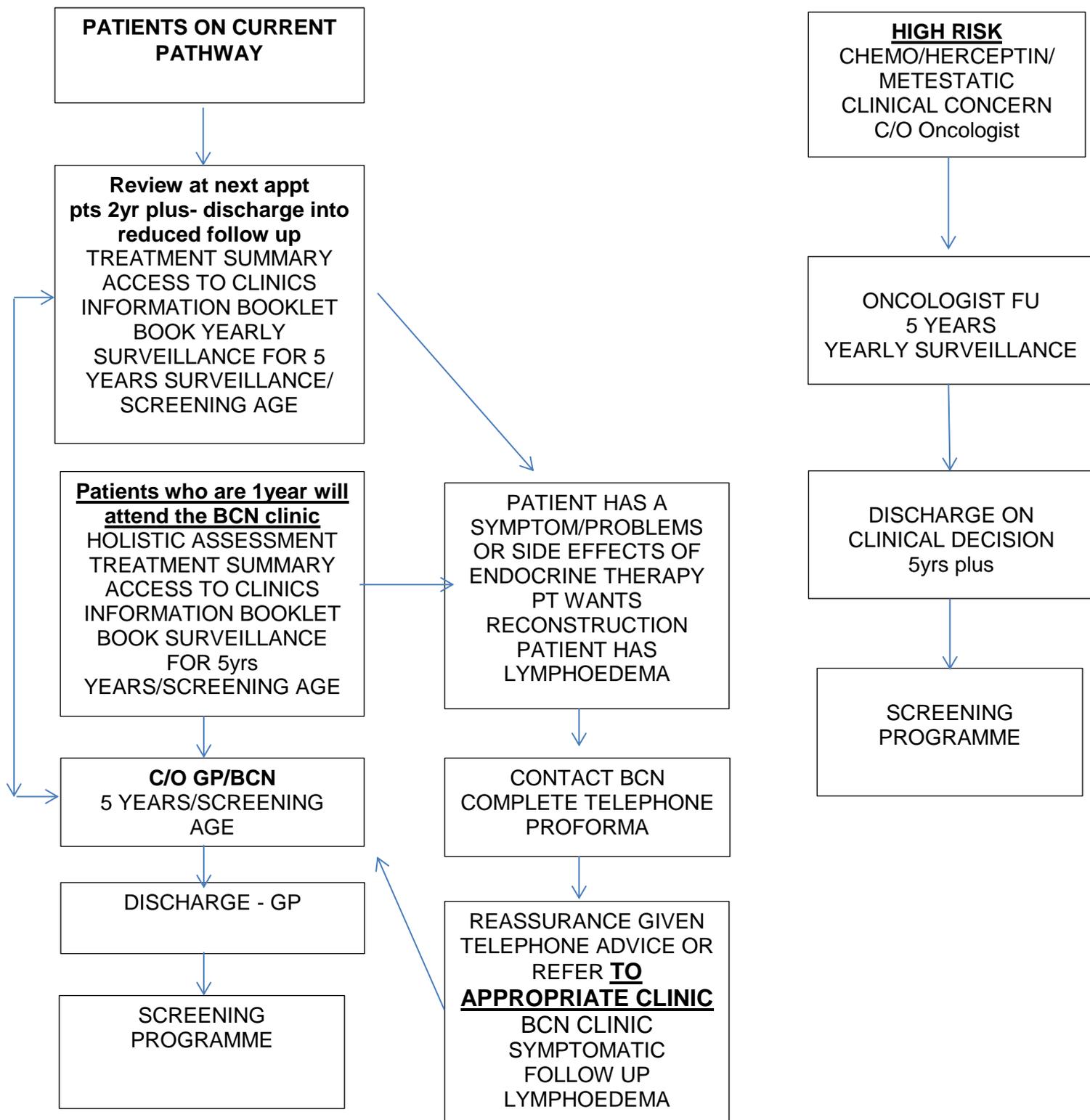
## Data Protection

Any personal information is kept confidential. There may be occasions where your information needs to be shared with other care professionals to ensure you receive the best care possible. In order to assist us to improve the services available your information may be used for clinical audit, research, teaching and anonymised for National NHS Reviews. Further information is available in the leaflet Disclosure of Confidential Information IL137, via Gateshead Health NHS Foundation Trust website or the PALS Service.

Appendix 5

FOLLOW UP PATIENT PATHWAY

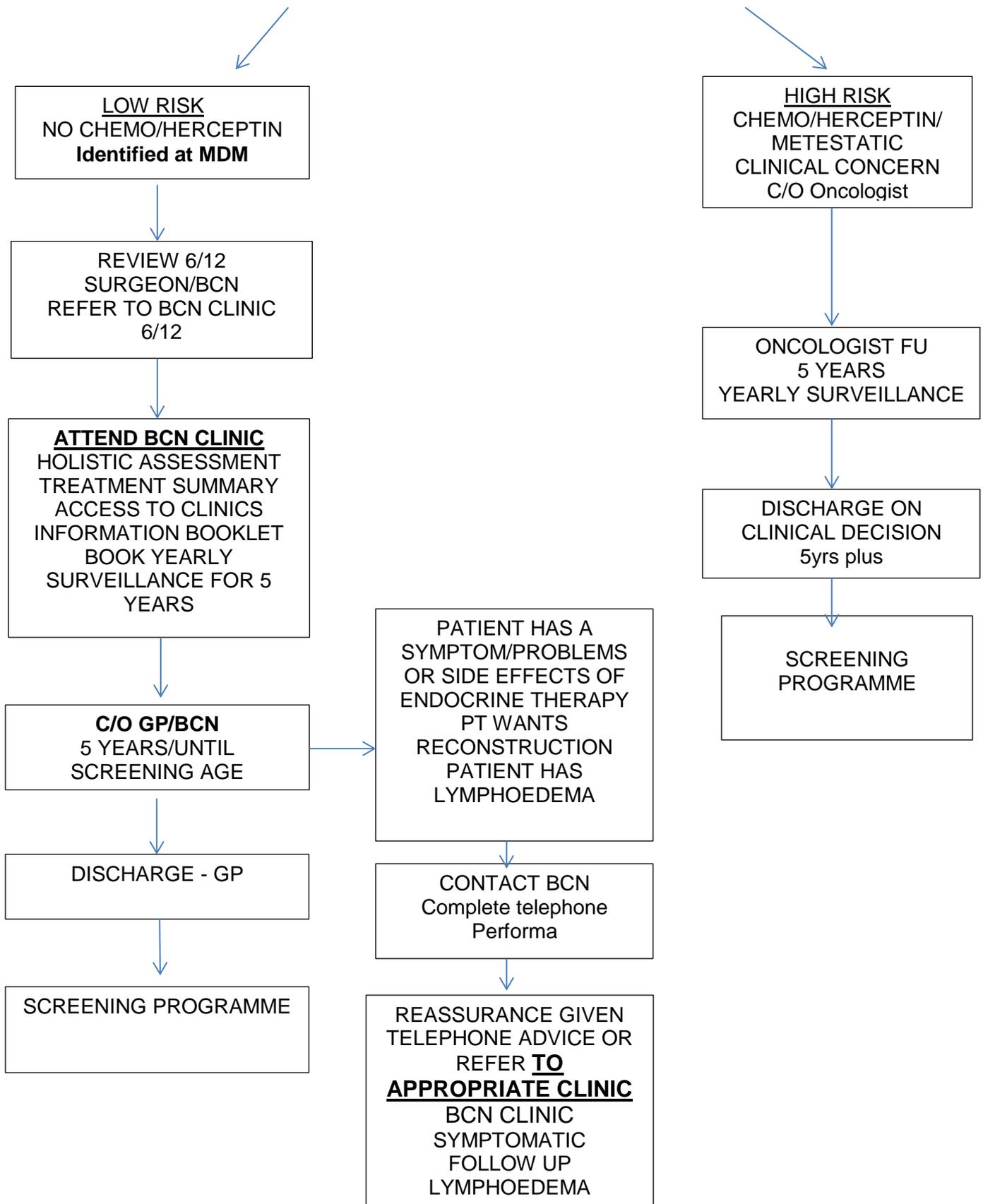
Existing patients



Appendix 6

FOLLOW UP PATIENT PATHWAY

PATIENT COMPLETES SURGERY ADJUVANT/CHEMO/DXT /TREATMENTS



## Mammogram pathway

Patient identified at MDT to be low risk and clinically suitable for surveillance mammography only follow-up pathway  
Noted on Dendrite by MDT Coordinator



- Patient undergoes yearly review with BCN including provision of
- End of treatment summary (copied to GP)
  - Information booklet including methods to contact BCN
    - Holistic needs assessment if required
    - ICE request made – 1 for mammography that day
  - Surgeon/BCN to complete Treatment Summary form and send via email to OM/DOM in BSU
  - Patient is handed a clinic instruction slip for breast low risk pathway appointment for 1 years' time
    - for 1 years' time



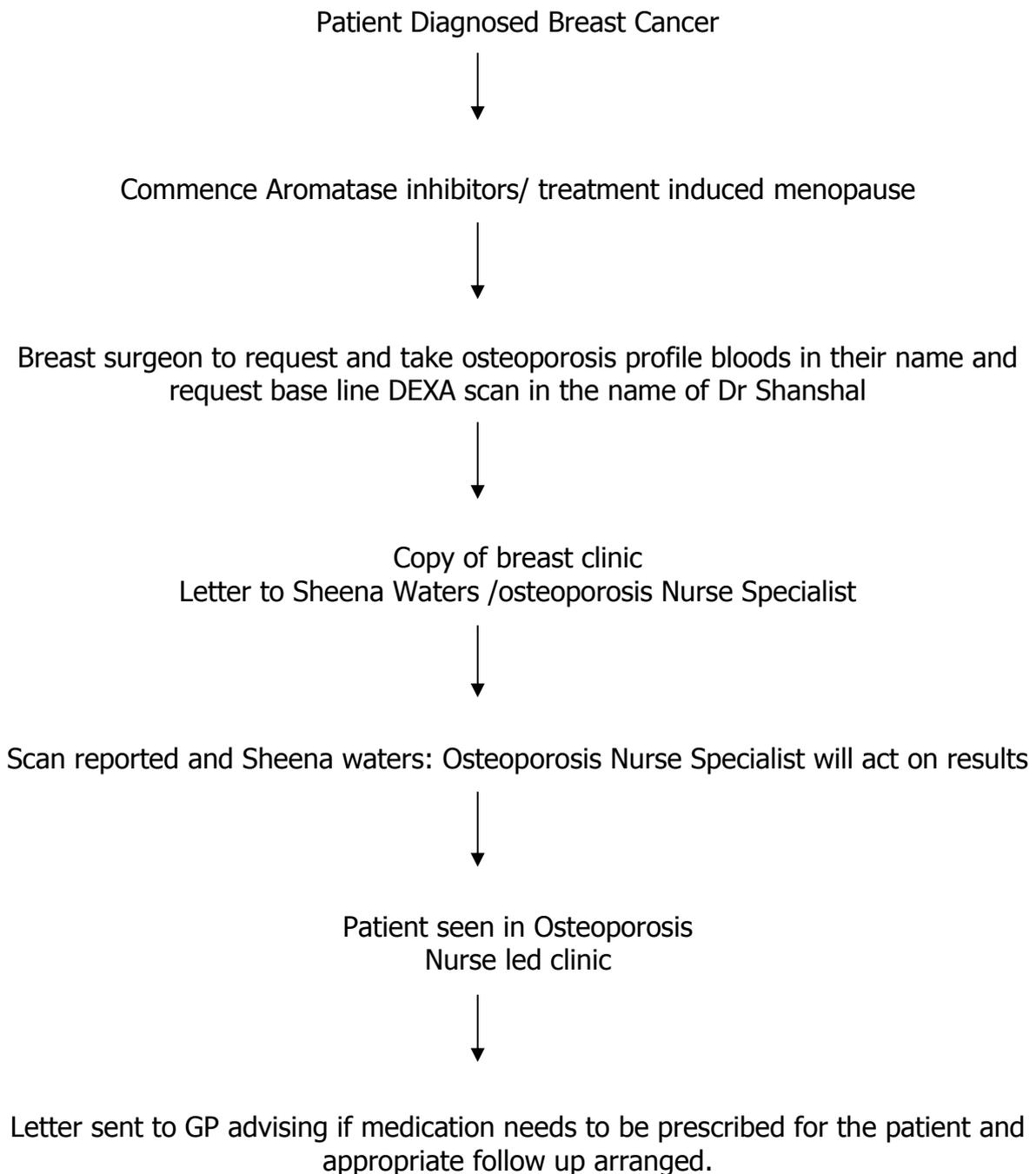
Patient goes to breast screening reception and is booked in for mammography examination and also for a low risk appointment on Medway for 1 years' time. Receptionist adds 2yr review in appointment comments so when she receives her last mammogram (5yrs f/up) she can be discharged from clinic.



If at any point during the 5 year period that the patient requires additional advice/care first point of call will be BCN via telephone. Advice will be given over telephone or patient may need to attend relevant clinic. GP will be notified.

## Appendix 8

### Osteoporosis Breast cancer Pathway



## RAPID ACCESS PATIENT PATHWAY

