

## **Quality Standards for Breast Cancer Units within Greater Manchester – Supporting Information**

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**“Commitment to quality - the pathway to success”**

## Greater Manchester Cancer

### Breast Pathway Board

Outlining the quality standards expected from all Diagnostic Breast Cancer Units within the  
Greater Manchester Region

#### Greater Manchester Cancer Breast Pathway Board

#### Keywords

Greater Manchester Cancer Breast Pathway Board (GMCBPB), Clinical Commissioning Groups (CCGs), symptomatic breast services, screening breast services, Greater Manchester (GM).

#### Mission Statement

The Greater Manchester Cancer Breast Pathway Board (GMCBPB), made up of clinical leaders from different Trusts and supported by other related professionals (including primary care clinicians, commissioners and people affected by cancer), is committed to provide the highest quality care to patients referred to the Breast services across Greater Manchester.

The GMCBPB has set out in the following document our 'commitment to quality', and a vision of clinical standards that will guide the delivery of these high quality services within Breast Units throughout the region. This document does not attempt to encompass the (neo) adjuvant treatment of patients with primary or metastatic breast disease. In Greater Manchester this management is guided by oncologists employed by the Christie Hospital.

#### Current GM Breast Services Configuration

Breast services in the UK fall into two broad categories: symptomatic services, which are commissioned locally by clinical commissioning groups (CCG's) and breast screening services, which are procured through NHS England. Within Greater Manchester (GM) the following trusts provided breast services in 2015. The nature of the service provided at each trust and the number of new breast cancers diagnosed each year is set out below:

Trust	Service type	New cancer cases 2015
Bolton	Screening/symptomatic	440
CMFT	<i>No breast service – SPC pts only</i>	4
East Cheshire	Screening/symptomatic	301
Pennine	Symptomatic only	406
Salford	Symptomatic only	156
Stockport	Symptomatic only	185
Tameside	Symptomatic only	159
UHSM	Screening/symptomatic	789
Wigan	Screening/symptomatic	422
Christie	<i>First adjuvant treatment</i>	23
GM total		2885

<https://nww.cancerstats.nhs.uk>

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In 2016, Salford Royal Foundation Trust subcontracted out their breast service to University Hospital South Manchester as an interim measure. A sustainable solution will be developed led by Salford CCG, in collaboration with UHSM and breast units from the North West sector of GM.

In 2009, an independent review of breast services in the GM was undertaken. The subsequent report by Prof Martin Lee was unequivocal around the need for change to ensure high quality and equitable services for all patients within the region. **The Lee Report concluded that whilst services in 2009 were clinically safe, they were not future proof.** Quality Assurance standards in breast screening are high and subject to rigorous peer review every 3 years as part of the NHS Breast Screening Programme. Although breast units which manage symptomatic patients only are expected to comply with national cancer standards, they are not subjected to the same rigorous review as the screening units. Consequently, the Lee report recognised that there is a clear potential for a widening gap in the standard of breast cancer services provided in symptomatic only and combined units.

Different configurations (alignment and integration) of breast services in the region have been suggested, but seven years on no changes have taken place because of the recommendations within the Lee report. The GMCBPB recognises the need for change and wishes to outline in this document the quality standards expected for **all** breast units within the GM and the need for partnership and alignment/integration with screening services. The ultimate aim is to provide equitable, high quality care that is sustainable and future proof.

The methodology used to describe the standards is a combination of literature searches, consensus statements and leading expert opinions/panels (see references). The recommendations are generic and scalable depending on the size of the population served. This document does not attempt to reconfigure services; this is the responsibility of local commissioners.

To reach the standards outlined in the text there will need to be a critical appraisal of the current infrastructure, work force and IT systems (which is the subject of a parallel piece of work). The agreed clinical standards will be mandatory for all breast service providers and will be an aid for commissioners.

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#### **Global Objectives**

1. To eliminate regional variation in patient experience in terms of access to breast specialist diagnostic services, surgical management, cancer outcomes, patient survivorship and holistic care.
2. To establish world-class breast centres which will have all the necessary expertise, resources and work force to provide gold standard care for all patients. All services will be primarily based at these centres.
3. To best utilise a finite number of breast specialists in the GM Breast Cancer System to achieve this goal.
4. To apply best practice consistently throughout the network with the universal application of all NICE and regional pathways and agreed quality standards to improve overall cancer survival rates.
5. To share outcome data (including overall survival and patient reported outcome measures) throughout GM so that areas in need of improvement can be identified early and acted upon appropriately. This data needs to be readily available to commissioners of the service.

#### **Current Difficulties Identified within the GM Region**

A key challenge within the region is to ensure that in each breast unit, there are sufficient key members of the breast care team to provide cross cover and ensure that patient management discussions take place in multidisciplinary team meetings with relevant key specialties in attendance.

The current demand for new patient referrals is unprecedented and unlikely to diminish, as breast symptoms are common in primary care with the incidence of breast cancer of 1 in 8 in the UK.

The biggest pressure in terms of service delivery is the lack of capacity to see the increasing demand of new patients referred to “one stop” breast clinics. Smaller units will struggle to meet this consistent demand over a 52-week period during periods of leave. This situation is compounded by a national shortage of specialist breast radiologists. The GMCBPB is committed to using all expertise within the region efficiently and effectively and to improve the standard of care experienced by all patients treated. For this to occur, each unit within the Region should comply with the quality standards, described below.

**Quality Standards for GM Breast Units**

*Patient Population and Cancer Volumes*

A meta-analysis of available evidence has shown that survival after breast cancer surgery is improved in high-volume breast centres (Gooiker et al. 2010), with one of the larger population-based studies demonstrating that centres that treat >150 cancers per annum have statistically better outcomes (Vrijens et al. 2012).

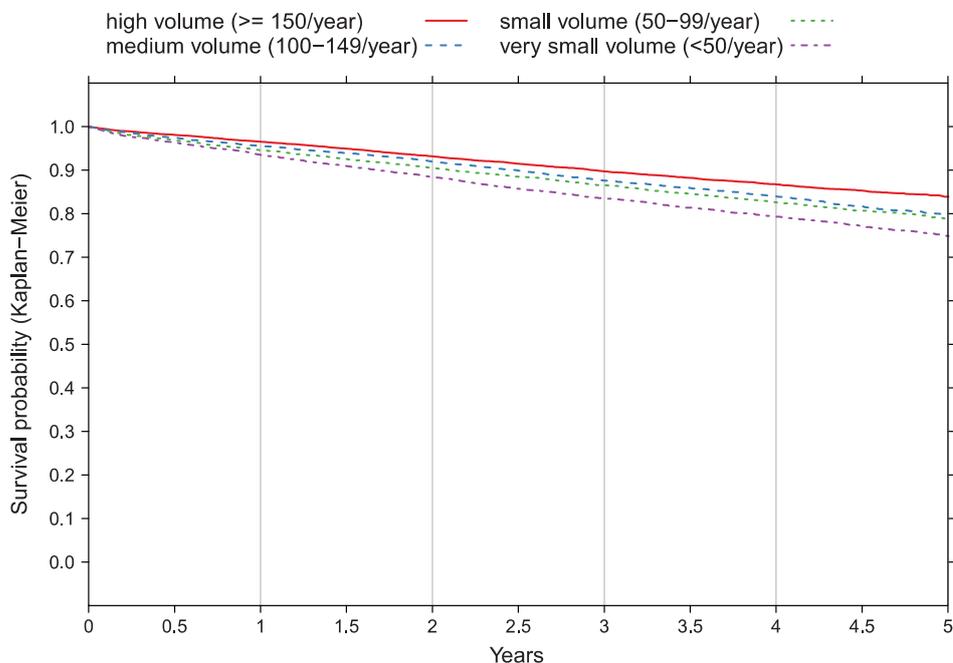


Fig. 1. Survival curves by hospital volume.

(Taken from Vrijens et al 2012).

European guidelines therefore state that a specialist breast centre should treat a minimum of 150 cancers per year and should serve a population base of at least 250 000 to maintain expertise (Wilson et al. 2013). The GMCBPB, following extensive consultation, recommends that each unit should strive to exceed this minimum standard and treat a minimum of 300 cancers a year. This number would allow each specialist breast surgeon within the unit to surgically treat at least 50 cancer per annum to maintain expertise (allowing for drop out of women who chose not to undergo surgery or are medically unfit). This is assuming there is a minimum of 3 whole time equivalent (WTE) surgeons working within each unit to ensure effective MDT working and annual leave cover,

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as suggested by the GMCBPB later in this document. Staff grade surgical support should also be available as needed.

#### **The “One Stop” Diagnostic Breast Clinic (Triple Assessment)**

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The diagnostic assessment of patients with breast symptoms is based on the Multidisciplinary “Triple Assessment” method. Each new patient symptomatic assessment clinic should offer (where deemed clinically appropriate):

1. Clinical assessment
2. Radiological assessment
3. Pathological assessment

These should be available at the first symptomatic clinic visit for the majority of patients in all breast units (**target  $\geq 98\%$  of patients**). There should be clear and efficient administrative links between surgeons, radiologists and pathologists to ensure efficient service delivery, best use of resources and effective clinic scheduling.

#### **MDT Facilities and Working**

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In the UK, multidisciplinary team working (MDT) is a mandatory component of breast cancer care. The MDT working is regulated through a National Quality Assurance Framework that assesses adherence to national cancer standards. The GMCBPB recognises the importance of MDT working and recommends that all units should adhere to national guidance in terms of facilities, staffing, administrative support and working processes (Characteristics of an effective MDT 2010).

To allow such a service to work effectively and efficiently, each breast unit requires a minimum number of key personnel. The descriptions below describe the quantity and level of expertise required to provide high quality MDT care. Where specific data/guidance is lacking in the literature regarding certain measures the GMCBPB through consensus of its members have put forward sensible standards with the explicit intent of improving quality and help to build in resilience to an already over-stretched service within Greater Manchester.

**Clinical Services**

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**Radiology**

Although the Royal College of Radiologists (The Royal College of Radiologists 2013) and Eusoma (Wilson et al. 2013) suggest that preferably all specialist breast radiologists should participate in both screening and symptomatic imaging work, they acknowledge that this ideal is not always possible or practical within the UK. Therefore, there are different professional standards, set out for screening and symptomatic only specialist breast radiologists within the UK. Whereas screening mammography should only be interpreted by readers who satisfy the professional standards required by the NHSBSP (NHSBSP 2011), the Royal College of Radiologists states that specialist radiologists involved in interpreting symptomatic only breast imaging should:

1. Interpret and report on a minimum of 500 symptomatic mammograms per annum
2. Have designated time in their job plan to be involved in the MDT assessment of symptomatic breast patients
3. Have at least three programmed activities within their job plan dedicated to breast assessment. This should include participation in diagnostic breast clinics which are organised in such a way that direct and timely consultation with other members of the clinical team can occur (The Royal College of Radiologists 2013).

The GMCBPB agrees that radiologists within GM should have at least three programmed activities dedicated to breast assessment to comply with these regional standards.

A table summarising and comparing the UK standards for screening and symptomatic specialist breast radiologists is provided in Appendix 1 of this document.

European guidelines are even more stringent, recommending that each symptomatic specialist breast radiologist within a unit should read a minimum of 1000 mammograms per annum, and that double reporting should be encouraged if the mammogram workload is 3000 per annum or less within a unit.

The GMCBPB is aspirational and striving for excellence and therefore recommends for there to be integration of breast radiology expertise within the region, to allow each breast centre to benefit from screening and symptomatic radiology expertise. Each centre should have a minimum of three

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consultant Breast Radiologists working within the unit, all of whom should contribute to symptomatic clinics and MDT working. At least one of these radiologists should also participate and meet the professional standards required by the NHSBSP (NHSBSP 2011).

The GMCBPB recognises and values the high quality service provided within the region by other breast imaging specialists including advanced practitioners, consultant mammographers, breast physicians, mammographers and assistant practitioners. Multi-professional working within specialist breast imaging is actively encouraged by the GMCBPB and it is recognised that the efficiency and quality of the breast service can be enhanced through multi-professional working in breast imaging.

Mammography and breast ultrasound reporting by all imaging specialists should be completed using recognised and recommended descriptive terminology and include details of site, imaging size and nature of any abnormality with an opinion as to the likely diagnoses and recommendations for any further diagnostic procedure or intervention as per Royal College Guidelines (The Royal College of Radiologists 2013). It is also recommended that all breast imaging specialists should participate in personal breast imaging audit and MDT service audit – this will be included in the GM Breast Pathway Board audit programme. All specialists should also comply with the requirements for training and continuing professional development as prescribed by the Royal College of Radiologists and associated bodies.

### **Pathology**

The Royal College of Pathologists recommends the reporting of breast pathology by specialist breast pathologists working in CPA accredited laboratories. The GM Breast Service should aim to have at least three specialist pathologists per breast centre to cover leave and effectively support MDT working.

As breast pathology specialists, each practitioner should report at least 50 breast cancers per annum, reported according to the national quality assurance guidelines provided by the NHS BSP and Royal College of Pathologists (NHS Cancer Screening Programmes & The Royal College of Pathologists 2005). Each service should achieve Royal College of Pathologists key performance indicators.

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Any patient with a core biopsy taken and reported upon needs to be discussed with the relevant clinical information in a multidisciplinary meeting attended by all the key members as recommended by NICE (National Institute for Clinical Excellence 2002), regardless of the degree of suspicion. This ensures concordance between clinical, radiological and pathological results before options for the patient's definitive management can be agreed with the patient.

### **Surgery**

The operative management of all breast cancer patients will be discussed at a pre-operative multidisciplinary meeting with all key specialities represented.

The Royal College of Surgeons and the Association of Breast Surgery recommend that all surgical treatment of patients with breast cancer must be carried out by surgeons with a specialist interest and training in breast disease with each individual surgeon operating on at least 30 cancers per annum (Association of Breast Surgery 2009). More recent European guidelines state however that individual breast surgeons should be operating on at least 50 new breast cancer cases per annum to maintain expertise (Wilson et al. 2013) and this is the minimum standard that the GMCBPB recommends within its units.

Surgeons within each unit should audit their own practise and aim to comply with the guidelines set out by the Association of Breast Surgeons (Association of Breast Surgery 2009). Particular attention should be paid to local recurrence rates after breast conserving surgery and mastectomy (<5% at 5 years for invasive breast cancer, with an aspirational recurrence rate of 3% at five years and <10% recurrence rate for DCIS at 5 years). The GMCBPB expects that all units will audit recurrence rates and share outcome data regularly to ensure standards are met. Results of these audits will be discussed at pathway board and published regularly.

Oncoplastic and reconstructive breast surgery is now a minimum standard of care for patients with breast cancer and all breast units within GM should offer this service and comply with the standards set by the Association of Breast Surgery (Rainsbury & Willett 2012). Importantly, recurrence rates in patients undergoing skin-sparing mastectomy should be comparable to a matched population undergoing simple mastectomy, to ensure oncological treatment is maintained. A table summarising the oncoplastic guidelines minimum standards is shown in appendix 2.

It is recommended that each patient considering breast reconstruction should be discussed at a multidisciplinary meeting (Rainsbury & Willett 2012). The GMCBPB suggests that this discussion should take place at a MDT attended by at least two oncoplastic breast surgeons. All available options for reconstruction should then be discussed with the patient.

Units specialising in free flap procedures should perform a minimum of 50 procedures per annum. Medical photography must be available in all breast units so that patients undergoing immediate or delayed breast reconstruction have pre-operative and post-operative medical photographs taken as part of their medical record (Rainsbury & Willett 2012). This must meet Caldicott guidelines and images must be stored on PACS or an equivalent platform.

It is recognised by the Association of Breast Surgeons that within a region, not every unit will be able to manage more complex revisional oncoplastic breast surgery and micro-vascular procedures. GMCBPB suggests that the referral of patients requiring complex revisional oncoplastic surgery should be to units with this particular expertise. Outcome data for such cases (including unexpected readmission rate, unexpected return to theatre rate, implant loss rate, flap loss rate, PROMS data) should be readily available however and shared openly across GM. Patient data should also be entered into National Audit databases such as the current “iBRA” audit. The GMCBPB will agree standard audits for services, participation will be mandatory.

Pathways and arrangements for microvascular referrals within GM will be developed, as services should only be available in a small number of centres within the region to ensure the quality standard for minimum caseload is met. The GMCBPB suggests that a regional centre should be performing an adequate number of free flap procedures per year to maintain expertise and that patient outcome data should be audited regularly and shared.

### **Oncology**

Although the remit of this document does not cover the standards required for (neo) adjuvant therapy for breast cancer patients within Greater Manchester, it is important to stipulate that to meet national quality assurance standards, a clinical oncologist must be available at every post-operative MDT meeting to discuss the appropriate adjuvant treatment of each patient. Where

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possible a medical oncologist should attend, and this is mandatory if the local clinical oncologist does not specialise in chemotherapy. The GMCBPB therefore recommends that to support MDT working and to ensure cover for annual leave, each breast unit should have the minimum of two named, oncologists (National Institute for Clinical Excellence 2009; Wilson et al. 2013).

As well as being offered standard (neo) adjuvant therapies as recommended by NICE (National Institute for Clinical Excellence 2009), patients should be actively recruited into clinical trials where appropriate and the number of patients recruited from each unit within the region should be audited. Each unit within the Region should aim to recruit 7.5% of patients into interventional trials and 20% into therapeutic trials.

### **Nursing , Allied Health Professional, and Living With & Beyond Cancer**

The recommendations outlined in screening guidelines along with national breast cancer standards underpin the Nursing/AHP standards and are reflective of other NHS publications.

The psychological wellbeing and care of women in the NHSBSP and symptomatic breast service and those diagnosed with advanced breast cancer, is dependent on the provision of a high quality specialist nursing care. As a core member of the MDT, the clinical nurse specialist (CNS) must ensure that all women receive high quality evidence-based care and information irrespective of the route of referral.

In the cancer setting the CNS is universally recognised to be a core member of the multidisciplinary team (MDT) and plays a crucial role in improving the overall quality of cancer care (Sullivan2007). Both breast screening and symptomatic guidelines state that a breast CNS should be present when bad news is given to a patient (NHSBSP 2009) and should provide on-going support and information at all key stages throughout the patient's journey. It is well recognised that the negative effects associated with high levels of anxiety can be mitigated by an effective CNS, making this role pivotal to the provision of a high-quality breast service. Many studies have demonstrated the value of the CNS in identifying and reducing psychological morbidity in women diagnosed with breast cancer (McQueen 2009, Videll et al 2011).

It is also important to recognise the needs of patients when they are diagnosed with advanced breast cancer as different from those with primary disease. The Breast Cancer Care Secondary

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Taskforce (2008) identified that patients often felt they had less support second time around, because health professionals assumed they knew what to expect. Higher levels of psychological morbidity are seen in this patient group (NICE 2004).

Face to face contact with the CNS should be available at key stages throughout the patient pathway including: a diagnosis of cancer, when recurrence, disease progression or metastatic disease is suspected or confirmed.

The Breast CNS should be available for psychological and informational support to all patients who have been diagnosed with breast cancer across the full patient pathway: from diagnosis, during treatment, including primary and adjuvant treatments, and living with and beyond cancer and for support while receiving palliative treatment

People with primary, recurrent or advanced breast cancer should have access to a named Key Worker. At key points of the patient pathway, the key worker/CNS should assess the individual's holistic needs (physical, social, psychological, and spiritual needs) and ensure appropriate support is provided and documented in a care plan. All CNS should assess for significant psychological morbidity and refer directly when specialist services are required. All CNS should have level 2 psychological support skills as this is a national quality assurance requirement and recommended by NICE.

Telephone support is a valid cost effective and convenient means of care delivery, which can lead to reduced levels of anxiety, and negates the needs of the patients to attend multiple hospital appointments thus leading to a better use of patient and clinician time. It is recognised by all members of the multidisciplinary and primary care teams with patient initiated activity recorded as a telephone clinic in line with national guidance. Appropriate nursing records should be maintained in line with NMC (2009), Caldecott, NBSP and employing Trust guidelines.

Where nurses work in breast units undertaking tasks that were formally carried out by doctors, the nurse must not undertake the extended or advanced practice until accredited training has been undertaken and clinical competence is verified. Suitable protocols for the extended role must be in place (James 2011, Hutchinson 2011). Those nurses who extend their role must be made aware they will be legally responsible for their actions and all job descriptions should include details of role

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advancement/ extension. The CNS/ANP should audit their own clinical practice, pathways of care, and patient experience

When cancer is diagnosed a minimum of 1 WTE CNS per 75 new cases is required to fulfil the role of supportive care from diagnosis to discharge. A breast unit managing 300 new cases of breast cancer would be expected to have 4-5 WTE Breast CNS to allow for adequate cover during periods of leave. Due to the lack of data collected around advanced breast cancer, there is no national consensus or guidance for the number of WTE CNS required to support this patient population, although there is evidence of unmet need (NICE 2004).

Extended and Advanced practice is not included in this calculation and will require additional staffing depending upon the demands of the service with the establishment adjusted accordingly. Extended duties must be adequately funded so as not to compromise the standard of existing supportive care for women. Specialist, extended and advanced practice roles require high levels of experience and skills. Consideration should be given with robust business planning, to the introduction of development of associate CNS and Trainee ANP roles to provide a sustainable future proof workforce.

Programmes relating to LWBC, survivorship and Living with Secondary Breast Cancer form an integral part of the breast care nursing role. When new programmes are developed skill mix and liaison with Allied Health Care Professionals should be considered with robust business cases to support workforce/establishment changes.

All breast outpatient clinics within GM should be supported by dedicated and appropriately skill clinic nursing teams who have an understanding of the psychological needs of the patient population and are able to assist with all clinical procedures undertaken. A designated breast ward and appropriate day-case facilities should be available with nurses educated to the same standard as outpatient staff.

Cancer rehabilitation has 4 key components, preventative, restorative, supportive and palliative. Historically the importance of breast cancer rehabilitation has been under represented and subsequently under resourced across large areas of Greater Manchester. The Greater Manchester Cancer Living With and Beyond Cancer Pathway Board recommend rehabilitation be a core consideration for each site specific cancer and it is important to include this service in all breast

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cancer units. Rehabilitation and reablement are fundamental to ensuring that we maximise the effect of treatment for people with cancer. It is not an optional 'add on' but integral to high quality, cost effective care (NCAT 2013).

Physiotherapy for primary breast cancers should provide accelerated recovery from treatment through prehabilitation (Prehab) and then access to rehabilitation, delivered by a level 3 physiotherapist. Enhanced recovery makes this more important and should be available to all patients to minimise risk of future complications, by educating, encouraging self-management, promoting physical activity and signposting to local services as part of the recovery package. For those who require more complex interventions for either primary or advanced disease there should be locally available specialist service with level 4 skills (NICE 2002) to deliver a timely intervention.

All patients should also have timely and local access to specialist lymphoedema, psychological, genetic and prosthetic services if required. Patients should be signposted to support services such as benefits advice, complementary therapy, based on holistic needs assessment. It is acknowledged that there are differences in referral patterns across GM due to local commissioning arrangement but all patients should be afforded the same quality of specialist care regardless of the point of delivery.

The long term effects of lymphoedema on quality of life and cost of care are well known. Patient education on prevention, skin care and appropriate exercise are crucial parts of the treatment for each 'at risk' breast patient and should be delivered by an appropriately trained practitioner in each unit. When patients develop lymphoedema, prompt access to appropriate services will give better long term outcomes and prevent more chronic physiological changes (Macmillan 2015). Specialist services should be available for moderate to severe cases to reduce complications, and avoid costly hospital admissions. Nationally the optimum number of lymphoedema patients per WTE specialist practitioner for all categories of lymphoedema including prevention is 150.

There are different pathways of care across GM for the management of patients with recurrent/metastatic disease, with many patients travelling to the Christie for adjuvant/palliative chemotherapy. Previously such patients have been supported by Christie Breast CNS team. In line with recent service redesign, following a review of the Christie Breast CNS activity, only metastatic patients will be managed with local breast services being required to support for patients undergoing adjuvant treatments closer to home.

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## Resources and Specialist Equipment

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To ensure the highest quality, efficient and convenient breast service within the Greater Manchester area, the GMCBPB recommends that all specialist breast centres should provide breast-imaging facilities within an integrated, dedicated breast unit, in keeping with national guidance (Willett et al. 2010).

### Radiology Equipment

Each breast unit should be equipped with a minimum of two digital mammography machines as well as two high-resolution ultrasound machines for diagnostic and therapeutic purposes. This allows for one machine to be utilised for stereo-tactic biopsy and localisation procedures (for the smooth running of theatre lists) and one for symptomatic imaging (for concurrent new patient clinics). The absolute number of machines (above the minimum standard) will depend on workload/activity and should be adjusted accordingly. To allow image-guided biopsy, and an accurate pre-operative diagnosis in the majority of cases (reducing the need for surgical excision biopsy) the GMCBPB recognises that each unit also requires stereotactic and vacuum assisted biopsy equipment and expertise. A breast unit must also provide the facilities and training to allow the safe pre-operative injection of technetium<sup>99</sup> into the breast for sentinel lymph node biopsy. Access to nuclear medicine imaging is preferable but not essential.

Digital tomosynthesis is a relatively new imaging modality that is being adopted by modern-day breast units as it can improve the assessment of dense breast tissue and can reduce the need for patient recalls for further imaging and assessment, thereby improving the patient experience and increasing clinic efficiency. The GMCBPB recognises that to future-proof GM breast services, each breast unit within the region will have access to digital tomosynthesis equipment in the future.

Although the need and demand for MRI-guided biopsy is relatively low, all breast units within the Greater Manchester region should have **open** access to timely MRI guided biopsy equipment and expertise. At each MR biopsy site there should be at least two radiologists trained in the technique to allow cover for annual leave. It is not essential for every unit to have this on site, but there should be an agreed referral system in place within the region to allow for safe and efficient patient investigation.

### Pathology Equipment

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Each breast centre should be supported by comprehensive pathology services in the diagnosis and further assessment of breast malignancies and other lesions. Such services should include core biopsy and cytology services for diagnosis of breast and axillary lesions as well comprehensive assessment of resection specimens to inform surgical and other adjuvant treatments. Provision of “hot” assessment of breast lesions should be available and access to a frozen section service should be available. Pathology services should meet the service specification and quality standards laid out in NHS BSP Publication No.2 “Quality Assurance Guidelines for Breast Pathology”. Facilities must also be available for the specialist breast pathologists to support MDT working.

### **Surgical Equipment**

Surgeons need to be able to view mammogram and ultrasound scan images at the time of surgery to allow accurate planning of surgical incision and approach. Appropriate computer equipment and PACS viewing screens must therefore be available in all breast theatres. It is recommended that all wide local excision specimens are orientated and x-rayed at the time of surgery to allow a timely decision on the adequacy of resection by the operating surgeon in conjunction with a breast radiologist if necessary (Association of Breast Surgery 2009). To facilitate this, the GMCBPB suggests that all breast operating theatres within the region should have access to Intraoperative real-time imaging machines (faxitron or equivalent) with the infrastructure capable of rapid reporting.

To allow accurate detection of the sentinel lymph node intra-operatively, a well maintained gamma probe should be available within each breast theatre. Where multiple breast surgeons are operating at the same time, there may be a need for more than one probe per unit.

The National Oncoplastic breast guidelines recommend the use of laminar airflow systems in theatres, particularly for implant-based reconstruction cases. Although the evidence for laminar airflow systems is lacking in breast reconstruction surgery, there is evidence in orthopaedic implant surgery that their use can reduce joint implant infection risk. GMCBPB suggests that all breast units should have access to laminar flow theatres for implant-based reconstruction cases (Rainsbury & Willett 2012). In addition the GMCBPB recommends that every unit should be equipped with lipomodelling equipment and expertise, in keeping with national guidance (Rainsbury & Willett 2012).

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A new treatment option for patients with early breast cancer that has received recent draft NICE approval is intraoperative radiotherapy. This allows patients undergoing breast conserving surgery to receive their radiotherapy treatment in a single intra-operative dose rather than having to attend an oncology centre daily for treatment over a three-week period. Although long-term data is not yet available, 5-year recurrence data is comparable with current standard treatment and it is felt that intraoperative radiotherapy may be preferable to a large number of patients and offer an improved quality of life to this patient group. Currently no breast unit in the Greater Manchester region is equipped to be able to offer this treatment but if breast services were to be reconfigured in the Greater Manchester region then this should be a consideration. The cost of an *intrabeam* radiotherapy machine is £500,000 with an associated critical mass of patients circa 200 per year treated. NICE will report on its final recommendation in 2017. If this is a positive recommendation, the GMBCPB will consider the implications in the future.

#### **Audit**

GMBCPB will develop regional audits that will be mandatory for all units to participate. The topics of the audit programme will focus on the quality of services delivered and achievement of national and GM quality standards. Topics will include the short stay breast surgery pathway (day case / 23 hour stay), diagnostic outcomes, clinical outcomes, provision of the Recovery Package, staff and patient experience. The audit programme for each year will be agreed in consultation with GMBCPB members and commissioners.

#### **Research**

As well as being offered standard therapies patients should be actively recruited into appropriate clinical trials. Each unit should aim to recruit 7.5% of patients into interventional trials and 20% into therapeutic trials. Any units not meeting these targets will be identified by the National Research Recruitment Report and supported to enable recruitment.

#### **Conclusions**

By applying a set of quality clinical standards and quality indicators it is essential to improve organisation, performance and outcomes in breast care. Through a shared common vision, the GM breast community can improve care by adopting the standards outlined in this document. The

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chronic problems around workforce and its subsequent planning should bring about a willingness to consolidate services and ultimately build breast units that are attractive places to work in. This will “future proof” GM breast services and drive up standards of care. Teamwork, infrastructure and detailed analysis of outcomes will be the backbone of the transformation goal.

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Appendix One

**Radiologists involved in the NHSBSP and other breast screening**

Professional standards for radiologists involved in the NHSBSP have been previously established (*Quality Assurance Guidelines for Breast Cancer Screening Radiology*, NHSBSP Publication No 59 March 2011). The screening and symptomatic breast imaging professional guidelines are compared and summarised below.

<b>Breast screening</b>	<b>Symptomatic breast imaging</b>
<p><i>In order to gain and maintain expertise, each radiologist involved in breast screening should fulfil the following criteria:</i></p>	<p><i>In order to gain and maintain expertise each radiologist involved in symptomatic breast work should fulfil the following criteria:</i></p>
<ul style="list-style-type: none"> <li>a. Be employed for a minimum of three programmed activities dedicated to direct clinical care in breast imaging</li> <li>b. Undertake a minimum of 5,000 screening and/or symptomatic cases a year.</li> </ul>	<ul style="list-style-type: none"> <li>a. Be employed for a minimum of two programmed activities dedicated to direct clinical care in breast imaging with time specifically allocated for multidisciplinary breast assessment</li> <li>b. Undertake a minimum of 500 symptomatic cases per year.</li> </ul>
<p><i>In addition, each radiologist should fulfil the following criteria:</i></p>	<p><i>In addition, each radiologist should fulfil the following criteria:</i></p>
<ul style="list-style-type: none"> <li>a. Have attended an RCR approved course</li> <li>b. Be normally involved and skilled in all aspects of breast screening, including mammography reading, screening assessment, and MDT meetings at which screening cases are discussed</li> <li>c. Attend regular multidisciplinary clinical management meetings</li> <li>d. Comply with RCR requirements for training and continuing professional development (CPD)</li> <li>e. Have access to pathology and/or surgical follow-up data</li> <li>f. Undertake formal audit of performance</li> <li>g. Participate in an approved radiologists' performance quality assurance scheme for mammography.</li> </ul>	<ul style="list-style-type: none"> <li>a. Have attended an RCR approved course</li> <li>b. Be normally involved and skilled in all aspects of symptomatic breast imaging, including mammography interpretation, breast assessment, and MDT meetings at which symptomatic cases are discussed</li> <li>c. Attend regular multidisciplinary clinical management meetings</li> <li>d. Comply with RCR requirements for training and continuing professional development (CPD)</li> <li>e. Have access to pathology and/or surgical follow-up data</li> <li>f. Undertake formal audit of performance.</li> </ul>
<p><i>It would be advantageous also to meet the following criteria:</i></p>	<p><i>It would be advantageous also to meet the following criteria:</i></p>
<ul style="list-style-type: none"> <li>a. Be involved with symptomatic breast work</li> <li>b. Have skills in clinical examination</li> <li>c. Have training in communication and 'breaking bad news', as required by the cancer peer review standards.</li> </ul>	<ul style="list-style-type: none"> <li>a. Be involved with breast screening</li> <li>b. Have skills in clinical examination</li> <li>c. Participate in an approved radiologists' performance quality assurance scheme for mammography</li> <li>d. Have training in communication and 'breaking bad news', as required by the cancer peer review standards.</li> </ul>

**Appendix Two**

The complete list of quality criteria set out in this guideline are provided below:

QUALITY CRITERIA	
1	<b>OPBS is discussed with patients requiring a mastectomy</b> NMBRA outcome: The risks and benefits of breast reconstruction was discussed with a surgeon or BCN in 61% of mastectomy only patients Target: OPBS is discussed in 100% of patients requiring a mastectomy
2	<b>When a referral for OPBS is made from one MDT to another MDT, full information is made available at the time of the referral and reciprocated following treatment</b> Target: Full information is available in 100% of patients referred and following treatment
3	<b>The oncological and reconstructive management is discussed at the MDM. A treatment plan and subsequent modifications are agreed and recorded, including plans for onward referral</b> Target: The oncological and reconstructive strategy is discussed at the MDM in 100% of patients suitable for OPBS
4	<b>Medical photography (pre-and post-operative) is part of the clinical record</b> Target: Medical photography is offered in 100% of BR patients
5	<b>Patients have access to a BCN or equivalent key worker with expertise in OPBS and psychological assessment and management</b> Target: Access to a key worker with expertise in OPBS and psychological assessment and management is available in 90% of patients
6	<b>Patients receive information in a format and level of detail that meets their individual needs. The letter to the GP summarises the information provided and is copied to the patient</b> NMBRA outcomes: Written information about the risks and benefits of breast reconstruction was received by 47% of mastectomy only patients. Dissatisfaction with the level of information provided was reported by 20% of mastectomy only patients. Target: Written information about the risks and benefits of breast reconstruction is provided to 90% of mastectomy patients
7	<b>Patients are MRSA (+MSSA in implant cases) screened prior to admission and have topical suppression where positive in accordance with national/local policy</b> Target: MRSA screening occurs in 100% of patients prior to admission
8	<b>Patients are risk-assessed for thromboembolism and preventative measures adopted</b> Target: Risk assessment for thromboembolic risk, and thromboprophylaxis occurs in 100% of patients

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9	<p><b>Patients are admitted to a single sex ward with dedicated, elective beds</b>  NMBRA outcome: Dedicated beds are reserved for breast cancer surgical patients in 35% of units  Target: Dedicated surgical beds are reserved for breast cancer patients in 100% of units</p>
10	<p><b>The site of surgery is marked pre-operatively and checked with patients, and correlated with imaging and histopathology records and hospital notes</b>  Target: Notes including relevant imaging and histopathology reports are available in 100% of OPBS patients</p>
11	<p><b>Patients undergoing implant-based reconstruction are given a single intravenous dose of appropriate antibiotic(s) on induction</b>  Target: All patients undergoing implant-based reconstruction receive intravenous antibiotics on induction</p>
12	<p><b>A formal flap and pain monitoring protocol is in place</b>  Target: Post-operative monitoring of pain and flap viability occurs according to an agreed protocol in 100% of cases</p>
13	<p><b>Patients have their post-operative pain levels assessed and recorded</b>  The Audit Commission recommends that less than 5% of patients should report severe post-operative pain  NMBRA outcome: Severe pain was experienced by 6% of patients following mastectomy, 17% following IBR and 20% following DBR  Target: Less than 5% of patients report severe pain within the first 24 hours</p>
14	<p><b>BCN, physiotherapy and psychological reviews take place at key points, including pre-operatively and before discharge</b>  Target: Review by the key worker occurs in 100% of cases prior to discharge</p>
15	<p><b>Implant loss at 3 months following BR is assessed and audited</b>  NMBRA outcome: Of women having an implant, 9% of IBR patients reported implant loss, and 7% of DBR patients reported implant loss  Target: Complications leading to implant loss occur in less than 5% of cases at 3 months</p>
16	<p><b>Unplanned return to theatre following BR is assessed and audited</b>  NMBRA outcome: Following implant or pedicle flap BR, 5% of IBR and 6% of DBR patients have an unplanned return to theatre. Following free flap BR, 13% of IBR and 11% of DBR patients have an unplanned return to theatre  Target: Unplanned return to theatre occurs in less than 5% of cases for non-free flap IBR, and in less than 10% of cases for free-flap IBR</p>
17	<p><b>Unplanned re-admission is assessed and audited</b>  NMBRA outcome: Re-admission within 3 months is reported in 9% of mastectomy patients, 16% of IBR patients and 14% of DBR patients  Target: Unplanned readmission occurs in less than 5% of cases within 3 months</p>
18	<p><b>Post-operative complications, return to theatre and length of stay are documented in departmental BR database</b>  Target: There is a regular audit and discussion of all patients with post-operative complications</p>
19	<p><b>Patients' satisfaction with BR outcome is measured using standardised assessment tools</b>  NMBRA outcome: At 3 months 72% of patients reported satisfaction with information provision  Target: Satisfaction with information provision is reported by 80% of patients at 3 months</p>
20	<p><b>Patients' satisfaction with BR outcome is measured using standard assessment tools</b>  NMBRA outcome: At 18 months over 90% of BR patients reported satisfaction with their appearance clothed, and over 60% unclothed  Target: At 18 months, over 90% of BR patients report satisfaction with their appearance</p>

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QUALITY CRITERIA CONTINUED	
21	<p><b>Local recurrence rates following OPBS should be no higher than for breast cancer surgery as a whole</b>            ABS at BASO Surgical guidelines for the management of breast cancer state that local recurrence rates should be less than 5% at 5 years with a target of less than 3% at 5 years            Target: Local recurrence rates are less than 3% at 5 years</p>
22	<p><b>Eligible patients are invited to take part in local and national clinical trials and audits of OPBS</b>            Target: Screening for eligibility for clinical trials and national audits occurs in 100% of OPBS patients</p>
23	<p><b>Senior trainees with a subspecialty interest in Breast Surgery attend at least one Royal College, Association or International postgraduate meeting or course annually</b>            Target: Over 90% of senior sub-specialty trainees attend a relevant training course or national meeting or equivalent annually</p>
24	<p><b>Consultant surgeons performing OP surgery attend at least one Royal College, Association or International postgraduate meeting which includes OP topics annually</b>            Target: Over 90% of Consultants attend a relevant training course or national meeting or equivalent annually</p>
25	<p><b>Other MDT members providing an OP service attend at least one educational event annually to support further professional development</b>            Target: 50% of other MDT members providing an OP service attend a relevant training course or national meeting or equivalent annually</p>