Clinical Management Guideline:
Management of Breast Cancer

The information within this document should be used only to guide the management of adult patients with breast cancer and who have not been entered in a clinical trial.

PRESENTLY UNDER REVIEW
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[Note: The following intended Appendices are presently available as separately sourced documents but will be CMG included following September 2016 review]

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NOSCAN Breast Cancer CMG Development process – summary
INTRODUCTION

The North of Scotland (NoS) Breast Cancer MCN/ advisory group is a multidisciplinary group of

- specialist clinicians and nurses,
- supporting services personnel,
- network management personnel and
- service users/patient representatives

from the six North of Scotland Health Boards of Eileanan Siar (Western Isles), Grampian, Highland, Orkney, Shetland and Tayside.

As such, it meets 3-4 times annually to oversee and co-ordinate the specialist care of patients presenting with breast cancer in the North of Scotland, which for specialist input is primarily covered by services at Aberdeen Royal Infirmary, Ninewells Hospital in Dundee, and Raigmore General Hospital in Inverness.

The following guidelines have been developed by the NoS Breast Cancer MCN/Group to ensure that the clinical management and care for this group of patients throughout the NoS is not only more regionally consistent (as required by CEL 30 etc), but conforms to evidenced best practice in the UK and worldwide.

I am indebted to the many dedicated professional colleagues and others who are to be complimented on their effort and for setting aside the time required to develop and producing these guidelines.

Mr Douglas Brown
NOSCAN Breast MCN Clinical Lead
SECTION 1: REFERRAL

General Principles

All patients referred for investigation of symptoms potentially indicative of breast cancer should receive an appointment to a specialist breast Out-Patient clinic.

Pathway overview

Screening: the Scottish Breast Screening Programme (or SBSP) invites women aged between 50 and 70 years old for screening every three years. Women aged 71 and over are encouraged to attend through self referral to their local screening centre. Women are recalled for assessment in accordance with SBSP radiology guidelines.

- A minimum of 90% of patients should receive an assessment appointment within 3 weeks of screening.

Symptomatic: Patients should be vetted in accordance with Scottish Referral Guidelines (copied on next page for convenience).

- Urgent referrals should receive an appointment within 2 weeks of referral by primary care.

- Where possible, routine referrals should be seen within 6 weeks

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Scottish Urgent Suspicion of Cancer Referral Guidelines – Breast Cancer

Breast symptoms are a relatively uncommon presentation in primary care. It is estimated that between 0.35% and 0.6% of all consultations in Scotland are for breast symptoms. Many of these consultations will be in young women, whereas the biggest risk factor, after gender, is increasing age. Incidence of breast cancer in women aged 30-35 is 33 per 100,000 population and approximately 81% of breast cancers occur in women over the age of 50.

Breast cancer accounts for 30% of cancers in women and around 4,400 people are diagnosed with breast cancer in Scotland each year; approximately 20 of these are men. The following recommendations seek to improve the referral and effective management of breast symptoms in women and men in primary care. Guidance for referral to regional genetics centres for those with a family history of breast cancer is available at www.sehd.scot.nhs.uk/mels/CEL2009_06.pdf
Table 1: As per Page 9 of ‘Scottish Referral Guidelines for Suspected Cancer’

<table>
<thead>
<tr>
<th></th>
<th>Urgent Suspicion of cancer referral</th>
<th>Routine referral</th>
<th>Primary care management. Issue relevant advice leaflet</th>
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<tbody>
<tr>
<td><strong>Lump</strong></td>
<td>• Any new discrete lump (in patients over 35 years)                                                                ---------------------------------------------------------------------------------------------------</td>
<td>• Any new discrete lump in patients under 35 years with no other suspicious features</td>
<td>• Women with longstanding tender lumpy breast and no focal lesion</td>
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<td></td>
<td>• New asymmetrical nodularity that persists at review after menstruation (in patients over 35 years)</td>
<td></td>
<td>• Tender developing breasts in adolescents</td>
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<td></td>
<td>• Unilateral isolated axillary lymph node in women</td>
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<td></td>
<td>• Cyst persistently refilling or recurrent cyst</td>
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<tr>
<td><strong>Nipple symptoms</strong></td>
<td>• Bloodstained discharge</td>
<td>• Persistent discharge sufficient to stain outer clothes</td>
<td>• Transient nipple discharge which is not bloodstained</td>
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<td></td>
<td>• New nipple retraction</td>
<td></td>
<td>• Check prolactin levels when discharge present</td>
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<tr>
<td></td>
<td>• Nipple eczema if unresponsive to topical steroids (such as 1% hydrocortisone) after a minimum of 2 weeks</td>
<td></td>
<td>• Longstanding nipple retraction</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Nipple eczema if eczema present elsewhere</td>
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<tr>
<td><strong>Skin changes</strong></td>
<td>• Skin tethering</td>
<td></td>
<td>• Obvious simple skin lesions such as sebaceous cysts</td>
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<tr>
<td></td>
<td>• Fixation</td>
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<tr>
<td></td>
<td>• Ulceration</td>
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<tr>
<td></td>
<td>• Peau d’orange</td>
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<tr>
<td><strong>Abscess/infection</strong></td>
<td>• Mastitis or breast inflammation which does not settle after one course of antibiotics</td>
<td>• Abscess or breast inflammation even after settled in patients over 35 years</td>
<td>• Abscess* or inflammation - try one course of antibiotics to cover staphylococcus and streptococcus (also consider possible anaerobic infection as per local guidelines)</td>
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<tr>
<td>Urgent Suspicion of cancer referral</td>
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<td>Primary care management. Issue relevant advice leaflet</td>
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<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Unilateral persistent pain in post menopausal women</td>
<td>• Women with moderate degrees of breast pain and no discrete palpable lesion</td>
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<tr>
<td></td>
<td>• Intractable pain that interferes with the patient’s lifestyle or sleep</td>
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<tr>
<td><strong>Gynaecomastia</strong></td>
<td>• Exceptional aesthetics referral to plastic surgery pathway if required</td>
<td>• Examine and exclude abnormalities such as lymphadenopathy or evidence of endocrine condition</td>
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<tr>
<td></td>
<td>• Exclude or treat any endocrine cause prior to referral</td>
<td>• Review to exclude drug causes</td>
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<tr>
<td></td>
<td>• Measure hormones (oestrogen, testosterone, prolactin, humanchorionic gonadotropin and alpha-fetoprotein)</td>
<td>• Reassure</td>
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*Any acute abscess requires immediate discussion with secondary care.*
SECTION 2: INITIAL ONE STOP ASSESSMENT CLINIC (as presently provided at Aberdeen Royal Infirmary, Ninewells Hospital – Dundee, Perth Royal Infirmary and Raigmore General Hospital – Inverness, only)

General principles

- There has to be a nominated consultant surgeon supervising with a nominated consultant radiologist or equivalent signing off the reports.

- Mammography and ultrasound (US) assessment should be available with immediate reporting capability.

- Where core biopsy (CB) is indicated, this should wherever possible be undertaken at that clinic.

- In all malignant cases axillary nodes must be assessed and sampled if clinically indicated.

- The diagnostic assessment of patients with breast symptoms is based on the Multidisciplinary Triple Diagnostic Method:
  
  A  Clinical assessment
  
  B  Imaging assessment
  
  C  Needle biopsy

Specifics

- The tests used in an individual case will be determined by the presenting symptom(s), the clinical findings and the age of the patient.

- The assessment clinic should be organised so that all appropriate tests can be carried out during the same clinic attendance.

- Use of the Triple Diagnostic Method will enable a diagnosis to be established in the majority of patients and diagnostic surgical excision should be rarely required.

- Patients in whom the Triple Assessment is negative should be advised to seek advice from their GP if they remain concerned or if there is a change in symptoms or signs.

- The breast imaging facilities should include x-ray mammography and high frequency ultrasound with probes suitable for breast imaging (12 MHz or more).

- Patients with implant augmentation should be assessed as for patients without implants in accordance with the following guidelines.
• Patients with autologous or implant reconstruction should not undergo mammography of the reconstructed breast.

• The technical quality of mammography should be equivalent to that in the NHS Scotland Breast Screening Service (NHSSBS)

• Breast imaging facilities should be integrated with, or be within reasonable distance of the breast clinic for patient convenience and efficient service delivery

• 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. MRI should be carried out according to local policy agreed by the multidisciplinary team.

• There should be clear administrative links between breast imaging and the breast clinic in order to ensure:
  - efficient service delivery
  - best use of resources
  - clear and rapid communication for clinic scheduling, exchange of information and results of tests
SECTION 3: ASSESSMENT AND MANAGEMENT OF BREAST LUMPS

1: CLINICALLY BENIGN LUMP

AGED 25 YEARS AND UNDER

Ultrasound (US)
- If solid benign mass – NO BIOPSY – discharge back to Secondary Care
- If solid mass with any indeterminate features (CORE BIOPSY or FNA)
- If normal – NO BIOPSY – discharge back to Secondary Care

AGED 26 – 30 YEARS

Consider Core BIOPSY or FNA

AGED 31 - 40 YEARS

Ultrasound
- If solid benign mass – Core Biopsy or/and FNA
- If normal – CLINICAL Core Biopsy or/and FNA

AGED OVER 40 YEARS

Mammogram and Ultrasound
- If patient has had mammogram in last 12 months – discuss with Radiologist
- Radiologically benign solid mass visible on US – CORE BIOPSY
- Clinically benign lumps consistent with a lipoma\(^1\) or fat lobule clinically may not require imaging or biopsy.
- If ultrasound is performed, and is either normal or consistent with lipoma or hamartoma\(^2\), the lesion may not require biopsy.
- If there is a history of recurrent cysts and a new lump is thought clinically to be another cyst, aspiration by a breast clinician without ultrasound is reasonable.

If US suggests Fat Necrosis and there is a history of trauma or visible bruise, BIOPSY MAY NOT BE REQUIRED

Ultrasound = CYST

Aspirate cyst - Discard aspirate and discharge patient unless:

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\(^1\) Lipomas are non-cancerous (benign) soft, fatty lump that are caused by an overgrowth of fat cells under the skin. They are harmless and can usually be left alone if they’re small and painless. They can grow anywhere in the body where there are fat cells, but are usually seen on the shoulders, neck, chest, arms, back, buttock, or thigh. They feel soft and “doughy” to touch and range from the size of a pea to a few centimetres across. As they tend to grow very slowly, they don’t usually cause any other problems.

\(^2\) A hamartoma is a benign, focal malformation that resembles a neoplasm in the tissue of its origin. This is not a malignant tumour, and it grows at the same rate as the surrounding tissues. It is composed of tissue elements normally found at that site, but which are growing in a disorganized mass. They occur in many different parts of the body and are most often asymptomatic and undetected unless seen on an image taken for another reason.
a) **Residual clinical abnormality** ie cyst not the palpable abnormality – repeat clinical examination
b) **Uniform blood stained aspirate** – core biopsy the cyst wall
c) **Intracystic Filling Defect** – core or FNA should be performed
d) **Recurrent individual cyst** – should be considered for repeat triple assessment

2: **INDETERMINATE LUMP**

Clinically or US indeterminate lump:
- If aged <35 – discuss indications for Mammography with Radiologist prior to CORE BIOPSY or FNA)
- if aged ≥35 years – Mammogram and Core Biopsy +/- FNA

3: **CLINICALLY SUSPICIOUS LUMPS**

**Age < 35**
US all patients
- (Discuss indication for mammography with Radiologist
  - If the ultrasound shows a suspicious mass and the mammographic density is BIRADS 3 or 4, then whole breast ultrasound is indicated.
    - If US Normal – CLINICAL CORE BIOPSY +/- FNA
    - If US Abnormal - CORE BIOPSY +/- FNA
  - Ultrasound the ipsilateral axilla in all patients with a clinically or radiologically suspicious lump.
    - If abnormal node is identified, proceed to US CORE BIOPSY or FNA
    - If multiple very abnormal nodes are present in the axilla, then US of the supraclavicular fossa (SCF) is indicated

**Age > 35 as above + mammogram**

*Appropriate REVIEW to be arranged after MDT to discuss triple assessment findings*

4: **SKIN TETHERING**

Skin tether without palpable lump, and patient
a) aged <40 years = US; consider mammogram
b) aged ≥40 years = mammogram + US

Review after an interval of 2-3 months in ‘New Referral Clinic’ where considered clinically appropriate
5: PAGET'S DISEASE/NIPPLE ECZEMA
Unilateral nipple eczema requires PUNCH BIOPSY

If patient aged >40 years = requires mammogram
   If proven Paget’s disease: breast ultrasound and mammogram should be performed prior to breast surgery
   If mammogram normal: MRI should be considered.

6: WOMEN WHO ARE PREGNANT/BREAST FEEDING
It is generally felt that clinical examination of the breast in women who are pregnant or breast feeding can be more difficult and that breast ultrasound is also less reliable.

In the presence of a palpable lump or suspicious thickening:
   • If ultrasound is normal, there should be a low threshold for undertaking clinical core biopsy.
   • If normal tissue or lactational change, further review where considered clinically appropriate.

   Mammography only performed if cancer is proven histologically

7: NIPPLE DISCHARGE
   a) Patient aged <40 years = US if single duct or blood stained consider mammography
   b) Patient aged >40 years = mammogram (+ US IF UNILATERAL or bloodstained )

Further management to be guided by imaging results

8: (LESS THAN 12 MONTHS) fixed unilateral NIPPLE INVERSION
   a) Patient aged <40 years = US and consider mammography
   b) Patient aged >40 years = mammogram; and consider US

9: BREAST PAIN (MASTALGIA) NB Not/exclude chest wall pain
   • Patient aged <40 years = Normal clinical examination requires no radiological investigation
   • Patient aged > 40 years = mammogram if no mammogram in last 12 months.
   • Clinical thickening/lump: investigate according to above guidelines

10: PATIENT FEELS LUMP – CLINICAL EXAMINATION NORMAL
Patient aged <40 years = then Ultrasound should be considered.
   • Patient aged >40 years = mammogram and consider US (MAY NOT BE REQUIRED IF BIRADS 1)
11: CLINICAL THICKENING

Clinically symmetrical benign thickening
- if patient under 40 years – no imaging required
- if patient OVER 40 years – CONSIDER mammogram

Clinically asymmetrical localised thickening
Patient aged <35 years: US
If imaging
- normal = discharge back to Secondary Care
- abnormal = manage according to imaging

Patient aged ≥35 years: mammography, and US (may not be required if BIRADS 1). If imaging
- normal = consider CLINICAL CORE BIOPSY or review in 3/12
- abnormal = manage according to imaging
12: MALE PATIENTS

If not already done by GP - Check bloods (hormone profile and testicular tumour markers)

- Patient aged <40 years: Clinically benign = no imaging REQUIRED and discharge back to Primary Care
- Patient aged ≥40 years:
  a) bilateral = no imaging and discharge back to Primary Care
  b) unilateral = mammogram +/- US. If suspicious = US core biopsy

- Idiopathic gynaecomastia: A 3 month course of Tamoxifen 20mg may be beneficial.

- Bilateral gynaecomastia or significant unilateral gynaecomastia may be considered for therapeutic mammoplasty after formal psychological assessment via plastic surgery exceptional referrals pathway
SECTION 4 - THERAPEUTIC MANAGEMENT

1 Surgery

B3 Lesions (see also Appendix 2)
- B3 lesions on core or diagnostic vacuum assisted biopsy (VAB) should undergo repeat VAB.
- If B3 lesion without atypia on first core/VAB is confirmed by repeat VAB, then patients can be discharged to routine screening.
- B3 lesions on first core/VAB who are upgraded to atypia on repeat VAB should be offered diagnostic excision.
- B3 lesions with atypia which are not upgraded or downgraded by repeat VAB should be offered mammographic follow up.

Lobular In Situ Neoplasia (LISN)
- See B3 protocol Pleomorphic LCIS should be treated as for DCIS.

Ductal Carcinoma In Situ (DCIS)
- Women with DCIS who are undergoing breast surgery should be offered the choice of either
  - breast conservation surgery
  or
  - mastectomy.
- Patients with large areas of in situ disease may be considered for oncoplastic conservation surgery instead of mastectomy.
- In women with DCIS undergoing conservation surgery the radial margins must be clear (≥1 mm).

Invasive Cancer
- Women with invasive breast cancer who are undergoing breast surgery should be offered the choice of either
  - breast conservation surgery
  or
  - mastectomy.
- The choice of surgery must be tailored to the individual patient: the patient should be fully informed of the options and made aware that present RCT evidence suggests
there is no survival benefit to mastectomy,

- local recurrence rates are slightly higher following breast conservation

- breast irradiation is required following conservation,

- and that
  - further surgery may be required if the radial margins are not clear of tumour.

- In patients undergoing breast conservation surgery, the radial tumour margins must be clear (≥1 mm).

- Patients with larger tumours may be considered for oncoplastic conservation surgery instead of mastectomy.

### Management of the axilla

- All patients with invasive cancer should undergo preoperative ultrasound examination of the axilla. Suspicious nodes should have further assessment by core or FNA.
  
  - Node negative patients should undergo combined blue dye/radioisotope sentinel lymph node biopsy (SLNB).
  - Patients with isolated tumour cells or micrometastases (< 2mm) should not have further axillary surgery.

- While it is recognized that up to 60% of patients will have no further positive nodes after a positive sentinel node biopsy, these patients should be offered further axillary treatment.

- Radiotherapy is a valid alternative to axillary clearance in patients with a low burden of disease (ABS consensus + AMAROS Trial).

- Patients with 1 or 2 sentinel nodes with macrometastases should be offered entry into the POSNOC trial.

- Patients with 3 or more sentinel nodes with macrometastases should be offered axillary clearance. Patients with extracapsular extension may also be considered for axillary clearance.

Sentinel Node Biopsy should be considered in patients with only DCIS on diagnostic biopsy where a large volume oncoplastic resection or a mastectomy is being performed.

### Reconstructive surgery
• All patients undergoing mastectomy should have reconstructive surgery discussed, including:
  o all the options and regardless of local availability
  o performed as an immediate or delayed procedure.

• Immediate reconstruction may cause a delay in the delivery of adjuvant chemotherapy in up to five per cent of patients: Neoadjuvant chemotherapy may be considered before surgery to obviate this delay.
2. Neo-adjuvant Systemic Anti-Cancer Therapy (SACT)

**Chemotherapy**

- Neoadjuvant chemotherapy should be considered for all patients with breast cancer whose disease is either:
  - inoperable (locally advanced or inflammatory) but localised to the breast/locoregional lymph node groups,
  or
  - the only surgical option is mastectomy and downstaging might offer the patient the opportunity for breast conservation.

- Neoadjuvant chemotherapy is associated with higher rates of breast conservation than adjuvant chemotherapy, with equivalent rates of overall survival and locoregional recurrence, providing surgery is part of the treatment pathway.

- For patients with proven axillary lymph node disease preoperatively (by core or SLNB), axillary lymph node clearance (ALND) should be considered: the disadvantage of this approach is the possibility that ALND will be performed when all disease has been eradicated by chemotherapy.

- In patients in whom the axilla was negative pretreatment, sentinel node biopsy should be performed. Consideration should be given to removing 4 nodes due to the higher false negative rate of up to 10%.

**Oncologists to comment/provide further detail on next section:**

- Anthracycline-taxane-based chemotherapy combinations should be considered for all patients receiving neoadjuvant chemotherapy.

- Patients with HER-2 positive breast cancer, receiving neoadjuvant chemotherapy, should receive trastuzumab, either as adjuvant treatment or with non-anthracycline-based neoadjuvant chemotherapy.

- Neo adjuvant chemotherapy should be considered for patients who would be predicted to benefit from chemotherapy in the adjuvant setting.

All patients should be monitored by imaging (ultrasound or MRI) at midpoint and on completion of treatment: this may require clip insertion to mark tumour prior to, or during treatment.

The SACT Regimens approved for use in the North of Scotland are detailed in Appendix [This is currently in a separate document which is still under development]
Endocrine therapy

- An aromatase inhibitor (AI) is recommended for ER positive postmenopausal women receiving neoadjuvant endocrine therapy.

- Patients to be monitored by U/S 3 monthly. Surgery should/to be offered when tumour is conservable or once maximum endocrine response has been achieved as defined by clinical and ultrasonic assessment.

- There is insufficient data to guide the optimum therapy in premenopausal women.

3. Adjuvant Systemic Anti Cancer Therapy – need oncologist input

- Current published evidence indicates that adjuvant systemic cytotoxic therapy be offered based on the evidence calculated by validated online predictor tools [ie Adjuvant Online: PREDICT]

- Adjuvant trastuzumab should be given to all patients with HER-2 positive breast cancer who receive adjuvant chemotherapy.

- Adjuvant trastuzumab should not be given concurrently with anthracyclines, but may be given either concurrently with taxane based regimens or sequentially

- (In keeping with new QPI for adjuvant chemo), Patients with an overall survival benefit ≥ 5% at 10 years should be offered adjuvant chemotherapy

- Patient’s age and co-morbidity should be considered

- Borderline tests may benefit from Genomic tests

[Note: Oncologists to provide further commentary on this section as part of September review]

MPEP/MPC Advice Note 2016 - 01 Oncotype DX®

- Delaying chemotherapy beyond three months after surgery may have a detrimental outcome in older patients (over 65 years), but the evidence for this association is weak.

- In patients being treated with anthracyclines
  
  - Cardiac function should be monitored
  
  - Trastuzumab should be used with caution in patients with significant cardiac comorbidity.
• The benefits of adjuvant chemotherapy with or without trastuzumab may be outweighed by the potential harms in these patients, and treatment should only be recommended after careful consideration.

The SACT Regimens approved for use in the North of Scotland are detailed in Appendix.

Staging

• CT staging of Chest, Abdomen and Pelvis +/- Bone scan should be offered to all patients
  o undergoing neo-adjuvant therapy
  o with 4 or more +ve nodes post operatively.

• CT staging may be offered to other groups dependent upon clinical level of suspicion.

Adjuvant hormonal therapy

It is noted that clinical evidence is changing regarding the role of hormonal therapy in the adjuvant setting.

• If in doubt, the (present) MCN recommendation is giving 10 years of endocrine treatment:
• Low risk (ie <2% benefit on PREDICT) may not require any therapy
• All other Patients with ER positive cancers should be offered endocrine treatment.

• [Pre-menopausal women with ER positive invasive breast cancer should be treated with tamoxifen for at least five years, to a total of ten years, unless there are contraindications or side effects].
[Note: further commentary on the above as part of September review]

• Low risk post menopausal women should be offered Tamoxifen for at least 5 years. High risk post menopausal women should be considered for 5 years of an Aromatase Inhibitor (AI).

• Further review in 6/12 [ie September 2016]

• Patients with early invasive breast cancer should be considered for a baseline dual energy X-ray absorptiometry (DEXA) scan to assess bone mineral density if they are commencing an aromatase inhibitor.

• Bisphosphonate therapy should be considered for patients with osteopoenia/osteoporosis.

Radiotherapy
All patients with ductal carcinoma in situ should be considered for breast radiotherapy following breast conservation surgery.

Postoperative External Beam Radiotherapy (EBRT) to the conserved breast should be considered for all patients undergoing conservation surgery for early breast cancer.

Shorter fractionation schedules (e.g., 4,005 cGy in 15 fractions over three weeks) should be considered in early breast cancer.

Radiotherapy boost is recommended in all patients aged 50 years or under at diagnosis.

Radiotherapy boost should be considered in patients 50 years or older at diagnosis, especially those with high-grade cancer.

Post-mastectomy radiotherapy should be advised in patients with lymph node-positive breast cancer if they have high risk of recurrence (≥4 positive lymph nodes or T3/4 tumours).

Post-mastectomy radiotherapy may be considered in patients with intermediate risk of recurrence (high-risk node-negative tumours or one to three positive axillary lymph nodes).

Supraclavicular radiotherapy may be of benefit in patients with more than 4 positive axillary nodes.

The Radiotherapy Regimens approved for use in the North of Scotland are detailed in Appendix.
SECTION 5. FOLLOW-UP AND AFTERCARE

UK breast cancer follow-up practice is currently under review: it is recognised that future follow up should be based around the principles of self directed aftercare (SDA) and survivorship

The 5 principles of follow up are:

- To provide information and support from diagnosis
- To promote recovery
- To sustain recovery
- To manage consequences
- To support patients with active and advanced disease

A written treatment summary and care plan should be provided at the end of first treatment by the Breast Care Nurse Team and should include plans for follow up: this information should be provided not only to the patient but to the GP.

The treatment summary should include details of:
- a key contact, usually a Specialist Breast Care Nurse
- who to contact out of hours.

Information should be provided on
- potential post treatment symptoms and
- how these can be managed.

Patients should be supported about day to day concerns and be made aware of appropriate support services (local and/or regional/national as appropriate).

1 After surgery.

General principles:
There is no identified survival benefit of clinical follow-up: the MCN is currently in the process of reviewing the evidence available to advice on any clinical follow up that might be required, and the following is provided for interim guidance only.
[Note: Further work aligned within the national Transforming Care After Treatment (TCAT) programme is presently being progressed across the North of Scotland. Further guidance on arrangements will be provided as soon as this becomes identified]

Patients aged < 50

- mammography every 1 -2 years for a follow-up period of at least 3 years until the patient reaches age 50
- thereafter consider discharge to the routine screening programme where appropriate.
Patients aged > 50

- Annual mammograms for 3 years then discharge to routine screening
- Open access nurse follow-up clinics for self referral

After Oncology

Adjuvant patients

All patients in receipt of targeted and/or cytotoxic therapy should be discharged straight after treatment conclusion
APPENDICES

Appendix 1: PROTOCOL FOR RADIOLOGICAL ASSESSMENT OF LUMP

Clinical Examination

Palpable/Confirmed Lump

Age < 25

Ultrasound

U1/U2

U3-5

Age 26-39*

Ultrasound

U1/2

U3

Age <35: See note**
Age ≥35: Mammogram

Ultrasound

Mammogram

[Whole Breast U/S and Axillary U/S if U4/U5]

Core Biopsy +/- FNA

Ultrasound where possible, Hand held if U1

B1

B2

B3

B4/5 Protocod

Discharge to Secondary Care

*Note: Patients aged 26-30 years may not require Core Biopsy if US suggests fibroadenoma
** Indications for mammography to be discussed with radiologist for patients aged < 35
Level of clinical concern may necessitate biopsy irrespective of radiological concern
Appendix 3: AXILLARY PROTOCOL

Axillary U/S

- Normal Axilla
- Abnormal Axilla

  Core or FNA

    - Benign
    - Malignant

Combined blue dye/radioisotope Sentinel Node Biopsy

  - Normal ITC's or Micromets
  - 1 or 2 Macromets
  - >2 Macromets Or Extracapsular Spread *

No further axillary treatment

Axillary clearance or Axillary Radiotherapy or POSNOC

Axillary clearance

Note:
ITC – Isolated Tumour Cells

* Can’t remember if we decided to remove/delete “or Extracapsular spread”
Appendix 4: PROTOCOL FOR BREAST BIOPSY IN PATIENTS TAKING ANTIPLATELET AND ANTICOAGULANT THERAPY

- Take a drug history. If patient on clopidogrel ask about coronary stenting and establish date of insertion.

- Inform ALL patients of the risk of bleeding and haematoma formation – and that this risk is greater for those taking any antiplatelet or anticoagulant medication.

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<th></th>
<th>FNA</th>
<th>Core Biopsy</th>
<th>VACB</th>
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<tr>
<td>Warfarin</td>
<td>Continue medication</td>
<td>INR&lt;4</td>
<td>INR&lt;2.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INR &gt; 4 stop 3days</td>
<td>INR &gt;2.5 stop 3days</td>
</tr>
<tr>
<td>Asprin/</td>
<td>Continue medication</td>
<td>Stop medication for 7 days</td>
<td></td>
</tr>
<tr>
<td>Clopidogrel</td>
<td></td>
<td>excepting as listed below</td>
<td></td>
</tr>
</tbody>
</table>

- Continue Clopidogrel medication in patients who have had:
  - a coronary stent,
  - a Myocardial Infarct (MI) in last 6 months or
  - a recent Transient Ischaemia Attack (TIA).

- One pass core biopsy can be performed on cases not suitable to stop medication.

- Patients requiring a vacuum procedure require individual assessment and planning.

- Stable INR levels do not require rechecking - assess on a case by case basis.

If there are any concerns, consult with patients GP or Cardiologist prior to stopping any medication.

## Appendix 5: AJCC TNM STAGING – 7th Edition

<table>
<thead>
<tr>
<th>TNM</th>
<th>Surgical-Pathologic Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>TX</td>
<td>Primary tumour cannot be assessed</td>
</tr>
<tr>
<td>T0</td>
<td>No evidence of primary tumour</td>
</tr>
<tr>
<td>Tis</td>
<td>Carcinoma in situ (ie pre-invasive carcinoma)</td>
</tr>
<tr>
<td>Tis (DCIS)</td>
<td>Ductal Carcinoma in Situ</td>
</tr>
<tr>
<td>Tis (LCIS)</td>
<td>Lobular Carcinoma in Situ</td>
</tr>
<tr>
<td>Tis (Paget's)</td>
<td>Paget’s disease of the nipple NOT associated with invasive cancer and/or carcinoma in situ (DCIS and/or LCIS) in the underlying breast parenchyma. Carcinomas in the breast parenchyma associated with Paget’s disease are characterised based on the size and characteristics of the parenchyma disease, although the presence of Paget’s disease should still be noted.</td>
</tr>
</tbody>
</table>

| T1  | Tumour <20mm in greatest dimension |
| T1a | Tumour >1mm but <5mm in greatest dimension |
| T1b | Tumour >5mm but <10mm in greatest dimension |
| T1c | Tumour >10mm but <20mm in greatest dimension |
| T2  | Tumour >20mm but <50mm in greatest dimension |
| T3  | Tumour >50mm in greatest dimension |
| T4  | Tumour of any size with direct extension to the chest wall and/or to the skin (ulceration or skin nodules). Note: Invasion of the dermis alone does not qualify as T4 |
| T4a | Extension to the chest wall, not including only pectoralis muscle adherence/invasion |
| T4b | Ulceration and/or ipsilateral satellite nodules and/or oedema (including peau d’orange) of the skin, which do not meet the criteria for inflammatory carcinoma |
| T4c | Both T4a and T4b |
| T4d | Inflammatory carcinoma (see “Rules for Classification”) |

### Regional lymph nodes (N) – Clinical NOTE: there are different criteria for pathologic (PN)

#### NX
Regional lymph nodes cannot be assessed (for example, previously removed)

#### N0
No regional lymph node metastases

#### N1
Metastases to movable ipsilateral level I,II axillary lymph node(s)

#### N2
Metastases in ipsilateral level I,II axillary lymph nodes that are clinically fixed or matted; or in clinically detected* ipsilateral internal mammary nodes in the absence of clinically evident axillary lymph node metastases.

#### N2a
Metastases in ipsilateral level I,II axillary lymph nodes fixed to one another (matted) or to other structures

#### N2b
Metastases only in clinically detected* ipsilateral internal mammary nodes and in the absence of clinically evident level I, II axillary lymph node metastases.

#### N3
Metastases in ipsilateral infraclavicular (level III axillary) lymph node(s) with or without level I,II axillary lymph node involvement; or in clinically detected* ipsilateral internal mammary node(s) with clinically evident level I, II axillary lymph node metastases; or metastases in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement

#### N3a
Metastases in ipsilateral infraclavicular lymph node(s)

#### N3b
Metastases in ipsilateral internal mammary node(s) and axillary lymph node(s)

#### N3c
Metastases in ipsilateral supraclavicular lymph node(s)

### Distant metastasis (M)

#### M0
No clinical or radiographic evidence of distant metastases

#### cM0(i+)
No clinical or radiographic evidence of distant metastases, but deposits of molecularly or microscopic detected tumour cells in circulating blood, bone marrow, or other non-regional nodal tissue that are longer than 0.2mm in a patient without symptoms or signs of metastases

#### M1
Distant detectable metastases as determined by classic clinical and radiographic means and/or histologically proven larger than 0.2mm

Appendix 6: Systemic Anti-Cancer Therapy (SACT) regimens for use in the management of Breast cancer in the North of Scotland

[Note: Appendix 6 is presently available as separately document but once finalised will be included as part of September 2016 review]

Appendix 7: FOLLOW-UP & AFTERCARE

[Note: Appendix 7 is presently available as separately Board sourced documents but once merged and finalised, the intention is to be included as part of September 2016 review]
Source materials & references

Adjuvant On-Line
https://adjuvantonline.com/

American Cancer Society

Macmillan Cancer Support
http://www.macmillan.org.uk/cancerinformation/cancertypes/breast/aboutbreastcancer/typesandrelatedconditions/her2%20positive.aspx

Molecular Pathology Evaluation Panel and Molecular Pathology Consortium

Plastic Surgery - Exceptional Referrals Patient Pathway April 2005
http://www.pathways.scot.nhs.uk/Plastic%20Surgery/Plastics%20Exceptional%20Referrals%20Apr05.pdf

PREDICT
http://predict.nhs.uk/technical.html

Scottish Breast Cancer Screening
http://www.nsd.scot.nhs.uk/services/Screening/breastscreening/index.html

Scottish Urgent Suspected Cancer Referral Guidelines
**ABBREVIATIONS:** The following abbreviations have been used throughout the preceding document

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABS</td>
<td>Association of Breast Surgeons</td>
</tr>
<tr>
<td>ALND</td>
<td>Axillary Lymph Node Dissection/Clearance</td>
</tr>
<tr>
<td>AMAROS</td>
<td>A Clinical Trial - Radiotherapy or surgery of the axilla after a positive sentinel node in breast cancer patients</td>
</tr>
<tr>
<td>BCN</td>
<td>Breast Care Nurse</td>
</tr>
<tr>
<td>BIRADS</td>
<td>Breast Imaging-Reporting and Data System</td>
</tr>
<tr>
<td>CB</td>
<td>Core Biopsy</td>
</tr>
<tr>
<td>CT</td>
<td>Computer Tomography</td>
</tr>
<tr>
<td>DEXA</td>
<td>Dual Energy X-ray Absorptiometry</td>
</tr>
<tr>
<td>DCIS</td>
<td>Ductal Carcinoma in Situ</td>
</tr>
<tr>
<td>EBRT</td>
<td>External Beam Radiography</td>
</tr>
<tr>
<td>FNA</td>
<td>Fine Needle Aspiration</td>
</tr>
<tr>
<td>Gy</td>
<td>Gray – unit of measurement (in Radiotherapy)</td>
</tr>
<tr>
<td>HER-2</td>
<td>HER2 (human epidermal growth factor) is a protein that can affect the growth of some cancer cells. It is found on the surface of normal breast cells.</td>
</tr>
<tr>
<td>LISN</td>
<td>Lobular In Situ Neoplasia</td>
</tr>
<tr>
<td>MCN</td>
<td>Managed Clinical Network</td>
</tr>
<tr>
<td>MDT</td>
<td>Multidisciplinary Team</td>
</tr>
<tr>
<td>SNLB</td>
<td>Sentinel Lymph Node Dissection</td>
</tr>
<tr>
<td>POSNOC</td>
<td>A clinical trial - Positive Sentinel Node adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy</td>
</tr>
<tr>
<td>MDT</td>
<td>Multidisciplinary Team</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
</tr>
<tr>
<td>SACT</td>
<td>Systemic Anti-Cancer Therapy</td>
</tr>
<tr>
<td>SBSP</td>
<td>Scottish Breast Screening Programme</td>
</tr>
<tr>
<td>US</td>
<td>Ultrasound</td>
</tr>
<tr>
<td>VAB</td>
<td>Vacuum Assisted Biopsy</td>
</tr>
</tbody>
</table>
NOSCAN Breast Cancer CMG Development process - summary

Stage 1- Key Developers
Mr Douglas Brown – Surgeon & NHST Breast Lead
Miss Elizabeth Smyth - Surgeon & NHSH Breast Lead
Mr Nick Abbot - Surgeon & deputising for NHSH Breast Lead
+ input from others

Stage 2 - Initial ‘Sense check’ –
Mr Douglas Brown – Surgeon & NHST Breast Lead
Miss Elizabeth Smyth - Surgeon & NHSH Breast Lead
Mr Nick Abbot - Surgeon & deputising for Mr Ian Daltrey, NHSH Breast Lead
Dr Trevor McGoldrick – Medical Oncologist, NHSG

Stage 3 - Executive review group:

<table>
<thead>
<tr>
<th>NHS Tayside</th>
<th>NHS Highland</th>
<th>NHS Grampian</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mr Ian Daltrey – Breast Lead</td>
<td></td>
</tr>
<tr>
<td>Dr Dougal Adamson - Clinical Oncologist</td>
<td>Dr Jayaram Mohanamurali Clinical Oncologist</td>
<td>Dr Ravi Sharma - Clinical Oncologist</td>
</tr>
<tr>
<td>Dr Colin Purdie - Pathologist</td>
<td>Dr Mark Ashton - Pathologist</td>
<td>Dr Lesley Carson - Pathologist</td>
</tr>
<tr>
<td>Dr Andy Evans - Radiologist</td>
<td>Dr Peter Hendry - Radiologist</td>
<td>Dr Gerald Lip - Radiologist</td>
</tr>
<tr>
<td>Avril Gunning – Breast CNS</td>
<td>Karen Daltrey - Breast CNS</td>
<td>Sheila Ingram - Breast CNS</td>
</tr>
<tr>
<td></td>
<td>Russell Mullen – Oncoplastic Surgeon</td>
<td></td>
</tr>
</tbody>
</table>

Stage 4 – formal MCN consultation
Stage 5 – Posting and implementation