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# The National Mastectomy & Breast Reconstruction Audit Data Manual

## Final Version

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## Introduction

This document accompanies the prospective dataset for the National Mastectomy & Breast Reconstruction Audit. It supplements the dataset tables and has several important functions. First, it provides an overview of the in-patient clinical dataset for the user. Second, it describes the source and definition of each individual data item within this dataset. Third, it outlines the rationale behind the inclusion of each data item. Finally, it clarifies the definition of each individual option within the data items where not self-evident.

The dataset was produced by the Audit Project Team and was developed with extensive clinical input from representatives of the Association of Breast Surgery at the British Association of Surgical Oncology and the British Association of Plastic, Reconstructive and Aesthetic Surgeons. Advice and revisions were also incorporated from the Audit's Clinical Reference Group and other key stakeholders.

Reference was made to the National Cancer Dataset[1] (NCDS version 4.5) and the NHS Data Dictionary[2] wherever possible. Where a data item is analogous to one in these datasets, the value options have been kept as similar as possible to improve consistency and the ease of data collection. Where appropriate, references to equivalent data items have been included in this manual.

The manual is divided into eight chapters which correspond to the eight components of the dataset, namely:

- Patient registration data
- Previous treatment data
- Co-morbidity data
- Patient-reported outcomes consent data
- Operative and planned treatment data
- Reconstructive decision making data
- Morbidity data
- Tumour characteristics data

Each chapter contains a description of the purpose of that component of the dataset. Each data item is also defined, together with its purpose, available choices, and definition source. Detailed definitions for each of the values of a data item are also included where required to ensure clarity.

## How to use this manual

- The organisation of this manual corresponds with the order of sections and fields in the National Mastectomy & Breast Reconstruction Audit dataset.

- This manual only includes dataset items regarding the in-patient stay that require collection and entry by clinical or data collection teams at the local or regional level.

- It does not include items that will be collected centrally or through the patient-reported outcomes component of the Audit.

- Each section starts with a table listing
    - the names of data items
    - reference numbers and the source of the definition

- After the table, each data item is listed with its detailed format and specific guidance on its completion if relevant.

- Where a data item is in the National Cancer Dataset (NCDS), the NCDS reference is identified in the table at the start of the section and with each item description.

## Paper datasheets

- Two distinct paper datasheets that reflect the clinical dataset have been created to enable easy recording of data on the wards, in the outpatient clinic or within MDT meetings.

- One is for all patients undergoing mastectomy with or without immediate reconstruction, and the other is for delayed reconstruction patients.

- The items and arrangement are closely matched to the IT system to allow easy transcription of data at a suitable time.

## Mandatory items and CSV (comma separated variable) uploads

- All items within a particular section of the dataset are mandatory and must be completed when entering data directly into that section via the online server – incomplete sections will not be saved by the system.

- The only exception to this rule is in the case of partial uploads of data via CSV files, where incomplete sections uploaded will be automatically saved until completed manually.

- To facilitate direct data entry, users can upload data via CSV files as well as entering data directly into the web-based Audit IT system. Users should read this manual in conjunction with the relevant CSV specification document.

- Prior to submitting data via CSV upload, individuals should always confirm that they are using the correct hospital code with which to label this data. An up-to-date and complete list of these codes may be found at the National Administrative Codes Service web site at http://www.nhs.uk/nacs - full details are contained within the Appendix.

## Data collection and the patient pathway

For the purposes of this Audit, there are three clearly defined and differentiated treatment pathways that have been taken into consideration in designing and structuring the dataset. Patients may enter one of three distinct pathways:

- Mastectomy only
- Mastectomy with immediate breast reconstruction
- Delayed breast reconstruction (following a previous mastectomy)

The proportion of patients within each group will depend on the range of services provided, and will therefore vary significantly between hospitals.

As these groups undertake a dissimilar pathway, not all data items are relevant to all patients. The total numbers of data items that relate to particular types of mastectomy & breast reconstruction patients are outlined below:

| | |
|---|---|
| Mastectomy only | 44 items |
| Mastectomy with immediate reconstruction | 39 items |
| Delayed reconstruction | 38 items |

To simplify data collection, the dataset has been designed so that all data items are available at or shortly after four easily identifiable time points within the patient pathway, as indicated in the table below:

| Sections | Data description | Time point (items) |
|---|---|---|
| 1, 2, 3, 4 (and 8*) | Patient registration, previous treatment, co-morbidity and patient-reported outcomes consent data | At time of pre-admission or admission clerking and operative consent (17 or 23*) |
| 5 & 6 | Operative, planned treatment and reconstructive decision-making data | At time of operation (7 to 13) |
| 7 | Morbidity data | At time of discharge (8) |
| 8* | Tumour characteristics data | At time of pathology report, discharge summary or post-operative MDT (6 or 0*) |

*Collect with data items in Sections 1 to 4 if a delayed reconstruction case

## Section 1 – Patient registration data

This data should ideally be collected at the time of pre-admission or admission clerking and pre-operative consent.

It is required to create and save a patient record within the web-based IT system.

| Dataset Reference | Data item | Status | Source of definition | Unique Ref |
|---|---|---|---|---|
| **1.1** | NHS NUMBER | Mandatory unless 1.2 completed | NHS Data Dictionary | NCDS1.1 |
| **1.2** | PRIVATE HOSPITAL PATIENT IDENTIFIER | Mandatory if 1.1 not completed | New definition | MBR1.2 |
| **1.3** | PATIENT FAMILY OR SURNAME | Mandatory | NHS Data Dictionary | NCDS1.5 |
| **1.4** | PATIENT FORENAME OR GIVEN NAME | Mandatory | NHS Data Dictionary | NCDS 1.6 |
| **1.5** | POSTCODE OF PATIENT ADDRESS | Mandatory | NHS Data Dictionary | NCDS 1.8 |
| **1.6** | DATE OF BIRTH | Mandatory | NHS Data Dictionary | NCDS 1.10 |
| **1.7** | ETHNIC CATEGORY CODE | Mandatory | NHS Data Dictionary | NCDS 1.15 |

### 1.1: NHS Number

**NCDS 1.1**

Record the patient's unique 10 digit new format NHS number.

If the NHS number is not available for a patient it can be accessed via the NHS Tracing Service. Access to the NSTS is via the secure website at:

http://www.connectingforhealth.nhs.uk/nsts

This item is essential for two reasons. Firstly it is a unique identifier for all NHS patients. Secondly it will allow the Audit to match records from different data sources (for example the Office of National Statistics and the Hospital Episode Statistics)

### 1.2: Private Hospital Patient Identifier

**New definition**

Record the patient's local unique alphanumeric format hospital number.

This is only to be used for private sector patients for whom the NHS number is not available.

### 1.3: Patient Family or Surname

**NCDS 1.5**

Record the patient's surname at diagnosis.

This item will be used to ensure the person in the dataset is correctly identified.

In the event of the surname changing (e.g. through marriage), the surname used should be the surname at time of presentation. The definition of surname according to the NHS Data Dictionary is "That part of a person's name which is used to describe family, clan, tribal group, or marital association."

### 1.4: Patient Forename or Given Name

**NCDS 1.6**

Record the patient's forenames.

This item will be used to ensure the person in the dataset is correctly identified.

### 1.5: Postcode of Patient Address

**NCDS 1.8**

Record the postcode of the patient's address at diagnosis.

If the patient changes postcode, ensure that the postcode at the time of diagnosis is still available. If a Patient has no fixed abode this should be recorded with the appropriate code (ZZ99 3VZ). For overseas visitors the Postcode field must show the relevant country pseudo postcode commencing ZZ99 plus space followed by a numeric, then an alpha character, then a Z. For example, ZZ99 6CZ is the pseudo-postcode for India. Pseudo-Country postcodes can be found in the NHS Postcode Directory. A list of all pseudo postcodes and country names is also given in the Organisation Codes Service Handbook. This is available on the **NHSnet**.

This item enables analysis by locality / region of patients and analysis of outcomes by social deprivation quintile

### 1.6: Date of Birth

**NCDS 1.10**

Record the patient's date of birth, in date format DD/MM/YYYY

This item enables analysis by age at diagnosis

### 1.7: Ethnic Category Code

**NCDS 1.15**

Record the patient's ethnic category code.

The NHS Data Dictionary defines this as the ethnicity of a person, as specified by the person.

The national codes are defined as:

White
- A British
- B Irish
- C Any other White background

Mixed
- D White and Black Caribbean
- E White and Black African
- F White and Asian

G Any other mixed background

Asian or Asian British
H Indian
J Pakistani
K Bangladeshi
L Any other Asian background

Black or Black British
M Caribbean
N African
P Any other Black background

Other Ethnic Groups
R Chinese
S Any other ethnic group

Z Not stated

This item will allow the analysis of access to and outcomes following mastectomy and reconstruction with respect to self-identified ethnic category or group.

## Section 2 – Previous treatment data

This data should ideally be collected at the time of pre-admission or admission clerking and pre-operative consent.

| Dataset Reference | Data item | Status | Source of definition | NCDS / OPCS |
|---|---|---|---|---|
| **2.1** | DIAGNOSIS DATE (CANCER) | Mandatory | NCDS | NCDS 4.1 |
| **2.2** | DATE OF DECISION TO TREAT (SURGERY) | Mandatory for M and IR patients only | NCDS | NCDS 7.5 |
| **2.3** | TREATMENT MODALITIES USED TO TREAT IPSILATERAL BREAST CANCER BEFORE CURRENT SURGERY | Mandatory Select all that apply | New definition | MBR2.3 |
| **2.4** | DATE OF ORIGINAL MASTECTOMY | Mandatory for DR patients only | New definition | MBR2.4 |

### 2.1: Diagnosis date (Cancer)

**NCDS 4.1**

Record the date of diagnosis of the tumour.

The definition provided conforms to the international requirements specified by the European Network of Cancer Registries (ENCR). In order of declining priority:

1. Date of first histological or cytological confirmation of this malignancy (with the exception of histology or cytology at autopsy). This date should be, in the following order:

    a. date when the specimen was taken
    b. date of receipt by the pathologist
    c. date of the pathology report

2. Date of admission to hospital because of this malignancy.

3. When evaluated at an out-patient clinic only: date of first consultation at the out-patient clinic because of this malignancy.

4. Date of diagnosis, other than 1, 2 or 3.

5. Date of death, if no information is available other than the fact that the patient has died because of malignancy.

6. Date of death, if the malignancy is discovered at autopsy.

It is required with the date of birth to derive the age at diagnosis and is used in the analysis of incidence trends and in the calculation of treatment, outcome and survival rates.

## 2.2: Date of decision to treat (surgery)

**NCDS 7.5**

Record the date that it was decided that this patient should receive surgery, in date format DD/MM/YYYY.

This is the date that the consultation between the patient and the clinician took place and a treatment plan for surgery was agreed.

It is required to define the delay between referral/diagnosis by the specialist team and definitive surgical treatment.

## 2.3: Treatment modalities used to treat ipsilateral breast cancer before current surgery

**New definition**

Record any treatments that this patient has undergone specifically to treat ipsilateral (same sided) breast cancer, PRIOR to admission for their current surgical episode.

The options are:

00 – None
(no previous surgical treatment)

01 – Breast-conserving surgery
(any previous surgery removing part of the breast i.e. lumpectomy, wide local excision, segmentectomy, quadrantectomy, subtotal mastectomy)

02 – Axillary surgery
(any previous surgery to the axilla i.e. sentinel node biopsy, axillary sampling, axillary clearance to any level)

03 – Radiotherapy
(any therapeutic irradiation of the breast, axilla or chest wall)

04 – Chemotherapy
(any systemic chemotherapeutic drug regimen)

05 – Hormone therapy
(any previous hormone-based therapy)

This item will allow previous oncological treatments undergone by the patient to be taken into account in the analysis of access to and outcomes following mastectomy and reconstruction.

## 2.4: Date of original mastectomy

**New definition**

*For delayed breast reconstruction patients only*

Record the date that it was decided that this patient underwent their original mastectomy surgery, in date format DD/MM/YYYY.

This is the date that the patient underwent mastectomy surgery to treat their primary breast cancer, and therefore must be prior to their current admission for delayed reconstructive surgery.

It is required to define the delay between mastectomy surgery and subsequent delayed breast reconstruction surgery in this patient group.

## Section 3 – Co-morbidity data

This data should ideally be collected at the time of pre-admission or admission clerking and pre-operative consent.

| Dataset Reference | Data item | Status | Source of definition | NCDS / OPCS |
|---|---|---|---|---|
| **3.1** | SMOKING STATUS | Mandatory | NHS DD / reduced options | MBR3.1 |
| **3.2** | BODY MASS INDEX | Mandatory | NHS DD | MBR3.2 |
| **3.3** | DIABETES TYPE | Mandatory | NHS DD | MBR3.3 |
| **3.4** | AMERICAN SOCIETY OF ANAESTHESIOLOGISTS (ASA) GRADING | Mandatory | ASA | MBR3.4 |
| **3.5** | PERFORMANCE STATUS (ADULT) RATED BEFORE SURGERY | Mandatory | NCDS | NCDS 5.10 |

### 3.1: Smoking status

**NHS DD**

Record the smoking status of the patient at the time of surgery:

1 – current smoker (still smoking at time of surgery)

2 – ex-smoker (previously a smoker, but not smoking at time of surgery)

4 – never smoked (not a smoker at time of surgery or at any point previously)

NHS DD options 3 (non-smoker - history unknown) and 9 (unknown) were removed for the purposes of this Audit, due to the importance of smoking history in our analysis.

This item will allow the patient's smoking habits to be taken into account in analysis of access to and outcomes following mastectomy and reconstruction.

### 3.2: Body mass index

**NHS DD**

Record the body mass index of the patient at the time of surgery, in numerical format to one decimal place.

This is calculated by dividing the patient's body weight in kilograms by the square of their height in metres.

i.e. BMI = (weight in kg) / (height in m)$^2$

This item will allow the patient's body habitus to be taken into account in the analysis of access to and outcomes following mastectomy and reconstruction.

A BMI calculator is included in the IT system.

### 3.3: Diabetes type

**NHS DD**

Record if the patient has diabetes mellitus, and if so of which subtype, by selecting one option:

00 – not diabetic
01 – type I diabetes
02 – type II diabetes

Option 00 was added for the purposes of this Audit, as the NHS data dictionary options (01 and 02) do not differentiate between an unrecorded item and a non-diabetic patient.

This item will allow the patient's diabetes status to be taken into account in the analysis of access to and outcomes following mastectomy and reconstruction.

### 3.4: American Society of Anaesthesiologists Grading[4]

**ASA**

Record the patient's ASA grade by selecting one option:

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

Grade V (a moribund patient who is not expected to survive without the operation) and grade VI (a declared brain-dead patient whose organs are being removed for donor purposes) were removed as they are not relevant to our patient population.

This pre-operative classification of physical status was defined by the ASA to help in the assessment of fitness for anaesthesia and surgery.

It is particularly important in analysing access to breast reconstruction, which is likely to require both additional and longer surgical procedures than mastectomy alone.

### 3.5: Performance Status (adult) rated before surgery[5]

**NCDS 5.10**

Record the patient's performance status by selecting one option:

0 - Able to carry out all normal activity without restriction
1 - Restricted in physically strenuous activity but able to walk and do light work
2 - Able to walk and capable of all self care but unable to carry out any work. Up and about more than 50% of waking hours
3 - Capable of only limited self care, confined to bed or chair more than 50% of waking hours
4 - Completely disabled. Cannot carry on any self care. Totally confined to bed or chair

These definitions come from the World Health Organisation (WHO) Handbook and were included in the NCDS (5.10) with option 5 (not recorded). Due to its importance, we have removed option 5 in our dataset, which means it is now back in its original WHO form.

This item will allow for performance status, an important prognostic indicator, to be taken into account in the analysis of outcomes following mastectomy and reconstruction.

## Section 4 – Patient-reported outcomes consent data

This data should ideally be collected at the time of pre-admission or admission clerking and pre-operative consent.

| Dataset Reference | Data item | Status | Source of definition | NCDS / OPCS |
|---|---|---|---|---|
| **4.1** | PATIENT REPORTED OUTCOMES CONSENT STATUS | Mandatory | New definition | MBR4.1 |
| **4.2** | REASON PATIENT WAS JUDGED INCAPABLE OF COMPLETING THE QUESTIONNAIRES | Mandatory | New definition | MBR4.2 |

### 4.1: Patient-reported outcomes consent status

**New definition**

Record whether the patient has given consent (using the Audit consent form) to participate in the patient-reported outcome component of the Audit.

01 – Patient has consented to receive questionnaires
02 – Patient does not wish to receive questionnaires
03 – Patient was judged incapable of completing the questionnaires
04–Patient was capable but not asked whether they were happy to receive questionnaires

This item will indicate whether the patient may be tracked using the NHS Strategic Tracing Service and be sent questionnaires to their home address at three and eighteen months after their surgery.

### 4.2: Reason patient was judged incapable of completing the questionnaires

New definition

Record the reason for the patient being judged incapable of completing the questionnaires. Only if 4.1 = 03

01 – Poor eyesight
02 – Literacy or language comprehension problems
03 – Cognitive impairment
04 – Other (please specify)

The patient-reported outcome questionnaires are designed to be completed by the patient themselves (rather than administered in person or by telephone) and are only available in English. They will be available for review online at the start of prospective data collection.

If the patient will not be able to complete the questionnaire due to problems with their eyesight, difficulties with written English or cognitive impairment, this should be indicated as the sole reason for not being consented.

This item will help to describe and explain reasons for incomplete recruitment into the patient-reported outcomes study.

## Section 5 – Operative and planned treatment data

This data should ideally be collected at or immediately after the operative procedure.

| Dataset Reference | Data item | Status | Source of definition | NCDS / OPCS Ref. |
|---|---|---|---|---|
| **5.1** | ADMISSION DATE (SURGERY EPISODE) | Mandatory | NCDS | NCDS 7.8 |
| **5.2** | PROCEDURE DATE | Mandatory | NCDS / None | NCDS 7.9 |
| **5.3** | DETAILS OF MASTECTOMY SURGERY PERFORMED FOR CANCER | Mandatory | New definition and OPCS | MBR5.3 |
| **5.4** | DETAILS OF AXILLARY SURGERY PERFORMED | Mandatory | New definitions and OPCS | MBR5.4 |
| **5.5** | PRIMARY RECONSTRUCTIVE SURGERY | Mandatory | New definitions and OPCS | MBR5.5 |
| **5.6** | CONTRALATERAL SYMMETRISATION SURGERY | Mandatory | New definitions and OPCS | MBR5.6 |
| **5.7** | PLANNED ADJUVANT TREATMENTS | Mandatory for M and IR patients only | New definitions | MBR5.7 |
| **5.8** | PLANNED SECONDARY RECONSTRUCTIVE PROCEDURES | Mandatory for IR and DR patients only | New definitions | MBR5.8 |

### 5.1: Admission date (surgery episode)

**NCDS 7.8**

Record the date of admission for the hospital stay during which this procedure took place, in date format DD/MM/YYYY.

This item will be used to measure length of in-patient stay for mastectomy or reconstructive surgery.

### 5.2: Procedure date

**NCDS 7.9**

Record the date the surgical procedure below started, in date format DD/MM/YYYY.

This item will be used to determine the time interval between diagnosis by the specialist team and start of surgical treatment.

### 5.3: Details of mastectomy surgery performed for cancer

**New definition**

Record the operative technique for the mastectomy performed to treat the patient's breast cancer. Select one option only.

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

Within the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures, 4th revision (OPCS-4.4), coded items (B27.x) for mastectomy are inadequate in fully describing the different options above; they have therefore been adapted to create an improved coding system for this purpose.

This item will be used to determine the type of mastectomy surgery performed and enable analysis of surgically related outcome data.

### 5.4: Details of axillary surgery performed

**New definition**

Record the operative technique for the axillary surgery performed to treat the patient's breast cancer. Select one option only.

00 – None
01 - Sentinel node biopsy
02 - Axillary sampling
03 - Level 1 axillary clearance
04 - Level 2 axillary clearance
05 - Level 3 axillary clearance

Level 1 = Lymph nodes lying lateral to the lateral border of the pectoralis muscle. Level 1 represents the tissue between the latissimus dorsi muscle and the lateral border of the pectoralis minor muscle.
Level 2 = Lymph nodes lying behind pectoralis minor muscle. Level 2 is the axillary tissue between and inferior to the lateral and medial borders of the pectoralis minor muscle.
Level 3 = Lymph nodes located medial to the medial border of the pectoralis muscle. Level 3 is the tissue between the medial border of the pectoralis minor and the apex of the axilla.

Within the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures, 4th revision (OPCS-4.4), coded items (T85-87, T91) for axillary surgery are inadequate in describing the different options above. This has already been noted in the creation of new modified codes for the National Cancer Dataset (which includes level of axillary clearance). They have therefore been adapted to create an improved coding system for this purpose.

This item will be used to determine the type of axillary surgery performed and enable analysis of surgically related outcome data.

## 5.5: Primary reconstructive surgery

**New definition**

Record the operative technique for the reconstructive surgery performed after a mastectomy to treat the patient's breast cancer. Select multiple options if required (e.g. LD flap + Fixed volume implant).

00 – None (mastectomy only)
The patient has not undergone reconstructive surgery

01 - Tissue expander
Insertion of skin expander into subcutaneous tissue of breast

02 – Fixed volume implant
Insertion of definitive prosthesis for the breast

03 - Latissimus Dorsi flap
Pedicled tissue transfer of latissimus dorsi muscle +/- skin, based on thoracodorsal vessels

04 - TRAM pedicle flap
Pedicled tissue transfer of rectus abdominus muscle + overlying tissue, based on superior epigastric vessels

05 - TRAM free flap
Free tissue transfer of part of the rectus abdominus muscle + overlying tissue, based on deep inferior epigastric vessels

06 - DIEP free flap
Free tissue transfer of abdominal tissue, sparing the rectus abdominus muscle and based on the deep inferior epigastric perforator (DIEP) vessels

07 - SIEA free flap
Free tissue transfer of abdominal tissue, sparing the rectus abdominus muscle and based on the superficial inferior epigastric artery (SIEA) vessels

08 - TDAP flap
Pedicled tissue transfer of tissue from the lateral chest wall, under the arm, sparing the muscle and based on the thoracodorsal artery perforator (TDAP) vessels

09 - TMG/TUG free flap
Free tissue transfer of the gracilis muscle along with overlying tissue from the upper inner thigh (transverse myocutaneous gracilis / transverse upper gracilis) and based on the ascending branch of the medial circumflex femoral artery.

10 - SGAP free flap
Free tissue transfer of tissue from the upper buttock (muscle-sparing) based on the superior gluteal artery perforator (SGAP) vessels

11 - IGAP free flap
Free tissue transfer of tissue from the lower buttock (muscle-sparing) based on the inferior gluteal artery perforator (SGAP) vessels

12 - Nipple reconstruction

Any method of reconstruction (nipple graft, local flap or other) to reconstruct a nipple on the side of the original mastectomy

Reconstructive surgical techniques may be sub-categorised into three groups:

1. Implant/expander based, where artificial (usually silicone or saline filled) implants are inserted under the pectoralis muscle to recreate the breast mound. Definitive implants are of fixed size; expanders may be increased in size after surgery using injections of saline.

2. Pedicled tissue transfer, where tissue is taken from another part of the body (abdomen or back) and moved to the breast area while preserving the blood vessels supplying it.

3. Free tissue transfer, where the tissue is removed from the donor site, along with the blood vessels supplying it, and then repositioned in the breast region. The supplying vessels are then attached (anastomosed) to blood vessels in the chest or armpit region using microvascular (operating under a microscope) suturing techniques to provide a blood supply at the new site.

Within the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures, 4th revision (OPCS-4.4), coded items (B29.x, B30.1, B38.x, B39.x and S48.2) for reconstruction are inadequate in fully describing and differentiating the different options above; they have therefore been adapted to create a new coding system for this purpose.

This item will be used to determine the type of reconstructive surgery performed and enable analysis of surgically related outcome data.

### 5.6: Contralateral symmetrisation surgery

**New definition**

Record the operative technique for any contralateral (to the other breast) surgery performed at the time of mastectomy or breast reconstruction to improve symmetry. Select one option only.

00 – None
01 – Tissue expander (Insertion of skin expander into subcutaneous tissue of breast)
02 – Augmentation mammoplasty (Insertion of fixed volume implant)
03 – Reduction mammoplasty (Breast reduction – any technique to reduce volume)
04 – Mastopexy (Skin reduction only to reshape the breast without altering volume)

Within the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures, 4th revision (OPCS-4.4), coded items (B30.1, B31.1-31.3 and S48.2) do describe the different options above. However, due to concerns about their accuracy in coding certain procedures (B30.1 and B31.1 in particular) they have been adapted to create a new clarified coding system for this purpose.

This item will be used to determine the type (if any) of symmetrisation surgery performed at the time of mastectomy or reconstructive surgery and enable analysis of surgically related outcome data.

### 5.7: Planned adjuvant treatments

**New definition**

Record any treatments that this patient is planned to undergo specifically to treat ipsilateral (same sided) breast cancer, AFTER admission for their current surgical episode. This refers to planned therapy before final histology data is available.

This item is only applicable to patients undergoing mastectomy with or without immediate reconstruction; it does not apply to delayed reconstruction patients. This refers to planned therapy before final histology data is available.

00 – None
(no planned adjuvant treatment)

01 – Radiotherapy
(any therapeutic irradiation of the breast, axilla or chest wall)

02 – Chemotherapy
(any systemic chemotherapeutic drug regimen)

03 – Hormone therapy
(any planned hormone-based therapy)

04 – Specialist palliative care
(formal referral to a Palliative Care Team for therapy)

This item will allow planned oncological treatments to be undergone by the patient to be taken into account in the analysis of access to mastectomy and reconstruction.

### 5.8: Planned secondary reconstructive procedures

**New definition**

Record any treatments that this patient is planned to undergo specifically to treat ipsilateral (same sided) breast cancer, AFTER admission for their current surgical episode. This refers to reconstructive procedures already planned at the time of surgery.

This item is only applicable to patients undergoing immediate or delayed breast reconstruction; it does not apply to mastectomy-only patients.

00 – None
(no planned secondary reconstructive procedures)

01 – Tissue expansion of breast mound
(expansion of a tissue expander inserted at the primary reconstructive procedure)

02 – Exchange of expander for definitive fixed volume implant
(exchange tissue expander inserted at the primary reconstruction for a fixed volume implant)

03 – Nipple reconstruction
(reconstruction of nipple on breast mound using any technique e.g. free nipple graft, local flap)

04 – Areolar tattooing
(tattooing of areolar region on breast mound to restore pigmentation and appearance)

05 – Symmetrisation procedure (e.g. contralateral reduction or augmentation)
(surgery to the other breast to improve appearance and symmetry)

06 – Exchange of implant/expander for autologous flap

This item will allow planned secondary reconstructive treatments to be undergone by the patient to be taken into account in the analysis of access to and outcomes following reconstruction.

## Section 6 – Reconstructive decision making data

| Dataset Reference | Data item | Status | Source of definition | NCDS / OPCS Ref. |
|---|---|---|---|---|
| **6.1** | WAS IMMEDIATE RECONSTRUCTION OFFERED TO THIS PATIENT? (M & DR GROUPS) | Mandatory for M only and DR patients | New definition | MBR6.1 |
| **6.2** | IF IMMEDIATE RECONSTRUCTION WAS NOT OFFERED, WHY WAS THIS? (M & DR GROUPS) | Mandatory for M only and DR patients | New definitions | MBR6.2 |
| **6.3** | HAS DELAYED RECONSTRUCTION BEEN OFFERED TO THIS PATIENT? (M GROUP ONLY) | Mandatory for M only patients | New definition | MBR6.3 |
| **6.4** | IF IT HAS BEEN, HAVE THEY ACCEPTED THE OFFER? (M GROUP ONLY) | Mandatory for M only patients for whom 6.3 = 01 | New definition | MBR6.4 |
| **6.5** | IF DELAYED RECONSTRUCTION HAS NOT BEEN OFFERED, WHY IS THIS? (M GROUP ONLY) | Mandatory for M only patients for whom 6.3 = 02 | New definitions | MBR6.5 |

### 6.1: Was immediate reconstruction offered to this patient?

**New definition**

Record whether or not this patient was offered immediate breast reconstruction at the time of their mastectomy surgery.

This item is only applicable to patients undergoing mastectomy-only or delayed breast reconstruction; it does not apply to immediate reconstruction patients.

01 – Yes (go to 6.3 if mastectomy-only patient)
02 – No (go to 6.2)

This item will allow the offer of immediate reconstruction to the patient to be taken into account in the analysis of access to reconstruction.

### 6.2: If immediate reconstruction was not offered, why was this?

**New definition**

Record why this patient was not offered immediate reconstruction at the time of their mastectomy surgery if this was the case (item 6.1 = 02 – No). Please select all options that apply.

This item is only applicable to patients undergoing mastectomy-only or delayed breast reconstruction; it does not apply to immediate reconstruction patients.

01 – Advanced stage of disease
02 – Concerns about local recurrence

03 – Age of patient
04 – Degree of co-morbidity
05 – Lifestyle factors (e.g. smoking)
06 – Cognitive impairment (unable to understand and consent to complex procedure)

07 – Mental health issues (significant acute or chronic psychiatric illness)

08 – Recent neo-adjuvant chemotherapy
09 – Anticipated adjuvant radiotherapy to chest wall
10 – Delay to anticipated adjuvant therapies

11 – Immediate reconstruction not available locally (at the site where mastectomy is provided)
12 – Immediate reconstruction would significantly delay mastectomy surgery

This item will allow the reasons for not offering immediate reconstruction to the patient to be taken into account in the analysis of access to reconstruction.

### 6.3: Has delayed reconstruction been offered to this patient?

**New definition**

Record whether or not this patient has been offered delayed breast reconstruction to be undertaken at some point in the future.

This item is only applicable to mastectomy-only patients.

01 – Yes (go to 6.4)
02 – No (go to 6.5)

This item will allow the offer of delayed reconstruction to the patient to be taken into account in the analysis of access to reconstruction.

### 6.4: If it has been, have they accepted the offer?

**New definition**

Record whether or not this patient has accepted the offer of delayed breast reconstruction.

This item is only applicable to mastectomy-only patients.

01 – Yes
02 – No

This item will allow the patient response to the offer of delayed reconstruction to be taken into account in the analysis of access to reconstruction.

### 6.6: If delayed reconstruction has not been offered, why is this?

**New definition**

Record why this patient has not been offered delayed breast reconstruction. Please select all options that apply.

This item is only applicable to mastectomy-only patients.

01 – Patient choice (patient previously stated that they were not interested in delayed reconstruction)

02 – Advanced stage of disease
03 – Concerns about local recurrence

04 – Age of patient

05 – Degree of co-morbidity
06 – Lifestyle factors (e.g. smoking)
07 – Cognitive impairment (unable to understand and consent to complex procedure)
08 – Mental health issues (significant acute or chronic psychiatric illness)

10 – Delayed reconstruction not available locally (at the site where mastectomy is provided)

This item will allow the reasons for not offering delayed reconstruction to the patient to be taken into account in the analysis of access to reconstruction.

## Section 7 – Morbidity data

| Dataset Reference | Data item | Status | Source of definition | Unique Ref. |
|---|---|---|---|---|
| **7.1** | DISCHARGE DATE (SURGERY EPISODE) | Mandatory | NCDS | NCDS 7.12 |
| **7.2** | DID THE PATIENT RETURN TO THEATRE DURING THE ADMISSION? | Mandatory | New definition | MBR7.2 |
| **7.3** | DID THE PATIENT REQUIRE EMERGENCY TRANSFER TO HDU OR ITU DURING THE ADMISSION? | Mandatory | New definition | MBR7.3 |
| **7.4** | DEATH DURING ADMISSION (DISCHARGE METHOD) | Mandatory | NHS DD<br><br>01 = DD Option 4 – Patient died<br><br>02 = DD Option 1,2 or 3 – Other discharge methods | MBR7.4 |
| **7.5** | COMPLICATIONS REQUIRING THERAPEUTIC INTERVENTION AT MASTECTOMY OR FLAP DONOR SITE (Please specify site) | Mandatory | New definitions | MBR7.5 |
| **7.6** | FLAP RELATED COMPLICATIONS (IF APPLICABLE) REQUIRING THERAPEUTIC INTERVENTION | Mandatory | New definitions | MBR7.6 |
| **7.7** | IMPLANT/EXPANDER RELATED COMPLICATIONS (IF APPLICABLE) REQUIRING THERAPEUTIC INTERVENTION | Mandatory | New definitions | MBR7.7 |
| **7.8** | DISTANT OR SYSTEMIC COMPLICATIONS REQUIRING THERAPEUTIC INTERVENTION | Mandatory | New definitions | MBR7.8 |

### 7.1: Discharge date (surgery episode)

**NCDS 7.12**

Record the date on which the patient was discharged, in date format DD/MM/YYYY

This item will help us to measure the length of in-patient stay.

### 7.2: Did the patient return to theatre during the admission?

**New definition**

Record whether the patient returned to theatre for further surgery during their admission.

01 – Yes
02 – No

This item will help in the analysis of clinical outcomes following mastectomy and reconstruction surgery.

### 7.3: Did the patient require emergency transfer to HDU or ITU during the admission?

**New definition**

Record whether or not the patient required emergency (not elective or planned) transfer to the High Dependency or Intensive Therapy Unit for monitoring or treatment during their admission.

01 – Yes
02 – No

This item will help in the analysis of clinical outcomes following mastectomy and reconstruction surgery.

### 7.4: Death during admission (discharge method)

**NHS DD**

Record whether or not the patient died during their admission for mastectomy or reconstruction surgery.

This has been mapped to Discharge Method within the NHS DD to improve ease of coding locally.

01 – Yes (mapped to 4 – patient died)
02 – No (mapped to 1, 2, 3 – other discharge methods)

This item will identify in-patient mortality from any cause, and will help in the analysis of clinical outcomes following mastectomy and reconstruction surgery.

### 7.5: Complications requiring therapeutic intervention at mastectomy or flap donor site (please specify site)

**New definition**

Record whether the patient experienced any complications at the mastectomy (all patients) or the flap donor (if applicable) sites requiring intervention and treatment while an in-patient. Please select all that apply.

00 – None

01 – Wound infection requiring intravenous antibiotics - mastectomy site
02 – Wound infection requiring surgical debridement - mastectomy site
03 – Skin flap necrosis requiring surgical debridement - mastectomy site
04 – Wound dehiscence requiring re-closure - mastectomy site
05 – Haematoma/seroma requiring aspiration or drainage - mastectomy site

06 – Wound infection requiring intravenous antibiotics - flap donor site
07 – Wound infection requiring surgical debridement - flap donor site
08 – Skin flap necrosis requiring surgical debridement - flap donor site
09 – Wound dehiscence requiring re-closure - flap donor site
10 – Haematoma/seroma requiring aspiration or drainage - flap donor site

This item will identify significant in-patient morbidity requiring treatment, and will help in the analysis of clinical outcomes following mastectomy and reconstruction surgery.

### 7.6: Flap related complications (if applicable) requiring therapeutic intervention

**New definition**

Record whether the patient experienced any complications related to the flap (if applicable) requiring intervention and treatment while an in-patient. Please select all that apply.

00 – None

01 - Impaired flap perfusion requiring re-exploration or revision of anastomosis
02 - Partial flap necrosis or failure requiring debridement
03 - Total flap necrosis or failure requiring removal

98 – Not applicable

This item will identify significant in-patient morbidity requiring treatment, and will help in the analysis of clinical outcomes following mastectomy and reconstruction surgery.

### 7.7: Implant / expander related complications (if applicable) requiring therapeutic intervention

**New definition**

Record whether the patient experienced any complications related to the tissue expander or definitive fixed volume implant (if applicable) requiring intervention and treatment while an in-patient. Please select all that apply.

00 – None

01 - Displaced implant /expander requiring re-positioning
02 - Infected implant /expander requiring intravenous antibiotic therapy
03 - Infected implant /expander requiring removal
04 - Ruptured implant /expander requiring removal

98 – Not applicable

This item will identify significant in-patient morbidity requiring treatment, and will help in the analysis of clinical outcomes following mastectomy and reconstruction surgery.

### 7.8: Distant or systemic complications requiring therapeutic intervention

**New definition**

Record whether the patient experienced any distant (away from operative site) or systemic complications requiring intervention and treatment while an in-patient. Please select all that apply.

00 – None

01 - Haemorrhage requiring blood transfusion
02 - Deep venous thrombosis (DVT) requiring formal anticoagulation
03 - Pulmonary embolism (PE) requiring formal anticoagulation
04 - Acute myocardial infarction (MI) requiring anticoagulation +/- thrombolysis

This item will identify significant in-patient morbidity requiring treatment, and will help in the analysis of clinical outcomes following mastectomy and reconstruction surgery.

## Section 8 – Tumour characteristics data

| Dataset Reference | Data item | Status | Source of definition | Unique Ref |
|---|---|---|---|---|
| **8.1** | TUMOUR LATERALITY | Mandatory | NCDS | NCDS 4.3 |
| **8.2** | INVASIVE STATUS (BASED ON HISTOPATHOLOGY) | Mandatory | New definition | MBR8.2 |
| **8.3** | INVASIVE LESION SIZE (BASED ON HISTOPATHOLOGY) | Mandatory if 8.2 = 01 | NCDS / NHS DD | NCDS 8.8 |
| **8.4** | GRADE OF DIFFERENTIATION (BASED ON HISTOPATHOLOGY) | Mandatory | NCDS (site-specific for breast cancer) - Nottingham modification of the Bloom Richardson system | NCDS 4.6 |
| **8.5** | LYMPH NODE INVOLVEMENT (BASED ON HISTOPATHOLOGY) | Mandatory if 8.2 = 01 | New definition | MBR8.5 |
| **8.6** | RECORDED NOTTINGHAM PROGNOSTIC INDEX SCORE (BASED ON HISTOPATHOLOGY) | Optional | Haybittle JL | MBR8.6 |

### 8.1: Tumour laterality

**NCDS 4.3**

Record the side on which the tumour is present.

**Bilateral tumours are excluded from the Audit.**

R – Right
L – Left

This will allow us to define the site of the pathology specimen.

### 8.2: Invasive status (based on histopathology)

**New definition**

Record whether the tumour is of an invasive histological type or represents ductal carcinoma in situ. These are the only two types of tumours to be included for the purposes of the Audit.

01 – Invasive
02 – DCIS (ductal carcinoma in situ)

This will allow us to differentiate the two groups and tell us whether the Nottingham Prognostic Index represents an appropriate and valid outcome indicator. It will also provide case-mix and risk adjustment data.

### 8.3: Invasive lesion size (based on histopathology)

**NCDS 8.8**

Record the size of the tumour in millimetres, as measured in the histopathology specimen.

Numeric entry in millimetres

This will help us to calculate the Nottingham Prognostic Index where appropriate and provide an independent prognostic indicator when investigating outcomes. It will also provide case-mix and risk adjustment data.

### 8.4: Grade of DCIS or invasive carcinoma (based on histopathology)

**NCDS 4.6/8.11**

Record the qualitative assessment of the grade of the tumour expressed as the extent to which a tumour represents the normal tissue at that site.

1 – low (DCIS) or well differentiated (invasive)
2 – intermediate (DCIS) or moderately differentiated (invasive)
3 – high (DCIS) or poorly differentiated (invasive)

For invasive carcinoma, this is defined by the Nottingham (Elston-Ellis[7]) modification of the Bloom-Richardson[6] grade.

This invasive grading scheme is based on three morphologic features: degree of tumour tubule formation, tumour mitotic activity and nuclear pleomorphism of tumour cells (nuclear grade)

Seven possible scores are condensed into three Bloom-Richardson grades based on these morphological features. See references for full details if required.

For DCIS, this is consistent with the pathological reporting standards set out in 'Pathology reporting of breast disease', published in January 2005 by the NHS Breast Screening Programme with input from the Royal College of Pathologists.

This will help us to calculate the Nottingham Prognostic Index where appropriate (invasive carcinoma) and provide an independent prognostic indicator when investigating outcomes. It will also provide case-mix and risk adjustment data.

### 8.5: Lymph node involvement (based on histopathology)

**New definition**

Record the number of involved axillary nodes (i.e. nodes with microscopic or macroscopic evidence of metastasis on histological examination) and the total number of axillary nodes removed (to provide a denominator).

XX / YY

Where XX = number of involved nodes (see above) within pathological specimen
YY = total number of nodes within pathological specimen

This will help us to calculate the Nottingham Prognostic Index where appropriate and provide an independent prognostic indicator when investigating outcomes. It will also provide important case-mix and risk adjustment data, and help to explain morbidity (e.g. lymphoedema).

### 8.6: Recorded Nottingham Prognostic Index Score (based on histopathology)

**New definition**

Record the calculated Nottingham Prognostic Index (NPI) Score if available.

NPI Score = (0.2 x Invasive Size) + Grade + Nodes

Invasive size is in centimetres (Item 8.3 x 0.1)

Grade is the modified Bloom & Richardson grade (Item 8.4)

Nodes = 1 for no positive nodes, 2 for 1, 2 or 3 positive nodes, or 3 for ≥ 4 positive nodes

This will provide an independent prognostic indicator when investigating outcomes. It will also provide case-mix and risk adjustment data.

## Appendix: How to obtain a list of hospital site codes (for CSV uploads)

The National Administrative Codes Service (NACS) is provided by NHS Connecting for Health. It is responsible for national policy and standards for organisation and practitioner codes, which form part of the NHS data standards. NHS Connecting for Health is also responsible for the day-to-day operation of the NACS and for its overall development.

The reference data covers not just healthcare organisations but also practitioners, post codes and other administrative details.

The NACS provides information via the NHSNet, via a quarterly release of data on CD-Rom and on the internet.

The NACS is supported by a number of agencies throughout the UK. Examples are the Prescription Pricing Agency (PPA) and the Dental Practice Board, who supply codes and data for GPs and dentists.

1. To download a file containing hospital site codes:

Access the National Administrative Codes Service web site: http://www.nhs.uk/nacs

Click ‘Data Downloads’

Click ‘Downloads Index’

Click ‘NHS Trust sites’

Click ‘etrust.zip’ link against ‘NHS Trusts and Trust sites’.

2. To obtain a particular NHS Trust, NHS Trust site or non-NHS Organisation Code:

Access the National Administrative Codes Service web site: http://www.nhs.uk/nacs

Use the Online enquiries, ‘Search using name, address or postcode’ link.

## References

World Wide Web links to key references are provided wherever possible.

### General:

1. National Cancer Dataset (NCDS) Version 4.5
http://www.ic.nhs.uk/our-services/standards-and-classifications/datasets/document-downloads/cancer

2. National Health Service Data Dictionary (NHS DD)
http://www.datadictionary.nhs.uk/web_site_content/navigation/main_menu.asp

3. Guidance on Cancer Services: Improving outcomes in breast cancer
National Institute for Clinical Excellence (NICE), 2002
http://www.nice.org.uk/csgbcguidance

### Item-specific:

#### Data item 3.4 – ASA Grading

4. American Society of Anaesthesiologists (ASA) Physical Status Classification System
http://www.asahq.org/clinical/physicalstatus.htm

#### Data item 3.5 – Performance Status (Adult) rated before surgery

5. ECOG / WHO Performance Status (Adult)
http://www.ecog.org/general/perf_stat.html

Eastern Co-operative Oncology Group (ECOG), Robert Comis MD, Group Chair
Oken, MM, Creech, RH, Tormey, DC, Horton, J, Davis, TE, McFadden, ET and Carbone, PP
Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group.
*Am J Clin Oncol* 5:649-655, 1982.

#### Data item 8.4 – Grade of differentiation

6. Bloom, HJ and Richardson WW
Histological grading and prognosis in breast cancer.
*Br. J. Cancer*, 11, 359-377, 1957

7. Elston, CW and Ellis IO
Pathological prognostic factors in breast cancer. I. The value of histological grade in breast cancer: experience from a large study with long-term follow-up.
*Histopathology*, 19, 403-10, 1991

#### Data item 8.6 – Nottingham Prognostic Index

8. Haybittle JL, Blamey RW, Elston CW, Johnson J, Doyle PJ, Campbell FC, Nicholson RI, Griffiths K.
A prognostic index in primary breast cancer.
*Br J Cancer*, 45(3), 361-6, 1982