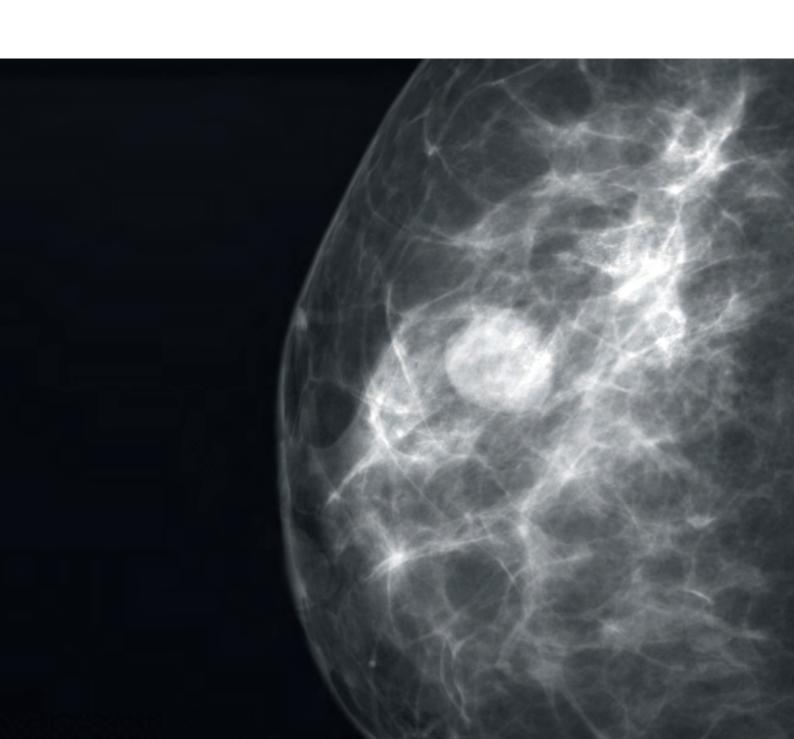
National Mastectomy and Breast Reconstruction Audit 2010



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The Royal College of Surgeons is an independent professional body committed to enabling surgeons to achieve and maintain the highest standards of surgical practice and patient care. As part of this it supports audit and the evaluation of clinical effectiveness for surgery.



The Association of Breast Surgery (ABS) at The British Association of Surgical Oncology (BASO) is the specialty society that represents breast cancer surgeons and is part of the British Association of Surgical Oncology. It is one of the key stakeholders leading the Audit.



British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS) is the specialty society that represents plastic surgeons. It is one of the key stakeholders leading the Audit.



The Royal College of Nursing is an independent professional body that represents nurses and nursing, promotes excellence in practice and shapes health policies, and in particular aims to improve the quality of patient care.



The NHS Information Centre for Health and Social Care (The NHS IC) is England's central, authoritative source of essential data and statistical information for frontline decision makers in health and social care. The NHS IC managed the publication of the 2008-2009 annual report.



The Healthcare Quality Improvement Partnership (HQIP) promotes quality in healthcare. HQIP holds commissioning and funding responsibility for the National Mastectomy and Breast Reconstruction Audit and other national clinical audits.

National Mastectomy and Breast Reconstruction Audit 2010

A national audit of provision and outcomes of mastectomy and breast reconstruction surgery for women in England

Third Annual Report 2010



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We would finally like to acknowledge the contribution of the NCASP Helpdesk.

Forewords

This report highlights some very good aspects of breast cancer surgery in the UK, as well as identifying areas for improvement. The overall participation and ascertainment in the audit has been remarkably high, and the safety of mastectomy and reconstruction has been underlined, with a low incidence of serious complications, low hospital mortality, and minimal need for high dependency or intensive care support. It is impressive that nearly 7000 women completed PROMs (patient reported outcome measures), and although this new information should be interpreted with caution, it is starting to provide interesting and useful insights.

Positive findings, in comparison with general NHS care ratings, are the overall good experience of care, treatment with respect and dignity, and provision of information. However, whilst pain control appears to be better after mastectomy than that for other major cancer procedures, it is less good after reconstructive surgery. Other areas are identified where work is needed to improve access and standards, and these include providing more information to patients about reconstruction and making sure that all the options are available; variations in complication rates after mastectomy and reconstructive procedures also need to be addressed.

I have no doubt that we are moving in the right direction by determining more accurately what is happening at a local level in breast units and sharing this information more widely. Whilst the process can be uncomfortable, it produces strong levers to support the development of training and service provision and is a sure route to give our patients better information and improve the quality of their care.

Martin LeeAssociation of Breast Surgery at the British Association of Surgical Oncology



Breast reconstruction has progressed significantly in the last decade and excellent aesthetic results can now be achieved. Although NICE has stated "All appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally," not all women currently are able to access this.

In this Third Report of the National Mastectomy and Breast Reconstruction Audit, the figures show varying results. The emphasis in the future must be to improve these nationwide by ensuring women have timely and comprehensive information relating to immediate and delayed reconstruction. They should not be prevented from having the procedure they feel is right for them simply because their hospital does not provide the necessary expertise. This may mean the development of recognised regional centres that, with plastic surgical input, are able to provide all types of reconstruction (including microsurgical reconstruction) to the highest standards, evidenced by outcome measures.

Plastic surgeons have a continuing opportunity to collaborate with colleagues in Breast Units and MDTs to enhance the services provided for their patients. This Audit, the first national study in this area worldwide, makes a very significant contribution to the goal of improving the quality life experienced by women following their mastectomy.

Eric FreedlanderPresident, British Association of Plastic,
Reconstructive and Aesthetic Surgeons (BAPRAS)



The findings of this report provide clear evidence that women need the supportive care of a knowledgeable and skilled clinical nurse specialist at all stages of their care pathway. In particular:

- to provide information about the reconstructive options available and the procedures they are about to undergo
- to ensure access to adequate pain relief
- to provide adequate psychological care
- to advocate for women within the multidisciplinary team

The Audit highlights areas where women's needs are not being fully met, specifically in the domains of psychological care, pain control, and information. The reasons for this are unclear but shorter inpatient stays, the education of nurses in psychological care, the recruitment and retention of experienced specialist nurses and the competing priorities within specialist roles are all factors for consideration.

The recommendations outlined in this report offer clinical nurse specialists working in breast cancer care an opportunity to develop and shape practice in line with patient needs.

Maria Noblet

Chair, Royal College of Nursing Cancer Nursing Forum



Executive summary

This is the Third Annual Report of the National Mastectomy and Breast Reconstruction Audit. The Audit aims to describe the provision of mastectomy and breast reconstruction services across England, and investigate the determinants and outcomes of care for women with breast cancer having a mastectomy with or without breast reconstruction.

Mastectomy (removal of all breast tissue) is a treatment undergone by many women with breast cancer. The breast mound may be reconstructed at the time of mastectomy (immediate reconstruction) or at a later date (delayed reconstruction). In 2002, the National Institute for Health and Clinical Excellence (NICE) published guidance on improving breast cancer outcomes, and recommended that "reconstruction should be available [to all women with breast cancer] at the initial surgical operation." In February 2009, towards the end of the Audit's data collection period, NICE published revised guidance and re-emphasised the importance of reconstruction after mastectomy:

- [Clinicians should] discuss immediate breast reconstruction with all patients who are being advised to have a mastectomy, and offer it except where significant comorbidity or (the need for) adjuvant therapy may preclude this option.
- All appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally.

This report focuses on the process of surgical care and short-term outcomes and combines data from two sources. The report uses the details of the women's condition, their treatment and outcomes while admitted to hospital. The data were prospectively collected by clinicians on women treated between 1 January 2008 and 31 March 2009. The report also contains information on post-discharge complications, experience of care and satisfaction with treatment options, reported by women three months after their surgery.

Audit participation

Overall participation in the Audit was excellent. Data were submitted by all 150 NHS acute trusts in England that provide mastectomy and breast reconstruction surgery, with 81 per cent of eligible patients registered. More than two-thirds of the English trusts submitted data on at least 75 per cent of the operations they performed. Data were also submitted by 114 independent sector hospitals and six NHS trusts in Wales and Scotland.

In total, 18,216 women had complete information entered about their mastectomy or breast reconstruction surgery. During the Audit period, 16,485 women underwent mastectomy. Of these women, 3,389 (21 per cent) had a concurrent immediate reconstruction. The remaining 1,731 women underwent a primary delayed breast reconstruction.

Engagement with the patient-reported outcomes component of the Audit was variable among participating NHS trusts and independent hospitals. 8,159 women were sent a questionnaire at three months after their surgery representing 51.2 per cent of consenting patients deemed eligible for this component of the Audit. The remaining eligible patients were not asked to participate in the patient-reported outcomes part of the Audit, mostly because of logistical difficulties at the hospital level. Of the patients who were sent a 3-month questionnaire, 6,963 (85.3 per cent) responded.

Information given to women before their surgery

In the 3-month questionnaire, women were asked about how much information they were given before their surgery. Overall, nine out of ten women felt that they had received the right amount of information about their chosen type of procedure (mastectomy, mastectomy with immediate reconstruction, delayed reconstruction). The majority were satisfied with the information on the surgical procedures (how it was performed, recovery time, and possible complications). Around one-half of women were very satisfied with the information they received on what their scars would look like and what postoperative pain to expect.

Women may receive information on breast reconstruction verbally, in written form or be shown photos of patients who had undergone the procedure. Among women undergoing a reconstructive procedure, almost all reported discussing their surgery with a clinician, and eight in ten women were shown photographs. In comparison, around two-thirds of women who underwent mastectomy were provided with reconstructive information verbally, and only one-quarter were shown photographs.

Women who had a mastectomy only were asked about the information they had received on reconstruction. Only 65 per cent felt that they had received the right amount. In addition, 42 per cent reported that the lack of information contributed to not choosing to have immediate reconstruction. Women who felt that they did not receive the right amount of information on reconstruction were much less likely to have received information in each of the different formats.

Overall rating of experience and satisfaction with care

The overall experience of care for women with mastectomy and breast reconstruction was excellent. 88 per cent of patients felt that they had always been treated with respect and dignity while in hospital, and 90 per cent of women rated the care they received as excellent or very good.

Inpatient complication rates

The Audit asked NHS trusts and independent hospitals to record inpatient complications that required some form of therapeutic intervention. Overall, around 10 per cent of women undergoing mastectomy had a local complication. For mastectomy and immediate reconstruction, the proportion of women who had a least one complication

ranged from 15 per cent to 18 per cent across the different types of procedure due to reconstruction specific factors. There was an increased risk of haematoma/seroma complications for pedicle flap reconstructions at their flap donor site and an increased risk of re-examination for free-flap reconstructions. A similar pattern of complication is observed for women undergoing delayed reconstruction.

Rates of flap failure for flap-based reconstructions were low. For pedicle flap reconstructions, the total flap failure rate was 0.20 per cent (95 per cent CI 0.06 to 0.46). For free flap reconstructions, the total flap failure rate was 1.98 per cent (95 per cent CI 1.21 to 3.04). The higher rate for free-flap reconstruction reflects the characteristics of the procedure, in which the flap's blood vessels are reattached to vessels in the breast area. In a pedicle flap procedure, the vessels are kept intact.

We provide inpatient complication rates for NHS trusts and independent hospitals to support local benchmarking. Figures were produced for return to theatre, mastectomy-site complications and distant/systemic complications. Mastectomy site complication rates included wound infection requiring antibiotics, wound dehiscence and skip-flap necrosis. The rates were adjusted for differences in patient characteristics and type of surgery. Funnel plots were used to compare organisations and identify whether rates differed significantly from the average rate for England. Unfortunately, despite a 2-month data checking period, 50 organisations were excluded from this comparative analysis due to low case-ascertainment or incomplete complications data.

The initial analysis identified a few organisations with higher than expected adjusted rates of complication. These organisations were notified and given an opportunity to respond because the variation in complication rates could be due to various factors. All organisations provided, in writing, additional information. This identified various data errors, which on correction, led to all organisations having adjusted complication rates within the expected range.

Variation in complication rates should be interpreted with care because the differences could be due to various factors. The analysis took account of data quality and patient characteristics as far as possible but it is possible that these issues still had an influence. Variation may also arise from differences in the clinical protocols at hospitals. Nonetheless, it is important that clinicians and management teams review their practice to ensure that there are no systematic deficiencies in care.

National post-discharge complications at 3-months after surgery

There is little information available on the rate of postdischarge complications. Women were asked to report these in the 3-month questionnaire. The key findings were as follows:

- One in ten mastectomy patients and almost one in six reconstruction patients were readmitted for unplanned further treatment or surgery after their primary admission
- One in five mastectomy patients and one in four reconstruction patients required antibiotic treatment for a wound infection post-discharge
- One in two mastectomy patients (with or without immediate reconstruction) and a third of all delayed reconstruction patients required aspiration or drainage of a collection of fluid at their operative site.

It is not possible to state whether these reported levels of morbidity represent a problem with the quality of care provided – they may simply represent the inherent risks associated with mastectomy and breast reconstruction. The information should be used to better inform patients about the procedures and for benchmarking.

Pain management in the first 24-hours after surgery

In the Audit, all women seemed equally satisfied that the staff treating them had done everything they could to control their pain. However, levels of severe pain in the first 24 hours differed between the types of surgery. Women undergoing mastectomy reported low levels of severe pain in the first 24 hours following surgery. Their rate was 6.2 per cent, which compares well to an 11 per cent rate for other types of major surgery. Women undergoing immediate and delayed reconstruction reported higher rates (respectively, 16.5 per cent and 20.1 per cent). Hospitals should examine whether the levels of severe pain experienced by women undergoing reconstruction can be improved.

Implications for clinical practice

The Audit is the first national study of mastectomy and breast reconstruction surgery. Our findings show that the overall experience of care for women undergoing mastectomy and breast reconstruction in England was excellent.

However, we have identified some specific areas of concern. Local providers and Cancer Networks should use these results to benchmark performance and reflect on areas where there is large deviation from national averages. Areas for particular attention include the provision of information about reconstruction to women prior to their surgery, and the assessment and management of postoperative pain. Clinical teams should also examine local clinical protocols and practice with the aim of reducing postoperative complication rates.

We would like to thank all those organisations who participated in the Audit for their support and effort. The high-level of case ascertainment they achieved has enabled us to provide figures against which practice can be now benchmarked. Hospitals should review the key findings, identify any areas in which local improvements are required, and act to improve the outcomes of surgery in this group of women.

Recommendations

- Clinicians should act to better inform women about both the procedures they decide to undergo and the reconstructive options available. As per the 2009 NICE guidance, clinicians should ensure that women are offered a full range of appropriate reconstructive options, whether or not these are available locally.
- NHS trusts and independent hospitals should ensure that women understand how to report their levels of pain and access appropriate pain relief, and that they are provided with adequate psychological support following their surgery.
- 3. NHS trusts and independent hospitals should continue to monitor patients' experience with care and act to maintain the high levels of satisfaction reported.
- 4. Clinicians should use the data on inpatient and postoperative complications to inform women about risks of different operations. Women considering reconstruction should be pre-operatively informed that the chance of requiring further surgery either during their initial admission or postoperatively is around one in ten.
- 5. Multidisciplinary teams at NHS trusts and independent hospitals should review the outcomes of their own patients and compare them with the national outcomes described in this report to ensure that they are delivering a high quality of care.
- 6. The Surgical Associations and Royal Colleges involved in mastectomy and breast reconstruction surgery should consider issuing new guidance on patient selection, operative techniques and postoperative care.

1. Introduction

1.1 Overview of the Audit

The National Mastectomy and Breast Reconstruction Audit began on 1 January 2007. The principal aims of the Audit are to describe the provision of breast reconstruction services across England, and investigate the determinants and outcomes of care for women with breast cancer having a mastectomy with or without breast reconstruction.

This is the Third Annual Report of the Audit. It provides information on operations performed in 2008 and 2009 using two sources: clinician-reported data about patient characteristics, treatment and outcomes; and patient-reported data about the experience of care and post-discharge complications.

Breast reconstruction is a safe option for most women undergoing mastectomy. In 2002, the National Institute for Health and Clinical Excellence (NICE) recommended that "reconstruction should be available [to all women with breast cancer] at the initial surgical operation. In February 2009, towards the end of the Audit's data collection period, NICE published revised guidance. This re-emphasised the importance of access to breast reconstruction by recommending that:

- [Clinicians should] discuss immediate breast reconstruction with all patients who are being advised to have a mastectomy, and offer it except where significant comorbidity or (the need for) adjuvant therapy may preclude this option.
- All appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally.

The Audit was originally designed as a three year project. Its principal component was a prospective study of the care received, and the outcomes attained by women undergoing mastectomy or reconstruction surgery. The Audit was funded to include women who underwent surgery between 1 January 2008 and 30 September 2008. Additional funding enabled extension of the enrolment period to 31 March 2009 and the collection of long-term (18 month) outcome data from patients. The reporting timetable for the Audit was therefore extended to include a fourth year.

A Fourth Annual Report will be published in early 2011 and will include a number of additional analyses. First, it will include data on patient quality of life collected 18 months after surgery. Second, it will include an analysis of the Audit data linked to Hospital Episode Statistics at the individual patient level. The linked dataset will allow us to validate the Audit data reported by clinicians, in particular both national and local complication rates.

The key findings from the Audit's First and Second Annual Reports are summarised in Appendix 1 to provide a background to this report.

1.2 Role of mastectomy and breast reconstruction surgery

The incidence of breast cancer has been increasing steadily in England for many years. Between 1977 and 2006, the age-standardised incidence per 100,000 women rose from 75 to 122.4 The majority of women treated for breast cancer have invasive disease. However, following the introduction of the National Health Service (NHS) breast cancer screening programme in 1988, ductal carcinoma in situ (DCIS), a non-invasive tumour, is being detected more frequently and as a consequence DCIS is the indication for an increasing proportion of all breast cancer surgery. The screening programme and increased breast cancer awareness have also led to more cancers being detected at an earlier stage.

The primary aim of breast cancer treatment is to reduce the risk of premature death by removing or ablating the tumour. Surgery is the first line of treatment for most women, whether or not their tumour is invasive (see box). It may involve removal of part (breast conserving surgery) or all (mastectomy) of the breast tissue. Mastectomy may be used when breast conserving surgery would significantly distort the breast shape and contour, when the tumour is multifocal (in more than one area of the breast), or when most of the breast is involved. Some women, when offered the choice, may also prefer mastectomy to the option of breast conserving surgery.

A breast reconstruction procedure recreates the breast mound following mastectomy, and consequently restores symmetry. Reconstruction can be performed either at the same time as the initial mastectomy (immediate) or at a later date (delayed).

There are various approaches to breast reconstruction. One involves the use of an implant under the pectoralis major muscle. These procedures may involve a tissue expander (an implant into which saline may be injected to increase its size) or the direct insertion of a fixed volume implant.

Reconstruction using the patient's own tissue may be performed in two distinct ways. "Pedicle flap" breast reconstruction involves rotating a "flap", comprised of skin, fat and usually muscle, from the patient's back or abdomen to the breast area, while keeping intact a tube of tissue containing its blood supply. "Free flap" breast reconstruction involves a similar flap being completely detached from the patient's body (abdomen, buttock or thigh) along with its supplying blood vessels. It is then placed at the mastectomy site, where microsurgery is used to restore its blood supply by joining the vessels that supply the flap to vessels in the breast area.

Overview of surgical treatments for invasive and non-invasive breast cancer

Invasive disease

For women with invasive disease, surgical management of the tumour may involve breast conserving surgery, mastectomy alone, or mastectomy with immediate or delayed breast reconstruction. Axillary surgery is normally undertaken at the time of the breast conserving or mastectomy procedure.

Axillary surgery involves removal of some or all of the lymph nodes from the axilla (armpit), and is usually performed to determine the prognosis and plan adjuvant therapy. However, extensive axillary surgery may disrupt the drainage of lymphatic fluid from the arm and increase the risk of chronic lymphoedema (swelling). This is particularly a risk for the small number of women who have surgery followed by radiotherapy to the axilla. Sentinel lymph node biopsy involves removing only the first few nodes draining the breast area and is increasingly used to assess spread while minimising this associated risk of lymphoedema.⁵

The likelihood that breast cancer surgery involves mastectomy, mastectomy with immediate reconstruction or breast conserving surgery, depends on factors such as the size of the tumour, its location and its type. These factors also play a role in deciding the types of adjuvant treatments needed. Adjuvant treatments such as radiotherapy may impair the cosmetic results of an immediate breast reconstruction. Immediate reconstruction generally involves a longer wound healing and recovery period than mastectomy alone; this may also delay the administration of radiotherapy and chemotherapy. For these reasons, an anticipated need for such treatments may reduce the likelihood of a woman undergoing mastectomy having immediate reconstruction.

Post-mastectomy radiotherapy to the chest wall, axilla and supraclavicular fossa (area above the collarbone) is given to women at higher risk of cancer recurrence in the breast area. Axillary radiotherapy increases the risk of lymphoedema, but independently reduces the likelihood of local and regional recurrence in those treated.6 Radiotherapy in the postoperative period may impair the cosmetic outcome of a flap or implant and is seen as a relative contraindication to immediate breast reconstruction.

If indicated, chemotherapy may be given before or after mastectomy. Pre-mastectomy chemotherapy is increasingly used in women with large tumours. It may ensure that a subsequent mastectomy can remove the entire tumour, or even reduce its size to such an extent that breast conserving surgery becomes an option. Chemotherapy reduces the risk of recurrence and death from breast cancer in all age groups.7

Ductal carcinoma in situ

For women with isolated ductal carcinoma in situ (DCIS), surgical management may involve breast conserving surgery, mastectomy alone, or mastectomy with immediate or delayed breast reconstruction. As DCIS may be more extensive and multi-focal than invasive disease, a greater proportion of women with isolated DCIS undergo mastectomy even though they have no invasive disease component.

Radiotherapy and hormone therapy are not normally administered to women with non-invasive tumours (eg, DCIS) undergoing mastectomy. This reduced need for adjuvant therapies means that they are more likely to be deemed appropriate candidates for immediate breast reconstruction.

Pedicle flaps are frequently used in conjunction with an implant whereas this is very rarely the case for free flap procedures. Thus, there are four main types of reconstruction:

- a tissue expander without the use of autologous tissue
- an implant (or expander) covered by a pedicle flap
- a pedicle flap without the use of an implant or expander
- a free flap procedure.

The likelihood of a woman having a breast reconstruction at the time of her mastectomy depends on many factors, including:

- her personal preferences
- the timing and nature of other treatments for her breast cancer (adjuvant therapies)
- her fitness for reconstructive surgery as determined by factors such as age, general health status, lifestyle and the type of tumour involved
- the type of reconstructive surgery available in the area in which the patient lives.

While there is much uncertainty about the appropriateness of breast reconstruction for certain patients (eg, those with other health problems), it is accepted that women should not be prevented from having a breast reconstruction if their hospital does not provide the operation they want. The recent NICE guideline stated that "all appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally".3

1.3 Outcomes of mastectomy and reconstruction

Clinical outcomes

Mastectomy and breast reconstruction surgery are comparatively safe procedures. The surgery is elective and this enables a formal, pre-operative risk assessment to be performed. Less than 1 in 400 patients die as a result of their surgery⁸ and emergency transfer to a high dependency or intensive therapy unit is relatively rare.

However, a variety of short-term complications are possible. These include complications related to the removal of breast tissue, the transfer of reconstructive tissue away from a donor site, and the reconstructive procedure itself. Common complications that might occur during the initial admission or after discharge include: wound infection, would dehiscence (opening of the surgical wound), skin flap necrosis (death of skin adjacent to the wound) or haematoma (the collection of blood between layers of tissue). If serious, these may require medical treatment or reoperation. Other post-discharge problems include persistent pain and numbness

in the surgical sites and functional difficulties related to arm and shoulder movement. Treatment of these problems may require readmission to hospital.

The rate of reoperation is increasingly used as an indicator of quality. It is recognised as being potentially useful for breast cancer surgery because a return to theatre during the primary hospital admission is likely to reflect clinical concerns or a complication. However, interpreting this indicator is not straight forward. For many patients, a return to theatre may have been planned. For reconstruction operations, it may indicate a minor adjustment to the reconstruction and have no negative consequences for the long-term outcome.

Patient reported outcomes

It is widely accepted that patients can give a valid and reliable perspective on their care experience and the effectiveness of their treatment⁹. Patients' experience of care is a key dimension of healthcare quality, alongside safety and clinical effectiveness. For patients undergoing mastectomy with or without breast reconstruction the core elements of a high quality care experience include:

- involvement in decisions
- provision of appropriate information
- provision of appropriate choices and access to care
- satisfaction with the behaviour of doctors and nurses
- pain control
- treatment with respect and dignity throughout the episode.

Many dimensions of a woman's quality of life can be affected by breast cancer surgery including body image, self-esteem, confidence, sex life, physical pain, activities of daily living and social life. An aim of the Audit is to deepen our understanding of the impact of mastectomy and breast reconstruction on quality of life and information on these outcomes will be provided in the fourth and final Audit report.

1.4 Responsibility for patient management at a local level

In this report, we provide information about care quality at the individual NHS trust level. This is because although NHS trusts have surgeons operating at multiple sites, and in some cases delivering care through multiple multidisciplinary teams, the trust management team have overall responsibility for care quality.

The responsibility for patients is organised differently within independent sector hospitals. Here, local management teams have responsibility for the care delivered at each hospital. We therefore report outcomes at the hospital level in the independent sector.

2. Participation and the patient population

2.1 Prospective Audit methodology

All NHS acute trusts and independent sector hospitals that provide mastectomy and breast reconstruction surgery in England were invited to participate in the prospective audit of practice and outcomes. Hospitals were asked to enrol all women aged 16 years and over diagnosed with breast cancer or DCIS who underwent unilateral mastectomy or primary breast reconstruction between 1 January 2008 and 31 March 2009. Data collection was required from both the local staff treating the patient and the patient themselves.

Data collected by hospital staff

The dataset collected by local hospital staff was split into five sections. The first section recorded patients' demographics and their willingness to receive follow-up questionnaires at their home address. Subsequent sections recorded information about the type of operation and the reconstructive choices made available, previous treatments and comorbidity, tumour characteristics, and complications before discharge. Sample clinical datasheets can be viewed on the Audit website at: www.ic.nhs.uk/mbr

Data were submitted online into a custom-built secure database either manually or via CSV (comma separated variable) file uploads. The database incorporated validation rules for each data item, and all items in each section had to be complete before data could be saved.

The deadline for the submission of data to the Audit was 14 May 2009. To increase levels of completeness and ensure the validity of submitted data, all participating organisations were provided with an opportunity to review the data they had submitted.

Data collected from patients

Women who consented to complete the Audit's patientreported outcome measures were asked to complete questionnaires at 3 and 18 months after surgery. Both were administered in the same way. At the appropriate time, women were posted the questionnaire and were asked to complete and return it in the supplied prepaid envelope. If the questionnaire was not received after 5 weeks, participants were sent a reminder letter with an additional questionnaire.

The 3-month questionnaire addressed the provision of information, reconstructive choices, pain management, postoperative complications and their overall care experience. Distinct questionnaires were developed for women undergoing mastectomy, immediate reconstruction and delayed reconstruction due to differences in their treatment pathways.

The 18-month questionnaire covered various dimensions of women's quality of life. There were two distinct questionnaires, one for women who had undergone mastectomy alone, and the other for women who had undergone immediate or delayed reconstruction. Results from the 18-month questionnaires will be presented in the Fourth Annual Report. Sample questionnaires can be viewed on the Audit website at: www.ic.nhs.uk/mbr

Statistical analysis

Rates of activity and complications are typically expressed as percentages, being derived either for all women or for women who underwent one of the primary procedures (mastectomy, mastectomy with immediate reconstruction or delayed reconstruction). The statistical significance of differences between percentages was assessed using the chi-squared test. Where necessary, multiple logistic regression was used to adjust for potential confounders such as age. All p-values are two-sided and those lower than 0.05 were considered to indicate a statistically significant result. STATA software was used for all statistical calculations.

Complication rates were calculated for each NHS trust and independent hospital. Multivariable logistic regression was used to examine the relationship between the rate of each type of complication, measures of patient risk (age, deprivation, ASA grade, ECOG score, smoking status, diabetes, body mass index, previous cancer treatments) and the type of operation performed (type of mastectomy, type of axillary surgery, type of reconstruction). Complicationspecific regression models were then used to derive risk-adjusted complication rates for each NHS trust and independent hospital.

For each complication, the variation in adjusted rates of the hospital organisations was examined using a funnel plot. 10 This plot tests whether the complication rate of any single NHS trust or independent hospital differs significantly from the national rate. We used two funnel limits that indicate the ranges within which 95 per cent (representing a difference of two standard deviations from the national rate) or 99.8 per cent (representing a difference of three standard deviations) would be expected to fall if variation was due only to sampling error. The funnel plots use exact binomial limits which become narrower as the number of procedures performed increases. Following convention, we use the 99.8 per cent limits to identify "outliers", as it is unlikely for an organisation to be beyond these limits solely because of random variation (a 1 in 500 chance).

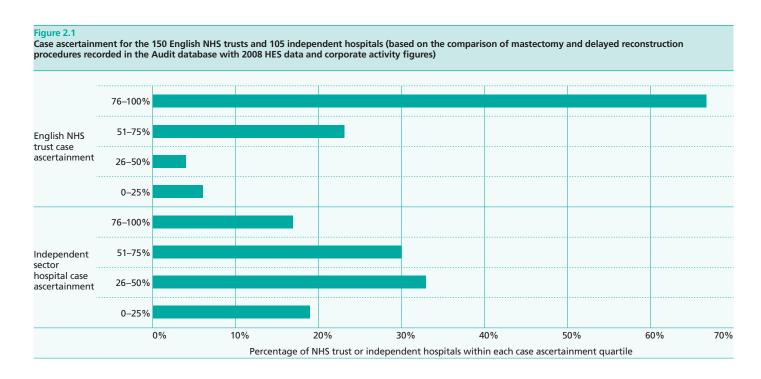
2.2 NHS trust and independent hospital participation

Participation by healthcare providers was generally excellent. Data were submitted by all 150 NHS acute trusts in England that perform mastectomy or breast reconstruction and by 114 independent sector hospitals. A further six NHS trusts in Wales and Scotland chose to participate.

A total of 19,336 women were registered during the Audit. Of these, 819 women were excluded from subsequent analysis because information about the type of operation performed was not submitted. A further 301 were excluded because their operation date was outside the 15 month inclusion period. This left 18,216 records for women treated within the inclusion period and which had contained complete information about their mastectomy, immediate reconstruction or delayed reconstruction surgery. Of these, 16,558 were treated by English NHS trusts, 1,249 by independent hospitals, and 409 by non-English NHS trusts.

The proportion of eligible English NHS patients within the Audit was estimated using HES data for 1 January to 31 December 2008; HES data for the first quarter of 2009 were not yet available. Overall, NHS case ascertainment was 81.4 per cent. More than two-thirds of the 150 NHS trusts submitted operative data for at least 75 per cent of the expected number of cases (Figure 2.1).

Five major independent healthcare companies provided us with the number of eligible patients treated at their hospitals within the 15 month audit period. This allowed us to calculate case-ascertainment for 105 of the 114 participating independent hospitals (Figure 2.1). Case-ascertainment estimates for NHS trusts and independent hospitals are included in Appendix 5.



2.3 Completeness of data recorded by hospital staff

The dataset was divided into five discrete sections to allow hospitals to submit clinical information as and when it became available. The proportion of patients for whom each section was complete was very high, exceeding 96 per cent for all sections (Table 2.1).

Within each section, the overall quality of the data was also very high. Hospitals had been aided in this by various validation rules within the IT system. A section could not be saved unless all data items were completed in the correct format. Almost all data items had one or more options which could be selected from a short list. For the few items with free-text responses (eq dates, body mass index), validation rules ensured that data could not be saved unless entered in the correct units and within an appropriate absolute and relative range. For example, the date of admission could not be later than the date of procedure or date of discharge.

2.4 Patient-reported outcomes: rates of consent and response

The extent to which patients were successfully recruited to the patient-reported component of the Audit varied across NHS trusts and independent hospitals. In total, 10,632 women were asked to consent to take part in this element of the Audit. The remaining 8,704 women were not asked for consent. The proportions of eligible women who were asked to consent to take part are given at the NHS trust and independent hospital level in Appendix 5.

In some cases, hospital staff did not ask for consent due to legitimate concerns regarding poor eyesight (n=27), literacy or language comprehension issues (n=166), or cognitive impairment (n=202). However, a large number of women were not approached for this element of the Audit due to logistical problems with consent procedures. At 11 English NHS trusts and 42 independent hospitals, no women were asked for consent.

Among those women that were asked, 8.725 (82 per cent) women agreed to participate. Of these women, 7,783 (89 per cent) were being treated at 139 NHS acute trusts in England and 696 (8 per cent) were being treated at 72 independent sector hospitals. The final 246 (3 per cent) women were consented at the six participating non-English NHS trusts.

Delays in registering some patients meant that their three month questionnaires could not be sent out on time. A number of consented women also died during or following their admission. After excluding these two groups of women, 8,159 women (93.5 per cent) had a three month auestionnaire sent to their home address. Of these, 2,580 (31.6 per cent) did not initially respond and were sent a reminder questionnaire after five weeks.

In total, 6,882 (84.3 per cent) women returned a completed questionnaire. Response rates were similar across the three groups, although a lower proportion of mastectomy patients gave their consent compared to those who underwent reconstruction (Table 2.2).

The returned questionnaires were, in general, well completed, with no specific concerns about missing values or data quality.

Table 2.1 Data completeness			
Data section	Patients with complete operative data treated within the inclusion period for whom the data section was completed		
	Number	Per cent	
Operative and decision-making	18,216	100.0	
Inpatient peri-operative morbidity	18,027	99.0	
Previous treatments and comorbidity	17,779	97.6	
Pathology	17,568	96.4	

Three month questionnaires: number asked for consent, proportion that gave consent, number sent questionnaire, proportion that responded by surgery type (M, IR, DR)

Patient characteristics	Mastectomy only	Immediate reconstruction	Delayed reconstruction	Overall
Number of women asked for their consent	7,251	2,163	1,107	10,521
Number (%) of women who gave consent when asked	5,713 (79)	1,939 (90)	984 (89)	8,636 (82)
Number of women sent a questionnaire	5,418	1,857	884	8,159
Number (%) of those sent a questionnaire who returned it	4,637 (86)	1,553 (84)	692 (78)	6,882 (84)

2.5 Interpretation of patient-reported outcomes data

Patients' recall of events may change over time and this may influence their reporting of outcomes and ratings of patient experience. The Audit tried to keep the distribution of questionnaires within a narrow period of time around the 3-month census point. However, this was not always possible. During the Audit, there were delays in the consent status of patients being recorded in the online database at some organisations. There were additional problems due to delayed linkage with the National Strategic Tracing Service, which was necessary to ensure that patients had not died and to obtain their current address. Finally, the five week reminder letters (with enclosed questionnaires) to non-respondents increased the interval between surgery and questionnaire completion.

Overall, 67 per cent of the 3-month questionnaires were returned between 3 and 6 months. 90 per cent were returned between 3 and 9 months. We examined whether there was a relationship between the interval of completion and the various patient-reported outcomes (the analysis used 4 categories of response interval: under 3 months, 3 to 6 months, 6 to 9 months and more than 9 months, with differences being tested using the chi-square test). In the majority of cases, there was no statistical association between time interval and an outcome measure. Important exceptions were:

- 1. The level of satisfaction with the quantity of information decreased across the longer response intervals from 92 per cent to 89 per cent.
- 2. The level of satisfaction among mastectomy-only patients with the quantity of information on reconstruction was slightly higher among women who responded between 3-6 months compared to the other intervals.
- 3. Among women who returned the questionnaire 3 to 6 months after surgery, a slightly higher proportion reported that they were always treated with respect, and reported their overall rating of care as excellent or very good.
- 4. Rates of postoperative complications were not statistically different across the response intervals with the exception of the proportion of women experiencing the collection of fluid requiring drainage. This increased with time.

Although the response interval had a statistically significant effect on some questions, the size of the effect tended to be small. Consequently, we considered that this bias was likely to be less than the bias that might be introduced if the analysis was restricted to only those women who returned their questionnaire between 3 and 6 months. Moreover, the effect of including the data from women with a long response interval tended to reduce the estimated levels of patient experience. Thus, the patient-reported outcomes may be conservative.

Given these issues, we decided to provide only national data on postoperative complications and patient experience in this Report. The figures should be considered to be preliminary. In the Fourth Annual Report, we will provide more detailed figures, both nationally and (if shown to be valid and reliable) for individual NHS trusts and independent hospitals.

3. Patient characteristics and patterns of care

3.1 Patient characteristics

Of the 18,216 women with complete operative data, 16,485 underwent mastectomy, of whom 3,389 (20.6 per cent) had an immediate reconstruction. The remaining 1,731 women underwent a delayed breast reconstruction, a breast reconstruction some time after the primary mastectomy, during the 15-month audit period. The socio-demographic and clinical characteristics of these women, grouped by type of surgery, are summarised in Table 3.1 and Table 3.2. As expected, women undergoing mastectomy-only tended to be older and be in poorer health.

Although women from non-white ethnic groups accounted for only 5 per cent of women (where ethnicity was known), there was considerable variation between Cancer Networks. The five London Cancer Networks had the highest proportions of non-white women (22 per cent for London overall), while Thames Valley and Pan Birmingham also recorded proportions substantially higher than average (see Appendix 3 for more details).

3.2 Pathology data

Pathology information plays an important role in the decision to provide and/or choose to have a breast reconstruction. In general, the likelihood of undergoing breast reconstruction at the time of mastectomy is reduced in women with more advanced disease, although exact thresholds of appropriateness are not agreed.

Pathology data were available for 17,568 women of whom 85 per cent had invasive carcinoma with or without ductal carcinoma in situ (DCIS). The remainder were treated for DCIS alone. As noted in Chapter 1, women with DCIS alone have a different treatment profile than women with an invasive carcinoma. In particular, radiotherapy is almost never indicated for women who have had a mastectomy for DCIS alone because it has no benefits in terms of local recurrence or survival.³ This is one reason why a higher proportion of women with DCIS had immediate reconstruction (38 per cent) compared to women with invasive disease (17 per cent).

For women with invasive tumours, the grade of disease for women who had immediate reconstruction was slightly lower compared to those who had mastectomy alone. Women who underwent immediate reconstruction also had smaller tumours on average and were less likely to have positive axillary lymph nodes than those who underwent mastectomy alone.

Socio-demographic characteristics, peri-operative fitness and functional status of women having the three types of procedure (column proportions)

		-	•	•
Patient characteristics	Mastectomy only	Immediate reconstruction	Delayed reconstruction	Overall
Number of women	13,096	3,389	1,731	18,216
Age in years (%): Under 40	4	11	9	6
40 to 49	15	34	34	20
50 to 59	20	34	36	24
60 to 69	26	19	18	24
70 to 79	22	2	3	17
80 and over	13	0	0	9
White ethnicity (%)	95	93	95	95
Current smokers (%)	14	11	10	13
Obese (BMI≥30) (%)	29	17	22	26
Diabetic (%)	8	2	2	6
ASA grade ¹ III or IV (%)	13	2	2	10
ECOG score ² 2 or more (%)	16	1	1	11

American Society of Anaesthesiologists (ASA) six category physical status classification system for assessing patients before surgery. Grades I to IV are defined by the presence and severity of systemic disease. Grade I represents a normal healthy patient; while Grade III and IV indicate severe systemic disease that limits activity.

Eastern Cooperative Oncology Group (ECOG) score for performance status in cancer patients. 0 denotes perfect health and 4 a patient who is bed-bound, completely disabled and unable to carry out any self-care. Patients scoring 2 or more cannot perform light / office work.

Among the women undergoing mastectomy for DCIS, 1,693 (70 per cent) underwent concurrent axillary surgery. A further 253 (11 per cent) underwent axillary surgery prior to their mastectomy. A proportion of these women were reported to have positive axillary lymph nodes, which was unexpected given the lack of invasive disease. As hospitals had to submit all pathology data at the same time, it seems unlikely hospitals would have submitted pre-operative biopsy data that identified DCIS but not an invasive focus found after mastectomy.

There are two possible explanations. First, these women may have had an invasive primary cancer that was not detected in the breast. Second, these women may have had a previous breast conserving procedure that removed all invasive disease but left residual DCIS requiring a mastectomy. The original invasive pathology might then have been overlooked during data collection. However, this second explanation seems unlikely. There were 1,323 women with DCIS who had undergone a mastectomy with axillary surgery but who had not undergone previous breast conserving surgery. Among these women, 197 (15 per cent) were recorded as having lymph node involvement.

Invasive carcinoma				
Patient characteristics	Mastectomy only	Immediate reconstruction	Delayed reconstruction	Overal
Number of women	11,255	2,311	1,347	14,913
Mean invasive tumour size / mm	32	25	29	30
Grade of disease (%)				
Grade 1	10	12	11	10
Grade 2	47	49	47	47
Grade 3	43	39	42	43
Number (%) of women who had axillary surgery before or at time of mastectomy	10,598 (94)	2,175 (94)	843 (63)	13,616 (93
Lymph node involvement in women who had axillary surgery at time of mastectomy (%)				
0 nodes	48	63	49	51
1 to 3 nodes	30	26	33	29
4 or more nodes	22	11	18	20
Nottingham Prognostic Index (NPI) (mean) ²	4.7	4.3	4.8	4.7
Ductal carcinoma in situ (DCIS)				
Patient characteristics	Mastectomy only	Immediate reconstruction	Delayed reconstruction	Overal
Number of women	1,497	927	231	2,655
			30	34
Mean DCIS tumour size / mm	33	37	50	٠.
Mean DCIS tumour size / mm Grade of disease (%)	33	37	30	J-
	11	10	12	
Grade of disease (%)				10
Grade of disease (%) Low	11	10	12	10
Grade of disease (%) Low Intermediate	11 27	10 24	12 28	10 20 64
Grade of disease (%) Low Intermediate High Number (%) of women who had axillary surgery before or	11 27 62	10 24 67	12 28 60	10 20 64
Grade of disease (%) Low Intermediate High Number (%) of women who had axillary surgery before or at time of mastectomy Lymph node involvement in women who had axillary surgery at time of mastectomy (%)	11 27 62	10 24 67	12 28 60	10 26 64 2,051 (79)
Grade of disease (%) Low Intermediate High Number (%) of women who had axillary surgery before or at time of mastectomy Lymph node involvement in women who had axillary	11 27 62 1,187 (79)	10 24 67 764 (82)	12 28 60 100 (43)	10 26 64 2,051 (79

Whether a tumour was invasive or DCIS was recorded on the pathology data section which was available for 17,568 women.

The Nottingham Prognostic Index (NPI) combines information about tumour size, grade and nodal involvement for patients with invasive disease. Higher values are associated with worse prognosis.

3.3 Types of primary breast reconstruction

Table 3.3 describes the types of immediate and delayed reconstruction procedure performed on women in the Audit. Most immediate reconstruction patients had a reconstruction that involved an implant (with or without a flap), while the majority of delayed reconstruction patients underwent reconstruction using only a flap of their own tissue. There is no evidence from trials to suggest that one type of reconstruction is better than another in terms of quality of life or patient safety.

For 8 per cent of the women who underwent implant-only immediate reconstruction, clinicians indicated that they planned to eventually replace the implant or expander placed at the time of mastectomy with an autologous flap. This type of temporising or 'immediate-delayed' process is used for women who are expected to undergo adjuvant chest wall radiotherapy, and is thought to improve the aesthetic outcomes of delayed reconstruction by preserving skin in the breast area. As post-mastectomy radiotherapy is administered to a significant number of women in some parts of the country, this may partly explain the high rate of immediate implant-only reconstruction.

Relatively few women underwent implant-only delayed reconstruction. There are several possible reasons for this. First, many delayed reconstruction patients would have undergone post-mastectomy radiotherapy. Radiotherapy reduces the elasticity and blood supply of the skin in the breast area. If implant-only delayed reconstruction is performed following radiotherapy, there is an increased likelihood of wound dehiscence and subsequent implant extrusion. It is also generally thought to provide poor cosmetic results in the post-radiotherapy group. Flap reconstruction is considered a better option because it may be used to replace the irradiated skin in addition to the breast volume. In the Audit, this was reflected by the fact that just 14 per cent of implant-only delayed reconstruction patients had previously undergone radiotherapy compared with 45 per cent of those whose delayed reconstruction involved a flap.

Second, while most breast oncoplastic surgeons perform the first three types of reconstruction, only plastic surgeons undertake free flap reconstruction. It is therefore possible that the figures reflect variable access to free flap reconstructive services. 11 We plan to undertake further analysis to explore how the pattern of reconstructive surgery is influenced by patient preferences, clinical suitability and the availability of specialist reconstructive services.

Table 3.3 Type of primary reconstruction				
Type of surgery	Immediate reconstruction	(%)	Delayed reconstruction	(%)
Implant/expander-only	1,246	(36.8)	281	(16.2)
Pedicle flap + implant/expander	735	(21.7)	438	(25.3)
Pedicle flap (autologous)	932	(27.5)	446	(25.8)
Free flap	476	(14.0)	566	(32.7)
Total	3,389		1,731	

3.4 Types of contralateral and secondary reconstructive procedures

Both mastectomy and breast reconstruction are complex undertakings, and can often involve more than one operative procedure. To provide a full service, Cancer Networks and NHS trusts need to take into account this extended patient pathway and the resources it requires.

Some of these procedures may be performed at the time of the first (primary) reconstructive operation. For example, women can have surgery to the other breast (augmentation, reduction, or lift) to improve symmetry. Other procedures are performed at a later date (secondary). For instance, in women with a tissue expander, the delay allows serial stretching of the overlying skin before the expander is replaced with a breast implant.

We asked clinicians to report the additional procedures performed at the time of the primary reconstruction and any planned secondary procedures. Overall, only 781 (4 per cent) women underwent surgery to their other breast to improve symmetry (Table 3.4). This was particularly rare in the mastectomy-only group, where contralateral risk-reducing surgery is still relatively uncommon and most women choose to wear a prosthesis postoperatively.

Delayed reconstruction patients were much more likely than immediate reconstruction patients to undergo surgery to the other breast to improve symmetry at the time of their operation (18 per cent v 11 per cent) or to have this type of procedure planned for a later date (27 per cent v 13 per cent). This is because the breast skin is usually preserved with a skin-sparing mastectomy when women have an immediate reconstruction. In a delayed reconstruction, patients have previously undergone a simple mastectomy which removes all of the breast skin in addition to all breast tissue. Thus, for a delayed reconstruction, the surgeon must reconstruct the breast's skin in addition to its volume. Obtaining sufficient skin from a donor site (such as the back or abdomen) to replace all of the excised skin is not possible in many women. In such cases, surgeons commonly reconstruct the breast and then reduce the breast tissue and skin (breast reduction) or just the breast skin (mastopexy) of the other unaffected breast to achieve symmetry.

Nipple reconstruction and areolar tattooing were the most commonly recorded planned secondary procedures in both immediate and delayed reconstruction patients. Overall, 49 per cent of women had a planned nipple reconstruction while 41 per cent had planned areolar tattooing. Only 1 per cent of women had their nipple reconstructed at the time of their breast reconstruction. The delay allows the reconstructed breast to settle into its final position and helps to ensure that the reconstructed nipple is placed correctly to match the other side.

Table 3.4 Symmetrisation surgery and its timing				
Contralateral symmetrisation surgery				
	Mastectomy only (%)	Immediate reconstruction (%)	Delayed reconstruction (%)	Overall (%)
Undertaken at time of surgery	86 (0.7)	384 (11.3)	311 (18.0)	781 (4.3)
Planned for later date	53 (0.4)	425 (12.9)	466 (27.0)	944 (5.3)

4. Patient experience of information provision and choice

4.1 Information on mastectomy and reconstruction procedures

One of the key questions of the Audit was to determine if women undergoing mastectomy are given enough information pre-operatively to make an informed decision about breast reconstruction. In 2002, the Improving Outcomes guidance from NICE [2002] outlined the standard that clinicians should try to achieve for all breast cancer patients:

"At every stage, patients should be offered clear, objective, full and prompt information in both verbal and written form. Each patient should receive information relevant to her case about the disease, diagnostic procedures, treatment options and effectiveness. The amount and timing of information should take each patient's preferences into account. When there is a genuine choice between treatments, the information given must be sufficiently clear and detailed to allow the woman to make a decision based on evidence of differences in outcome."

"They should be offered well-produced information leaflets which are both accurate and comprehensible, and guidance from a member of the breast care team when required."

In the 3-month questionnaire, women were asked about how much information they were given before their operation: not enough, the right amount or too much. In all three surgical groups, nine out of ten women felt that they had received the right amount of information about their surgery (Table 4.1). This compares very well to how other groups of hospital inpatients rate the provision of information about their treatment. In 2008, the national inpatient survey of English patients reported an equivalent figure of 79 per cent.12

Women undergoing mastectomy only were asked additional questions about the amount of information provided about breast reconstruction and about the reasons why they did not have an immediate breast reconstruction. This found that, while 91 per cent of these women felt that they had received the right amount of information about their mastectomy, only 65 per cent felt that they had received the right amount of information about breast reconstruction.

All women were asked about their satisfaction with the pre-operative information provided on different aspects of the surgery. Table 4.2 gives the proportion of women who were very satisfied. There are no set standards for these items at present. However, organisations may use these results as a benchmark and to identify areas in which information provision may be improved. Levels of satisfaction were highest for the information on the surgical procedures: how it was performed, recovery time, and possible complications. Around one-half of women were very satisfied

Table 4.1 Quantity of information about surgery provided pre-operatively				
	Percenta	ge of women who gave ea	ach rating	
	Mastectomy only (%)	Immediate reconstruction (%)	Delayed reconstruction (%)	
Not enough	7.7	8.9	8.4	
The right amount	91.1	89.3	91.0	
Too much	1.2	1.8	0.6	

Information domain	Percentage of women who were very satisfied			
	Mastectomy only (%)	Immediate reconstruction (%)	Delayed reconstruction (%)	
How the surgery was to be done	69.9	78.8	82.2	
Healing and recovery time	61.7	61.4	65.8	
Possible complications	57.7	61.6	69.9	
How much pain to expect during recovery	56.2	53.8	62.4	
What other women experience with their surgery	38.6	34.3	40.5	
What the scars would look like	43.3	54.6	57.6	
Options regarding types of breast reconstruction	N/A	70.9	75.0	
Having a breast reconstruction at the time of mastectomy versus later	N/A	74.5	44.0	
How long the process of breast reconstruction would take	N/A	63.0	61.4	
What size you could expect your breasts to be	N/A	62.8	64.4	
What you could expect your breasts to look like	N/A	55.7	61.9	
How long it would take to feel like yourself / feel normal again	N/A	43.1	52.1	
How the surgery would affect future breast cancer screening (eg mammograms)	N/A	40.2	39.5	
Lack of sensation in your reconstructed breast and nipple	N/A	49.8	57.6	

with the information they received on what their scars would look like and what postoperative pain to expect. The area of information with the lowest proportion of women being very satisfied was on what other women experience with their surgery.

In the 3-month questionnaire, women were asked about how they had been provided with information about the benefits and risks of breast reconstruction. In 2002, NICE stated that:

"At every stage, patients should be offered clear, objective, full and prompt information in both verbal and written form... They should be offered well-produced information leaflets which are both accurate and comprehensible, and guidance from a member of the breast care team when required."²

It is generally accepted that discussion with a surgeon is essential for the technical aspects of reconstructive procedures to be explained. In addition, women are also considered to require pictures of the results in order to make an informed decision about reconstruction; these help to ensure that they have a realistic idea of what to expect.

Table 4.3 gives the proportion of women who received information in these different formats for each of the three surgical groups. Provision of information was very good among women undergoing a reconstructive procedure. Almost all reported discussing their surgery with either a surgeon or breast care nurse, and eight in ten women were shown photographs of patients who had undergone breast reconstruction. In comparison, a much lower proportion of women who underwent mastectomy were provided with reconstructive information verbally or in written form. Only a quarter were shown pictures.

For women who underwent mastectomy only, the relationship between information quantity and the format in which it was provided is described in Table 4.4. Women who felt that they did not receive the right amount of information were less likely to have received information in each of the formats. This suggests that, while information provision on reconstruction is very good among women who have this procedure, a large proportion of women who undergo mastectomy without reconstruction feel that their information needs were not met.

Table 4.3 Percentage of women who received information about the benefits and risks of breast reconstruction in different formats			
Format of information	Mastectomy only (%)	Immediate reconstruction (%)	Delayed reconstruction (%)
Discussion with surgeon or BC nurse	61.6	99.3	99.5
Discussion with a surgeon	46.0	96.5	99.0
Discussion with a breast care nurse	53.6	93.7	83.8
Written information	47.5	95.3	92.8
Pictures of reconstructive results	25.1	81.1	79.1

Table 4.4 Relationship between women receiving the right amount of information about breast reconstruction and the format of information they were given				
Format of information	Percentage of women who got this format and who reported having the right amount of information	Percentage of women who did not get this format and who reported having the right amount of information		
Discussion with a surgeon	86.6	38.2		
Discussion with a breast care nurse	82.3	36.5		
Written information	77.7	45.8		
Pictures of postoperative results	84.3	52.9		

4.2 Choice of reconstruction provided in the preoperative period

The 2009 NICE guideline stated that "all appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are available locally".3 Consequently, a key Audit objective was to explain reasons for variation in access to and uptake of reconstruction, such as patient characteristics (eg, co-morbidities), and healthcare provider processes (eg. type of information and advice given to patients). One aspect of this was to examine the choices provided to patients.

Mastectomy-only patients

There are many reasons for a woman not to be offered immediate reconstruction; legitimate reasons (as defined by NICE in 2009) include the presence of other medical problems or the need for adjuvant therapies. In the 3-month questionnaire, we asked for the reasons why women undergoing mastectomy only did not have immediate reconstruction. Their responses are summarised in Table 4.5. The first column gives the proportion of women who mentioned the reason (whether or not it was the only reason or one of several). The second column gives the proportion of women for whom it was the only reason given.

The table reveals that many women chose not to have the option or were advised to wait for clinical reasons. However, 42 per cent of mastectomy-only patients cite the lack of information about immediate reconstruction as a contributing reason. This is consistent with the results in the previous section and again suggests hospitals should examine their provision of information.

It was very rare for informed women deemed appropriate for surgery to identify local access to reconstruction as the sole reason they did not have the operation but we note that:

- 8 per cent of women stated that a lack of local availability was the reason for which they did not have an immediate reconstruction, and
- 6 per cent said that it was due to their preferred type not being available.

Women who were offered the option of breast reconstruction but chose not to have it were also asked a further set of questions to identify the reasons for their choice (Table 4.6). The majority of women responded that their cancer treatment was their only priority and that they were unconcerned about the aesthetic outcomes. However, a sizeable minority of women also highlighted a lack of information or insufficient time in which to make their decision as reasons for not taking up an offer. Organisations should be aiming to provide an environment in which women do not feel that (at least in part) they have to refuse an offer of immediate reconstruction because of these issues.

Table 4.7 describes the relationship between how satisfied women were with the choices they were given and the information provided about immediate reconstruction. It shows a clear association between satisfaction with choices and satisfaction with the amount of information provided. This underlines the role of information provision in fostering an environment where women feel they have genuine choices.

Table 4.5 Perceptions of mastectomy-only patients about the reasons why they did not have an immediate breast reconstruction Reason Contributing reason (%) Sole reason (%) Given no information 41.6 0.5 Not offered the option 52.2 1.6 Told that it was not an option because of health reasons 16.6 0.7 Told that they should wait and have a delayed reconstruction 37.9 2.6 8.2 Told that it was not available at hospital where mastectomy performed 0.1

Told that preferred type not available at hospital where mastectomy was performed

Offered the option but chose not to have it

Table 4.6 Perceptions of mastectomy-only patients who were offered immediate breast reconstruction about the reasons they chose not to accept the offer			
Reason	Contributing reason (%)	Sole reason (%)	
Cancer treatment sole priority	91.8	4.8	
Not concerned with breast area appearance	68.2	1.6	
Did not have enough information	33.6	0.6	
Did not have enough time to decide	22.3	0.2	
Worried about length of time to recover	42.0	0.0	
Worried about complications	55.3	0.6	

Table 4.7 Satisfaction of mastectomy-only patients with their choices about immediate breast reconstruction stratified by their views on the amount of information provided						
Satisfaction with choices	Women satisfied with choice (%)					
		Not enough (%)	Right amount (%)	Too much (%)		
Very dissatisfied	13.4	62.2	37.6	0.2		
Somewhat dissatisfied	17.1	78.2	21.5	0.3		
Somewhat satisfied	27.8	32.3	66.8	0.9		
Very satisfied	41.7	4.9	94.4	0.7		

0.0

28.5

6.1

41.1

5. National-level inpatient complication rates

An aim of the Audit is to describe the complications of surgery for women undergoing mastectomy with or without breast reconstruction, and to assess the extent to which these outcomes vary across NHS trusts and independent hospitals. Publishing these figures will provide healthcare providers with a national benchmark against which to compare their current and future performance, and further inform patients about what to expect following these types of procedure.

In collecting complications data, the Audit asked NHS trusts and independent hospitals to record inpatient complications that required some form of therapeutic intervention. This meant that the complications had required specific and additional treatment, and had thus affected the patient experience. It also served to standardise complication definitions and thereby reduce variation in reporting.

In this chapter, we provide national-level information on complications occurring during the patient's inpatient stay. For mastectomy patients, the inpatient stay was typically between 2 and 5 days. For patients having an immediate or delayed reconstruction, it was typically 4 to 7 days. The complication figures were derived using patient records which had both complete operative and complication data. This corresponded to 17,844 (98 per cent) of the 18,216 total in the dataset.

5.1 Overall inpatient complication rates

Significant adverse events were rare following mastectomy and breast reconstruction surgery (Table 5.1). During the Audit, only 35 patients (0.19 per cent) died during their admission and 109 patients (0.61 per cent) required emergency transfer to a high dependency or intensive therapy unit (HDU or ITU). Both these rates were similar for the three types of surgery. Rates of return to theatre were higher among women undergoing reconstruction than those undergoing mastectomy only but this was expected because there is an additional risk of reconstruction-specific complications for these more complex procedures.

5.2 Risk profiles of different types of surgery

To help inform patients and clinicians of the overall likelihood of a local or systemic complication requiring therapeutic intervention, we report unadjusted national complication rates stratified by the type and timing of surgery (Table 5.2). Some complications can occur in all types of mastectomy and reconstruction surgery, while others can only occur in patients undergoing a specific procedure. For example, some complications are related to an implant or flap used to reconstruct the breast, or to the area of the body from which a flap is taken.

For women undergoing mastectomy only, complications can arise at the mastectomy site or be distant/systemic. Mastectomy site complications were the more common, affecting about 10 per cent of women. The majority of these complications were haematoma (affecting 8.9 per cent of mastectomy only patients). Among the 117 patients with a distant/systemic complication, 91 had a haemorrhage requiring a blood transfusion.

For women undergoing mastectomy with immediate reconstruction, similar rates of complications occur at the mastectomy site. The slightly lower rates in Table 5.2 reflect small differences in the characteristics of the patients and there was no statistical evidence to suggest mastectomy-site complication rates differed between similar women undergoing mastectomy with or without immediate reconstruction*. However, only around 5 per cent of women undergoing delayed reconstruction experienced mastectomy site complications.

Table 5.1

Overall rates of inpatient postoperative adverse events for women with complete operative and complications data.

Rates given with 95 per cent exact binomial confidence intervals

Adverse outcome or complication requiring therapeutic intervention	Mastectomy only patients (n=12,841)	Immediate reconstruction patients (n=3,304)	Delayed reconstruction patients (n=1,699)
Death during admission (%)	0.23 (0.16–0.33)	0.12 (0.03–0.31)	0.06 (0.001–0.33)
Emergency transfer to HDU or ITU (%)	0.54 (0.43–0.69)	0.85 (0.56–1.22)	0.65 (0.32–1.16)
Return to theatre (%)	1.85 (1.63–2.10)	4.63 (3.94–5.40)	5.60 (4.55–6.80)

^{*} Relative risks of postoperative complications by type of surgery were estimated using logistic regression,

with adjustment for age, smoking status, BMI, diabetic status, ASA grade and ECOG score.

*** Relative risks of implant-related complication by type of reconstruction were estimated using logistic regression, with adjustment for age. Other factors were not included due to lack of statistical power.

^{***} Relative risks of flap-related complication by type of reconstruction were estimated using logistic regression, with adjustment for age. Other factors were not included due to lack of statistical power.

Implant-related complications

Implant (or expander) based reconstruction may be undertaken in the immediate and delayed settings, with or without a flap. An implant-specific complication could be displacement requiring reposition, infection requiring antibiotics or removal, or rupture requiring removal. Overall, 82 women (3 per cent) having an implant-based reconstruction had an implant-related complication, and this risk was not affected by the type of procedure or timing**. The most common complication was infection requiring removal (45 women).

Flap-related complications

Participating organisations were asked to record flap re-exploration, partial flap necrosis or failure requiring debridement and total flap failure or necrosis requiring removal. Table 5.2 shows that the risk of flap-related complications was lowest in women who underwent reconstruction with a pedicle flap and implant, was higher in the group who underwent autologous pedicle flap reconstruction, and highest in women who had a free flap. This pattern was observed in both immediate and delayed procedures. However, there was no statistical evidence that the risk of this complication differed between immediate and delayed procedures***.

Type of surgery	ma	centage with stectomy site olications (%)	who ha with im	ge of women d an implant plant-related blications (%)	who had a fi	ge of women ap with flap- plications (%)	who ha flap dono	ge of women d a flap with or site-related olications (%)		e with distan complication: (%
Mastectomy (n=12,841)	10.30	(9.78–10.84)	N/A	N/A	N/A	N/A	N/A	N/A	0.91	(0.75–1.09)
Immediate reconstruction										
Implant/expander only (n=1,207)	9.20	(7.63–10.97)	3.48	(2.52–4.67)	N/A	N/A	N/A	N/A	1.24	(0.70–2.04)
Pedicle flap with implant (n=722)	7.48	(5.67–9.65)	3.32	(2.14–4.91)	0.69	(0.23–1.61)	8.45	(6.52–10.72)	2.77	(1.70-4.25)
Autologous pedicle flap (n=920)	7.17	(5.59–9.04)	N/A	N/A	1.96	(1.16–3.07)	9.67	(7.84–11.77)	3.37	(2.30-4.75)
Free flap (n=455)	9.45	(6.92–12.52)	N/A	N/A	9.45	(6.92–12.52)	5.49	(3.59-8.00)	7.91	(5.60–10.79)
Delayed reconstruction										
Implant/expander only (n=280)	2.86	(1.24–5.55)	2.14	(0.79–4.61)	N/A	N/A	N/A	N/A	0.36	(0.01–1.97)
Pedicle flap with implant (n=432)	3.24	(1.78–5.38)	2.31	(1.12–4.22)	1.16	(0.38–2.68)	6.02	(3.97–8.69)	1.39	(0.51–3.00)
Autologous pedicle flap (n=433)	7.85	(5.50–10.80)	N/A	N/A	3.70	(2.13–5.93)	10.85	(8.09–14.17)	4.39	(2.66–6.77)
Free flap (n=554)	4.69	(3.09–6.80)	N/A	N/A	7.94	(5.83–10.52)	3.43	(2.08-5.30)	3.61	(2.22–5.52)

Among these flap-related complications, flap re-exploration was the most common, particularly for free-flap procedures. This is to be expected for this complex operation and reflects surgical practice aimed at preventing flap failure and long-term morbidity. Among women who had a freeflap reconstruction, the rate of return to theatre was 11.8 per cent (95 per cent CI 9.9 to 13.9).

For the different types of flap-based reconstruction, rates of flap failure were as follows:

- For pedicle flap reconstructions, the partial and total flap failure rates were 1.20 per cent (95 per cent CI 0.81 to 1.70) and 0.20 per cent (95 per cent CI 0.06 to 0.46); respectively
- For free flap reconstructions, the partial and total flap failure rates were 2.18 per cent (95 per cent CI 1.37 to 3.28) and 1.98 per cent (95 per cent CI 1.21 to 3.04), respectively

Flap donor site complications

Flap donor site complications included haematoma or seroma, wound infection, skin flap necrosis, and wound dehiscence that required intervention at the donor site. The most common of these was haematoma or seroma. This particular complication accounted for the differences in the rates of flap donor site complications shown in Table 5.2. Excluding haematoma or seroma, each type of flap-based reconstruction had a donor-site complication rate of around 2 per cent.

The rate of inpatient aspiration/drainage of a haematoma or seroma was:

- 7.50 per cent for pedicle flap reconstructions (95 per cent CI 6.50 to 8.60)
- 2.28 per cent for free flap reconstructions (95 per cent CI 0.15 to 3.40)

There was no statistical evidence that the risk of this complication differed between immediate and delayed procedures, whether or not the haematoma or seroma component was included.*

5.3 Summary of national complication rates

For patients undergoing mastectomy and breast reconstruction surgery, life-threatening complications are rare. As expected, the likelihood of return to theatre, and of systemic complications (primarily haemorrhage requiring blood transfusion), was higher when undergoing immediate or delayed breast reconstruction compared to mastectomy alone (Table 5.2).

Overall, around 10 per cent of women undergoing mastectomy only can expect to have a local complication requiring some therapeutic intervention. For mastectomy with immediate reconstruction, the proportion of women who can expect to have a least one complication requiring a therapeutic intervention is higher (Table 5.3). There is an increased likelihood of haematoma/seroma complications for pedicle flap reconstructions at their flap donor site and an increased risk of re-examination for free-flap reconstructions (the second column of Table 5.3 illustrates the relative contribution of these two complications to the total number). A similar pattern of complications is observed for women undergoing delayed reconstruction.

Table 5.3
Proportion of women undergoing breast reconstruction who have one or more local inpatient complication.
Rates are provided with 95 per cent exact binomial confidence intervals

Type of reconstruction	Local complications (%)		Local complications excluding haematoma / seroma and flap re-examination (%)			
Immediate reconstruction						
Implant/expander only (n=1,207)	11.02	(9.31–12.92)	11.02	(9.31–12.92)		
Pedicle flap with implant (n=722)	15.79	(13.20–18.66)	9.83	(7.76–12.24)		
Autologous pedicle flap (n=920)	15.65	(13.36–18.16)	9.46	(7.64–11.53)		
Free flap (n=455)	18.24	(14.80-22.10)	14.29	(11.2–17.84)		
Delayed reconstruction						
Implant/expander only (n=280)	5.00	(2.76-8.25)	5.00	(2.76-8.25)		
Pedicle flap with implant (n=432)	10.65	(7.90–13.95)	6.71	(4.54-9.50)		
Autologous pedicle flap (n=433)	19.86	(16.21–23.94)	11.09	(8.29–14.43)		
Free flap (n=554)	12.64	(9.98-15.69)	8.48	(6.30-11.12)		

Relative risks of donor site complication by type of reconstruction were estimated using logistic regression, with adjustment for age. Other factors were not included due to lack of statistical power.

6. NHS trust and hospital-level inpatient complication rates

6.1 Reporting complication rates at the organisation level

Hospitals that perform mastectomy and breast reconstruction surgery may differ in their rates of postoperative complications for a number of reasons. Variation can arise from:

- 1. the influence of random fluctuations
- 2. differences in the completeness of the data submitted
- 3. differences in the interpretation of the data item by hospitals
- 4. differences in the mix of patients seen at hospitals
- 5. differences in the clinical protocols adopted by hospitals
- 6. differences in the quality of care provided.

Conclusions about quality of care can only be reasonably drawn from the comparison of postoperative complication rates after differences due to factors (1) to (5) are excluded. Some of these factors were addressed directly during the analysis of the Audit data. First, funnel plots identified how much of the difference would be expected from random fluctuations. Second, all NHS trusts and independent hospitals were asked to validate their data, both in terms of its completeness and its accuracy. A two-month data checking period was provided and it resulted in an additional 1,157 patients with complete operative data being included in the Audit. Third, the organisation figures were also adjusted to take account of patients' morbidity and treatment history and so remove any variation due to differences in their patient population. Finally, we contacted hospitals identified as having higher than expected rates. Organisations had two weeks to respond in writing if they wanted to provide an explanation.

Despite this, organisational complication rates cannot be regarded as direct indicators of surgical performance. If an organisation has an unexpectedly high rate of complications, this might be due to issues of data quality or differences in local clinical protocols rather than differences in the quality of care delivered. For example, a high intervention rate may reflect different monitoring protocols or a lower threshold for preventive action rather than indicate poor practice. Consequently, we caution against the over-interpretation of outliers. It is the responsibility of local organisations to examine the causes of their complication rates and ensure patient care is of high quality.

The Audit will undertake some further data validation work after this report. We have not yet been able to cross-reference the Audit data from the English NHS with contemporaneous data from the HES database. This work will determine whether our results have been influenced by the under-reporting of complications and data completeness at individual organisations. The results of this validation exercise will be reported in the Fourth Annual Report in 2011.

6.2 Organisation-level complication rates

Complication rates were calculated for each participating NHS trust and independent hospital. The rates were adjusted for differences in patient characteristics and types of primary treatment at the various organisations (see chapter 2 for details). Individual risk models were developed for each outcome.

Low levels of case-ascertainment or the incomplete submission of complications data increases the risk of selection bias. To minimise this risk, we excluded 39 independent sector and 11 NHS organisations with very low case-ascertainment (less than 40 per cent) and 3 organisations with incomplete inpatient complications data for their patients with complete operative data (less than 85 per cent had complete data on complications). The organisations, along with the reasons for their exclusion, are listed in Appendix 5.

A number of organisations also reported treating very few patients. In these cases, the discriminatory power of the funnel plot to determine whether a difference in complication rates is due to factors other than random variation is greatly reduced. The majority of low-volume organisations were hospitals in the independent sector. However, it should not be inferred that surgeons at these hospitals perform few breast cancer procedures. Surgeons typically undertake mastectomy or reconstruction surgery at an NHS trust and at one or more independent sector hospitals.

We excluded 35 organisations where the number of women with complete operative and complications data was less than 10 cases because the estimated rates would not be sufficiently robust (high statistical uncertainty). These organisations participated fully in the Audit and were only excluded from the organisation-level analyses to ensure adequate precision. A further 11 organisations with unknown case-ascertainment and under 25 records submitted to the Audit were also excluded. Overall, 99 of the 270 NHS trusts and independent hospitals were not included in these comparative analyses of complication rates.

For complications that were extremely rare, it did not make sense to report them by individual organisations. In these cases, there were insufficient complications with which to develop a robust risk model or to determine whether differences between organisations were unlikely to have occurred because of random fluctuations. Consequently, we report organisation (NHS trust or independent hospital) level data for three specific types of adverse event:

- 1. return to theatre
- 2. mastectomy-site complications
- 3. distant or systemic complications.

Return to theatre

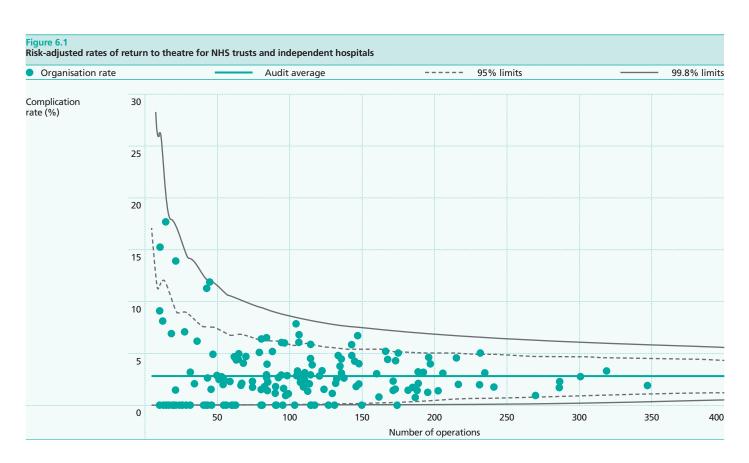
Return to theatre following mastectomy and breast reconstruction is a reasonable proxy indicator of a significant postoperative complication. However, rates vary according to the operation type (see previous chapter) and specific patient characteristics.

For the organisations included in this analysis, the overall rate of return to theatre was 2.76 per cent. Based on the unadjusted complication rates, there were many organisations that had a higher than expected rate of return to theatre. These were primarily organisations with a high reconstructive caseload, and adjusting for patient characteristics and operation type (including the type of reconstruction) meant that almost all organisations were within the 99.8 per cent funnel limits. This demonstrates the importance of risk-adjustment for this particular outcome measure.

Two organisations were highlighted as having return to theatre rates that were higher than expected, although neither had a rate that was far from the expected range of values. After being contacted, both organisations responded by identifying a number of errors in their data. These were corrected and their rates of return to theatre subsequently fell within the expected range. Figure 6.1 shows the final adjusted rates of return to theatre.

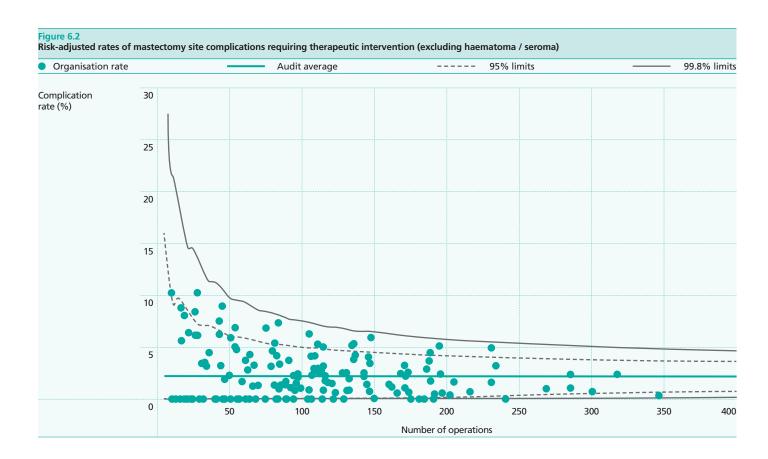
Mastectomy site complications

During exploratory analyses at the time of the Second Annual Report, we analysed the five mastectomy site complications recorded (wound infection requiring intravenous antibiotics, wound infection requiring surgical debridement, skin flap necrosis requiring surgical debridement and haematoma or seroma requiring aspiration or drainage) individually and as a group. Nationally, 1,393 women (7.58 per cent) required inpatient aspiration or drainage of a haematoma or seroma following their surgery. However, it was evident that "haematoma or seroma requiring aspiration or drainage" was coded differentially across organisations, as there was a wide range of reported rates.



Organisations were asked to check this data item during the two month data checking window. However, the problem persisted. This suggests that the item was either misinterpreted or that the threshold for inpatient aspiration or drainage is variable. We considered the latter reason more likely and that the variation reflected the timing (inpatient or outpatient) of different interventional approaches rather than different rates of this complication. In view of this, we decided not to report this item at the organisational level. Nonetheless, we considered that reporting the national rate would help to inform women undergoing mastectomy or reconstruction surgery (see chapter 5). For organisations, we derived adjusted mastectomy site complication rates with this item excluded. Consequently, these rates relate to wound infection requiring intravenous (IV) antibiotics or debridement, skin flap necrosis requiring debridement, and wound dehiscence requiring re-closure.

The national rate for all organisations included in this analysis was 2.21 per cent. There were six organisations which had complication rates that were higher than expected. Most of these complications were infections that required IV antibiotics. The contacted organisations highlighted a number of data errors, some of which were related to the erroneous inclusion of high-risk women (eg, those known to be MRSA carriers) given IV antibiotics prophylactically to reduce the risk of, rather than to treat, a postoperative wound infection. Correcting these errors meant that the all organisations had mastectomy site complication rates that fell within the expected range. Figure 6.2 shows the final adjusted rates.



Distant or systemic complications

Nationally, distant and systemic complications were rare: haemorrhage requiring blood transfusion; deep venous thrombosis or pulmonary embolism requiring formal anticoagulation and acute myocardial infarction requiring anticoagulation with or without thrombolysis. The national rate for those included in the analysis was 1.52 per cent, and the initial analysis identified three organisations as having higher than expected rates of complication, though only one exceeded the limit by more than 1 per cent. Examination of the data from these organisations rates revealed that the majority of the complications were related to blood transfusion for peri-operative haemorrhage.

In response to being contacted, one organisation highlighted that the women who had experienced these complications all suffered from major co-morbidities. We examined the risk adjustment model for this complication and were able to improve its performance by changing how co-morbidities were incorporated. This reduced the adjusted rates at all three outlier organisations. This further work also suggested another outlier was a statistical artefact. Less than 30 per cent of the women from this organisation had data on the various confounding factors and consequently the risk-adjustment could not be reliably applied. Its adjusted rate was therefore defined to be its unadjusted value (in this as well as the other complications). The final outlier organisation identified a number of errors in their data, which were corrected.

Figure 6.3 shows the final adjusted rates of distant/systemic complication. The review process, again, resulted in the adjusted rates of all organisations falling within the expected ranges.

6.3 Interpretation of organisation-level findings

These findings of NHS trust and independent hospital variation in complication rates must be interpreted taking into account the six issues set out in section 6.1.

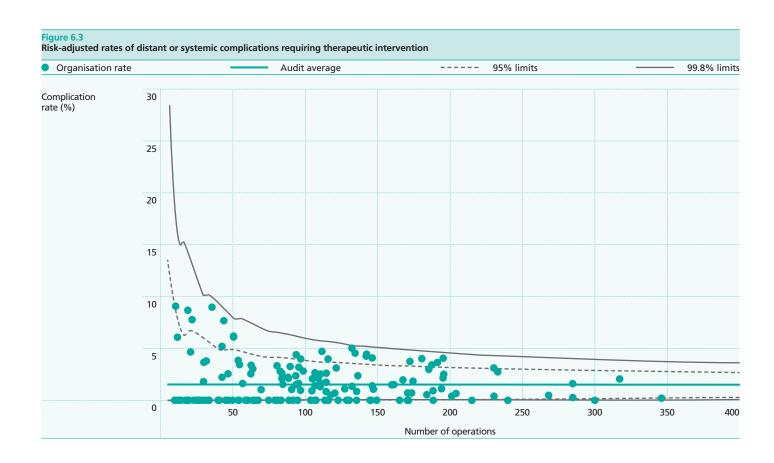
Using funnel plots means that the chance an organisation being identified as an outlier due to chance alone is extremely low. The probability of being outside the upper limit if the variation was solely due to random variation is 1 in 1000.

It is possible that some of the variation may reflect selection bias. However, we have reduced the risk of this by excluding units with low ascertainment (under 40 per cent) and by excluding organisations with incomplete data on complications (more than 15 per cent of cases). This means that the influence of any bias is probably small in comparison to the observed differences in organisational rates.

Another potential cause of differences between organisations is that they treat different populations of patients, and undertake different procedures. We adjusted the rates to minimise the risk of this confounding, and took account of various patient characteristics including age, smoking status, body mass index, diabetes status, ASA grade, and ECOG score. We also adjusted for the type and complexity of the surgical procedure undertaken. Based on previous work in this area, adjusting for these factors is likely to have accounted for most of the effects of potential confounders.

Some hospitals appeared to interpret or manage particular complications differently from others. This was of particular concern with haematoma/seroma requiring aspiration or drainage. To manage this complication, some organisations intervene early when the problem arises; others prefer to wait until outpatient follow up to aspirate or drain blood or fluid that has collected in the breast, armpit or donor site area. Because of this, we excluded this specific complication from the comparative analysis. Nonetheless, this problem is commonly encountered by women undergoing mastectomy and breast reconstruction surgery, and has therefore been reported nationally in chapter 5.

In summary, we found that no organisation in the comparative analysis had complication rates that were higher than the expected rate, after taking account of random variation and patient characteristics. While this is re-assuring, we note that 50 organisations were excluded due to low case-ascertainment or incomplete complications data, despite the 2-month data checking window. It is important that clinicians and management teams at all organisations take this opportunity to review and further audit their practice to ensure that there are no systematic deficiencies in the care they provide.



7. Patient reported outcomes at 3 months after surgery

7.1 Overall rating of experience and satisfaction with care

The Care Quality Commission (CQC) undertakes an annual survey of patient satisfaction with care across all NHS trusts. The survey questionnaire, designed by the Picker Institute, is freely available and may be used for local and national surveys. To enable comparisons with a national baseline, we included two questions from the national inpatient survey in the 3-month postoperative questionnaire.

The first question asked if women felt they were treated with respect and dignity while they were in hospital. The second asked how they would rate the care received overall.

The results are given in Table 7.1, broken down by surgery type and with results from the contemporaneous national inpatient survey. Compared to the general population of patients treated as inpatients in the NHS in 2008¹², women who underwent mastectomy or breast reconstruction surgery were more likely to feel that they had been treated with respect and dignity while in hospital, and to rate the care they received as excellent or very good.

It is encouraging to know that women undergoing mastectomy and reconstruction surgery generally rate the care they have received very highly. Nonetheless, the results should be interpreted with caution. The comparisons are with the population of all NHS hospital patients treated in 2008, admitted through both the emergency and elective pathways. In addition, our sample includes women treated in the independent sector. Both may influence the comparison with the NHS survey.

7.2 The incidence of post-discharge complications 3 months after surgery

Women undergoing mastectomy and reconstruction surgery can experience a range of complications after discharge. There is little information available on the rate at which these occur. Consequently, the 3-month questionnaire asked women to report what types of problems had arisen.

Table 7.2 gives the percentages of women who reported particular post-discharge complications stratified by the type of surgery. Most complications are relatively rare, affecting less than 2 per cent of patients. However,

- One in ten mastectomy patients and almost one in six reconstruction patients was readmitted for unplanned further treatment or surgery after their primary admission
- One in five mastectomy patients and one in four reconstruction patients required antibiotic treatment for a suspected wound infection post-discharge.

Table 7.1 Overall assessment of treatment at 3 months after surgery						
Question	Response	NHS survey (2008) (%)	Mastectomy only (%)	Immediate reconstruction (%)	Delayed reconstruction (%)	
Overall, did you feel you were treated with respect and dignity while you were in the hospital?	Yes, always	79	88.7	85.5	88.9	
	Yes, sometimes	18	10.1	13.2	9.7	
	No	3	1.2	1.3	1.4	
Overall, how would you rate the	Excellent	43	65.8	71.9	74.1	
care you received?	Very good	35	23.8	19.3	17.2	
	Good	14	7.3	6.3	6.7	
	Fair	5	2.2	2.0	1.2	
	Poor	2	0.8	0.5	0.9	

Table 7.2 Proportion of women reporting post-discharge complications 3 months after surgery						
Complication	Mastectomy only (%)	Immediate reconstruction (%)	Delayed reconstruction (%)			
Readmission for unplanned further treatment or surgery	8.9	15.8	13.9			
Bleeding requiring transfusion or surgery	1.1	1.7	1.9			
Wound opening up requiring more surgery	1.3	5.1	6.0			
Wound infection requiring antibiotics	17.0	24.1	26.8			
Breast skin turned dark and died	4.0	6.1	5.5			
Blood clot in legs	1.3	1.1	1.3			
Blood clot in lungs	1.0	0.7	0.8			
Heart attack	0.5	0.3	0.5			

Patients undergoing reconstruction also reported a number of complications specific to their types of reconstruction after discharge from hospital. Among women having an implant, 8.9 per cent of patients having immediate reconstruction and 6.9 per cent of patients having a delayed reconstruction reported having a complication that required the implant to be removed. These rates were higher than expected and should be interpreted cautiously. We will investigate this issue further and provide a more-detailed analysis in the Fourth Annual Report.

Less than 1 per cent of women who had a flapreconstruction reported that it had completely failed since they had been discharged (Table 7.3). However, around 5 per cent of women reported partial flap failure.

Table 7.4 describes the percentages of women who experience other unfavourable outcomes in the 3 months after surgery. It might be argued that these are anticipated sequelae rather than complications per se. Nonetheless, they can have a marked effect on women's care experience. The table reveals several important findings:

- One in two women had persistent pain or tenderness three months postoperatively, and two-thirds had persistent numbness
- One in two mastectomy patients (with or without immediate reconstruction) and a third of all delayed reconstruction patients required aspiration or drainage of a collection of fluid at their operative site
- Swelling of the arm was reported by a fifth of all mastectomy patients, a tenth of immediate reconstruction patients, and only one in fifty of those who underwent delayed reconstruction
- Between a quarter and a third of women had difficulty moving their shoulder and arm after their surgery.

Clinicians should use this information to fully inform their patients about the risks associated with their operation before it is undertaken.

Table 7.3 Flap-specific post-discharge complications in women with a flap reconstruction					
Complication	Immediate reconstruction (%)				
Part of flap turned dark and died	3.2	6.2			
All of flap turned dark and died	0.7	0.0			
Operation to remove some or all of flap	3.1	4.9			
Hernia (weakness or bulge) in area from which flap was taken	4.5	3.9			

Table 7.4 Proportion of patients experiencing other post-discharge outcomes 3 months after surgery						
Adverse outcome	Mastectomy only (%)	Immediate reconstruction (%)	Delayed reconstruction (%)			
Persistent pain or tenderness	49.0	51.9	40.9			
Persistent numbness	68.0	70.6	61.0			
Fluid collection that required removal with a needle or drain	51.3	46.5	34.0			
Swelling of the arm	17.5	9.4	15.9			
Difficulty moving shoulder and arm	27.7	34.2	26.5			

7.3 Pain management after surgery

There are national standards set out for pain management following surgery. In 1997, the Audit Commission recommended that less than 5 per cent of patients should report that they experienced severe postoperative pain.¹⁴

In the Audit, women were asked about the pain that they experienced in the postoperative period and about the assistance provided by hospital staff to control this pain. Table 7.5 gives the breakdown of responses for the three patient groups.

The levels of severe pain reported were low for mastectomy and close to the target suggested by the Audit Commission. They were also low compared to other types of major surgery. A systematic review of postoperative pain following major abdominal gynaecological surgery, major orthopaedic surgery, and any laparotomy or thoracotomy found that the overall incidence of severe pain reported in the literature was 11 per cent.

Patients undergoing reconstruction did not fare as well, particularly in the first 24 hours. These results suggest that breast reconstruction procedures pose more problems for the assessment and management of pain than mastectomy and many other forms of elective surgery. Further work is necessary to identify reconstructive procedures where there is an especially high risk of severe pain being experienced by the patient.

However, although immediate and delayed reconstruction patients were much more likely to experience moderate or severe pain in the postoperative period, they seemed equally satisfied that the staff treating them had done everything they could to control it. On average, women reported that hospital staff had been responsive around pain management, with levels of satisfaction above the average of 72 per cent reported nationally for all inpatient episodes in 2008.¹²

7.4 Access to postoperative psychological support

In its 2002 breast cancer guidelines, NICE stated that "Psychosocial support should be available at every stage to help patients and their families cope with the effects of the disease. These issues should be considered in the design and provision of all aspects of treatment services. Health care personnel should have training to improve their ability to recognise the psychological needs of patients and to deal with them appropriately."²

In the Audit period, the proportion of women who reported receiving psychological support or counselling after their surgery was:

- 30.3 per cent for mastectomy-only patients
- 27.6 per cent for immediate reconstruction patients
- 16.9 per cent for delayed reconstruction patients

We found that relatively few women received psychological support from a healthcare professional within the 3 month postoperative period. This limited access may reflect the tendency towards early discharge after surgery, leaving breast care nurses little time in which to see women after their operation. It may also reflect access to psychosocial support in specialist reconstructive units and in the independent sector, where there may not be an identified, on-site breast care nurse readily available.¹¹

Table 7.5 Proportion of patients reporting severe pain and perceptions about pain management in the postoperative period						
Adverse outcome	Mastectomy only (%)	Immediate reconstruction (%)	Delayed reconstruction (%)			
Severe pain in the first 24 hours (target < 5%)	6.2	16.5	20.1			
Severe pain in the first week (target < 5%)	5.2	11.4	9.4			
Hospital staff definitely did everything they could to control pain	88.8	86.8	87.9			

8. Conclusion

8.1 Implications for clinical practice

The Audit is the first national study of mastectomy and breast reconstruction surgery conducted worldwide. Our findings show that overall clinicians are providing high quality of care for women with breast cancer undergoing mastectomy in England. In particular, the majority of women rate their care to be excellent, and overall, levels of satisfaction compared favourably with that of the general NHS inpatient population.

However, as with any in-depth study of practice and outcomes, we identified some specific areas of concern. First, women undergoing mastectomy did not receive the same amount of information about reconstruction as women undergoing reconstruction and this seems to have affected their satisfaction with their choice of surgery. Second, women undergoing immediate and delayed reconstruction reported higher rates of severe pain in the 24 hours after surgery (respectively, 16.5 per cent and 20.1 per cent) compared to women undergoing mastectomy (6.2 per cent).

In this report, we provided a detailed description of inpatient complications, with the aim of helping clinicians to inform women of the overall likelihood of particular events. Overall, for mastectomy and breast reconstruction, life-threatening complications are extremely rare. Nonetheless, around 10 per cent of women undergoing mastectomy can expect to have a local complication requiring some therapeutic intervention. For mastectomy and immediate reconstruction, the proportion of women who can expect to have a least one complication requiring a therapeutic intervention is slightly higher and reflect the characteristics of the procedure. There was an increased risk of haematoma/seroma complications for pedicle flap reconstructions at their flap donor site and an increased risk of re-examination for freeflap reconstructions. A similar pattern of complications was observed for women undergoing delayed reconstruction.

We have only been able to report these findings due to the tremendous participation across NHS and independent hospital organisations, the support of the professional bodies and patient groups involved in breast cancer care, and of course the funding provided by the Healthcare Quality Improvement Partnership.

Participating organisations, and their multidisciplinary and management teams, need to review the key findings, identify areas in which local improvements are required, and act appropriately to minimise the risk to and improve the results of surgery in this group of women. These responses are the most important component of the Audit, and will help to ensure the provision of safe, effective and high quality care for women who are diagnosed with breast cancer.

8.2 Recommendations

- 1. Clinicians should act to better inform women about both the procedures they decide to undergo and the reconstructive options available. As per the 2009 NICE guidance, clinicians should ensure that women are offered a full range of appropriate reconstructive options, whether or not these are available locally.
- 2. NHS trusts and independent hospitals should ensure that women understand how to report their levels of pain and access appropriate pain relief, and that they are provided with adequate psychological support following their surgery.
- 3. NHS trusts and independent hospitals should continue to monitor patients' experience with care and act to maintain the high levels of satisfaction reported.
- 4. Clinicians should use the data on inpatient and postoperative complications to inform women about risks of different operations. Women considering reconstruction should be pre-operatively informed that the chance of requiring further surgery either during their initial admission or postoperatively is around one in ten.
- 5. Multidisciplinary teams at NHS trusts and independent hospitals should review the outcomes of their own patients and compare them with the national outcomes described in this report to ensure that they are delivering a high quality of care.
- 6. The Surgical Associations and Royal Colleges involved in mastectomy and breast reconstruction surgery should consider issuing new guidance on patient selection, operative techniques and postoperative care.

Appendix 1: Summary of the First and Second Annual Reports

The First Annual Report, published in March 2008, described initial results of the Audit's evaluation of surgical services for women with breast cancer in England and Wales. Three separate but related studies were undertaken, all of which assessed different aspects of the provision of mastectomy and reconstruction surgery:

- a qualitative study of interviews with 30 stakeholders to highlight the characteristics of high quality surgical care for women with breast cancer
- an organisational survey of NHS acute trusts and independent hospitals to investigate service provision and reconstructive access
- an analysis of routine hospital data to describe trends in the number and type of breast cancer operations performed in the English NHS between 1997 and 2006.

The combined results of these studies suggested that breast cancer surgery services in England and Wales provided a high standard of care in difficult circumstances. Service providers were responding well to the rising incidence of breast cancer but concerns remained with certain aspects of the service (see Box, page 37). The most important issue identified was inequitable access to immediate breast reconstruction.

The Second Annual Report focused on the use of reconstructive surgery for women with breast cancer and short-term surgical outcomes. The results were based on prospectively collected data and describe adult women who underwent mastectomy or reconstructive breast surgery between 1 January 2008 and 31 March 2009. The Audit received data from all 150 English NHS trusts and 106 independent hospitals. Six non-English NHS trusts also chose to participate. In total, clinical information was supplied on 17,059 women, of whom 85 per cent had invasive carcinoma. The remainder were being treated for ductal carcinoma in situ (DCIS).

The Second Annual Report highlighted that, over the past few years, the proportion of women having immediate reconstruction increased from approximately 11 per cent (between 1 April 2005 and 31 March 2006) to 21 per cent (between 1 January 2008 to 31 March 2009). Nonetheless, there was significant variation in both reconstructive utilisation and offer rates across English Cancer Networks. This variation was not explained by the characteristics of the local population. The variation seen in the proportion of women who accepted an offer of immediate reconstruction may reflect the timing of the offer, the way in which it was communicated, and whether accepting the offer involved a delay in primary cancer treatment.

In addition, the higher use of implant (or tissue expander) only reconstructions in the immediate setting suggested that a proportion of women are not able to access all appropriate reconstructive options. This raised questions about how easily patients may be referred from breast to plastic surgery units, especially if the latter are not available locally.

Summary of findings from the initial year of the National Mastectomy and Breast Reconstruction Audit, published in the First Annual Report

Service configuration

- Due to its rising incidence, the number of breast cancer operations performed by the English NHS rose from 24,684 in 1997 to 33,814 in 2006, an increase of 37 per cent
- Between 1997 and 2006, the proportion of mastectomy patients undergoing immediate reconstruction rose from 7 per cent to 11 per cent
- Local access to breast reconstruction services is not uniform across England and Wales.

Communication with patients

Breast care nurses have a key role in supporting women through the decision about whether or not to have immediate breast reconstruction. Women's access to reconstruction may be impaired by the relatively small number of specialist nurses employed in the English NHS.

Time to allow informed and reasoned decision making

To make an informed decision about immediate breast reconstruction, women need enough time to digest the information and choices available. There is a perception that decisions about reconstruction may be rushed by the need to provide the first definitive treatment within 31 days of diagnosis.

Training of staff

80 NHS trusts reported that pedicle flap breast reconstructions were being performed by general surgeons with a specialty interest in breast surgery. However, breast reconstruction surgery is still being performed at a number of NHS trusts with relatively little experience in this area. These units provide a poor environment in which to train and improve reconstructive skills.

Communication between clinicians

94 per cent of private hospitals reported that their breast cancer surgery patients are discussed by a multidisciplinary team elsewhere. This may impair the quality and timeliness of reconstructive decision making for these patients.

Summary of findings from the Second Annual Report of the National Mastectomy and Breast Reconstruction Audit

Patterns of surgical care

The most common type of procedure for women undergoing immediate reconstruction was an implant or tissue expander based reconstruction (38 per cent). For women undergoing delayed reconstruction, the most common type was free flap reconstruction (33 per cent). This may reflect difficulties in access to a specialist reconstructive team while meeting the target of starting definitive treatment within 31 days of decision to treat.

Time from decision to treat to first definitive treatment

The time from decision to treat to first definitive surgical treatment varied between Cancer Networks. The proportion of women treated within 31 days varied from 76 per cent to 94 per cent for women having mastectomy only, and from 28 per cent to 84 per cent for women having mastectomy with immediate reconstruction. Poorer levels of performance may reflect variable resources and capacity at breast units in England.

Reconstructive offer and uptake across English Cancer Networks

- Among the 15,479 women who underwent mastectomy, 3,216 (21 per cent) underwent immediate breast reconstruction
- Rates of immediate reconstruction varied significantly from 9 per cent to 43 per cent between the 30 English Cancer Networks (p-value<0.001). This variation was not explained by the socio-demographic and clinical characteristics of the women treated
- The proportion of women offered immediate reconstruction varied significantly between Networks (p-value<0.001). Again, this variation was not explained by patient characteristics or planned clinical treatment. Moreover, offer rates were not strongly correlated with actual rates of reconstruction in the Cancer Networks
- The reasons given by clinicians for not offering women immediate reconstruction were: women were deemed inappropriate for clinical, health or lifestyle problems, or a perceived need for adjuvant radiotherapy.

Postoperative outcomes of surgery

- Mastectomy and breast reconstruction are safe procedures, with a very low incidence of mortality (<0.3 per cent) or complications requiring emergency transfer to intensive or high-dependency care (<1 per cent).
- The total flap failure rate for free flap reconstructions was 1.95 per cent (95 per cent confidence intervals 1.08 to 2.82); the partial flap failure rate was 2.46 per cent (95 per cent confidence intervals 1.49 to 3.44).

Appendix 2: Organisational representatives

National Mastectomy and Breast Reco	nstruction Audit Project Board	
Julie Henderson **	Project Board Executive	The NHS Information Centre for health and social care
Jan van der Meulen	Senior Supplier	Clinical Effectiveness Unit, The Royal College of Surgeons of England
Steve Dean	Senior Supplier	National Clinical Audit Support Programme, The NHS Information Centre for health and social care
Hugh Bishop	Senior User	Association of Breast Surgery at BASO
Venkat Ramakrishnan	Senior User	British Association of Plastic, Reconstructive and Aesthetic Surgeons
Helen Laing	Commissioner	Healthcare Quality Improvement Partnership
** replaced Martin Old, formerly of The	NHS Information Centre for health and social care	

Clinical Reference Group	
Dick Rainsbury, Chair	Association of Breast Surgery at BASO
Chris Holcombe	Association of Breast Surgery at BASO
Emma Pennery	Breast Cancer Care
Elaine Sassoon	British Association of Plastic, Reconstructive and Aesthetic Surgeons
Eva Weiler-Mithoff	British Association of Plastic, Reconstructive and Aesthetic Surgeons
Di Riley	Cancer Action Team
Lucy Elliss-Brookes	Cancer Networks
Gillian Ross	Faculty of Clinical Oncology
Karen Woo	Independent sector
Bethan Lloyd Owen	Independent sector
Catherine Boyle	Macmillan Cancer Support
Christianne Forrest	Patient representative, Breast Cancer Voices
Kate Jones	The Chartered Society of Physiotherapists
Helen Mcleod	The Chartered Society of Physiotherapists
Peter Venn	The Royal College of Anaesthetists
Maria Noblet	The Royal College of Nursing
Janet Litherland	The Royal College of Radiologists
Gill Lawrence	United Kingdom Association of Cancer Registries
lan Monypenny	Cancer Services Co-ordinating Group, Wales

Appendix 3: Mastectomy and breast reconstruction among ethnic groups

Where ethnicity was known, women from non-white ethnic groups accounted for 5 per cent of the women who underwent mastectomy with or without immediate breast reconstruction, and delayed reconstruction. There were 373 women (2.3 per cent) who described their background as Asian (Indian, Pakistani, Bangladeshi, Other Asian), and 274 women (1.7 per cent) whose background was Black African or Caribbean. A further 201 women (1.3 per cent) were from another ethnic background.

In Table A3, we give a brief description of the women in the four ethnic groups and the type of surgery that they underwent. The numbers of women in the non-white ethnic groups were comparatively small and so the estimates should be treated with caution. Women of non-white backgrounds were, on average, slightly younger than white women. There were also differences in the proportion of women in the four ethnic groups who smoked, had a BMI above 30 or who were diabetic. The differences in the types of tumour across the four groups were not statistically significant.

The rate of immediate reconstruction differed between women in each of the ethnic groups, with Asian women (16 per cent) having the lowest rate and Black women having the highest (35 per cent). We used logistic regression to assess to what degree these differences were due to patient characteristics (such as age, current smoker, BMI, diabetes). For Asian women, the adjusted rate of IR remained lower when compared to White women. However, the higher rate among Black women compared to White women was explained by their younger age profile.

There was little difference among the rates of delayed reconstruction among women in the various ethnic groups.

There were slight differences in the type of reconstruction chosen by women in the four ethnic groups. However, due to the small number of procedures in each group, the differences were not statistically significant.

		Ethnic	group	
	White	Asian	Black	Other
No. of women	15,102	373	274	201
Age in years (%): Under 40	5	15	15	11
40 to 49	20	24	38	29
50 to 59	24	32	22	33
60 to 69	24	17	14	14
70 to 79	17	8	11	8
80 and over	9	3	2	4
Current smokers (%)	13	2	9	7
Obese (BMI ≥ 30) (%)	26	34	37	25
Diabetic (%)	6	19	9	11
Type of cancer				
Invasive (%)	85	86	80	82
DCIS (%)	15	14	20	18
Type of procedure				
Mastectomy only (%)	72	77	59	66
Immediate reconstruction (%)	18	14	31	26
Delayed Reconstruction (%)	10	9	9	8

Appendix 4: Data quality and outlier management protocol for inpatient outcomes

Stage	Required action	Detail
1	The Clinical Effectiveness Unit (CEU) advises The NHS Information Centre (IC) that analyses reveal outlying distributions at participating Trusts / hospitals. Identity of Trusts and hospitals restricted to the MBR Project Team (PT).	Unadjusted data analysed in line with the agreed statistical methodology.
2	IC contacts the Trusts / hospitals with details of the patient(s) and data item(s) involved. They also identify a data editing window. Identity of Trusts and hospitals restricted to the PT.	The Lead Clinician (in writing) and all registered users at the units (by e-mail) contacted with the NHS or hospital numbers of patients involved and the outlying data items. A data editing window to be provided.
3	The Trusts / hospitals involved act to review +/- edit the data within the timeframe set out. Identity of Trusts and hospitals restricted to the PT.	Trusts / hospitals to inform the IC if they feel that data accurately represents practice and outcomes. All such communications to have source, date and content clearly recorded.
4	The CEU review the edited data and proceed to final analysis phase. Identity of Trusts and hospitals restricted to the PT.	Following editing, adjusted analyses in line with the agreed statistical methodology.
5	The CEU review the final adjusted data and report outliers to the PT. Identity of Trusts and hospitals restricted to the PT.	Adjusted analyses of outcomes at the individual Trust / hospital level.
6	The PT, with the appropriate professional bodies, contacts identified outliers and seeks a formal response from their Lead Clinicians. Identity of Trusts and hospitals shared with senior representatives of ABS / BAPRAS / RCS.	PT, ABS and BAPRAS (+/- RCS) write to the Lead Clinician. Informal contact may be required in addition to this formal approach.
7	The PT reports the situation to the Chief Executives of the Trusts / hospitals after a response from their Lead Clinicians.	CEO informed before identifiers released to the Clinical Reference Group (CRG) and Project Board (PB).
8	Draft Third Annual Report is sent to CRG and PB for comment. Identity of Trusts and hospitals shared with the CRG and PB.	No further action required.
9	Draft Third Annual Report is sent to HQIP for review. Identity of outlier Trusts and hospitals shared with HQIP at this point.	No further action required.

Appendix 5: NHS trust and independent hospital participation and inpatient complication rates

Overanization Name	Number of	Ni mala an mith	Fetimeted sees	Daveanta no of
Organisation Name	Number of women registered	Number with complete operative data	Estimated case ascertainment (%)	Percentage of eligible women asked for PROMs consent
Aintree University Hospitals NHS Foundation Trust	96	93	75 to 100	98
Airedale NHS Trust	81	79	75 to 100	93
Ashford and St Peter's Hospitals NHS Trust	78	66	50 to 75	61
Barking, Havering and Redbridge Hospitals NHS Trust	154	146	75 to 100	73
Barnet and Chase Farm Hospitals NHS Trust	86	85	50 to 75	100
Barnsley Hospital NHS Foundation Trust	62	57	50 to 75	98
Barts and The London NHS Trust	127	118	75 to 100	75
Basildon and Thurrock University Hospitals NHS Foundation Trust	26	26	50 to 75	100
Basingstoke and North Hampshire NHS Foundation Trust	49	43	50 to 75	0
Bedford Hospital NHS Trust	65	64	75 to 100	36
Blackpool, Fylde and Wyre Hospitals NHS Trust	131	131	75 to 100	44
Bradford Teaching Hospitals NHS Foundation Trust	205	175	75 to 100	83
Brighton and Sussex University Hospitals NHS Trust	117	117	75 to 100	2
Bromley Hospitals NHS Trust	116	114	75 to 100	92
Buckinghamshire Hospitals NHS Trust	134	133	75 to 100	40
Burton Hospitals NHS Trust	61	61	75 to 100	13
Calderdale And Huddersfield NHS Foundation Trust	144	129	75 to 100	98
Cambridge University Hospitals NHS Foundation Trust	205	205	75 to 100	85
Chelsea and Westminster Healthcare NHS Trust	3	3	75 to 100	100
Chesterfield Royal Hospital NHS Foundation Trust	178	162	75 to 100	33
City Hospitals Sunderland NHS Foundation Trust	77	43	50 to 75	31
Colchester Hospital University NHS Foundation Trust	54	42	25 to 50	35
Countess of Chester Hospital NHS Foundation Trust	120	111	50 to 75	88
County Durham and Darlington NHS Foundation Trust	192	192	75 to 100	79
Dartford and Gravesham NHS Trust	67	67	75 to 100	28
Derby Hospitals NHS Foundation Trust	271	270	75 to 100	25
Doncaster and Bassetlaw Hospitals NHS Foundation Trust	203	188	75 to 100	0
Dorset County Hospitals NHS Foundation Trust	64	63	75 to 100	92
Dudley Group of Hospitals NHS Trust	152	146	75 to 100	5
Ealing Hospital NHS Trust	8	8	25 to 50	83
East and North Hertfordshire NHS Trust	7	6	0 to 25	71
East Cheshire NHS Trust	150	136	75 to 100	74
East Kent Hospitals NHS Trust	65	60	25 to 50	40
East Lancashire Hospitals NHS Trust	37	35	0 to 25	97
East Sussex Hospitals NHS Trust	175	174	75 to 100	9
Frimley Park Hospital NHS Foundation Trust	118	107	75 to 100	68
Gateshead Health NHS Foundation Trust	117	85	50 to 75	35
George Eliot Hospital NHS Trust	63	63	75 to 100	66
Gloucestershire Hospitals NHS Foundation Trust	146	143	50 to 75	14
Great Western Hospitals NHS Foundation Trust	92	92	75 to 100	98
Guy's and St Thomas' NHS Foundation Trust	218	213	75 to 100	46
Harrogate and District NHS Foundation Trust	41	31	50 to 75	69
Heart of England NHS Foundation Trust	200	162	50 to 75	65
Heatherwood and Wexham Park Hospitals NHS Trust	94	91	75 to 100	49
Hereford Hospitals NHS Trust	92	90	75 to 100	98
Hinchingbrooke Health Care NHS Trust	20	4	0 to 25	5
Homerton University Hospital NHS Foundation Trust	34	29	75 to 100	100
Hull and East Yorkshire Hospitals NHS Trust	249	241	75 to 100	3
Imperial College Healthcare NHS Trust	144	139	50 to 75	96
Ipswich Hospital NHS Trust	123	122	75 to 100	C
Isle of Wight NHS Primary Care Trust	105	84	75 to 100	17
James Paget University Hospitals NHS Foundation Trust	124	115	75 to 100	97
Kettering General Hospital NHS Trust	110	107	75 to 100	90
King's College Hospital NHS Foundation Trust	39	39	75 to 100	C
Kingston Hospital NHS Trust	54	54	50 to 75	35
Lancashire Teaching Hospitals NHS Foundation Trust	123	123	50 to 75	79
Leeds Teaching Hospitals NHS Trust	243	231	75 to 100	84
Liverpool Women's NHS Foundation Trust	47	47	75 to 100	41
Luton and Dunstable Hospital NHS Trust	10	10	0 to 25	100

English NHS Trusts	(continued)
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Organisation Name	Number of women registered	Number with complete operative data	Estimated case ascertainment (%)	Percentage of eligible womer asked for PROMs consent
Maidstone and Tunbridge Wells NHS Trust	99	99	75 to 100	90
Mayday Healthcare NHS Trust	94	83	75 to 100	80
Medway NHS Foundation Trust	49	47	25 to 50	94
Mid Essex Hospital Services NHS Trust	233	231	75 to 100	73
Mid Staffordshire General Hospitals NHS Trust	9	2	0 to 25	100
Mid Yorkshire Hospitals NHS Trust	225	222	75 to 100	30
Milton Keynes General Hospital NHS Trust	43	40	50 to 75	2
Newham University Hospital NHS Trust	26	26	50 to 75	96
Norfolk and Norwich University Hospital NHS Trust	301	301	75 to 100	4:
North Bristol NHS Trust	184	181	75 to 100	82
North Cumbria Acute Hospitals NHS Trust	133	133	75 to 100	99
North Middlesex University Hospital NHS Trust	3	0	0 to 25	100
North Tees and Hartlepool NHS Foundation Trust	200	195	75 to 100	59
North West London Hospitals NHS Trust	90	55	50 to 75	52
Northampton General Hospital NHS Trust	49	14	0 to 25	71
Northern Devon Healthcare NHS Trust	47	45	75 to 100	98
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust	40	37	25 to 50	100
Northumbria Healthcare NHS Foundation Trust	111	108	50 to 75	98
Nottingham University Hospitals NHS Trust	293	290	75 to 100	19
Oxford Radcliffe Hospitals NHS Trust	186	175	50 to 75	94
Pennine Acute Hospitals NHS Trust	243	234	75 to 100	46
Peterborough and Stamford Hospitals NHS Foundation Trust	136	136	75 to 100	28
Plymouth Hospitals NHS Trust	219	216	75 to 100	22
Poole Hospital NHS Foundation Trust	83	81	75 to 100	90
Portsmouth Hospitals NHS Trust	221	175	75 to 100	71
Queen Elizabeth Hospital NHS Trust	45	45	50 to 75	2
Queen Mary's Sidcup NHS Trust	46	44	75 to 100	13
Queen Victoria Hospital NHS Foundation Trust	121	121	75 to 100	98
Royal Berkshire NHS Foundation Trust	121	105	75 to 100	34
Royal Bolton Hospital NHS Foundation Trust	199	197	75 to 100	84
Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	96	94	75 to 100	88
Royal Cornwall Hospitals NHS Trust	174	171	75 to 100	17
Royal Devon and Exeter NHS Foundation Trust	160	150	50 to 75	69
Royal Free Hampstead NHS Trust	133	111	50 to 75	23
Royal Liverpool and Broadgreen University Hospitals NHS Trust	169	168	75 to 100	49
Royal Surrey County Hospital NHS Trust	80	80	75 to 100	64
Royal United Hospital Bath NHS Trust	132	131	75 to 100	99
Royal West Sussex NHS Trust	65	64	75 to 100	74
Salford Royal Hospitals NHS Foundation Trust	90	89	75 to 100	97
Salisbury NHS Foundation Trust	179	173	75 to 100	40
Sandwell and West Birmingham Hospitals NHS Trust	199	189	75 to 100	90
Scarborough and North East Yorkshire Healthcare NHS Trust	25	24	75 to 100	100
Sheffield Teaching Hospitals NHS Foundation Trust	210	196	75 to 100	54
Sherwood Forest Hospitals NHS Foundation Trust	138	136	75 to 100	87
South Devon Healthcare NHS Foundation Trust	116	116	75 to 100	92
South Tees Hospitals NHS Trust	192	189	75 to 100	25
South Tyneside NHS Foundation Trust	51	51	75 to 100	96
South Warwickshire General Hospitals NHS Trust	76	76	50 to 75	100
Southampton University Hospitals NHS Trust	155	149	75 to 100	6
Southend Hospital NHS Trust	95	94	75 to 100	7
Southport and Ormskirk Hospital NHS Trust	35	32	50 to 75	14
St George's Healthcare NHS Trust	83	70	50 to 75	58
St Helens and Knowsley Hospitals NHS Trust	117	115	75 to 100	63
Stockport NHS Foundation Trust	70	68	75 to 100	73
Surrey and Sussex Healthcare NHS Trust	87	86	75 to 100	100
Tameside Hospital NHS Foundation Trust	51	50	75 to 100	88
Taunton and Somerset NHS Trust	120	114	75 to 100	70
The Christie NHS Foundation Trust	48	47	75 to 100	77
The Hillingdon Hospital NHS Trust	61	61	75 to 100	100

Englis	h NHS Trusts (continued)
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Organisation Name	Number of women registered	Number with complete operative data	Estimated case ascertainment (%)	Percentage of eligible women asked for PROMs consent
The Mid Cheshire Hospitals NHS Trust	99	98	75 to 100	91
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	321	318	75 to 100	90
The Princess Alexandra Hospital NHS Trust	107	107	75 to 100	99
The Queen Elizabeth Hospital King's Lynn NHS Trust	104	104	75 to 100	100
The Rotherham NHS Foundation Trust	81	81	75 to 100	99
The Royal Marsden NHS Foundation Trust	351	347	75 to 100	6
The Royal Wolverhampton Hospitals NHS Trust	96	95	75 to 100	66
The Shrewsbury and Telford Hospital NHS Trust	147	147	75 to 100	97
The Whittington Hospital NHS Trust	32	17	50 to 75	78
United Lincolnshire Hospitals NHS Trust	190	188	50 to 75	29
University College London Hospitals NHS Foundation Trust	32	8	0 to 25	0
University Hospital Birmingham NHS Foundation Trust	119	100	50 to 75	75
University Hospital of North Staffordshire NHS Trust	63	59	25 to 50	16
University Hospital of South Manchester NHS Foundation Trust	204	202	50 to 75	0
University Hospitals Bristol NHS Foundation Trust	99	97	75 to 100	68
University Hospitals Coventry and Warwickshire NHS Trust	150	150	75 to 100	97
University Hospitals of Leicester NHS Trust	302	287	75 to 100	70
University Hospitals of Morecambe Bay NHS Trust	133	132	25 to 50	23
Walsall Hospitals NHS Trust	96	96	75 to 100	33
Warrington and Halton Hospitals NHS Foundation Trust	86	83	75 to 100	7
West Hertfordshire Hospitals NHS Trust	116	115	75 to 100	58
West Middlesex University Hospital NHS Trust	36	36	75 to 100	94
West Suffolk Hospitals NHS Trust	94	94	75 to 100	81
Weston Area Health NHS Trust	55	55	75 to 100	91
Whipps Cross University Hospital NHS Trust	60	59	75 to 100	42
Winchester and Eastleigh Healthcare NHS Trust	85	84	75 to 100	64
Wirral University Teaching Hospital NHS Foundation Trust	88	77	75 to 100	43
Worcestershire Acute Hospitals NHS Trust	172	171	75 to 100	42
Worthing and Southlands Hospitals NHS Trust	118	118	75 to 100	99
Wrightington, Wigan and Leigh NHS Trust	207	114	50 to 75	100
Yeovil District Hospital NHS Foundation Trust	51	51	75 to 100	94
York Hospitals NHS Foundation Trust	169	166	75 to 100	96

ndependent hospitals					
Organisation Name	Number of women registered	Number with complete operative data	Estimated case ascertainment (%)	Percentage of eligible women asked for PROMs consent	
BMI Bath Clinic	20	19	75 to 100	100	
BMI Bishops Wood Hospital	2	0	0 to 25	100	
BMI Chatsworth Suite	2	1	0 to 25	50	
BMI Chelsfield Park Hospital	6	5	50 to 75	100	
BMI Fawkham Manor Hospital	4	4	75 to 100	100	
BMI Goring Hall Hospital	7	0	0 to 25	0	
BMI Mount Alvernia Hospital	32	32	50 to 75	100	
BMI Sarum Road Hospital	13	13	50 to 75	100	
BMI The Alexandra Hospital	4	4	0 to 25	0	
BMI The Beaumont Hospital	8	8	50 to 75	100	
BMI The Blackheath Hospital	3	3	25 to 50	100	
BMI The Cavell Hospital	9	8	Unknown	100	
BMI The Chaucer Hospital	11	11	25 to 50	0	
BMI The Chiltern Hospital	28	28	75 to 100	86	
BMI The Clementine Churchill Hospital	10	2	0 to 25	0	
BMI The Droitwich Spa Hospital	7	6	50 to 75	100	
BMI The Esperance Hospital	13	12	50 to 75	0	
BMI The Foscote Hospital	1	1	0 to 25	0	
BMI The Hampshire Clinic	15	13	25 to 50	0	

Independent hospitals (continued)

Organisation Name	Number of women registered	Number with complete operative data	Estimated case ascertainment (%)	Percentage of eligible women asked for PROMs consent
BMI The Harbour Hospital	16	7	25 to 50	100
BMI The Highfield Hospital	1	0	0 to 25	100
BMI The Kings Oak Hospital	12	8	50 to 75	100
BMI The Lincoln Hospital	1	1	Unknown	(
BMI The Manor Hospital	8	8	50 to 75	13
BMI The Park Hospital	63	55	50 to 75	83
BMI The Princess Margaret	32	30	75 to 100	100
BMI The Priory Hospital	36	34	50 to 75	100
BMI The Ridgeway Hospital	5	4	0 to 25	100
BMI The Sandringham Hospital	4	4	25 to 50	100
BMI The Saxon Clinic	11	11	25 to 50	100
BMI The Shelburne Hospital	9	9	50 to 75	100
BMI The Sloane Hospital	17	17	50 to 75	82
BMI The Somerfield Hospital	24	21	25 to 50	100
BMI The Winterbourne Hospital	2	2	50 to 75	50
BMI Thornbury Hospital	11	1	0 to 25	100
BMI Werndale Hospital	6	4	75 to 100	C
BMI Woodlands Hospital	3	3	75 to 100	C
Cromwell Hospital	22	21	Unknown	100
HCA Lister Hospital	1	1	0 to 25	100
HCA London Bridge Hospital	21	16	75 to 100	0
HCA The Harley Street Clinic	15	10	25 to 50	7
HCA The Princess Grace Hospital	86	84	75 to 100	82
Hospital of St John & St Elizabeth	16	10	Unknown	94
Nuffield Health Bournemouth Hospital	2	0	0 to 25	100
Nuffield Health Brentwood Hospital	30	22	25 to 50	100
Nuffield Health Brighton Hospital	14	14	50 to 75	100
Nuffield Health Cambridge Hospital	5	5	75 to 100	100
Nuffield Health Cheltenham Hospital	13	12	50 to 75	100
Nuffield Health Derby Hospital	15	14	75 to 100	40
Nuffield Health Exeter Hospital	7	7	50 to 75	100
Nuffield Health Grosvenor Hospital Chester	7	6	50 to 75	100
Nuffield Health Hereford Hospital	4	4	50 to 75	100
Nuffield Health Hull Hospital	7	7	Unknown	C
Nuffield Health Ipswich Hospital	9	9	75 to 100	100
Nuffield Health Newcastle-upon-Tyne Hospital	10	9	50 to 75	70
Nuffield Health North Staffordshire Hospital	3	3	0 to 25	100
Nuffield Health Plymouth Hospital	6	5	25 to 50	50
Nuffield Health Shrewsbury Hospital	2	2	25 to 50	100
Nuffield Health St Mary's Hospital Bristol	1	1	0 to 25	100
Nuffield Health Taunton Hospital	15	15	75 to 100	27
Nuffield Health Tees Hospital	11	3	25 to 50	9
Nuffield Health Wassey Hearital	12	12	75 to 100	25
Nuffield Health Wessex Hospital	8	8	75 to 100	100
Nuffield Health Woking Hospital	7	5	50 to 75	100
Nuffield Health Wolverhampton Hospital	3	0	0 to 25	100
Nuffield Health York Hospital	9	9	25 to 50	100
Parkside Hospital	10	10	Unknown	100
Ramsay Ashtead Hospital	1	0	0 to 25	0
Ramsay Duchy Hospital	1	1	25 to 50	100
Ramsay Euxton Hall Hospital	9	7	25 to 50	100
Ramsay Fitzwilliam Hospital	8		50 to 75	50
Ramsay Mount Stuart Hospital	2	2	25 to 50	50
Ramsay New Hall Hospital	6	6	25 to 50	100
Ramsay Oaks Hospital	1	0	0 to 25	100
Ramsay Park Hill Hospital	3	3	50 to 75	100
Ramsay Rivers Hospital	11	11	50 to 75	100
Ramsay Rowley Hospital			0 to 25	(
Ramsay Springfield Hospital	21	17	25 to 50	95

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Organisation Name	Number of women registered	Number with complete operative data	Estimated case ascertainment (%)	Percentage of eligible women asked for PROMs consent
Ramsay West Midlands Hospital	18	10	25 to 50	100
Ramsay Yorkshire Clinic	20	15	25 to 50	0
Spire Alexandra Hospital	5	5	50 to 75	100
Spire Bristol Hospital	34	29	50 to 75	100
Spire Bushey Hospital	18	9	25 to 50	100
Spire Cambridge Lea Hospital	17	17	50 to 75	100
Spire Cheshire Hospital	9	9	50 to 75	0
Spire Clare Park Hospital	12	8	25 to 50	33
Spire Dunedin Hospital	22	20	50 to 75	0
Spire Elland Hospital	10	9	50 to 75	100
Spire Gatwick Park Hospital	22	18	50 to 75	0
Spire Harpenden Hospital	2	1	0 to 25	100
Spire Hartswood Hospital	7	7	50 to 75	14
Spire Hull and East Riding Hospital	5	3	25 to 50	40
Spire Leeds Hospital	27	24	25 to 50	100
Spire Little Aston Hospital	33	30	75 to 100	52
Spire Liverpool Hospital	3	2	25 to 50	67
Spire Manchester Hospital	25	25	25 to 50	0
Spire Methley Park Hospital	6	5	25 to 50	100
Spire Murrayfield Hospital Wirral	13	12	50 to 75	62
Spire Norwich Hospital	25	22	50 to 75	80
Spire Parkway Hospital	23	21	50 to 75	64
Spire Portsmouth Hospital	7	6	25 to 50	0
Spire Regency Hospital	5	4	50 to 75	0
Spire Roding Hospital	4	4	25 to 50	0
Spire South Bank Hospital	5	5	50 to 75	100
Spire Southampton Hospital	19	19	75 to 100	95
Spire St Saviour's Hospital	8	7	75 to 100	0
Spire Sussex Hospital	2	2	50 to 75	0
Spire Thames Valley Hospital	15	15	75 to 100	67
Spire Tunbridge Wells Hospital	3	2	25 to 50	100
Spire Washington Hospital	7	7	50 to 75	100
Spire Wellesley Hospital	5	5	50 to 75	100
St Josephs Private Hospital	11	11	Unknown	100
The London Clinic	93	89	Unknown	0
The New Victoria Hospital	4	3	Unknown	50

Nam Emplish	NILIC	Tourante
Non-English	ипэ	irusts

Organisation Name	Number of women registered			Percentage of eligible women asked for PROMs consent
Abertawe Bro Morgannwyg University NHS Trust	19	18	Unknown	100
Cardiff and Vale NHS Trust	4	4	Unknown	100
Cwm Taf NHS Trust	116	112	Unknown	97
Gwent Healthcare NHS Trust	25	25	Unknown	100
NHS Grampian	143	143	Unknown	1
North West Wales NHS Trust	109	107	Unknown	99

Organisations excluded from comparative analysis of complication rates

English NHS Trusts		
Organisation Name	Number with complete operative and complications data	Reason in not included in analysis
East and North Hertfordshire NHS Trust	1	Low case-ascertainment
East Kent Hospitals NHS Trust	59	Low case-ascertainment
East Lancashire Hospitals NHS Trust	35	Low case-ascertainment
Hinchingbrooke Health Care NHS Trust	4	Low case-ascertainment
King's College Hospital NHS Foundation Trust	3	Incomplete complication data
Luton and Dunstable Hospital NHS Trust	9	Low case-ascertainment
Mid Staffordshire General Hospitals NHS Trust	2	Low case-ascertainment
North Middlesex University Hospital NHS Trust	0	Low case-ascertainment
Northampton General Hospital NHS Trust	14	Low case-ascertainment
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust	37	Low case-ascertainment
Oxford Radcliffe Hospitals NHS Trust	165	Incomplete complication data
University College London Hospitals NHS Foundation Trust	8	Low case-ascertainment
University Hospital of North Staffordshire NHS Trust	59	Low case-ascertainment

Organisation Namo	Number with complete operative	Posson in not included in analysis
Organisation Name	and complications data	Reason in not included in analysis
BMI Bishops Wood Hospital	0	Low case-ascertainmen
BMI Chatsworth Suite	1	Low case-ascertainmen
BMI Goring Hall Hospital	0	Low case-ascertainmen
BMI The Alexandra Hospital	4	Low case-ascertainmen
BMI The Blackheath Hospital	3	Low case-ascertainmen
BMI The Clementine Churchill Hospital	2	Low case-ascertainmen
BMI The Foscote Hospital	1	Low case-ascertainmen
BMI The Hampshire Clinic	13	Low case-ascertainmen
BMI The Harbour Hospital	6	Low case-ascertainmen
BMI The Highfield Hospital	0	Low case-ascertainmen
BMI The Ridgeway Hospital	4	Low case-ascertainmen
BMI The Saxon Clinic	11	Low case-ascertainmen
BMI Thornbury Hospital	0	Low case-ascertainmen
HCA Lister Hospital	1	Low case-ascertainmen
HCA London Bridge Hospital	2	Incomplete complications data
Nuffield Health Hospital Bournemouth	0	Low case-ascertainmen
Nuffield Health Hospital Bristol	1	Low case-ascertainmen
Nuffield Health Hospital North Staffordshire	3	Low case-ascertainmen
Nuffield Health Hospital Plymouth	5	Low case-ascertainmen
Nuffield Health Hospital Shrewsbury	2	Low case-ascertainmen
Nuffield Health Hospital Tees	3	Low case-ascertainmen
Nuffield Health Hospital Wolverhampton	0	Low case-ascertainmen
Nuffield Health Hospital York	9	Low case-ascertainmen
Ramsay Ashtead Hospital	0	Low case-ascertainmen
Ramsay Duchy Hospital	1	Low case-ascertainmen
Ramsay Euxton Hall Hospital	8	Low case-ascertainmen
Ramsay Mount Stuart Hospital	2	Low case-ascertainmen
Ramsay New Hall Hospital	6	Low case-ascertainmen
Ramsay Oaks Hospital	0	Low case-ascertainmen
Ramsay Rowley Hall Hospital	1	Low case-ascertainmen
Ramsay Springfield Hospital	17	Low case-ascertainmen
Ramsay The Yorkshire Clinic	15	Low case-ascertainmen
Ramsay West Midlands Hospital	7	Low case-ascertainmen
Spire Clare Park Hospital	8	Low case-ascertainmen
Spire Harpenden Hospital	0	Low case-ascertainmen
Spire Liverpool Hospital	2	Low case-ascertainmen
Spire Methley Park Hospital	5	Low case-ascertainmen
Spire Portsmouth Hospital	5	Low case-ascertainmen
Spire Roding Hospital	4	Low case-ascertainmen
Spire Tunbridge Wells Hospital	2	Low case-ascertainmen

Comparative analysis of organisational complication rates

Reasons for NHS trust or of complication rates	independent hospital not being included in analysis
Unkn CA	Unknown case-ascertainment and less than 25 cases
Low Act	Under 10 cases performed

Organisation name	Number with complete operative and complications data	Reason not included in analysis	Return to theatre rate		Mastectomy site complication rate (excluding seroma or haematoma)		Distant or systemic complication rate	
			Crude	Adjusted	Crude	Adjusted	Crude	Adjusted
Aintree University Hospitals NHS Foundation Trust	89		1.1%	1.1%	2.2%	1.3%	2.2%	2.1%
Airedale NHS Trust	79		3.8%	5.1%	2.5%	3.2%	0.0%	0.0%
Ashford and St Peter's Hospitals NHS Trust	66		1.5%	1.8%	1.5%	1.2%	0.0%	0.0%
Barking, Havering and Redbridge Hospitals NHS Trust	146		1.4%	1.7%	3.4%	4.0%	0.0%	0.0%
Barnet and Chase Farm Hospitals NHS Trust	85		2.4%	2.2%	1.2%	1.3%	1.2%	1.6%
Barnsley Hospital NHS Foundation Trust	57		0.0%	0.0%	0.0%	0.0%	1.8%	1.6%
Barts and The London NHS Trust	109		2.8%	3.0%	4.6%	4.2%	1.8%	2.1%
Basildon and Thurrock University Hospitals NHS Foundation Trust	26		0.0%	0.0%	7.7%	8.4%	0.0%	0.0%
Basingstoke and North Hampshire NHS Foundation Trust	43		2.3%	2.6%	9.3%	7.5%	2.3%	2.2%
Bedford Hospital NHS Trust	64		4.7%	4.9%	4.7%	4.3%	3.1%	3.1%
Blackpool, Fylde and Wyre Hospitals NHS Trust	131		1.5%	2.1%	2.3%	2.6%	0.0%	0.0%
Bradford Teaching Hospitals NHS Foundation Trust	172		1.7%	1.5%	2.9%	2.2%	0.0%	0.0%
Brighton and Sussex University Hospitals NHS Trust	116		0.0%	0.0%	0.9%	1.7%	0.0%	0.0%
Bromley Hospitals NHS Trust	114		1.8%	2.1%	2.6%	2.8%	0.0%	0.0%
Buckinghamshire Hospitals NHS Trust	133		3.0%	2.5%	0.8%	0.8%	1.5%	1.4%
Burton Hospitals NHS Trust	61		1.6%	4.6%	3.3%	3.7%	0.0%	0.0%
Calderdale And Huddersfield NHS Foundation Trust	129		0.8%	1.1%	0.0%	0.0%	0.0%	0.0%
Cambridge University Hospitals NHS Foundation Trust	205		5.4%	3.0%	1.5%	1.6%	1.0%	0.6%
Chelsea and Westminster Healthcare NHS Trust	3	Low Act						
Chesterfield Royal Hospital NHS Foundation Trust	162		0.6%	0.7%	1.2%	1.2%	1.2%	1.5%
City Hospitals Sunderland NHS Foundation Trust	43		7.0%	11.3%	4.7%	6.2%	2.3%	5.2%
Colchester Hospital University NHS Foundation Trust	42		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Countess of Chester Hospital NHS Foundation Trust	111		1.8%	2.3%	2.7%	2.6%	0.9%	1.3%
County Durham and Darlington NHS Foundation Trust	192		3.1%	3.1%	0.5%	0.5%	3.6%	3.7%
Dartford and Gravesham NHS Trust	67		1.5%	2.1%	3.0%	3.3%	0.0%	0.0%
Derby Hospitals NHS Foundation Trust	269		0.7%	0.9%	1.1%	1.0%	0.4%	0.4%
Doncaster and Bassetlaw Hospitals NHS Foundation Trust	186		0.5%	0.8%	2.2%	2.9%	1.6%	3.0%
Dorset County Hospitals NHS Foundation Trust	63		3.2%	4.4%	0.0%	0.0%	1.6%	2.6%
Dudley Group of Hospitals NHS Trust	146		3.4%	4.2%	1.4%	1.4%	0.0%	0.0%
Ealing Hospital NHS Trust	7	Low Act	3.170	1.2 /0	1.170	11.170	0.070	0.070
East Cheshire NHS Trust	135	LOWACE	3.0%	3.7%	5.2%	5.1%	3.7%	4.6%
East Sussex Hospitals NHS Trust	174		0.0%	0.0%	0.6%	0.6%	0.6%	0.7%
Frimley Park Hospital NHS Foundation Trust	105		6.7%	7.8%	6.7%	6.3%	1.9%	2.1%
Gateshead Health NHS Foundation Trust	85		3.5%	3.9%	3.5%	3.4%	2.4%	2.1%
George Eliot Hospital NHS Trust	63		0.0%	0.0%	1.6%	2.8%	1.6%	3.4%
	143		4.9%	5.8%		2.2%	4.2%	4.4%
Gloucestershire Hospitals NHS Foundation Trust Great Western Hospitals NHS Foundation Trust	92		2.2%	2.6%	2.1% 1.1%	1.1%	0.0%	0.0%
Guy's and St Thomas' NHS Foundation Trust	189		7.4%	3.1%	6.3%	4.5%	1.6%	0.9%
Harrogate and District NHS Foundation Trust	31		0.0%	0.0%	3.2%	3.4%	0.0%	0.0%
Heart of England NHS Foundation Trust	160		2.5%	3.0%	1.3%	1.4%	1.3%	1.5%
Heatherwood and Wexham Park Hospitals NHS Trust	91		2.2%	1.8%	4.4%	3.7%	1.1%	1.0%
Hereford Hospitals NHS Trust	90		0.0%	0.0%	0.0%	0.0%	2.2%	3.2%
Homerton University Hospital NHS Foundation Trust	28		7.1%	7.1%	14.3%	10.3%	0.0%	0.0%
Hull and East Yorkshire Hospitals NHS Trust	241		2.1%	1.6%	0.0%	0.0%	0.0%	0.0%
Imperial College Healthcare NHS Trust	137		2.2%	2.6%	3.6%	4.2%	2.2%	2.4%
Ipswich Hospital NHS Trust	122		3.3%	3.3%	0.0%	0.0%	4.1%	3.1%
Isle of Wight NHS Primary Care Trust	84		4.8%	6.4%	8.3%	7.3%	0.0%	0.0%
James Paget University Hospitals NHS Foundation Trust	115		5.2%	5.8%	3.5%	3.1%	1.7%	1.8%
Kettering General Hospital NHS Trust	107		4.7%	6.8%	0.0%	0.0%	0.0%	0.0%
Kingston Hospital NHS Trust	54		1.9%	2.0%	5.6%	5.0%	0.0%	0.0%
Lancashire Teaching Hospitals NHS Foundation Trust	123		1.6%	1.4%	0.8%	0.6%	0.0%	0.0%

English	NHS.	Trusts	(continu	ıed)
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	Number with complete operative and complications data	Reason not included in analysis	Return to theatre rate		con rate (tomy site nplication excluding seroma or ematoma)	Distant or systemic complication rate	
			Crude	Adjusted	Crude	Adjusted	Crude	Adjusted
Leeds Teaching Hospitals NHS Trust	231		2.2%	2.0%	5.2%	4.9%	0.4%	0.4%
Liverpool Women's NHS Foundation Trust	47		0.0%	0.0%	2.1%	1.9%	0.0%	0.0%
Maidstone and Tunbridge Wells NHS Trust	99		1.0%	1.0%	1.0%	1.0%	3.0%	2.8%
Mayday Healthcare NHS Trust	83		1.2%	1.5%	3.6%	4.1%	2.4%	2.7%
Medway NHS Foundation Trust	47		4.3%	4.9%	0.0%	0.0%	2.1%	2.5%
Mid Essex Hospital Services NHS Trust	231		15.6%	5.0%	2.2%	1.6%	9.1%	3.2%
Mid Yorkshire Hospitals NHS Trust	220		2.8%	4.6%	0.0%	0.0%	4.6%	4.1%
Milton Keynes General Hospital NHS Trust	40		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Newham University Hospital NHS Trust	26		0.0%	0.0%	11.5%	6.1%	0.0%	0.0%
Norfolk and Norwich University Hospital NHS Trust	301		3.7%	2.7%	0.7%	0.7%	0.0%	0.0%
North Bristol NHS Trust	181		1.7%	1.4%	0.0%	0.0%	4.4%	4.0%
North Cumbria Acute Hospitals NHS Trust	133		3.8%	4.7%	1.5%	1.9%	3.8%	5.0%
North Tees and Hartlepool NHS Foundation Trust	195		1.0%	1.2%	5.1%	5.1%	1.0%	1.1%
North West London Hospitals NHS Trust	54		0.0%	0.0%	7.4%	6.9%	1.9%	3.8%
Northern Devon Healthcare NHS Trust	45		8.9%	11.8%	8.9%	8.9%	0.0%	0.0%
Northumbria Healthcare NHS Foundation Trust	108		1.9%	2.8%	1.9%	2.9%	0.0%	0.0%
Nottingham University Hospitals NHS Trust	286		3.1%	2.2%	1.4%	1.1%	0.3%	0.3%
Pennine Acute Hospitals NHS Trust	234		2.6%	3.0%	3.4%	3.2%	2.6%	2.7%
Peterborough and Stamford Hospitals NHS Foundation Trust	136		3.7%	4.4%	4.4%	3.8%	0.7%	0.9%
Plymouth Hospitals NHS Trust	216		0.9%	1.9%	0.5%	0.7%	0.0%	0.0%
Poole Hospital NHS Foundation Trust	81		1.2%	1.5%	1.2%	1.3%	2.5%	3.3%
Portsmouth Hospitals NHS Trust	175		6.3%	5.0%	0.0%	0.0%	2.3%	1.8%
Queen Elizabeth Hospital NHS Trust	45		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Queen Mary's Sidcup NHS Trust	44		0.0%	0.0%	2.3%	3.2%	4.5%	7.7%
Queen Victoria Hospital NHS Foundation Trust	121		10.7%	2.8%	2.5%	1.5%	2.5%	0.7%
Royal Berkshire NHS Foundation Trust	105		2.9%	3.2%	1.0%	0.9%	1.0%	0.9%
Royal Bolton Hospital NHS Foundation Trust	197		3.0%	3.9%	0.5%	0.5%	2.0%	2.5%
Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	94		5.3%	6.0%	2.1%	2.3%	4.3%	4.4%
Royal Cornwall Hospitals NHS Trust	171		1.8%	2.3%	2.9%	3.3%	0.0%	0.0%
Royal Devon and Exeter NHS Foundation Trust	147		4.8%	4.0%	0.7%	0.7%	1.4%	1.4%
Royal Free Hampstead NHS Trust	111		7.2%	3.0%	3.6%	2.9%	3.6%	1.6%
Royal Liverpool and Broadgreen University Hospitals NHS Trust	168		3.6%	4.3%	3.0%	2.4%	1.8%	1.9%
Royal Surrey County Hospital NHS Trust	80		0.0%	0.0%	3.8%	4.7%	0.0%	0.0%
Royal United Hospital Bath NHS Trust	131		0.0%	0.0%	0.8%	0.8%	0.0%	0.0%
Royal West Sussex NHS Trust	64		3.1%	4.3%	0.0%	0.0%	0.0%	0.0%
Salford Royal Hospitals NHS Foundation Trust	89		1.1%	1.3%	0.0%	0.0%	2.2%	2.2%
Salisbury NHS Foundation Trust	173		6.4%	4.3%	2.9%	2.5%	5.2%	3.8%
Sandwell and West Birmingham Hospitals NHS Trust	185		1.6%	1.6%	0.0%	0.0%	0.5%	0.5%
Scarborough and North East Yorkshire Healthcare NHS Trust	24		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Sheffield Teaching Hospitals NHS Foundation Trust	196		4.1%	4.7%	2.6%	2.4%	2.0%	2.2%
Sherwood Forest Hospitals NHS Foundation Trust	136		2.2%	3.0%	5.1%	5.3%	0.0%	0.0%
South Devon Healthcare NHS Foundation Trust	116		3.4%	3.8%	2.6%	2.2%	4.3%	4.0%
South Tees Hospitals NHS Trust	189		2.1%	2.0%	1.6%	1.7%	0.0%	0.0%
South Tyneside NHS Foundation Trust	51		2.0%	2.5%	5.9%	5.9%	3.9%	6.1%
South Warwickshire General Hospitals NHS Trust	75		1.3%	1.7%	6.7%	6.8%	0.0%	0.0%
Southampton University Hospitals NHS Trust	148		1.4%	2.0%	4.7%	5.9%	0.7%	1.1%
Southend Hospital NHS Trust	94		0.0%	0.0%	2.1%	2.2%	1.1%	1.5%
Southport and Ormskirk Hospital NHS Trust	32		0.0%	0.0%	0.0%	0.0%	3.1%	3.8%
St George's Healthcare NHS Trust	70 115		5.7% 7.0%	4.7% 4.5%	1.4%	1.3%	1.4%	1.0%
St Helens and Knowsley Hospitals NHS Trust	68				6.1%	5.0%	4.3%	2.6%
Stockport NHS Foundation Trust			2.9%	4.0%	0.0%	0.0%	0.0%	0.0%
Surrey and Sussex Healthcare NHS Trust	84		1.2%	2.6%	0.0%	0.0%	0.0%	0.0%
Tameside Hospital NHS Foundation Trust	50		2.0%	2.7%	2.0%	2.3%	0.0%	0.0%
Taunton and Somerset NHS Trust	114		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
The Christie NHS Foundation Trust	46		2.2%	1.5%	0.0%	0.0%	0.0%	0.0%
The Hillingdon Hospital NHS Trust	61 98		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
The Mid Cheshire Hospitals NHS Trust	318		2.0% 4.1%	2.8% 3.3%	0.0% 2.8%	0.0% 2.4%	1.0% 2.5%	1.6% 2.0%

English NHS Trusts (continued)									
Organisation name	Number with complete operative and complications	complete included in operative and analysis		Return to theatre rate				Distant or systemic complication rate	
	data		Crude	Adjusted	Crude	Adjusted	Crude	Adjusted	
The Princess Alexandra Hospital NHS Trust	107		4.7%	6.0%	1.9%	2.3%	0.9%	1.4%	
The Queen Elizabeth Hospital King's Lynn NHS Trust	104		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
The Rotherham NHS Foundation Trust	81		0.0%	0.0%	1.2%	1.3%	0.0%	0.0%	
The Royal Marsden NHS Foundation Trust	347		2.9%	1.9%	0.3%	0.3%	0.3%	0.2%	
The Royal Wolverhampton Hospitals NHS Trust	95		0.0%	0.0%	1.1%	0.8%	0.0%	0.0%	
The Shrewsbury and Telford Hospital NHS Trust	147		4.1%	6.6%	2.0%	3.4%	2.0%	4.1%	
The Whittington Hospital NHS Trust	17		0.0%	0.0%	5.9%	8.8%	0.0%	0.0%	
United Lincolnshire Hospitals NHS Trust	188		1.1%	1.4%	3.7%	3.7%	2.7%	3.4%	
University Hospital Birmingham NHS Foundation Trust	97		1.0%	0.9%	2.1%	2.0%	1.0%	0.9%	
University Hospital of South Manchester NHS Foundation Trust	202		1.5%	1.3%	0.5%	0.4%	0.5%	0.4%	
University Hospitals Bristol NHS Foundation Trust	97		6.2%	6.0%	3.1%	2.4%	5.2%	4.0%	
University Hospitals Coventry and Warwickshire NHS Trust	150		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
University Hospitals of Leicester NHS Trust	286		2.1%	1.7%	2.4%	2.4%	1.7%	1.6%	
University Hospitals of Morecambe Bay NHS Trust	128		0.0%	0.0%	1.6%	2.5%	0.8%	1.1%	
Walsall Hospitals NHS Trust	96		1.0%	1.5%	1.0%	1.6%	2.1%	3.2%	
Warrington and Halton Hospitals NHS Foundation Trust	82		1.2%	1.7%	0.0%	0.0%	0.0%	0.0%	
West Hertfordshire Hospitals NHS Trust	115		2.6%	2.9%	0.9%	0.8%	0.9%	0.9%	
West Middlesex University Hospital NHS Trust	36		5.6%	6.1%	5.6%	4.5%	11.1%	9.0%	
West Suffolk Hospitals NHS Trust	94		2.1%	2.9%	1.1%	1.1%	2.1%	2.3%	
Weston Area Health NHS Trust	55		1.8%	2.4%	0.0%	0.0%	1.8%	3.5%	
Whipps Cross University Hospital NHS Trust	59		1.7%	2.2%	1.7%	1.7%	0.0%	0.0%	
Winchester and Eastleigh Healthcare NHS Trust	84		6.0%	6.4%	1.2%	0.9%	2.4%	2.1%	
Wirral University Teaching Hospital NHS Foundation Trust	75		1.3%	2.2%	0.0%	0.0%	0.0%	0.0%	
Worcestershire Acute Hospitals NHS Trust	171		1.2%	1.4%	1.2%	1.1%	0.6%	0.7%	
Worthing and Southlands Hospitals NHS Trust	118		0.0%	0.0%	0.8%	1.5%	0.8%	0.5%	
Wrightington, Wigan and Leigh NHS Trust	111		1.8%	1.7%	5.4%	5.3%	2.7%	2.5%	
Yeovil District Hospital NHS Foundation Trust	51		2.0%	2.8%	0.0%	0.0%	3.9%	6.2%	
York Hospitals NHS Foundation Trust	166		4.8%	5.1%	0.6%	0.6%	0.0%	0.0%	

Organisation name	Number with complete operative and complications	Reason not included in analysis	Return to theatre rate					r systemication rate
	data		Crude	Adjusted	Crude	Adjusted	Crude	Adjusted
BMI Bath Clinic	19		5.3%	6.9%	5.3%	8.1%	0.0%	0.0%
BMI Chelsfield Park Hospital	5	Low Act						
BMI Fawkham Manor Hospital	4	Low Act						
BMI Mount Alvernia Hospital	32		3.1%	3.2%	3.1%	3.5%	0.0%	0.0%
BMI Sarum Road Hospital	13		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
BMI The Beaumont Hospital	7	Low Act						
BMI The Cavell Hospital	8	Unkn CA						
BMI The Chaucer Hospital	11		9.1%	9.1%	0.0%	0.0%	9.1%	9.1%
BMI The Chiltern Hospital	28		0.0%	0.0%	3.6%	6.1%	0.0%	0.0%
BMI The Droitwich Spa Hospital	6	Low Act						
BMI The Esperance Hospital	12		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
BMI The Kings Oak Hospital	8	Low Act						
BMI The Lincoln Hospital	1	Unkn CA						
BMI The Manor Hospital	8	Low Act						
BMI The Park Hospital	55		0.0%	0.0%	5.5%	4.8%	0.0%	0.0%
BMI The Princess Margaret	30		0.0%	0.0%	0.0%	0.0%	3.3%	3.7%
BMI The Priory Hospital	34		2.9%	2.0%	2.9%	3.2%	0.0%	0.0%
BMI The Sandringham Hospital	4	Low Act						
BMI The Shelburne Hospital	9	Low Act						
BMI The Sloane Hospital	17		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
BMI The Somerfield Hospital	21		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
BMI The Winterbourne Hospital	2	Low Act						

Organisation name	Number with complete operative and complications	Reason not included in analysis	Return to theatre rate		,		Distant or system complication rat	
	data		Crude	Adjusted	Crude	Adjusted	Crude	Adjusted
BMI Werndale Hospital	4	Low Act						
BMI Woodlands Hospital	3	Low Act						
Cromwell Hospital	21	Unkn CA						
HCA The Harley Street Clinic	10		0.0%	0.0%	10.0%	10.2%	0.0%	0.0%
HCA The Princess Grace Hospital	84		2.4%	2.9%	0.0%	0.0%	2.4%	2.7%
Hospital of St John & St Elizabeth	10	Unkn CA						
Nuffield Health Brentwood Hospital	21		4.8%	1.4%	0.0%	0.0%	0.0%	0.0%
Nuffield Health Brighton Hospital	14		14.3%	17.7%	0.0%	0.0%	0.0%	0.0%
Nuffield Health Cambridge Hospital	5	Low Act						
Nuffield Health Cheltenham Hospital	12		8.3%	8.1%	0.0%	0.0%	8.3%	6.1%
Nuffield Health Derby Hospital	14		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Nuffield Health Exeter Hospital	7	Low Act						
Nuffield Health Grosvenor Hospital Chester	6	Low Act						
Nuffield Health Hereford Hospital	4	Low Act						
Nuffield Health Hull Hospital	7	Unkn CA						
Nuffield Health Ipswich Hospital	9	Low Act						
Nuffield Health Newcastle-upon-Tyne Hospital	9	Low Act						
Nuffield Health Taunton Hospital	15		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Nuffield Health Tunbridge Wells Hospital	11		9.1%	15.2%	0.0%	0.0%	0.0%	0.0%
Nuffield Health Wessex Hospital	8	Low Act		1012,1			212,0	
Nuffield Health Woking Hospital	5	Low Act						
Parkside Hospital	10	Unkn CA						
Ramsay Fitzwilliam Hospital	7	Low Act						
Ramsay Park Hill Hospital	3	Low Act						
Ramsay Rivers Hospital	11	LOW ACC	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spire Alexandra Hospital	5	Low Act	0.070	0.0 /0	0.0 /0	0.0 /0	0.070	0.0 /0
Spire Bristol Hospital	29	LOW ACC	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spire Bushey Hospital	9	Low Act	0.070	0.0 /0	0.0 70	0.070	0.070	0.070
Spire Cambridge Lea Hospital	17	LOW ACC	0.0%	0.0%	5.9%	5.6%	0.0%	0.0%
Spire Cambridge Lea Hospital Spire Cheshire Hospital	9	Low Act	0.0 76	0.0 70	3.970	3.0 70	0.070	0.0 70
Spire Dunedin Hospital	20	LOW ACT	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spire Elland Hospital	9	Low Act	0.0 76	0.0 70	0.0 70	0.0 70	0.070	0.0 70
Spire Gatwick Park Hospital	18	LOW ACC	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spire Hartswood Hospital	7	Low Act	0.0 %	0.0%	0.076	0.076	0.0%	0.0 %
	3	Low Act						
Spire Hull and East Riding Hospital		LOW ACT	0.00/	0.00/	0.00/	0.00/	0.00/	0.00/
Spire Leeds Hospital	23		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spire Little Aston Hospital	30		0.0%	0.0%	0.0%	0.0%	3.3%	1.8%
Spire Manchester Hospital	25		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spire Murrayfield Hospital Wirral	12		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spire Norwich Hospital			9.1%	13.9%	4.5%	6.4%	4.5%	7.8%
Spire Parkway Hospital	21	1 A -4	0.0%	0.0%	0.0%	0.0%	4.8%	4.7%
Spire Regency Hospital	5	Low Act						
Spire South Bank Hospital		LOW ACT	0.00/	0.00/	0.00/	0.00/	E 20/	0.70/
Spire Southampton Hospital	19	1 6 :	0.0%	0.0%	0.0%	0.0%	5.3%	8.7%
Spire St Saviour's Hospital	6	Low Act						
Spire Sussex Hospital	2	Low Act	0.00/	0.00/	0.00/	0.00/	0.00/	0.004
Spire Thames Valley Hospital	15		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spire Washington Hospital	7	Low Act						
Spire Wellesley Hospital	5	Low Act						
St Josephs Private Hospital	11	Unkn CA	_	_	_			
The London Clinic	89		3.4%	5.2%	1.1%	1.7%	0.0%	0.0%

Non-English NHS trusts								
Organisation name	Number with complete operative and complications	Reason not included in analysis	rate		Mastectomy site complication rate (excluding seroma or haematoma)		complication rate	
	data		Crude	Adjusted	Crude	Adjusted	Crude	Adjusted
Cardiff and Vale NHS Trust	1	Unkn CA						
Cwm Taf NHS Trust	112		0.9%	1.3%	1.8%	2.4%	2.7%	4.7%
Gwent Healthcare NHS Trust	4	Unkn CA						
NHS Grampian	143		4.2%	4.8%	2.1%	2.5%	3.5%	4.2%
North West Wales NHS Trust	107		1.9%	2.2%	4.7%	4.1%	2.8%	2.7a%

Glossary

95 per cent confidence intervals

This interval indicates how certain we are that a value that we derive from a sample is close to the true value for the complete population. We would expect the 95 per cent confidence interval will not include the value for the population 5 per cent of the time. For example, if we took 100 random samples of women and measured their height, we would expect that the 95 per cent confidence interval for the average height in 95 samples would contain the value of the average height for the population of women.

Ablation of a tumour

The destruction or removal of a tumour using surgical or non-surgical methods.

ABS

The Association of Breast Surgery (ABS) is the specialty society that represents breast cancer surgeons and is part of the British Association of Surgical Oncology. It is one of the key stakeholders leading the Audit.

Adjuvant treatment

An additional therapy (eg chemotherapy, radiotherapy, hormone drug therapy) provided to improve the effectiveness of the primary treatment (eg breast cancer surgery). This may aim to reduce the chance of local recurrence of the cancer or to improve the patient's overall chance of survival. These treatments may be provided before or after surgery.

Autologous breast reconstruction

The reconstruction of the breast mound (or shape) using only the patient's own tissue (without any prosthesis or implant).

Breast conserving surgery

A surgical procedure to remove a discrete lump or abnormal area of tissue from the breast, without the removal of all breast tissue.

Breast reconstruction surgery

The surgical recreation of the breast mound (or shape) after some or all of this has been lost or removed (eg after breast cancer surgery).

BAPRAS

The British Association of Plastic, Reconstructive and Aesthetic Surgeons is the specialty society that represents plastic surgeons. It is one of the key stakeholders leading the Audit.

The British Association of Surgical Oncology is a specialty society that is comprised of the Association of Breast Surgery and the Association of Cancer Surgery.

Cancer Registry

The Cancer Registries (eight in England, and one each for Wales, Scotland and Northern Ireland) collect, analyse and report data on cancers in their area, and submit a standard dataset on these registrations to the Office for National Statistics.

Chemotherapy

Drug therapy used to treat cancer. It may be used alone, or in conjunction with other types of treatment (eg surgery or radiotherapy).

Comorbidity

A coexisting medical condition that is unrelated to the primary breast cancer.

CRG

The Audit's Clinical Reference Group is comprised of representatives of the key stakeholders in breast cancer care. They advise the Project Team on particular aspects of the project and provide input from the wider clinical and patient community.

CFU

The Clinical Effectiveness Unit is an academic collaboration between The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine, and undertakes national surgical audit and research. It is one of the key stakeholders leading the Audit.

Delayed breast reconstruction

The reconstruction of the breast mound (or shape) after a mastectomy has already been performed. This is undertaken as a separate operative procedure.

Ductal carcinoma in situ (DCIS)

A non-invasive / pre-invasive type of breast tumour that is confined to the lactiferous ducts.

Flap necrosis

The death of flap tissue usually because of impaired blood supply.

Free flap breast reconstruction

The breast mound (or shape) is reconstructed using the patient's own tissue (eg skin, fat, muscle) from another part of the body (donor area). The tissue is completely detached from the donor area before it is moved, with microsurgery used to reioin its arteries and veins to those in the breast area. This means that tissue can also be taken from areas not adjacent to the breast, such as the buttock or thigh.

Haematoma

A localised collection of blood in the space between layers of tissue.

HOIP

The Healthcare Quality Improvement Partnership was established in 2008. They aim to promote quality improvement in healthcare, and in particular increase the impact of clinical audit on the services provided by the NHS and independent healthcare organisations.

HES

Hospital Episode Statistics is a database which contains data on all inpatients treated within NHS Trusts in England. This includes details of admissions, diagnoses and those treatments undergone.

ICD₁₀

International Classification of Diseases, Tenth Revision. This is the World Health Organisation international standard diagnostic classification, and is used to code diagnoses and complications within the Hospital Episode Statistics database of the English NHS.

Immediate breast reconstruction

The reconstruction of the breast mound (or shape) at the same time as the mastectomy, undertaken as part of the same operative procedure.

The NHS Information Centre for health and social care

The NHS Information Centre is a special health authority that provides facts and figures to help the NHS and social services run effectively. The National Clinical Audit Support Programme (NCASP) is one of its key components.

Implant-only breast reconstruction

The breast mound (or shape) is reconstructed using a tissue expander (the volume can be increased by injecting saline through a port placed under the skin) or a definitive implant (the volume is fixed). The expander or implant is placed under the pectoral (chest) muscle. A tissue expander may be exchanged for a definitive implant or left in place after expansion.

Lymphoedema

Swelling due to the build up of protein-rich fluid in the tissues. In breast cancer patients this occurs when the lymphatic drainage system that normally removes this fluid is damaged by surgery or radiotherapy to the armpit. The swelling usually affects the arm on the treated side.

Mastectomy

The removal of all breast tissue, usually performed as a treatment for breast cancer. Variations involve leaving some or all of the skin over the breast (skin-sparing) or removing some of the underlying pectoral muscle as well (total).

Metastatic disease

When cancer has spread from the place in which it started to other parts of the body.

MDT

The breast cancer multi-disciplinary team is a group of professionals from diverse specialties that works to optimise diagnosis and treatment throughout the patient pathway.

NCASP

The National Clinical Audit Support Programme is part of the NHS Information Centre for Health and Social Care, and manages a number of national clinical audits in the areas of cancer, diabetes and heart disease. It is one of the key stakeholders leading the Audit.

NICE

The National Institute of Health and Clinical Excellence is an independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

The Office for National Statistics (ONS) is the government department responsible for collecting and publishing official statistics about the UK's society and economy. This includes cancer registration data.

Pedicle flap breast reconstruction

The breast mound (or shape) is reconstructed by moving a 'flap' of skin, muscle and fat from the patient's back or abdomen to the breast area, while keeping intact a 'pedicle' or tube of tissue containing its supplying arteries and veins.

Peri-operative period

The time period surrounding a patient's surgical procedure.

Project Board

The Audit's Project Board consists of senior representatives of the key stakeholders and the Healthcare Quality Improvement Partnership, and acts to ensure that the Audit is meeting its contractual targets and objectives.

Project Team

The Audit's Project Team consists of clinical, audit and management representatives of the key stakeholders and works on the design, implementation, analysis and reporting of the Audit.

RCN

The Royal College of Nursing is an independent professional body that represents nurses and nursing, promotes excellence in practice and shapes health policies, and in particular aims to improve the quality of patient care.

The Royal College of Surgeons of England is an independent professional body committed to enabling surgeons to achieve and maintain the highest standards of surgical practice and patient care. As part of this it supports audit and the evaluation of clinical effectiveness for surgery.

Wound dehiscence

the spontaneous re-opening of a surgical incision or wound, which may be secondary to a number of local or systemic postoperative problems.

References

- 1. Malata CM, McIntosh SA, Purushotham AD. Immediate breast reconstruction after mastectomy for cancer. Br J Surg 2000; 87:1455-72.
- 2. National Institute for Clinical Excellence (NICE). Guidance on cancer services. Improving outcomes in breast cancer - manual update. London: NICE, 2002. http://www.nice.org.uk/nicemedia/pdf/Improving_ outcomes breastcancer manual.pdf
- 3. National Institute for Health and Clinical Excellence (NICE). Early and locally advanced breast cancer: diagnosis and treatment. (Clinical guideline 80.) London: NICE, 2009. http://www.nice.org.uk/nicemedia/pdf/ CG80NICEGuideline.pdf
- Office for National Statistics. Breast Cancer: Little change in incidence. November 2009. http://www.statistics.gov.uk/cci/nugget.asp?id=575
- 5. Quan ML, McCready D. The evolution of lymph node assessment in breast cancer: an overview. J Surg Oncol. 2009; 99(4):194-8.
- 6. Fisher B, Jeong JH, Anderson S, Bryant J, Fisher ER, Wolmark N. Twenty-five-year follow-up of a randomized trial comparing radical mastectomy, total mastectomy, and total mastectomy followed by irradiation. N Engl J Med. 2002; 347(8): 567-75.
- 7. Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. Lancet 2005; 365: 1687-1717.

- 8. El-Tamer MB, Ward BM, Schifftner T, Neumayer L, Khuri S, Henderson W. Morbidity and mortality following breast cancer surgery in women: national benchmarks for standards of care. Ann Surg. 2007; 245(5): 665-71.
- 9. Black N, Jenkinson C. Measuring patients' experiences and outcomes. BMJ. 2009; 339:b2495.
- 10. Spiegelhalter DJ. Funnel plots for comparing institutional performance. Stat Med 2005; 24: 1185-1202.
- 11. Jeevan R, Browne J, van der Meulen J, Caddy CM, Pereira J, Sheppard C, et al. First Annual Report of the National Mastectomy and Breast Reconstruction Audit 2008. Leeds: The NHS Information Centre, 2008. http://www.ic.nhs.uk/mbr
- 12. Care Quality Commission (CQC). National NHS patient survey programme - Survey of adult inpatients 2008. Full national results with historical comparisons. London: CQC, 2009. www.cgc.org.uk
- 13. Jeevan R, Cromwell D, Browne J, van der Meulen J, Caddy CM, Pereira J, Sheppard C, et al. Second Annual Report of the National Mastectomy and Breast Reconstruction Audit 2009. Leeds: The NHS Information Centre, 2009. http://www.ic.nhs.uk/mbr
- 14. Audit Commission. Anaesthesia under Examination. London: Audit Commission, 1997.

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