Heart of England NHS
NHS Foundation Trust

Review of surviving mastectomy patients previously under the care of former Consultant Surgeon, Ian Paterson

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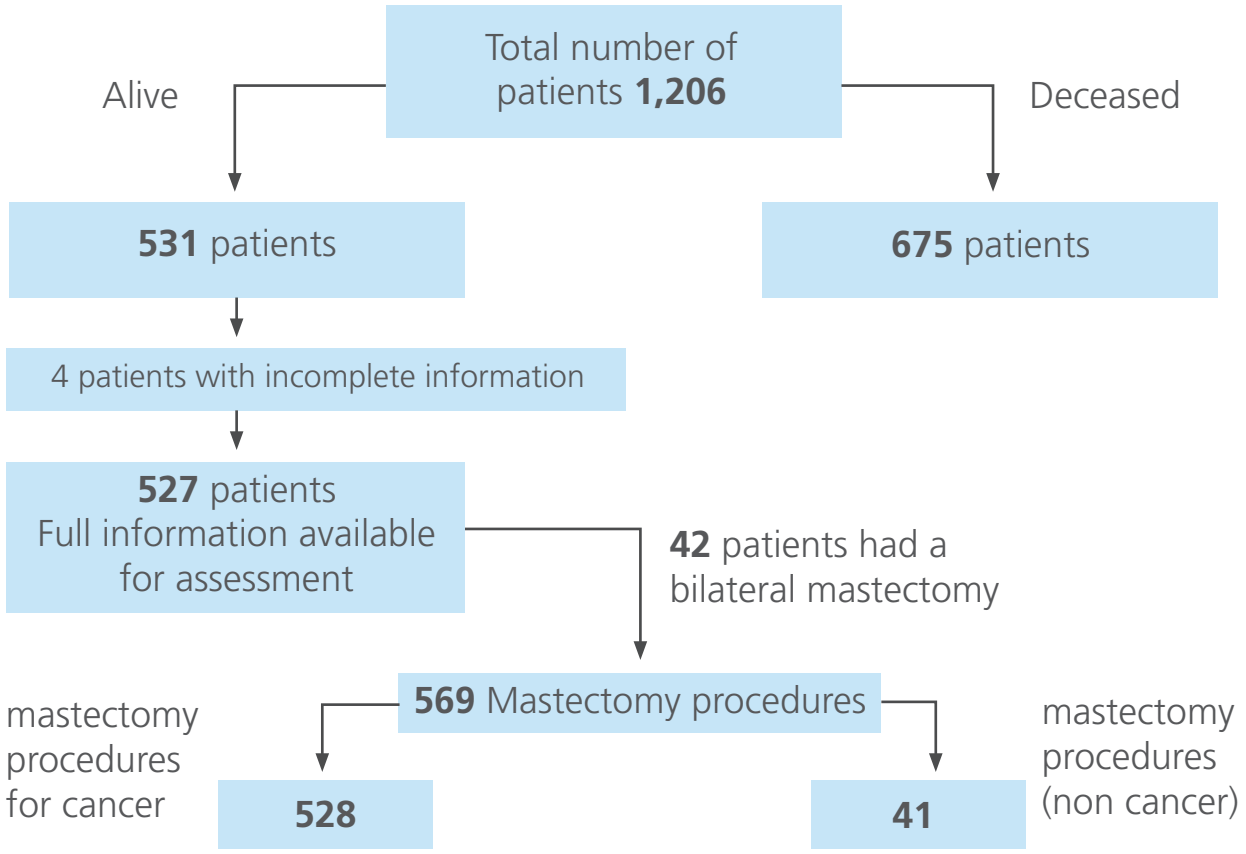
Contents

Executive Summary

This report examines the treatment received by surviving NHS patients who underwent mastectomy under the care of former consultant breast surgeon Ian Paterson. Between 1993 and 2011 Mr Paterson performed mastectomies on 1,206 NHS patients. In 2015, a national 'virtual' multidisciplinary review team[1] (vMDT) was established by the Board of Heart of England NHS Foundation Trust to conduct a review of the 531 survivors. The main aim was to provide advice for each individual patient on the adequacy of their care, and to recommend appropriate follow-up.

Sufficient information for detailed assessment by the vMDT was available in 527 of the 531 patients. As 42 patients had had both breasts removed, there was a total of 569 mastectomies, of which 528 were carried out for breast cancer, 35 for risk reduction and 6 for non-cancerous conditions.

Patients who had a mastectomy by Ian Paterson



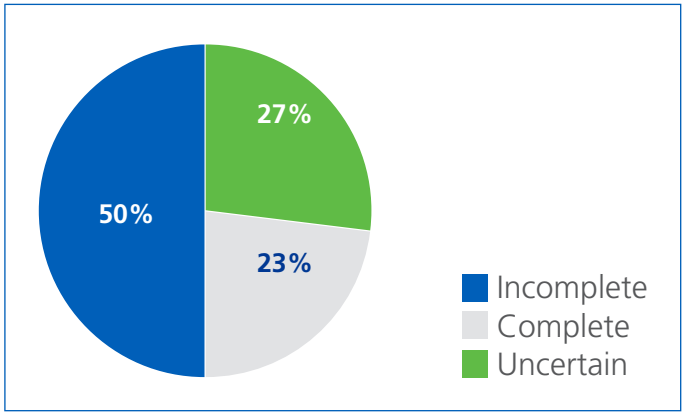
[1] Multi-disciplinary team (MDT): The MDT comprises specialist doctors e.g. surgeon, oncologist, radiologist, pathologist and nurses, who meet regularly to establish that every patient's diagnosis is correctly made. The MDT will then discuss and recommend the best form of treatment based on local and national guidelines and on each individual patient's circumstances

The adequacy of treatment for each cancer patient was assessed, to determine if appropriate and effective local and systemic treatments had been provided to control the cancer in the breast area and reduce the risk of local and distant recurrence. The assessment took into account:

i. *local treatment of the breast and lymph nodes:*
   a. *was a complete mastectomy performed, fully removing the cancer and removing axillary lymph nodes for cancer staging?*
   b. *was post-operative radiotherapy given?*
ii. *systemic treatments: was appropriate chemotherapy and/or hormone therapy given*?

In those patients who had bilateral mastectomies (both breasts removed), the adequacy of treatment was assessed and recorded for each side.

Completeness of Mastectomy

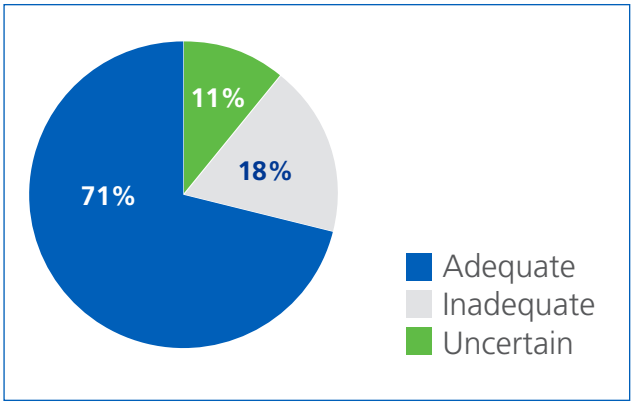


Half of the mastectomies reviewed (285 of 569, 50%) were found to have been incomplete following their initial surgery. In these patients there was evidence of residual breast tissue at the site of their surgery, often after a so-called "cleavage sparing mastectomy". Consequently 104 patients (20%) underwent further operations, mostly by other surgeons, to complete their mastectomy.

The adequacy of a further 152 mastectomies was uncertain due to the presence of a breast reconstruction or absence of objective clinical documentation. Thus in 436 (77%) of mastectomies, the initial surgery to remove the breast was either incomplete, or may not have been complete.

It was found that 132 mastectomies were initially complete (23%). These patients had undergone a standard full mastectomy.

Adequacy of Breast Cancer Treatment



Axillary surgery, and systemic treatments with chemotherapy and hormonal therapy generally met accepted national standards.

Surgery and radiotherapy both have important roles in achieving local control of breast cancer. For patients with breast cancer taking radiotherapy, as well as surgery, into account meant that local treatment of the breast was judged to be ultimately adequate in 71% (374 of 528 mastectomies). This includes patients who had:

- a complete initial mastectomy
- a delayed completion mastectomy
- a mastectomy that was incomplete, or possibly incomplete, but who received radiotherapy to the residual breast tissue (similar cancer treatment in effect to wide local excision plus radiotherapy, an accepted breast conserving approach with equivalent survival outcomes).

Local breast cancer treatment was considered inadequate in 18% (97 of 528 mastectomies), as the surgery was incomplete and no radiotherapy given. Local breast cancer treatment may not have been adequate in 11% (57 of 528 mastectomies) as completeness of surgery was uncertain and no radiotherapy given.

Local or regional cancer recurrences were recorded in 60 patients (11%), and distant spread in 20 (4%).

Based on the findings of the review team, a summary of the adequacy of treatment was provided for each patient, along with individual recommendations for any additional follow-up care and breast imaging. Clinical review by a breast specialist was offered to discuss the findings and communicated by letter to those who were unable or did not wish to attend.

Key Findings:

- Half (50%) of the mastectomies were found to be incomplete at the time of initial surgery and another 27% may not have been complete.
- One in every five patients (20%) underwent further operations, mostly by other surgeons, to complete their mastectomy.
- 71% of patients were judged, in the end, to have had adequate local treatment of their breast cancer when radiotherapy and further surgery were taken into account.
- 11% of patients have had local/regional breast cancer recurrence and 4% distant metastases.

1. Introduction

1.1 In November 2012 Heart of England NHS Foundation Trust commissioned Sir Ian Kennedy[2] to chair an independent review into how the organisation had handled the issues that arose from the surgical practice and behaviour of Mr Ian Paterson. Mr Paterson formerly operated in the Breast Care Units of Good Hope Hospital (1993-1998) and Solihull Hospital (1998-2011). In the Kennedy report a number of actions were identified and a key recommendation was the need to offer affected patients an independent review of their treatment. This was to include all patients previously recalled to the Trust who had undergone a procedure which came to be known as a "Cleavage Sparing Mastectomy".

1.2 A multi-disciplinary meeting of experts in the field of breast cancer was held in February 2015 to agree a consensus approach to reviewing this group of patients. The outcome was to establish a national virtual multidisciplinary team (vMDT), which developed guidelines and then used these as the basis for detailed individual treatment review. In view of the number of patients and detailed clinical information required, the review process took two years to complete. Only those patients who were still alive were considered. An individual summary statement was generated for every patient, covering their diagnosis, surgery and other treatments received. The role of the vMDT was to confirm that the details were accurate, reach a conclusion on the adequacy of breast cancer treatment, and make recommendations for any additional follow-up including breast imaging. The terms of reference of the vMDT, the method for identifying patients, and the procedures for gathering the required information are attached in Appendices 1 and 2.

1.3 Many patients had already been reviewed as part of a formal Trust assessment carried out between 2010 and 2012; their treatment was re-assessed by the vMDT. Patients who had undergone planned breast conservation surgery, by wide local excision combined with radiotherapy, were not included in the review unless they had subsequently undergone a mastectomy, for example, following local recurrence. It is important to recognise that as the review did not include deceased patients, or those treated entirely in the private sector, it does not provide comparative data on the cancer outcomes of all patients receiving mastectomy under the care of Mr Paterson.

[2] Kennedy, I (2013) Solihull Hospital Kennedy Breast Care Review; Review of the Response of Heart of England NHS Foundation Trust to Concerns about Mr Ian Paterson's Surgical Practice; Lessons to be Learned: and Recommendations

2. Process for patient review

2.1 Altogether 531 patients were identified for review by the vMDT. Enough information was available for adequate review in all but 4 patients: 2 had moved out of the area and 2 declined access to records. The dates of breast cancer diagnosis, classified as invasive carcinoma and/or ductal carcinoma in situ (DCIS) were made between the years 1993 and 2011 i.e. all more than 5 years ago. Patients who underwent planned wide local excision for cancer were not included. Not all the operations were carried out for cancer: 5 patients with a strong family history, or a known breast cancer gene, had bilateral risk reducing mastectomy, and in a further 25 patients the normal breast was removed for risk reduction after a diagnosis of breast cancer on the other side. Six mastectomies were carried out in 5 patients with non-cancer diagnoses: 2 for Phyllodes tumour, 2 for persistent breast pain, 1 for Lobular Carcinoma in Situ (LCIS) and 1 in a patient with a pre-operative diagnosis of breast cancer on needle cytology that was not confirmed. Thus, a full review was carried out in 527 patients who in total had 569 mastectomies of which 528 were done to remove breast cancer (see flow chart on page 4). Eleven of the cancer patients had disease in both breasts; in these patients, each cancer was reviewed separately and both are included in the analysis.

2.2 The TNM stage, tumour grade and receptor status of each patient's breast cancer was checked from histopathology reports and verified.

2.3 The overall adequacy of cancer treatment, judged at the time of vMDT review, was then considered for each individual patient taking into account:

a. the completeness of mastectomy, including any further surgery undertaken
b. whether the cancer was fully excised with no involvement of margins
c. appropriate treatment and staging of the axilla
d. additional treatments provided – radiotherapy, chemotherapy and hormone therapy.

2.4 The final mastectomy status, including the impact of any later completion surgery, was determined for each patient to be "complete", "incomplete", or "may not be complete". This latter category included patients in whom the adequacy of their mastectomy could not be determined, such as women who had not previously had an independent clinical review which documented the adequacy of their surgery; and those with a breast reconstruction following mastectomy in whom completeness of mastectomy could not be ascertained by clinical examination, imaging, or pre-reconstruction clinical photographs. In those patients who had attended the previous Trust recall process, that assessment often established the presence of residual breast tissue, or the finding of a standard complete mastectomy. These patients had already received some advice on further treatment and follow-up.

2.5 Most patients in the "incomplete mastectomy" category were already documented to have had the so-called "cleavage sparing mastectomy procedure" carried out by Mr Paterson. This category also included any patient in whom there was evidence of residual breast tissue

at the mastectomy site other than the cleavage area, and those with evidence of incomplete skin-sparing mastectomy performed to enable immediate breast reconstruction.

2.6 The final margin status of excision of cancer, based on histopathology reporting, was determined to be "not involved" or "involved".

2.7 Documentation of all adjuvant treatments was obtained to verify that these had been given and completed.

2.8 Individual recommendations were made for each patient concerning any requirement for further investigation and treatment, taking into account their previous medical history, current health, and the psychological impact of the findings. A protocol for surveillance imaging was devised, based on national guidance, and applied as appropriate in the recommendation for each patient. (See Appendix 3).

3. Findings

3.1 Completeness of mastectomy (all diagnoses)

3.1.1 For the whole group of patients, including those with mastectomies carried out for cancer, non-cancer diagnoses, and risk reduction, 50% of the mastectomies reviewed (285 of 569) were found to have been incomplete at the time of their initial surgery. In these patients, there was evidence of residual breast tissue, a so-called "cleavage sparing mastectomy", or as residual breast tissue at the site of a breast reconstruction after incomplete skin-sparing mastectomy.

3.1.2 Delayed further surgery was carried out to remove residual breast tissue in 104 patients (20% or one in every five patients); most of these operations were done by other breast surgeons, and in some patients major revision of a previous breast reconstruction was required.

3.1.3 The adequacy of a further 151 mastectomies was uncertain due to the presence of a breast reconstruction or absence of objective clinical documentation. Thus in 436 (77%) of all mastectomies, the initial surgery to remove the breast was either incomplete, or may not have been complete.

3.1.4 It was found that 132 mastectomies were initially complete (23%). These patients had undergone a standard full mastectomy.

3.2 Adequacy of Breast Cancer Treatment

3.2.1 Four main categories of adequacy of local breast cancer treatment were identified and ascribed to each patient undergoing mastectomy for cancer. Adequate local treatment was defined as complete treatment of the whole breast, plus nodal areas as indicated, by a combination of surgery and radiotherapy. In the immediate complete mastectomy category, radiotherapy was also required for local treatment to be adequate in patients who had a high risk of local recurrence, including those with 4 or more positive axillary lymph nodes or other evidence of locally advanced disease. For patients with bilateral disease each side is separately included. The numbers of patients (individual breast cancer diagnoses) in each category are shown in the table on the next page:

3.2.2 The table identifies that 261 (49%) of the 528 assessable mastectomies performed for cancer were incomplete at the time of initial treatment. This includes patients with incomplete mastectomies in categories 1 and 2 (164 operations), plus those in categories 4 and 4a (97 operations) who had undergone delayed completion surgery. In all these patients there was documented evidence of residual breast tissue on the side of their breast cancer surgery, often referred to as the so-called "cleavage sparing mastectomy", or they had subsequently undergone delayed surgery to remove residual breast tissue.

	Adequacy of Local Cancer Treatment	Patient Numbers
1.	Incomplete mastectomy, with radiotherapy. Adequate local treatment.	67
1a	Mastectomy may not be complete, with radiotherapy. Adequate local treatment	78
2	Incomplete mastectomy, with no radiotherapy. Inadequate local treatment.	97
2a	Mastectomy may not be complete, with no radiotherapy. Local treatment may not have been adequate.	57
3	Immediate complete mastectomy, with or without radiotherapy. Adequate local treatment.	132
4	Delayed completion mastectomy. Inadequate local treatment initially. Local treatment now adequate following completion mastectomy.	58
4a	Delayed completion mastectomy. Adequate local treatment initially (as radiotherapy given).	39
	TOTAL	528

3.2.3 Additionally, there were patients in categories 1a and 2a (135 operations, 26%) in whom there was uncertainty about the completeness of mastectomy, either because they had not had an independent documented clinical review, or this could not be determined following reconstructive surgery.

3.2.4 Overall, 396 of initial mastectomies performed for breast cancer (those listed in categories 1, 1a, 2, 2a, 4 and 4a in Table 1), were incomplete or there was uncertainty about the completeness. This represents 75% of the group of 528 mastectomies for cancer reviewed.

3.2.5 132 mastectomies for cancer (25%) were found to be complete. These patients had undergone a standard full mastectomy.

3.2.6 Assessments of the adequacy of local cancer treatment patients received were based on both surgery and radiotherapy. Thus, where a complete mastectomy had been performed, (plus radiotherapy in those with high risk disease), local treatment was deemed to be adequate. If there was an incomplete mastectomy, but the patient received radiotherapy to the residual breast, this was also deemed to be adequate. This is because in terms of local breast cancer control, it was equivalent to a wide local excision combined with radiotherapy, which is an accepted and effective breast conserving approach.

3.2.7 Histopathology reports of 472 mastectomy specimens (89%) confirmed that the patient's cancer had been fully excised. In 9 cases this was unknown due to incomplete information on histology. Historically there tended to be less detailed information available on excision margins from the earlier period of the review, before a standardised approach to margins became incorporated into breast histopathology reporting. In 47 patients (9%), excision of cancer was considered likely to be incomplete, with invasive tumour or DCIS

close to or present at a margin of excision. In 10 of them the deep margin of excision was the only one found to be close or involved, with further surgery considered unlikely to help, and 10 patients had been operated on for locally advanced disease. In 35 patients the initial mastectomy was judged to have been incomplete or may not have been complete. Most of this group of patients in whom completeness of excision of their cancer was not proven, 42 of 47, received adjuvant postoperative chest wall radiotherapy. Breast cancer recurrence was observed in 7 patients, of whom 4 had ipsilateral breast recurrences including 3 who had not received adjuvant radiotherapy.

3.2.8 Management of the axilla was noted for each patient and generally found to be within the accepted range of standard practice, including latterly the use of sentinel lymph node biopsy (SLNB). Axillary node clearance was the usual procedure until 2007, when the selective use of SLNB was introduced.

3.2.9 Adjuvant systemic treatments with chemotherapy, hormonal therapy, and Herceptin were found generally to meet accepted national standards; occasional exceptions were noted where patients had declined treatments or been unfit to proceed.

3.2.10 Patients in whom a delayed completion mastectomy had been performed, either to remove residual normal breast tissue or deal with a local recurrence, were judged now to have had adequate local treatment (categories 4 and 4a: 97 procedures). Those in whom this was carried out for local recurrence received additional treatments i.e. radiotherapy, chemotherapy and hormonal treatment as indicated.

3.2.11 Local breast cancer treatment was judged ultimately to be adequate in 374 patients (71%). These patients, in categories 1, 1a, 3, 4 and 4a, had combinations of surgery and radiotherapy that ultimately provided sufficient local control of cancer.

3.2.12 Local breast cancer treatment was judged to have remained inadequate in 97 patients after incomplete mastectomy as radiotherapy was not given (category 2; 18%). There were a further 57 patients (category 2a; 11%) where completeness of mastectomy was uncertain and no radiotherapy was given, so treatment may not have been adequate.

3.2.13 In summary we found that in patients undergoing mastectomy for breast cancer:

a. 374 patients in categories 1, 1a, 3, 4 and 4a (71%) eventually received adequate local treatment for their breast cancer, either initially or following radiotherapy and/or subsequent completion surgery.
b. 154 patients in categories 2 and 2a (29%) received local treatment that was either inadequate or may not have been adequate.

3.3 Cancer Recurrence

3.3.1 Information on recurrent cancer following mastectomy was also collected as part of the review process, and is shown in the table below. Sufficient follow-up information to identify recurrences was available in all but four patients

Adequacy of Treatment	**Patient Numbers**	**Recurrences**			
		Numbers			Percent - all patients
		Loco-regional	Distant	Local and Distant	
1 - Incomplete mastectomy with radiotherapy. Adequate local treatment.	67	4	2	0	9.0
1a - Mastectomy may not be complete with radiotherapy. Adequate local treatment	78	4	3	0	9.0
2 - Incomplete mastectomy with no radiotherapy. Inadequate local treatment.	97	6	2	1	9.3
2a - Mastectomy may not be complete with no radiotherapy. Local treatment may not have been adequate.	57	3	0	0	5.3
3 - Immediate complete mastectomy with or without radiotherapy. Adequate local treatment.	132	13	8	1	16.7
4 - Delayed completion mastectomy. Inadequate local treatment initially. Local treatment now adequate following completion mastectomy.	58	20	0	2	37.9
4a - Delayed completion mastectomy. Adequate local treatment initially.	39	6	1	0	17.9
Total	528	56	16	4	14.4

3.3.2 Recurrence was classified as local (in the breast/chest area), regional (lymph nodes around the breast area, axilla or neck), or distant metastases (such as in bone, liver or brain). The majority of loco-regional recurrences occurred in the chest wall or residual breast.

3.3.3 Overall, of the 528 mastectomies assessed, loco-regional recurrence was documented in 60 (11%) and distant metastases in 20 (4%). The relatively small number of patients observed to have distant metastases might be expected in a selected group of longer survivors, i.e. all more than 5 years from diagnosis. Most of the distant recurrences (15 of 20) were seen in patients who had received adequate initial treatment by complete mastectomy or the addition of radiotherapy (categories 1, 1a, 3, 4a), possibly indicating poor prognosis disease at diagnosis for which more aggressive treatment was given.

3.3.4 Where patients were judged to have received adequate initial local treatment (316 in categories 1, 1a, 3 and 4a), loco-regional recurrence was documented in 28 (9%) and distant recurrence in 15 (5%).

3.3.5 For the group of patients (212 in categories 2, 2a and 4) in whom initial treatment was considered to be inadequate or may not have been adequate, loco-regional recurrence was observed in 32 (15%), and distant recurrence in 5 (2%).

3.3.6 When initial treatment was judged to be definitely inadequate (155 in categories 2 and 4) loco-regional recurrence was observed in 29 (19%), and distant recurrence in 5 (3%)

3.3.7 Local recurrence was observed in 28 of the 97 patients undergoing delayed completion mastectomy (29%). These recurrences were found in residual breast tissue removed at the time of further surgery, either diagnosed pre-operatively or as an incidental finding. A particularly high number of local recurrences, 22 in 58 patients (38%), were seen in the group undergoing delayed completion mastectomy whose initial local treatment had been inadequate. Only 1 distant recurrence was seen in this group, suggesting the problem was failure of local surgical control, rather than innately aggressive disease.

3.3.8 In view of the wide range of variable factors among patients within the different treatment categories, including age, cancer stage, tumour characteristics and time from diagnosis, and the relatively small numbers in each sub-group, we have not carried out formal statistical analysis of recurrence rates.

3.4 Non-cancer and risk reducing mastectomies

3.4.1 None of the 6 mastectomies performed for non-cancer diagnoses (2 Phyllodes, 2 persistent breast pain, 1 LCIS, and 1 incorrect malignant diagnosis on cytology) were found on review to be complete. Four were incomplete, and in two there was uncertainty due to the presence of an immediate reconstruction.

3.4.2 Thirty five risk-reducing mastectomies were assessed: 5 bilateral procedures performed in women with a strong family history or known breast cancer gene, and 25 unilateral mastectomies following a diagnosis of contralateral breast cancer (on the other side). Most of these patients underwent reconstructive surgery; 26 breast reconstructions, either immediate or delayed, were carried out. Eleven mastectomies in 10 patients (one bilateral) have subsequently required delayed operations by another team to complete the mastectomy and revise their breast reconstruction. In the remainder, 10 mastectomies in 8 patients (2 bilateral) were found to be incomplete, and there was uncertainty about the completeness of 14 mastectomies in 12 patients (2 bilateral).

Patients	Risk Reducing Mastectomy Status		
	Incomplete	May not be complete	Complete only after further surgery
Breast cancer gene or strong family history (bilateral - 5 patients)	4	4	2
Contralateral breast cancer (unilateral - 25 patients)	6	10	9
TOTAL	10	14	11

4 Summary and conclusions:

4.1 The initial mastectomy was incomplete in 50% of the patients reviewed and was identified with certainty to be complete in only 23%. These figures demonstrate the level of inadequacy of Ian Paterson's mastectomy practice.

4.2 When additional treatments including radiotherapy and further surgery are taken into account just over two thirds (71%) of the surviving mastectomy patients reviewed have ultimately received adequate local breast cancer treatment. In many patients, the administration of adjuvant radiotherapy by the consultant clinical oncologists in the breast unit mitigated the impact of Mr Paterson's inadequate surgery. Subsequent operations by other consultants in the unit also played an important part in securing adequate breast cancer control. Unfortunately, some patients have needed additional treatments that would not have been required if their original mastectomy had been carried out correctly.

4.3 The group of 97 breast cancer patients who underwent delayed completion mastectomy were at risk of local recurrence between their initial and completion mastectomies. Nearly a third (29%) had a local recurrence at the time of their further surgery; these recurrences were potentially avoidable if the initial operation had been performed correctly.

4.4 It is apparent from reviewing those patients undergoing delayed surgery to remove

residual breast tissue and revise a previous breast reconstruction that Mr Paterson's skin sparing mastectomy (SSM) technique fell short of the fastidious dissection required to remove all identifiable breast tissue. Whilst some patients have had this corrected there are others who remain at risk and require long term imaging surveillance.

4.5 Most of the patients undergoing mastectomy for risk reduction had the SSM technique with immediate reconstruction. Revision surgery has been required in 10 to remove residual breast tissue, and the remaining patients are either known to, or may have residual tissue. It is a matter of concern that surgery carried out ostensibly to reduce high breast cancer risk was not adequately performed, and that patients have either needed further surgery, often with complex revision of a reconstruction, or continue to require long term imaging surveillance. Although risk reducing mastectomy does not eliminate cancer risk, removal of the breast tissue should be carried out as completely as possible.

4.6 The importance of obtaining adequate local control in breast cancer surgery is underlined by the finding that local recurrences were observed more frequently in patients with inadequate, or possibly inadequate, initial local breast cancer treatment (32 out of 212), than in those who had received adequate initial local treatment (28 out of 316). The diagnosis of recurrent cancer is devastating for patients. Although local breast cancer recurrence can often be effectively controlled, it may have an adverse impact on cancer survival.

4.7 The question of margin involvement arose after 47 mastectomies; the majority received adjuvant radiotherapy and this appears to have largely protected them, with cancer recurrence not being observed more frequently than in the whole group of mastectomies assessed.

4.8 Those patients who have not had adequate local treatment remain exposed to an increased risk of recurrent disease. Many have previously been considered for further surgery, but did not proceed, on the grounds of choice, frailty, state of health, or the length of time that had elapsed since initial diagnosis. Most have already received advice on long term surveillance and breast imaging, and all have now been offered updated recommendations following the current vMDT review. Individual recommendations on follow-up imaging address the small ongoing risk, for any patient with a past diagnosis of breast cancer, of developing further cancer in either breast; and also the potentially higher risk of local recurrence in the operated breast of those with inadequate local treatment.

4.9 Only a small number of distant metastases were observed in these surviving patients. This is not unexpected, as the greatest hazard for breast cancer recurrence is within 5 years of diagnosis; all were diagnosed more than 5 years ago, and having survived the highest risk period in general they now have an improved outlook. Although most of the distant recurrences (15 of 20) were seen in patients with adequate initial treatment, this apparent paradox may be due to poorer prognosis cancers being treated more aggressively at diagnosis.

4.10 It is not possible to estimate the overall outcomes of Mr Paterson's mastectomy practice from this review, as only surviving patients within the NHS sector were considered, and there is no information on breast cancer recurrence or breast cancer related death in non-survivors.

4.11 The virtual MDT has produced a treatment summary for each patient. This includes follow-up recommendations, and the offer of a clinic appointment with a Consultant Surgeon and Clinical Nurse Specialist to explain and discuss the findings. The aim of the process has been to fulfil the professional duty of candour by providing an open and honest account to each patient of the care they received, explain the impact of this, and provide advice and support concerning recommended clinical follow-up and surveillance.

Appendix 1

Process for review of the surviving mastectomy patients

1. How was this group of patients identified?

An extensive validation of all data sources took place from February 2014 onwards. The Informatics team was asked to conduct a search using all OPCS codes relating to any breast procedures. Examples include:

B27.4 = Total mastectomy
B27.5 = Subcutaneous mastectomy
B28.2 = Wire guided partial excision of breast
B27.6 = Skin sparing mastectomy
B28.0 = Excision/biopsy of breast lump/fibroadenoma of breast

In addition, as it was known that Mr Paterson (IP) operated with a plastic surgeon, a search using the primary procedure code for reconstruction was also used. Examples include:

B29.1 = Reconstruction of breast using myocutaneous flap of latissmus dorsi muscle
B29.2 = Reconstruction of breast using local flap of skin
B29.3 = Reconstruction of breast using flap of skin of abdomen
B29.4 = Reconstruction of breast using distant flap of skin.

This data was then categorised as one of the following:

Mastectomy,
Wide Local Excision (WLE),
Lumpectomy,
Other Breast Procedures.

A check was carried out by examining data provided by the West Midlands Cancer Intelligence Unit for patients reported as having had breast cancer between 1994 and 2011.

Data was checked for other breast surgeons to ensure that the consultant code had been coded correctly.

In addition, a sample of all breast histopathology specimens from Good Hope Hospital 1994 -1998 and Solihull Hospital from 1998 to 2011 were reviewed and cross checked to ensure that all patients were accounted for.

Circa 19,000 patients records were validated to see if IP was involved in their care.

2. Clinical Prioritisation

In early 2015, patients were placed in order of clinical priority. Five categories were developed. These were as follows;-

Group 1: Patient known to have had a Mastectomy by IP and have **not been seen in any previous recall clinics.**

Group 2: Patients who have been recalled and known to have **significant breast tissue** and are now in a follow-up programme.

Group 3a: All patients who have a **flat chest wall** after initial surgery and those who have been seen in recall clinics and subsequently had the **residual tissue removed** – all now in a follow-up programme.

Group 3b: Patients who have had immediate or delayed reconstruction who have been recalled and had:

- Deconstruction and further reconstruction or mastectomy.
- Imaging and clinical surveillance only.
- Family History / Risk Reducing Mastectomy + / - reconstruction for BRCA1 and BRCA2.

Group 4: Other patients who have now:

- Declined or did not attend the recall programme in 2009 or 2011.
- Significant co morbidities.
- Second primaries and on treatment.
- Those in clinical trials and on specific follow-up schedules.
- In Oncology follow-up (these patients will be listed as 4a on the database).

Group 5: Discharged (patients seen in recall clinics and discharged back to the GP) or referred back to the NHS Breast Screening Programme. Patients who should be in the breast screening programme but where there is no evidence of this will be classed as 5*.

Group 6: Deceased patients

In summary, those patients where it was known that there was definitely remaining breast tissue, or a possibility of there being remaining breast tissue, were reviewed sooner than those where it was known that further surgery had taken place to remove it.

3. Was permission sought from patients to review their care?

In May/June 2016, all patients were notified that their NHS notes had been reviewed or were going to be reviewed.

One patient contacted the Trust as she did not wish to have her notes reviewed.

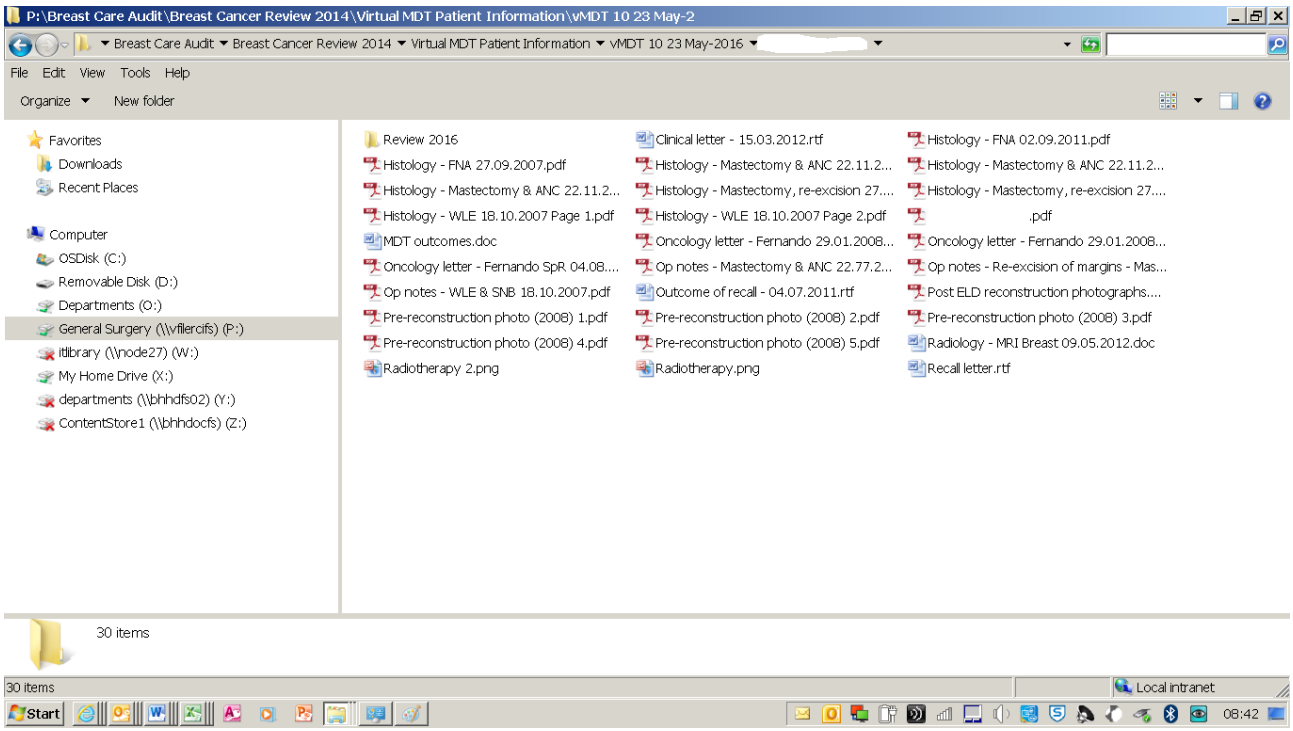
As some of the patients' care took place in other hospitals e.g. Spire Parkway, Spire Little Aston, Sandwell and West Birmingham Hospitals NHS Trust and hospitals out of the Midlands region, it was not possible to provide a thorough assessment of the treatment given on the HEFT notes alone. In this instance, patients were contacted and permission sought to request information from other providers. Consent to approach other organisations was granted by all except one patient.

4. Data Collection / Preparation

The Review and Recall team prepared the information for the vMDT to review. This collation of information was a detailed process requiring each patient's breast cancer pathway to be mapped out chronologically with full supporting evidence available to the vMDT. For example, some patients were treated by IP as far back as 1993 so any treatment and on-going surveillance in relation to the patient's breast cancer had to be mapped for 24 years.

In most patients not all of the information was available in the Trust's notes, as additional treatments were carried out in other institutions. For example, enquiries regarding radiotherapy and chemotherapy had to be made with cancer centres at University Hospitals Coventry and Warwickshire NHS Trust and University Hospitals Birmingham NHS Foundation Trust; family history and genetics information were requested from the Regional Clinical Genetics Unit at Birmingham Women's and Children's NHS Foundation Trust; and additional histopathology reports were sometimes required from other NHS Trusts locally and around the country in order to ensure complete data collection.

A database was constructed containing individual patient files with all relevant material, and a list containing this information was shared with the vMDT for reading prior to each vMDT meeting. (See an example on the next page).



5. What are the qualifications of the vMDT members to carry out this task with independence and authority?

Membership of the core vMDT

Role	Name	Dates Served
Oncologist (vMDT Chair)	Professor Robert Leonard BSc, MBBS, MD, FRCP, FRCPE	May 2015 onwards
Breast Surgeon (vMDT Vice Chair)	Mr Martin Lee MB ChB, MA, MSc, FRCS	May 2015 onwards
Radiologist	Dr Colin Walker MB BS, MRCP, FRCR	May 2015 onwards
Pathologist	Professor Gordon Stamp MB ChB; FRCPath	May 2015 onwards
Clinical Nurse Specialist	Lynne Dodson RGN, M.Med.Sci	May 2015 onwards
Clinical Psychologist	Dr Ray Owen CPsychol, BA(Hons), MSc, DClinPsych	May 2015 onwards

The vMDT process

1. For each patient the vMDT:

- Reviewed the original diagnosis including histopathological confirmation
- Reviewed appropriateness and adequacy of treatment already undertaken
- Took into account any information available on the current disease status and health of the individual patient
- Made recommendations on any further treatment and follow-up for each patient, and communicated these to the local clinical review team.
- Ensured all recommendations were based on available evidence following published guidelines and established clinical practice.

2. It should be noted that the vMDT recommendations were based on information provided in patients' health records; i.e. they did not have direct clinical contact with patients. Direct clinical responsibility remained with the local breast care team.

3. An example of the summary information presented on the vMDT recommendations is shown on the next page. The same format was followed for each patient to ensure a consistent approach and help the local team navigate the vMDT opinion and recommendations. The local team were able to pose questions directly back for the vMDT for any clarification required. When this occurred the question and response were documented on the recommendations sheet.

Patient Details – PID / NHS No.	**Patient Summary**	**vMDT Recommendations**
Name: **DoB:** **Age:** years **NHS No:** **PID:** **Date of Diagnosis::** **Age at diagnosis:** years **Length of time post op:** years Agreed and signed Date: Professor Robert Leonard Chair of the vMDT	**Diagnostic summary: Right / left breast (year):** T (x mm) N(x) (x/y) Mx grade ER status, PR status HER 2 status **Final Margin Status:** Involved/ Not involved **Treatment summary :** 1. Diagnostic biopsy 2. Therapeutic surgery 1 (surgeon(s) and date) 3. Therapeutic surgery 2 (surgeon(s) and date) **Adjuvant Therapy:** 1. Radiotherapy/ no radiotherapy (dates and dosage) 2. Chemotherapy / no chemotherapy (dates and dosage) 3. Endocrine Therapy / no endocrine therapy (dates and dosage) **Co-morbidities: Yes /** No **Recurrence**: **Yes /** No Local/regional/distant **Formal Recall Date to the Trust (2010 to 2012): Yes /** No **/ Declined (Details)** **Final Mastectomy status right side:** Complete / Incomplete / May not be complete **Current Status**: In follow up / discharged **Date of last Breast Clinic Attendance**: Date and details **Date of next Breast Clinic Attendance**: Date **Date of last Imaging**: ultrasound, mammography / MRI; (dates and details)	**Recommendations:** **Adequacy of Treatment:** **(Left / right / bilateral)** Including detail of category for breast cancer patients (1, 1a, 2, 2a, 3, 4 or 4a) **Clinical Follow up:** If the patient chooses to attend for a review, she /he should be provided with a written care plan, end of treatment summary and a completed HNA. **Imaging Follow up:** NHS Breast Screening Programme / additional requirements for mammography or MRI **Additional Comments:** As indicated

4. As well as tracking the patient's pathway, the patient's final cancer margin status was assessed and documented, along with the completeness of the mastectomy procedure. The margin is the edge or border of the tissue removed in cancer surgery and can be described as 'not involved' when the pathologist finds no cancer cells at the edge of the tissues or 'involved' when the pathologist finds cancer cells at or very close to the edge of the tissue, suggesting that not all of the cancer has been removed.

5. Margins of excision were interpreted in accordance with national guidelines[3]

6. The same terminology was used consistently so that the local team become familiar with what the vMDT meant by its statements. For example, the terminology used for mastectomy status can be 'complete', 'incomplete' or 'may not be complete'.

7. Finally, an 'adequacy of treatment' statement was added. This was added because, for example, whilst the mastectomy may not have been complete, the patient also received radiotherapy to the remaining breast tissue, or underwent delayed completion mastectomy Examples of the type of statements the vMDT has made are:

"Mastectomy may not be complete, with radiotherapy. Adequate local treatment"

"Incomplete mastectomy with no radiotherapy. Inadequate local treatment."

"Delayed completion mastectomy. Inadequate local treatment initially. Local treatment now adequate following completion mastectomy."

8. Once the recommendations had been drafted, a second meeting took place at the Trust where the Chair and Vice Chair of the panel reviewed the written record of the meeting with the Review and Recall team and checked for accuracy. The recommendations for each patient were then signed off by the Chair of the panel and uploaded onto the patient's electronic health record.

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[3] The Royal College of Pathologists (June 2016): Pathology Reporting of Breast Disease in Surgical Excision Specimens incorporating the dataset for histological reporting of breast cancer.

6. How was the information shared with patients, their carers, and the GP?

Any recommendations made by the vMDT were communicated to patients via letter and a copy of the letter sent to the GP.

All patients were invited to discuss the vMDT recommendations at a consultation with either one of the local surgeons or an independent surgeon of their choosing. Most patients were accompanied by a family member or a friend.

An hour to an hour and a half was allocated for each patient. Time was spent with the consultant (CNS in attendance). After this, further time was spent with the Clinical Nurse Specialist. The patient was provided with a Treatment Summary (also copied to the patient's GP) and a Holistic Needs Assessment was completed if this was something the patient chose to do. This assessment would identify whether there were any further information needs or additional support required. Support could range from signposting to other organisations or organising a referral to psychology services.

On rare occasions, the patient returned for a further appointment if this was needed.

Appendix 2

Terms of Reference for the Virtual Multidisciplinary Team (vMDT)

Aim

The aims of the virtual multidisciplinary team (vMDT) are:

1. To enable a formal mechanism for multidisciplinary input into advising clinicians regarding the ongoing management and care of patients who had the unrecognised procedure known as a Cleavage Sparing Mastectomy (CSM) performed by Ian Paterson (IP).
2. To ensure that a co-ordinated approach to high quality patient care is offered to all patients who are invited to the breast recall/review. The virtual MDT will make recommendations about what they consider to be the most appropriate next steps or options for the patient, be that further investigations or surgery, imaging surveillance, information giving or referral to other members of the clinical team e.g. clinical psychologist.
3. To provide support and advice to the clinicians who will see the patients at the independent review. During patient consultations, the advice that will be given will be that of the virtual MDT rather than that of a single clinician.

Objectives of the vMDT meeting are to;

1. Review the original diagnosis including histopathological confirmation and ensure this is validated
2. Review the appropriateness and adequacy of treatment already undertaken
3. Take account of all the information we have on the current disease status and health of the individual patient.
4. Make recommendations on any further treatment and follow-up for each patient, and communicate these to relevant team members including the independent provider and the local NHS breast cancer service.
5. Ensure all recommendations are based on available evidence and follow national and local guidelines

N.B. It should be noted that the vMDT recommendations will be based on information provided in patients' health records; i.e. there will be no direct clinical contact with patients. Direct clinical responsibility will remain with the local breast care team.

Membership of the core vMDT

Role	Name	Dates Served
Oncologist	Professor Robert Leonard	May 2015 onwards
Breast Surgeon	Mr Martin Lee	May 2015 onwards
Radiologist	Dr Colin Walker	May 2015 onwards
Pathologist	Professor Gordon Stamp	May 2015 onwards
Clinical Nurse Specialist	Lynne Dodson	May 2015 onwards
Clinical Psychologist	Dr Ray Owen	May 2015 onwards

The vMDT will be supported by the Review and Recall team. Any member of the vMDT can be contacted via the Head of Patient Review and Recall or the Project Manager.

Recording of vMDT Decisions

All treatment decisions and discussion at the vMDT will be recorded live. The draft recommendations will be checked by the Clinical Nurse Specialist before they are circulated to the team for comment.

Comments received will be passed on to the vMDT Chair and Vice-Chair for review, and any necessary changes made to the draft recommendations.

Draft recommendations will be recirculated by the Project Manager (if changes have been made) for vMDT members to confirm accuracy. Once accuracy has been confirmed, the Chair and Vice-Chair will be responsible for signing off each individual patient's vMDT recommendations.

The Project Manager is responsible for ensuring that a signed copy of each vMDT meeting is available.

Appendix 3

Ian Paterson (IP) Cohort - Imaging Guidelines for Patients who were treated with a procedure known as a Cleavage Sparing Mastectomy (CSM) – Version 1

Guideline Readership

This guideline has been developed for use by breast surgeons, radiologists and clinical nurse specialists involved in the management and follow-up of patients who had a cleavage sparing mastectomy.

Guideline Objectives

This guideline serves to ensure that a standardised, consensus approach is used for the follow-up imaging of any asymptomatic patients who were treated with a procedure which came to be known as a 'Cleavage Sparing Mastectomy' (CSM) (Kennedy, 2013); an unrecognised procedure performed by consultant breast surgeon Mr Ian Paterson. These operations took place between 1993 and 2011. This guideline should be read in conjunction with the clinical follow-up guideline designed specifically for this cohort of patients.

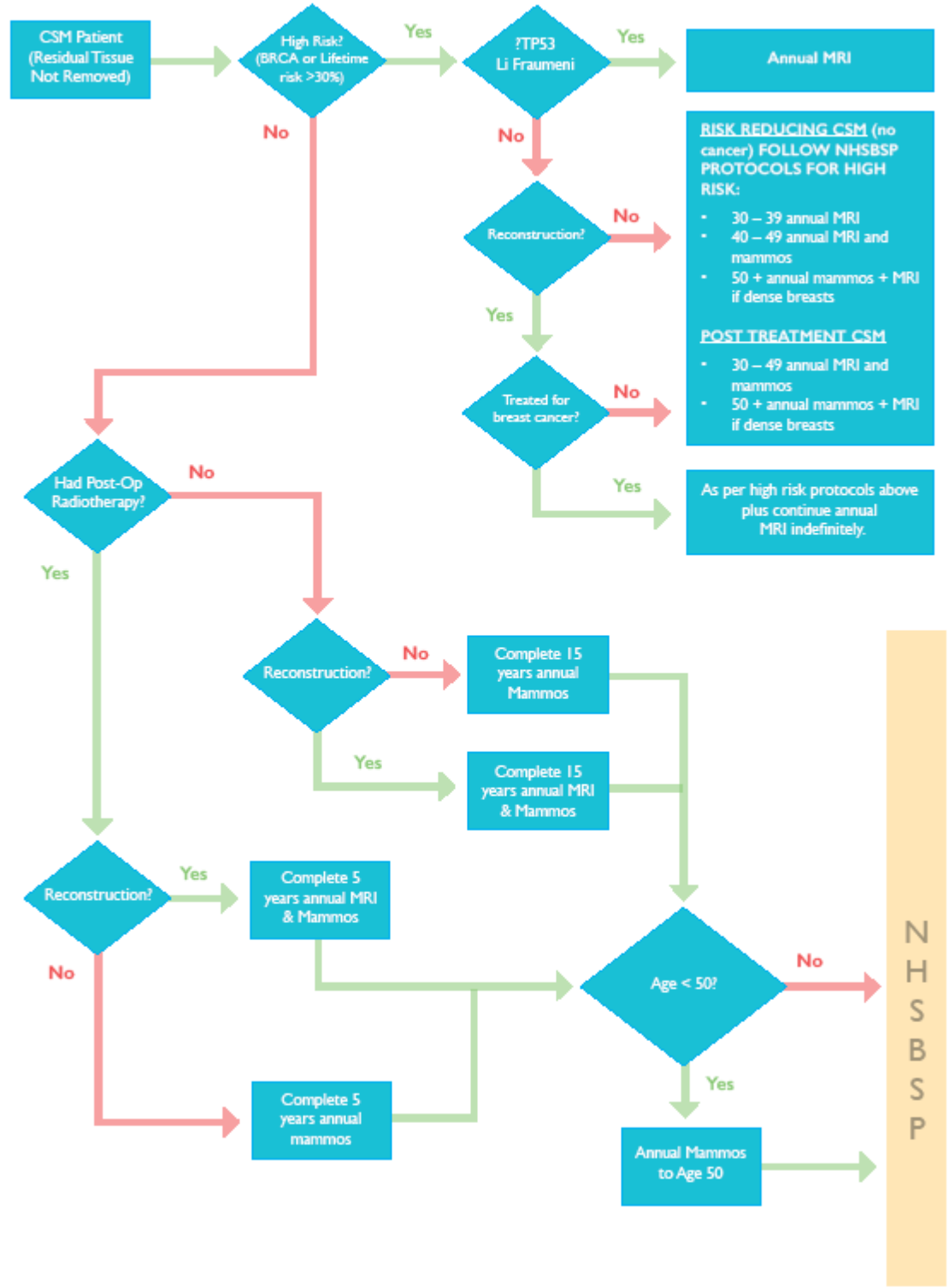
Other Guidance

There is no published guidance which covers the follow-up of women following CSM and there is no published research on this topic. This guideline uses Network / NICE / NHSBSP guidelines (NHSBSP (2013a), NICE (2013) and NHSBSP (2013b)) where women fit into comparable groups (e.g. CSM followed by radiotherapy can be considered similar to a wide local excision with radiotherapy

Ratified Date: 02.06.2016
Launch Date: 22.06.2016
Review Date: January 2018
Guideline Authors: Dr Alison Duncan, Consultant Radiologist, University Hospitals Coventry and Warwickshire NHS Trust; Dr Colin Walker, Consultant Radiologist, University Hospitals Birmingham NHS Foundation Trust; Dr Nadya Polunin, Consultant Radiologist, Heart of England NHS Foundation Trust.

1. Flow Chart

Flow Chart: Imaging Protocol I.P. CSM Cohort



2. Executive Summary and Overview

This guideline serves to ensure that a standardised, consensus approach is used for the follow-up imaging of any asymptomatic patients who were treated with a procedure which came to be known as a 'Cleavage Sparing Mastectomy' (CSM) (Kennedy, 2013). These operations took place between 1994 and 2011.

3. Body of Guideline

When determining the imaging follow-up for these patients, there are a number of factors to consider;-

- Whether the patient is considered to be of high genetic risk such as those diagnosed with the BRCA1 and BRCA2 gene (or equivalent risk) and whether their surgery was for treatment or risk reducing purposes,
- The current age of the patient,
- The number of years that have elapsed since CSM surgery,
- Whether the patient treated by incomplete (CSM) mastectomy had radiotherapy within a year of their surgery,
- Whether reconstructive surgery has been performed.

GENETIC HIGH RISK

This section covers the follow-up of women considered to be of high genetic risk such as those diagnosed with the BRCA1 and BRCA2 gene (or considered at genetic assessment to be at >30% lifetime risk):

CSM surgery within the high risk group could have been performed for either risk reducing purposes or as part of their breast cancer treatment.

Women with TP53 Li Fraumeni should not have mammography but should be followed up with annual MRI whether they have had risk reducing or treatment CSM.

Women at all ages who are at high risk who have had a risk reducing (non-treatment) CSM should be imaged as per NHS Breast Screening Programme high risk guidance (NHSBSP (2013b)) which is summarised in Appendix 1.

Women at high risk who have had CSM for breast cancer treatment under the age of 40 years should have annual mammography in addition to MRI as shown in the flow chart.

Women over 40 years whether the CSM was for risk reducing or treatment purposes should have annual MRI and mammography to age 50 then mammography in the NHS Breast

Screening Programme. If the breasts are dense, MRI should be added and continued after age 50. The additional MRI should be reviewed on an annual basis dependant on breast density over the age of 50 years.

If a reconstruction has been performed then MRI should also be continued annually for all ages, as per the flow chart.

Women at high risk will not be not managed by the routine screening programme at age 50 but continue with annual high risk screening according to NHSBSP protocols. The NHSBSP high risk screening programme is currently being commissioned and expected to commence in the West Midlands region from April 2016.

NON GENETIC HIGH RISK.

For women who are not at genetic high risk, the first factor to take into consideration is whether the patient had radiotherapy within a year of surgery or not.

Radiotherapy given within a year of surgery

These women can be considered to be at equivalent risk to those treated conventionally by wide local excision and radiotherapy and can have equivalent follow-up (Pan Birmingham Cancer Network, July 2012).

If a reconstruction has been performed there is the added difficulty of clinically examining any residual breast tissue lying under the reconstruction or implant. No published evidence is available for follow-up in these circumstances but in view of potential recurrences being difficult to detect either clinically or with mammography, the addition of MRI follow-up for these women is recommended.

Patients who have radiotherapy after CSM should be offered annual bilateral mammography for five years or to age 50 years whichever is longer, and then be discharged to the national breast cancer-screening programme (NHSBSP).

At age 73 years they should be advised that they can continue to opt into the national breast cancer screening programme (NHSBSP). Both breasts should be imaged when screened.

If a reconstruction has been performed MRI should be added to the above for 5 years.

Example 1: A patient diagnosed at age 32 years will require annual bilateral mammography to 37 years old then an extra 13 years annual mammography to enter NHSBSP at age 50 years.

Example 2: A patient diagnosed at age 47 will require annual bilateral mammography to 52 years and then enter NHSBSP at age 52 years.

Example 3: A patient diagnosed at 71 years will require 5 years of annual bilateral mammography until 76 years old and then the patient should be encouraged to opt into the NHSBSP.

Example 4: A patient diagnosed at age 32 years who had a reconstruction will require annual bilateral mammography and MRI to age 37 years and then an extra 13 years annual mammography to enter NHSBSP at age 50 years.

*The 5 years is calculated from the date of the breast cancer diagnosis.

Radiotherapy not given within a year of surgery

If a patient treated for breast cancer by incomplete (CSM) mastectomy has NOT had post-surgical radiotherapy, the risk of local recurrence in this group is higher than those who have had radiotherapy. There is no current evidence regarding the extent of the risk or at what point in time following surgery the risk of recurrence is likely to be highest.

The recommendation for follow-up in this group is not based on any published evidence, but it is the consensus of the radiologists to recommend longer follow-up than for those who have been given radiotherapy.

If a reconstruction has been performed there is the added difficulty of clinically examining any residual breast tissue lying under the reconstruction or implant. No published evidence is available for follow-up in these circumstances but in view of the difficulties of examining the residual tissue under the reconstruction, both clinically and with mammography, the addition of MRI follow-up for these women has been recommended.

Patients who have not had radiotherapy after CSM should be offered bilateral annual mammography for fifteen years after diagnosis or to age 50 years, whichever of these is longer, and then be discharged to the national breast cancer-screening programme (NHSBSP).

At age 73 years they should be advised that they can continue to opt into the NHS national breast cancer screening programme (NHSBSP), both breasts to be imaged.

If a reconstruction has been performed then MRI should be added to the above for 15 years.

Example 1: A patient diagnosed at age 32 years will require 15 years of annual bilateral mammography to age 47 years old then an extra 3 years annual mammography to enter NHSBSP at age 50.

Example 2: A patient diagnosed at age 43 will require 15 years of annual mammography to 58 years old, then enter NHSBSP age 58.

Example 3: A patient diagnosed at 71 years will require 15 years of annual mammography until 86 years old and then the patient should be encouraged to opt into the NHBSP.

Example 4: A patient diagnosed at age 32 years who had a reconstruction will require annual bilateral mammography and MRI to age 47 years and then an extra 3 years annual mammography to enter NHSBSP at age 50 years.

*The 15 years is calculated from the date of the breast cancer diagnosis.

N.B. For ALL patients treated with CSM:-

Follow up and NHSBSP mammography should be of **both breasts.**

MRI may not be possible in more elderly or disabled patients (or where there are contraindications e.g. a pacemaker).

If the patient is over 73 years, they should be encouraged to self-refer to the NHS Breast Screening Programme every 3 years.

Analysis of CSM patient data will be undertaken and may give information regarding the relative risk of recurrence in the future. Should such information become available, it is recommended that these follow-up guidelines be reviewed with the benefit of any further evidence and changed if appropriate. These guidelines must be reviewed on an annual basis.

4. Reason for Development of the Guideline

As a Cleavage Sparing Mastectomy (CSM) is not a recognised surgical procedure for the treatment of breast cancer and has no known ICD code; there was a need to establish guidelines for clinicians conducting patient reviews for this cohort of patients.

The CSM operation was a type of incomplete mastectomy which left a variable amount of residual breast tissue behind. Patients who had this procedure have or may have residual breast glandular tissue. Many of these patients were not treated with the addition of radiotherapy in line with the current conventional treatment given to residual breast tissue after a wide local excision. As a result, these patients are likely to be at higher risk of recurrent disease, although the exact risk of this is not currently known.

A consensus multi-disciplinary meeting was held in February 2015 where discussions regarding this unique cohort took place. The group of radiologists at that meeting (listed later) took responsibility for compiling the initial version of these guidelines which have since been updated by two of the radiologists from the group. The guidelines relate to the follow-

up imaging of women who have had a CSM procedure, and have not had further additional surgery to remove the residual breast tissue. In some cases it is not clear if there is residual tissue and this guidance will also cover women for whom it is possible, but not proven, that there is residual breast tissue (for example tissue under a breast implant).

5. Methodology

There is no published guidance which covers the follow-up of women following CSM and there is no published research on this topic. This guideline uses Network / NICE / NHSBSP guidelines (NHSBSP (2013a), NICE (2013) and NHSBSP (2013b)) where women fit into comparable groups (e.g. CSM followed by radiotherapy can be considered similar to a wide local excision with radiotherapy).

There is no comparative, conventionally treated cohort that can be used as guidance for women who have not had radiotherapy following CSM. The recommendations for follow-up in these women therefore have no evidence base but have been reached as a 'best guess' consensus agreement by the guideline authors, and should be reviewed in the light of any future clinical or published evidence regarding this unique patient group.

6. Implementation in HEFT and Community

This guideline was presented at an extraordinary meeting of the breast cancer team 5th February 2016. The presentation was made by two of the key authors, Dr Colin Walker and Dr Alison Duncan. Further discussion and explanation has taken place on a 1 – 1 basis.

7. Monitoring and Suggested Quality Standards

The guideline will be audited annually over a random 4 week period. A minimum of 20 sets of records will be reviewed. The audit will comprise of checks monitoring whether or not the guidance provided in the virtual MDT's recommendations has been followed. Cases whereby the guidance has not been followed will be investigated. The post holder responsible for auditing this guideline is lead radiologist for breast cancer.

8. References

Kennedy, I (2013) Kennedy Breast Care Review: Review of the Response of Heart of England NHS Foundation Trust to concerns about Mr Ian Paterson's Surgical Practice: Lessons to be learned and Recommendations

NHS Breast Screening Programme (NHSBSP), (2013b) Protocols for the surveillance of women at higher risk of developing breast cancer Version 4 NHSBSP Publication No 74 – June 2013

NICE, 2013 Familial breast cancer. Classification and care of people at risk of familial breast cancer and management of breast cancer and related risks in people with a family history of breast cancer (NICE clinical guidelines 164). Manchester: NICE, June 2013

NHS Breast Screening Programme (NHSBSP), (2013a) Guidelines on organising the surveillance of women at higher risk of developing breast cancer in an NHS Breast Screening Programme. NHSBSP Publication No 73 March 2013

Pan Birmingham Cancer Network (July 2012) Guideline for the Follow up of Patients following Treatment for Breast Cancer.

Appendix 1: Protocol for the surveillance of the High Risk Patients, women at high risk of developing breast cancer who have had risk reducing surgery only.

Ref	Risk	Age	Surveillance Protocol	Frequency	Notes
1	BRCA1 or BRCA2 carrier or not tested, equivalent high risk.	20-29	Not applicable (N/A)	N/A	
		30-39	MRI	Annual	
		40-49	MRI and mammography	Annual	
		50+	Mammography +/- MRI	Annual	Review MRI annually on basis of background density once over 50 yrs.
2	TP53 (Li-Fraumeni)	20+	MRI	Annual	No mammography
3a	A-T homozygotes	25+			No mammography
3b	A-T Heterozygotes	40-49	Mammography	18 monthly	Routine screening from 50 years
		50+	Mammography	Routine screening (3 yearly)	

N.B. For women who are at high risk who have been treated for breast cancer - see appendix 2 on next page.

Appendix 2: Follow up imaging protocol for women treated for breast cancer by incomplete (CSM) mastectomy

Factors	Risk	Current age	Surveillance protocol	Frequency	Notes
High Risk	High Risk women – BRCA 1 and 2 or equivalent risk treated for breast cancer by CSM (NB For risk reducing CSM with no cancer diagnosis follow Appendix 1)	<50	MRI and mammography	Annual	No upper age limit
		50+	Mammography +/- MRI depending on breast density	Annual	Review need for MRI annually based on breast density No upper age limit
Non-high risk, patient has had radiotherapy	No reconstruction	<50	Mammogram yearly to age 50 or for 5 years whichever is longer then enter NHSBSP	Annual	*The 5 years is calculated from the date of the breast cancer diagnosis
		50+	Mammogram yearly for 5 years then enter NHSBSP		
	Reconstruction	<50	Mammogram and MRI yearly for 5 years then annual mammography to age 50 then enter NHSBSP	Annual	*The 5 years is calculated from the date of the breast cancer diagnosis
		50+	Mammogram and MRI yearly for 5 years then enter NHSBSP	Annual	
Non-high risk, patient has not had radiotherapy	No reconstruction	<50	Annual mammography to age 50 or for 15 years whichever is longer then enter NHSBSP. Yearly mammography for 15 years then enter NBSBSP	Annual	* The 15 years is calculated from the date of the breast cancer diagnosis
		50+		Annual	
	Reconstruction	<50	Mammogram and MRI yearly for 15 years then annual mammography to age 50 then enter NHSBSP	Annual	* The 15 years is calculated from the date of the breast cancer diagnosis
		50+	Mammogram and MRI yearly for 15 years enter NHSBSP	Annual	

Glossary

Adjuvant therapy is additional cancer treatment given after breast cancer surgery, to lower the risk of the cancer coming back. It includes local radiotherapy, and systemic therapies with drugs that act throughout the body to treat cancer cells wherever they may be.

Axillary surgery is performed in breast cancer patients to see if cancer has spread to lymph nodes under the arm. This gives important information on cancer stage, and improves local cancer control. Removing multiple nodes by axillary clearance was routine UK practice until sentinel lymph node biopsy (SLNB) became widely available ten years ago. In SLNB a few targeted nodes are removed, and the postoperative risk of lymphoedema (arm swelling) is reduced.

Contralateral: on the opposite side of the body

Ductal Carcinoma in Situ (DCIS) is a growth of breast cancer cells contained inside the milk ducts, and with no invasion into the normal surrounding breast tissue.

HEFT: Heart of England NHS Foundation Trust

Holistic Needs Assessment (HNA) is a discussion with the Clinical Nurse Specialist to talk about physical, emotional and social needs. The focus is on the patient as a whole – not just the illness. It is an opportunity for the patient to talk about any worries or concerns they have. It helps to clarify needs and ensure that patients are referred to those who can help best.

Invasive Breast Cancer is a cancer that started in the milk ducts (invasive ductal carcinoma) or breast lobules (invasive lobular carcinoma) and has invaded normal surrounding breast tissue. It has the potential to spread to lymph nodes and other parts of the body.

Ipsilateral on the same side of the body.

LCIS: Lobular Carcinoma in Situ is abnormal cell growth within breast lobules. It is not a true cancer, but a warning sign of an increased risk for developing an invasive cancer in the future in either breast.

The **margin** is the edge or border of the tissue removed in cancer surgery and can be described as 'not involved' when the pathologist finds no cancer cells at the edge of the tissues or 'involved' when the pathologist finds cancer cells at or very close to the edge of the tissue, suggesting that the cancer has not been completely removed.

The **MDT (Multi-disciplinary team)** comprises specialist doctors e.g. surgeon, oncologist, radiologist, pathologist and nurses, who meet regularly to establish that every patient's diagnosis is correctly made. The MDT will then discuss and recommend the best form of treatment based on local and national guidelines and on each individual patient's circumstances

NHSBSP: NHS Breast Screening Programme

OPCS (Office of Population Censuses and Surveys) coding is a categorisation or grouping system used by NHS staff to identify specific surgical, medical or diagnostic interventions. It is used for example to support operational and strategic planning, resource utilisation, performance management and reimbursement.

Phyllodes tumours are rare breast tumours; the majority are benign tumours but are excised more radically than other non-cancerous tumours in the breast, because they can regrow locally and some can become malignant.

Receptor status: Breast cancer cells often have receptors (proteins) that hormones or other proteins can attach to and stimulate the cancer to grow. Cancers are called hormone receptor-positive or hormone receptor-negative based on whether or not they have these receptors. Roughly two out of every three breast cancers test positive for hormone receptors. Testing for hormone receptors is important because the results help to decide whether the cancer is likely to respond to hormone therapy.

Risk-reducing breast surgery is an operation to remove healthy breasts in people with a breast cancer gene or strong family history, to reduce their risk of developing breast cancer.

Skin sparing mastectomy (SSM): In a traditional mastectomy all the breast tissue and overlying skin and nipple are removed. In skin sparing mastectomy the breast tissue, and usually the nipple, are removed, while leaving most of the breast skin intact. The technique is used to enable immediate breast reconstruction following mastectomy, with better restoration of the natural breast shape using transferred tissue and implants .

Staging is the process of finding out how much cancer is in a person's body and where it's located.

TNM classification: T (Tumour) describes the size of the tumour; N (Node) describes whether the cancer has spread to the lymph nodes and M (Metastasis) describes whether the cancer has spread to a distant part of the body.

The Treatment Summary is a document produced by hospital staff at the end of treatment and sent to the patient's GP. It provides important information for GPs, including possible treatment toxicities, information about side effects and consequences of treatment, signs and symptoms of a recurrence and any actions for the GP.

Tumour grade. The grade of tumour indicates what the cancer cells look like under the microscope and gives an idea of how quickly the cancer may grow and spread.

Wide local excision (sometimes called lumpectomy or breast conserving surgery) involves removal of a breast cancer together with a margin of normal breast tissue around it. This is normally followed by breast radiotherapy.