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## Document History

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These guidelines should be seen as a living document to be updated and refined as necessary, and at least annually.
1.0 Introduction

The Macmillan Living With And Beyond Cancer (MLWABC) Programme in South Yorkshire, Bassetlaw and North Derbyshire Cancer Alliance is a five year programme of work, across eight CCGs and six acute providers. It is focused on implementing stratified follow-up pathways, Recovery Package interventions and supported self-management for breast, colorectal and prostate cancers.

Risk stratified follow-up pathways improve aftercare services for people living with or beyond cancer by matching the level of support on offer, to individual patients’ holistic and clinical needs, whilst also addressing the likelihood of treatment related side effects and the risks of recurrence.

Three tumour specific groups were set up to engage with multidisciplinary team (MDT) leads, cancer nurse specialists (CNSs), and representatives from radiology and pathology, commissioners and primary care, meeting every quarter. The groups have advised on the refreshing and implementation of stratified follow up guidance for breast, colorectal and prostate cancer patients across the Cancer Alliance to reduce variation in cancer care.

Breast stratified follow-up guidelines were well established across the geography. The Clinical Delivery Group reviewed and agreed refreshed guidelines in March 2018. Two patient cohorts were identified: low-risk and high-risk.

Early on in the pathway, it is explained to all patients that follow-up is a five year process combining clinical input and surveillance. Low-risk patients, assessed as low clinical risk with a lower degree of psycho-social need, are more likely to be followed-up in clinic for one year before moving onto supported self-management. For five years, they will also have routine annual mammograms, organised through an electronic system. High-risk patients, assessed as having either higher clinical risk and/or a higher degree of psycho-social need, also have access to a five year follow up process combining clinical input and surveillance, however this group of patients have more regular face-to-face contact over the five years.

CNSs and cancer support workers (CSWs) provide support to patients before they move onto self-management through the Recovery Package interventions, designed to deliver a person centred approach to care. This includes a holistic needs assessment (HNA) and care planning process. In some trusts, CSWs support the HNA as well as providing information and support. Outside an acute hospital setting, patients have conversations about their needs with experienced care navigators, social prescribers, support workers or volunteers based in a range of organisations. Patients also have access to a range of courses such as the Breast Cancer Care Moving Forward course and the Macmillan Hope course.

30th September 2017, Author: Lynda Wyld, Reader in Surgical Oncology, University of Sheffield, Honorary Consultant Surgeon, Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Updated following 3rd Breast Clinical Delivery Meeting in October 17, 2nd review by Matt Winter and Julia Dicks – draft for discussion. 13th December 2017.

Updated August 2018 for further discussion.
Breast cancer outcomes are improving steadily with 5 year survival rates now over 80% and very low rates of loco-regional recurrence, quoted at 0.2 to 0.5% per year in the latest studies. These advances are multifactorial and due to improvements in surgery and adjuvant therapies, combined with earlier diagnosis due to screening.

As a result of this success, there is a large population of women who are long term breast cancer survivors. They may suffer an array of adverse effects from their breast cancer diagnosis and treatment. These may be severe and life changing or of more minor impact, but all cause concern and may require advice, reassurance or active therapy.

Routine follow up has not been shown to confer a survival benefit for women affected by breast cancer. It may provide psychological reassurance, allow opportunities to manage treatment related side effects, manage ongoing therapies (such as adjuvant anti-oestrogens and bisphosphonates) and ensure that appropriate breast imaging surveillance is in place. In addition post-operative issues such as cosmetic concerns, lymphoedema and psychological issues may be identified and treatment offered. It is therefore important that follow up is not merely considered to be for the purpose of detecting recurrence.

It is recommended that all women have a follow up consultation after the completion of primary treatment to review their holistic needs, ensure they are aware of their ongoing treatment recommendations, define their follow-up schedule and are offered a ‘recovery package’. Education and information provision about adverse events and the symptoms and signs of recurrence should be provided.

Risk stratified follow up should be tailored to the likely needs of the patient, both in terms of the likelihood of treatment related side effects and the risks of recurrence.

2.0 Metastatic Recurrence

For the majority of women who develop recurrence, this will be in the form of metastatic disease, (20-25% over 10 years) which is substantially more common than local recurrence (<5% over 10 years). Routine scans and monitoring of serum tumour markers have never been shown to be advantageous in the earlier detection of metastatic recurrence as there is no survival advantage[1, 2]. Similarly clinical examination does not usually identify this type of recurrence at clinic visits with the majority presenting symptomatically between visits. Therefore the purpose of follow up is not for the early detection of metastatic disease, even in high risk women. Services should have rapid access facilities for urgent referral back into the system, if metastatic disease is suspected.

3.0 Local and Regional Recurrence

Local and regional recurrence (LRR) may potentially be treated with curative intent, and therefore timely diagnosis may be of value in prolonging life[3] and hence imaging surveillance is routine, although the optimal duration and frequency of such surveillance is currently being evaluated by trials such as Mammo 50[4].

Rates of local and regional recurrence (LRR) are falling and are now 0.2-0.5% per year with modern multimodal therapy[5, 6]. There are 2 broad types of LRR, which differ significantly in their prognostic impact. Women with local recurrence after mastectomy, where the disease tends to be linked with high risk primary cancer (aggressive biology, vascular invasion, advanced stage, high grade) and is often associated with metastatic recurrence[7]. This is thought to be due to residual dermal lymphatic permeation remaining after surgery.
and adjuvant therapy. In these women the recurrence usually presents as cutaneous nodularity, usually within the first 2 to 3 years after therapy (60-85% occur within the first 3 years[8]), is often linked to synchronous metastatic recurrence[7] and, if not systemically disseminated, may be challenging to treat/cure locally.

Local recurrence after breast conservation is usually much more variable in timing and prognostic impact and may occur decades after surgery, especially in women with low risk disease. Although it is thought to have adverse prognostic significance[9] there are some subgroups where outcomes are good[10]. It is thought to be due to residual foci of microscopic disease within the breast which was not excised at primary surgery and did not respond to adjuvant radiotherapy and systemic therapy. It is much less likely to be associated with metastatic disease and may cured by mastectomy. This type of recurrence may present symptomatically between clinic visits with a change in the scar, breast contour deformity, a new lump or, more usually, via follow up mammography[11].

The risk of local recurrence varies between patients. Risk factors include positive margins[12-14], high grade disease[15] certain high risk immune-phenotypes (triple negative and Her-2 positive cancer[16]), vascular invasion[17], omission of adjuvant radiotherapy or systemic therapy and young patient age[16]. Many of these risk factors will more than double the rate of local recurrence relative to the UK average. The risk of recurrence tends to be in the first few years in patients with high risk disease, where it has more adverse prognostic significance[16] but may occur over several decades in women with low risk (low grade, ER+) disease. There are on line calculators which may be used to estimate LRR risk such as IBTR[18]. For women with DCIS only, recurrence risk is minimal after mastectomy (1%) but higher after conservation surgery and risk may be predicted using a range of scoring algorithms such as the modified van Nuy’s Prognostic Index[19] and more recently with DCIS arrays[20]. The risk is once again dependant on tumour size, biology, margin status, adjuvant therapy and age.

Source – see page 15 for references

4.0 Treatment Related Adverse Events

A major cause of concern and reduced quality of life for breast cancer survivors are treatment related side effects. The majority of these may be treated and should be actively enquired about so that treatment may be offered.

Some side effects are transient and usually resolve spontaneously (radiotherapy induced breast inflammation, chemotherapy induced hair loss), with management offered during the treatment phase. Some are on later. Examples include depression, anxiety, lymphoedema, menopausal symptoms, joint pain and cosmetic concerns. An appointment after completion of active treatments is therefore beneficial.

5.0 Management of Late Effects (LE)

Over the past two decades, increasing attention has been given to understanding the long-term and late effects experienced by cancer survivors as a result of their cancer diagnosis or treatment. Long-term (side) effects caused by cancer or its treatment that are present during treatment and may persist for months or years may be physical or psychosocial in nature.

In contrast, late effects of the cancer or cancer therapy may occur months or even years after a cancer diagnosis and again may include second cancers, physical problems, or
psychosocial issues. Along the cancer continuum, there are at least three distinct phases: from diagnosis to the end of initial treatment, the transition from treatment to extended survival, and long-term survival. While clinical practice guidelines exist for diagnosis and treatment, there are few evidence-based clinical care guidelines for posttreatment care.

The ever increasing number of cancer survivors living posttreatment poses a challenge to oncology and primary care clinicians to provide ongoing optimal clinical follow-up care.6 To meet this demand, it is important to equip primary care clinicians with the necessary resources to recognize and manage the health risks and maximize quality of life (QoL) of cancer survivors.


**How late effects care can be integrated into the risk stratified pathway**

The purpose of follow-up for some clinicians can focus on clinical care, psychosocial support and surveillance tests to check for recurrence of disease. It is therefore imperative that late effects screening and management is specifically detailed.

The risks of late effects increase with disease and treatment intensity so it is linked to risk stratification. The risk stratified model recommends an MDT approach to complex cases. This includes management of late effects.

In relation to late effects when implementing this risk stratification guidance patients should be categorised into 3 groups:

**Low risk (disease)**

Low risk patients who are deemed fit for self-management – common late effects associated with treatment should be communicated a) with the patient at diagnosis b) on the treatment summary along with the necessary screening required and the frequency of screening for GPs to do C) as part of a scheduled meaningful conversation at the end of or approaching the end of definitive treatment.

**Medium Risk**

For patients who are medium risk and are on nurse led follow-up – the same common late effects (and specific where necessary, clinically appropriate) associated with treatment a) with the patient at diagnosis b) on the treatment summary along with the necessary screening required and the frequency of screening for nurses to do C) as part of a scheduled meaningful conversation at the end of or approaching the end of definitive treatment.

**High / complex risk**

For complex cases who will stay under the care of a MDT- the same common late effects associated with treatment plus specific late effects according to treatment a) with the patient at diagnosis b) on the treatment summary along with the necessary screening required and the frequency of screening for physician/surgeon to lead on/facilitate C) as part of a scheduled meaningful conversation at the end of or approaching the end of each treatment line.
Core commonality in current practice across the LWBC programme (August 2018)

- **Under the new plans** high risk patients will continue to be followed up, with the lower risk patients discharged at the end of treatment (EOT) appointment.

- High risk women will follow the standard follow up pathway; EOT appointment, at appointments at 3 years and 5 years.

- The treatment summary and in particular end of treatment summary includes information around the consequences of treatment / late effects.

- Breast patients are offered the Moving Forward course which informs patients about late effects and offered the Moving Forward booklet.

- Patients have open access for up to 5 years so they can arrange a further appointment if they have any concerns. After 5 years, the GP refers back to the Trust.

- Patients are aware that they may contact the Breast Care Nurse with a new problem & are directed either to the GP or book them into the appropriate clinic or advice & talk through the concern.

- All high risk patients from MDTs and Oncologist’s are referred to the STH LE clinic.

- Patients are supported with the consequences of treatment via various ways: from information to referral to support resources to address physical symptoms to additional information within the newly designed Treatment Summaries.

- ALL patients are advised to contact cancer teams if they have any concerns.

- The recommendations for the End of treatment (EOT) appointment are being delivered by the CNS at the EOT Holistic Needs Assessment (HNA), which all our patients are offered.

- ALL patients are informed by letter of a plan of yearly mammograms for 5 years.

- Endocrine therapy is discussed with the patient. It is switched, stopped or continued as appropriate to the patient’s treatment plan (which will have been confirmed at the post treatment visit to the Breast Care nurse. The plan is usually made by the oncologist).

- In some cases, guidelines have changed to include the offer of extended adjuvant treatment. Patients are informed about their options. Low risk patients will be advised that risks outweigh benefits, high risk patients are advised of the benefits of extended adjuvant treatment and intermediate risk patients have a free choice. We take into account risks and side effects of treatment. Menopausal status is taken into account and a blood test done if uncertain. If the nurse practitioner is unsure about the advice to give, they consult with a surgeon or oncologist, usually while the patient is there but occasionally they have to bring the patient back to their own clinic or an oncology clinic.
To note – the Holistic Needs Assessment (HNA) is not a tool for identification, assessment or monitoring of late effects.

**Summary of adverse effects of Breast Cancer Therapy**

- Anxiety
- Chronic Pain
- Lymphoedema
- Body Image
- Implant problems (leakage, capsule formation)
- Neuropathic pain Infertility after Chemotherapy
- Cardiac issues
- Breast oedema
- Breast fibrosis
- Hot flushes
- Osteoporosis
- Joint pain
- Endometrial hyperplasia and neoplasia
- Fertility issues
- Recurrence risk
- Increased familial risk of second primary
- Bone Issues

**7.0 Risk Stratified Imaging Follow-up**

For most women, mammographic screening after breast conservation surgery is advised on a yearly or biennial basis for 5 years after diagnosis. There is evidence that early detection of local recurrence may have a survival advantage with recurrences of 10mm having better survival rates than those with 20mm tumours[3].

Thereafter routine 3 yearly screening via the NHS BSP is advised unless they are at an increased familial risk, when they may be offered extended enhanced screening as per the NICE Familial breast cancer guidelines[21]. Women who are known BRCA gene carriers have a 4 fold increased risk of developing a new contralateral primary cancer and a 10-25% increased risk of an IBTR compared to non-BRCA carriers [22] and hence surveillance for these women should be more frequent up to age 70 (unless they have had bilateral mastectomy in which case they will require no formal breast imaging).

There are also a small minority of women who may theoretically benefit from MRI surveillance if they have had a mammographically occult primary cancer and have dense breasts. MRI is the most sensitive modality for the detection of invasive breast tumour recurrence [3] compared to clinical examination and mammography but is not currently funded by the NHS for this indication.

For women who have had a mastectomy for their primary cancer, mammographic surveillance is simply enhanced screening of their contralateral breast. For older women who are over the age of normal screening, and especially those who are frail or suffer with significant co-morbidities, there is little logic in arranging contralateral breast mammography. This should be discussed on a case by case basis with the patient.
For women who have had breast conservation, imaging of the affected breast is performed to look for local recurrence. This is usually performed annually for 5 years, followed by routine triennial screening via the NHS BSP. The below diagram shows the algorithm for breast imaging following a breast cancer diagnosis.

8.0 Anti-oestrogen therapy

All women with ER positive breast cancer are offered a minimum of 5 years of anti-oestrogen treatment. This is in the form of tamoxifen (plus or minus GnRH agonist injection) for premenopausal women or an aromatase inhibitor (AI) if post-menopausal. For women with high risk cancers, these treatments may be extended to 10 years. Whilst patients currently are being commenced on therapy will have treatment plans that specify whether 5 or 10 years of therapy is appropriate, women diagnosed more than 2 years ago may not be aware of the benefits of extended adjuvant therapy and review at 5 years allows the opportunity for review of their ideal therapy duration. Patients who have undergone premature ovarian suppression or started on an AI should have a DEXA scan and appropriate bone health management. The recommendation for DEXA scans needs to take into account concurrent use of adjuvant bisphosphonates to prevent recurrence and patients receiving adjuvant bisphosphonates do not routinely require DEXA scanning.

9.0 Adjuvant BPs

Post-menopausal women with invasive breast cancer at sufficient increased risk (>12% 10 year risk of breast cancer death) will be offered a bisphosphonate for 3 years duration in order to reduce the risk of bone recurrence and improve breast cancer survival. Refer to local guidelines for the recommended bisphosphonate regimen and schedule.
10.0 Risk Stratified Clinical Follow-Up

As mentioned above clinical follow up has little value for the diagnosis of metastatic recurrence and rarely identifies local recurrence which is usually identified after symptomatic self-referral or by routine imaging. Imaging is much more sensitive than clinical examination in this respect. One large Dutch study found that 262 imaging tests versus nearly 1400 clinical examinations were needed to diagnosis one LRR[11]. However women may have a range of clinical concerns and side effects relating to their adjuvant therapy and suffer side effects from their surgery, radiotherapy or chemotherapy.

The recommendation is to see all women on completion of treatment (end of treatment [EOT] appointment) to review the follow-up plan, ensure they have no side effects from their anti-oestrogens or their previous treatments, ensure they have appropriate mammographic surveillance arranged and ensure they have no major psychological issues or informational needs.

A low risk group of women who are unlikely to benefit from clinical follow up for their breast cancer may be discharged at this end of treatment appointment from clinical follow up if they have no ongoing problems following therapy. This group include:

- Patients who have had lower risk cancers for metastatic recurrence (NPI <3.4 if ER negative and <4.4 if ER positive), and if Oncotype testing has been performed (in ER+ve, HER2-ve , node negative patients), those patients with lower-risk Recurrence score (<25)
- Low risk for loco-regional recurrence (ER+ve, <2cm, HER2-ve, node negative, clear margins)
- DCIS only
- No serious adverse events at their end of treatment appointment
- Patients whose life expectancy is likely to be low due to non-breast cancer causes (extreme old age, frailty, severe co-morbidities, prior diagnosis of terminal non-breast cancer) regardless of breast cancer risk.

A schematic for low risk clinical follow up is shown below:

![Flowchart showing low risk clinical follow up](image-url)
Patients who are likely to benefit from face to face consultation at 3 and 5 years will follow the standard clinical follow up pathway. These patients include:

- Higher risk patients (all chemotherapy and biological therapy, axillary clearance surgery).
- Young patients with possible fertility issues.
- Patients who struggled psychologically with diagnosis or treatment or have a history of mental health problems, or patients with learning difficulties where self-care may be a concern.
- Patients who did not comply with standard management.
- Patients who suffer side effects from their cancer therapy and would benefit from ongoing review (cardiac problems after chemotherapy, significant breast or arm oedema, post-operative pain etc).

Patients will be seen at 3 and 5 years post diagnosis, as most NHS trusts have the facilities to book appointments up to 2 years in advance. At 5 years they will be discharged to the care of the GP with instructions about whether they require ongoing anti-oestrogen therapy. The GP will manage longer term therapy beyond 5 years.

A schematic for standard clinical follow up is shown below:
11.0 References


26. NICE 2018 - Early and locally advanced breast cancer: diagnosis and management - NICE guideline

27. NABON 2012 *Breast cancer, Dutch Guideline*, version 2.0