National Mastectomy and Breast Reconstruction Audit 2009

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BAPRAS
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National Mastectomy and Breast Reconstruction Audit 2009

A national audit of provision and outcomes of mastectomy and breast reconstruction surgery for women in England
Second Annual Report 2009

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Foreword

This historic document is of vital importance to breast cancer clinicians, patients, and all involved in the commissioning and provision of breast cancer care; for the first time we have national prospective information on the availability of breast reconstruction surgery in England. It is encouraging to see that the rate of immediate reconstruction over the past 3 years has increased, though wide variation exists across English Cancer Networks. Clearly there is still some way to go to meet the NICE recommendations that immediate breast reconstruction be discussed with all mastectomy patients and all appropriate surgical options offered irrespective of whether they are available locally.

The variations observed highlight the difficulty some areas have in meeting standard treatment time targets when immediate reconstruction is performed. It also seems likely that different decisions are being reached on the basis of co-morbidity and need for adjuvant therapies.

There are a number of key recommendations for Cancer Networks in this report; it is imperative that they embrace these to improve communication, access and timeliness of reconstructive surgery for women with breast cancer who require mastectomy. The report is a tribute to the determination and commitment of those who have led and contributed to the project, and underlines the strength of collaborative working between breast and plastic surgeons across the country. I encourage you to disseminate and act on the findings of this very important audit.

Martin Lee
Association of Breast Surgery at BASO President

Foreword

To write a few words at the beginning of this report is a privilege. It can be taken for granted that, like all who read it, I am impressed by the material, the value and the thought that this audit represents. What will we learn next and how will we improve? So far we know something about the shape of the service, its variations and some postulates as to why these variations exist. But I have another interest, another curiosity. How well are breast surgeons and plastic surgeons working together?

I ask this because, in this joint endeavour, the plastic surgeon has a unique role in providing microsurgical reconstruction. Everything else is done also by breast surgeons, and it is to be hoped that the two groups perform equally well, an aspiration that may be tested by future audits. Will breast surgeons ever perform microsurgery, and will plastic surgeons undertake surgical oncology, and if not why not? Surely neither is so complex as to be the sole preserve of a very small group of surgeons with some peculiar gifts?

As the treatment pathways around Britain converge and harmonise, what will a mature breast cancer surgery team look like? Will the oncologist (or oncoplastic surgeon) have expunged any need for plastic surgeons, or will plastic surgeons jealously guard their secrets whilst trying to deliver the oncological aspects of care? I hope that a mature team will have found both distinct and overlapping roles for each specialty, which after all bring separate heritages and cultures to the teams, to the benefit of each and all. To achieve this, both will need to share their knowledge and skills and continue to strive inclusively toward that greater good: the perfect intervention for the woman diagnosed with breast cancer. Each specialty has a lot to offer and neither is so capable alone.

Knowing the availability of each treatment is the start of understanding how to provide what women want. Only then can we tell if we are providing services promptly, sympathetically and in sufficient volume, while ensuring the highest quality of care.

Both specialties must engage fully in working towards that magnificent goal, and BAPRAS wholly supports this ideal in cooperation with the Association of Breast Surgery.

Simon Kay
British Association of Plastic, Reconstructive and Aesthetic Surgeons President

Executive Summary

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 in England, and investigate the determinants and outcomes of care for women with breast cancer having a mastectomy with or without breast reconstruction.

Breast reconstruction is a safe option for most women undergoing mastectomy for breast cancer, and may be performed at the time of the mastectomy (immediate) or at a later date (delayed). In 2002, the National Institute for Health and Clinical Excellence (NICE) recommended that reconstruction should be available at the time of the mastectomy. In 2009, NICE re-emphasised the importance of reconstruction after mastectomy in its updated guidance, stating that:

1. [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
2. All appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally.

The incidence of breast cancer has risen substantially in the last decade, and this has led to a corresponding increase in the demand for surgery. Between 1997 and 2006, the number of breast cancer operations performed by the English NHS rose from 24,684 to 33,814, an increase of 37 per cent. There was also an increase in the number of English NHS trusts performing reconstruction surgery but, over the same period, the proportion of women having immediate reconstruction only rose from 7 to 11 per cent.

This Second Annual Report focuses on the use of reconstructive surgery for women with breast cancer and short-term surgical outcomes. The results are based on prospectively collected data and describe adult women who underwent mastectomy or reconstructive breast surgery between 1 January 2008 and 31 March 2009. All English NHS trusts and independent sector hospitals that provide this surgery were invited to participate in the Audit.

Audit participation

The Audit received data from all 150 English NHS trusts that provide breast cancer surgery in the 30 English Cancer Networks. The overall level of case-ascertainment was estimated to be 74 per cent over the full 15 month audit period, and more than half of NHS trusts had an estimated case-ascertainment of 75 per cent or more. This reflects considerable leadership among the breast surgeons, plastic surgeons and breast care nurses at these NHS trusts, as well as the support of their audit and data management staff.

A further 106 independent hospitals participated in the Audit. 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). Of the 15,479 women who had a mastectomy, 3,216 (21 per cent) underwent immediate reconstruction. A much higher proportion of women with DCIS underwent immediate reconstruction than women with invasive disease (38 per cent v 17 per cent). The remaining 1,580 women underwent primary delayed breast reconstruction.

Patterns of surgical care

Patients should have access to the full range of reconstructive options at the time of mastectomy. There are four main types of reconstruction:

1. The insertion of a tissue expander or fixed volume implant
2. The insertion of an expander or implant placed with additional coverage from a pedicle flap from the back or abdomen
3. The use of a pedicle flap on its own
4. The use of a free flap from a distant donor site.

In England, plastic surgeons perform all types of reconstruction, while breast oncoplastic surgeons perform the first three.

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.

Surgery to check if the cancer has spread to the armpit was performed in all women with invasive disease, and in 80 per cent of women with DCIS. Sentinel node biopsy, a procedure which reduces the number of nodes removed and is likely to reduce the risk of postoperative lymphoedema, was used in 19 per cent of women undergoing mastectomy surgery.

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. This suggests that current waiting time targets may be too rigid and do not allow women sufficient time in which to consider reconstructive options. Poorer levels of performance may also 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. The rate has increased from the 11 per cent estimated for English NHS trusts during the 2005/06 financial year. However, 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.

Immediate reconstruction offer rates also 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. This variation in the proportion of women who accept an offer of immediate reconstruction may reflect several factors: the timing of the offer, the way in which it was communicated, and whether accepting the offer involved delaying primary cancer treatment.

Clinicians gave their reasons for not offering women immediate reconstruction during the audit period. In most cases, women were deemed inappropriate for clinical, health or lifestyle problems, or a perceived need for adjuvant radiotherapy. However, in 4 of the 30 Networks, "the lack of a local or a timely reconstructive service" was the reason stated for over 20 per cent of mastectomy only patients.

Postoperative outcomes of surgery

Mastectomy and breast reconstruction procedures are extremely safe, 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).

Less than 2 per cent of "mastectomy only" patients return to theatre. Around 5 per cent of women undergoing reconstruction returned to theatre during their admission, but this may indicate a low threshold for intervention. Particularly for those who have undergone free flap reconstruction, early intervention for any concerns may lower the likelihood of a flap failing and consequently improve long term outcomes.

The total flap failure rate for free flap reconstructions was 1.95 per cent (95% confidence intervals 1.08 to 2.82); the partial flap failure rate was 2.46 per cent (95% confidence intervals 1.49 to 3.44).

In the Third Annual Report, we will describe inpatient complication rates at individual NHS trusts and independent hospitals. The inpatient complications reported by clinicians will be linked to the post-discharge complications reported by patients in the 3-month follow up questionnaires to provide a detailed picture of short-term surgical outcomes. All participating NHS trusts and independent hospitals will have the opportunity to check and validate their data on complications to ensure published results are accurate.

Recommendations

1. Cancer Networks should act to reduce the variation in access to immediate reconstruction by ensuring it is offered to all women, unless precluded by comorbidity or adjuvant therapies.

2. Cancer Networks should improve local access by ensuring adequate service provision to meet the increasing demand. This is particularly important for the Networks who could not offer "a local or a timely reconstructive service" for a high proportion of women.

3. NHS trusts and independent hospitals should review the way in which the offer of reconstruction is communicated to ensure barriers to women accepting the offer are minimised.

4. Cancer Networks should ensure women are able to access all appropriate reconstructive options within current waiting time targets, even if not available locally. This will require all breast units to have rapid referral pathways to plastic surgery units in place if they are to meet the 2009 NICE recommendation.

5. Clinicians and patient support groups should use the Audit's findings to help inform women due to undergo mastectomy and reconstructive procedures. This is the first national prospectively collected source of information on reconstructive access, the relative risk of postoperative complications, and the outcomes attained by mastectomy with or without breast reconstruction surgery.

6. Clinicians should check their Audit data on inpatient surgical complications to ensure the reporting of robust, case-mix adjusted outcomes at the level of individual NHS trusts and independent hospitals. This will be included in the Third Annual Report.

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.

Breast reconstruction is a safe option for most women undergoing mastectomy.[1] 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."[2] In February 2009, towards the end of the Audit's data collection period, NICE published revised guidance.[3] This re-emphasised the importance of reconstruction after mastectomy, and stated 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 designed as a three year project. Its principal component was a study to prospectively collect data on the care received and the outcomes attained by women who underwent mastectomy or reconstruction surgery. The Audit was originally funded to include women who underwent surgery between 1 January 2008 and 30 September 2008. However, additional funding enabled extension of the enrolment period from 9 to 15 months, ending on 31 March 2009. It also allowed the Audit to collect information on patient-reported outcomes at 3 and 18 months rather than the 6 months originally proposed. The project and reporting structure were therefore extended to include a fourth year.

This Second Annual Report focuses on the process of surgical care and short-term outcomes. It primarily uses the information, prospectively collected in 2008 and 2009, that was specified in the Audit dataset. The report also contains a secondary analysis of linked ONS Cancer Registry data and the Hospital Episodes Statistics (HES) database. The collection of patient-reported outcome measures is still ongoing and the findings derived from these measures will be published in later reports.

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

1.2 Role of mastectomy and reconstruction in breast cancer treatment

The incidence of breast cancer has been increasing steadily in Britain for many years. Between 1977 and 2006, the age-standardised incidence per 100,000 women rose from 75 to 122. The majority of women treated for breast cancer have invasive disease. However, with the introduction of the national breast cancer screening programme, ductal carcinoma in situ (DCIS), a non-invasive tumour, is being detected more frequently.

The primary aim of breast cancer treatment is to effectively remove or ablate the tumour and thereby reduce the risks of recurrence, spread and associated mortality. Surgery continues to be first line treatment for most women, whether their tumour is invasive or non-invasive. It may involve removal of part (breast conserving surgery) or all (mastectomy) of the breast tissue. Mastectomy may be indicated when the breast shape and contour would be significantly distorted by the removal of a large tumour, when the tumour is multi-focal (in more than one area of the breast), or where most of the breast is involved. Some women, when offered the choice, may also prefer mastectomy to the option of breast conserving surgery.

It is widely accepted that effective cancer treatment is not compromised by concurrent or subsequent breast reconstruction.[1] Reconstruction aims to improve the aesthetic results and quality of life outcomes for women who have undergone mastectomy.

Invasive disease

For women with invasive disease, surgical management of the primary tumour may involve breast conserving surgery, mastectomy alone, or mastectomy with immediate or delayed breast reconstruction. The likelihood of mastectomy 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 and may therefore affect the likelihood of concurrent reconstructive surgery.

Axillary surgery involves removal of some or all of the lymph nodes from the 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 (armpit). 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.[4]

Post-mastectomy radiotherapy to the chest wall, axilla and supraclavicular fossa (the 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.[5]

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.[6]

Hormone therapy is given to most women with hormone-receptor positive invasive tumours and reduces the risk of recurrence and mortality.[6, 7]

Non-invasive disease

For women with non-invasive tumours (eg DCIS), radiotherapy should only be considered for women who undergo breast conserving surgery. This additional treatment is not normally administered in combination with mastectomy.

Breast reconstruction

Breast reconstruction aims to create a breast mound that matches the remaining breast following mastectomy, and consequently provide symmetry. Reconstruction can be performed either at the same time as the initial mastectomy (immediate) or at a later date (delayed). The timing of reconstruction depends on both the adjuvant treatments anticipated and patient choice.

Several different techniques are used to reconstruct a breast mound. These include:

- implant-only reconstruction
- reconstruction using the patient's own tissue (autologous)
- a combination of both methods.

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 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.

Various combinations of these approaches give four main types of reconstruction:

- a tissue expander (an implant into which saline may be injected to increase its size) or fixed volume implant placed under the pectoralis major muscle
- an expander or implant covered by a pedicle flap from the back or abdomen
- a pedicle flap from the back or abdomen on its own
- a free flap from a distant donor site such as the abdomen, buttock or thigh.

1.3 Cancer Networks and the Audit

In 1995, Calman and Hine published a report which aimed "to create a network of care in England and Wales which will enable a patient, wherever he or she lives, to be sure that the treatment and care received is of a uniformly high standard."[8] These Cancer Networks were to span primary care, cancer units and cancer centres and ensure the delivery of high quality care.

In 2000, Networks became the organisational model through which the NHS Cancer Plan was to be implemented in England.[9] Cancer Networks bring together health service commissioners and providers, along with the voluntary sector and local authorities. Each Network plans cancer services across the care pathway, and takes local responsibility for service delivery and resource allocation.

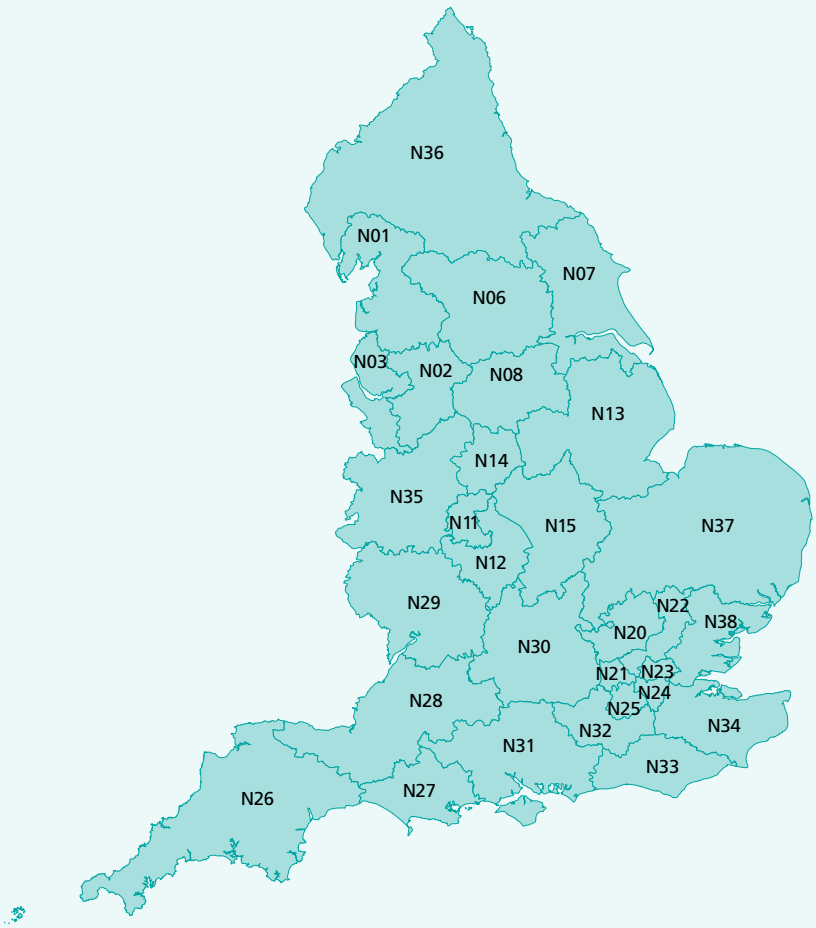
In the First Annual Report of the Audit, we described the current organisation of reconstructive service provision.[10] This review identified the importance of analysing and reporting reconstructive rates by Cancer Networks instead of by individual NHS trust. Patients who wish to have breast reconstruction are commonly referred to regional specialist centres, while in almost all cases mastectomy surgery is undertaken at the hospital of diagnosis. Reporting reconstruction rates by NHS trust ignores these referral practices and could suggest that women at certain trusts have no access to reconstruction, when in fact those that wish to undergo it are treated at a distant site.

For this reason, regional analyses are reported at the Cancer Network level throughout this report. Patients were allocated to Cancer Networks based on their postcode of residence. In the vast majority of cases, using a patient's residence instead of their surgery hospital did not change the Network allocation. However, a small proportion of women travelled across Network boundaries to access specialist reconstructive surgery. By allocating patients to Networks by postcode, we can fully describe the services commissioned by Networks for their patients and ensure that cross-Network referral pathways are taken into account.

At the start of the Audit, there were 30 Cancer Networks in England (Figure 1.1) and we present the regional patterns of care using these areas. However, on 1 October 2008, three Cancer Networks (Leicestershire, Northamptonshire and Rutland, Derby / Burton and Mid Trent) were combined to create East Midlands Cancer Network.

Figure 1.1
The 30 Cancer Networks in England that existed at the start of the Audit

Code	Name
N01	Lancashire and South Cumbria
N02	Greater Manchester
N03	Merseyside and Cheshire
N06	Yorkshire
N07	Humber and Yorkshire Coastal
N08	North Trent
N11	Pan Birmingham
N12	Arden
N13	Mid Trent
N14	Derby / Burton
N15	Leicestershire, Northamptonshire and Rutland'
N20	Mount Vernon
N21	West London
N22	North London
N23	North East London
N24	South East London
N25	South West London
N26	Peninsula
N27	Dorset
N28	Avon, Somerset and Wiltshire
N29	3 Counties
N30	Thames Valley
N31	Central South Coast
N32	Surrey, West Sussex and Hampshire
N33	Sussex
N34	Kent and Medway
N35	Greater Midlands
N36	North of England
N37	Anglia
N38	Essex



2. Participation and the patient population

2.1 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.

The Audit dataset was split into five sections. The first section recorded patient demographics and whether or not consent had been given to receive the 3- and 18-month patient-reported outcomes questionnaires. Subsequent sections recorded clinical information, including the type of operation and the decision about reconstruction, previous treatments and comorbidity, tumour characteristics, and inpatient peri-operative morbidity. Sample clinical datasheets are provided in Appendix 2.

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 a particular section were mandatory. The deadline for the submission of data to the Audit was 14 May 2009.

The statistical significance of differences between percentages were assessed using the chi-squared test. Where necessary, multiple logistic regression was used to adjust for potential confounders such as age and sex. All p-values are two-sided and those lower than 0.05 were considered to indicate a statistically significant result. STATA software (version 9.2) was used for all statistical calculations.

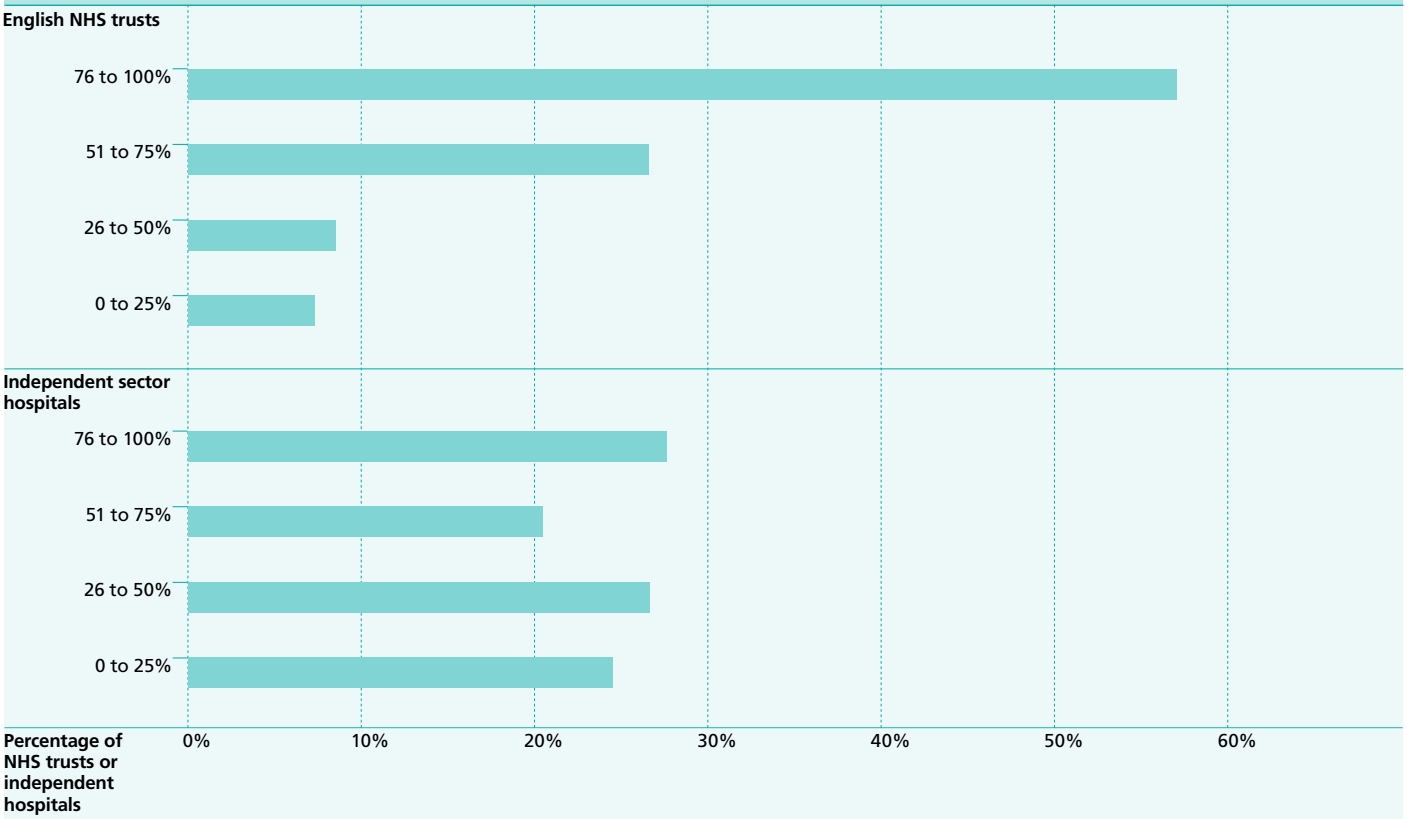
2.2 NHS trust and independent hospital participation

Participation in the Audit was excellent among hospitals performing surgery for breast cancer. Data were submitted to the Audit by all 150 NHS acute trusts in England that provide breast cancer surgery and by 106 independent sector hospitals. A further six NHS trusts in Wales and Scotland chose to participate.

A total of 18,071 women were registered during the 15 month audit period. Of these, 17,059 women (94 per cent) had complete information about their operation (mastectomy with or without immediate reconstruction, or delayed reconstruction).

Levels of case-ascertainment for England and individual English NHS trusts were calculated with respect to patients with complete operative data (Appendix 3). The expected number of operations for each trust was estimated using

Figure 2.1
Case ascertainment for the 150 English NHS trusts (based on the comparison of mastectomy procedures recorded in the Audit database and 2008 HES data*) and 97 English independent hospitals (based on the comparison of mastectomy and delayed reconstruction procedures recorded in the Audit database with the 2008-09 corporate activity figures provided)



* Rates of delayed reconstruction derived from HES are under-estimated because the previous mastectomy procedure linked to the delayed reconstruction may be outside the years for which HES data were available. The NHS calculations are therefore based solely on women who underwent mastectomy with or without immediate reconstruction.

the HES data for the period between 1 January and 31 December 2008. National case ascertainment was 74 per cent, based on the 14,080 mastectomy patients (with or without immediate reconstruction) with complete operative data entered by the English NHS Trusts. Individually, more than half of the 150 NHS trusts submitted at least 75 per cent of the expected number of operations (Figure 2.1).

For the independent sector, five major healthcare provider groups provided us with the number of eligible patients treated at their hospitals within the 15 month audit period. This allowed us to estimate case-ascertainment for 97 of the 106 participating independent hospitals (Figure 2.1). Case-ascertainment estimates for individual hospitals are included in Appendix 3.

2.3 Data completeness

The dataset was divided into five discrete sections so that hospitals could submit clinical information as and when it became available. A consequence of this was that patients might not have all five sections completed. However, the number of patients for whom each section was complete was very high, exceeding 95 per cent for all sections (Table 2.1). Data quality within each section was also very high.

2.4 Patient characteristics

Among the 17,059 women, 15,479 underwent mastectomy, of whom 3,216 (21 per cent) had an immediate reconstruction. The remaining 1,580 women underwent a primary delayed breast reconstruction during the 15 month audit period. The socio-demographic and clinical characteristics of these women, grouped by type of surgery, is summarised in Tables 2.2 and Table 2.3.

The mean age was highest in the "mastectomy only" group, as was the proportion of women with increased comorbidity and disability. 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.

Of the 16,342 women in the Audit with pathology data, 85 per cent had invasive carcinoma with or without ductal carcinoma in situ (DCIS). The remainder were treated for DCIS alone. This is important because women with DCIS

Table 2.1
Data completeness

	Patients with operative data for whom the data section was complete	
Data section	**Number**	**Per cent**
Operative and decision-making	17,059	100.0
Previous treatments and comorbidity	16,598	97.3
Inpatient peri-operative morbidity	16,847	98.8
Pathology	16,342	95.8
Registration and consent	18,071	N/A

Table 2.2
Socio-demographic characteristics, peri-operative fitness and functional status

Patient characteristics	Mastectomy only	Immediate reconstruction	Delayed reconstruction	Overall
Number of women	12,263	3,216	1,580	17,059
Age in years (mean and range)	64 (21-100)	51 (23-88)	49 (24-88)	60 (21-100)
White ethnicity (%)	95	94	95	95
Smokers (%)	14	12	10	13
Obese (%)	29	17	22	26
Diabetic (%)	8	2	2	6
ASA grade[1] III or IV (%)	13	2	3	10
ECOG score[2] 2 or more (%)	16	1	1	11

[1] 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.
[2] 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.

were much more likely to undergo immediate reconstruction (38 per cent) compared to women with invasive disease (17 per cent). This may reflect the fact that radiotherapy is almost never indicated for women who have had a mastectomy for DCIS alone. Radiotherapy may impair the cosmetic outcome of immediate reconstruction and is seen as a relative contraindication.

For women with invasive tumours, the grade of disease was similar for those women who had immediate reconstruction and those who had mastectomy alone. However, women who underwent immediate reconstruction had smaller tumours and were less likely to have positive axillary lymph nodes than those who underwent mastectomy alone. For invasive cancers, information about tumour size, grade and nodal involvement can be combined as the Nottingham Prognostic Index (NPI). Higher values are associated with worse prognosis and increase the likelihood of adjuvant therapies. For example, women with a higher NPI are more likely to require post-mastectomy radiotherapy.

Among the women undergoing mastectomy for DCIS, 1,838 (80 per cent) underwent axillary surgery. A small but significant proportion of these were found to have positive axillary lymph nodes, suggesting an invasive primary cancer that was not detected in the breast.

Table 2.3
Tumour characteristics and prognostic factors, by type of tumour[1]

Invasive carcinoma

Patient characteristics	Mastectomy only	Immediate reconstruction	Delayed reconstruction	Overall
Number of women	10,460	2,152	1,224	13,836
Mean invasive tumour size (mm)	31	24	28	30
Grade of disease (%)				
Grade 1	10	13	11	10
Grade 2	47	48	47	47
Grade 3	43	39	42	43
Number of women who had axillary surgery before or at time of mastectomy	10,460	2,152	785	13,397
Lymph node involvement in women having axillary surgery (%)				
0 nodes	47	61	45	49
1 to 3 nodes	28	25	34	28
4 or more nodes	25	13	20	23
Nottingham Prognostic Index (NPI) (mean)[2]	4.7	4.3	4.6	4.7

Ductal carcinoma in situ (DCIS)

Patient characteristics	Mastectomy only	Immediate reconstruction	Delayed reconstruction	Overall
Number of women	1,412	878	216	2,506
Mean DCIS tumour size (mm)	27	27	23	27
Grade of disease (%)				
Low	10	9	13	10
Intermediate	28	24	29	27
High	62	66	59	63
Number of women who had axillary surgery before or at time of mastectomy	1,117	721	97	1,935
Lymph node involvement in women having axillary surgery (%)				
0 nodes	80	94	81	85
1 to 3 nodes	11	3	13	8
4 or more nodes	9	3	7	7

[1] Whether a tumour was invasive or DCIS was recorded on the pathology data section which was available for 16,342 women
[2] 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. Overall patterns of surgical care

One of the aims of the Audit is to describe current clinical practice with respect to mastectomy and breast reconstruction surgery, as national data with which to inform both patients and clinicians is currently lacking. In this chapter, we describe overall patterns of surgical care during the audit period with respect to the primary and secondary reconstructive techniques in use, the types of axillary surgery undertaken, the planned adjuvant therapies and the timeliness of the primary procedures. These figures provide a baseline against which hospitals can compare their current practice and can be used to support quality improvement.

3.1 Types of primary breast reconstruction

There are four main types of reconstruction (see section 1.2 for explanation):

1. The insertion of a tissue expander or fixed volume implant
2. The insertion of an expander or implant with additional coverage from a pedicle flap
3. The use of a pedicle flap from the back or abdomen on its own
4. The use of a free flap from a distant donor site.

In England, plastic surgeons undertake all four types of reconstruction while most breast oncoplastic surgeons perform the first three.[10]

Table 3.1 describes the types of immediate and delayed reconstruction procedure performed on women in the Audit. Most immediate reconstruction patients had an implant-based reconstruction, while the majority of delayed reconstruction patients underwent autologous reconstruction with a flap of their own tissue.

Relatively few women undergo implant-only delayed reconstruction. This is likely to be explained by two factors. First, cancer waiting time targets do not apply in this situation, with women more likely to be referred to a specialist reconstructive team. Second, many delayed reconstruction patients have had post-mastectomy radiotherapy. Radiotherapy reduces the elasticity and blood supply of the skin in the breast area. If implant-only delayed reconstruction is performed, there is an increased likelihood of wound dehiscence and subsequent implant extrusion. Flap reconstruction is a better option because it may be used to replace the irradiated skin in addition to the breast volume.

However, the proportion of women who undergo implant-only immediate reconstruction varied greatly by Cancer Network, from 12 per cent to 87 per cent (p-value<0.001). This variation is not explained by patients' characteristics, and is likely to reflect impaired local access to a full range of reconstructive options at the time of mastectomy, when cancer waiting time targets apply.[3] The proportion of women who undergo implant-only delayed reconstruction also varied from 0 per cent to 46 per cent (p-value<0.001) across Networks.

For 8 per cent of the women who underwent implant-only immediate reconstruction, clinicians indicated that they planned to 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.

3.2 Types of contralateral and secondary reconstructive procedures

Breast reconstruction is a complex undertaking, and generally involves more than one operative procedure. To provide a full reconstructive service, Cancer Networks and NHS trusts need to take into account this extended patient pathway and the additional resources required.

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

Table 3.1
Type of primary reconstruction

Type of surgery	Type of surgery	(%)	Delayed reconstruction	%
Implant/expander-only	1,190	(37.0)	256	(16.2)
Pedicle flap + implant/expander	683	(21.2)	385	(24.4)
Pedicle flap (autologous)	892	(27.7)	416	(26.3)
Free flap	451	(14.0)	523	(33.1)
Total	**3,216**		**1,580**	

women reconstructed with a tissue expander, the delay allows serial stretching (expansion) of the overlying skin before the expander is replaced with a fixed volume breast implant.

Decisions about the type and timing of these procedures depend on both the type of primary reconstruction performed and the preferences of the patient and surgeon. To inform both patients and service providers about the typical patient pathway, we asked clinicians to report additional procedures performed at the time of the primary reconstruction and those secondary procedures planned in future.

Overall, 710 (4 per cent) women underwent surgery to their other breast to improve symmetry at the time of primary procedure. The proportion varied from 1 per cent in the mastectomy group to 11 per cent of immediate and 18 per cent of delayed reconstruction patients, with breast reduction the most common procedure performed on the other breast. However, a greater proportion of women had these procedures planned for a later date. Symmetrisation surgery to the other breast was planned for 13 per cent of women having immediate reconstruction and for 27 per cent of women undergoing delayed reconstruction.

Delayed reconstruction patients were much more likely to undergo surgery to the other breast to improve symmetry or to have this type of procedure planned in future. This would be expected for the following reason.

During immediate reconstruction, the breast skin is usually preserved through what is called a skin-sparing mastectomy. In a delayed reconstruction, patients have previously undergone a simple mastectomy and this removes all of the breast skin in addition to all breast tissue. For a delayed reconstruction, the surgeon must therefore reconstruct the breast's skin in addition to its volume. Obtaining sufficient skin from a donor site (such as the back or abdomen) to completely replace 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.

In summary, breast reconstruction commonly involves multiple procedures and an extended care pathway. Networks and NHS trusts should include estimates of demand for contralateral and secondary reconstructive procedures when planning local services, and, in particular, the additional resource requirements incurred by delaying primary reconstruction.

3.3 Axillary surgery and mastectomy

Identifying current practice in axillary surgery is essential in reporting the oncological, functional and aesthetic outcomes of mastectomy surgery. The outcomes attained following mastectomy and breast reconstruction surgery cannot be separated from those procedures performed alongside it, and the majority of women undergoing mastectomy will have concurrent axillary surgery.

Axillary surgery involves removal of the lymph nodes from the axilla (armpit). These nodes are then examined by a pathologist to look for evidence of the cancer having spread beyond the breast. The results help clinicians to decide on the need for further treatment (eg chemotherapy) and may be used to inform the patient about their prognosis. In addition, removing these nodes reduces the risk of spread of cancer beyond the breast.

However, the lymph nodes and vessels in the armpit help to drain excess fluid from both the breast area and the arm. Disrupting this drainage system by removing lymphatic tissue may lead to swelling of the arm (lymphoedema) with significant functional and aesthetic consequences for the women affected.

The high axillary clearance rate in "mastectomy only" patients with DCIS could represent over-treatment. However, for women undergoing mastectomy with immediate reconstruction, clearance may be performed pre-emptively to avoid further axillary procedures that might put at the risk the blood vessels in the axilla that supply a pedicle or free flap.

Pre-mastectomy axillary staging using sentinel node biopsy is an emerging practice that will help reduce over-treatment and subsequent morbidity in these cases. It informs reconstructive decision-making by identifying two key groups of women: those in need of post-mastectomy radiotherapy; and those whose diagnostic biopsy only detects DCIS but who actually have invasive disease which has spread beyond the breast.

3.4 Adjuvant therapies and mastectomy

Adjuvant therapy treatment patterns may help to explain current practice in mastectomy and breast reconstruction surgery. Adjuvant chemotherapy and radiotherapy may reduce the risk of local recurrence and death in breast cancer patients, and are an integral component of disease management for many women diagnosed with breast cancer. As breast reconstruction involves a longer healing process than mastectomy alone, it may delay the delivery of these therapies.

Radiotherapy in particular plays an important role in reconstructive decision-making. Radiation to a reconstructed breast may increase the risk of capsular contracture (scarring) around an implant or impair the blood supply of a flap, leading to loss of volume, altered shape, and poor aesthetic results. For this reason, many clinicians are averse to the idea of immediate reconstruction when post-operative adjuvant radiotherapy to the chest wall is expected.

The use of adjuvant therapies depend on both the patient and the tumour being treated. Tables 3.2 and 3.3 display the planned use of adjuvant chemotherapy and radiotherapy by age group for women undergoing mastectomy; it is important to note that a further 10 per cent of women with invasive disease had chemotherapy prior to their mastectomy.

Women were much less likely to need adjuvant therapies if they had DCIS alone without invasive disease. Younger women were also much more likely to have received adjuvant treatments. However, we found a notable degree of variation between Cancer Networks in the use of adjuvant therapies. For women with invasive disease, the proportion for whom both chemotherapy and radiotherapy were planned varied from 11 per cent to 35 per cent (p-value<0.001) across the Networks. Moreover, for women with DCIS, the proportion for whom both treatments were planned varied from 0 per cent to 25 per cent (p-value<0.001).

Table 3.2:
Proportion of women with invasive tumours who have adjuvant therapies planned following mastectomy

	Age of women at diagnosis (years)					
	Under 40	40 to 49	50 to 59	60 to 69	70 to 79	80 plus
Number of mastectomies	571	2,133	2,697	3,048	2,503	1,657
No planned adjuvant therapies (%)	19	25	35	45	57	70
Planned chemotherapy (%)	22	22	20	15	7	1
Planned radiotherapy (%)	20	15	13	13	25	28
Planned chemotherapy and radiotherapy (%)	39	38	32	26	12	1

Table 3.3:
Proportion of women with DCIS alone who have adjuvant therapies planned following mastectomy

	Age of women at diagnosis (years)					
	Under 40	40 to 49	50 to 59	60 to 69	70 to 79	80 plus
Number of mastectomies	76	381	705	665	341	122
No planned adjuvant therapies (%)	63	70	83	86	91	88
Planned chemotherapy (%)	17	7	8	4	3	2
Planned radiotherapy (%)	8	12	4	6	5	10
Planned chemotherapy and radiotherapy (%)	12	10	6	4	1	1

For this reason, there has been a trend towards selective sampling of lymph nodes. In sentinel node biopsy, only the first few nodes draining the breast are identified and removed, and more extensive axillary surgery is only undertaken if these nodes show evidence of cancer spread. It therefore reduces the likelihood of extensive axillary surgery and its resultant morbidity.

In those women with invasive disease who underwent mastectomy, 86 per cent had concurrent axillary surgery and the remaining 14 per cent had all undergone axillary surgery prior to their mastectomy. In contrast, 70 per cent of women with DCIS alone had axillary surgery with their mastectomy, and a further 10 per cent had it previously.

The breakdown for the type of axillary surgery undertaken at the time of mastectomy with or without immediate reconstruction is shown in Figure 3.1. Less aggressive axillary surgery was provided to women with DCIS and to those who had immediate reconstruction. This reflects the lower tumour burden and better prognosis in the DCIS group.

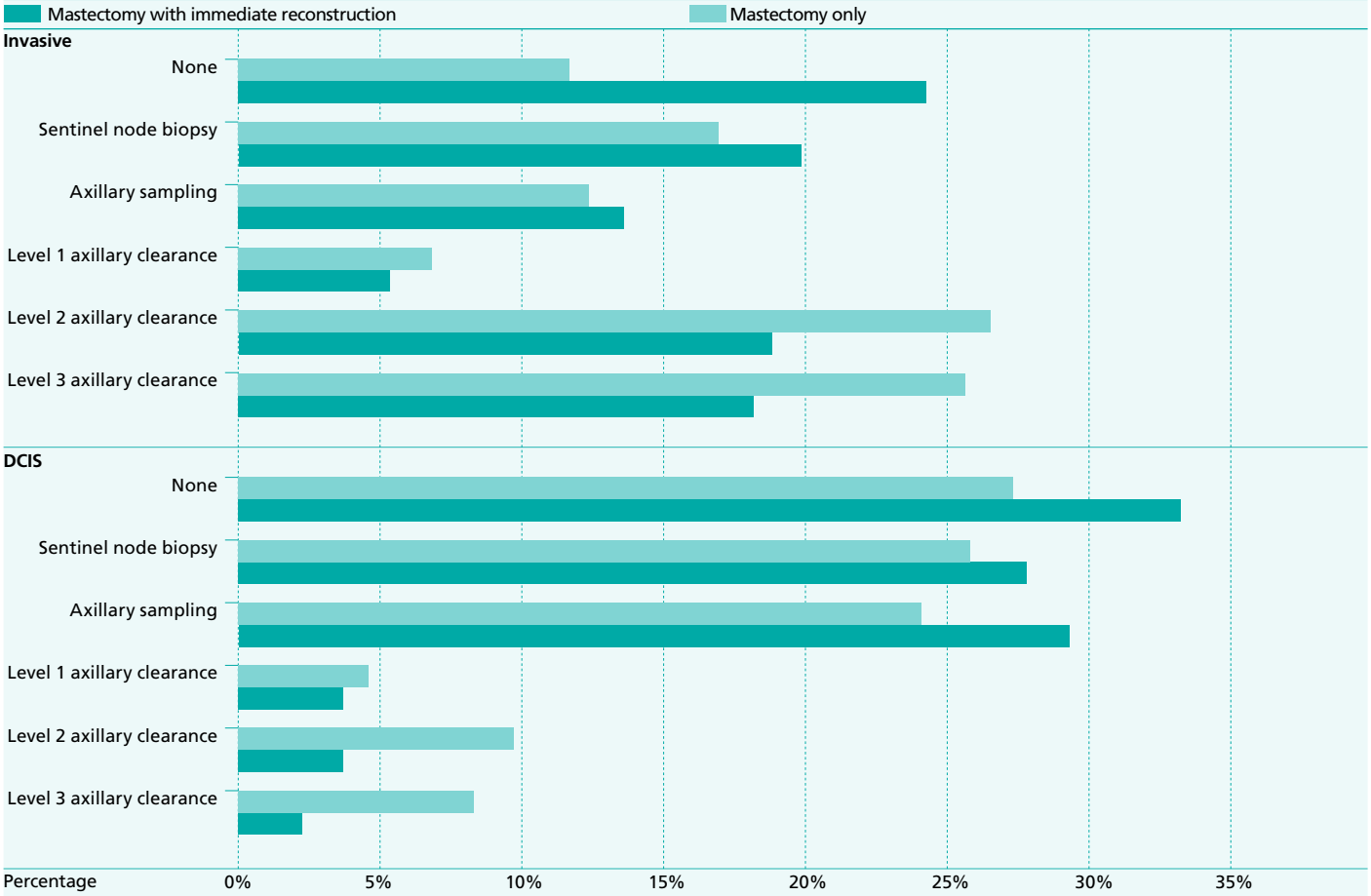
Three additional areas of practice stand out. First, 28 per cent of the immediate reconstruction group had undergone axillary surgery prior to their mastectomy. This compares with 12 per cent of the "mastectomy only" group.

For women who have had breast conserving surgery and go on to have mastectomy for incomplete or insufficient margins, surgeons are likely to know if they will require adjuvant radiotherapy in advance of the mastectomy. If it will not be required, women are more likely to be deemed suitable for immediate reconstruction. For this reason, a high regional rate of failed breast conservation surgery (where women then proceed to mastectomy as a secondary cancer treatment) will to some degree inflate the rate of immediate reconstruction.

Second, sentinel node biopsy was used in just 19 per cent of women undergoing mastectomy surgery, leaving the remaining women at a relatively increased risk of postoperative lymphoedema. Some women may have evidence of nodal involvement on clinical examination or radiological imaging of the axilla, making sentinel node biopsy inappropriate. However, in most cases, low utilisation may indicate local or regional barriers to the relevant training and resources.

Third, axillary staging is used to assess and reduce the risk of the cancer spreading beyond the breast. In patients with DCIS, there is little indication to undertake extensive axillary surgery in view of the additional risks involved. However, 18 per cent of mastectomy patients with DCIS alone had an axillary clearance.

Figure 3.1
Type of axillary surgery performed at time of mastectomy[1]



[1] All women with invasive tumours who had no axillary surgery at the time of mastectomy had had it previously

3.5 Time from decision to treat to first definitive treatment

In 2000, the NHS Cancer Plan set a maximum time of one month (31 days) from date of decision to treat to first definitive treatment. For women undergoing mastectomy, NHS trusts and independent hospitals provided both these dates to the Audit, and the time between the decision to treat and the date of surgery could be calculated for women who were undergoing mastectomy (rather than pre-mastectomy chemotherapy or breast conserving surgery) as their first definitive treatment.

For women having a mastectomy in the NHS, the mean time from decision to treat to surgery was 20 days, with 87 per cent treated within 31 days. For women having mastectomy with immediate reconstruction in the NHS, the mean time was 29 days, and only 65 per cent of immediate reconstruction patients were treated within 31 days.

The time from decision to treat and the date of surgery varied between English Cancer Networks. The mean elapsed time for mastectomy only surgery varied from 16 to 28 days, and the proportion of women treated within 31 days ranged from 75 per cent to 94 per cent.

Greater variation was seen for women having immediate reconstruction. The mean elapsed time ranged from 18 to 54 days, and the proportion of women starting treatment within 31 days ranged from 29 per cent to 83 per cent across English Networks.

Independent sector mastectomy patients were treated more rapidly on average, with a mean elapsed time of 13 days from date of decision to treat; 91 per cent were treated within 31 days. However, although the mean elapsed time for immediate reconstruction was 20 days in the independent sector, only 84 per cent of patients were treated within 31 days.

The poorer level of performance seen for immediate reconstruction in both the NHS and independent sector raises two issues. First, as the targets were not met in the independent sector, where resource issues are unlikely to play a major role, it suggests that current waiting time targets may be too inflexible to allow women the additional time that they require to consider reconstructive options. This issue was raised in our earlier qualitative study (see Appendix 1).

Second, with the rising incidence of breast cancer and corresponding increase in demand for surgery placing more pressure on NHS trusts, the targets could act as a disincentive to offering immediate reconstruction given likely capacity constraints.

4. Rates of immediate breast reconstruction and clinical decision-making among English Cancer Networks

4.1 Rates of immediate reconstruction

Among the 15,479 women with complete operative data who underwent mastectomy during the audit period, 3,216 (21 per cent) underwent immediate breast reconstruction. This indicates a sharp rise in the proportion of women having immediate reconstruction in the last few years. In the First Annual Report, the proportion of all women undergoing mastectomy in English NHS trusts was estimated to be 11 per cent between April 2005 and March 2006.

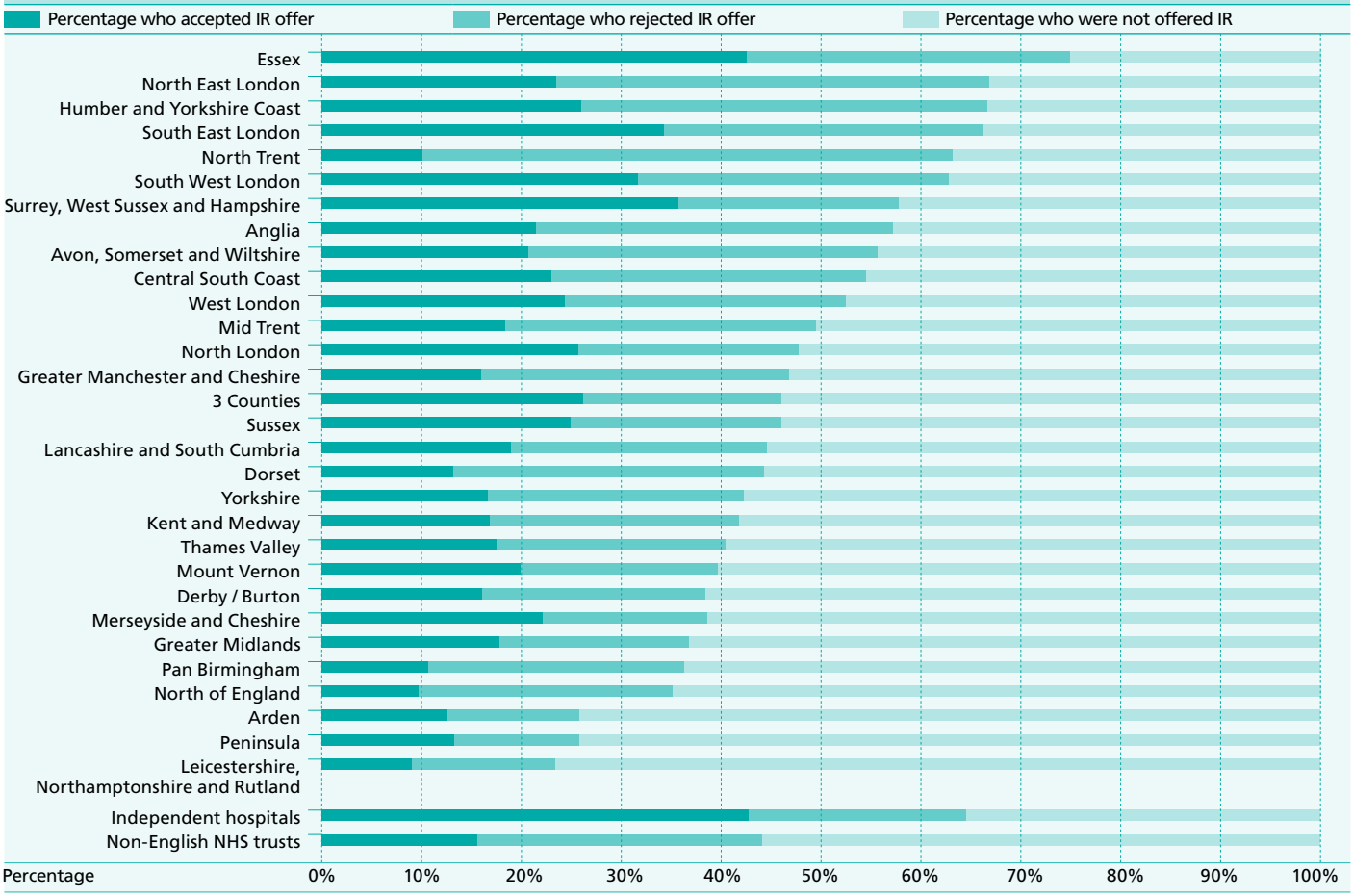
We were able to compare our figures with estimates derived from the national HES dataset for the period from 1 January until 31 December 2008. Although this did not correspond to the entire audit period, it indicates the degree to which the Audit, which captured 74 per cent of the procedures in the English NHS, represents overall practice.

In HES, the rate of immediate reconstruction was 17 per cent in those women who underwent mastectomy and had a recorded diagnosis of breast cancer (ICD10 C50 and D05). Among English NHS trusts that participated in the Audit, the rate of immediate reconstruction was 19 per cent. The HES and Audit based estimates varied slightly for individual Cancer Networks but figures were typically within 3 per cent of each other. The differences were small in comparison to the differences in the rates between English Cancer Networks, and the remaining analyses are based only on the Audit dataset.

The rate of immediate breast reconstruction varied substantially across the English Cancer Networks, ranging from 9 per cent to 43 per cent (p-value<0.001). Four networks have rates considerably higher than the other 26. Three of these networks have rates between 32 per cent and 36 per cent, while the other has a rate of 43 per cent. Rates at the majority of the remaining networks fall between 14 per cent and 27 per cent.

Overall, 48 per cent of mastectomy patients were offered immediate reconstruction. However, the proportion of women offered immediate reconstruction varied considerably between Cancer Networks. Curiously, there was not a strong association between the proportion of women offered immediate reconstruction and the proportion who took up the offer (Figure 4.1). Although some of the Networks with high and low reconstruction rates had correspondingly high and low offer rates, there were exceptions to this rule. For instance, although 63 per cent of women in the North Trent Network were offered immediate reconstruction, only 10 per cent underwent the operation.

Figure 4.1
Immediate breast reconstruction offer and uptake rate among English Cancer Networks. Networks sorted by the proportion of all women offered immediate reconstruction



The South West London Network offered reconstruction to a similar proportion of women and yet had a rate of immediate reconstruction of 32 per cent. Overall, the proportion of women who accepted an offer varied from 17 per cent to 62 per cent between Cancer Networks.

Figure 4.1 also shows the proportion of women who were offered immediate reconstruction and the proportion who took up the offer among participating independent hospitals and non-English NHS trusts.

Independent hospitals appear to have high immediate reconstruction rates. However, the rate looks to be over-estimated. Not all independent hospitals participated in the Audit, and those that did participate registered a high proportion of their immediate reconstruction patients but a relatively low proportion of their "mastectomy only" patients. Thus, while the immediate reconstruction rate for the independent sector as a whole was 43 per cent, among the participating independent hospitals for which the Audit had activity figures, their true immediate reconstruction rate was actually 30 per cent. Across all independent hospitals (participating and non-participating) in the five largest groups, the rate was also 30 per cent. The rate derived from the provider group activity data suggests the actual rate of immediate reconstruction in the independent sector was comparable to those Cancer Networks with the higher rates of immediate reconstruction.

4.2 Reconstructive decision-making

Table 4.1 summarises the reasons that clinicians gave for not offering women immediate reconstruction. Clinicians were allowed to select multiple reasons, so the proportions can add up to more than 100 per cent.

Women were most commonly deemed inappropriate for reconstructive surgery due to their age, comorbidities, cognitive function, mental health, lifestyle factors such as smoking, and concerns about local recurrence. Such reasons were given for between 37 per cent and 97 percent of patients across Networks.

Treatment pathway issues that precluded an offer were recent chemotherapy, anticipated radiotherapy to the chest wall and concerns about immediate reconstruction delaying other adjuvant therapies. These were given as reasons for 15 per cent to 70 per cent of women among the Networks.

Reconstructive availability issues referred to immediate reconstruction not being available locally or only being available in a timeframe that would significantly delay mastectomy surgery. In most Cancer Networks, these issues did not affect a high proportion of women. Nonetheless, clinicians at four Networks gave this as the reason that reconstruction was not offered for over 20 per cent of women, indicating that some regions still suffer from resource constraints despite the overall increase in capacity.

The NICE guidance suggests that, among the various patient characteristics, only comorbidity should legitimately preclude an offer of immediate reconstruction. In fact, a woman's age was the single most important factor in predicting whether they were offered reconstruction (Figure 4.2). After a threshold of approximately 70 years of age, the proportion of women who were offered reconstruction fell as their age increased. This may reflect the declining rate of acceptance among women of increasing age among those over 55 years. However, the acceptance rate was not negligible and it is unclear to what extent it was lowered artificially by the way in which clinicians offered reconstruction.

The First Annual Report of the Cancer Reform Strategy stated that ageism was still pervasive in cancer treatment.[9] It gave the example of radiotherapy not being provided to older patients with lung cancer, and recommended action to address this. The findings of this Audit suggest that action is also required to improve equity in the treatment of women with breast cancer.

In women aged under 70 years, over 50 per cent were offered immediate reconstruction. However, the proportion of women offered reconstruction differed markedly between Cancer Networks. Some offered reconstruction to over 80 per cent of mastectomy patients, while others offered it to less than 40 per cent (Figure 4.3). This variation between Networks was reduced only slightly when the rates were adjusted for patient characteristics and planned therapies.

Table 4.1:
Clinical reasons for not offering immediate reconstruction by Cancer Network

Cancer Network	Number to whom immediate reconstruction was not offered	Percentage to whom immediate reconstruction was not offered	Percentage of patients with particular reasons for not being offered reconstruction		
			Patient inappropriate for surgery	Adjuvant therapy issues	Reconstructive availability issues
Essex	79	25%	86%	32%	8%
North East London	105	30%	93%	20%	16%
Humber and Yorkshire Coast	100	33%	58%	48%	0%
South East London	123	33%	70%	34%	1%
Avon, Somerset and Wiltshire	175	34%	63%	45%	1%
Surrey, West Sussex and Hampshire	90	35%	80%	23%	0%
North Trent	230	36%	62%	27%	5%
South West London	129	37%	81%	33%	3%
Central South Coast	237	40%	83%	24%	1%
Anglia	385	43%	76%	32%	1%
West London	153	47%	79%	42%	0%
Sussex	178	48%	67%	39%	0%
Mid Trent	270	50%	76%	35%	36%
North London	133	51%	48%	65%	0%
Lancashire and South Cumbria	198	52%	80%	15%	5%
Dorset	113	52%	72%	43%	4%
Greater Manchester and Cheshire	486	52%	66%	38%	13%
3 Counties	95	53%	62%	58%	1%
Yorkshire	442	57%	55%	30%	19%
Greater Midlands	229	58%	64%	23%	24%
Thames Valley	278	58%	79%	40%	5%
Kent and Medway	160	58%	67%	43%	0%
Mount Vernon	116	60%	59%	57%	1%
Merseyside and Cheshire	386	61%	56%	28%	23%
Derby / Burton	154	61%	78%	23%	4%
Pan Birmingham	309	64%	82%	32%	3%
North of England	700	65%	68%	42%	12%
Peninsula	347	68%	83%	44%	1%
Arden	249	74%	89%	25%	1%
Leicestershire, Northamptonshire and Rutland	283	76%	40%	44%	30%
Independent hospitals	328	35%	58%	50%	10%
Non-English NHS Trusts	223	55%	90%	22%	0%
Overall	**7,483**	**50%**	**70%**	**36%**	**9%**

Figure 4.2
Proportion of women who are offered immediate reconstruction and the proportion who have immediate reconstruction overall, by women's age

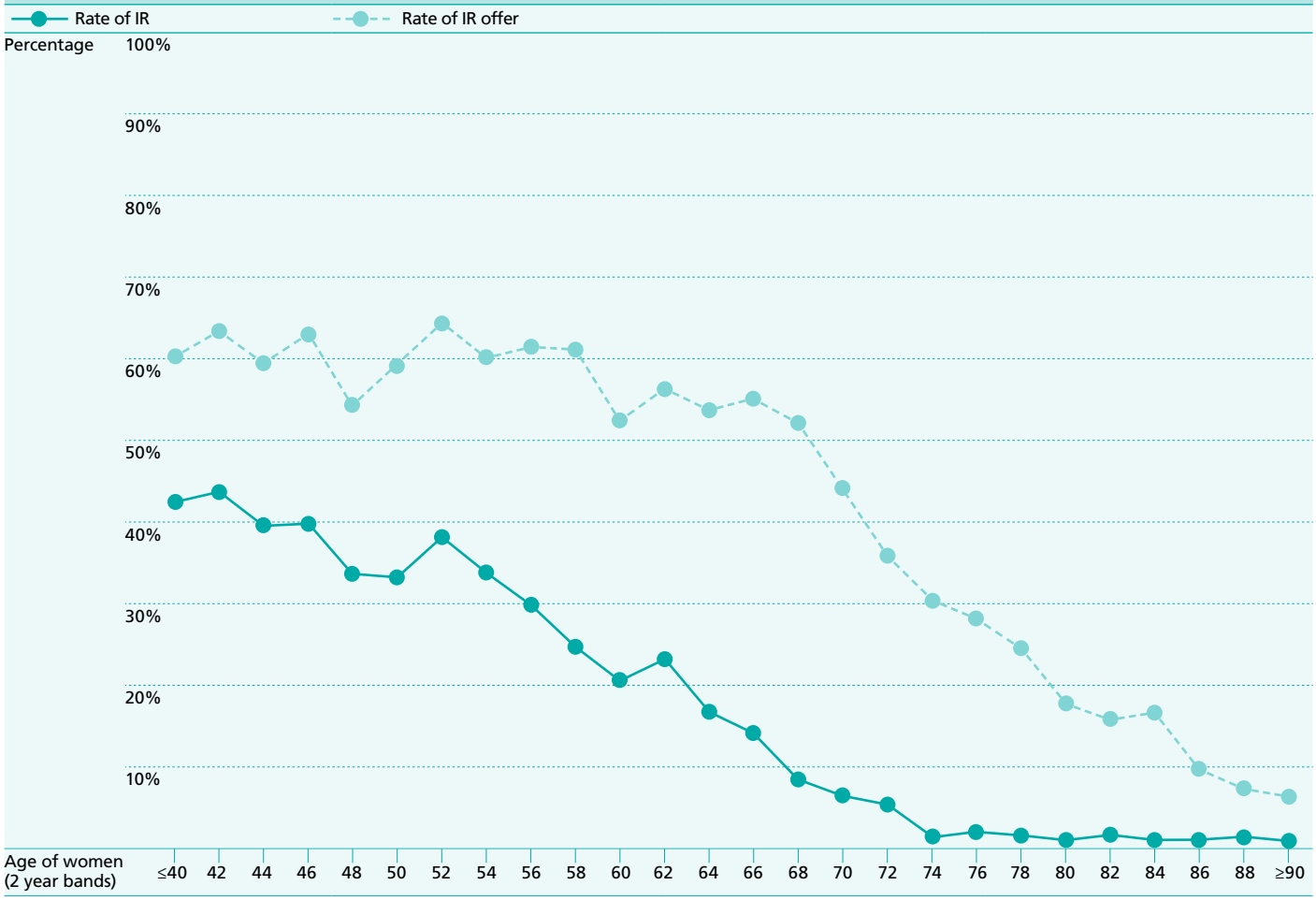
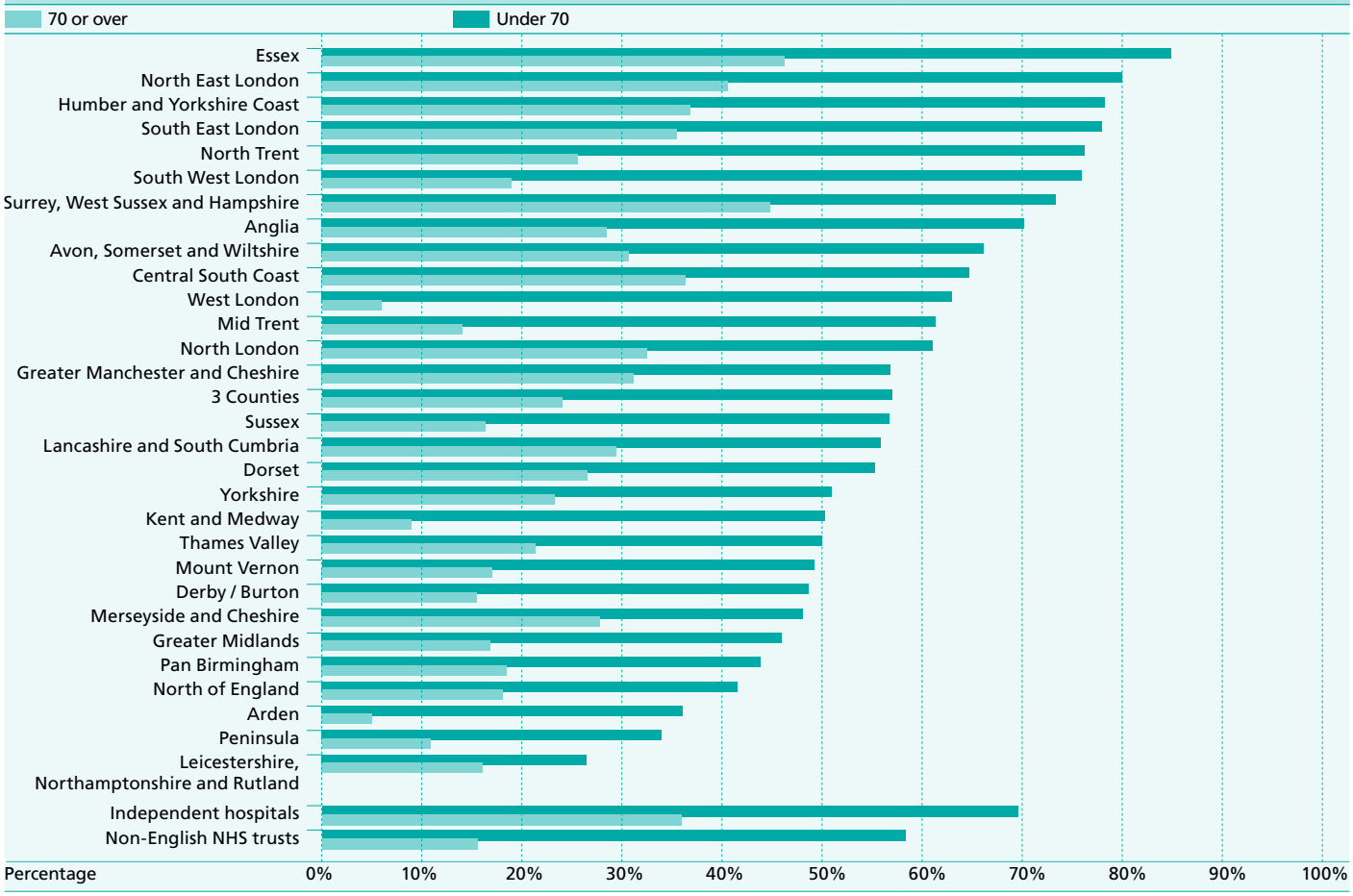


Figure 4.3
Proportion of women offered immediate reconstruction among English Cancer Networks, grouped by women's age (under 70 years, 70 years or over). Networks sorted by the proportion of women under 70 offered immediate reconstruction



5. Postoperative outcomes of surgery

A principal aim of the Audit is to describe the outcomes 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 and those who inform them about what to expect following these types of procedure.

In this chapter, we provide national information on length of inpatient stay and peri-operative complications. We further outline the strategy that we will follow for publishing outcomes at the level of individual providers.

5.1 Patterns of length of stay

The massive increase in throughput over the last decade has put all breast and plastic surgery units under increased pressure to deliver key services promptly. Actions targeted at reducing length of stay are one way in which this pressure may be alleviated. The First Annual Report of the Cancer Reform Strategy covered various principles for the improvement of inpatient cancer care and included an example of how reducing length of stay can be beneficial to patients (by lowering hospital-acquired infection rates and increasing patient satisfaction).[9]

During the Audit, information was collected on length of stay for all mastectomy and reconstruction patients. Length of stay varied greatly across English NHS trusts and independent hospitals for mastectomy only cases. This was partly due to variation in the proportion of patients admitted as day-cases. Among the 140 English providers who performed more than 10 mastectomies (without reconstruction), 26 providers admitted more than 25 per cent of these patients as day-cases, while another 42 providers admitted less than 2 per cent. There were also differences in the durations of inpatient stay for non day-case patients. Among the same 140 English providers, the median length of stay for non day-case patients was 3 days or less for 49 providers, while 15 providers had a median length of stay of 6 or more days.

Reducing length of stay is unlikely to be appropriate for all patients, particularly those women undergoing free-flap breast reconstruction. However, the current degree of variation in length of stay suggests that there are opportunities to reduce it further.

5.2 National postoperative complication rates

Participating NHS trusts and independent hospitals were asked to record inpatient complications for women entered in the Audit. Table 5.1 provides the overall complication rates by type of surgery for all patients within the Audit.

The rates of significant complications are very low for all types of surgery, although (as would be expected) are higher for reconstruction.

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). The differences between the rates for immediate and delayed reconstruction (Table 5.2) were not statistically significant.

Although around 1 in 10 women returned to theatre following their first procedure, there was a low flap failure rate. The comparatively high rate of return is likely to reflect a low threshold for re-exploration aimed at preventing flap failure and long-term morbidity.

Table 5.1:
Overall inpatient postoperative complications for women undergoing surgery for breast cancer. Rates given with 95% confidence intervals.

Adverse outcome or complication requiring therapeutic intervention	Percentage of mastectomy only patients (n=12,146)	Percentage of immediate reconstruction patients (n=3,141)	Percentage of delayed reconstruction patients (n=1,560)
Death during admission	0.26 (0.18 – 0.37)	0.13 (0.03 – 0.33)	0.06 (0.001 – 0.36)
Emergency transfer to HDU or ITU	0.52 (0.40 – 0.66)	0.86 (0.57 – 1.25)	0.58 (0.26 – 1.09)
Return to theatre	1.81 (1.58 – 2.07)	4.56 (3.85 – 5.34)	5.64 (4.55 – 6.91)
Mastectomy site complications	10.36 (9.82 – 10.92)	8.18 (7.24 – 9.19)	4.78 (3.77 – 5.96)
Distant or systemic complications	0.85 (0.70 – 1.03)	3.16 (2.57 – 3.83)	3.01 (2.22 – 3.99)
Implant / expander specific complications (in women who had an implant)	N/A	3.32 (2.55 – 4.24)	2.51 (1.44 – 4.04)
Flap specific complications (in women who had a flap)	N/A	2.89 (2.19 – 3.72)	5.22 (4.08 – 6.57)
Flap donor site specific complications (in women who had a flap)	N/A	8.18 (7.00 – 9.48)	7.35 (5.98 – 8.91)

Table 5.2:
Reconstruction-specific postoperative inpatient complications for women having free flap breast reconstruction. Rates given with 95 per cent confidence intervals

Adverse outcome or complication requiring therapeutic intervention	Percentage of immediate reconstruction patients (n=451)	Percentage of delayed reconstruction patients (n=523)
Return to theatre	12.88 (9.85 – 16.43)	10.60 (8.08 – 13.57)
Partial flap failure	1.55 (0.63 – 3.17)	3.25 (1.90 – 5.15)
Total flap failure	2.88 (1.54 – 4.88)	1.15 (0.42 – 2.48)

5.3 Postoperative outcomes among NHS trusts and independent hospitals

When reporting comparative outcomes across NHS trusts and independent hospitals, our foremost priority is to ensure that the data is of high quality, validated, and adjusted for case-mix. Patients and health professionals must have confidence that published outcomes of care are unlikely to lead to erroneous judgements about the underlying quality of care.

The four annual reports of the Audit aim to provide regular and prompt feedback to clinicians, patients and those involved in commissioning and providing care for women with breast cancer. In this report, we had intended to describe case-mix adjusted inpatient complication rates at individual trusts and independent hospitals. To ensure that these rates were accurate, we had planned to compare the complication data reported by clinicians against that recorded within the HES database. This is important because, if a group of NHS trusts incompletely reported their complications, the remaining trusts with complete data would appear to have relatively high complication rates.

Unfortunately, contemporaneous HES data for the full audit period is not currently available. Consequently, to avoid compromising the rigour of our approach, identifiable provider-level outcomes will now be included in our Third Annual Report in February 2010.

In addition to allowing us to more extensively validate the Audit data against the HES database, this new approach has two key advantages. First, all participating trusts and independent hospitals will have time to check their complications data and, if necessary, improve its completeness. Second, we will provide a more complete picture of outcomes by linking the inpatient complications reported by clinicians to the post-discharge complications and adverse events reported by patients in the 3-month follow up questionnaires.

The Audit has adopted a protocol to ensure the reporting of reliable and accurate outcome information (see Appendix 4). To illustrate the importance of this, we now discuss issues related to the interpretation of postoperative complication rates in more detail.

Providers 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 reasons (1) to (5) are excluded. The validation of the Audit data will minimise the influence of data completeness and data item interpretation, while the inclusion of patients' morbidity and treatment history will allow for appropriate adjustment of outcomes due to differences in patient characteristics. However, two key issues arise in relation to the other reasons that influence how inpatient complication rates are interpreted.

First, hospitals were asked only to record those complications that required therapeutic intervention. However, in some areas, a high intervention rate may reflect closer monitoring or a lower threshold for preventive action rather than indicate poor practice. For example, by taking a patient back to theatre to re-explore a flap with which there are concerns, the surgeon may prevent its loss, resulting in better long-term outcomes.

Second, a number of hospitals treated very few patients. This is particularly common in the independent sector. The discriminatory power of statistical tests to determine whether a difference in complication rates is due to factors other than random variation is much reduced for such hospitals.

It is essential that these factors are taken into account in future analyses and reporting.

6. Patterns of treatment and reconstruction in England captured by routine datasets

6.1 Creation of a national linked HES-Registry dataset

In 2008, the National Cancer Intelligence Network (NCIN) coordinated work to link the Office for National Statistics (ONS) cancer registration database to the HES database. The ONS database records the date of each patient's cancer diagnosis and identifies the provision of surgery, chemotherapy, radiotherapy and hormone therapy. Cancer Registries aim to record all treatments provided within six months of diagnosis but the ONS database (which is a subset of the Registry data) does not include details of these interventions or when and where they were delivered.

A linked HES and ONS database would provide more complete routine information on patterns of care. The HES database would augment the ONS treatment information by providing details of the type, timing and location of surgery. It could further add information on patients' comorbidities and peri-operative complications. In this chapter, we examine the patterns of treatment for women with breast cancer that can be produced from this linked database. We were supported in this work by the West Midlands Cancer Intelligence Unit (WMCIU).

The linkage of the two national datasets was undertaken jointly by the Thames Cancer Registry and the Northern and Yorkshire Cancer Registry and Information Service (NYCRIS).

A subset of the linked dataset, restricted to women diagnosed with invasive and non-invasive breast tumours, was supplied to the Audit project team. The linked dataset covered women diagnosed between 1 January 1998 and 31 December 2004, the latest year available from ONS at the time of the linkage. The HES database contained episodes of care between 1 April 1997 and 30 June 2007. This allowed the Audit to determine patterns of surgery that included procedures at least 2.5 years after diagnosis.

6.2 Patterns of surgical treatment

Between 1 January 1998 and 31 December 2004, the ONS Registry dataset identified 241,271 women diagnosed with an invasive tumour (ICD10 C50) and 21,517 women with a non-invasive breast tumour (ICD10 D05). The number of women diagnosed increased in successive years (Table 6.1), and most had invasive tumours. However, perhaps due to the introduction of the NHS Breast Screening Programme, the proportion of non-invasive tumours increased from 7.1 per cent in 1998 to 9.2 per cent in 2004.

Table 6.1:
Number of women diagnosed with breast cancer between 1998 and 2004, grouped by tumour type

Year of diagnosis	Invasive tumours	(%)	Non-invasive tumours	(%)	Total
1998	32,332	92.9%	2,465	7.1%	34,797
1999	34,050	92.6%	2,738	7.4%	36,788
2000	33,384	91.9%	2,932	8.1%	36,316
2001	34,228	91.9%	3,019	8.1%	37,247
2002	34,322	91.4%	3,209	8.6%	37,531
2003	36,481	91.3%	3,470	8.7%	39,951
2004	36,474	90.8%	3,684	9.2%	40,158

Among the 262,788 women in the ONS dataset, information on inpatient treatments was found in HES for 198,463 (75.5 per cent) women. The proportion of women in the ONS database matched to the HES database was consistent between 1998 and 2004, although there were small differences between Cancer Registries.

The type of surgical procedure that women with breast cancer underwent is summarised in Table 6.2. As described in the Audit's First Annual Report, the number of breast cancer operations has been steadily increasing due to rising breast cancer incidence. The data also shows that women often have more than one surgical procedure for their cancer.

For women diagnosed in 2004 and treated primarily with breast conserving surgery, 12 per cent of those with invasive tumours and 17 per cent of those with non-invasive tumours went on to have a mastectomy.

However, while the linked HES-ONS dataset provides a large sample of women having both breast conserving and mastectomy procedures, it is not complete. A higher proportion of women would be expected to undergo surgical treatment, and the numbers identified are fewer than those found in the First Annual Report. The reasons for this are unclear but may reflect missed matches due to an incomplete or erroneous set of patient identifiers in either dataset.

6.3 Patterns of reconstruction after mastectomy

Although the linked HES-ONS dataset provided only a sample of patients undergoing mastectomy, it is possible to estimate the proportion of women who have particular types of care. This includes the proportion of women who have reconstructive surgery.

For women diagnosed between 1998 and 2004, the proportion of mastectomy patients who underwent immediate reconstruction was 7.5 per cent overall, but differed by tumour type. Among those with invasive tumours, 6.5 per cent underwent immediate reconstruction, compared to 22 per cent of those with non-invasive tumours. Women with non-invasive tumours were more likely to have immediate reconstruction across all age groups, although very few women aged 70 years or over underwent it (Table 6.3).Overall, 8.4 per cent of mastectomy patients underwent delayed reconstruction, with little difference in the proportions for those with invasive and non-invasive disease. Of women with invasive tumours, 8.2 per cent had delayed reconstruction within 2.5 years of mastectomy.

For women with non-invasive tumours, this proportion was 12 per cent. As with immediate reconstruction, women who underwent a delayed reconstruction were generally less than 70 years old.

Table 6.2:
Numbers of women diagnosed with breast cancer grouped by the type of surgical procedure recorded in HES. Women grouped by year of diagnosis and type of tumour.

Invasive tumours				
Year of diagnosis	Women having breast conserving surgery (BCS) as their first procedure	Women having mastectomy		
		As first procedure	After BCS	Total
1998	11,853	6,781	1,706	8,487
1999	12,647	7,534	1,622	9,156
2000	12,465	7,545	1,637	9,182
2001	12,562	7,993	1,619	9,612
2002	13,053	8,130	1,668	9,798
2003	14,217	8,608	1,595	10,203
2004	14,543	8,664	1,676	10,340

Non-invasive tumours				
Year of diagnosis	Women having breast conserving surgery (BCS) as their first procedure	Women having mastectomy		
		As first procedure	After BCS	Total
1998	1,076	425	245	670
1999	1,270	456	281	737
2000	1,308	492	257	749
2001	1,458	457	306	763
2002	1,573	589	295	884
2003	1,738	608	333	941
2004	1,908	612	323	935

6.4 Patterns of adjuvant therapy

A potential benefit of the linked HES-ONS dataset is that a more complete picture of the adjuvant therapies provided to women may be obtained. It could provide estimates of the proportion of women who received chemotherapy, radiotherapy, and hormone therapy in addition to surgery. Preliminary analysis of the data suggested that not all Cancer Registries were able to collect this information to the same degree. Consequently, the patterns of care described in this section are restricted to a subset of five Cancer Registries with relatively high levels of data completeness. We have also excluded hormone therapy for simplicity as it does not affect reconstructive decision making.

Table 6.4 describes the patterns of adjuvant therapy for women with invasive tumours who underwent mastectomy between 1998 and 2004. Adjuvant therapies were particularly common among women under 50, although radiotherapy was used to treat 40 per cent of women aged up to 80 years. Adjuvant chemotherapy and radiotherapy were little used among women with invasive tumours who had a mastectomy. The proportion of these women without either of these treatments was 90 per cent for women under 50 years and over 96 per cent for women of 50 years or more. This is consistent with current trends in clinical practice.

6.5 Potential of routine data in monitoring patterns of care

Creating a linked HES-ONS dataset is an important step towards using routine data to examine patterns of surgical care for women with breast cancer. The NHS must reduce the burden placed on staff collecting clinical data and greater use of routine data should facilitate this. However, the usefulness of the dataset is currently limited by two key aspects of the data.

First, it was possible to link approximately 75 per cent of the ONS records to HES and further work is needed to assess the degree to which the resulting dataset provides a representative sample of surgical practice. The estimates derived here are similar to those derived from HES-alone which suggests that it will be possible to undertake reliable analyses of the patterns of care. However, this potential source of bias will hopefully become less of an issue as the quality of the ONS and HES patient identifiers and the linkage algorithm improve.

Second, the adjuvant therapies recorded in the ONS dataset varied in their completeness. Although using a subset of the Registry data reduced the likelihood of under-estimation, it is possible that adjuvant treatments are used more widely than is reported here.

Table 6.3
Proportion of women who underwent immediate reconstruction, by type of tumour. Figures based on linked HES-Registry records of women diagnosed with breast cancer between 1998 and 2004

	Age of women at diagnosis (years)					
	Under 40	40 to 49	50 to 59	60 to 69	70 to 79	`80 plus
Number of women with invasive tumours who had mastectomy	3,244	8,833	12,942	12,344	13,247	5,259
Mastectomy only (%)	80	85	90	97	100	100
Mastectomy with immediate reconstruction (%)	20	15	10	3	0	0
Number of women with non invasive tumours who had mastectomy	214	536	1,441	914	447	128
Mastectomy only (%)	60	60	72	90	99	100
Mastectomy with immediate reconstruction (%)	40	40	28	10	1	0

Table 6.4
Proportion of women with invasive tumours who have adjuvant therapies with mastectomy. Figures based on women diagnosed between 1998 and 2004 in a subset of Cancer Registries

	Age of women at diagnosis (years)					
	Under 40	40 to 49	50 to 59	60 to 69	70 to 79	80 plus
Number of mastectomies	1,084	3,409	5,696	5,927	6,388	2,530
Surgery only (%)	21	26	40	51	61	75
Surgery with chemotherapy (%)	37	32	23	12	2	0
Surgery with radiotherapy (%)	7	9	13	25	34	24
Surgery with chemotherapy and radiotherapy (%)	36	34	24	13	3	0

7. Conclusion

This is the first national audit of mastectomy and breast reconstruction surgery to be conducted anywhere in the world. As such, it has the potential to provide benchmark measures of reconstructive access and outcomes for the substantial number of women with breast cancer who undergo mastectomy, either as a primary treatment or following initial breast conserving surgery.

In this report, we have described the characteristics of women who undergo mastectomy from both the screening and symptomatic diagnostic pathways in England. This information has not been previously available because other studies have enrolled either screening or symptomatic patients alone. This is important for understanding reconstruction because there appears to be distinct patterns of care for women with invasive and non-invasive disease.

The prospective audit has highlighted that, over the past few years, the proportion of women having immediate reconstruction has 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). Although comparison with a HES-based estimate suggests the Audit-based rate is a slight over-estimate, this expansion is a real achievement for breast cancer services.

Nonetheless, we have found 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. Moreover, offer rates were not strongly correlated with actual rates of reconstruction in the Cancer Networks.

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, there were noticeable differences in the time that elapsed from the decision to treat to first definitive treatment between women undergoing mastectomy with or without immediate reconstruction. Poorer levels of performance were found for immediate reconstruction across the Cancer Networks. This may indicate that current waiting time targets act as a barrier to the offer of immediate reconstruction because women require time to consider their options. It may also reflect variation in the resources and capacity of breast units in England.

The policy of having a maximum time of 31 days from the date of decision to treat to first definitive treatment may also be influencing the types of reconstruction procedure performed. The higher use of implant or expander reconstructions in the immediate setting suggests that a proportion of women are not able to access all appropriate reconstructive options within current waiting time targets. This raises questions about how easily patients may be referred from breast to plastic surgery units, especially if the latter are not available locally.

We have provided national rates of inpatient postoperative complications for mastectomy and breast reconstruction procedures. Rates of major complications for reconstruction are low and this information should be made available to women considering this option. In our Third and Fourth Annual Reports, we will describe the short term and long term outcomes for women undergoing mastectomy surgery with or without reconstruction. This will include both inpatient and outpatient complication rates, along with patient-reported levels of satisfaction and quality of life at 3 and 18 months after mastectomy surgery. Postoperative complication rates will also be reported for NHS trusts and independent hospitals. By so doing, we aim to provide women with information about the safety of different care options and provide both Cancer Networks and individual healthcare providers with information to improve their services.

Recommendations

1. Cancer Networks should act to reduce the variation in access to immediate reconstruction by ensuring it is offered to all women, unless precluded by comorbidity or adjuvant therapies.

2. Cancer Networks should improve local access by ensuring adequate service provision to meet the increasing demand. This is particularly important for the Networks who could not offer "a local or a timely reconstructive service" for a high proportion of women.

3. NHS trusts and independent hospitals should review the way in which the offer of reconstruction is communicated to ensure barriers to women accepting the offer are minimised.

4. Cancer Networks should ensure women are able to access all appropriate reconstructive options within current waiting time targets, even if not available locally. This will require all breast units to have rapid referral pathways to plastic surgery units in place if they are to meet the 2009 NICE recommendation.

5. Clinicians and patient support groups should use the Audit's findings to help inform women due to undergo mastectomy and reconstructive procedures. This is the first national prospectively collected source of information on reconstructive access, the relative risk of postoperative complications, and the outcomes attained by mastectomy with or without breast reconstruction surgery.

6. Clinicians should check their Audit data on inpatient surgical complications to ensure the reporting of robust, case-mix adjusted outcomes at the level of individual NHS trusts and independent hospitals. This will be included in the Third Annual Report.

Appendices

Appendix 1: Summary of findings from the First Annual Report

In the Audit's first year, a number of studies were undertaken to assess the provision of surgical services for women with breast cancer in England and Wales. The results were described in the First Annual Report, published in March 2008.

Three separate but related studies were undertaken into 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 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 1). The most important issue identified was inequitable access to immediate breast reconstruction.

Box 1

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. Womens' 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 multi-disciplinary team elsewhere. This may impair the quality and timeliness of reconstructive decision making for these patients.

Appendix 2: Sample clinical datasheets

National Mastectomy & Breast Reconstruction Audit Datasheet
Mastectomy +/- Immediate Reconstruction

Patient Registration data

Surname | **Forename**

NHS/Private Hospital Number | **Date of birth**

Postcode | **Ethnicity**

Patient-reported outcomes consent

Has this patient consented to being sent outcome questionnaires?

- ☐ Patient has consented to receive questionnaires
- ☐ Patient does not want to receive questionnaires
- ☐ Patient judged incapable of completing a written questionnaire in English
- ☐ Patient was capable but not asked whether they were happy to receive questionnaire

Reason patient was judged incapable of completing the questionnaires (if applicable):

- ☐ Poor eyesight
- ☐ Literacy or language comprehension problems
- ☐ Cognitive impairment

DO NOT SUBMIT DATA ELECRONICALLY UNTIL THS SECTION IS COMPLETED

Previous treatment data

Date of breast cancer diagnosis

Date of decision to treat (mastectomy)

Treatments for ipsilateral breast cancer prior to this admission (please select all that apply):

- ☐ None
- ☐ Axillary surgery (including Sentinel Node Bx)
- ☐ Chemotherapy
- ☐ Breast-conserving surgery
- ☐ Radiotherapy
- ☐ Hormone Therapy

Co-morbility data

Smoking status:

- ☐ Current smoker
- ☐ Ex-smoker
- ☐ Never smoked

Body mass index:

Weight/kg

Height/m

BMI (W/H^2)

Diabetes status:

- ☐ Not diabetic
- ☐ Type I diabetes
- ☐ Type II diabetes

ASA Grading (from pre-operative assessment):

- ☐ I – Normal healthy individual
- ☐ II – Mild systemic disease that does not limit activity
- ☐ III – Severe systemic disease that limits activity but is not incapacitating
- ☐ IV – Incapacitating systemic disease which is constantly life-threatening

Pre-operative performance status (ECOG/WHO):

- ☐ 0 - Fully active
- ☐ 1 - Light/office work
- ☐ 2 - Ambulatory / self care, up and about > 50% of the time
- ☐ 3 - Limited self care, confined to bed / chair > 50% waking hours
- ☐ 4 - Completely disabled, no self care and totally confined to bed / chair

Appendix 2: Sample clinical datasheets

National Mastectomy & Breast Reconstruction Audit Datasheet
Mastectomy +/- Immediate Reconstruction

Operative data

Date of admission for surgery

Date of mastectomy

Type of mastectomy (please select one option only):

- ☐ Simple mastectomy
- ☐ Subcutaneous or skin sparing mastectomy via circumareolar approach (nipple excised)
- ☐ Subcutaneous or envelope mastectomy via lateral or submammary approach (nipple spared)
- ☐ Total mastectomy with excision of any part of pectoralis muscle
- ☐ Total mastectomy with excision of both pectoral muscles + part of chest wall

Type of axillary surgery (please select one option only):

- ☐ None
- ☐ Sentinel node biopsy
- ☐ Axillary sampling
- ☐ Level 1 axillary clearance
- ☐ Level 2 axillary clearance
- ☐ Level 3 axillary clearance

Type of immediate *primary* reconstruction performed (please select all that apply):

- ☐ None
- ☐ Tissue expander
- ☐ Fixed volume implant
- ☐ Latissimus Dorsi flap
- ☐ TRAM pedicle flap
- ☐ TRAM free flap
- ☐ DIEP free flap
- ☐ SIEA free flap
- ☐ TDAP flap
- ☐ TMG/TUG free flap
- ☐ SGAP free flap
- ☐ IGAP free flap
- ☐ Nipple reconstruction

Type of contralateral symmetrisation surgery performed (please select all that apply):

- ☐ None
- ☐ Tissue expander
- ☐ Augmentation mammoplasty
- ☐ Reduction mammoplasty
- ☐ Mastopexy (skin reduction only)

Planned adjuvant treatments:

- ☐ Radiotherapy
- ☐ Chemotherapy
- ☐ Hormone therapy
- ☐ Specialist palliative care

Planned *secondary* reconstructive procedures:

- ☐ Tissue expansion of breast mound
- ☐ Exchange of expander for fixed volume implant
- ☐ Nipple reconstruction
- ☐ Areolar tattooing
- ☐ Symmetrisation procedure
- ☐ Exchange of implant/expander for autologous flap

Appendix 2: Sample clinical datasheets

National Mastectomy & Breast Reconstruction Audit Datasheet
Mastectomy +/- Immediate Reconstruction

Reconstructive decision-making data

PLEASE COMPLETE IF IMMEDIATE RECONSTRUCTION HAS NOT BEEN PERFORMED

Was immediate reconstruction offered to this patient? ☐ Yes ☐ No

If immediate reconstruction was not offered, why was this? (please select all that apply)

Patient appropriateness for surgery:

- ☐ Advanced stage of disease
- ☐ Concerns about local recurrence
- ☐ Age of patient
- ☐ Degree of co-morbidity (e.g. cardio-respiratory disease)
- ☐ Lifestyle factors (e.g. smoking)
- ☐ Cognitive impairment
- ☐ Mental health issues (e.g. psychiatric illness)

Treatment pathway issues:

- ☐ Patient has undergone recent neo-adjuvant chemotherapy
- ☐ Adjuvant radiotherapy to chest wall anticipated for this patient
- ☐ Reconstructive surgery would delay other anticipated adjuvant therapies

Service access issues:

- ☐ Immediate reconstruction not available locally
- ☐ Immediate reconstruction would significantly delay mastectomy surgery

Has delayed reconstruction been offered to this patient? ☐ Yes ☐ No

If yes, have they accepted the offer? ☐ Yes ☐ No

If delayed reconstruction has not been offered, why is this? (please select all that apply)

Patient appropriateness for surgery:

- ☐ Advanced stage of disease
- ☐ Concerns about local recurrence
- ☐ Age of patient
- ☐ Degree of co-morbidity (e.g. cardio-respiratory disease)
- ☐ Lifestyle factors (e.g. smoking)
- ☐ Cognitive impairment
- ☐ Mental health issues (e.g. psychiatric illness)

Service access issues:

- ☐ Delayed reconstruction not available locally

Appendix 2: Sample clinical datasheets

National Mastectomy & Breast Reconstruction Audit Datasheet
Mastectomy +/- Immediate Reconstruction

Reconstructive decision-making data

Date of discharge

Return to theatre during admission	☐ Yes	☐ No
Emergency transfer to HDU or ITU during admission	☐ Yes	☐ No
Death during admission	☐ Yes	☐ No

Inpatient complications (please select all that apply):

Complications requiring therapeutic intervention at:	Mastectomy site	Flap donor site (if applicable)
None	☐	☐
Wound infection requiring intravenous antibiotics	☐	☐
Wound infection requiring surgical debridement	☐	☐
Skin flap necrosis requiring surgical debridement	☐	☐
Wound dehiscence requiring re-closure	☐	☐
Haematoma or seroma requiring aspiration or drainage	☐	☐

Flap-related complications requiring therapeutic intervention:

- ☐ Not applicable
- ☐ None
- ☐ Impaired flap perfusion requiring re-exploration or revision of anastomosis
- ☐ Partial flap necrosis or failure requiring debridement
- ☐ Total flap necrosis or failure requiring removal

Implant/expander-related complications requiring therapeutic intervention:

- ☐ Not applicable
- ☐ None
- ☐ Displaced implant/expander requiring re-positioning
- ☐ Infected implant/expander requiring intravenous antibiotic therapy
- ☐ Infected implant/expander requiring removal
- ☐ Ruptured implant/expander requiring removal

Distant or systemic complications requiring therapeutic intervention:

- ☐ None
- ☐ Haemorrhage requiring blood transfusion
- ☐ Deep venous thrombosis (DVT) requiring formal anticoagulation
- ☐ Pulmonary embolism (PE) requiring formal anticoagulation
- ☐ Acute myocardial infarction (MI) requiring anticoagulation +/- thrombolysis

Appendix 2: Sample clinical datasheets

National Mastectomy & Breast Reconstruction Audit Datasheet
Mastectomy +/- Immediate Reconstruction

Pathology data (from post-operative histology report)

Tumour laterality: ☐ Right ☐ Left

Invasive status: ☐ Invasive ☐ DCIS (ductal carcinoma in situ)

Grade of DCIS or Invasive Carcinoma:

☐ 1 – low (DCIS) or well differentiated (invasive)

☐ 2 – intermediate (DCIS) or moderately differentiated (invasive)

☐ 3 – high (DCIS) or poorly differentiated (invasive)

Lymph node involvement: (/)

(number of positive axillary nodes / total number of axillary nodes in pathology specimen)

Invasive lesion size (mm): _____

Recorded Nottingham Prognostic Index Score (if invasive): _____

Appendix 2: Sample clinical datasheets

National Mastectomy & Breast Reconstruction Audit Datasheet
Mastectomy +/- Delayed Reconstruction

Patient Registration data

Surname _____ **Forename** _____

NHS/Private Hospital Number _____ **Date of birth** _____

Postcode _____ **Ethnicity** _____

Patient-reported outcomes consent

Has this patient consented to being sent outcome questionnaires?

☐ Patient has consented to receive questionnaires

☐ Patient does not want to receive questionnaires

☐ Patient judged incapable of completing a written questionnaire in English

☐ Patient was capable but not asked whether they were happy to receive questionnaire

Reason patient was judged incapable of completing the questionnaires (if applicable):

☐ Poor eyesight

☐ Literacy or language comprehension problems

☐ Cognitive impairment

DO NOT SUBMIT DATA ELECRONICALLY UNTIL THS SECTION IS COMPLETED

Previous treatment data

Date of breast cancer diagnosis _____

Date of original mastectomy _____

Treatments for ipsilateral breast cancer prior to this admission (please select all that apply):

☐ None

☐ Axillary surgery (including Sentinel Node Bx)

☐ Chemotherapy

☐ Breast-conserving surgery

☐ Radiotherapy

☐ Hormone Therapy

Co-morbility data

Smoking status:

☐ Current smoker

☐ Ex-smoker

☐ Never smoked

Body mass index:

Weight/kg _____

Height/m _____

BMI (W/H^2) _____

Diabetes status:

☐ Not diabetic

☐ Type I diabetes

☐ Type II diabetes

ASA Grading (from pre-operative assessment):

☐ I – Normal healthy individual

☐ II – Mild systemic disease that does not limit activity

☐ III – Severe systemic disease that limits activity but is not incapacitating

☐ IV – Incapacitating systemic disease which is constantly life-threatening

Pre-operative performance status (ECOG/WHO):

☐ 0 - Fully active

☐ 1 - Light/office work

☐ 2 - Ambulatory / self care, up and about > 50% of the time

☐ 3 - Limited self care, confined to bed / chair > 50% waking hours

☐ 4 - Completely disabled, no self care and totally confined to bed / chair

Appendix 2: Sample clinical datasheets

National Mastectomy & Breast Reconstruction Audit Datasheet
Mastectomy +/- Delayed Reconstruction

Pathology data (from post-operative histology report)

Tumour laterality: ☐ Right ☐ Left

Invasive status: ☐ Invasive ☐ DCIS (ductal carcinoma in situ)

Grade of DCIS or Invasive Carcinoma:

☐ 1 – low (DCIS) or well differentiated (invasive)

☐ 2 – intermediate (DCIS) or moderately differentiated (invasive)

☐ 3 – high (DCIS) or poorly differentiated (invasive)

Lymph node involvement: (/)

(number of positive axillary nodes / total number of axillary nodes in pathology specimen)

Invasive lesion size (mm): _____

Recorded Nottingham Prognostic Index Score (if invasive): _____

Delayed reconstruction data

Date of admission for surgery _____

Date of delayed reconstruction _____

Type of delayed *primary* reconstruction performed (please select all that apply):

☐ Tissue expander
☐ Fixed volume implant
☐ Latissimus Dorsi flap
☐ TRAM pedicle flap
☐ TRAM free flap
☐ DIEP free flap
☐ SIEA free flap
☐ TDAP flap
☐ TMG/TUG free flap
☐ SGAP free flap
☐ IGAP free flap
☐ Nipple reconstruction

Type of contralateral symmetrisation surgery performed (please select all that apply):

☐ None
☐ Tissue expander
☐ Augmentation mammoplasty
☐ Reduction mammoplasty
☐ Mastopexy (skin reduction only)

Planned *secondary* reconstructive procedures:

☐ Tissue expansion of breast mound
☐ Exchange of expander for fixed volume implant
☐ Nipple reconstruction
☐ Areolar tattooing
☐ Symmetrisation procedure
☐ Exchange of implant/expander for autologous flap

Appendix 2: Sample clinical datasheets

National Mastectomy & Breast Reconstruction Audit Datasheet
Mastectomy +/- Delayed Reconstruction

Reconstructive decision-making data

Was immediate reconstruction originally offered to this patient? ☐ Yes ☐ No

If immediate reconstruction was not offered, why was this? (please select all that apply)

Patient appropriateness for surgery:

- ☐ Advanced stage of disease
- ☐ Concerns about local recurrence
- ☐ Age of patient
- ☐ Degree of co-morbidity (e.g. cardio-respiratory disease)
- ☐ Lifestyle factors (e.g. smoking)
- ☐ Cognitive impairment
- ☐ Mental health issues (e.g. psychiatric illness)

Treatment pathway issues:

- ☐ Patient has undergone recent neo-adjuvant chemotherapy
- ☐ Adjuvant radiotherapy to chest wall anticipated for this patient
- ☐ Reconstructive surgery would delay other anticipated adjuvant therapies

Service access issues:

- ☐ Immediate reconstruction not available locally
- ☐ Immediate reconstruction would significantly delay mastectomy surgery

Appendix 2: Sample clinical datasheets

National Mastectomy & Breast Reconstruction Audit Datasheet
Mastectomy +/- Delayed Reconstruction

Peri-operative morbidity date

Date of discharge

Return to theatre during admission	☐ Yes	☐ No
Emergency transfer to HDU or ITU during admission	☐ Yes	☐ No
Death during admission	☐ Yes	☐ No

Inpatient complications (please select all that apply):

Complications requiring therapeutic intervention at:	Mastectomy site	Flap donor site (if applicable)
None	☐	☐
Wound infection requiring intravenous antibiotics	☐	☐
Wound infection requiring surgical debridement	☐	☐
Skin flap necrosis requiring surgical debridement	☐	☐
Wound dehiscence requiring re-closure	☐	☐
Haematoma or seroma requiring aspiration or drainage	☐	☐

Flap-related complications requiring therapeutic intervention:

- ☐ Not applicable
- ☐ None
- ☐ Impaired flap perfusion requiring re-exploration or revision of anastomosis
- ☐ Partial flap necrosis or failure requiring debridement
- ☐ Total flap necrosis or failure requiring removal

Implant/expander-related complications requiring therapeutic intervention:

- ☐ Not applicable
- ☐ None
- ☐ Displaced implant/expander requiring re-positioning
- ☐ Infected implant/expander requiring intravenous antibiotic therapy
- ☐ Infected implant/expander requiring removal
- ☐ Ruptured implant/expander requiring removal

Distant or systemic complications requiring therapeutic intervention:

- ☐ None
- ☐ Haemorrhage requiring blood transfusion
- ☐ Deep venous thrombosis (DVT) requiring formal anticoagulation
- ☐ Pulmonary embolism (PE) requiring formal anticoagulation
- ☐ Acute myocardial infarction (MI) requiring anticoagulation +/- thrombolysis

Appendix 3: NHS trust and independent hospital participation

English NHS trusts	Number of patients registered	Number of patients with operative data	Estimated case ascertainment (mastectomy with or without immediate reconstruction)
Aintree University Hospitals NHS Foundation trust	95	93	76 to 100%
Airedale NHS trust	81	81	76 to 100%
Ashford and St Peter's Hospitals NHS trust	46	38	26 to 50%
Barking, Havering and Redbridge Hospitals NHS trust	154	142	51 to 75%
Barnet and Chase Farm Hospitals NHS trust	86	85	51 to 75%
Barnsley Hospital NHS Foundation trust	61	58	76 to 100%
Barts and The London NHS trust	127	118	76 to 100%
Basildon and Thurrock University Hospitals NHS Foundation trust	26	26	51 to 75%
Basingstoke and North Hampshire NHS Foundation trust	49	43	51 to 75%
Bedford Hospital NHS trust	65	64	76 to 100%
Blackpool, Fylde and Wyre Hospitals NHS trust	131	131	76 to 100%
Bolton Hospitals NHS trust	185	184	76 to 100%
Bradford Teaching Hospitals NHS Foundation trust	113	113	51 to 75%
Brighton and Sussex University Hospitals NHS trust	118	118	76 to 100%
Bromley Hospitals NHS trust	114	75	76 to 100%
Buckinghamshire Hospitals NHS trust	100	99	51 to 75%
Burton Hospitals NHS trust	61	61	76 to 100%
Calderdale And Huddersfield NHS Foundation trust	140	114	51 to 75%
Cambridge University Hospitals NHS Foundation trust	184	184	76 to 100%
Chelsea and Westminster Healthcare NHS trust	3	3	76 to 100%
Chesterfield Royal Hospital NHS Foundation trust	175	173	76 to 100%
Christie Hospital NHS trust	48	48	76 to 100%
City Hospitals Sunderland NHS Foundation trust	69	9	0 to 25%
Countess of Chester Hospital NHS Foundation trust	119	114	76 to 100%
County Durham and Darlington NHS Foundation trust	193	193	76 to 100%
Dartford and Gravesham NHS trust	47	46	51 to 75%
Derby Hospitals NHS Foundation trust	256	256	76 to 100%
Doncaster and Bassetlaw Hospitals NHS Foundation trust	173	164	51 to 75%
Dorset County Hospitals NHS Foundation trust	64	63	76 to 100%
Dudley Group of Hospitals NHS trust	152	151	76 to 100%
Ealing Hospital NHS trust	8	8	26 to 50%
East and North Hertfordshire NHS trust	7	6	0 to 25%
East Cheshire NHS trust	134	125	76 to 100%
East Kent Hospitals NHS trust	65	64	26 to 50%
East Lancashire Hospitals NHS trust	37	35	0 to 25%
East Sussex Hospitals NHS trust	174	174	76 to 100%
Essex Rivers Healthcare NHS trust	54	42	26 to 50%
Frimley Park Hospital NHS Foundation trust	79	75	51 to 75%
Gateshead Health NHS Foundation trust	114	95	51 to 75%
George Eliot Hospital NHS trust	65	65	76 to 100%
Gloucestershire Hospitals NHS Foundation trust	19	19	0 to 25%
Guy's and St Thomas' NHS Foundation trust	222	207	51 to 75%
Harrogate and District NHS Foundation trust	32	26	26 to 50%
Heart of England NHS Foundation trust	201	167	51 to 75%
Heatherwood and Wexham Park Hospitals NHS trust	94	93	76 to 100%
Hereford Hospitals NHS trust	73	65	51 to 75%
Hinchingbrooke Health Care NHS trust	20	5	0 to 25%
Homerton University Hospital NHS Foundation trust	34	29	76 to 100%
Hull and East Yorkshire Hospitals NHS trust	249	243	76 to 100%
Imperial College Healthcare NHS trust	144	141	51 to 75%
Ipswich Hospital NHS trust	123	123	76 to 100%
Isle of Wight Healthcare NHS trust	105	102	76 to 100%
James Paget University Hospitals NHS Foundation trust	103	100	76 to 100%
Kent and Medway NHS trust	49	48	26 to 50%
Kettering General Hospital NHS trust	114	108	76 to 100%
King's College Hospital NHS Foundation trust	38	38	76 to 100%
Kingston Hospital NHS trust	30	30	26 to 50%
Lancashire Teaching Hospitals NHS Foundation trust	112	111	51 to 75%
Leeds Teaching Hospitals NHS trust	222	198	51 to 75%
Liverpool Women's NHS Foundation trust	47	47	76 to 100%
Luton and Dunstable Hospital NHS trust	10	7	0 to 25%

English NHS trusts cont.	Number of patients registered	Number of patients with operative data	Estimated case ascertainment (mastectomy with or without immediate reconstruction)
Maidstone and Tunbridge Wells NHS trust	99	99	76 to 100%
Mayday Healthcare NHS trust	96	76	76 to 100%
Mid Essex Hospital Services NHS trust	233	232	76 to 100%
Mid Staffordshire General Hospitals NHS trust	10	7	0 to 25%
Mid Yorkshire Hospitals NHS trust	223	223	76 to 100%
Milton Keynes General Hospital NHS trust	43	40	51 to 75%
Newham University Hospital NHS trust	26	26	26 to 50%
Norfolk and Norwich University Hospital NHS trust	292	292	76 to 100%
North Bristol NHS trust	182	181	76 to 100%
North Cheshire Hospitals NHS trust	74	73	51 to 75%
North Cumbria Acute Hospitals NHS trust	132	132	76 to 100%
North Middlesex University Hospital NHS trust	3	0	0 to 25%
North Tees And Hartlepool NHS Foundation trust	193	191	76 to 100%
North West London Hospitals NHS trust	62	29	26 to 50%
Northampton General Hospital NHS trust	48	16	0 to 25%
Northern Devon Healthcare NHS trust	47	45	76 to 100%
Northern Lincolnshire and Goole Hospitals NHS Foundation trust	29	26	0 to 25%
Northumbria Healthcare NHS Foundation trust	109	106	51 to 75%
Nottingham University Hospitals NHS trust	300	264	51 to 75%
Oxford Radcliffe Hospitals NHS trust	186	177	51 to 75%
Pennine Acute Hospitals NHS trust	184	182	51 to 75%
Peterborough and Stamford Hospitals NHS Foundation trust	59	59	26 to 50%
Plymouth Hospitals NHS trust	218	216	76 to 100%
Poole Hospital NHS Foundation trust	61	61	51 to 75%
Portsmouth Hospitals NHS trust	220	191	76 to 100%
Queen Elizabeth Hospital NHS trust	41	41	51 to 75%
Queen Mary's Sidcup NHS trust	46	44	76 to 100%
Queen Victoria Hospital NHS Foundation trust	121	119	76 to 100%
Royal Berkshire NHS Foundation trust	121	107	51 to 75%
Royal Bournemouth and Christchurch Hospitals NHS Foundation trust	102	100	76 to 100%
Royal Cornwall Hospitals NHS trust	174	171	76 to 100%
Royal Devon and Exeter NHS Foundation trust	131	123	51 to 75%
Royal Free Hampstead NHS trust	132	112	51 to 75%
Royal Liverpool and Broadgreen University Hospitals NHS trust	169	168	76 to 100%
Royal Surrey County Hospital NHS trust	80	80	76 to 100%
Royal United Hospital Bath NHS trust	131	131	76 to 100%
Royal West Sussex NHS trust	66	65	76 to 100%
Salford Royal Hospitals NHS Foundation trust	89	88	76 to 100%
Salisbury NHS Foundation trust	174	152	76 to 100%
Sandwell and West Birmingham Hospitals NHS trust	193	182	76 to 100%
Scarborough and North East Yorkshire Healthcare NHS trust	25	25	76 to 100%
Sheffield Teaching Hospitals NHS Foundation trust	211	211	76 to 100%
Sherwood Forest Hospitals NHS Foundation trust	128	126	76 to 100%
South Devon Healthcare NHS Foundation trust	103	103	76 to 100%
South Manchester University Hospitals NHS trust	123	123	26 to 50%
South Tees Hospitals NHS trust	189	188	76 to 100%
South Tyneside NHS Foundation trust	51	51	76 to 100%
South Warwickshire General Hospitals NHS trust	76	76	51 to 75%
Southampton University Hospitals NHS trust	95	95	51 to 75%
Southend Hospital NHS trust	95	95	76 to 100%
Southport and Ormskirk Hospital NHS trust	35	32	51 to 75%
St George's Healthcare NHS trust	83	69	51 to 75%
St Helens and Knowsley Hospitals NHS trust	117	116	51 to 75%
Stockport NHS Foundation trust	70	68	76 to 100%
Surrey and Sussex Healthcare NHS trust	87	87	76 to 100%
Swindon and Marlborough NHS trust	92	92	76 to 100%
Tameside Hospital NHS Foundation trust	51	50	51 to 75%
Taunton and Somerset NHS trust	119	113	76 to 100%
The Hillingdon Hospital NHS trust	61	61	76 to 100%
The Mid Cheshire Hospitals NHS trust	99	98	76 to 100%
The Newcastle Upon Tyne Hospitals NHS trust	315	313	76 to 100%
The Princess Alexandra Hospital NHS trust	106	106	76 to 100%
The Queen Elizabeth Hospital King's Lynn NHS trust	103	103	76 to 100%
The Rotherham NHS Foundation trust	81	81	76 to 100%
The Royal Marsden NHS Foundation trust	353	351	76 to 100%
The Royal Wolverhampton Hospitals NHS trust	96	96	76 to 100%
The Shrewsbury and Telford Hospital NHS trust	150	144	76 to 100%

English NHS trusts cont.	Number of patients registered	Number of patients with operative data	Estimated case ascertainment (mastectomy with or without immediate reconstruction)
The Whittington Hospital NHS trust	32	17	51 to 75%
United Bristol Healthcare NHS trust	88	86	76 to 100%
United Lincolnshire Hospitals NHS trust	188	188	51 to 75%
University College London Hospitals NHS Foundation trust	32	0	0 to 25%
University Hospital Birmingham NHS Foundation trust	82	73	51 to 75%
University Hospital of North Staffordshire NHS trust	56	56	26 to 50%
University Hospitals Coventry and Warwickshire NHS trust	142	142	76 to 100%
University Hospitals of Leicester NHS trust	297	284	76 to 100%
University Hospitals of Morecambe Bay NHS trust	131	130	26 to 50%
Walsall Hospitals NHS trust	96	96	51 to 75%
West Hertfordshire Hospitals NHS trust	116	116	76 to 100%
West Middlesex University Hospital NHS trust	36	36	76 to 100%
West Suffolk Hospitals NHS trust	87	87	76 to 100%
Weston Area Health NHS trust	57	57	76 to 100%
Whipps Cross University Hospital NHS trust	60	59	76 to 100%
Winchester and Eastleigh Healthcare NHS trust	85	84	76 to 100%
Wirral University Teaching Hospital NHS Foundation trust	88	77	51 to 75%
Worcestershire Acute Hospitals NHS trust	172	171	76 to 100%
Worthing and Southlands Hospitals NHS trust	118	118	76 to 100%
Wrightington, Wigan and Leigh NHS trust	205	112	51 to 75%
Yeovil District Hospital NHS Foundation trust	52	52	76 to 100%
York Hospitals NHS trust	166	164	76 to 100%

English independent hospitals	Number of patients registered	Number of patients with operative data	Estimated case ascertainment (mastectomy with or without immediate reconstruction and delayed reconstruction)
Aspen Healthcare Parkside Hospital	10	10	Not available
BMI Bath Clinic	22	20	76 to 100%
BMI Bishops Wood Hospital	2	0	0 to 25%
BMI Chatsworth Suite	2	1	0 to 25%
BMI Chelsfield Park Hospital	6	5	51 to 75%
BMI Fawkham Manor Hospital	4	4	76 to 100%
BMI Mount Alvernia Hospital	32	32	51 to 75%
BMI Sarum Road Hospital	13	13	51 to 75%
BMI The Alexandra Hospital	4	4	0 to 25%
BMI The Beaumont Hospital	8	8	51 to 75%
BMI The Cavell Hospital	8	7	76 to 100%
BMI The Chaucer Hospital	11	11	26 to 50%
BMI The Chiltern Hospital	24	24	51 to 75%
BMI The Droitwich Spa Hospital	7	6	26 to 50%
BMI The Esperance Hospital	13	12	51 to 75%
BMI The Foscote Hospital	1	1	0 to 25%
BMI The Hampshire Clinic	15	13	26 to 50%
BMI The Harbour Hospital	16	9	26 to 50%
BMI The Highfield Hospital	1	0	0 to 25%
BMI The Kings Oak Hospital	7	7	26 to 50%
BMI The Lincoln Hospital	1	1	76 to 100%
BMI The Manor Hospital	8	8	51 to 75%
BMI The Park Hospital	40	36	26 to 50%
BMI The Princess Margaret Hospital	32	30	76 to 100%
BMI The Priory Hospital	36	35	51 to 75%
BMI The Ridgeway Hospital	1	0	0 to 25%
BMI The Sandringham Hospital	4	4	26 to 50%
BMI The Saxon Clinic	13	13	26 to 50%
BMI The Shelburne Hospital	9	9	51 to 75%
BMI The Sloane Hospital	15	14	51 to 75%
BMI The Somerfield Hospital	25	22	26 to 50%
BMI The Winterbourne Hospital	1	0	0 to 25%
BMI Thornbury Hospital	11	1	0 to 25%
BMI Werndale Hospital	6	4	76 to 100%
BUPA Cromwell Hospital	23	23	Not available
HCA London Bridge Hospital	21	18	26 to 50%
HCA The Harley Street Clinic	15	10	0 to 25%
HCA The Lister Hospital	1	1	0 to 25%
HCA The Princess Grace Hospital	87	85	26 to 50%

English independent hospitals cont.	Number of patients registered	Number of patients with operative data	Estimated case ascertainment (mastectomy with or without immediate reconstruction and delayed reconstruction)
Hospital of St John & St Elizabeth	16	14	Not available
Nuffield Health Bournemouth Hospital	2	0	0 to 25%
Nuffield Health Brentwood Hospital	31	26	76 to 100%
Nuffield Health Brighton Hospital	13	13	51 to 75%
Nuffield Health Bristol Hospital	1	1	0 to 25%
Nuffield Health Cambridge Hospital	5	5	51 to 75%
Nuffield Health Cheltenham Hospital	14	13	51 to 75%
Nuffield Health Derby Hospital	7	7	26 to 50%
Nuffield Health Exeter Hospital	8	8	51 to 75%
Nuffield Health Hampshire Hospital	6	6	51 to 75%
Nuffield Health Hereford Hospital	4	4	51 to 75%
Nuffield Health Hull Hospital (now NHS)	7	7	0 to 25%
Nuffield Health Ipswich Hospital	9	9	51 to 75%
Nuffield Health Newcastle Hospital	10	9	26 to 50%
Nuffield Health North Staffordshire Hospital	3	3	0 to 25%
Nuffield Health Plymouth Hospital	6	6	26 to 50%
Nuffield Health Shrewsbury Hospital	2	2	26 to 50%
Nuffield Health Taunton Hospital	6	6	26 to 50%
Nuffield Health Tees Hospital	11	3	0 to 25%
Nuffield Health The Grosvenor Hospital Chester	7	6	26 to 50%
Nuffield Health Tunbridge Wells Hospital	12	12	76 to 100%
Nuffield Health Woking Hospital	7	5	26 to 50%
Nuffield Health Wolverhampton Hospital	3	0	0 to 25%
Nuffield Health York Hospital	9	9	26 to 50%
Ramsay Ashstead Hospital	1	0	0 to 25%
Ramsay Duchy Hospital	1	1	Not available
Ramsay Euxton Hall Hospital	9	8	26 to 50%
Ramsay Fitzwilliam Hospital	9	9	76 to 100%
Ramsay Mount Stuart Hospital	2	2	26 to 50%
Ramsay Oaks Hospital	1	0	0 to 25%
Ramsay Park Hill Hospital	3	3	51 to 75%
Ramsay Rivers Hospital	11	11	26 to 50%
Ramsay Rowley Hospital	1	1	0 to 25%
Ramsay Springfield Hospital	21	18	26 to 50%
Ramsay West Midlands Hospital	18	10	26 to 50%
Spire Alexandra Hospital	4	2	26 to 50%
Spire Cambridge Lea Hospital	17	17	51 to 75%
Spire Cheshire Hospital	9	9	76 to 100%
Spire Dunedin Hospital	22	21	76 to 100%
Spire Elland Hospital	10	9	76 to 100%
Spire Gatwick Park Hospital	22	18	76 to 100%
Spire Hartswood Hospital	7	7	76 to 100%
Spire Hospital Bristol	36	32	76 to 100%
Spire Hospital Bushey	18	9	76 to 100%
Spire Hospital Harpenden	2	1	0 to 25%
Spire Hospital Leeds	29	26	76 to 100%
Spire Hospital Little Aston	32	29	76 to 100%
Spire Hospital Norwich	25	22	76 to 100%
Spire Hospital Southampton	20	19	76 to 100%
Spire Hospital Tunbridge Wells	3	2	26 to 50%
Spire Hospital Washington	7	7	76 to 100%
Spire Hull and East Riding Hospital	2	0	0 to 25%
Spire Liverpool Hospital	3	2	0 to 25%
Spire Manchester Hospital	26	26	76 to 100%
Spire Methley Park Hospital	2	2	0 to 25%
Spire Murrayfield Hospital Wirral	13	12	76 to 100%
Spire Parkway Hospital	19	17	51 to 75%
Spire Regency Hospital	5	4	76 to 100%
Spire Roding Hospital	4	0	0 to 25%
Spire South Bank Hospital	5	5	Not available
Spire St Saviour's Hospital	8	7	76 to 100%
Spire Sussex Hospital	2	2	Not available
Spire Thames Valley Hospital	15	15	76 to 100%
Spire Wellesley Hospital	5	5	76 to 100%
The London Clinic	23	21	Not available
The New Victoria Hospital	4	3	Not available

Non-English NHS trusts and independent hospitals	Number of patients registered	Number of patients with operative data
Abertawe Bro Morgannwg University NHS trust	4	4
Gwent Healthcare NHS trust	116	116
North West Wales NHS trust	112	112
Cwm Taf NHS trust	18	18
Cardiff and Vale NHS trust	25	25
St Josephs Private Hospital Newport	13	13
NHS Grampian	143	143

Appendix 4: Proposed data quality and outlier management plan for the reporting of outcomes in the Third Annual Report

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: Organisational representatives

National Mastectomy and Breast Reconstruction Audit Project Board

Martin Old
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

Clinical Reference Group

Dick Rainsbury
Chair
Association of Breast Surgery at BASO

Chris Holcombe
Association of Breast Surgery at BASO

Emma Pennary
Breast Cancer Care

Elaine Sassoon
British Association of Plastic,
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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

Ian Monypenny
Cancer Services Co-ordinating Group, Wales

Glossary

95% 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% confidence interval will not include the value for the population 5% of the time. For example, if we took 100 random samples of women and measured their height, we would expect that the 95% 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 (e.g. chemotherapy, radiotherapy, hormone drug therapy) provided to improve the effectiveness of the primary treatment (e.g. 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 (e.g. 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.

BASO
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 (e.g. 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.

CEU
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.

Dehiscence
The separation of a surgical incision or rupture of a wound

Ductal carcinoma in situ (DCIS)
A non-invasive / pre-invasive type of breast tumour that is confined to the lactiferous ducts.

Free flap breast reconstruction
The breast mound (or shape) is reconstructed using the patient's own tissue (e.g. 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 rejoin 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.

HQIP
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.

ONS
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.

RCS
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.

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. 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. Early and locally advanced breast cancer: diagnosis and treatment. (Clinical guideline 80.) London: NICE, 2009. http://www.nice.org.uk/nicemedia/pdf/CG80NICEGuideline.pdf

4. Quan ML, McCready D. The evolution of lymph node assessment in breast cancer: an overview. J Surg Oncol. 2009; 99(4):194-8.

5. 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.

6. Early Breast Cancer Trialists' Collaborative Group (EBCTCG) (2005). Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. Lancet 365: 1687–1717

7. Sharma R, Hamilton A, Beith J. LHRH agonists for adjuvant therapy of early breast cancer in premenopausal women. Cochrane Database of Systematic Reviews 2008, Issue 4. Art. No.: CD004562.

8. A policy framework for commissioning cancer services : A report by the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales. London: The Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales, 1995. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/docum ents/digitalasset/dh_4014366.pdf

9. The NHS Cancer plan: a plan for investment, a plan for reform. London: Department of Health, 2000. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4014513.pdf

10. 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/webfiles/Services/NCASP/Cancer/new%20web%20documents%20(MBR)/New%20web%20documents/163447%20IC%20MBR%20Audit%20Final.pdf

11. Department of Health. The cancer reform strategy: maintaining momentum, building for the future - first annual report. London: Department of Health, 2008.

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