Avon Somerset and Wiltshire Cancer Network Breast Cancer Clinical Care Guidelines

August 2011

Avon, Somerset and Wiltshire NHS
Cancer Services

Agreed by Dr Dorothy Goddard, NSSG Chair, on behalf of the ASWCS Breast Site Specialist Group August 2010

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If you need this document in a different format please telephone ASWCS on 0117 900 2324

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Review Date	August 2010
Publication Date	September 2010
Review Date	September 2011

Contents

Introduction

1 Background

1.1 Introduction:

This document outlines the Avon Somerset and Wiltshire Cancer Services (ASWCS) clinical management guidelines for breast cancer. The guidelines have been discussed and agreed by the ASWCS Network Breast Site Specialist Group as part of an ongoing guideline review and development programme. Where appropriate, the document incorporates both local and national guidance, developed by specialist professional groups, along with relevant NICE guidelines. Readers are encouraged to both refer to the national guidelines and to look at original references cited in the relevant sections of this document.

Each section of the breast cancer guidelines has been written separately by topic for use by healthcare professionals. Whilst this leads to some duplication, it allows each clinical guideline to be read individually. The guidelines are available for professional and public access on the ASWCS web-site at:

http://www.aswcs.nhs.uk/main.cfm?type=BRST

1.2 ASWCS Breast Services

ASWCS Network serves a population of 2.096 million with approximately 1650 new breast cancers diagnosed each year within the network (2006 data on file). Most patients will be referred by primary health care teams to their local hospital trust specialist breast care multi-disciplinary team (MDT). Within ASWCS, specialist breast care teams are based at:

- North Bristol NHS Trust (NBT)
- Royal United Hospital Bath NHS Trust (RUH)
- Taunton and Somerset NHS Foundation Trust (TST)
- University Hospitals Bristol NHS Foundation Trust (UHB)
- Weston Area Health NHS Trust (WAHT)
- Yeovil District Hospital NHS Foundation Trust (YDH).

All teams have contributed to the development and agreement of these guidelines through the network breast SSG.

Referral Guidelines

2 Referral Guidelines for Suspected Breast Cancer

2.1 Summary:

- All patients with suspected breast cancer should be referred to a team specialising in the management of breast cancer using the urgent two week referral standard (2ww)
- From the 1st January 2010 all patients with breast symptoms should be referred using the 2ww standard
- The starting point for this standard (i.e. day 0) is the receipt of the referral in the appropriate breast clinic. The end point is the date the patient is first seen in the breast clinic (i.e. by day 14)
- Patients may be referred on locally agreed network forms to the relevant point of contact (see below) or directly through 'Choose and Book'.

Agreed local referral pathways within ASWCS are:

Name of MDT / Host Organisation	Point of Contact	Referring PCT
Royal United Hospital Bath NHS Trust (RUH)	Bath Breast Unit: F: 01225 824912	Bath and North East Somerset
		Wiltshire
		Somerset
Taunton and Somerset NHS Foundation Trust (TST)	Fast Track Cancer Office: F: 01823 343417	Somerset
Yeovil District Hospital NHS Foundation Trust (YDH)	Central Cancer Referrals: F: 01935 384640	Somerset
University Hospitals Bristol NHS Foundation Trust (UHB)	Fast Track Cancer Office: T: 0117 3420619 F: 0117 3420652	Bristol Bath and North East Somerset
Weston Area Health NHS Trust (WAHT)	Fast Track Cancer Office: T: 01934 647227 F: 01934 647129	North Somerset
North Bristol NHS Trust (NBT)	Fast Track Cancer Office: T: 0117 9186666 F: 0117 9596034	South Gloucester Bristol

2.2 Information for Referring Healthcare Professionals

- Breast cancer is the most common cancer in females with approximately 45 000 women diagnosed in the UK in 2005. The lifetime risk of a woman developing breast cancer in the UK is approximately 1/9 with 80% of breast cancers developing after the menopause. Breast cancer in men is rare
- The majority of patients will present with a discrete breast lump. However, other symptoms can include breast asymmetry, nipple changes, nipple discharge, breast inflammation or skin changes or breast pain associated with dominant nodularity. Some patients will present with local spread to the lymph nodes of the ipsilateral axilla. Less than 5% of patients present initially with distant metastases
- Breast cancer may recur at a local or distant site many years after the initial diagnosis
- People of all ages who suspect they have breast cancer may have particular information and support needs. The referring healthcare professional should discuss these needs with the patient and respond sensitively to them
- In most cases, the definitive diagnosis will not be known at the time of referral, and many patients who are referred will be found not to have cancer. In general, healthcare professionals should convey optimism about the effectiveness of treatment and survival for breast cancer
- Primary healthcare professionals should encourage all patients, including women over 50 years old, to be breast aware1 in order to minimise delay in the presentation of symptoms.

2.3 Physical Examination

- The referring healthcare professional should, with the patient's consent, perform bilateral breast examination in the presence of a chaperone
- Examination should document details of any breast lumps including shape, size, and texture, position within the breast, mobility and tenderness
- Breast asymmetry, nipple retraction, nipple discharge and skin changes should be noted
- Assessment of the regional lymph nodes (axilla and supra-clavicular fossa) should be performed to document lymphadenopathy.

2.4 Investigations

- In patients presenting with symptoms and/or signs suggestive of primary breast cancer, investigation prior to referral is not recommended.

[1] Breast awareness means the woman knows what her breasts look and feel like normally. Evidence suggests that there is no need to follow a specific or detailed routine such as breast self examination, but women should be aware of any changes in their breasts (see http://cancerscreening.org.uk/breastscreen/breastawareness for further information).

2.5 Referral to Other MDT's

- Where appropriate patients with breast cancer may be referred to another specialist breast care team within ASWCS or outside the network e.g. those requiring complex oncoplastic surgery. This should be arranged directly between teams to minimise treatment delays
- Patients seen by specialist breast teams who, on investigation, are found to have other cancers e.g. malignant melanoma, lymphoma will be referred to appropriate local or specialist network MDT's for further management.

2.6 References

1. NICE clinical guideline 80 – Early and locally advanced breast cancer. February 2009. http://guidance.nice.org.uk/CG80
2. NICE improving outcomes in breast cancer. 2002. http://guidance.nice.org.uk/CSGBC
3. NICE clinical guideline 27 – Referral guidelines for suspected cancer. June 2005. http://guidance.nice.org.uk/CG27

2.7 Documentation

2.7.1 Document Location

The document is located in the ASWCS Network office, in hardcopy and electronic format.

2.7.2 Revision History

Date	Version	Status	Author/Revisor	Agreed by
December 2005	1	Draft	ASWCS NSSG	Mr Zenon Rayter NSSG Chair
11 August 2009	2	Draft	Dr Jeremy Braybrooke	ASWCS NSSG
July 2010	3	Draft	Dr Jeremy Braybrooke	ASWCS NSSG

Imaging Guidelines

3 Imaging Guidelines

3.1 Introduction

The NSSG should agree network-wide imaging guidelines for the diagnosis and review of the cancer site or sites of the group. The guidelines should address:

- Imaging modalities and their specific indications

These guidelines have been reviewed and revised following the publication of "Best practice diagnostic guidelines for patients presenting with breast symptoms" published November 2010.

3.2 Assessment of Screen Detected Abnormalities or Symptomatic Problems and Clinical Management

Within the ASW Cancer Network the assessment of women who have clinical or radiological suspicious findings in the symptomatic service or suspicious mammograms identified through screening are clinically managed in the same way with all patients being discussed through a breast MDT.

Assessment should occur in a multidisciplinary setting using the principles of triple assessment (clinical assessment, imaging and core biopsy or fine needle aspiration cytology). This is best achieved in designated specialist breast clinics in which both radiologists and surgeons work closely together. These clinics should:

- Provide rapid patient access with all patients with breast problems to be seen within 2 weeks of receipt of referral from January 1st 2010
- Be organised to ensure that, where possible, all necessary diagnostic procedures on women with clinical abnormalities are carried out at the initial clinic visit (where this is not achievable imaging of women with clinically suspicious abnormalities should be performed and reported within five working days)
- Where practical, imaging should precede any needle aspiration or biopsy procedures
- There should be clear administrative links between breast imaging and the breast clinic in order to ensure efficient service delivery, best use of resources and clear and rapid communication for clinic scheduling, exchange of information and results of tests.

3.3 Imaging Guidelines

- The breast imaging facilities should include x-ray mammography and high frequency ultrasound with probes suitable for breast imaging (12 mHz or more) Digital mammography is preferred to film screen mammography for women below 50 years and those with dense breast tissue. Ideally, the breast imaging facilities should be integrated with or within reasonable distance from the breast clinic for patient convenience and efficient service delivery
- The technical quality of mammography within non-screening facilities should be equivalent to that in the NHSBSP (1)

- Ultrasound is the imaging method of choice for women aged less than 40 years, during pregnancy and lactation
- X-ray mammography is used in the investigation of women aged > 40 years, with the addition of ultrasound when indicated
- X-ray mammography is not indicated for the majority of patients aged < 40 years.
- X-ray mammography should be carried out in patients aged 35-39 years with clinically suspicious or malignant findings (P4,P5) and should be considered in patients with clinically indeterminate lesions (P3) if ultrasound is normal.
- Mammography should include MLO and CC views of each breast, and for younger, pre menopausal women or those with dense breasts, digital mammography is preferred to film screen mammography.
- If a suspicious abnormality is demonstrated on mammography, it may be helpful to further characterise the mammographic features using magnification or spot compression views. These should be carried out during the clinic as directed by the radiologist, breast imaging clinician or the consultant radiographer in breast imaging.
- Ultrasound should be performed for further evaluation of suspicious lesions found on mammography or for clinically suspicious lesions in the absence of any mammographic abnormality
- Mammography and ultrasound findings should be recorded including the site, size and likely nature of any abnormality found – the use of a diagram is recommended to facilitate this
- The level of suspicion for malignancy should be recorded using the RCR Breast Group Classification U1-U5 and M1-M5.

  1 = Normal.
  2 = Benign.
  3 = Indeterminate/probably benign
  4 = Suspicious of malignancy
  5 = Highly suspicious of malignancy

- The routine use of magnetic resonance imaging (MRI) of the breast is not recommended in the preoperative assessment of patients with biopsy-proven invasive breast cancer or ductal carcinoma in situ (DCIS).
- Offer MRI of the breast to patients with invasive breast cancer:
  - If there is discrepancy regarding the extent of disease from clinical examination, mammography and ultrasound assessment for planning treatment
  - If breast density precludes accurate mammographic assessment
  - To assess the tumour size if breast conserving surgery is being considered for invasive lobular cancer
- Pre-treatment ultrasound evaluation of the axilla should be performed for all patients being investigated for early invasive breast cancer and, if morphologically abnormal lymph nodes are identified, ultrasound-guided needle sampling should be offered

- Consider staging with CXR, CT chest and abdomen and skeletal isotope scan only if there is clinical suggestion or evidence of metastatic disease

3.4 Follow-up Imaging

In line with NICE guidance for early and advanced breast cancer (published February 2009): Offer annual mammography to all patients with early breast cancer, including DCIS until they enter the NHS Breast Screening Programme (NHSBSP). Patients diagnosed with early breast cancer that are already eligible for screening should have annual mammography for 5 years.

On reaching the NHSBSP screening age or after 5 years of annual mammography follow-up screening frequency should be stratified in line with patient risk category.

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

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

3.5 Screening for Family History and High Risk Groups such as Hodgkins Disease – Post Chest Irradiation.

These guidelines are to be reviewed and updated once the national working group has made its recommendations. The current practice continues as per the NICE Familial Breast Cancer Guidance 2006:

With annual mammography from age 40-50 years for those at moderate or high risk from their family history of breast cancer, using digital mammography where available.

And annual MRI from age 40-50 years for those at very high risk including BRCA genetic mutations.

3.6 Breast MRI

- The routine use of magnetic resonance imaging (MRI) of the breast is not recommended in the preoperative assessment of patients with biopsy-proven invasive breast cancer or ductal carcinoma in situ (DCIS).
- Offer MRI of the breast to patients with invasive breast cancer if there is discrepancy regarding the extent of disease from clinical examination, mammography and ultrasound assessment for planning treatment, if breast density precludes accurate mammographic assessment or to assess the tumour size if breast conserving surgery is being considered for invasive lobular cancer.
- Breast MRI does not form part of the initial imaging assessment of patients in the symptomatic breast clinic. It may, however, be useful in the further investigation of some breast lesions and in the evaluation of patients with confirmed breast cancer. The decision to carry out MRI should be made at the MDM.
- Breast MRI should be performed using only dedicated breast coils, must include a T2 weighted sequence and T1 weighted dynamic post contrast series to include a subtraction or equivalent post processing technique. (3)

3.6.1 References:

Quality Assurance Guidelines for Mammography: Including Radiographic Quality Control NHSBSP Publication no 63 April 06

Pisano E, Gatsonis C, Hendrick E, Yaffe M, Baum J, Acharyya S, Conant E, Fajardo L, Bassett L, D'Orsi C, Jong R, and Rebner M. Diagnostic Performance of Digital versus Film Mammography for Breast Cancer Screening - The Results of the American College of Radiology Imaging Network (ACRIN) Digital Mammographic Imaging Screening Trial (DMIST). NEJM, published online September 16, 2005 and in print on October 27, 2005.

European Breast MRI Guidelines Published by European Radiology in July 2008 Eur Radiol (2008) 18: 1307–1318

3.7 Documentation

3.7.1 Document Location

The document is located in the ASWCS Network office, in hardcopy and electronic format.

3.7.2 Revision History

Revision Date	Version	Author	Agreed by
November 2005	1	Avon Somerset & Wiltshire Cancer Services (ASWCS) Network Imaging Group and the Network Service Improvement Lead.	ASWCS NSSG Chair Mr Zenon Rayter
September 2009	2	Dr Dorothy Goddard, Consultant Radiologist	Dr Jeremy Braybrooke, NSSG Chair
July 2010	3	Dr Dorothy Goddard, Consultant Radiologist	NSSG

Pathology Guidelines

4 Pathology Guidelines

Breast cancer is currently the commonest cause of death from cancer in women with a UK incidence of 1 in 9. Breast tumour classification is important for consistency in patient treatment and because it provides a basis for epidemiological and biological studies.

The network guidelines for the examination and reporting of breast cancer specimens take into account the following publications:

1. Pathology Reporting of Breast Disease, NHS Breast Screening Programme and the Royal College of Pathologists incorporating National Minimum Data Set for Breast Pathology : NHSBSP Publication No. 58. January 2005
2. TNM classification of malignant tumours (7th edition). UICC (2010).
3. Guidelines of inter-departmental despatch of samples from patients sent to another hospital or centre for assessment and/or treatment. The Royal College of Pathologists (2004).
4. ACP Broadsheet 116 July 1987 Examination of Breast Specimens.
5. Guidelines for Non-Operative Diagnostic Procedures and Reporting in Breast Cancer Screening NHSBSP Publication No50 July 2001
6. Guidelines for Breast Needle Core Biopsy Handling and Reporting in Breast Cancer Screening Assessment, Ellis IO, Humphreys S, Michell M, Pinder SE, Wells CA, Zakhour HD, J Clin Pathol 2004;57:897-902.
7. ACP Best Practice no 176. Updated recommendations for HER2 testing in UK.
8. IO Ellis, J Bartlett, M Dowsett, S Humphreys, B Jasani, K Miller, SE Pinder.A Rhodes, R Walker. J Clin Pathol 2004; 57: 233-237

The Pathologist plays a central role in the diagnosis of breast cancer and its typing. In resection specimens, the information required for the accurate diagnosis, staging of breast malignancy depends largely upon the selection of the tissue blocks from specimens as well as the extent of sampling. Staging of breast cancer is based on the size of the primary tumour (T), the lymph node status (N) and the presence of metastases (M), which is known as the TNM system.

The WHO classification of breast tumours depends on the presence of specific differentiation based on histological characteristics seen in surgical biopsies and resection specimens.

All breast cancer cases should be reviewed by a breast cancer multi-disciplinary team, which has a histopathologist as a core member. There should be a nominated breast pathologist for the service but all pathologists reporting breast cancer specimens should participate in an appropriate EQA scheme and in local audit (including an assessment of consistency of reporting as appropriate to the site). It is most important that all difficult cases (benign and malignant) are discussed at the Breast MDT. It is good practice that any problem/difficult diagnostic cases are discussed between colleagues prior to the report being issued.

Specimens should be reported within an agreed time frame so as to allow appropriate clinical decisions to be made at a scheduled treatment planning breast MDT meeting.

4.1 Specimen Types

Diagnostic specimens: FNA, Core biopsy, Mammotome biopsy, Diagnostic open biopsy.

Therapeutic specimens: segmental excision, wide local excisions, needle localised wide local excisions, mastectomy.

Axillary specimens: Sentinel node biopsy, axillary node sample, axillary node clearance.

4.2 Specimen Examination

The local protocol for specimen examination should take into account national guidelines and should be regularly reviewed and updated by the lead breast pathologist in consultation with other pathologists who participate in the service delivery.

The RCPath guidelines on excision margins indicates that the closest relevant margin should be recorded. This is the radial margin. In addition the closest deep and superficial margin should be recorded if involved.

4.3 Grading and Staging of Breast Tumours

Tumour grading: Is by the Nottingham modification of the Bloom and Richardson criteria as out lined in reference publication 1.

Tumour staging: TNM classification of malignant tumours (7th edition) outlined in reference publication 1.

4.4 Use of Ancillary Laboratory Techniques

All laboratories providing a pathology service in the network must have at least conditional CPA accreditation and ensure participation in an appropriate EQA programme which demonstrates satisfactory laboratory performance.

A wide range of immunohistochemical markers are available within the network. Those which are most relevant to breast cancer include:

CK5/6, CK8, CK18, CK20, p63, EMA, CEA, e-Cadherin, Smooth muscle actin, S100 protein, High molecular weight cytokeratin (34bE12), Laminin, CD45.

In addition to the above diagnostically useful markers a number of therapeutically relevant markers should be made available to the referring clinician through pathology laboratories either provided direct or after referral. These include Oestrogen receptor (ER), Progesterone receptor (PR), and Her 2 immunohistochemistry . The latter should also be available by in situ hybridisation (FISH). In each case the test should be provided by a standardised and validated test and subject to external EQA programmes.

ER status can be measured by different scoring methods. It is important that Pathology Departments give clear guidance on scoring methods particularly where more than one scoring method will be found in a centre eg referred cases. The ER and PR score should be given as percentage of cells staining and intensity of cells staining. (In addition departments may wish to add local scores). The cut off for treatments is out with the scope of this document but will be reviewed by ASWCS in the near future.

Small biopsies sectioned at multiple levels should yield adequate numbers of spare sections to allow immunostaining of tumour if required.

Where image guided specimens are received the specimen should be processed in such a way as to allow clear identification of the imaged lesion.

4.5 Audit

All pathologists reporting breast cancer specimens should participate in the National NHSBSP EQA scheme and local audits (including an assessment of consistency where more than one pathologist participates in service provision). The audits/reviews should include:

(i) Review of compliance with procedures for specimen examination and reporting.

(ii) Completeness of minimum datasets.

(iii) Diagnostic agreement/disagreement during review of cases for MDTs.

The results of the audit process should be discussed with all pathologists who participate in service delivery.

Comment

Diagnostic disagreement should be for major disagreements. For example, where there are minor single issues over grading then one would not expect this to be flagged up unless there was a persistent pattern of similar problems.

4.6 Referral for Review or Specialist Opinion

As outlined in the ASWCS Pathology Group agreed referral guidelines.

4.7 Minimum Dataset for Reporting

These are based on the minimum dataset for breast cancer histopathology reports as published by the NHSBSP and Royal College of Pathologists January 2005 (reference document 1) but with the following local amendments/clarifications agreed by the ASWCS Pathology Group. This January 2010 document is the first revision of the local guidelines.

- Clarification of disease extent; localised (single focus 1 quadrant), multifocal (more than 1 focus in 1 quadrant), multicentric (invasive foci in more than 1 quadrant). This should be added to text rather than drop down boxes
- Clarifying margins to include specific radial margins and chest wall margin comments. All margins <5mm should be commented on in the text report. The dataset includes the closest radial margin. The superficial and deep margins should be recorded in the dataset if involved
- ER score changed to reflect percentage of cells staining and intensity of staining. Local scores can be provided in addition
- Removal of c-erb B2 testing
- Removal of extent of extranodal spread in the axilla
- TNM classification, currently 7th edition.

4.8 Breast Cancer Histopathology Minimum Data Set

4.8.1 Excision Specimens

Surname..... Forename.....

Date of Birth .....-.....-..... Sex.....

Hospital..... Hospital Number.....

NHS Number..... Pathologist.....

Date of Receipt..... Date of Reporting.....

Lab Number..... Surgeon / Physician.....

Side ☐ Right ☐ Left

Specimen Type ☐ Localisation Biopsy ☐ Open biopsy
☐ Wide local excision ☐ Segmental excision
☐ Mastectomy

Specimen Weight ……g

Axillary procedure ☐ No lymph node procedure ☐ Sentinel node biopsy
☐ Axillary node sample ☐ Axillary node clearance

In situ carcinoma ☐ **Not present**

☐ Ductal carcinoma in situ

DCIS grade ☐ High ☐ Intermediate ☐ Low ☐ Not assessable

DCIS growth patterns ☐ Solid ☐ Cribriform ☐ Micropapillary ☐ Papillary
☐ Apocrine ☐ Flat ☐ Other (please specify)……

Size ……mm (DCIS only)

☐ lobular carcinoma in situ

☐ Paget's disease

Microinvasion ☐ Not present ☐ Present

Invasive carcinoma ☐ **Not present**

Size Invasive tumour ……mm (Largest dimension of dominant invasive tumour focus)

Whole size of tumour ……mm (Invasive plus surrounding DCIS if DCIS Extends > 1 mm beyond invasive)

Type ☐ No special type (ductal NST)
☐ Pure special type (90% purity, specify components present below)

☐ Mixed tumour type (50-90% special type component, specify components present below)

☐ Other malignant tumour (please specify) ……

Specify type component(s) present for pure special type and mixed tumour types:

☐ Tubular/cribriform ☐ Lobular ☐ Mucinous ☐ Medullary like ☐ Ductal/no special type (NST)

☐ Other (please specify) ……..

Invasive grade ☐ 1 ☐ 2 ☐ 3 ☐ Not assessable

Tumour extent ☐ Localised ☐ Multifocal ☐ Multicentric

Localised (single focus 1 quadrant),

Multifocal (more than 1 focus in 1 quadrant),

Multicentric (invasive foci in more than 1 quadrant or >40mm apart)

Vascular invasion ☐ Not seen ☐ Present ☐ Possible

Axillary nodes present: ☐ no ☐ Yes (total number) …… Number positive ……

For single node positivity, specify ☐ Metastasis (> 2mm)

☐ Micrometastaseis (≤ 2mm to >0.2 mm)

☐ Isolated tumour cells (≤ 0.2 mm)

Other nodes present ☐ No ☐ Yes Total number …….. Number positive ……

Site of other nodes ……..

Axillary extra-nodal spread ☐ No ☐ Yes

Excision margins (For DCIS or invasive carcinoma)

☐ Not assessable ☐ Does not reach radial margin ☐ Reaches Radial margin (specify below)

☐ Superior ☐ Inferior ☐ Medial ☐ Lateral

Closest radial margin (specify) …… Distance ……

Reaches deep margin/chest wall ☐ Yes ☐ No If no, distance ……...

Reaches superficial margin ☐ Yes ☐ No If no, distance ……...

If Invasive plus DCIS– Put Invasive margin distances above, DCIS below:

Closest radial margin of DCIS (specify) …… Distance ……

TNM: ……..

(Edition –7th)

Receptor status

Oestrogen ☐ Negative ☐ Positive
Percentage of cells staining …..%
Intensity of cell staining …..%

Progesterone ☐ Negative ☐ Positive
Percentage of cells staining …..%
Intensity of cell staining …..%

Hercep Test ☐ Not done Score…… (0, 1+, 2+, 3+)

In-situ Hybridisation ☐ Not done ☐ Normal ☐ Amplified

COMMENT: ……..

4.9 Breast Cancer Histopathology Minimum Data Set

4.9.1 Breast Core Specimens

MINIMUM DATA SET
BREAST SCREENING WIDE BORE NEEDLE BIOPSY FORM

Side : Number of cores:

Calcification present on specimen X-ray?

Histological calcification :

Provisional Grade :

Localisation technique :

Opinion :

Vascular Invasion :

If applicable, ER block :

Comment:

Receptor Status

Oestrogen :
Local ER score: Progesterone : Local PR score:

c-erb B2 :

Score : OR
Hercep Test :
Score :

FISH :

4.10 Documentation

4.10.1 Document Location

The document is located in the ASWCS Network office, in hardcopy and electronic format.

4.10.2 Revision History

Revision Date	Version	Author	Agreed by
2005	1	ASWCS Pathology Group	ASWCS Breast NSSG 2006
July 2010	2	ASWCS Pathology Group	ASWCS Breast NSSG July 2010

Clinical Guidelines – Surgical Management

5 Surgical Guidelines for the Management of Breast Cancer – Adapted from the Association of Breast Surgery at BASO (2009)

ASWCS have agreed to adopt the surgical and oncoplastic guidelines for the management of breast cancer produced by the Association of Breast Surgery at the British Association of Surgical Oncology (BASO). This was ratified by the Breast SSG in June 2009 and sections of the guidelines are reproduced below. The full guidelines are available on the ASWCS web-site at:

http://www.aswcs.nhs.uk/main.cfm?type=BRST

5.1 Diagnosis

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

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

5.1.1 Diagnostic Excisions

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

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

5.1.2 Frozen Section Pathology

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

5.1.3 Diagnosis

Quality objectives	Outcome measures
To minimise the cosmetic impairment of diagnostic open biopsy.	The fresh weight of tissue removed for all cases where a diagnostic open biopsy is performed should be recorded. ≥90% of open surgical biopsies carried out for diagnosis, which prove to be benign, should weigh ≤20 g All cases where open surgical diagnostic biopsies which prove to be benign and weigh >40g should be discussed at the post-operative MDT meeting and any mitigating reasons recorded.
To minimise patient anxiety between a decision that a diagnostic operation is required to confirm or exclude malignancy and the date for an operation.	Patients should be admitted for a diagnostic operation within 2 weeks. Minimum standard - ≥90% within 2 weeks Target - ≥100% within 2 weeks
To minimise unnecessary surgery, i.e. open surgical diagnostic biopsies that prove to be malignant.	Invasive breast cancers should have a non-operative pathological diagnosis Minimum standard - ≥90% Target - ≥95% Non-invasive breast cancers should have a non-operative pathological diagnosis Minimum standard - ≥85% Target - ≥90%

5.2 Treatment Planning and Patient Communication

Each breast unit must have written guidelines for the treatment of breast cancer, which have been formulated and agreed by the breast multidisciplinary team. The treatment of patients should usually follow these guidelines, although it is accepted that there may be reasonable exceptions. The reasons for not following guidelines should be discussed at the MDT meeting and documented.

Following confirmation of a breast cancer diagnosis and appropriate MDT discussion to plan management, the results should be discussed with the patient. Patients should be encouraged to bring a partner or friend with them when the results are being discussed. The person conducting the consultation should be a member of the Breast MDT and the breast care

nurse should usually be present. It should take place in an appropriate environment with adequate privacy. The follow up arrangements should be clear and the patient must know how to access the breast care nurse and other relevant components of their care plan.

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

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

Breast cancer at diagnosis can be broadly classified into three clinical categories:

5.2.1 Operable Primary Breast Cancer

The majority of breast cancer cases, presenting symptomatically or diagnosed through breast screening, will fall into this category. Surgery will usually be the first treatment and will be discussed in further detail in these guidelines. Neoadjuvant endocrine treatment may be appropriate in some instances to downstage bulky disease to facilitate breast conserving surgery in post menopausal women with ER positive breast cancers. There is currently no consensus regarding the use of neoadjuvant chemotherapy in this circumstance. However the available data from randomised trials shows that breast conserving surgery after neoadjuvant therapy is associated with a significantly increased risk of local recurrence. Where neoadjuvant therapy is being considered the increased risk of local recurrence should be discussed with women and taken into consideration given the recent reports from the Oxford overview which shows that the avoidance of local recurrence in the conserved breast prevents about one breast cancer death for every four such recurrences avoided (7).

5.2.2 Locally Advanced Primary Breast Cancer

The management of locally advanced primary breast cancer should be multidisciplinary and will initially require a core biopsy and staging investigations. In some patients medical treatment (hormonal/chemotherapy) and/or radiation therapy may be the most appropriate initial treatment. The management of locally advanced primary breast cancer will not be discussed further in these guidelines.

5.2.3 Metastatic Breast Cancer

Following the symptomatic presentation of distant metastases, average life expectancy is approximately 2 years, with virtually all

patients eventually dying from breast cancer. The aim of treatment is to palliate symptoms and to maintain the highest possible quality of life. The management of patients with metastatic breast cancer should be multidisciplinary. Although the majority of patient care is likely to be delivered by oncologists and the palliative care team some surgeons with established experience in this field may continue to be involved in the multidisciplinary team. In addition all breast surgeons need to be involved with the local control of the disease. The management of metastatic breast cancer will not be discussed further in these guidelines.

5.2.4 Recurrent Breast Cancer

A multidisciplinary approach is needed in the management of patients with recurrent breast cancer. All patients presenting with recurrent breast cancer should be restaged prior to definitive management. A significant proportion of patients presenting with 'local recurrence' will have systemic relapse as well. Those patients with widespread disease should be managed by systemic therapy if possible. The management of recurrent breast cancer will not be discussed further in these guidelines.

5.2.5 Treatment Planning

Quality objectives	Outcome measures
Breast cancer treatment should be provided in a consistent manner according to agreed local guidelines.	Each breast unit must have written guidelines for the management of breast cancer.
The management of patients with breast cancer should be discussed by a multidisciplinary team.	The management of all patients with newly diagnosed breast cancer should be discussed at a MDT meeting and the conclusions documented in each patient's notes.

5.3 Organisation of Breast Cancer Surgical Services

5.3.1 Personnel

Surgical treatment of patients with breast cancer must be carried out by surgeons with a special interest and training in breast disease (8-10) (Level 3 evidence). Each surgeon involved in the NHS BSP should maintain a surgical caseload of at least 10 screen-detected cancers per year, averaged over a three year period. It is expected that surgeons with low caseloads should be able to demonstrate an annual surgical workload of at least 30 treated breast cancers. Breast surgeons should work in breast teams, which have the necessary expertise and facilities for a multidisciplinary approach.

5.3.2 Waiting Times For Surgical Treatment

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

The NHS Cancer Plan 4 states that patients should have a maximum wait of 31 days from 'decision to treat' to first treatment. In 2002, this standard was extended to a maximum 62 days wait from urgent GP referral to first treatment. A similar 62 days wait target now applies to screen detected breast cancers from December 2008, following publication of the Cancer Reform Strategy (6). To achieve these targets resources must be available, and in particular staffing levels must be appropriate. The 'decision to treat' is taken as the date on which the patient is informed by the treating clinician that they require treatment. As previously stated, an operation for diagnostic purposes should be carried out within two weeks of the decision to operate.

5.3.3 Pre-operative Investigations

A pre-operative search for occult metastases by bone scan and liver ultrasound does not yield useful information in patients with operable primary breast cancer (11) (Level 3 evidence). These investigations should not normally be carried out unless the patient is symptomatic, partaking of a clinical trial or is recommended for neo-adjuvant therapy (12,13). A pre-operative chest x-ray is of limited value and its use should be agreed by local protocol. The patient should have a full blood count, liver function tests and routine biochemistry and any abnormalities should be investigated appropriately.

5.3.4 Organisation of Surgical Services

Quality Objectives	Outcome Measures
To ensure specialist surgical care	Breast cancer surgery should only be performed by surgeons with a specialist interest in breast disease (defined as at least 30 surgically treated cases per annum)
To minimise patient anxiety between a decision that a **diagnostic** operation is required to confirm or exclude malignancy and the date for an operation	Patients should be admitted for a diagnostic operation within 2 weeks. Minimum standard - ≥90% within 2 weeks Target – 100% within 2 weeks
To minimise patient anxiety between a decision that a **therapeutic** operation is required for cancer and the date for operation	100% of patients should receive their first treatment within 31 days of the "decision to treat". If surgery is the primary treatment, then patients should be offered a date for surgery with 31 days of the "decision to treat". Target – 100% admitted for operation within 31 days, if surgery is the first treatment.
To minimise the delay between referral for investigation and first breast cancer treatment	100% of patients diagnosed with breast cancer should receive their first treatment within 62 days of an

	urgent GP referral with suspected breast cancer or recall from the NHSBSP. If surgery is the primary treatment, then patients should be offered a date for surgery within 62 days of the date of referral. Target – 100% admitted for operation within 62 days, if surgery is the first treatment
To minimise unnecessary investigations prior to breast cancer treatment	Non-operative investigations for metastatic disease should not be routinely performed

5.4 Surgery for Invasive Breast Cancer

5.4.1 Type of Breast Surgical Procedure

Long term follow up of randomised clinical trials have reported similar survival rates for women treated by mastectomy or breast conservation surgery (14-16). However all of these studies had selection criteria and indeed the vast majority of patients in these studies presented with tumours <2.5 cms.

Accurate pre-operative assessment of the size and extent of the tumour is essential for deciding whether breast conservation surgery is an alternative option to mastectomy. Routine methods for assessing the extent of disease in the breast are clinical examination, mammography and ultrasound. In a significant number of cases the true extent of disease is underestimated, particularly with invasive lobular cancer. Selective use of magnetic resonance imaging (MRI) may be useful in planning surgical treatment and in particular if: there is a discrepancy between the clinical and radiological estimated extent of disease; if there is a dense breast pattern on mammography; or the diagnostic core biopsy suggests an invasive lobular cancer. The decision to offer MRI should be discussed at the MDT meeting and be according to local guidelines.

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

Wherever possible, patients should be offered an informed choice between breast conservation surgery and mastectomy. Patients choosing or advised to have mastectomy for invasive breast cancer should have the opportunity to discuss whether breast reconstruction is appropriate and feasible. The reasons for not offering choice and/or breast reconstruction to a patient should be documented in the patient's case notes.

5.4.2 Margins of Excision

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

Intra-operative specimen radiography is mandatory for impalpable lesions requiring radiological localization, and recommended for all wide local excision procedures. Dedicated equipment (eg, digital specimen radiography cabinet) should be available so that a radiograph can be taken of the specimen and reported to or by the surgeon within 20 minutes. Interpretation of specimen radiographs must be clearly recorded. If this is done by the operating surgeon, the result must be confirmed by the radiologist at the subsequent multidisciplinary team meeting. If the radiologist reports the film at once, no more than 20 minutes should elapse before the reported film is received by the operating surgeon. If a specimen radiograph is performed, this should be available to the reporting pathologist. The surgeon should orientate and mark the specimen prior to delivery to the pathologist. The breast unit must have a clear protocol for specimen orientation and the handling of pathological specimens. Histologically involved margins lead to an excessively high risk of local recurrence, even if adjuvant radiotherapy is given. Approximately one in four patients with later local recurrence will succumb to their disease, who otherwise would not have died of breast cancer if they had not developed a local recurrence.

There are no data to support a specific margin of excision. There are no randomised trials of margins of excision. While further occult foci of disease can be found more than 2 cm from the supposed margin in up to 43% of patients (17) the wider the margin the less occult foci are found. Whilst NICE have previously recommended a minimum margin of 2 mm, there are no data to substantiate this. Units should have local guidelines regarding acceptable margin width and individual cases should be discussed at the treatment MDT meeting. If, after MDT meeting discussion, the margin of excision is deemed to be inadequate then further surgery to obtain clear margins should be recommended.

5.4.3 Marking of Surgical Cavities in Breast Conservation Surgery

New advances in radiation therapy have led to more accurate and consistent planning and delivery of therapy. Intensity modulated radiotherapy (IMRT) is now increasingly used to deliver satisfactory treatment doses to the clinical tumour volume, whilst also providing the ability to spare normal tissues. Consistent and accurate localisation of the tumour resection bed after breast conservation is important if the full benefits of IMRTand further radiotherapy advances are to be obtained. Previous studies have shown that estimating the tumour bed from the position of the surgical scar is inaccurate. The marking of the tumour bed is especially important when oncoplastic techniques are used to improve the cosmetic

outcome. The insertion of markers, such as surgical clips or gold seeds, in the tumour bed by the operating surgeon provides a way of visualising the tumour bed. Surgical clips are easy and cheap and allow radiotherapy planning either by CT or kilo-voltage exit portals. Surgeons referring to radiotherapy centres using megavoltage exit portals may need to consider the use of gold seeds, as clips cannot always be easily visualised on mega-voltage equipment.

5.4.4 Local Recurrence Rates

The main aim of surgery is to achieve good local control of both the primary tumour and the regional nodes in the axilla. In patients with operable breast cancer, complete excision of the primary tumour with clear margins is essential. The major randomised trials of breast conservation surgery and radiotherapy versus mastectomy for invasive cancer report local recurrence rates for breast conservation surgery ranging between 3% at 6 years to 17% at 10 years and for mastectomy ranging between 2% at 10 years and 9% at 8 years (14-16,18) although as noted above the majority of tumours in these trials were <2.5 cms.

However, the START trial has now reported and shows excellent low rates of local recurrence (3.5% at 5 years) following breast conservation surgery in the UK.19 Hence the recommended minimum standards and targets for local recurrence after breast conservation surgery for invasive cancer have been revised to a maximum of 5% at 5 years and a target of <3% at 5 years.

5.4.5 Surgery for Invasive Breast Cancer

Quality Objectives	Outcome Measures
Patients should be fully informed of the surgical treatment options available to them.	When appropriate patients should be given an informed choice between breast conservation surgery and mastectomy. If a choice of breast conservation surgery is not offered the reasons should be documented in the patient's case notes.
Patients should have access to breast reconstruction surgery	All patients having treatment by mastectomy (by choice or on advice) should have the opportunity to discuss their breast reconstruction options and have immediate breast reconstruction if appropriate. If breast reconstruction is not offered the reasons should be documented in the patient's case notes.
To ensure adequate assessment of surgical excision of an invasive cancer treated by breast conservation surgery.	Intra-operative specimen radiography should be carried out for all cases requiring radiological localisation and is recommended for all wide local excision specimens. All specimens must be marked by the

	surgeon according to local protocols to allow orientation by the reporting pathologist.
To ensure adequate surgical excision of an invasive cancer treated by breast conservation 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.
To minimise the number of therapeutic operation in women undergoing conservation surgery for an invasive cancer	Minimum standard - >95% of patients should have three or fewer operations Target – 100% of patients should have ≤3 operations.
To minimise local recurrence after breast conservation surgery for invasive malignancy	Minimum standard - <5% of patients treated by breast conservation surgery should develop local recurrence within 5 years Target - <3% of patients treated by breast conservation surgery should develop local recurrence within 5 years
To minimise local recurrence after mastectomy for invasive malignancy	Minimum standard - <5% of patients treated by mastectomy should develop local recurrence within 5 years Target - <3% of patients treated by mastectomy should develop local recurrence within 5 years

5.5 Axillary Node Management in Invasive Breast Cancer

The presence of axillary node metastases is the most powerful prognostic determinant in primary operable breast cancer and its assessment requires histological examination of excised axillary lymph nodes. Appropriate management of the axilla is also important in the prevention of uncontrolled axillary relapse. Axillary relapse is defined as relapse in the axilla itself and does not include supraclavicular recurrence.

Some patients with invasive breast cancer may be diagnosed with axillary disease prior to definitive surgery. The use of pre-operative axillary assessment with ultrasound and appropriate fine needle aspiration (or core biopsy if feasible) can yield a diagnosis of involved nodes in some cases. If a positive non-operative diagnosis of axillary nodal metastasis is made in a patient with early breast cancer, that patient should normally proceed to an axillary clearance. If an axillary clearance is carried out all axillary lymph

nodes should be removed unless there are specific reasons or unit policies not to do this. In the latter cases the anatomical level of dissection should be specified in the operation note. The number of nodes retrieved from axillary node clearance histology specimens will be both surgeon and pathologist dependent. However, for a full axillary clearance at least 10 nodes should be retrieved in >90% of cases.

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

Complete axillary clearance (level 3) is effective in controlling regional disease. Recurrence rates of 3%-5% at 5 years have been reported, (20-23) but some of these studies with level 2 clearance included both lymph node negative and positive cases. It is suggested that axillary node recurrence should be less than 5% at five years with a target of less than 3%. Lesser degrees of surgery without axillary radiotherapy lead to correspondingly higher rates of axillary recurrence. The Edinburgh study on patients receiving selective axillary radiotherapy for positive nodes after axillary sampling demonstrated similar control to that of full (level 3) axillary clearance (20,24) (Level 2 evidence).

In the last few years, sentinel node biopsy (SNB) has become a standard approach for axillary staging. This technique provides accurate assessment of the axilla, with few false negatives and a significant reduction in surgical morbidity, especially lymphoedema (25). Breast surgeons are encouraged to adopt the SNB technique and take part in the NEW START or equivalent training programmes. The combined technique (blue dye and radio-isotope) is the recommended method. Surgeons should be able to achieve minimum standards with a >90% sentinel node identification rates and <10% false negative rates over a minimum 30 case audit series.

Surgical staging of the axillary lymph nodes should be performed according to local protocols. If there is a non-operative diagnosis of invasive malignancy, then an axillary staging procedure should be carried out at the same time as surgery to resect the primary tumour other than in exceptional circumstances eg, prior to immediate LD flap reconstruction. Axillary staging may be achieved by sentinel node biopsy (recommended in the majority), sampling, or clearance. If axillary node sampling is carried out, then at least 4 nodes should be obtained. Blue dye may be used to augment axillary node sampling and if used this should be documented in the operation note. Routine use of axillary node clearance as an axillary staging procedure will be over treatment for the majority of patients.

Where the sentinel node is positive (macrometastasis or micrometastasis), further axillary treatment (axillary dissection or radiotherapy) as well as adjuvant systemic therapy is recommended. However, the management of patients with positive sentinel nodes is currently under investigation. The EORTC-AMAROS trial compares axillary clearance versus radiotherapy. The ACOS-OG Z0011 trial compares axillary clearance versus observation only. These studies will not report for some time. The decision to carry out a completion (full) axillary clearance or to give axillary radiotherapy if the sentinel node is positive should be discussed at the MDT meeting and with the patient, be according to local guidelines, and be documented in the patient's case notes. The significance of isolated tumour cells in axillary

lymph nodes is currently uncertain and these should be regarded as lymph node negative and routine axillary treatment is not recommended.

5.5.1 Axillary Node Management in Invasive Breast Cancer

Quality Objectives	Outcome Measures
To increase the non-operative diagnosis of axillary node metastases	Target – all patients diagnosed with invasive breast cancer undergoing surgical treatment should have a pre-operative axillary ultrasound scan, and if appropriate FNA or core biopsy should be carried out.
To ensure adequate surgical treatment of involved axillary lymph nodes	If a positive non-operative diagnosis of axillary nodal metastasis is made in a patient undergoing surgery for breast cancer, the patient should normally proceed to an axillary clearance. Patients with positive (macrometastases or micrometastases) axillary staging procedures should proceed to subsequent treatment for axilliary disease. This may take the form of completion (i.e, full) axillary clearance, axilary radiotherapy or entry into an appropriate clinical trial. This should be discussed at the MDT meeting according to local guidelines and the reasons should be documented in the patient's case notes. When axillary node clearance is carried out, the level of anatomical dissection should be specified, and at least 10 nodes should be retrieved. Minimum standard - >90% Target – 100%
To ensure adequate staging of the axilla in patients with invasive breast cancer	Patients treated surgically for early invasive breast cancer should have an axillary staging procedure carried out if metastatic nodal metastasis is not confirmed non-operatively Minimum standard - >90% Target – 100% When axillary node sampling is carried out at least 4 nodes should be retrieved Minimum standard - >90% Target – 100%
To minimise morbidity from axillary	Sentinel node biopsy using the

surgery to obtain staging information	combined blue dye/radioisotope technique is a recommended axillary staging procedure for the majority of patients with early invasive breast cancer
Axillary recurrence should be minimised by effective staging and treatment where appropriate	Minimum standard - <5% axillary recurrence at 5 years Target - <3% axillary recurrence at 5 years

5.6 Surgical Management of Ductal Carcinoma in Situ

Ductal carcinoma in situ (DCIS) is a malignant precursor of invasive breast cancer. The aim of surgery is to achieve complete excision of the in situ tumour and to minimise local recurrence. The grade of the tumour (26) and clear resection margins (>1 mm margin) (27) are important factors in the management of DCIS.

Tumour multifocality is not uncommon and can lead to high local failure rates (28) Approximately 50% of local relapses after treatment for DCIS are invasive and not in situ. The indications for mastectomy are uncertain but extensive micro calcification on the pre-operative mammogram is a risk factor for local recurrence after conservation surgery. High recurrence rates occur with larger tumours (>40 mm diameter) and mastectomy should be considered for such cases. While mammographic findings do not always correspond to pathological size the mammographic size is more commonly an underestimate of the final histological size. If mastectomy is being considered for the treatment of DCIS on the basis of multifocality, then at least two areas of the breast should ideally be biopsied to confirm this.

There have been randomised trials of adjuvant radiotherapy after breast conservation for DCIS. In the EORTC study, (27) clear margins (>1 mm) were associated with a local recurrence rate of 15% at 5 years compared to 36% in patients with close or involved margins (<1 mm or frankly involved), regardless of the use of radiotherapy. Likewise, low grade DCIS is associated with a low risk of recurrence.

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

Intra-operative specimen radiography should be carried out for all cases of DCIS treated by breast conservation surgery, the vast majority of which will be impalpable lesions requiring radiological localization. Dedicated equipment (eg, digital specimen radiography cabinet) should be available so that a radiograph can be taken of the specimen and reported to or by the surgeon within 20 minutes. Interpretation of specimen radiographs must be clearly recorded. If this is done by the operating surgeon, the result must be confirmed by the radiologist at the subsequent multidisciplinary team meeting. If the radiologist reports the film at once, no more than 20 minutes should elapse before the reported film is received by the operating surgeon.

If a specimen radiograph is performed, this should be available to the reporting pathologist. The surgeon should orientate and mark the specimen prior to delivery to the pathologist. The breast unit must have a clear protocol for specimen orientation and the handling of pathological specimens.

There are no data to support a specific margin of excision. 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.

Lymph node staging is not normally required for patients with a non-operative diagnosis of DCIS alone. However, some patients may be at high risk of an occult invasive carcinoma being found at subsequent pathological examination. These would include patients undergoing surgery for: an extensive area of microcalcification; a palpable mass; high grade disease; or where micro-invasion or frank invasion is suspected on the non-operative biopsies. In such cases SNB or four node sampling may be considered. Axillary clearance is contra-indicated in the treatment of patients with a non-operative diagnosis of DCIS alone. The decision to carry out an axillary staging procedure should be discussed at the MDT meeting and with the patient, be according to local guidelines, and be documented in the patient's case notes.

The management of screen detected non-invasive breast cancer (and atypical hyperplasias) is the subject of a national audit, the Sloane Project. All breast screening units should participate in this.

5.6.1 Surgery for Ductal Carcinoma in Situ

Quality Objectives	Outcome Measures
Patients with DCIS should be fully informed of the surgical treatment options available to them	When appropriate, patients should be given an informed choice between breast conservation surgery and mastectomy. This includes the difference in local recurrence rates between the two approaches. If a choice of breast conservation surgery is not offered the reasons should be documented in the patient's case notes.
Patients with DCIS should have access to breast conservation surgery	All patients having treatment by mastectomy (by choice or on advice) should have the opportunity to discuss their breast reconstruction options and have immediate breast reconstruction if appropriate. If breast reconstruction is not offered the reasons should be documented in the patient's case notes.
To ensure adequate assessment of surgical excision of DCIS treated by breast conservation surgery	Intra-operative specimen radiography should be carried out for all cases of DCIS treated by breast conservation surgery.

	All specimens must be marked by the surgeon according to local protocols to allow orientation by the reporting pathologist.
To ensure adequate surgical excision of DCIS treated by breast conservation 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.
To minimise the number of therapeutic operation in women undergoing conservation surgery for DCIS	Minimum standard - >95% of patients should have three or fewer operations Target – 100% of patients should have ≤3 operations
To minimise local recurrence after breast conservation surgery for DCIS	Patients with extensive (>40mm diameter) or multi-centric disease should usually undergo treatment by mastectomy
To minimise morbidity from axillary surgery	Axillary staging surgery is not routinely recommended for patients having treatment for DCIS alone. It may be considered in patients considered to be at high risk of occult invasive disease. The decision to carry out an axillary staging procedure should be discussed at the pre-operative MDT meeting and recorded in the patient's case notes. Axillary node clearance is contra-indicated in patients with DCIS alone
To minimise local recurrence after breast conservation surgery for DCIS	Target - <10% of patients treated by breast conservation surgery should develop local recurrence within 5 years
To increase understanding of the diagnosis and treatment of DCIS	All breast screening units should participate in the national audit of the management of non-invasive breast cancer, the Sloane Project.

5.7 Surgery for Lobular in Situ Neoplasia

Lobular in situ neoplasia, LISN, (formerly known as lobular carcinoma in situ or LCIS) is often an incidental finding and is usually occult. LISN may not be a local malignant precursor lesion, but it does confer an increased future risk, approximately seven-fold, of invasive breast cancer in both breasts (29-32) (Level 3 evidence). The risk of developing breast cancer is approximately 1% per year.

It is suggested that breast lesions containing LISN should be excised for definitive diagnosis, as some patients may have a co-existing invasive malignancy. The limited data available on LISN suggests that clear resection margins are not required following surgery for LISN alone. A policy of close surveillance after excision biopsy is appropriate (Level 3 evidence).

The management of screen detected LISN is included in a national audit, the Sloane Project. All breast screening units should participate in this.

5.7.1 Recommendations

Patients with a pre-operative diagnosis of LISN should be considered for diagnostic excision biopsy.

Post-operative surveillance is appropriate in these patients as they have an elevated risk of subsequent breast cancer.

Each breast unit should have agreed surveillance guidelines for patients treated for conditions that lead to an increased risk of later breast malignancy (such as LISN ADH etc.).

All breast screening units should participate in the Sloane Project.

5.8 Breast Reconstruction

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

For patients, who express an interest in breast reconstruction, discussions should take place on the ideal timing of the reconstruction. This should include the risks and benefits of immediate versus delayed techniques. Ideally breast units should have clinicians with oncoplastic expertise &/or breast surgeons who work with plastic and reconstructive surgeons with an established interest in breast reconstruction, who can provide this service. Where units offer breast reconstruction, adequate facilities, including theatre time and outpatient clinic time to counsel patients prior to surgery should be available. Facilities should be available for revisional surgery.

Further guidance has been published by the Association of Breast Surgery at BASO, the British Association of Plastic, Reconstructive and Aesthetic Surgeons and the Training Interface Group in Breast Surgery: Oncoplastic breast surgery e a guide to good practice (33)

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

5.8.1 Breast Reconstruction

Quality Objectives	Outcome Measures
Patients should have access to breast reconstruction surgery	All patients having treatment by mastectomy (by choice or on advice) should have the opportunity to discuss their breast reconstruction options and have immediate breast reconstruction if appropriate. If breast reconstruction is not offered the reasons should be documented in the patient's case notes. Breast Units should have surgeons with oncoplastic experience &/or have the rapid availability of a plastic surgeon. Adequate time for consultation and surgery must be available.
Patients not undergoing immediate breast reconstruction should be provided with breast prostheses	Breast prostheses should be freely available to patients treated by mastectomy together with easy access to a fitting service.

Clinical Guidelines – Oncoplastic Breast Surgery

6 Oncoplastic Breast Surgery

6.1 Defining the Service

The Breast Oncoplastic Service is defined as a core component of the breast multidisciplinary team with sufficient experience to offer patients access to the full range of procedures encompassed by oncoplastic breast reconstructive surgery, which include:

- Appropriate adequate surgery to extirpate the cancer
- Partial reconstruction to correct wide excision defects
- Immediate and delayed total reconstruction with access to a full range of techniques
- Correction of asymmetry of the reconstructed and the contralateral unaffected breast.
- It is envisaged the service will rely on inter-specialty collaboration across sites. Essential components of the service include:
- Multi-disciplinary team (MDT)3
- Administration
- Clinical skill mix
- Resources
- Data collection
- Clinical governance
- Education and training.

The following sections expand on these points. An oncoplastic service will also consider the evolution of a surgical career. Consideration needs to be given to the needs and requirements of newly appointed and mature surgeons as well as those surgeons in the latter stages of their career.

6.2 The Patient's Journey

6.2.1 Diagnosis

All women with suspected breast cancer should undergo formal assessment and investigation in accordance with practice defined in the NHS Breast Screening (www.cancerscreeing.nhs.uk/breastscreen) guidelines or guidelines for symptomatic women produced by the ABS at BASO. [3]

6.2.2 Decision-making

Decisions about immediate reconstruction may have to be made by the patient and her surgeon before the risk of local recurrence and the likely use of radiotherapy is known. [4, 5] Decisions about reconstructive surgery must:

- Not compromise oncological principles
- Consider risk factors evident in the individual concerned, particularly smoking, obesity, diabetes, hypertension, co-morbidity and complications of previous surgery such as deep vein thrombosis
- Take into account the potential delay in adjuvant treatment which may occur as a result of complications
- Consider how adjuvant treatment may adversely affect the outcome of reconstruction.

The oncoplastic team must ensure that the patient has adequate time:

- To make an informed decision
- To be supported by an appropriately trained specialist nurse
- To satisfy their information needs
- To have an opportunity to meet other patients who have, or have not, undergone oncoplastic surgery
- To view a range of educational materials, including images of a variety of reconstructive techniques
- To discuss perceived risks and benefits
- To discuss the full range of additional procedures that may be required.

This implies that the patient will frequently require more than one preoperative consultation.

The team must also ensure that:

- Patients contemplating oncoplastic surgery have realistic expectations about the outcome of breast reconstruction
- Patients are aware of the potential long-term implications of oncoplastic surgery
- Patients are aware that complete breast reconstruction in-cluding the nipple-areola reconstruction may require several separate surgical procedures 6
- Women who decide against immediate reconstruction should be reassured that they can discuss delayed reconstruction subsequently.

Women who find the decision about reconstruction particularly difficult may benefit from referral to a psychologist to help them through the decision-making process. It may be preferable for these women to consider reconstruction as a delayed procedure.

Deciding upon and undergoing breast oncoplastic surgery may be stressful and can have profound psycho-social sequelae. Members of the breast care team can help to alleviate the impact of these

decisions by developing an ethos of care in which psycho-social and appearance-related concerns can be freely raised and addressed. [7]

Adjusting to an altered body image after breast reconstruction can be a lengthy process, and may never be fully resolved. The patient has to adjust to: scarring, altered or loss of sensation, changes at any donor sites, concerns about implants and complications of surgery. 8 ,9, 10

The patient's own perceptions about the results of her surgery may not concur with the perception of a third party. Any decisions regarding further surgery to enhance the aesthetic result of surgery must be made by the patient, after consultation with the reconstruction team.

It is important to recognise that the experience of oncoplastic surgery will also have an impact upon the patient's partner and family, who may also need access to information about reconstructive surgery and support through the process.

6.2.3 Consent

Informed consent should follow nationally established guidelines (ref: www.doh.gov.uk/consent; Good practice in consent: achieving the NHS Plan commitment to patient centred consent practice).

6.3 Perioperative Preparation and Anaesthesia

6.3.1 Introduction

Oncoplastic surgical operations are often long and frequently complex. As so often in surgical practice, careful patient selection (which factors in both co-morbidity and patient expectation) is the key to success.

6.3.2 Preoperative Assessment

This should pay particular attention to cardiovascular disease, respiratory disease, obesity, smoking and diabetes. These are known to increase the risks of surgery, especially cardiac events, chest complications, deep venous thrombosis, skin and flap necrosis, wound infection and delayed healing.[11-19]

6.3.3 Intraoperative Management: General Principles

Particular attention should be paid to correct positioning of the patient with the appropriate operating table attachments thereby preventing pressure sores, maintaining perfusion pressure and the avoidance of hypothermia.[20]

6.3.4 Post-operative Care

All staff should be aware of the importance of observation, especially of changes in colour and temperature of a transposed flap. Appropriate physiotherapy should be started postoperatively.

6.3.5 Discharge Process

The discharge process should be planned and should include:

- An explanation of the importance of early signs of complication and action to be taken should they arise
- Arrangements for access to the team including a contact telephone number
- A date for a clinic visit.

6.3.6 Subsequent Management

Arrangements for subsequent review by appropriate members of the multidisciplinary team should be made including:

- A plan for tissue expansion
- Outpatient physiotherapy
- Attendance for wound inspection and seroma aspiration
- Psycho-social support.

Following tumour excision, the histopathological results must be discussed at the multidisciplinary meeting (MDM). The decisions reached will be discussed with the patient and an adjuvant therapy and follow-up programme will be agreed.

6.4 Selection of Breast Reconstruction Techniques

Historically, the goals of breast reconstruction were to improve the appearance when clothed and to avoid an external prosthesis. Surgical advances and increased patient expectations have modified these goals. The current aim is to produce symmetry that satisfies the patient's wishes within the limits of technical feasibility, whilst matching the remaining breast in terms of its contour, dimension and position. This may involve the use of breast implants and the use of corrective surgery to the opposite breast.

6.4.1 Breast-conserving Surgery and Reconstruction

Rationale

Poor planning in breast-conserving surgery can result in unacceptable deformity. Thought must be given to the likely cosmetic result and the impact and timing of additional treatment. Plastic surgery techniques can be used to remodel the conserved breast and surgery to the opposite breast can be anticipated to achieve better symmetry[21]. The use of implants to correct volume deficiency can lead to bad results. [22]

Oncoplastic techniques extend the scope for breast-conserving surgery by combining an extensive local excision of the breast parenchyma with a simultaneous reconstruction of the defect to avoid local deformity. [23]

Indications

Breast-conserving surgery and reconstruction should be considered in those patients where adequate local excision cannot be achieved without significant risk of local deformity. [24] This frequently occurs after:

- Resection of more than 20% of the breast volume

- Central, medial and lower pole resections
- Axillary dissection through lumpectomy incision
- Periareolar incisions in inferior quadrants
- Incomplete mobilisation of breast parenchyma to allow reshaping of the breast.

Other indications include women considering a breast reduction in addition to excision. [25]

Deformities in patients who have had poorly planned conservation treatment are often severe and difficult to manage [26]. Subsequent reconstruction of these deformities result in a higher risk of complications and recurrent deformities and are only improved in 50% of patients.

Salvage mastectomy is not easily accepted by these patients. Every effort has to be made to avoid these late deformities at the time of the original surgery.

Contraindications

Breast-conserving reconstruction is contraindicated:

- When clear margins cannot be assured without performing a mastectomy
- In patients with T4 tumours
- In those patients with multicentric disease
- In patients with extensive malignant mammographic microcalcification
- In patients with inflammatory carcinoma.

Timing of procedure

Breast-conserving surgery and reconstruction can be performed as a one-stage procedure, or as a two-stage procedure to allow formal margin analysis [27]. Patients opting for a one-stage procedure must be informed preoperatively of the potential for further surgery if positive margins are reported.

Technique selection

Reconstruction following breast-conserving surgery may be carried out using volume replacement or volume displacement techniques.

Volume replacement. Autologous tissue is harvested and transferred from a remote site into the resection defect, replacing the volume of excised breast tissue. This commonly involves the use of latissimus dorsi (LD) flaps. As the volume is restored, contralateral surgery is rarely required to achieve symmetry. Complications include donor site morbidity, shoulder dysfunction and flap loss. Should a mastectomy be required at a later date, LD reconstruction cannot be used.

Volume displacement. Local glandular or dermoglandular flaps are mobilised and transposed into the resection defect. This leads to a

net loss in breast volume and the potential need for a simultaneous contralateral reduction to achieve symmetry. The resection of the tumour can be combined with a range of mammoplasty techniques including:

- Glandular remodelling
- Inferior pedicle techniques
- Superior pedicle techniques
- Vertical scar techniques
- Round block techniques
- Grisotti flaps.

Volume displacement is associated with the recognised complications of conventional reduction mammoplasty including parenchymal flap necrosis, nipple/areola necrosis, wound breakdown and potential cosmetic failure.

Follow-up after combined reconstruction and breast-conserving surgery. Wide local excision and reconstruction of the resulting defect by volume replacement or volume displacement and adjuvant radiotherapy may alter the mammographic appearance. There is no evidence that breast conserving reconstruction interferes with surveillance. Nevertheless additional imaging modalities such as ultrasound or MRI scanning may be required.

6.5 Reconstruction After Total Mastectomy

6.5.1 Timing of Reconstruction

The fundamental aim of surgery must be to provide safe and successful oncological treatment. Breast reconstruction, whether immediate or delayed must acknowledge the primacy of the breast cancer. A reconstruction service exerts its impact in two ways. Immediate reconstruction often requires co-ordination of a bigger team with greater pressure on theatre time. When delayed reconstruction cannot be performed within a reasonable timescale, patients may opt to be treated elsewhere. In this case it is imperative that continuity of care is ensured by proper clinical governance.

Immediate breast reconstruction. Published evidence to date indicates that immediate breast reconstruction does not adversely affect breast cancer outcome [28,29]. The reconstruction does not interfere with further treatment for advanced cancer and there is no significant difference in the survival rates between immediate or delayed reconstruction [30, 31, 32]. Adjuvant chemotherapy and radiotherapy may have detrimental effects on some types of breast reconstruction but these can be minimised by judicious choice of type and timing of the oncoplastic technique. [33, 29, 34]

Advantages of immediate breast reconstruction:

- Potential for a single operation and period of hospitalisation
- Maximum preservation of breast skin and preservation of the inframammary fold [35, 36, 37]

- Good quality skin flaps, which are unscarred and have not endured radiotherapy
- Better cosmetic results in skin-sparing mastectomy
- Reduced need for balancing surgery to the contralateral breast
- Lower cost than delayed reconstruction. [2]

Disadvantages of immediate reconstruction:

- Limited time for decision-making
- Increased operating time
- Difficulties of co-ordinating two surgical teams when required
- A potential in individual patients for complications to result in the delay of adjuvant treatment
- That the need for adjuvant treatment cannot always be predicted prior to surgery.

6.5.2 Delayed Breast Reconstruction

Advantages of delayed breast reconstruction:

- Allows unlimited time for decision making
- Avoids any potential delay of adjuvant treatment
- Avoids detrimental effects of radiotherapy or chemotherapy on the reconstruction.

Disadvantages of delayed breast reconstruction:

- Requires replacement of a larger amount of breast skin
- Mastectomy flaps may be thin, scarred, contracted or irradiated and poorly positioned
- May result in a less aesthetically pleasing outcome
- Requires separate episode of hospitalisation
- Increased treatment cost compared to immediate reconstruction
- Scheduling difficulties may occur.

6.5.3 Contraindications for Breast Reconstruction

- Non-resectable local chest wall disease
- Rapidly progressive systemic disease
- Patients who have serious co-morbidity
- Patients who are psychologically unsuitable.

6.5.4 Techniques of Breast Reconstruction

The ideal breast reconstruction is a soft natural feeling breast which maintains its characteristics over time, has a natural fluidity and a permanent and natural inframammary fold.

Implant based techniques require limited surgery initially but have certain limitations and are not always quick and trouble-free. These procedures allow patients some control over breast size, but the quality of the long-term result is directly related to their tolerance of breast implants. Further procedures may be required for complications and maintenance. The aesthetic results from autologous reconstruction are superior to those of implant based reconstruction due to their versatility, their more natural appearance, consistency and durability. Autologous tissue can better withstand radiotherapy. [38]

The autologous latissimus dorsi flap is highly versatile and has acceptable donor site morbidity. The skin and fat of the lower abdomen are ideal for autologous breast reconstruction but donor site morbidity is increasingly being appreciated. Muscle sparing techniques preserve the abdominal wall function at a cost of a more complex procedure. The effects of adjuvant radiotherapy on breast reconstruction using lower abdominal tissue are still under investigation.

The choice of technique depends on:

- Patient fitness for surgery
- Breast size
- Body habitus
- Laxity and thickness of remaining breast skin
- Condition of the underlying muscles
- Availability of donor flap sites
- Stage of disease
- Perceived need for adjuvant radiotherapy
- Patient preference if more than one reconstructive option is feasible. [39, 40, 41]

6.5.5 Tissue Expansion and Implant Reconstruction

Replacement of the breast volume with an implant or a tissue expander is the simplest method of breast reconstruction [42]. Patient selection and implant selection are crucial. Several techniques are possible:

- Fixed volume implant (single stage)
- Variable volume expander-implant (single stage)
- Tissue expansion followed by permanent implant (two stage).

Advantages of tissue expansion:

- Simple and flexible technique

- May not involve additional scarring
- Breast is reconstructed with local skin
- Allows insertion of larger implants
- Shorter procedure
- Shorter convalescence and rehabilitation
- Does not preclude further reconstruction options
- Avoids donor site morbidity.

Disadvantages of tissue expansion reconstruction:

- Multiple staged procedures.
- Multiple hospital visits for expansion
- Added complications of implants
- Need for revisional surgery
- Lack of projection
- Limited ptosis
- Less likely to achieve symmetry
- Less satisfactory long-term cosmetic outcome
- Capsular contracture particularly after adjuvant radiotherapy.[43, 44 , 45]

Indications for tissue expansion[40]:

- Patient of normal body mass index (BMI)
- Small to moderate non-ptotic breasts
- Good soft tissue cover, intact pectoralis major muscle
- Bilateral reconstruction
- Patients who are unwilling or unfit to undergo autologous tissue reconstruction.

Contraindications for tissue expansion[40]:

- Chest wall tissues are thin, damaged, inelastic or irradiated
- Extensive infra-clavicular tissue deformity or a vertical mastectomy scar
- Mastectomy skin deficit >8cm
- Radical mastectomy defect
- Patients who have unresolved concerns about the use of implants.

The complications of implant/tissue expansion:

- Complications related to wound failure
- Haematoma
- Wound infection
- Breast skin necrosis
- Wound dehiscence
- Implant failure
- Complications of breast implants
- Capsular contracture
- Asymmetry
- Displacement
- Thinning of the overlying skin. [30, 46 , 47, 48, 49]

6.5.6 Latissimus Dorsi Fap

The latissimus dorsi myocutaneous flap allows for the immediate or delayed reconstruction of a full range of breast volumes. It has particular advantages for patients with larger or more pendulous breasts. This technique can also be used for salvage surgery and chest wall reconstruction. [40, 50, 51 , 52]

Several variations of this technique are possible:

- Muscle only flap, without a skin island
- Myocutaneous flap with or without a breast implant or tissue expander
- Extended LD flap reconstructing the whole breast with autologous tissues only, avoiding the use of implants or tissue expanders
- Muscle sparing or perforator based techniques. [53-55 [V]]

Advantages of the latissimus dorsi flap:

- Versatile
- Reliable technique
- Dependable tissue perfusion.

Disadvantages of LD flaps:

- Donor site scar and contour defect on back
- Different skin colour between back and breast
- Possible shoulder impairment.

The functional deficit after transfer of an LD muscle affects some specific activities like rowing, cross country skiing or mountain climbing but appears to have little effect on most other activities [40, 51,

[52 , 56-59] . Additional physiotherapy may be required to restore full shoulder mobility.

Indications for LD flaps:

- Chest wall tissues that are unsuitable for tissue expansion
- Additional tissue requirements after mastectomy
- Chest wall reconstruction
- Partial breast reconstruction (after conservation surgery or partial or total loss of abdominal tissue flap).

Contraindications for LD flaps:

- Previous surgery which may have compromised the vascular supply to the flap
- Patient co-morbidity
- Absence of latissimus dorsi muscle.

Post-operative complications:

6.5.7 Flap Related

- Haematoma
- Infection
- Partial or total flap necrosis
- Delayed healing
- Expander failure
- Complications of breast implants.

6.5.8 Donor Site Related

- Haematoma
- Infection
- Skin loss
- Delayed healing
- Persistent seroma.[35,60]

6.5.9 The Use of Silicone Expanders and Breast Implants

All available information on the safety of silicone has been assessed by the Independent Review Group and the findings have been published in a report in 1998 (www.silicone-review.gov.uk, Level IV).

There is currently less information about the actual lifespan of an implant. Any patient receiving an implant or tissue expander based breast reconstruction has to be aware that the implant may require replacement.

6.5.10 Breast Reconstruction with Lower Abdominal Tissue

The lower abdomen is often an abundant source of tissue for autologous breast reconstruction. A sizeable and natural feeling breast mound can be created without an implant or tissue expander using tissue which is usually discarded during an aesthetic abdominoplasty procedure. The final appearance of the donor site defect is often acceptable and in some cases may offer a cosmetic improvement. Though this technique can provide excellent long-term results, donor site morbidity should not be underestimated. [61]

The triple blood supply to the lower abdominal tissue allows it to be used in a variety of techniques [52, 62, 63, 64-68]

- Pedicled transverse rectus abdominis myocutaneous flap (TRAM)
- Free transverse rectus abdominis myocutaneous flap (TRAM)
- Free deep inferior epigastric perforator flap (DIEP)
- Free superficial inferior epigastric artery flap (SIEA).

Surgeons have moved from pedicled TRAM flaps to free perforator flaps to try to reduce the morbidity of the donor site and preserve abdominal wall integrity and function. The complications encountered with techniques using lower abdominal tissue for breast reconstruction are related to;

- the extent of muscle resection
- Extent of fascia resection
- The use of a mesh to repair the abdominal wall.

These factors should be borne in mind when selecting the appropriate procedure for an individual patient. All these techniques will interfere with abdominal wall sensation.

Indications for breast reconstruction using lower abdominal tissue include:

- Sufficient lower abdominal tissue
- Large contralateral breast
- Divided or atrophic latissimus dorsi muscle
- Previous complications with implant based reconstruction
- Bilateral breast reconstruction.

6.5.11 Contraindications for Lower Abdominal Flaps

Reconstructions using lower abdominal tissue can be associated with significant complications and morbidity, and are contraindicated in the following circumstances.[69-71]

- Physiologically unfit patient
- Patients with significant co-morbidity including obesity, diabetes, autoimmune disease, vaso-spastic disorders, cardio-respiratory disease

- Smoking
- Psycho-social problems
- Abdominal scars disrupting the vascular anatomy
- Inadequate recipient vessels in free tissue transfer patients.

Pedicled TRAM flap. The pedicled TRAM flap relies on blood flow through the deep superior epigastric vessels within the substance of the rectus abdominis muscle to supply a horizontal ellipse of lower abdominal skin and fat. The flap is transferred onto the chest wall through a subcutaneous tunnel. It is not an appropriate technique for individuals in whom the distance from nipple to costal margin is greater than the distance form the costal margin to the umbilicus (short-waisted women).

Advantage of pedicled TRAM compared to free TRAM flap:

- No need for microvascular transfer.

Disadvantages of pedicled TRAM compared to free TRAM flap:

- Harvesting of large amount of muscle
- Reduced vascularity of the flap
- Higher incidence of fat necrosis
- Reduced abdominal wall function
- Long recovery time
- Costal nerve compression
- Complications of a mesh, if used to repair the abdominal wall.

The development of reliable free tissue transfer techniques has provided an alternative to the pedicled TRAM flap in an attempt to reduce abdominal wall damage and lower the risk of partial or total flap necrosis.[72, 73, 74]

Free TRAM flap. The deep inferior epigastric vessels are the dominant blood supply for a free TRAM flap. The lower abdominal skin is transferred with a segment of rectus abdominal muscle and the deep inferior epigastric vessels, which are then anastomosed to recipient vessels of the subscapular axis or the internal mammary system. [65]

Advantages of free TRAM flap:

- Better tissue perfusion compared to pedicled TRAM flap.
- More appropriate for larger breasts.
- Longer vascular pedicle compared to other free flaps.
- Larger vessel diameter for microsurgical anastomosis.
- Smaller amount of muscle harvested than in the pedicled TRAM.

- Reduced blood loss.

Disadvantages of free TRAM flap:

- Requires microsurgical techniques and the infrastructure to support the use of those techniques
- Longer duration of operation than pedicled TRAM.

Free tissue transfer is a major surgical procedure with an increased risk of general complications. Specific complications of free TRAM flaps can be related to the flap or the donor site. [75 , 76, 77, 78 , 79, 80]

Flap related complications of free TRAM flap:

- Microsurgical problems
- Haematoma
- Partial flap loss
- Total flap loss
- Fat necrosis
- Delayed healing.

Donor site complications of the free TRAM flap:

- Haematoma
- Wound infection
- Problems with mesh closure
- Asymmetry of umbilicus
- Bulging abdominal wall
- Hernia
- Abdominal weakness.

Free DIEP flap. The free DIEP flap spares the whole of the rectus abdominis muscle. No muscle or fascia is harvested and no mesh is required for donor site closure. The flap relies on the meticulous dissection of perforating vessels within the rectus abdominis muscle. [66, 67]

This technique is particularly indicated for young, athletic patients and those women requiring bilateral breast reconstruction. The DIEP flap has all the potential flap complications of any free tissue transfer but reduces donor site complications and morbidity.

Advantages of perforator flap breast reconstruction:

- Only skin and fat harvested, muscle preserved
- Comparable outcomes with the free TRAM flap
- Preservation of abdominal and back extensor muscle strength. [81-83]

Disadvantages of DIEP flap:

- Increased operating time
- High level of surgical expertise requiring specialised training in dissection techniques.

Flap related complications of free DIEP flap:

- Microsurgical problems
- Haematoma
- Partial flap loss
- Total flap loss
- Fat necrosis
- Delayed healing.

Donor site related complications of free DIEP flap:

- Haematoma
- Wound infection.

The free SIEA flap. Harvesting the SIEA flap does not disturb the rectus abdominis or the abdominal fascia. It relies on dissecting the superficial inferior epigastric (a branch of the femoral artery), and its vein, which supplies the fat and skin of the lower abdomen. Unfortunately, this vessel is absent in a third of patients and may have been damaged by previous surgery. [68]

Advantages of the free SIEA flap:

- No dissection of abdominal wall muscle or fascia
- No risk of post-operative weakness
- Shorter operating time, easier dissection
- Less post-operative pain.

Disadvantages of the free SIEA flap:

- Short pedicle
- Small diameter of vessels (1.5-2 mm)
- Higher rate of partial flap necrosis. [84-86]

Alternative free flap donor sites

There are further types of free flap transfer for breast reconstruction. However the expertise required for these is extremely demanding and the failure rates are potentially higher. They should be reserved for women in whom conventional techniques are deemed inappropriate.

Alternative options for autologous tissue breast reconstruction:

- Free superior and inferior gluteal perforator flaps
- Lateral transverse thigh flap

- Rubens peri-iliac fat pad flap
- Free latissimus dorsi flap from the contralateral side.

These may be indicated if the lower abdomen or back have insufficient tissue, have already been used, cannot be used due to disruption of the vascular pedicles, or if the patients want to avoid scars in more obvious parts of the body. [87-90]

6.5.12 Surgery to the Contralateral Breast

There are two situations in which contralateral surgery needs to be considered. One is where it is necessary to operate in order to achieve symmetry. The other is where a woman, deemed at high risk of contralateral breast cancer after a formal assessment of genetic risk, may consider a risk reducing mastectomy with reconstruction.

The resources for this additional surgery should be considered when setting up an oncoplastic service.

Complete breast reconstruction including the nipple-areola reconstruction will require on average 3.3 separate surgical procedures. [6]

6.5.13 Additional Procedures to the Reconstructed Breast

Further surgery may be necessary to the reconstructed breast.

Adjustment of size of reconstructed breast:

- Liposuction
- Excision of excess tissue
- Mastopexy
- Augmentation.

6.5.14 Adjustment of Position of Reconstructed Breast

- Repositioning on the chest wall
- Revision of flap inset.

6.5.15 Adjustment of Shape of Reconstructed Breast

- Capsulotomy or capsulectomy for capsular contracture
- Correction of projection
- Adjustment to the inframammary fold
- Recreation of an axillary fold
- Scar revision
- Change of implant.

6.5.16 Adjustment of Flap Donor Site

- Scar revision
- Liposuction

- Treatment of seroma
- Repair of abdominal bulge/hernia.

6.5.17 Treatment of Involuntary Muscle Contraction

- Temporary paralysis or permanent division of nerves
- Physiotherapy
- Revision of reconstruction.

6.5.18 Nipple-areola Reconstruction

The final part of the breast reconstruction is the reconstruction of the nipple-areola complex. Some patients are happy with a prosthetic nipple but patients should be offered the opportunity to proceed to nipple reconstruction. [91]

Techniques for nipple reconstruction:

- Prosthetic nipple
- Composite grafts
- Local flap reconstructions (multiple designs).

Techniques for areola reconstruction:

- Tattoo
- Full thickness skin grafts.

Skin grafting has been abandoned largely in favour of tattooing, a relatively simple technique with few complications. Improved colour match can be achieved by the use of a 3D colour-chart. [92, 93]

6.5.19 Salvage Surgery

Salvage surgery may be required for complications of the reconstruction or for oncological reasons.

6.5.20 Complications of Breast Reconstruction Requiring Salvage Surgery

Where there has been breast skin flap loss the situation can be redeemed by the following techniques:

- Advancement of breast skin or flap and direct closure
- Split thickness skin graft
- Salvage with an LD flap.

Implant extrusion due to wound dehiscence:

- Removal of implant and later reinsertion
- Conversion to an LD flap.

Partial flap loss:

- Debridement and direct closure

- Split thickness skin grafting
- Further flap procedure (LD, thoracoepigastric flap)
- May require surgery to the opposite breast to achieve symmetry.

Complete flap loss:

- Debridement and direct closure or split thickness skin graft
- Further flap procedure
- Insertion of tissue expander or implant.

6.5.21 Local Recurrence

Salvage surgery for chest wall recurrence often creates a surgical dilemma because although the patient has recurrence, they may have significant life expectancy. These reconstructions are often difficult because they rely on poor quality tissues.

The aims of surgery in this situation include:

- Local control of disease
- Palliation of symptoms
- Enhancing quality of life.

Reconstruction of the resultant defect often requires extensive surgery in form of:

- Local flaps or abdominal advancement
- Regional flaps such as latissimus dorsi, pectoralis major and parascapular flaps
- Pedicled or free abdominal flaps
- A combination of the above techniques.

These complex procedures should only be carried out in a multidisciplinary setting offering the full range of reconstructive options.

6.6 Additional Resources

6.6.1 Dedicated Outpatient Time

Patients require enough information to both make a decision and give informed consent about breast reconstruction. This is a resource intensive service and sufficient time must be available to:

- Assess the clinical problem and describe the options
- Allow the patient to digest and understand the information given to them
- Consult with the breast care nurse
- Allow for additional consultations to confirm the decision before proceeding with surgery

- Carry out practical procedures such as the aspiration of seroma.

6.6.2 Dedicated Operating Time

Surgeons undertaking reconstructive surgery need adequate facilities. They should be supported by:

- Access to an all day list
- Adequate assistance within the operating theatre
- A theatre team familiar with the nature of the surgery
- The facility to operate when necessary with a second team of surgeons.

6.6.3 Dedicated Inpatient and High Dependency Beds

In units undertaking oncoplastic surgery:

- Provision should be made for a ward to have as one of its dedicated interests breast and reconstructive surgery
- The staff of that ward to be given adequate opportunity to receive training and career development around such nursing
- Patients undergoing reconstructive surgery should be admitted to the designated ward, with enough time for them to settle in, so that final assessments and skin marking can be made before surgery
- There should be adequate facilities for post-operative monitoring commensurate with the type of surgery being performed. With appropriate facilities, this might be on the designated ward but may in some instances need access to a high dependency unit (HDU) facility or its equivalent
- A protocol for post-operative management should be available on all wards
- Ward facilities for out of hours consultations for recently discharged patients should be provided.

6.6.4 Medical Photography

Medical photographs represent an important record, therefore, all patients undergoing reconstructive surgery should have a photographic record that documents the progress and is kept with the clinical notes.

6.6.5 Implant Stock/System

The following points should be considered for a service providing implants:

- The quality, range, proven reliability and ready availability of prostheses
- The supplier's ability and willingness to provide support training and education

- Evaluation, reporting and compliance from the supplier for explanted products
- Value for money, budgetary considerations and the level of implant stock required to cover the workload.

6.6.6 Implant Stock

A full range of the selected types and sizes of implant should be available when the patient has her surgery. This can be provided economically by one or more of the following:

- Purchased shelf stock. Purchased stock is usually bought by the hospital and can provide either all the sizes needed or a core of sizes, which can be added to if a specific patient requires a less common implant
- Consignment or ‘‘bank’’ stock. Consignment stock belongs to the supplying company and will be placed by mutual arrangement with a formal agreement signed according to policies. It is a consideration that this stock is the total responsibility of the hospital while it remains on their premises
- Sale or return stock. Some suppliers offer a ‘‘sale or return’’ service where up to three sizes can be ordered for each procedure. After surgery the unused product is returned for credit. This is a good choice for units using a smaller number of implants and where there is a need for an unusual type of size or implant.

There are two particular issues which affect the stocking system and are often overlooked:

- Stock rotation must be practised. Most implants have a five-year sterility shelf life and an expiry date has to be shown on the packaging. This means stock can be easily tracked and the ‘‘oldest’’ should be used first
- Following the use of an implant the replacement shelf product should be ordered immediately in preparation for the next operation. This practice ensures the full choice of implant for every patient/surgeon.

6.6.7 Use of Implants

The following points are considered best practice:

- Before surgery the patient should be informed of all complications associated with breast implants. It is advisable to have a routine procedure to achieve this without exception
- Selection of styles and sizes of implant for a patient must allow sufficient time for the stock to be delivered
- A consistent method of sizing should be followed utilising a combination of templates, ‘‘sizers’’, volume displacement of tissue removed and other recognised methods
- Each implant should be used within the product data sheet recommendations

- The surgeon should be familiar with the product instructions for use
- A routine policy for dressing the wound and post-operative care should be practised.

6.6.8 Surgical Equipment

The oncoplastic operating theatre must be equipped to a level which supports the performance of a full range of reconstructive procedures and provides a safe and efficient working environment for surgeons and other theatre staff.

The writing committee has found the following pieces of equipment useful in the practice of oncoplastic surgery:

Operating table and support

- An electronically adjusted operating table is highly recommended. It facilitates easier movement of the patient to a near vertical position on completion of the procedure
- Adequate table attachments for safe positioning of patients
- Modern equipment to reduce the risks of lengthy surgery.

6.6.9 Lighting and Retraction

- Good theatre lighting which will allow two surgeons to operate independently
- Additional light sources such as head lights or lighted retractors of different length and tip design
- Appropriate retractors and forceps which may be insulated to reduce the risk of diathermy skin burns
- Optional: endoscopic equipment with or without video transmission.

6.6.10 Cutting and Coagulation

The extensive dissection encountered during breast reconstruction can be facilitated by the use of

- A Barron-pattern scalpel handle for making curved incisions
- Cutting diathermy equipment
- Bipolar diathermy forceps and scissors
- Ultrasonic cutting and coagulation equipment
- Tungsten carbide dissecting scissors for de-epithelialisation.

6.6.11 Additional Equipment

- Rubber-shod artery forceps for the atraumatic clamping of the filler tubes of tissue expanders
- A set of different-sized trephines for use during breast reduction and skin-sparing mastectomy

- Ultrasound Doppler 8-12 mHz
- Microinstruments
- Magnifying loops and microscope.
- Sizers for implants.

6.6.12 Micropigmentation Service (Tattooing)

There is currently no recognised qualification in micro-pigmentation. The micropigmentation service will be delivered by an appropriately trained practitioner. The important requirements include

- A treatment area with natural lighting conditions
- Facilities for test patching in atopic individuals
- A baseline photograph
- Consent
- Local anaesthesia
- Information leaflet
- Medical tattooing equipment and dyes.

Patients should be made aware that tattoos fade and may require further pigmentation procedures.

6.6.13 Physiotherapy Following Breast Reconstruction

Post-operative physiotherapy plays an important role in the rehabilitation of the patient. It is imperative that physiotherapy treatment starts as early as possible and is carried out under the supervision of an experienced physiotherapist who is familiar with the surgical techniques and attendant complications.

6.6.14 Patient Information

All patients, and if appropriate their partners must receive comprehensive information which:

- Realistically describes their options and anticipated possible outcomes
- States that a reconstructed breast will not be the same as the natural breast
- Describes specific complications that may occur
- Discusses possible functional and psychological sequelae
- Includes photographic appearances of planned procedures.

In addition, all units must have written information to be given to the patient. Units should ensure that these leaflets are kept up to date (sample leaflets are available on the Cancer Backup website: www.cancerbackup.org.uk).

Health professionals should be aware of the words they use when discussing surgery and present a balanced view based on factual accuracy.

In patients whose communication in English is limited, care should be taken to ensure that the patient fully understands the implications of treatment.

6.6.15 Adequate Space

The clinic environment should be designed in a way which provides

- An adequate waiting area for patients and their relatives
- A relaxed environment for consultation in privacy
- A separate space for counselling
- Easy access to refreshments.

6.6.16 Psychological Support

Most women deal very well with the psychological demands made of them by the diagnosis and treatment of breast cancer. However, many will require additional help and support over and above that provided by their assigned breast care nurse, who should also have up to date knowledge of breast reconstruction and oncoplastic surgery.[94]

6.6.17 Support Group/‘‘Buddy’’ System

Patients who have undergone oncoplastic surgery can provide beneficial support to others facing similar surgery. However, it is important to recognise this might place unexpected demands upon both women taking part. The motivation of those previous patients who are now offering their support to other women needs to be explored by the specialist nurse on a case-by-case basis, respecting the privacy of both parties. The nurse should also be in a position to provide support to women involved in a ‘‘buddy’’ system, as necessary.

6.7 Interprofessional Relationships

6.7.1 Local

The oncoplastic service will normally be on site and will constitute a core component of the multidisciplinary team (MDT). All patients should be discussed at the MDT and treatment planned accordingly. Where reconstructive surgery is performed at a different site to that of the initial surgery, full clinicopathological details should be made available to the reconstructive team. The multiprofessional breast reconstruction team should also include relevant anaesthetic, theatre and ward staff. There should also be a psychologist, medical photographer and clerical staff for data collection and audit. There should be adequate links with managerial and clinical governance staff, as well as with the patient advisory liaison service.

6.7.2 Network

Oncoplastic breast services in the NHS will be provided through a managed cancer network (www.doh.gov.uk/ HYPERLINK "http://www.doh.gov.uk/cancer/cancernetwork"cancer/cancernetwork). The service can use the resources of the cancer network for patient information, IT support and business planning and resources to participate in clinical trials. Units providing a comprehensive range of procedures can act as a resource for the management of more complex problems such as developmental abnormalities, revisional procedures and chest wall resection and reconstruction and should be the focus of onward referral from other units.

6.7.3 Commissioning

Primary care trusts will commission care of patients with breast problems but the main negotiations for cancer services is likely to take place through the cancer networks.

6.7.4 National Professional Bodies

Responsibility for defining, establishing and maintaining professional standards of oncoplastic surgery rests with the Royal Colleges representing the individual specialties which make up the MDT. They also have a responsibility for education, training and professional development in conjunction with the Association of Breast Surgery at BASO (ABS at BASO), and the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS). The Training Interface Group in Breast Surgery is the interprofessional body with responsibility for developing the oncoplastic training initiative. This group provides advice to the Specialty Advisory Committees (SACs) in general surgery and plastic surgery. It assists with the selection and evaluation of oncoplastic training posts and is developing appropriate clinical audit.

6.7.5 Patient Support Groups

Support for patients before and after breast reconstruction should be freely available through the local breast reconstruction unit, local patient support groups and the National breast cancer care organisations. There should also be a ‘‘buddy’’ system as already described (see Support group/‘‘buddy’’ system).

6.7.6 Independent Sector

Patients undergoing breast reconstruction in the independent healthcare sector should experience standards of care equivalent to those expected in the public sector. Surgeons undertaking oncoplastic breast surgery should normally have NHS appointments and be on the specialist register for general or plastic surgery and be members of the appropriate specialist group. Surgeons who do not hold NHS appointments must be able to prove training and experience to a level of competency equivalent to that of a newly appointed NHS consultant.

6.8 Data Collection, Clinical Governance and Information

A breast unit will require information to support service planning and evaluation, performance monitoring and clinical governance.

6.8.1 Data Collection

To ensure data are of the highest possible quality, there are some important principles of data collection that should be adhered to:

- Data should be collected once, as close to the point of service delivery or activity as possible
- The process of patient care should drive the data collection process, with data required for all other purposes being derived from this
- Data should be provided in an accurate and timely manner to suit the purpose for which they are required
- Only data for which there is a defined purpose should be collected.

6.8.2 Information Requirements

A Cancer Dataset (http://nww.nhsia.nhs.uk/cancer/ HYPERLINK "http://nww.nhsia.nhs.uk/cancer/pages/dataset/default.asp"pages/dataset/default.asp) has been drawn up and approved for national use. This will support the implementation of the National Cancer Plan and includes fields covering details of the patient, tumour, diagnosis, treatment and outcome.

The responsible clinician should ensure the accurate coding of operative procedures (ICD10 and OPCS4 codes should be used as an aid for identification). Necessary time and resources must be provided to carry this out. At the present time, aesthetic outcomes are not formally assessed. Nevertheless, a tool for measurement of aesthetic outcomes is required.

6.8.3 Clinical Governance

All clinicians have a responsibility to ensure that they are maintaining a programme of continuing professional development in association with monitoring and evaluating their own performance (ref: HSC 1999/065; Clinical Governance Reporting Processes NHS E Nov 2002). The national HES dataset is being expanded to include details of the clinicians responsible for distinct interventions such as the operating surgeon.

The breast unit should ensure that there are appropriate quality assurance processes in place, incorporating regular reviews of the information available about the service provided.

It is difficult to measure, compare and interpret outcomes of evolving procedures that are performed infrequently. Sufficient numbers are needed to draw meaningful comparisons and provide an evidence base to support change in clinical practice. Supplying data to a national audit with defined standards facilitates the measurement and assessment of individual performance and supports the appropriate further development of the specialty. A national dataset will inform this process.

In addition to a programme of clinical audit, oncoplastic surgeons should be reporting incidents which compromise patient safety to the National Patient Safety Agency. Participation in other initiatives designed to reduce risk to patients is encouraged. For example, an

adverse incident involving a breast prosthesis should be reported to the manufacturer (Vigilance System of the Medical Devices Directive 1993/42/EEC). A Confidential Reporting System in Surgery (CORESS), along the lines of that operated by the Civil Aviation Authority, has been established for the reporting of ‘‘near misses’’. Reports can be made, in confidence, via their website: www.coress.org.uk.

6.9 Education and Training

The specialty of breast oncoplastic surgery is developing concurrently with changes in the postgraduate training of surgeons. As the specialty expands it will be important to have an education and training programme to support

- Trainees wishing to enter the specialty
- Surgeons wishing to develop an interest in oncoplastic surgery and to acquire the necessary core skills
- Continuing professional development (CPD) of established oncoplastic surgeons.

A well structured, organised and managed framework for training and education is essential to assist the Postgraduate Medical Education and Training Board (PMETB) in reinforcing and maintaining professional standards. To do so, the competencies and skills required, together with an approach to training that recognises the need to consider the training experience from the perspective of trainer and trainee must be well documented and validated.

This section of the document focuses on the educational and training needs of the oncoplastic surgeon. Other members of the team will require education and training specific to their discipline.

Future training will be competency-based and defined by specialty curricula. Training resources will have to be accommodated alongside the service demands, matching the needs of surgeons to the programmes. The time for education and training is becoming shorter at all levels. It is important to ensure that sufficient clinical experience is gained and programmes are quality assured.

6.9.1 Definition of a Breast Reconstruction Unit

1. A Breast Reconstruction Unit is defined as a core component of the MDT with sufficient experience to offer patients access to the full range of procedures encompassed by oncoplastic breast surgery. Providers of oncoplastic education and training may require the trainee to attend one or more units as part of their education.

2. For training purposes, a Breast Reconstruction Unit will be classified according to the level of expertise and range of procedures available within the unit.

3. The status of the unit will depend on the level of service provided as defined by the caseload, case mix, timing of reconstruction, personnel, skills and experience and their capacity to meet the trainees’ needs.

A Level I Oncoplastic Training Unit will provide training to deliver a core oncoplastic service regardless of the clinical setting. Such a unit is likely to be of relevance to the training of a wide range of professionals, including all the surgeons identified above. This will imply:

- A caseload of at least 25 major reconstructive procedures per annum as the minimum requirement for a Level 1 oncoplastic training Unit. These must be performed by a surgeon(s) participating in a programme of CPD in oncoplastic surgery
- Exposure to a range of the core oncoplastic procedures such as implants, expanders and latissimus dorsi myocutaneous flaps
- Experience of immediate and delayed reconstruction
- At least one surgeon trained in breast reconstruction, supported by an appropriately constructed multidisciplinary team working with theatre and ward personnel, all with adequate levels of experience
- Formal lines of communication with a plastic surgery unit or Level II Oncoplastic Training unit who will provide the full range of more complex reconstructive procedures.

A Level II Oncoplastic Training Unit will provide training necessary to deliver a comprehensive oncoplastic service which includes all aspects of breast oncology and plastic reconstructive surgery. In addition to the core training provided by the Level I unit, key aspects of a Level II Training Unit will imply:

- A caseload of more than 50 reconstructive procedures per annum
- A comprehensive case mix, including autologous flaps, breast-conserving reconstruction using volume replacement and volume displacement techniques, correction of asymmetry and salvage surgery
- At least two surgeons trained to an advanced level in breast reconstruction, one of whom must be a plastic surgeon with a special interest in breast reconstruction
- Full supporting services, including dedicated high dependency beds, vascular imaging facilities, access to microvascular surgery, a comprehensive implant and expander resource and equipment for nippleareola pigmentation although the latter may also be available in a Level I unit.

6.9.2 Essential Skills in Oncoplastic Breast Surgery

1. All surgeons performing oncoplastic breast surgery should acquire core skills which will enable them to provide a Level I oncoplastic service, as previously defined.

2. The curricula for breast and plastic surgeons laid down by the Specialty Advisory Committees (SACs) of the parent specialties

define a skill base which includes knowledge-based, teamworking, communication, diagnostic and technical skills (Appendix A).

3. The knowledge-base of the oncoplastic surgeon or group of surgeons should include a detailed understanding of:

- The basic sciences relevant to the prevention, diagnosis, treatment and clinical research of breast disease
- Planning, monitoring and evaluation of services for breast cancer
- Medical practice within an ethical framework.

4. Teamworking and communication skills should be reinforced by the opportunity to experience and observe cohesive integrated teams in action. This implies:

- Attendance at the multidisciplinary meeting
- Joint consultations with other specialists
- Joint operating lists, involving breast, plastic and oncoplastic surgeons
- Exposure to different leadership and managerial styles
- Opportunity to participate in clinical research.

5. The diagnostic and technical skill base of the oncoplastic trainee will include competency in core procedures including:

- The investigation and management of breast abnormalities
- The investigation and management of the axilla
- A range of immediate and delayed reconstructive techniques (see Selection of breast reconstruction techniques)
- The management of complications associated with the above procedures.

6.10 Conflicts of Interest

The writing group was appointed by the Association of Breast Surgery at BASO, the British Association of Plastic, Reconstructive and Aesthetic Surgeons and the Interface Group. All members of the writing group declare no conflict of interest.

6.11 Role of Funding Source

The guidelines were partly sponsored by Allergan Ltd and Mentor Medical Systems. Other funding came from the Association of Breast Surgery at BASO. Both companies manufacture breast implants and were invited to be observers on the advisory group. Both companies have previously been involved in the support of educational courses run by the Royal College of Surgeons of England. Neither company's products are exclusively endorsed in these guidelines.

6.11.1 Levels of Evidence

The evidence cited in the guidelines has been classified as accurately as possible into 5 levels:

- Level I evidence is based on randomised, controlled trials (or meta-analysis of such trials) of adequate size to ensure a low risk of incorporating false-positive or false-negative results
- Level II evidence is based on randomised, controlled trials that are too small to provide level I evidence. These may show either positive trends that are not statistically significant or no trends and are associated with a high risk of false-negative results
- Level III evidence is based on nonrandomized, controlled or cohort studies, case series, case-controlled studies or cross-sectional studies
- Level IV evidence is based on the opinion of respected authorities or that of expert committees as indicated in published consensus conferences or guidelines
- Level V evidence expresses the opinion of those individuals who have written and reviewed these guidelines, based on their experience, knowledge of the relevant literature and discussion with their peers.

These 5 levels of evidence do not directly describe the quality or credibility of evidence. Rather, they indicate the nature of the evidence being used. In general, a randomised, controlled trial has the greatest credibility (level I); however, it may have defects that diminish its value, and these should be noted. Evidence that is based on too few observations to give a statistically significant result is classified as level II. In general, level III studies carry less credibility than level I or II studies, but credibility is increased when consistent results are obtained from several level III studies carried out at different times and in different places.

Decisions must often be made in the absence of published evidence. In these situations it is necessary to use the opinion of experts based on their knowledge and clinical experience. All such evidence is classified as ‘‘opinion’’ (levels IV and V). Distinction is made between the published opinion of authorities (level IV) and the opinion of those who have contributed to these guidelines (level V). However, it should be noted that by the time level V evidence has gone through the exhaustive consensus-building process used in the preparation of these guidelines, it has achieved a level of credibility that is at least equivalent to level IV evidence.

6.12 Documentation

6.12.1 Document Location

The document is located in the ASWCS Network office, in hardcopy and electronic format.

6.12.2 Revision History

Revision History Date	Version	Author	Agreed by
March 2009	1	Association of Breast Surgery at BASO 2009	ASWCS Breast NSSG June 2009
July 2010	1	Association of Breast Surgery at BASO 2009	ASWCS Breast NSSG July 2010

Clinical Guidelines – Chemotherapy

7 Adjuvant Chemotherapy

7.1 Indications

- Adjuvant therapy for patients with early breast cancer should be discussed at the appropriate local Multi-disciplinary team meeting (MDT). Discussions should take into consideration patient age and co-morbidity.
- Conventional pathological criteria should be used for assessing indications for chemotherapy including:
  - Lymph node status
  - Tumour size
  - Tumour grade
  - Lymphovascular invasion
  - ER status
  - HER2 status
- Further prognostic information may be derived from Adjuvant On Line, the Nottingham prognostic index or PREDICT to help inform discussions with patients. It is recommended that each MDT agree to use one prognostic model in order to provide patients with consistent information
- Radiological staging (eg CT Chest/Abdo + bone scan or CXR/Liver U/S + bone scan) should be considered for patients with four or more positive lymph nodes or those with symptoms suggestive of metastases. Where conventional staging investigations are indeterminate PET-CT may be requested according to agreed ASWCS guidelines
- Trastuzumab may be administered with or after chemotherapy depending upon schedule. Trastuzumab is only suitable for patients with cancers that are HER2 3+ (immunohistochemistry) or FISH positive (ratio of amplification $\geq$ 2.0)
- Following chemotherapy:
  - Appropriate patients should receive radiotherapy (see ASWCS guidelines)
  - Patients with ER/PR positive breast cancer should be offered adjuvant hormonal therapy (see ASWCS guidelines)

7.2 Clinical Trials

Where available patients should always be offered entry into appropriate clinical trials.

7.3 Schedules

Appropriate options for adjuvant chemotherapy for early breast cancer are listed below. For detailed information about prescribing of each schedule please refer to the ASWCS chemotherapy protocols web site and to the original papers referenced with each schedule.

7.3.1 FEC (Fluorouracil, Epirubicin, Cyclophosphamide)

FEC100 Fluorouracil 500 mg/m^2

Epirubicin 100mg/m^2

Cyclophosphamide 500mg/m^2

Or

FEC75 Fluorouracil 600 mg/m^2

Epirubicin 75mg/m^2

Cyclophosphamide 600mg/m^2

Schedule: Day 1 every 21 days. Usually 6 cycles

Indications: Adjuvant chemotherapy for appropriate patients with lymph node negative and lymph node positive early breast cancer (see also 1.3.2)

NB. Note different doses of Fluorouracil and cyclophosphamide as well as epirubicin in each schedule.

Randomised clinical trials have evaluated various schedules of FEC with doses of epirubicin between 50 and 120mg/m^2 for between 3 and 8 cycles. As yet there remains no clear consensus about optimal dosing. Evidence exists that 6 cycles of FEC100 is superior to FEC50 for patients with lymph node positive disease. Within the UK accepted practice has included the use of FEC60 and FEC75 although there is increasing use of FEC100 for higher risk patients. Primary prophylaxis with GCSF is recommended for FEC100. The ASWCS breast group have agreed that both FEC75 and FEC100 are appropriate schedules.

References:

1.French Adjuvant Study Group. Benefit of a high dose epirubicin regimen in adjuvant chemotherapy for node positive patients with poor prognostic factors. Five year follow up results of French adjuvant study group 05 randomized trial. *Journal of Clinical Oncology* 2001; 19: 602-611.

2. Fumoleau, P. et al. Randomized trial comparing six versus three cycles of epirubicin based adjuvant chemotherapy in pre-menopausal node positive breast cancer patients: 10 year follow up results of the French adjuvant study group 01 trial. *Journal of Clinical Oncology* 2003; 21: 298-305.

7.3.2 TAC (Docetaxel, Doxorubicin, Cyclophosphamide)

Docetaxel 75 mg/m^2

Doxorubicin 50 mg/m^2

Cyclophosphamide 500 mg/m^2,

Schedule: Day 1 every 21 days. Usually 6 cycles

Indications: NICE approved for patients with lymph node positive disease only. ASWCS have approved this schedule for patients with high risk lymph node negative breast cancer (e.g. Triple negative, grade 3)

NB: Primary prophylaxis with GCSF recommended.

Reference:

Martin, M. et al. Adjuvant docetaxel for node positive breast cancer. *New England Journal of Medicine* 2005; 352: 2302-13.

Martin, M et al Adjuvant docetaxel for high risk node negative breast cancer. *New England Journal of Medicine* 2010; 363: 2200-10

7.3.3 FEC/T (Fluorouracil, Epirubicin, Cyclophosphamide, Docetaxel)

FEC100 **Fluorouracil 500 mg/m^2**

(3 cycles) **Epirubicin 100mg/m^2**

Cyclophosphamide 500mg/m^2

Followed by **Docetaxel 100mg/m^2**

(3 cycles)

Schedule: Day 1 every 21 days. 6 cycles

Indication: Approved for patients with lymph node positive early breast cancer. Trastuzumab maybe administered concurrently with docetaxel for patients with HER2 positive breast cancer (lymph node negative and lymph node positive).

Reference:

Roche, H. et al. Sequential adjuvant epirubicin based and docetaxel chemotherapy for node positive breast cancer patients. The FNCLCC PACS 01 trial *Journal of Clinical Oncology*,2006; 24: 5664-71

7.3.4 TC (Docetaxel/Cyclophosphamide)

Docetaxel 75mg/m^2

Cyclophosphamide 600mg/m^2

Schedule: Day 1 every 21 days. 4 - 6 cycles

Indication: Approved for patients with lymph node positive or high risk lymph node negative early breast cancer where anthracyclines are not clinically appropriate.

Reference:

Jones, S. et al. Docetaxel with cyclophosphamide is associated with an overall survival benefit compared with doxorubicin and cyclophosphamide: 7 year follow up of US Oncology Research trial 9735. *Journal of Clinical Oncology,* 2009; 27:1177-83

7.3.5 TCarboH (Docetaxel/Carboplatin/Trastuzumab)

Docetaxel 75mg/m^2

Carboplatin AUC 6

Trastuzumab 8mg/kg loading dose then 6mg/kg

Schedule: Day 1 every 21 days. 6 cycles of chemotherapy, 18 cycles of trastuzumab

Indication: Approved for patients with HER2 positive early breast cancer where anthracylines are not clinically appropriate

Reference:

Slamon, D et al. Phase III Randomized Trial comparing Doxorubicin and Cyclophosphamide followed by Docetaxel (AC→T) with Doxorubicin and Cyclophosphamide followed by Docetaxel and Trastuzumab (AC→TH) with Docetaxel, Carboplatin and Trastuzumab (TCH) in Her2neu Positive Early Breast Cancer Patients: BCIRG 006 Study. *San Antonio Breast Cancer Symposium*, 2009; Abstract 62

7.3.6 Classical CMF (Cyclophosphamide, Methotrexate, Fluorouracil)

Cyclophosphamide 100mg/m^2 p.o. d1-14[1] or 600 mg/m^2 iv d1, 8

Methotrexate 40mg/m^2 d1, 8;

Fluorouracil 600 mg/m^2 d1, 8

Schedule: Day 1, day 8 every 28 days. 6 cycles

Indication: Rarely used but may be appropriate where anthracyclines and/or taxanes are not appropriate.

References:

1. Tancini, G et al. Adjuvant CMF in breast cancer: comparative 5 year results of 12 versus 6 cycles. *Journal of Clinical Oncology* 1983; 1: 2-10.

2. Bonadonna, G et al. Combination chemotherapy as an adjuvant treatment in operable breast cancer. *New England Journal of Medicine* 1976; 294:405-10.

7.3.7 Trastuzumab

Trastuzumab 8mg/kg loading dose followed by 6mg/kg maintenance dose

Schedule: Day 1 every 21 days (one year total duration of treatment ie.18 cycles).

Indication: Her 2 positive patients only (3+ on immunohistochemistry or FISH amplification with ratio ≥ 2.0). NICE approved after adjuvant chemotherapy and radiotherapy. ASWCS approved to administer concurrently with docetaxel for suitable patients.

References:

1.Piccart-Gebhart, M.J. et al. Trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer. *New England Journal of Medicine* 2005; 353:1659-72.

2. Smith, I. et al. 2-year follow-p of trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer: a randomised controlled trial. *Lancet* 2007; 369:29-36.

8 Neo-Adjuvant (Pre-Operative) Chemotherapy

Pre-operative chemotherapy may be offered to patients considered fit for chemotherapy to down stage the tumour and potentially allow breast conserving surgery.

8.1 Indications include:

- Inflammatory cancer;
- T4 cancer;
- T 2 or T3 where down-staging may allow breast conservation;
- Clinically palpable axillary lymph nodes secondary to breast cancer.

The MDT and treating oncologist should consider the most appropriate schedule for each patient. Recommended options are:

8.1.1 FEC100 (Fluorouracil, Epirubicin, Cyclophosphamide)

FEC100 **Fluorouracil 500 mg/m^2**

Epirubicin 100mg/m^2

Cyclophosphamide 500mg/m^2

Schedule: Day 1 every 21 days. Usually 6 cycles

References:

1. French Adjuvant Study Group. Benefit of a high dose epirubicin regimen in adjuvant chemotherapy for node positive patients with poor prognostic factors. Five year follow up results of French adjuvant study group 05 randomized trial. *Journal of Clinical Oncology* 2001; 19:602-611.

2. Therasse, P. et al. Final results of a randomized phase III trial comparing cyclophosphamide, epirubicin, and fluorouracil with a dose-intensified epirubicin and cyclophosphamide + filgrastim as neoadjuvant treatment in locally advanced breast cancer: an EORTC-NCIC-SAKK multicenter study**.** *Journal Of Clinical Oncology* 2003; 21:843-50

8.1.2 FEC-T (Fluorouracil, Epirubicin, Cyclophosphamide, Docetaxel)

FEC100 **Fluorouracil 500 mg/m^2**

(up to 4 cycles) **Epirubicin 100mg/m^2**

Cyclophosphamide 500mg/m^2

Docetaxel **100mg/m^2**

(up to 4 cycles)

Schedule: Day 1 every 21 days. Up to 8 cycles

NB. Trastuzumab should be administered concurrently with docetaxel for patients with HER2 positive breast cancer. Primary prophylaxis with GCSF is recommended.

References:

1. von Minckwitz, G. et al. Capecitabine in addition to anthracycline and taxane based neoadjuvant treatment in patients with primary breast cancer: phase III GeparQuattro study. *Journal of Clinical Oncology*, 2010; 28: 2015-23

2. Roche, H. et al. Sequential adjuvant epirubicin based and docetaxel chemotherapy for node positive breast cancer patients. The FNCLCC PACS 01 trial *Journal of Clinical Oncology*, 2006; 24: 5664-71

8.1.3 TAC (Docetaxel, Doxorubicin, Cyclophosphamide)

Docetaxel 75 mg/m^2

Doxorubicin 50 mg/m^2

Cyclophosphamide 500 mg/m^2,

Schedule: Day 1 every 21 days. 6 cycles

Indications: NICE approved for patients with lymph node positive disease only. ASWCS have also approved this schedule for high risk lymph node negative patients. Primary prophylaxis with GCSF recommended.

References:

1. Martin, M. et al. Adjuvant docetaxel for node positive breast cancer. *New England Journal of Medicine* 2005; 352: 2302-13.

2. Von Minckwitz, G. et al Intensified neo-adjuvant chemotherapy in early responding breast cancer: phase III randomized GeparTrio study. *Journal of the National Cancer Institute* 2008; 100:552-62

9 Palliative Chemotherapy

9.1 Indication

- Palliative treatment of advanced disease, unlikely to respond to hormonal treatment, in patients considered fit enough to tolerate cytotoxic chemotherapy.
- There is no single “correct” order for administering schedules of chemotherapy for advanced disease although, in general, newly diagnosed patients should initially be considered for an anthracycline (see notes below) with subsequent treatment offered as per NICE guidelines (where applicable).
- Most patients will be treated with sequential single agent schedules to minimise toxicity. There is no clear overall survival benefit from combination schedules although in certain circumstances (eg rapid disease progression) this may be appropriate.

- Other schedules, not listed, may be considered in some clinical situations and local approval should be obtained.

9.2 Schedules

9.2.1 EC (Epirubicin and cyclophosphamide)

Epirubicin 75 mg/m^2,

Cyclophosphamide 600mg/m^2

Schedule: Day 1 every 21 days. Up to 6 cycles depending upon response.

Indications: Consider as first line chemotherapy for advanced disease for patients fit for anthracycline based treatment. For patients who have received an anthracyline as adjuvant treatment, EC may be appropriate provided they have had a disease free interval of at least 2 years and will not exceed the safe cumulative dose for epirubicin (900mg/m^2) with 6 further cycles of treatment.

Reference:

Langley, R.E. et al. Phase III trial of epirubicin plus paclitaxel compared with epirubicin plus cyclophosphamide as first line chemotherapy for metastatic breast cancer: United Kingdom National Cancer Research Institute trial ABO1. *Journal of Clinical Oncology* 2005; 23:8322-30.

9.2.2 Epirubicin (Weekly)

Epirubicin 25mg/m^2 weekly

Schedule Up to 6 cycles or 18 weeks depending upon response.

Indications: Weekly treatment is usually considered for patients with poor performance status, significant co-morbidity or abnormal LFT's.

References:

1. Gasparini, G et al. Weekly epirubicin versus doxorubicin as second line therapy in advanced breast cancer. A randomized clinical trial. American *Journal of Clinical Oncology*; 1991:14(1);38-44.

2. Nicolella, D et al. Weekly low dose epirubicin in elderly cancer patients. *Tumori*; 1996: 82(4); 369-71.

9.2.3 Docetaxel

Docetaxel 100mg/m^2

Schedule: Day 1 every 21 days. Up to 6 cycles depending upon response.

Indications: Consider for patients where initial anthracycline containing chemotherapy has failed or is not appropriate. Starting dose should be reduced to 75 mg/m^2 or 60 mg/m^2 for heavily pre-treated patients, those with extensive bone metastases, abnormal LFT's significant co-morbidity or poor performance status. For patients with HER2 3+ tumours and adequate cardiac function treatment in conjunction with trastuzumab is recommended.

References:

1. Nabholtz, J.M et al. Prospective randomized trial of docetaxel versus mitomycin plus vinblastine in patients with metastatic breast cancer progressing despite previous anthracycline containing chemotherapy. *Journal of Clinical Oncology*, 1999: 17, 1413-24

2. Chan, S. et al. Prospective randomized trial of docetaxel versus doxorubicin in patients with metastatic breast cancer. *Journal of Clinical Oncology*, 1999: 17; 2341-54

9.2.4 Docetaxel and Capecitabine

Docetaxel 75mg/m^2

Capecitabine 1000mg/m^2 b.d. (days 1 – 14),

Schedule: 21 day cycle. Up to 6 cycles depending upon response.

Indications: Consider as first line treatment in patients where rapid disease control is required and anthracyclines are not appropriate. This schedule is associated with significant toxicity and is rarely used. It should only be considered for good performance status patients (PS 0) with no other significant co-morbidity.

NB. A starting dose of Capecitabine at 1000mg/m2 b.d. for the first cycle is recommended because of potential toxicity. The original trial used a dose of 1250mg/m2 bd. Patients may be increased to this dose if they do not experience significant toxicity.

Reference:

O'Shaughnessy, J. et al. Superior survival with capecitabine plus docetaxel combination therapy in anthracycline pre-treated patients with advanced breast cancer. Phase III trial results. *Journal of Clinical Oncology* 2002: 20; 2812-23.

9.2.5 Paclitaxel (weekly)

Paclitaxel 70 - 90 mg/m^2

Schedule: Day 1, 8, 15 every 28 days (may also be given every week). Usually up to 6 cycles depending upon response.

Indications: Consider for patients where initial anthracycline containing chemotherapy has failed or is not appropriate. Weekly paclitaxel schedules have higher response rates than three weekly paclitaxel. It may be more appropriate than docetaxel for heavily pre-treated patients, those with extensive bone metastases, abnormal LFT's significant co-morbidity or poor performance status. For patients with HER2 3+ tumours and adequate cardiac function consider treatment in conjunction with trastuzumab (see below).

Reference:

Verrill, M et al. Anglo-Celtic IV: First results of a UK National weekly versus three weekly paclitaxel in patients with locally advanced or metastatic breast cancer. *Journal of Clinical Oncology* 2007 ASCO Annual Meeting Proceedings Part I. Vol 25, No. 18S (June 20 Supplement).

9.2.6 Paclitaxel (3 weekly)

Paclitaxel 175 mg/m^2

Schedule: Day 1 every 21 days. Up to 6 cycles depending upon response.

Indications: This schedule is rarely used. It may be consider for patients where initial anthracycline containing chemotherapy has failed or docetaxel is not appropriate. For patients with HER2 3+ tumours and adequate cardiac function consider treatment in conjunction with trastuzumab (see below).

Reference:

Bishop, J et al. Initial paclitaxel improves outcome compared with CMFP combination chemotherapy as frontline therapy in untreated metastatic breast cancer. *Journal of Clinical Oncology* 1999; 17: 2355-64.

9.2.7 Paclitaxel and Gemcitabine

Paclitaxel 175 mg/m^2 day 1,

Gemcitabine 1250 mg/m^2 days 1,8

Schedule: Day 1 and 8 every 21 days. Usually up to 6 cycles depending upon response.

Indication: NICE approved as an option for first line treatment of advanced breast cancer when an anthracycline is not appropriate (consider also docetaxel or docetaxel + capecitabine).

Reference:

Albain, K et al. Global phase III study of gemcitabine plus paclitaxel (GT) vs. paclitaxel as frontline therapy for metastatic breast cancer (MBC): First report of overall survival. *Journal of Clinical Oncology*, 2004 ASCO Annual Meeting Proceedings. Vol 22, No. 14S (July 15 Supplement), abstract No. 510.

9.2.8 Capecitabine

Capecitabine 1250 mg/m^2 b.d. days 1 – 14, oral

Schedule: 21 day cycle.

Indications: NICE approved following anthracycline and / or taxane. May be used first line for suitable patients where anthracyclines/taxanes are not appropriate. Starting dose should be reduced to 1000 mg/m^2 bd for heavily pre-treated patients, those with extensive bone metastases, abnormal LFT's significant co-morbidity or poor performance status. If patients continue to get clinical benefit it is appropriate to treat until disease progression depending upon toxicity.

References:

1. Talbot, D.C. et al. Randomised phase II trial comparing oral capecitabine (Xeloda) with paclitaxel in patients with

metastatic/advanced breast cancer pretreated with anthracyclines *British Journal of Cancer* 86:1367-1372, 2002.

2. Blum, J. et al. Multi-centre phase II study of capecitabine in paclitaxel refractory metastatic breast cancer. *Journal of Clinical Oncology* 1999, 17:485-493.

9.2.9 Vinorelbine (iv or oral)

Vinorelbine 30mg/m^2 day 1 and 8, iv

Or

Vinorelbine 80mg/m^2 day 1 and 8 (first cycle start at 60mg/m^2 and increase dose depending upon toxicity – see protocol)

Schedule: Days 1 and 8 every 21 days. Usually Up to 6 cycles depending upon response.

Heavily pre-treated patients, those with significant co-morbidity, extensive bone metastases or abnormal LFTs should start at 25 mg/m^2 iv.

Indications: NICE approved as an option for second-line or later therapy. Heavily pre-treated patients, those with significant co-morbidity, extensive bone metastases or abnormal LFTs should start at 25 mg/m^2 iv and usually continue at 60 mg/m^2 oral dose. For patients with HER2 3+ tumours and adequate cardiac function consider treatment in conjunction with trastuzumab (see below).

References:

1. Weber, B.C. et al. Intravenous vinorelbine as first-line and second-line therapy in advance breast cancer. *Journal of Clinical Oncology* 1995: 13; 2722-30.

2. Jones, S. et al. Randomized comparison of vinorelbine and melphalan in anthracycline- refractory advanced breast cancer. *Journal of Clinical Oncology* 1995: 13; 2567-74.

3. Bourgeois, H. et al. Evaluation of oral versus intravenous dose of vinorelbine to achieve equivalent blood exposures in patients with solid tumours. *Cancer Chemotherapy and Pharmacology* 2007: 60; 407-13

9.2.10 Capecitabine and Vinorelbine

Capecitabine 1250mg/m2 bd oral for 14 days

Vinorelbine 25mg/m2 (IV) *OR* 60mg/m2 (oral) days 1 and 8

Schedule: 21 days. Usual maximum 6 cycles although may be continued beyond this for patients who continue to respond and have acceptable side effects

Indications: For most patients sequential single agent schedules are appropriate as palliative treatments. For some patients, with rapidly progressing disease combination treatment may be more appropriate. There is no phase III randomised trial evidence that demonstrates an overall survival advantage for this schedule.

References:

1. Anton A et al. Phase 1 Study of oral vinorelbine and capecitabine in patients with metastatic breast cancer. *Anticancer Research*, 2010: 30; 2255-61

2. Jones A et al. Phase II study of oral vinorelbine in combination with capecitabine as second line chemotherapy in metastatic breast cancer patients previously treated with anthracyclines and taxanes. *Cancer Chemotherapy and Pharmacology,* 2010: 65; 755-63

3. Tubiana-Mathieu N et al. All-oral combination of oral vinorelbine and capecitabine as first-line chemotherapy in her2-negative metastatic breast cancer: an international phase II trial. British Journal of Cancer, 2009: 101;232-7

4. Welt A et al. Phase I/II study of capecitabine and vinorelbine in pretreated patients with metastatic breast cancer. Annals of Oncology, 2005: 16; 64-9

9.2.11 Trastuzumab

Trastuzumab Loading dose of 8mg/kg then 6mg/kg for future cycles

Schedule: day 1 every 21 days

Indications: NICE approved for patients with HER2 3+ on immunohistochemistry or FISH positive breast cancers (ratio $\geq$ 2.0). Recommended in combination with a taxane or may be used as a single agent. Patients may continue maintenance trastuzumab after completion of chemotherapy. Regular cardiac monitoring should be performed

References:

1. Slamon, D et al. Use of chemotherapy plus a monoclonal antibody against HER2 for metastatic breast cancer that overexpresses HER2. *New England Journal of Medicine;* 2001: 344; 783-92.

2. Vogel et al. Efficacy and safety of trastuzumab as single agent in first line treatment of HER2 overexpressing metastatic breast cancer. *Journal of Clinical Oncology* 2002: 20; 719-26.

9.2.12 Cyclophosphamide, Methotrexate and Fluorouracil

Cyclophosphamide 600mg/m^2,

Methotrexate 40mg/m^2

Fluorouracil 600mg/m^2

Schedule: Day 1 every 21 days. Up to 6 cycles depending upon response.

Indications: Rarely used but may be considered for patients who have responded to previous chemotherapy schedules including an anthracyline and taxane

Reference:

Tannock, I et al. A randomized trial of two dose levels of cyclophosphamide, methotrexate and fluorouracil chemotherapy for patients with metastatic breast cancer. *Journal of Clinical Oncology*; 1988: 6;1377-87.

9.2.13 Carboplatin

Carboplatin AUC 5 or 6

Schedule: Day1 every 21 days. Usually up to 6 cycles depending upon response.

Indications: Usually used as third or fourth line therapy after previous treatment that has included a taxane and anthracycline. There is recent evidence supporting the activity of platinum based chemotherapy for patients with Triple negative cancers. In heavily pre-treated patients it is recommended to start at AUC 5.

References:

O'Brien, M. et al. Carboplatin in the treatment of advanced breast cancer. A phase II study using a pharmacokinetically guided dose schedule. *Journal of Clinical Oncology*; 1993: 11; 2112-7.

9.2.14 Carboplatin and Gemcitabine

Carboplatin AUC 4 day 1

Gemcitabine 1000mg/m2 day 1 and 8

Schedule: 21 days. Usually up to 6 cycles depending upon response.

Indications: Usually indicated in patients with good performance status who have previously been treated with and responded to chemotherapy that has included a taxane and anthracyclines. If well tolerated the carboplatin dose may be increased to AUC 5.

Reference:

Laessig, D. et al. Evaluation of gemcitabine plus carboplatin in pre-treated metastatic breast cancer patients. Final results of a phase II trial. *American Society of Clinical Oncology*, 2007. Abstract No 1074

9.2.15 Mitoxantrone, Methotrexate and Mitomycin C

Mitoxantrone 8 mg/m^2 (every 21 days)

Methotrexate 35mg/m^2 (maximum 50mg every 21 days)

Mitomycin C 8 mg/m^2 (alternate cycles only ie every 42 days))

Schedule: Up to 6 x 21 day cycles depending upon response.

Indications: Usually considered for patients with good performance status who have responded to previous chemotherapy but cancer has subsequently. Previous treatment would normally have included at least anthracyclines, taxanes, capecitabine and vinorelbine.

Reference:

Jodrell, D. et al. A randomised comparative trial of mitozantrone / methotrexate / mitomycinC (MMM) and

cyclophosphamide/methotrexate/ 5FU (CMF) in the treatment of advanced breast cancer. *British Journal of Cancer*; 1991: 63(5); 794-8.

9.2.16 Oral cyclophosphamide and methotrexate

Oral cyclophosphamide (50mg o.d. daily)

Methotrexate (2.5mg b.d. for 2 days per week).

Schedule: Continous treatment, usually until disease progression or unacceptable toxicity

Indications: This schedule is usually well tolerated with minimal myelosuppression Consider for patients not suitable for or unable to tolerate other chemotherapy treatments

Reference:

Colleoni, M et al. Low dose oral methotrexate and cyclophosphamide in metastatic breast cancer: antitumour activity and correlation with vascular endothelial growth factor. *Annals of Oncology*; 2002:13;73-80.

9.3 Documentation

9.3.1 Document Location

The document is located in the ASWCS Network office, in hardcopy and electronic format.

9.3.2 Revision History

Revision History Date	Version	Author	Agreed by
2005	1	Dr Jeremy Braybrooke	ASWCS breast SSG 2005
2007	2.0	Dr Jeremy Braybrooke	ASWCS Breast SSG September 2007
July 2010	3.0	Dr Jeremy Braybrooke	ASWCS NSSG July 2010
June 2011	4.0	Dr Jeremy Braybrooke	ASWCS NSSG June 2011

Clinical Guidelines – Endocrine Therapy

10 Endocrine Therapy for Early Invasive Breast Cancer

10.1 Guideline Summary

These guidelines, whilst not prescriptive, summarise recommendations for treatment developed by the ASWCS breast site specific group.

Patients with Oestrogen receptor positive (ER+) and/or progesterone receptor positive (PR+) breast cancer should be offered adjuvant endocrine therapy.

The St Gallen Expert Consensus suggests that **any** positive level of oestrogen receptor expression is sufficient to justify the use of endocrine therapy.

- For pre-menopausal women, Tamoxifen 20mg od for 5 years is considered standard treatment
- For post-menopausal women an aromatase inhibitor is the first line of treatment for the majority of patients but if not tolerated or dependant on individual risk factors tamoxifen is an acceptable alternative.
- Adjuvant endocrine therapy is normally started after surgery and completion of chemotherapy (where applicable), but can be prescribed concurrently with radiotherapy.

10.2 Background

Evidence for the benefit of at least 5 years of endocrine therapy for hormone receptor positive early breast cancer has been clearly established in randomised clinical trials and meta-analysis. The Early Breast Cancer Clinical Trialists overview suggested that 5 years of tamoxifen leads to a 12% absolute reduction in risk of recurrence (33.2% versus 45%) and a 9% absolute reduction in mortality (25.6% versus 34.8%) at 15 years follow up.

Benefits are seen for both pre- and post- menopausal women. Routine CYP2D6 testing to select patients for treatment with tamoxifen is not recommended. There is conflicting evidence but retrospective analysis of the ATAC and BIG 1-98 trials has shown no significant association between CYP2D6 phenotype and outcome in postmenopausal women with hormone receptor–positive early breast cancer receiving tamoxifen,

Case control and epidemiological studies have indicated that some SSRIs like fluoxetine and paroxetine increase the risk of recurrence and mortality when used in conjunction with tamoxifen. This was thought to be due to inhibition of CYP2D6 but there may be other explanations and where possible these drugs should be avoided. Citalopram and venlafaxine appear to have a minimal effect and are suitable alternatives.

Randomised clinical trials in post menopausal patients have demonstrated improved disease free survival when aromatase inhibitors are used in place of or as part of a switch policy before or after tamoxifen, but meta-analyses have shown no convincing evidence of improved overall survival. The 10 year analysis of the ATAC trial showed a 4.3% absolute improvement in time to recurrence between anastrozole and tamoxifen. This did not lead to a

corresponding difference in overall survival, with a reduction in the number of deaths in those with recurrence on anastrozole mostly offset by a small increase in deaths from other causes in those without recurrence.

The MA17 trial has suggested some benefit from extended (2-3 years after initial 5 years) hormone manipulation (especially for node positive patients) but this is limited to use of Letrozole after 5 years of tamoxifen. Currently there is no evidence of benefit supporting extending the use of AIs past 5 years if this has been the hormone treatment of choice before 5 years. Fortunately there is a carryover effect such that recurrence rates remain lower than tamoxifen after treatment is completed although this effect reduces with time (at year 8 in the ATAC trial).

Safety data for more than 5 years of aromatase inhibitors is lacking and there remains uncertainty about which women benefit most from aromatase inhibitors and optimal duration of treatment.

The aromatase inhibitors currently available (anastrozole, letrozole, exemestane) appear to have equivalent efficacy and side effects but exemestane is not licensed for first line use.

For premenopausal women meta-analyses of ovarian suppression in addition to tamoxifen have indicated an absolute reduction in the risk of recurrence and reduction in the risk of death from breast cancer. This benefit is much less in those who received chemotherapy and although it is not routinely recommended it may be considered in certain circumstances (see below)

There is no place for routine use of bisphosphonates as adjuvant treatment with discrepant results from recent trials. Sub group analysis suggests that those with very low levels of oestrogen may benefit and further trials are needed. Of course bone health is also a concern in such patients with the use of bisphosphonates appropriate in certain circumstances (see below)

10.3 Pre-Menopausal Women

Pre-menopausal women with ER+ and/or PR+ early breast cancer should, in the absence of contra-indications, be considered for Tamoxifen 20mg od for 5 years as part of their standard treatment. Certain SSRIs (especially fluoxetine and paroxetine) should avoided.

- Tamoxifen should be commenced after surgery, or, if chemotherapy is recommended, after completion of chemotherapy.
- Ovarian suppression using GnRH agonists can be considered for the following situations:
    - Women who are unable to take tamoxifen
    - In combination with tamoxifen in women with intermediate or high risk disease, in whom chemotherapy is not appropriate or tolerated.
    - In combination with tamoxifen in women who continue to menstruate after completion of chemotherapy. The evidence of benefit in this situation is limited and requires discussion on an individual basis
    - Its use in combination with aromatase inhibitors is currently mainly confined to trials but if there is doubt that a woman is

truly menopausal (e.g. periods stopped after chemotherapy – see comment below) it could be considered on an individual basis.

- Goserelin (Zoladex) is currently the only GnRH agonist licensed for use in breast cancer. The 3.6mg monthly dose should be used for 2 years. The 3 monthly dose is not licensed for breast cancer.
- Women who want to have a permanent menopause may, after appropriate discussion of risks and benefits, be considered for laparoscopic bilateral oophorectomy.
- Women who have become postmenopausal during tamoxifen treatment can be considered for a switch to an aromatase inhibitor but absence of menses post chemotherapy does not necessarily mean that a woman has become postmenopausal and aromatase inhibitors may promote ovarian recovery. Biochemical monitoring of LH/FSH/Oestradiol may be unreliable after chemotherapy and if used serial measurements are needed. The additional use of ovarian suppression with an AI needs consideration.

10.4 Post-Menopausal Women

- The first line treatment option for post-menopausal women is an aromatase inhibitor (e.g. anastrozole 1mg od, or letrozole 2.5mg od) for 5 years. The BIG 1-98 trial indicated that the alternative option of Letrozole for 2-3 years with a switch to tamoxifen to complete the 5 years is equivalent and allows less use of an aromatase inhibitor. Exemestane 25 mg od is not licensed for first line treatment but can be used as part of a switch policy after 2-3 years of tamoxifen.
- Tamoxifen 20mg daily is a suitable alternative for patients with Low Risk disease (NICE suggests the excellent or good prognostic group using the Nottingham Prognostic Index with predicted 10 year survival of 93% or greater) or for those unable to use an aromatase inhibitor.
- Postmenopausal women who have been on tamoxifen for 2-3 years can be switched to an AI to complete 5 years hormone manipulation.
- Node positive postmenopausal women who have completed 5 years of tamoxifen should be considered for extended therapy with letrozole for another 2-3 years.

10.5 Men

Men with ER and/or PR + breast cancer should be considered for adjuvant endocrine therapy with tamoxifen. The clinical benefit of aromatase inhibitors for men has not been established.

10.6 Additional Advice

10.6.1 Treatment Information

Patients

The local multi-disciplinary team will discuss treatment options with individual patients and supplement this with appropriate written

information. This should include information about duration of treatment and advice about possible side effects.

GP's

Endocrine therapy will be initiated by the specialist breast care team. The proposed schedule of treatment will be communicated to the patient's GP and normally the GP would be expected to take over prescribing as part of a shared care protocol. This should include prescribing of tamoxifen, aromatase inhibitors and, where appropriate Goserelin.

Bone Health

Treatment of early breast cancers e.g. premature menopause after chemotherapy and aromatase inhibitors, can be associated with an increased incidence of osteoporosis. A baseline DEXA scan is recommended for:

- Women who go through the menopause before the age of 45 years
- At the initiation of aromatase inhibitors.

Further DEXA scans are recommended (approximately every 2 years) if the initial scan indicated osteopenia. Where applicable; women should be given appropriate dietary and life-style advice including information about calcium and vitamin D supplementation. If osteoporosis is diagnosed, bisphosphonate therapy should beinitiated according to local guidelines (See NCRI breast group clinical guidelines on management of bone loss in early breast cancer for more details). Arrangements for DEXA scans should be made according to local trust policy.

10.6.2 Oestrogen Supplementation

Women with ER/PR + breast cancer should be advised to discontinue hormone replacement therapy. Short term topical vaginal oestrogen treatment is considered relatively safe for managing significant vaginal symptoms when patients are taking tamoxifen, but is contraindicated on aromatase inhibitors. For pre-menopausal women hormone based oral contraception (both combined oral contraception and progesterone only contraception) is not advised. There is currently no reliable data on the safety of intra-uterine contraceptive devices that contain progesterone (e.g. Mirena coil). Whilst many clinicians would consider this to be safe, there are theoretical risks from absorption of progesterone. Where possible patients should be advised to avoid the use of the Mirena coil. Potential risks and benefits should be discussed with the individual patient.

10.7 References (Selected)

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; 365, 1687-717.

NICE clinical guideline 80. February 2009

A. Goldhirsch et al. Thresholds for therapies: highlights of the St Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2009

Leyland-Jones B, Regan MM, Bouzyk M, et al. Outcome according to CYP2D6 genotype among postmenopausal women with endocrine-responsive early invasive breast cancer randomized in the BIG1-98 trial. Program and abstracts of the 33rd Annual San Antonio Breast Cancer Symposium; December 8-12, 2010; San Antonio, Texas. Abstract S1-8.

Dowsett M, Cuzick J, Ingle J, et al. Meta-analysis of breast cancer outcomes in adjuvant trials of aromatase inhibitors versus tamoxifen. J Clin Oncol. 2010;28:509-518.

Cuzick J, Sestak I, Baum M, et al. Effect of anastrozole and tamoxifen as adjuvant treatment for early-stage breast cancer: 10-year analysis of the ATAC trial. Lancet Oncol. 2010;11:1135-1141.

Cuppone F, Bria E, Verma S, et al. Do adjuvant aromatase inhibitors increase the cardiovascular risk in postmenopausal women with early breast cancer? Meta-analysis of randomized trials. Cancer. 2008;112:260-267.
Joseph A. Sparano Is there a role for ovarian function suppression in operable breast cancer? Breast Cancer Res Treat (2010) 123:311–313
Amir E, Ocaña A, Niraula S, Carlsson L, Seruga B. Toxicity of adjuvant endocrine therapy in postmenopausal breast cancer patients. Program and abstracts of the 33rd Annual San Antonio Breast Cancer Symposium; December 8-12, 2010; San Antonio, Texas. Abstract S2-7.
Cuzick J, Ambroisine L, Davidson N et al (2007) Use of luteinising-hormone-releasing hormone agonists as adjuvant treatment in premenopausal patients with hormone-receptor-positive breast cancer: a meta-analysis of individual patient data from randomised adjuvant trials. Lancet 369:1711–1723

Carlson RW, Allred DC, Anderson BO et al (2009) Breast cancer. Clinical practice guidelines in oncology. J Natl Compr Canc Netw 7:122–192

Smith IE, Dowsett M, Yap YS et al. Adjuvant aromatase inhibitors for early breast cancer after chemotherapy-induced amenorrhoea: caution and suggested guidelines. J Clin Oncol. 2006 24, 2444-7

Coleman RE, Thorpe HC, Cameron D, et al. Adjuvant treatment with zoledronic acid in stage II/III breast cancer. The AZURE Trial (BIG 01/04). Program and abstracts of the 33rd Annual San Antonio Breast Cancer Symposium; December 8-12, 2010; San Antonio, Texas. Abstract S4-5.
Gnant M, Mlineritsch B, Stoeger H, et al. Mature results from ABCSG-12: Adjuvant ovarian suppression combined with tamoxifen or anastrozole, alone or in combination with zoledronic acid, in premenopausal women with endocrine-responsive early breast cancer. Program and abstracts of the 2010 Annual Meeting of the American Society of Clinical Oncology; June 4-8, 2010; Chicago, Illinois. Abstract 533.

10.8 Management of Menopausal Symptoms

The management of menopausal symptoms for women with breast cancer is an issue that breast care nurses or medical staff are frequently asked to discuss with patients.

It is common for women who are taking endocrine therapies or who have undergone chemotherapy to have side effects such as hot flushes and night sweats, weight gain, sleep disturbance, joint pains, loss of libido, vaginal discomfort, urinary symptoms, and psychological issues such as mood changes and inability to concentrate. Women who come off HRT on diagnosis and start endocrine therapy for breast cancer seem to have particularly severe symptoms.

Most women who have had breast cancer – especially a hormone receptor positive cancer – will feel reluctant to take oestrogen containing preparations, and indeed, would be advised not to unless their symptoms cannot be improved using other measures.

The following measures may prove useful:

- Use of high dose evening primrose oil or starflower oil
- Taking the hormone treatment at a different time of the day or in divided doses (not reducing the total daily dose!)
- Provide with a fact sheet (breast cancer care) on managing menopausal symptoms with advice on multiple layers of clothing, cotton nightwear, reduction in caffeine and alcohol intake
- Encourage increase in exercise and relaxation
- Weight control.

Use of lubrication such as:

- ReplensMD moisturiser
- Lubricants such as V-gel, Senselle, Astroglide, Sylk, or KY jelly can be bought over the counter
- Oestrogen creams/pessaries for vaginal dryness (on prescription) to be used for short periods.

Other measures found useful although not available on the NHS are:

- The use of a chilled pillow at night – (such as the “Chillow” which is available by mail order online)
- Complementary therapies such as acupuncture, homeopathy, aromatherapy, reflexology or hypnotherapy.

It is standard practice to ensure women understand that the use of phytoestrogens and other herbal remedies may not be a good idea because of the unknown oestrogen effect on the cancer, and side effects with other medications.

When these measures fail to improve symptoms, the use of other drug treatments is often considered:

- Low dose megestrol acetate (Megace, 40mg od)

- Mild doses of antidepressant agents such as venlafaxine in a starting dose of 37.5 mg orally nocte rising to 75 mg orally nocte (works but effect reportedly wears off after a few weeks)
- Clonidine (Alpha-2 agonist), starting at 50mcg bd and increasing to 75mcg bd if necessary
- Gabapentin, starting at 100mg nocte, and increasing gradually as needed up to 300mg TDS if needed
- If the menopausal symptoms do not respond to these measures, the use of HRT may be considered. This is controversial and should be a Consultant decision. It may be acceptable with Tamoxifen or alone in patients with ER negative tumours, but is not acceptable in combination with aromatase inhibitors.

There is concern about the use of some drugs in patients on tamoxifen because of influences on other biochemical pathways. Tamoxifen is metabolised to the potent anti-oestrogen endoxifen by the cytochrome P450 CYP2D6 enzyme. There are 4 phenotypes of the CYP2D6 gene (poor, intermediate, extensive and ultra rapid metabolisers) affecting the levels of endoxifen, and as a result possibly the effectiveness of tamoxifen and its associated side effects.

The SSRI paroxetine used as an antidepressant and to treat vasomotor symptoms irreversibly inhibits CYP2D6. A recent study has shown that paroxetine use during tamoxifen treatment is associated with an increased risk of death from breast cancer, with the risk directly related to the duration of combined use. Therefore paroxetine is contraindicated in patients on tamoxifen. In the study, few patients were taking fluoxetine, also a strong inhibitor of CYP2D6. This should probably be avoided in patients on tamoxifen. Venlafaxine exhibits minimal CYP2D6 inhibition and was not associated with an increased mortality in the study.

For women already taking a potent inhibitor of CYP2D6 on commencement of tamoxifen, doctors should consider switching to a drug that has a low potential to inhibit the enzyme. This should be done gradually as abrupt discontinuation of an antidepressant confers risk itself.

It is not clear if or when a woman should be considered for a change of endocrine treatment – e.g. from Arimidex to letrozole or tamoxifen, or ceasing treatment early if the benefits of the treatment are considered to be low. This may be discussed with women as an option when simple measures fail to produce an impact on the symptoms.

For women who are not taking endocrine therapies either because they have completed the course or because they were ER negative, the use of the measures outlined above remain standard. The use of HRT in these women is not encouraged because of the increased risk of a second breast cancer.

Referral to an incontinence clinic for management of stress or urge incontinence may be required

10.9 References:

Atkins L and Fallowfield L. Intentional and non-intentional non-adherence to medication amongst breast cancer patients. Eu J Cancer 2006; 42(14):2271-6

Catt S, Fallowfield L and Langridge. What non-prescription treatments do UK women with breast cancer use? EU J Cancer Care 2006; 15(3):279-85

Fallowfield et al. Quality of life of postmenopausal women in the Arimidex, Tamoxifen, Alone or in Combination (ATAC) adjuvant breast cancer trial. J Clinical Oncology 2004; 22(21):4261-4271

Kelly CM et al. Selective serotonin reuptake inhibitors and breast cancer mortality in women receiving tamoxifen: a population based cohort study. BMJ 2010; (340) c693.

McGurk R, Fallowfield L and Winters Z. Information provision for patients by breast cancer teams about the side effects of hormone treatments Eu J Cancer Care 2006; 42(12):1760-7

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Pandya at al. Gabapentin for hot flashes in 420 women with breast cancer: a randomised double blind placebo controlled trial. Lancet 2005, 366 (9488), 818-824.

Royal College of Obstetricians and Gynaecologists Scientific advisory committee, 'Alternatives to HRT for the management of symptoms of the menopause. May 2006

Toulis KA et al. Gabapentin for the treatment of hot flashes in women with natural or tamoxifen-induced menopause: a systematic review and meta-analysis. Clin Ther 2009, 31(2),221-35.

10.10 Documentation

10.10.1 Document Location

The document is located in the ASWCS Network office, in hardcopy and electronic format.

10.10.2 Revision History

This document is located in the ASWCN office.Revision History Date	Version	Author	Agreed by
Dec. 2007	1	Dr Jeremy Braybrooke	ASWCS Breast SSG 26/2/08
August 2010	2		Marjorie Tomlinson Dr Dorothy Goddard, Dr Mark Berresford Aug 2010
Endocrine Therapy for Early Invasive Breast Cancer April 2011	2	Dr Geoff Sparrow	NSSG June 2011

Clinical Guidelines – Radiotherapy

11 Radiotherapy Guidelines – Carcinoma of the Breast and Ductal Carcinoma in Situ (DCIS)

The ASWCS breast SSG have agreed to adopt the radiotherapy guidelines produced by the Breast Clinical Oncologists based at the Bristol Haematology and Oncology Centre with additional input from Clinical Oncologists at The Royal United Hospital, Bath and Taunton and Somerset NHS Foundation Trust (TST). This document was ratified by the SSG in June 2009.

11.1 Decision to Treat

All patients should be discussed in a multidisciplinary meeting before the decision is made to offer radiotherapy. The exception may be very frail/elderly patients with locally advanced breast cancer in whom urgent palliation is required. The implications of the recommended treatment will be discussed with the patient before a final decision is made.

Most patients will have undergone radical surgery. There should be complete clearance of the primary tumour as judged by excision margins of >1mm in all but a very small minority.

Occasionally a decision is made to give primary radical radiotherapy, without surgery.

The indications for, and the timing of, systemic adjuvant therapies will depend on prognostic factors, tumour markers and ongoing clinical trials. Radiotherapy should not be given whilst the patient is undergoing chemotherapy, with the exception of CMF.

All surgical wounds should be well healed and seroma formation controlled before starting radiotherapy.

11.2 Indications for Radiotherapy

Radiotherapy to the whole breast is indicated following breast conserving surgery (BCS) for invasive breast cancer or high grade DCIS with the following exceptions:

1. Patient unfit/unwilling to receive radiotherapy;
2. Patient randomised into a clinical trial where partial breast irradiation/no radiotherapy is an option;
3. Patient very elderly/very low risk of local recurrence, as defined in the PRIME II protocol.

The role of radiotherapy in intermediate grade DCIS continues to be assessed in trials.

The role of radiotherapy in intermediate grade DCIS continues to be assessed in trials.

The risks of locoregional recurrence are to be discussed with the patient. Radiotherapy to the chest wall is indicated if the:

- Tumour extends to the excision margin
- 4 or more lymph nodes are involved on histological examination
- Margin <1mm
- Skin involvement
- Tumour >5cm diameter
- Tumour grade 3 and >2cm, or multifocal grade 3
- Radiotherapy should be considered if there is lymphovascular invasion.

Women with an intermediate risk of local recurrence should be considered for entry into clinical trials designed to assess survival benefits as well as local recurrence.

The effect of age on the risk of local recurrence appears to be much more significant after BCS than after mastectomy.

Radiotherapy is generally indicated after neoadjuvant chemotherapy and mastectomy regardless of the histological findings.

11.3 Radiotherapy to the Supraclavicular Fossa and Axilla

Treatment of the nodal areas is the subject of much debate, particularly as imaging techniques improve and surgical techniques such as sentinel node biopsy become more widely practised. Close liaison between surgeon and clinical oncologist is essential.

Radiotherapy to the supraclavicular fossa only is indicated when:

- ≥ 4 positive lymph nodes after a level II axillary clearance and a minimum of 10 lymph nodes retrieved

- After neoadjuvant chemotherapy if considered high risk.

Radiotherapy to the supraclavicular fossa and axilla is indicated when:

- No axillary surgery has been carried out (with the exception of DCIS and very good prognosis invasive carcinoma)
- Palpable/+ve axillary lymph node prior to neoadjuvant chemotherapy in patients who have had axillary sampling
- Sentinel node biopsy or sampling of lymph nodes is positive for axillary metastases and axillary dissection is not undertaken or the patient declines axillary clearance
- Extracapsular spread (except where minimal)
- A high node positive count and/or a high proportion of retrieved nodes are involved, should be a consideration for treating SCF and axilla.

Axillary radiotherapy should be considered in patients who have been treated with neoadjuvant chemotherapy if there are any positive nodes, or evidence of previous heavy nodal involvement as inferred from areas of necrosis on histological examination.

Boost to the tumour bed is indicated in:

- All patients aged less than 40
- All patients aged between 40 and 60, unless the primary tumour has favourable prognostic features
- Tumour extends 1mm or less from a radial margin and further surgery is not being considered (if cavity shaves are clear this may be sufficient – discuss with surgeon).

A boost could be considered if: grade 3. lymphovascular invasion. extensive intraductal component. lobular carcinoma.

11.4 Radiotherapy Technique

Cross sectional imaging (MRI, CT, CBCT) can be used in planning radiotherapy to the chest wall, breast and nodal areas, but must be indicated on the progress form if desired.

Whatever the planning and treatment position, they must be identical

- Supine on breast board with sternum horizontal to start with
- Arm poles to support arms abducted to 90^0
- Head turned to contralateral side.

Technique

All patients should be treated on megavoltage equipment with isocentric techniques. Electrons are used for boosts, some chest wall irradiation and in palliation.

11.5 Target Volume (BCS)

Clinical: Palpable breast tissue, down to deep fascia. If crosssectional imaging is available this should be used to define the CTV more accurately, and to enable margins to be adjusted.

Planning: CTV with 1cm margin. The PTV is defined by medial and lateral tattoos on the patient outline 1 cm outside of the CTV, representing the posterior 50% beam edge.

It may be necessary to exclude a small portion of the breast to limit cardiac or pulmonary morbidity. If margins have to be compromised to avoid inclusion of an excessive volume of lung or heart, then those margins furthest from the tumour bed should be restricted. Margins may need adjusting to encompass medial or lateral tumours.

Tangential fields are used to cover the volume.

When cervicoaxillary nodes are to be treated there should be 5^0 floor twist to eliminate divergence of the upper edge of the beam unless this is felt to compromise the dose in the lower part of the volume, in which case the clinician may decide to accept a small gap or overlap at the junction with the nodal fields.

The anterior edge of the beam should be at least 1cm clear of the skin surface.

The maximum thickness of lung included in the tangential field should not exceed 2.5cm.

The heart should be excluded from the volume if at all possible, unless the risks of local recurrence are judged to be higher than any risks from cardiac damage. If the heart cannot be excluded by adjusting the tangential fields then it may be possible to use the multileaf collimator to shield the heart.

11.5.1 Dose

40Gy in 15 fractions daily. 45Gy in 20 fractions daily. 50Gy in 25 fractions daily may be used for larger and/or fairskinned patients.

11.5.2 Boost

Applied electron field. Size and position to be determined by one or more of the following: clinical, surgical and histological information, preop mammogram, imaging with ultrasound, CT, CBCT or MRI Where the surgeon has used an oncoplastic technique it is essential to try and establish the position of the tumour before surgery.

11.5.3 Dose

12.5Gy in 5 fractions treating daily, or 10.5 Gy in 3 fractions treating daily. If the tumour has been incompletely excised the implications of using a higher dose should be discussed fully in the MDT, with the patient, and with at least one sitespecialist colleague in BHOC with full documentation in the notes. If necessary a planned photon boost may be required.

11.6 Post-Mastectomy

Position: As above.

Technique: As above. Electrons may be used instead of photons if the surface of the target volume is relatively flat.

CTV: Skin flaps, down to deep fascia.

PTV: As a rough guide the 50% isodose should lie on the following anatomical margins, although inspection of the contralateral breast may lead to variations.

- Superior between sternal notch and angle of Louis
- Iinferior 1cm below contralateral inframammary fold
- Medial midline
- Lateral midaxillary line
- Posterior to include the chest wall at the level of the tumour bed.

Medial and lateral tattoos on the central axis define the posterior edge of the tangential beams.

Bolus (0.5cm) is usually used for half the fractions to reduce skin sparing It may be necessary to omit one or both ends of the scar to limit the amount of lung or heart included in the treatment volume.

The reconstructed breast should be treated as for postmastectomy. However, definition of the target volume may be difficult depending on the techniques used for reconstruction.

11.6.1 Dose

40Gy in 15 fractions daily. 45Gy in 20 fractions daily. 50Gy in 25 fractions daily.

11.7 Radiotherapy to the Supraclavicular Fossa and Axilla

The following are guidelines only. The Oncologist should take account of the surgical pathology and the MDT discussion.

11.8 Supraclavicular Fossa Only

Position: as above.

Technique: Direct anterior beam using half beam blocking so that the central axis matches onto the upper border of the tangential fields. Either 6MV or 10MV photons may be used.

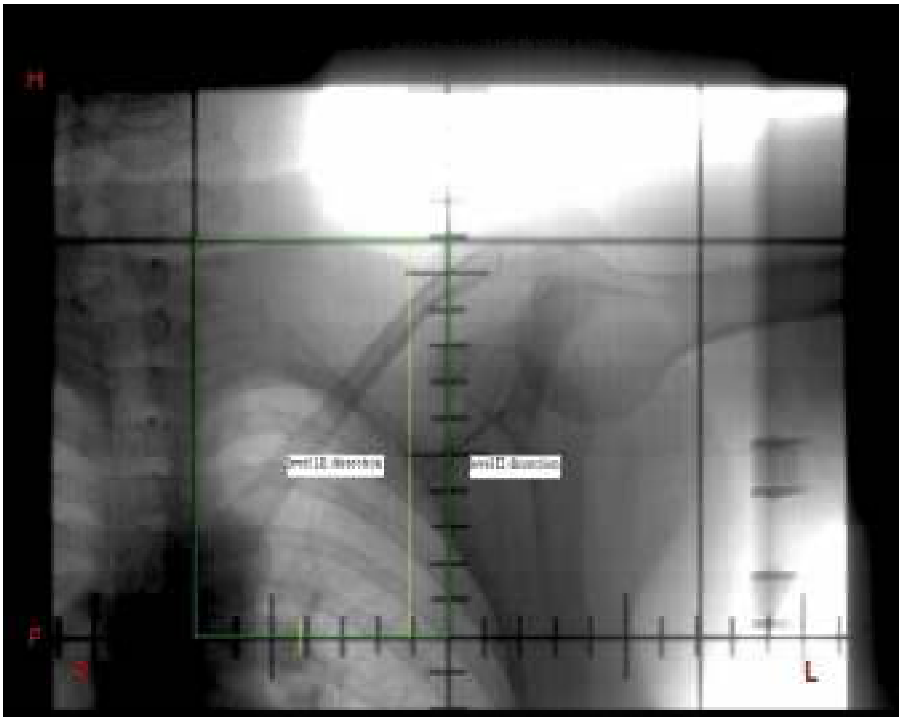
CTV: infraclavicular and supraclavicular lymph nodes

PTV: nodes + 1cm margin.

- Inferior border to match tangential fields
- Superior border to ensure coverage of the SCF or at the level of C7-T1 space

- Medial border sternoclavicular joint / abutting the lateral border of the ipsilateral vertebral body.

Lateral border In line with the outer border of the first rib (roughly covering medial 2/3 of clavicle) for a level III dissection. Patients who had clips placed at the time of surgery, the lateral border should be in line with the most superior and medial clip. Otherwise the lateral border should extend to the coracoid process for a level.



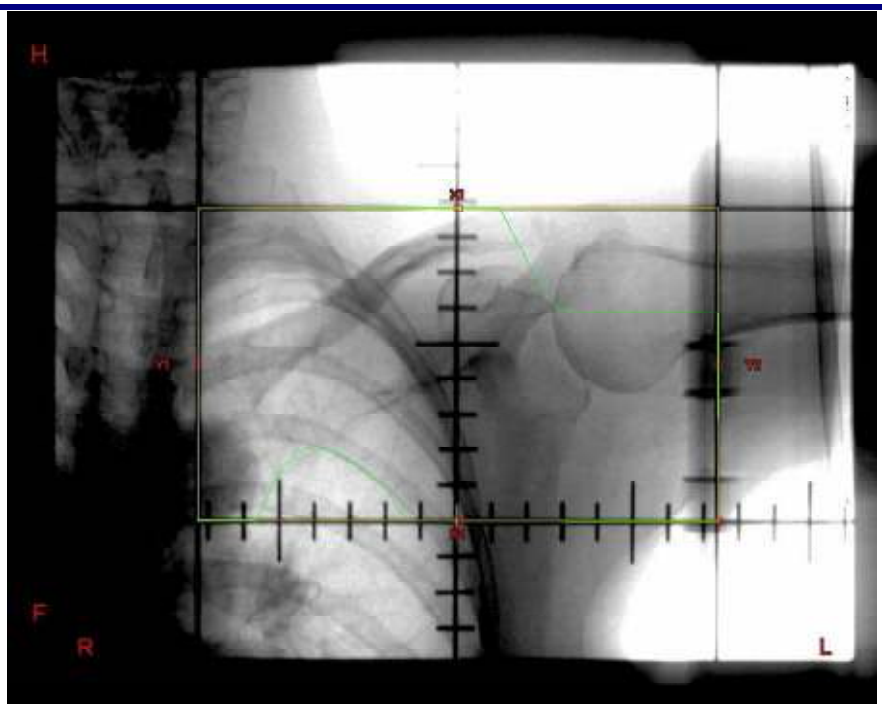
II dissection.

Supraclavicular fossa only. Lung shielding optional. Supraclavicular fossa and axilla Position: As above Technique: Direct anterior beam using half-beam blocking so that the central axis matches onto the upper border of the tangential fields. Either 6MV or 10MV photons may be used.

CTV: axillary chain and infraclavicular and supraclavicular lymph nodes.

PTV: nodes + 1cm margin.

- Inferior border to match tangential fields.
- Superior border to ensure coverage of the SCF or at the level of C7-T1 space.
- Medial border sternoclavicular joint / abutting the lateral border of the ipsilateral vertebral body.
- Lateral border to cover the head of humerus.

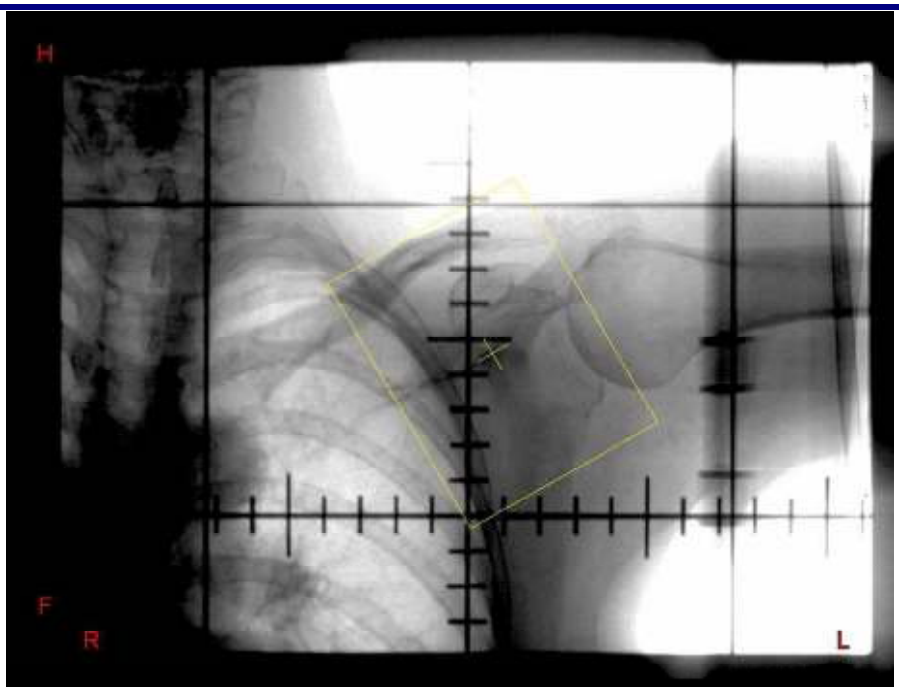


Supraclavicular fossa and axilla with shielding to lung and humeral head. If supraclavicular fields are short then lung shielding may be omitted.

11.9 Posterior Axillary Boost

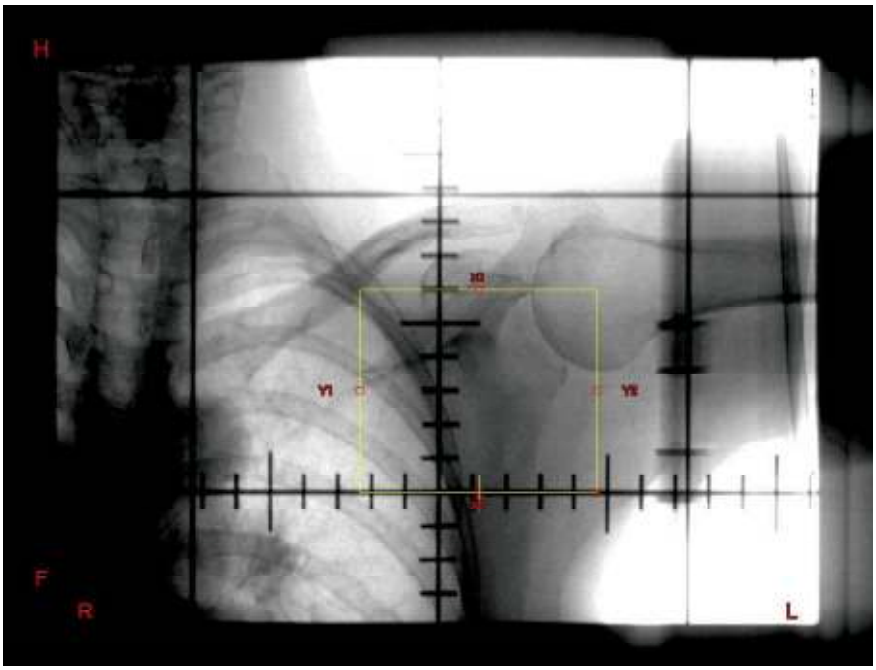
A posterior field may be used to increase the midplane dose in the axilla in patients where the separation is such that the dose is felt to be inadequate for the particular situation e.g. heavy nodal involvement, extensive extra-capsular spread. It is strongly recommended if the percentage is less than 75% of the applied anterior dose. Information from the operation note or from cross sectional imaging may help in making a decision.

If a posterior field is used, it should be treated daily throughout the prescribed course. Position: As above. Currently two methods are in use to treat posterior axillary boosts.



Conventional angled posterior axillary field.

Superior border:	To cover clavicle.
Inferior border:	Superior border of tangential fields.
Medial border:	2cm strip of lung parallel to ribcage.
Lateral border:	Medial 1cm of head of humerus.



Alternative straight posterior axillary field.

Superior border:	Midway through head of humerus.
Inferior border:	To match the inferior border of the anterior SCF field.

Medial border: Lateral to the edge of the first rib.
Lateral border: To cover 2/3 of head of humerus.

11.9.1 Dose

40Gy in 15 fractions daily with SCF only fields. 45Gy in 20 fractions daily. 50Gy in 25 fractions daily may be used for larger and/or fair skinned patients.

11.9.2 Verification.

All photon fields should be verified on set.

11.10 Palliative Radiotherapy

For elderly/infirm patients with fungating and/or bleeding tumours. These patients may be treated using simple plans or direct electron fields. Fractionation should be tailored to circumstances, but a dose of 30/36Gy in 5/6 weekly fractions is usually effective and well tolerated. Care should be taken to assess lung dose when treating chest walls with electrons.

On treatment reviews.

Most patients have little or no problems during their radiotherapy. They should be reviewed towards the end of treatment and given advice on skin care and their need for additional adjuvant therapy

11.11 Follow-up

This will vary according to stage, surgeon, referring hospital and patient preference. All patients should be seen as per the referring breast unit's protocol.

11.12 Audit

Reasons for deviations from the protocol should be recorded in the treatment sheet, and a nonconformity form completed if appropriate.

There will be a small number of patients who for reasons of comorbidity or exceptional circumstances require to have their treatment planned and prescribed completely outside of the above protocol.

11.13 Documentation

11.13.1 Document Location

The document is located in the ASWCS Network office, in hardcopy and electronic format.

11.13.2 Revision History

Revision History Date	Version	Author	Agreed by
December 2008	1	Breast Clinical Oncologists / S.Smith (agreed by S.Falk, Radiotherapy lead doctor)	ASWCS Breast SSG June 2009

Breast Cancer Follow Up Guidelines

12 Breast Cancer Follow Up Guidelines

12.1 Summary

The ASWCS network breast SSG has agreed the principles of follow up that should be offered to patients with early breast cancer after the completion of definitive surgery and any adjuvant or neo-adjuvant chemotherapy and adjuvant radiotherapy.

- Following primary treatment for early breast cancer, asymptomatic patients will be offered regular specialist assessments as part of their ongoing care – this will be at least with annual mammography for 5 years with a variable number and frequency of clinical assessments, according to risk and to local MDT protocols
- Each MDT should have an agreed local follow up protocol delivered by named staff groups according to local resources
- A follow up schedule should be agreed with the patient who should have a direct telephone contact number for their specialist breast care team to allow them to request advice or appointments
- Where applicable, specialist follow up appointments should include evaluation of ongoing treatment, symptoms (physical and psychological) and clinical assessment for loco-regional recurrence
- Mammography screening should be performed annually for the first 5 years with subsequent screening stratified in line with patient risk or continued on an annual basis until aged 50 years.

12.2 Clinical Follow-up

12.2.1 Organisation

The Association of Breast Surgery at BASO has made the following recommendations:

- Patients on continuing active treatment should be followed up until such treatment has been completed
- Patients with ER positive disease may need to be seen at planned intervals to discuss changes in therapy, the so called ‘switch’ or ‘extended’ therapy situations
- Follow up should be stratified according to disease risk. Patients should be given information regarding their personal follow up programme (clinical and imaging)
- High risk patients may be followed up more closely with joint care by surgeons and oncologists according to agreed local protocols
- Data about long-term follow up is essential in monitoring clinical outcomes e locally, regionally and nationally. Data collection must be reliable and functioning if hospital visits either occur or are omitted. Alternative means of data collection in the absence of hospital visits

should be considered such as postal or primary care follow up. Resources for data collection, both I.T. and managerial, should be provided by the hospital in collaboration with primary care. All breast units should participate in ongoing national audits such as the NHSBSP/ABS at BASO audits, the BCCOM audit and the Sloane Project. Mortality data should distinguish between deaths due to breast cancer and deaths which are unrelated or where the cause is uncertain. There must be a nominated surgeon who is responsible for the accuracy of the data collected by the breast unit

- Discharge of follow up to primary care should be an agreed and integrated process and subject to audit. Since most recurrences occur in the first 5 years and the most commonly used benchmarks for outcome in breast cancer are the 5 year recurrence or survival rate, it is recommended that patients should be followed up for 5 years but this period may vary with local and clinical trial protocols. Patients in clinical trials should continue to be followed up according to the trial protocol
- If a GP detects a possible recurrence, the patient should be referred back to the breast unit and there should be a mechanism to facilitate this
- Patients diagnosed and treated for breast cancer will have ongoing requirements to meet their psychosocial needs, surveillance of ongoing treatment effects, monitoring of primary treatment morbidity and monitoring of recurrence rates. All these aspects of care should be provided for in whatever follow up regime is proposed through local cancer networks.

  There will remain a substantial hospital outpatient requirement for patients previously treated for breast cancer and this requirement will need to be resourced.

12.2.2 Clinical Follow up

Quality Objectives	Outcome Measures
To ensure appropriate clinical follow up of breast cancer patients	Each breast unit should have agreed local guidelines for clinical follow up of patients with breast cancer (including mammographic surveillance) and mechanisms for the rapid re-referral of patients with suspected recurrence.
To ensure adequate collection of outcome data on all patients treated for breast cancer	Appropriate data management resources should be available to record follow up and outcome data.
To ensure breast unit participation in national audits	All breast units should participate in ongoing national audits such as the NHS Breast Screening Programme audits, the BCCOM audit and the Sloane Project.

12.2.3 Treatment summary and care plan

Patients treated for breast cancer should have a record of their treatment summary and 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
- Contact details for support services, for example support for patients with lymphoedema
- Contact points for Patients.

12.2.4 Clinical Follow-up Schedule

The ASWCS breast site specific group recommends that for those patients on a planned follow up care regime, specialist follow up by the local MDT should be no more than:

Patients reviewed at year one – then on a variable/annual basis stratified according to risk, either in the surgical or oncology clinic, up to a maximum of 5 years post treatment – or 7 years if on extended hormonal therapy.

All high risk patients to be reviewed by a member of the MDT at year five.

Hormone receptor positive patients may be reviewed at years 2, 5 and 7 years for those suitable for switch or extended therapy.

All patients to have information with direct contact details for Breast Cancer Nurse Specialists if there are concerns between appointments or after discharge – with rapid access back to specialist care where appropriate.

A summary of current practice at all the Trusts within the Network was compiled in April 2010 as a basis for development of a consensus protocol for follow up – see table enclosed.

12.2.5 Follow-up Imaging

Mammography can be expected to detect 30-40% of clinically occult recurrence and these are likely to have better prognostic features. The duration of follow up should take into account that the majority of recurrence will occur within 10 years of diagnosis and that 80% of contralateral breast cancers will have arisen within 10 years of the primary diagnosis.

In line with NICE guidance for early and advanced breast cancer (published February 2009):

- Offer annual mammography to all patients with early breast cancer including DCIS, for 5 years post treatment (which

should be continued on an annual basis until entering the NHS Breast Screening Programme if aged under 50 years)

- After 5 years of annual mammography, follow-up screening frequency should be stratified in line with patient risk category
- Do not offer mammography of the ipsilateral soft tissues after mastectomy
- Do not offer ultrasound or MRI for routine post-treatment surveillance in patients who have been treated for early invasive breast cancer or DCIS
- Each MDT is responsible for delegating requesting and arranging breast imaging to appropriate staff according to local resources.

12.2.6 References:

1 NICE, Improving Outcomes Guidance 2002

2 Rojas, M.P. et al. Follow up strategies for women treated for early breast cancer (Review). Cochrane Collaboration, 2000

3 Khatcheressian, J.L. et al. American Society of Clinical Oncology 2006 Update of the Breast Cancer Followup and Management Guidelines in the Adjuvant Setting. Journal of Clinical Oncology, 2006

4 Guidance on Screening and Symptomatic Breast Imaging Second Edition 2003 Ref No : BFCR(03)2 RCR Publications

5 NICE Guidance on Early and Locally Advanced Breast Cancer 2009

http://www.nice.org.uk/nicemedia/pdf/Improving_outcomes_breastcancer_manual.pdf

6 Association of Breast Surgeons at BASO

13 Organisation of Breast Cancer Follow-ups Within ASWCN

13.1 Table 1: Breast Units Within ASWCN

Host Organisation	Surgical Follow up	Oncology Follow up	Mammography surveillance	Further information
University Hospital Bristol at Bristol Royal Infirmary	Invasive disease and DCIS treated by breast conservation, yearly to 3 years, at 5 years and at 7 years if on active endocrine therapy and then discharge	Review 3 months after oncology treatment has finished and then as for surgical review. It will be either surgery or oncology review and NOT both	Yearly to 5 years, 2 yearly to 9 years and then discharge to NHSBSP. For patients not old enough to enter the screening programme, continue 2 yearly follow up and for patients older than the screening programme, discharge at 10 years.	
Taunton and Somerset NHS Trust	1 year 1 year 3½ years 5 years	Regular clinical follow up until end of radiotherapy and/or chemotherapy treatment then discharged to surgical clinic.	Annually for 5 years Then depends on age - annually until 50 - over 50, 18/12 alternating with screening - over 70, 2 yearly	We have 2 new Breast Surgeons and are about to review all follow ups so this is very timely and would really like to reach a network consensus.

Royal United Hospital Bath NHS Trust	Surgical Rx only seen at 1year then discharged to mammo surveillance. Some on hormonal Rx seen in oncology at 2 and 5 years then discharged to mammo surveillance	Surgical plus XRT +/- chemo seen in oncology at 1 year then discharged to mammo surveillance if not on hormonal Rx. Some on hormonal Rx may be reviewed at 2, 5 and 7years in oncology then discharged to mammo surveillance.	Annual mammography for 5 yrs post Rx (continues annually if aged under 50yrs) then 2yrly until 10yrs. At mammo surveillance questionnaires performed at each visit with Radiographers (+/-BCN's for advice) – with opportunity to return to clinic if there are concerns.	Follow ups in Bath recently rationalized with discharge from clinical follow up at year one for most patients. High risk and some on hormonal therapy continue to be reviewed – but stratified according to risk.
Yeovil District Hospital NHS Foundation Trust	No surgical follow-up once wound is satisfactorily healed.	All patients reviewed annually for 5 years & then discharged to mammo surveillance. .	Breast conserving surgery patients have annual mammo for 5 years & then 2 yrly until 10 years. Mastectomy patients have 2 yearly mammos for 10 years	All patients provided with contact information for Nurse Specialists if have concerns between appointments or following discharge. Discharge information leaflet provided.
North Bristol NHS Trust	All patients seen at 1 and 3 years. If on Hormonal therapy also seen at 5 years. Lymphoedema appts with Nurse specialist at 6 months, 1 year (combined with above) and 18 months.	Seen at approx 6 weeks after Chemo or DXT only	Annually for 10 years. Continue if still under 50	

Weston Area Health NHS Trust	Surgery +/- radiotherapy patients followed up by the BCNS or surgeons. Seen 3 monthly 1st year. then 6 monthly for a further 2 years. Then seen yearly for another 7 years.	Patients at higher risk followed by oncology team (E.g. Those who have had chemotherapy) Seen 3/12 for 1 year then 4/12 for 1 year then 6/12 for a further 2 years. Discharged at least 1 year after all hormones discontinued. Young woman not eligible for screening are followed up yearly until screening age	Mammography yearly for these with breast conserving surgery for 10 years. Those who have had a mastectomy have a mammogram of the contralateral breast 2 yearly for 10 years.	All Breast patients have open access to the service using the BCNS or oncology service.

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13.2 Documentation

13.2.1 Document Location

The document is located in the ASWCS Network office, in hardcopy and electronic format.

13.2.2 Revision History

Revision History Date	Version	Author	Agreed by
September 2009	1	Dr Jeremy Braybrooke	Chair of NSSG Dr Jeremy Braybrooke
	2	Dr Dorothy Goddard, Chair ASWCS Breast NSSG	Agreed by NSSG August 2010

Patient Experience

14 Communicating Significant News

The following section summarises the main points of the ASWCS Communicating Significant News Policy. The whole guidance is available online at http://www.aswcs.nhs.uk/supportivecare/bbnindex.htm

The User Involvement Group has also produced a leaflet summarising this policy. The leaflet has been distributed to all key MDT members.

14.1 Before a First Cancer Related Appointment

The information and support needs of patients and their carers need to be addressed at what could be a stressful time.

An appointment letter should be accompanied by a leaflet explaining why the patient has been referred by his/ her GP. The letter can also suggest that the patient can bring with him/ her a member of his/ her family or a significant other.

14.2 Breaking Bad News – Confirming a Diagnosis

A cancer diagnosis should be communicated honestly to the patient with the minimum of delay.

This information should be communicated in a comfortable quiet area with privacy and without interruption, ideally in the company of a close relative or a significant other, if this is the patient's preference.

Patient dignity is also important, and the aim is that the patient should be fully dressed.

The number of people present should be kept to a minimum, although it is suggested that a specialist nurse should be present.

Health professionals should also make sure that they introduce themselves at the start of the consultation.

Health professionals should also respect the wish of the patient if he/ or she does not wish to be told bad news. Further opportunities for discussion should be planned according to patient's wishes.

It must be remembered that screen, cubicle walls and curtains surrounding bed are not soundproof.

Exceptions may be made when patient care may be affected i.e. Intensive Care Unit- High Dependency Unit (ICU-HDU), recovery post anaesthesia and emergencies.

Information should be delivered in a way and a format that the patient can understand. Special attention should be paid to these needs of people with learning, memory or other sensory disabilities.

Patients should be given information to help make an informed decision on their treatment options. This should include written and verbal information on

the cancer type, diagnostic procedures, treatment options, effects and side effects, possible outcomes, post treatment options.

Patients should also be given an option to receive a patient held record/ diary if they so wish (either the Teamwork file or cancer specific patient held diaries that have been developed locally).

Patients should have an opportunity to review what has been said during the consultation and also ask further questions.

Breaking Bad News Training should be made available to all staff who have contact with cancer patients.

14.3 Holistic Needs Assessment Guidance

The Measure 1E-502 of the Manual of National Cancer Measures (2004), stipulates that the Network Partnership Group should develop a Holistic Needs Assessment Guidance addressing the needs of people affected by cancer. The terms holistic includes a number of different needs- physical, psychological, social, spiritual information and carers' needs.

A Network Workshop was held in Bath in November 2004 which was attended by a wide range of health care professionals, the voluntary sector, service users and carers. During the course of the Workshop all participants were asked to consider what they perceived to be essential core components of an holistic needs assessment at the following key points during the patient pathway:

- Pre Diagnosis – including GP referral
- Diagnosis
- Treatment
- Post treatment or living with cancer
- End of Life.

The Network Holistic Needs Assessment Framework aims to give prompts for needs that should be assessed throughout the cancer journey. This could be either user led, focusing on health and well being, or professionally led. The workshop participants were in agreement that local solutions could be found providing that all the core principles as detailed in the guidance were met and that information was easily transferable should users move around the Network and duplication of assessment did not take place.

The full guidance is available online at
http://www.aswcs.nhs.uk/supportivecare/holistic.htm

15 Patient Involvement and Information

The ASWCS network is committed to the development of a patient centred care. With this in mind the ASWCS User Involvement Group has produced a series of policy documents aiming to contribute to improved patient and carer experience.

15.1 Principles of Effective Patient Involvement and Information

The following summarises the level of service that people affected by cancer should expect. This is based on the service model of the NICE Supportive and Palliative Care Guidance.

People affected by cancer should be involved in decisions about their care and treatment. They should always be able to express their views or worries about their treatment and care.

People affected by cancer can expect their health team to communicate clearly with them. They should feel confident that the doctors, nurses and other health staff caring for them are honest and sensitive when talking to them, and explain things in a way they understand.

People affected by cancer should be told where they can get help and advice. The name and contact details of a key worker should be given to them so that they can get in touch if they need any information or advice.

People affected by cancer should be offered as much information as they want. Clinical Nurse Specialists have an important role to play in explaining the clinical care and treatment, while the information specialists at the Information and Support Centres (where available) can provide information about the impact of living with Cancer.

Health professionals looking after service users should be aware that your needs are not only physical and medical. They should ask you about the kind of practical and social support they may need as well and put them in touch with people and local organisations who can help.

Health staff should be aware that some people want emotional and spiritual support, and help them to find it - if that is what they want.

Service users should also be offered help living with the effects of cancer and its treatment.

Health and social care staff should ensure that families and friends are asked about their needs, particularly at crucial times such as diagnosis or bereavement, and get all the emotional and practical support they need.

People affected by cancer should expect a speedy response at times of greatest need.

Preferences about where and how someone wants die should be respected.

People affected by cancer should be offered an opportunity to get involved in making cancer services better; for example by being put in touch with the ASWCS User Involvement Group