Breast Cancer

Data Definitions for the National Minimum Core Data Set to support the introduction of Breast Quality Improvement Indicators

Definitions developed by ISD Scotland in Collaboration with the Breast Quality Improvement Indicator Development Group

Version 1.0: January 2012
# Breast Cancer – Data Definitions for Minimum Core Dataset for Quality Performance Indicators (QPIs)

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**Author** | Cancer Definitions Manager, ISD

## Revision History

<table>
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<th>Version</th>
<th>Date</th>
<th>Summary of Changes</th>
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**Approvals** This document requires the following approvals.

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<tr>
<td>Jean Harvey</td>
<td>Cancer Definitions Manager, ISD</td>
<td>05/04/2012</td>
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*Developed by ISD Scotland, 2012*
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PREFACE

Breast cancer services were among the earliest adopters of audit due to the rigorous quality assurance established for Breast Screening services. While some Breast Units have been collecting audit data since the mid 1990s, it has been widespread for the last decade.

The SIGN treatment guidelines were published in 1998 and recommended that a core dataset be established. This was provided by the former Scottish Cancer Therapy Network (SCTN) in 1999.

The strongest recommendations from the SIGN guidelines were used to form the basis for the first Clinical Standards Board (CSBS) standards which were produced in 2000. All Scottish breast units were visited by multidisciplinary peer teams in 2001 and a national report published in March 2002. At that time several units were identified that still did not have regular prospective audit in place.

Under the auspices of NHS Quality Improvement Scotland (QIS), the standards were updated and revised in 2007 (final version published in 2008). The cancer data set was developed by ISD in collaboration with the three cancer networks.

Following the publication of Better Cancer Care: An Action Plan in October 2008, the Scottish Government established the Scottish Cancer Taskforce to oversee its implementation, The NHS Scotland Healthcare Quality Strategy in 2010 expands on this by articulating quality ambitions. A quality measurement framework has been developed setting out measures and targets which will be used to monitor, challenge, manage and report progress. Part of this strategy is the development of national cancer quality performance indicators (QPIs) to drive quality improvement in cancer care throughout NHS Scotland.

As high quality data are required to enable comparisons over time and between regions, it is important that national data definitions are used to facilitate consistent data collection. National data definitions already in use have been used as much as possible to allow electronic data capture, thereby minimising duplication of data collection. Where national data definitions do not already exist, definitions used in other systems have been incorporated.

To ensure that findings are comparable across Scotland, the national dataset and data definitions in conjunction with the final quality performance indicators and the accompanying measurability document were agreed in public engagement and are now ready for implementation for patients diagnosed from 01/01/2012.

Mr Matthew Barber, Consultant Surgeon
Ms Alison Lannigan, Consultant Breast Surgeon
Dr Ruth Adamson, Consultant Pathologist
Dr Hilary Dobson, Clinical Director, WoS Breast Screening Service
Dr John Dewar, Consultant Clinical Oncologist

Breast Cancer QPI Development Group Subgroup Lead Clinicians

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NOTES FOR IMPLEMENTATION OF CHANGES

The following changes should be implemented for all patients who are diagnosed with breast cancer on or after 1st January 2012, who are eligible for inclusion in the breast cancer audit.

Changes to definitions fall into the following categories:

- to address problems with ongoing audit and standardise data definitions, where feasible, between different cancer sites
- to address problems with existing definitions
- to allow Quality Improvement Indicators to be measured and reported against

Enquires

For general or definitional queries regarding collection of the Minimum Core Data Set, please email NSS.ISDCANCERAUDIT@NHS.NET.

CONVENTIONS

The layout for each item is standard as shown below where it is applicable:

Common Name(s):
Main Source of Data Item Standard:
Definition:
Field Name:
Field Type:
Field Length:
Notes for Users:
Codes and Values:
Related Data Item(s):
Notes by Users:

In addition the following two conventions have been used in the document:

- {curly brackets} - definition relates to one specific named data set
- 'described elsewhere' - indicates there is a definition for the named item within this document
CRITERIA FOR INCLUSION OF PATIENTS IN AUDIT

To facilitate national comparisons the same patients must be audited throughout Scotland. The following eligibility criteria have been documented for this purpose.

Include

- all female and male patients with a confirmed new primary cancer of the breast with invasive or in situ disease (International Classification of Diseases, Tenth Revision [ICD 10] codes C50 and D05 - these codes include connective tissue of the breast but exclude skin). This includes patients with Paget's disease and patients who have had a previous primary malignancy of any site or a concurrent primary malignancy of another site.

- All patients who have received any part of their diagnosis / treatment within the NHS even if part of their treatment was carried out privately or outwith Scotland.

- All patients aged 16 years and over

Exclude

- patients where the origin of the primary is uncertain
- patients with recurrent disease (as opposed to a new primary tumour)
- patients with lymphoma of the breast
- patients with 'sarcoma' or 'phylloides'
- Death Certificate Only (DCO) cases
- All patients under 16 years of age
DOWNLOAD FORMAT
To assist with downloading data to ISD for the National Quality Assurance Programme and other agreed activities, all sites should be able to export data according to the following specification.

DATABASE SPECIFICATION

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Section 1: Demographic Items
Person Family Name (at Diagnosis)

Common Name(s): Surname, Family name

Main Source of Data Item Standard: Government Data Standards Catalogue

Definition:
That part of a person's name which is used to describe family, clan, tribal group, or marital association at the time of diagnosis.

Field Name: PATSNAME
Field Type: Characters
Field Length: 35

Notes for Users:
The surname of a person represents that part of the name of a person indicating the family group of which the person is part.

It should be noted that in Western culture this is normally the latter part of the name of a person. However, this is not necessarily true of all cultures. This will, of course, give rise to some problems in the representation of the name. This is resolved by including the data item Name Element Position in the structured name indicating the order of the name elements.

From SMR Definitions and Codes

Notes by Users:
Person Given Name

Common Name(s): Forename, Given Name, Personal Name

Main Source of Data Item Standard: Government Data Standards Catalogue

Definition:
The forename or given name of a person.

Field Name: PATFNAME
Field Type: Characters
Field Length: 35

Notes for Users:
The first forename of a person represents that part of the name of a person which after the surname is the principal identifier of a person.

Where the person's preferred forename is not the first forename, the related data item 'Preferred Forename' should be used to indicate this.

Notes by Users:
Patient Postcode at Diagnosis {Cancer}

Main Source of Data Item Standard: Government Data Standards Catalogue

Definition:
Postcode of patient's usual place of residence on the date of diagnosis

Field Name: PATPCODE
Field Type: Characters
Field Length: Maximum 8

Notes for Users:
Postcode is included in BS7666 Address (GDSC) but there is also a separate Post Code standard which will be populated from BS7666 Address Post Code.

This item can be derived from the date of diagnosis and patient address at that time

Related Data Item(s):
Date of Diagnosis
Date of Birth

Main Source of Data Item Standard: Government Data Standards Catalogue

Definition:
The date on which a person was born or is officially deemed to have been born, as recorded on the Birth Certificate.

Field Name: DOB
Field Type: Date
Field Length: 10

Notes for Users: Required for QPI(s): 10, 11

If the patient's date of birth is recorded differently on different occasions, the most frequently used or latest date should be recorded.

The patient's full date of birth inclusive of the century should be recorded. The format should be DD/MM/CCYY e.g. 01/02/2011.

Related Data Item(s):
CHI Number

Notes by Users:
**Person Sex at Birth**

**Common Name(s):** Sex at Birth

**Main Source of Data Item Standard:** Derived from the nearest equivalent Government Data Standards Catalogue standard ‘Person Gender at Registration’

**Definition:**
This is a factual statement, as far as is known, about the phenotypic (biological) sex of the person at birth

**Field Name:** SEX
**Field Type:** Integer
**Field Length:** 2

**Notes for Users:**
A person’s sex has clinical implications, both in terms of the individual’s health and the health care provided to them.

In the majority of cases, the phenotypic (biological) sex and genotypic sex are the same and the phenotypic sex is usually easily determined. In a small number of cases, accurate determination of genotype may be required

**Codes and Values:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Not specified/Indeterminate</td>
<td>Where it has not been possible to determine if the person is male or female at birth, e.g. intersex / hermaphrodite.</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

**Related Data Item(s):**
CHI Number

**Notes by Users:**
**CHI Number**

**Main Source of Data Item Standard:** Scottish Executive Health Department.

**Definition:**
The Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index.

**Field Name:** CHINUM  
**Field Type:** Integer  
**Field Length:** 10

**Notes for Users:**
The Community Health Index (CHI) is a computer based population index whose main function at present is to support primary care services. CHI contains details of all Scottish residents registered with a General Practitioner and was originally envisaged and implemented as a population-based index to help assess the success of immunisation and screening programmes. It is therefore closely integrated with systems for child health, cervical cytology and breast screening call and recall...It is intended that this number, the Scottish equivalent of the new NHS number in England and Wales, should become the Unique Patient Identifier throughout the NHS in Scotland.

From Designed to Care - Scottish Office

The CHI number is a unique numeric identifier, allocated to each patient on first registration with the system. The CHI number is a 10-character code consisting of the 6-digit date of birth (DDMMYY), two digits, a 9th digit which is always even for females and odd for males and an arithmetical check digit.

(ISD, Information Services, NHS National Services Scotland)

The CHI number should always be used to identify a patient. However, Health record identifiers, such as hospital numbers in Patient Administration Systems (PAS), may be used locally, in conjunction with the CHI number or in the absence of the CHI number, to track patients and their records.

Although there may be no number when a patient presents for treatment, there must be an allocation at some point in the episode of care as CHI is mandatory on all clinical communications.

Non-Scottish patients and other temporary residents can have a CHI number allocated if required but it is envisaged that future development may allow the identifying number used in other UK countries to be used in Scotland.

**Related Data Item(s):**
Date of Birth  
Person Sex at Birth

**Notes by Users:**

National Data Definitions for the Minimum Core Data Set for Breast Cancer.  
Developed by ISD Scotland, 2012  
Page 7
Hospital of Audit

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition: This will be the hospital of audit responsibility and will usually be the main hospital responsible for the patient's overall care.

Field Name: HOSPAUD
Field Type: Characters
Field Length: 5

Notes for Users: This is the main hospital for audit responsibility of the patient's pathway.
Regional arrangements of how this works locally apply.
Details of location codes for hospitals can be found in the "Definitions & Codes for the NHS in Scotland" manual produced by ISD Scotland.

Codes and Values: Location codes for hospitals are five character codes maintained by ISD Scotland and the General Register Office (Scotland). The first character denotes the health board, the next three are assigned and the fifth denotes the type of location (H=hospital) e.g.

A111H=Crosshouse Hospital
G107H=Glasgow Royal Infirmary
X1010=Inapplicable
X9999=Not recorded

Notes by Users:
Section 2: Presentation & Referral Details
Source of Cancer Referral

Main Source of Data Item Standard: The National Cancer Datasets developed by the Cancer Networks supported by ISD from SEHD guidance issued 13 April 2005.

Definition: This denotes the route by which the patient was referred to the breast cancer team for investigation and/or treatment of breast cancer.

Field Name: MREFER
Field Type: Integer
Field Length: 2

Notes for Users: Required for Survival QPI(s): 1, 2

A primary care clinician will usually be a general practitioner (GP) but may be any member of the primary care team e.g. practice nurse.

After attending for routine screening in a Screening Programme a patient may be referred for further investigation, 2 (screening service).

Some patients may be attending or referred to hospital for investigation or treatment of a condition unrelated to their cancer and a tumour is diagnosed (incidental finding), or may present at A&E before being referred on to the specialist team. These should be recorded as 14 (Secondary Care).

Patients may attend an outpatient cancer clinic as they are being followed up for benign disease or a previous cancer of the same site as diagnosed (4 review clinic) or because of a strong family history of cancer (15 Increased Risk Clinic).

13 (Other) includes following a domiciliary visit by a hospital clinician.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Specialty</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Primary Care Clinician (GP, Nurse practitioner)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Screening Service</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Secondary Care</td>
<td>Includes emergency admissions to A&amp;E</td>
</tr>
<tr>
<td>4</td>
<td>Review Clinic</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Increased Risk Clinic; Family History Clinic; Radiotherapy Exposure etc.</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Referral from private healthcare</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

Notes by Users:
Consultant in Charge

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This is the name of the consultant who is in overall charge of the of the patient’s care/management. This will normally be the breast surgeon but for patients with metastatic disease at diagnosis it may be an oncologist.

Field Name: CONS
Field Type: Characters
Field Length: 20

Notes for Users: Required to assist local analysis.

The surname and forename of the consultant should be recorded to distinguish between consultants with common surnames.
NB: On the database, the consultant’s name will be stored as a GMC number.

If the clinician’s name is not recorded code as 9999.

If the patient is managed by a team rather than with a consultant in overall charge, record as inapplicable, 1010.

If the patient is managed by a locum, record only that the clinician is a locum consultant, LOCUM.

Notes by Users:
Date of First Clinic

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The date on which a consultant clinician, (or one of his/her team), first sees a patient for investigation or management of breast cancer following referral from primary or secondary healthcare.

Field Name: FCLINDATE
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users: Required to continue with NHS QIS standards.

This does not refer to assessment clinics within the screening service as these are covered by NHS QIS Breast Screening standards.

Screening patients should be recorded as inapplicable (10/10/1010).

If the exact date is not documented, record as 09/09/0909.

Codes and Values: N/A

Notes by Users:
Section 3: Pre-treatment Investigations
Ultrasound Findings {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition: The findings from ultrasound examination of the axilla in a patient suspected of having breast cancer.

Field Name: ULTRA  
Field Type: Characters  
Field Length: 2  

Notes for Users: Required for QPI(s): 2  
An ultrasound scanner uses sound waves to scan an organ or area of the body. It does not use ionising radiation or a contrast agent.

The ultrasound score may be based on a combination of breast and axillary ultrasound. Where breast and axilla ultrasound are reported separately it is the axilla suspicion score which should be recorded.

A score of U3 or above would warrant FNA/core biopsy of the axilla, as detailed within explanatory notes below.

If there are multiple investigations or reports, record the one with the highest score.

In the case of bilateral disease, record the side with the worst prognosis.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>U1</td>
<td>Normal</td>
<td>No requirement for FNA/biopsy of axilla</td>
</tr>
<tr>
<td>U2</td>
<td>Benign</td>
<td>Normal - No requirement for FNA/biopsy of axilla</td>
</tr>
<tr>
<td>U3</td>
<td>Indeterminate</td>
<td>Abnormal – should go on to axillary FNA/biopsy</td>
</tr>
<tr>
<td>U4</td>
<td>Suspicious</td>
<td>Abnormal – should go on to axillary FNA/biopsy</td>
</tr>
<tr>
<td>U5</td>
<td>Malignant</td>
<td>Abnormal – should go on to axillary FNA/biopsy</td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td>Includes not performed</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td>Includes not recorded</td>
</tr>
</tbody>
</table>

Related Data Items:  
Ultrasound Examination of Axilla {Breast Cancer}  
Laterality {Cancer}  

Notes by Users:
Ultrasound Examination of Axilla (Pre-operative) {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
Indicates whether or not the axilla was examined by ultrasound.

Field Name: ULTRAXIL
Field Type: Integer
Field Length: 2

Notes for Users: Required for QPI(s): 2

An ultrasound scanner uses sound waves to scan an organ or area of the body. It does not use ionising radiation or a contrast agent.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td>Includes not recorded</td>
</tr>
</tbody>
</table>

Related Data Items:
Ultrasound Findings {Breast Cancer}
Laterality {Cancer}

Notes by Users:
Nodal Cytology of Axilla Results

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The appearance of the cells obtained by fine needle aspiration (FNA) or other cytological procedure.

Field Name: NODECYTOLOGY
Field Type: Integer
Field length: 2

Notes for Users: Required for QPI(s): 2

If more than one FNA or other cytological procedure is carried out on the lymph nodes record the most significant abnormality. If the procedure is repeated and the result is malignant, code as malignant.

In the case of bilateral disease, record the side with the worst prognosis.

NB: Screening patients should be included.

Codes and Values:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Non-diagnostic</td>
</tr>
<tr>
<td>2</td>
<td>Benign</td>
</tr>
<tr>
<td>3</td>
<td>Indeterminate</td>
</tr>
<tr>
<td>4</td>
<td>Suspicious</td>
</tr>
<tr>
<td>5</td>
<td>Malignant Breast</td>
</tr>
<tr>
<td>6</td>
<td>Malignant Other</td>
</tr>
<tr>
<td>7</td>
<td>Malignant Not known</td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
</tr>
</tbody>
</table>

Related Data Item(s):
Date Nodal Cytology of Axilla Performed

Notes by Users:
Date Nodal Cytology of Axilla Performed

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The date nodal cytology of the axilla was performed.

Field Name: NODEDATE
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users: Required for QPI(s): 2

This should be before date of surgery.

If no nodal cytology of the axilla is carried out, code as 10/10/1010 (inapplicable).
If the exact date is not documented, record as 09/09/0909.

Related Data Item(s):
Nodal Cytology of Axilla Results

Notes by Users:
Histological Opinion (Breast Core Biopsy)

**Main Source of Data Item Standard:** The Royal College of Pathologists, Pathology Reporting for Breast Disease, January 2005.

**Definition:**
The histological appearance as assessed by the pathologist in a breast core biopsy or vacuum assisted needle biopsy.

**Field Name:** NEEDBIO  
**Field Type:** Characters  
**Field length:** 3

**Notes for Users:** Required for QPI(s): 1  
Screening patients should be included.

**Codes and Values:**

<table>
<thead>
<tr>
<th>Codes</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1</td>
<td>Non-diagnostic</td>
<td></td>
</tr>
<tr>
<td>B2</td>
<td>Benign</td>
<td></td>
</tr>
<tr>
<td>B3</td>
<td>Atypia</td>
<td>Inc. LCIS</td>
</tr>
<tr>
<td>B4</td>
<td>Suspicious</td>
<td></td>
</tr>
<tr>
<td>B5a</td>
<td>Malignant In-situ</td>
<td></td>
</tr>
<tr>
<td>B5b</td>
<td>Malignant Invasive</td>
<td></td>
</tr>
<tr>
<td>B5</td>
<td>Malignant Not assessable</td>
<td>If not possible to clarify whether invasive or non-invasive on core biopsy.</td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

**Related Data Item(s):**
Date Breast Core Biopsy Performed

**Notes by Users:**
**Date Breast Core Biopsy Performed**

**Main Source of Data Item Standard:** The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

**Definition:**
The date the core biopsy of the breast was performed.

**Field Name:** NBIODATE  
**Field Type:** Date (DD/MM/CCYY).  
**Field Length:** 10

**Notes for Users:** Required for QPI(s): 1, 2

This should be before date of surgery.

If no breast core biopsy is carried out, code as 10/10/1010 (inapplicable). If the exact date is not documented, record as 09/09/0909.

**Codes and Values:** N/A

**Related Data Item(s):**  
Histological Opinion (Breast Core Biopsy)

**Notes by Users:**

*National Data Definitions for the Minimum Core Data Set for Breast Cancer.  
Developed by ISD Scotland, 2012*  
Page 19
**Histological Opinion (Nodal Core Biopsy)**

**Main Source of Data Item Standard:** The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

**Definition:**
The histological appearance as assessed by the pathologist in a nodal core biopsy or vacuum assisted needle biopsy of the axilla.

**Field Name:** NODEBIO  
**Field Type:** Integer  
**Field length:** 2

**Notes for Users:** Required for QPI(s): 1  
Screening patients should be included.

**Codes and Values:**

<table>
<thead>
<tr>
<th>Codes</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Non-diagnostic</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Benign</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Atypia</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Suspicious</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Malignant Breast</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Malignant Other, specify</td>
<td>e.g. Lymphoma</td>
</tr>
<tr>
<td>7</td>
<td>Malignant Not Known</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

**Related Data Items:**
Date Nodal Core Biopsy Performed.

**Notes by Users:**
Date Nodal Core Biopsy Performed

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The date the core biopsy of the axillary lymph nodes was performed.

Field Name: NODEBIODATE
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users: Required for QPI(s): 1, 2
This should be before date of surgery.
If no nodal core biopsy of the axilla is carried out, code as 10/10/1010 (inapplicable). If the exact date is not documented, record as 09/09/0909.

Related Data Item(s):
Histological Opinion (Nodal Core Biopsy)

Notes by Users:
TNM Tumour Classification (Pre-operative) {Breast Cancer}


Definition:
A record of the size and extent of the tumour of the breast as agreed at the multidisciplinary team (MDT) meeting according to TNM Classification (TNM Classification of Malignant Tumours, Seventh Edition, 2009).

Field Name: cT
Field Type: Characters
Field Length: 4

Notes for Users: "Required for QPI(s): 9 and Survival QPI(s) 1, 2

This is a pre/non-operative clinical/pathological classification as defined by the MDT based on best knowledge, including imaging, cytology or core biopsy.
NB: Pathological classification refers to biopsies only.

If stage is unable to be definitively determined from information in casenotes/clinical systems, do not deduce from other information and record as 'not recorded'.

In the case of multiple simultaneous tumours in a breast or bilateral tumours, the tumour with the highest T/N category should be used for classification.

Codes & Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0</td>
<td>No evidence of primary tumour</td>
</tr>
<tr>
<td>Tis</td>
<td>Carcinoma in situ (CIS)</td>
</tr>
<tr>
<td>TisA</td>
<td>Ductal Carcinoma in situ (DCIS)</td>
</tr>
<tr>
<td>TisB</td>
<td>Lobular Carcinoma in situ (LCIS)</td>
</tr>
<tr>
<td>TisC</td>
<td>Paget disease of the nipple not associated with invasive carcinoma and/or carcinoma in-situ (DCIS/ LCIS) in the underlying breast parenchyma. Carcinomas in the breast parenchyma associated with Paget disease are categorized based on the size and characteristics of the parenchymal disease, although the presence of Paget disease should still be noted.</td>
</tr>
<tr>
<td>T1</td>
<td>Tumour up to 2cm</td>
</tr>
<tr>
<td>T1mi</td>
<td>Microinvasion 0.1cm or less</td>
</tr>
<tr>
<td>T1a</td>
<td>Tumour &gt; 0.1cm but ≤ 0.5 cm</td>
</tr>
<tr>
<td>T1b</td>
<td>Tumour &gt; 0.5 cm but ≤ 1 cm</td>
</tr>
<tr>
<td>T1c</td>
<td>Tumour &gt; 1 cm but ≤ 2 cm.</td>
</tr>
<tr>
<td>T2</td>
<td>Tumour &gt;2 cm but ≤5 cm</td>
</tr>
<tr>
<td>T3</td>
<td>Tumour &gt;5 cm</td>
</tr>
<tr>
<td>T4</td>
<td>Tumour of any size with direct extension to chest wall and/or to skin (ulceration or skin nodules)</td>
</tr>
<tr>
<td>T4a</td>
<td>Extension to chest wall (does not include pectoralis muscle invasion only).</td>
</tr>
<tr>
<td>T4b</td>
<td>Ulceration, ipsilateral satellite skin nodules, or skin oedema (including peau d’orange).</td>
</tr>
<tr>
<td>T4c</td>
<td>Both 4a and 4b above</td>
</tr>
<tr>
<td>T4d</td>
<td>Inflammatory carcinoma</td>
</tr>
<tr>
<td>-----</td>
<td>------------------------</td>
</tr>
<tr>
<td>TX</td>
<td>Primary tumour cannot be assessed</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
</tr>
</tbody>
</table>

**Related Data Item(s):**
TNM Nodal Classification (Pre-operative) {Breast Cancer}
TNM Metastasis Classification (Pre-operative) {Breast Cancer}

**Notes by Users:**
TNM Nodal Classification (Pre-operative) {Breast Cancer}


Definition:  
The size and position of nodes in the axilla as agreed at the multidisciplinary team (MDT) meeting according to the official TNM Classification (TNM Classification of Malignant Tumours, Seventh Edition, 2009).

Field Name:  cN  
Field Type:  Characters  
Field Length:  3

Notes for Users:  Required for QPI(s): 9 and Survival QPI(s) 1, 2 

This is a pre/non-operative clinical/pathological classification as defined by the MDT based on best knowledge including imaging, cytology or core biopsy.  
NB: Pathological classification refers to biopsies only.

If stage is unable to be definitively determined from information in casenotes/clinical systems, do not deduce from other information and record as 'not recorded'.

In the case of multiple simultaneous tumours in a breast or bilateral tumours, the tumour with the highest T/N category should be used for classification.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>N0</td>
<td>No regional lymph nodes metastasis</td>
<td></td>
</tr>
<tr>
<td>N1</td>
<td>Metastasis to movable ipsilateral Level I, II axillary lymph node(s)</td>
<td></td>
</tr>
</tbody>
</table>
| N2   | Metastasis in ipsilateral Level I, II axillary lymph node(s) that are clinically fixed or matted; or in clinically detected* ipsilateral internal mammary lymph node(s) in the absence of clinically evident axillary lymph node metastasis. | Fixed nodal metastasis.  
* Detected by clinical examination or by imaging studies (excluding lymphoscintigraphy) and having characteristics highly suspicious for malignancy or a presumed pathological macrometastasis based on fine-needle aspiration biopsy with cytological examination. |
| N2a  | Metastasis in axillary lymph node(s) fixed to one another (matted) or to other structures. |  |
| N2b  | Metastasis only in clinically detected* internal mammary lymph node(s) and in the absence of clinically detected axillary lymph node metastasis. | * Detected by clinical examination or by imaging studies (excluding lymphoscintigraphy) and having characteristics highly suspicious for malignancy or a presumed pathological macrometastasis based on fine-needle aspiration biopsy with cytological examination. |
Metastasis in ipsilateral infraclavicular (Level III axillary) lymph node(s), with or without Level I, II axillary lymph node involvement, or in clinically detected* ipsilateral internal mammary lymph node(s) with clinically evident Level I, II axillary lymph node metastasis; or metastasis in ipsilateral supraclavicular lymph node(s), with or without axillary or internal mammary lymph node involvement.

Nodal metastasis above the clavicle.

* Detected by clinical examination or by imaging studies (excluding lymphoscintigraphy) and having characteristics highly suspicious for malignancy or a presumed pathological macrometastasis based on fine-needle aspiration biopsy with cytological examination.

<table>
<thead>
<tr>
<th>N3</th>
<th>Metastasis in infraclavicular lymph node(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N3a</td>
<td>Metastasis in infraclavicular lymph node(s)</td>
</tr>
<tr>
<td>N3b</td>
<td>Metastasis in internal mammary and axillary lymph node(s)</td>
</tr>
<tr>
<td>N3c</td>
<td>Metastasis in supraclavicular lymph node(s)</td>
</tr>
<tr>
<td>NX</td>
<td>Regional lymph nodes cannot be assessed (e.g. previously removed)</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
</tr>
</tbody>
</table>

**Related Data Item(s):**
- TNM Tumour Classification (Pre-operative) (Breast Cancer)
- TNM Metastasis Classification (Pre-operative) (Breast Cancer)

**Notes by Users:**
TNM Metastasis Classification (Pre-operative) {Breast Cancer}


Definition:
The extent of the spread of the disease outwith the breast and axilla as agreed at the multidisciplinary team (MDT) meeting according to the official TNM Classification (TNM Classification of Malignant Tumours, Seventh Edition, 2009).

Field Name: cM
Field Type: Characters
Field Length: 2

Notes for Users: Required for QPI(s): 5, 9 and Survival QPI(s) 1, 2

This is a pre/non-operative clinical/pathological classification as defined by the MDT based on best knowledge including imaging, cytology or core biopsy.

NB: Pathological classification refers to biopsies only.

If stage is unable to be definitively determined from information in casenotes/clinical systems, do not deduce from other information and record as 'not recorded'.

Includes patients discovered to have metastatic disease during the initial pathway or treatment normally within three months of diagnosis.

When there is no suspicion of metastasis record as M0.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>M0</td>
<td>No evidence of distant metastasis</td>
</tr>
<tr>
<td>M1</td>
<td>Distant metastasis present</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
</tr>
</tbody>
</table>

Related Data Item(s):
TNM Tumour Classification (Pre-operative) {Breast Cancer}
TNM Nodal Classification (Pre-operative) {Breast Cancer}

Notes by Users:
Date of Diagnosis {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The date of diagnosis is the date on which there was confirmation of the diagnosis of breast cancer whether by histology, cytology or clinical methods.

Field Name: DIAGDATE
Field Type: Date (DD/MM/CCYY)
Field Length: 10.

Notes for Users: Required for Survival QPI(s): 1, 2

The date recorded is the date the procedure was performed, not the date the report was issued.

If multiple histological or cytological findings have been carried out, the date of the first procedure that confirmed a positive diagnosis of breast cancer is taken.

If no histological or cytological procedures were undertaken, the date of diagnosis will be the date of any imaging procedure performed that confirmed a diagnosis of breast cancer; otherwise the date will be based on clinical findings and will be the first date upon which the clinician concludes a diagnosis of breast cancer.

If the exact date is not documented, record as 09/09/0909.

Notes by Users:
Most Valid Basis of Diagnosis {Cancer}


Definition:
The best evidence in support of the diagnosis of cancer.

Field Name: VALID
Field Type: Integer
Field Length: 2

Notes for Users: Required for Survival QPI(s): 1, 2
The conclusion of a diagnosis of cancer may be based on one or several procedures; clinical findings or as a report on the death certificate. Histological confirmation is considered as the most valid basis of diagnosis.

NB: With the emergence of molecular markers etc., there are plans to review the definition of this variable in the context of updating the IARC monograph, Cancer Registration Principles and Methods.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Clinical only</td>
<td>The diagnosis is based solely on clinical findings (history and/or physical examination). This is made before death but without the benefit of the following:</td>
</tr>
<tr>
<td>2</td>
<td>Clinical investigation</td>
<td>The diagnosis is supported by investigations such as x-ray, CT scan, ultrasound etc.</td>
</tr>
<tr>
<td>3</td>
<td>Exploratory surgery/endoscopy/autopsy (without concurrent or previous histology)</td>
<td>The tumour has been visualised or palpated but there is no confirmatory microscopic evidence</td>
</tr>
<tr>
<td>4</td>
<td>Tumour specific markers (biochemical/immunological tests)</td>
<td>The diagnosis is supported by specific tests</td>
</tr>
<tr>
<td>5</td>
<td>Cytology</td>
<td>The diagnosis is supported by cytology (the examination of cells whether from a primary or secondary site).</td>
</tr>
<tr>
<td>6</td>
<td>Histology of metastasis</td>
<td>The diagnosis is based on the histology of a metastasis (secondary deposit), e.g. resulting from a lymph node biopsy</td>
</tr>
<tr>
<td>7</td>
<td>Histology of primary</td>
<td>The diagnosis is based on the histology of the primary either resulting from a biopsy or from complete resection of the tumour.</td>
</tr>
<tr>
<td>8</td>
<td>Autopsy (with histology)</td>
<td>The diagnosis is based on the findings at autopsy supported by concurrent or previous histology.</td>
</tr>
<tr>
<td>10</td>
<td>Death Certificate only</td>
<td>The only information available to the registry is from a death certificate.</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

Notes by Users:
Laterality {Cancer}


Definition:
Side or laterality (i.e. left or right) of the body in which the tumour is located.

Field Name: SIDE
Field Type: Integer
Field Length: 2

Notes for Users:
Clinically relevant data item which can influence treatment decisions and prognosis. Required for sub-group analysis as incidence and survival may be associated with laterality.

If there are bilateral tumours at the time of initial diagnosis, the subsequent data items relate to the tumour with the with the worst prognosis e.g. highest tumour stage as classified according to the TNM Classification.

In case of unilateral axillary lymphadenopathy but no detectable primary, then laterality of the primary can be assumed to be the same side as that of the lymphadenopathy providing the pathology is consistent with a breast primary.

For patients who present with metastatic disease without identification of the breast primary, record as Not known.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Right</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Left</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Bilateral</td>
<td>At the time of the initial diagnosis</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td>Includes not recorded</td>
</tr>
</tbody>
</table>

Related Data Item(s):
Ultrasound Examination of Axilla Results {Breast Cancer}
Total Number of Lymph Nodes Involved {Cancer}

Notes by Users:
**Date Discussed by Care Team (MDT Pre-treatment)**

**Common name:** Date discussed by multidisciplinary team (MDT) \{Cancer\}

**Main source of data standard:** The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

**Definition:**
This denotes the date the care team meeting was held to discuss the management of the patient's care.

**Field Name:** MDTDATE  
**Field Type:** Date (DD/MM/CCYY)  
**Field Length:** 10

**Notes for Users:** Required for QPI(s): 8

May be used for analysis of generic QPI relating to MDT meetings.

A cancer multidisciplinary care team may include surgeons, oncologists, radiologists, pathologists, nurses, speech language therapists, physiotherapists and others relevant to the treatment of a specific cancer. The team meets on a regular basis to discuss optimal patient management. Documentation of the discussion should be included in the case-note or other formal documentation.

The first MDT meeting date will be recorded.  
**NB:** Where screening patients have been discussed initially at a screening centre MDT meeting, then subsequently discussed at a hospital MDT meeting, record the latter.

If the patient has not been discussed by the MDT prior to treatment or only discussed after treatment, record as inapplicable (10/10/1010).

If the date of the MDT meeting is unknown record as (09/09/0909).

**Related Data Item(s):**  
Human Epidermal Growth Factor Receptor-2 (HER2) Status Available at Initial MDT \{Breast Cancer\}

**Notes by Users:**
Type of First Cancer Treatment

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This denotes the first specific treatment modality administered to a patient.

Field Name: FIRSTTREATMODE
Field Type: Integer.
Field Length: 2

Notes for Users: Required for Survival QPI(s): 1, 2

For any particular modality it is the first treatment and not specifically the definitive treatment i.e. this does not include purely diagnostic biopsies such as incisional biopsies, needle biopsies or core biopsies. Some biopsies, such as excisional biopsies may be included as these may have some therapeutic benefits i.e. the removal of the tumour.

Patients receiving peri-operative endocrine treatment (or placebo) as part of current trials or for logistical reasons should have their first treatment recorded as hormone therapy but are not subject to later exclusions based on neo-adjuvant treatment.

Record patients as having 'no active treatment' if a decision was taken not to give the patient treatment as part of their primary therapy (some patients that have 'no active treatment' may subsequently have treatment when symptoms develop but this is not primary therapy). No active treatment includes watchful waiting and supportive care but not palliative chemotherapy and/or radiotherapy.

Radiotherapy includes teletherapy (external beam radiotherapy) and brachytherapy.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Surgery</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Chemotherapy</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Hormone therapy</td>
<td>e.g. Letrozole</td>
</tr>
<tr>
<td>2</td>
<td>Radiotherapy</td>
<td>includes peri-operative endocrine treatment.</td>
</tr>
<tr>
<td>15</td>
<td>Biological therapy</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>No active treatment</td>
<td>e.g. Herceptin</td>
</tr>
<tr>
<td></td>
<td>(Supportive care)</td>
<td>e.g. Bisphosphonates</td>
</tr>
<tr>
<td>11</td>
<td>Other therapy</td>
<td></td>
</tr>
<tr>
<td>95</td>
<td>Patient refused all</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>therapies</td>
<td>May include terminal care patients.</td>
</tr>
<tr>
<td>14</td>
<td>Patient died before</td>
<td></td>
</tr>
<tr>
<td></td>
<td>treatment</td>
<td></td>
</tr>
</tbody>
</table>

Related Data Item(s):
Date of First Cancer Treatment

Notes by Users:
**Date of First Cancer Treatment**

**Main Source of Data Item Standard:** The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

**Definition:**
This denotes the date the type of first cancer treatment was given to the patient.

**Field Name:** FIRSTTREATDATE  
**Field Type:** Date (DD/MM/CCYY)  
**Field Length:** 10

**Notes for Users:** Required for QPI(s): 8 and Survival QPI(s) 1, 2  
This field should be recorded for all patients including those with 'no active treatment' (see below).  
If type of first cancer treatment is 'no active treatment', the date recorded should be the first date the decision was taken not to give the patient treatment as part of their primary therapy. The aim of this date is to distinguish between patients who have initially had no treatment but receive some therapy when symptoms develop.

If hormone therapy is the first treatment, it is not always clearly documented when hormone therapy starts. In the patient discharge or clinic letter the clinician may ask the GP to prescribe hormone therapy, in this case, record the date as two days from the day the discharge letter or clinic letter was typed.

The date recorded should be that of the first type of cancer treatment.

If the patient died before treatment or the patient refused treatment, record as 10/10/1010.

If the exact date is not documented, record as 09/09/0909.

**Related Data Item(s):**  
Type of First Cancer Treatment

**Notes by Users:**
Section 4: Surgery
Final Definitive (or Only) Surgery Performed to Breast {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This is the final (or only) operation performed on the patient for primary treatment of the breast cancer.

Field Name: SURGBRST
Field Type: Integer
Field Length: 2

Notes for Users: Required for QPI(s): 3, 4, 5, 9

If the definitive diagnosis is made clinically or by imaging techniques only (i.e. no surgery is undertaken), code as 96 (Not applicable).

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Localising or excision biopsy</td>
<td>Removal of the tumour at biopsy without requirement for further surgery.</td>
</tr>
<tr>
<td>12</td>
<td>Conservation surgery</td>
<td>Removal of tumour with surrounding normal tissue without the removal of the whole breast. Wide local excision and re-excision are included in this category as are segmentectomy and quadrantectomy.</td>
</tr>
<tr>
<td>4</td>
<td>Mastectomy</td>
<td>Removal of the breast.</td>
</tr>
<tr>
<td>7</td>
<td>Mastectomy + Immediate Reconstruction Axillary surgery alone</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Axillary surgery alone</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>95</td>
<td>Patient refused treatment</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

Related Data Item(s):
Date of Final Definitive (or Only) Surgery Performed to Breast or Axilla {Breast Cancer}

Notes by Users:
Date of First Definitive Breast Surgery {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This is the date of the first operative procedure to the breast.

Field Name: BSURGDATE
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users: Required for QPI(s): 2, 3, 4

This is the first operative procedure with the intention of removing the whole tumour. It may be the same procedure as the final (or only) definitive surgery as described elsewhere.

Procedures such as needle core biopsy which are undertaken to establish a diagnosis in preparation for later breast surgery are not classed as definitive surgery.

Excision or localising biopsies, which both establish diagnosis and with the intention of removing the whole tumour, are classed as definitive surgery. This would still be the case where the margin is close or positive as the main bulk of the tumour has been removed.

If the exact date is not documented, record as 09/09/0909.

If no surgical procedure is carried out, code as 10/10/1010 (inapplicable).

Related Data Item(s):
Type of Hormonal Therapy {Breast Cancer}
Type of Chemotherapy {Cancer} (1-2)

Notes by Users:
Date of Final Definitive (or Only) Surgery Performed to Breast or Axilla {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This is the date of the final definitive operative procedure to the breast or axilla.

Field Name: LSURGDATE
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users: Required for QPI(s): 3, 5, 9

This is the final (or only) operative procedure with the intention of removing all of the tumour. It may be the same procedure as the first (or only) definitive surgery as described elsewhere.

Some patients undergo axillary surgery at a later date than the surgery performed to the breast. In these cases the date of the axillary surgery should be recorded.

Procedures such as needle core biopsy which are undertaken to establish a diagnosis in preparation of later breast surgery is not classed as definitive surgery.

Excision or localising biopsies, which both establish diagnosis and with the intention of removing the whole tumour, are classed as definitive surgery if no further surgery is performed. This would still be the case where the margin is close or positive as the main bulk of the tumour has been removed.

If the exact date is not documented, record as 09/09/0909.

If no surgical procedure is carried out, code as 10/10/1010 (inapplicable).

Related Data Items:
Final Definitive (or Only) Surgery Performed to Breast {Breast Cancer}
Final Axillary Surgery {Breast Cancer}

Notes by Users:
First Axillary Surgery {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This indicates the extent of the first surgery carried out in the axilla to remove a number of axillary lymph nodes to determine if the disease has spread outwith the breast.

Field Name: FIRSTAXIL
Field Type: Characters
Field Length: 2

Notes for Users: Required for QPI(s): 6

Types of axillary surgery are:
- Sample – at least four individual nodes should be picked out from the lower axillary fat. This includes blue dye only guided sample.
- Clearance – a block dissection of the axillary contents.
- Sentinel node biopsy – a biopsy of first node of tumour spread along the chain from the breast to axilla. This combines the use of isotope colloid and blue dye to localise the sentinel node. There is not a specific limit to the number of nodes.

If no axillary surgery is undertaken code as 96 (inapplicable).

If the sentinel node or sample is found to be positive an axillary clearance may be performed. This may occur at the same operation and if so, should be recorded as: First axillary surgery = SNLB/Sample: Final axillary surgery = Axillary Clearance.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Sub-values</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sample</td>
<td></td>
<td>This would include a blue dye only sample.</td>
</tr>
<tr>
<td>2</td>
<td>Clearance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Sentinel node biopsy (Isotope + Blue Dye)</td>
<td></td>
<td>If node positive, may be followed by clearance</td>
</tr>
<tr>
<td>4</td>
<td>Failed SNLB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4A</td>
<td>Proceeding to Sample</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4B</td>
<td>Leading to clearance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>95</td>
<td>Patient refused</td>
<td></td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes by Users:
Final Axillary Surgery {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This indicates the extent of the final surgery carried out in the axilla to remove a number of axillary lymph nodes to determine if the disease has spread outwith the breast.

Field Name: FINALAXIL
Field Type: Integer
Field Length: 2

Notes for Users: Required for QPI(s): 6

Types of axillary surgery are:
- Sample – at least four individual nodes should be picked out from the lower axillary fat. This includes blue dye only guided sample.
- Clearance – a block dissection of the axillary contents.
- Sentinel node biopsy – a biopsy of first node of tumour spread along the chain from the breast to axilla. This combines the use of isotope colloid and blue dye to localise the sentinel node. There is not a specific limit to the number of nodes.

If no axillary surgery is undertaken code as 96 (inapplicable).

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sample.</td>
<td>This would include a blue dye only sample.</td>
</tr>
<tr>
<td>2</td>
<td>Clearance</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Sentinel Node Biopsy</td>
<td>Isotope + Blue Dye</td>
</tr>
<tr>
<td>5</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>95</td>
<td>Patient refused</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

Related Data Item(s):
Date of Final (or Only) Surgery Performed to Breast or Axilla {Breast Cancer}

Notes by Users:
Section 5: Pathology Details
Type of Tumour {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This denotes the classification of tumour based on tissue or origin in the breast.

Field Name: TUMOUR
Field Type: Integer
Field Length: 2

Notes for Users: Required for QPI(s): 1, 2, 4, 9, 11

This determines whether the tumour is invasive or in situ (these are lesions which show cytology of malignancy but are contained within the ductal and lobular structures). In tumours with both invasive and non-invasive components record the invasive part.

If the definitive diagnosis is made clinically or by imaging techniques only (i.e. no histology is available), code as 96 (inapplicable).

On occasions a biopsy specimen and a specimen from definitive surgery may give differing tumour types. In this case code as the definitive type as stated by the pathologist in the final specimen report.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>DCIS (non-invasive)</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>‘Ductal’/no specific type (NST)</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Lobular carcinoma</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Medullary carcinoma</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Mucinous carcinoma</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Tubular carcinoma</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Mixed (invasive) carcinoma</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Other invasive carcinoma, specify</td>
<td>Includes Spindle Cell Carcinomas; Metaplastic, Microinvasive Tumours.</td>
</tr>
<tr>
<td>19</td>
<td>LCIS only (non-invasive)</td>
<td>This may be referred to as Lobular In-situ Neoplasia (LISN) but if this relates to Atypical Lobular Hyperplasia (ALH) this should not be included.</td>
</tr>
<tr>
<td>20</td>
<td>Paget’s (non-invasive)</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Other non-invasive</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Pleomorphic carcinoma in-situ</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not Known</td>
<td></td>
</tr>
</tbody>
</table>

Related Data Item(s): Tumour Grade {Breast Cancer}

Notes by Users:
Tumour Grade {Breast Cancer}

Main Source of Data Item Standard: Derived from Pathology Reporting for Breast Disease, NHSBSP Publication No 58, January 2005.

Definition:
The pathological assessment of tumour differentiation used as a prognostic indicator.

Field Name: TGRADE
Field Type: Integer
Field length: 4

Notes for Users: Required for QPI(s): 10
For DCIS the pathology report should state grade as high, intermediate or low. If there are mixed statements (e.g. low to intermediate grade) record the worst situation (intermediate in this example).

In specimens with both invasive and non-invasive tumour record only the grade for the invasive component.

Record lobular carcinoma in-situ (LCIS) or Paget’s disease as 96 (inapplicable)

If the specimens from biopsy and definitive surgery differ, record the excision grade. However, if the tumour grade is downgraded by neo-adjuvant therapy then the core biopsy grade should be recorded as this is the untreated status

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Grade I (invasive)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Grade II (invasive)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Grade III (invasive)</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Low grade Ductal Carcinoma In-Situ (DCIS)</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Intermediate grade Ductal Carcinoma In-Situ (DCIS)</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>High-grade Ductal Carcinoma In-Situ (DCIS)</td>
<td></td>
</tr>
<tr>
<td>8888</td>
<td>Not assessable</td>
<td>Grade cannot be determined, e.g. specimen too poorly preserved or too small. Includes microinvasion.</td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td>e.g. no surgery performed.</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

Related Data Item(s):
Type of Tumour {Breast Cancer}

Notes by Users:
Distance from Final Radial Excision Margin {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This denotes the distance of the invasive or ductal carcinoma in situ (DCIS) component of the tumour from the nearest resection margin.

Field Name: DISTEX
Field Type: Integer
Field Length: 4

Notes for Users: Required for QPI(s): 4

Radial margins may also be known as Superior, Medial, Lateral or Inferior margins.

This will be confirmed by microscopic examination and the result can be found on the pathology report relating to the specimen from the final definitive (or only) surgery performed to breast as described elsewhere.

Record the distance to the closest margin regardless of whether this is invasive or in-situ and this is in relation to any margin.

Lobular carcinoma in situ (LCIS) is a multifocal disease which is not localised therefore cases of LCIS only should be excluded from the margin fields and recorded as inapplicable. Ignore incidental foci of LCIS present in invasive/DCIS cases. This exclusion does not apply to pleomorphic lobular carcinoma in-situ which should be considered as similar to DCIS.

Where there is no residual disease after neo-adjuvant chemotherapy or endocrine therapy, record as ‘8888’ ‘Not Assessable’.

This is the final excision margin. If no distance is given or if a second procedure is carried out to achieve clear margins i.e. cavity shavings or completion mastectomy, record as code 4 if no residual disease. It is the FINAL excision margins and therefore this includes any cavity shaving whether done at same operation or later. Sometimes a measurement will be given which can be added to original margin of clearance but often it is only stated as “clear” in which case it should be recorded as code 4. Code 4 should only be used if there was no measurement and it was only stated as clear. Code 4 confirms the margins are clear and would be compliant with previous QIS standard.

If the patient is not treated by surgery, code as 96 (inapplicable).

Codes and Values:
The distance is measured in millimetres.

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&lt;1mm</td>
</tr>
<tr>
<td>2</td>
<td>1-5mm</td>
</tr>
<tr>
<td>3</td>
<td>&gt;5mm</td>
</tr>
<tr>
<td>4</td>
<td>Margins confirmed as clear; Cavity Shavings, Or Re-excision/completion mastectomy – no residual disease</td>
</tr>
<tr>
<td>8888</td>
<td>Not assessable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>99</td>
<td>Not known</td>
</tr>
</tbody>
</table>

**Related Data Item(s):**
- Final Definitive (or Only) Surgery Performed to Breast {Breast Cancer}
- Type of Tumour {Breast Cancer}

**Notes by Users:**
Maximum Invasive Pathological Diameter {Breast Cancer}

Main Source of Data Item Standard: Derived from Pathology Reporting for Breast Disease, NHSBSP Publication No 58, January 2005.

Definition: The size of the invasive tumour as measured in millimetres by the pathologist on microscopy.

Field Name: MAXPATH
Field Type: Integer
Field length: 4

Notes for Users: Required for QPI(s): 10, 11

In cases of multifocal disease, the size of the largest invasive component should be recorded.

If the patient does not undergo excision of breast lesion, code as ‘1010’ (inapplicable).

Where there is only in-situ disease found at surgery, code as ‘1010’ (inapplicable).

If the measurement is not recorded code as 9999.

If the patient has had neoadjuvant chemotherapy or endocrine therapy and there is no residual tumour found at time of definitive surgery, record as ‘8888’ (Not assessable).

If the tumour is excised in more than one operation, an amended pathology report may be issued. This may be reported at the MDT meeting. If the invasive tumour size remains unclear, advice should be sought from the pathologist.

In the case of occult tumours where the primary lesion is not found within the breast, record as ‘8888’, ‘Not Assessable’.

In cases of multifocal disease, i.e. \( \leq 1 \text{mm} \), record as ‘8888’ (Not assessable).

If this value is expressed with a decimal point in the pathology report then adopt the following rounding convention:

If the number after the decimal place is five or more, increase the value by one i.e. 27.5 becomes 28. Otherwise drop the number after the decimal point i.e. 27.4 becomes 27.

Related Data Item(s):
Maximum Microscopic Whole Tumour Diameter {Cancer}

Notes by Users:
Maximum Microscopic Whole Tumour Diameter {Cancer}

Common name: Whole Tumour Size

Main Source of Data Item Standard: Derived from the Royal College of Pathologists standards and datasets for reporting cancers.

Definition: The maximum microscopic size of the tumour as measured in millimetres (mm). This includes the invasive and DCIS component.

Field Name: WHOLEDIAM
Field Type: Integer
Field length: 4

Coding Details: Required for QPI(s): 3
If the measurement is not recorded code as 9999.
If the definitive diagnosis is made clinically or by imaging techniques only (i.e. no histology is available), code as 1010 (inapplicable).
If the patient has had neoadjuvant chemotherapy or endocrine therapy and there is no residual tumour found at time of definitive surgery, record as ‘8888’ ‘Not assessable’.
If the tumour is excised in more than one operation, an amended pathology report may be issued. This may be reported at the MDT meeting. If the whole tumour size remains unclear, advice should be sought from the pathologist.
IT systems should ensure that the unit of measurement for values is always clear to users, in whatever medium values are recorded.
The diameter of the specimen will be described in the pathology report and should be recorded in millimetres (mm).
If this value is expressed with a decimal point in the pathology report then adopt the following rounding convention:
If the number after the decimal place is five or more, increase the value by one i.e. 27.5 becomes 28. Otherwise drop the number after the decimal point i.e. 27.4 becomes 27.

Related Data Item(s):
Maximum Invasive Pathological Diameter {Breast Cancer}

Notes by Users:
Final Total Number of Lymph Nodes Examined Microscopically {Cancer}

Main Source of Data Item Standard: Derived from the Royal College of Pathologists standards and datasets for reporting cancers.

Definition: A record of the total number of lymph nodes examined microscopically after final surgery.

Field Name: EXNODES
Field Type: Integer
Field length: 4

Notes for Users: Required to continue with NHS QIS standards.

Where there is more than one operation to the axilla on the same side, nodes from each should be added together.

If the total number examined is not known or not recorded, code as 9999.

If no surgery is performed code as not applicable, 1010.

Codes and Values: N/A

Related Data Items: Laterality

Notes by Users:
Total Number of Lymph Nodes Involved {Cancer}

Main Source of Data Item Standard: Derived from the Royal College of Pathologists standards and datasets for reporting cancers.

Definition: The total number of lymph nodes reported as positive for the presence of tumour metastases by microscopy.

Field Name: INVNODES
Field Type: Integer
Field length: 4

Notes for Users: Required for QPI(s): 6, 10, 11

Where there is more than one operation to the axilla on the same side, nodes from each should be added together.

Micrometastases (> 0.2 mm to ≤2 mm) count as positive nodes, isolated tumour cells (≤ 0.2 mm) are regarded as negative.

If nodes are positive but the number is unknown, code as 7777.
If the total number examined is not known or not recorded, code as 9999.
If no surgery is performed code as not applicable, 1010.

Related Data Item(s):
Laterality

Notes by Users:
Tumour Extent {Breast Cancer}

Main Source of Data Item Standard: The Royal College of Pathologists, Pathology Reporting for Breast Disease, January 2005.

Definition:
An indicator of multiple separate foci of invasive tumour within the specimen.

Field Name: EXTENT
Field Type: Integer
Field length: 4

Notes for Users: Required for QPI(s): 3

If the patient does not undergo excision of breast lesion, code as 96 (not applicable).

Classification of Multiple foci should be based on the multidisciplinary team meeting (MDM) decision.

Cases of LCIS only should be recorded as not applicable, 96.

Codes and Values:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Localised</td>
<td>Includes DCIS</td>
</tr>
<tr>
<td>2</td>
<td>Multiple invasive foci</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Multiple DCIS foci*</td>
<td>Not yet covered by RCPath guidelines</td>
</tr>
<tr>
<td>4</td>
<td>Multiple foci includes Invasive &amp; DCIS</td>
<td>Not yet covered by RCPath guidelines</td>
</tr>
<tr>
<td>8888</td>
<td>Not assessable</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td>e.g. no surgery</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

*NB: Definitions for multiple foci of DCIS have yet to be agreed nationally.

Notes by Users:
Oestrogen Receptor (ER) Status {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
ER status denotes the results of an immunohistochemical staining technique used to determine the amount of oestrogen receptor sites in the tumour.

Field Name: ERSTATUS
Field Type: Integer
Field length: 4

Notes for Users:
The greater the value the greater the response is likely to be to an anti-oestrogen e.g. Tamoxifen.

The standard scoring system across Scotland is the Allred system.

ER status of multifocal disease may be not assessable.

Where there is a discrepancy between core and surgery, (if both specimens have been tested) the core ER status should be used. If in doubt, please record as agreed at the multidisciplinary meeting (MDM).

Cases of LCIS only should be recorded as not applicable, 96.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Negative (0-2)</td>
</tr>
<tr>
<td>3</td>
<td>Low Positive (3-5)</td>
</tr>
<tr>
<td>1</td>
<td>High Positive (6-8)</td>
</tr>
<tr>
<td>8888</td>
<td>Not assessable</td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
</tr>
</tbody>
</table>

Notes by Users:
Human Epidermal Growth Factor Receptor-2 (HER2) Status
Available at Initial MDT {Breast Cancer}

Definition:
An indication of whether or not the HER2 status, as defined by immunohistochemistry (IHC), is available and recorded at the initial multidisciplinary team (MDT) meeting.

Field Name: HER2AVAIL
Field Type: Integer
Field Length: 2

Notes for Users: Required for QPI(s): 8

This is the pathology report containing the HER2 status. Sometimes the pathology report is initially released without HER2 and an amended report is issued later with HER2 status. The report may also be given verbally at the MDT meeting.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>No</td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
</tr>
</tbody>
</table>

Related Data Item(s):
Human Epidermal Growth Factor Receptor-2 (HER-2) Status {Breast Cancer}
Date Discussed by Care Team (MDT) Pre-treatment

Notes by Users:
Final Human Epidermal Growth Factor Receptor-2 (HER2) Status {Breast Cancer}

Common name: Her2 Status

Main Source of Data Item Standard: The Royal College of Pathologists, Pathology Reporting for Breast Disease, January 2005.

Definition: The measurement of human epidermal growth factor receptor-2 (HER2) as detected by immunohistochemistry (IHC) and/or FISH analysis i.e. the final conclusion for invasive tumours only.

Field Name: HER2STATUS
Field Type: Characters
Field length: 4

Notes for Users: Required for QPI(s): 8, 11

If multifocal and the results differ between tumours, record the most positive score.

Her2 status should be recorded for invasive tumours only.

Cases of DCIS and LCIS only should be recorded as not applicable, 96.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Inconclusive</td>
<td>Patients with an inconclusive FISH result.</td>
</tr>
<tr>
<td>1</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>8888</td>
<td>Not assessable</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td>e.g. DCIS, Microinvasion</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td>e.g. where a 2+ (IHC) result is obtained but no FISH test is carried out.</td>
</tr>
</tbody>
</table>

Related Data Item(s):
Human Epidermal Growth Factor Receptor-2 (HER2) Status Available at Initial MDT {Breast Cancer}

Notes by Users:
Section 6: Radiotherapy
Radiotherapy Course Type

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The type of course of external beam radiotherapy administered for the treatment of the cancer.

Field Name: RADIO
Field Type: Integer
Field length: 2

Notes for Users: Required for QPI(s): 8

Combined treatments may be administered concurrently/synchronously e.g. chemotherapy and radiotherapy, intra-operative radiotherapy.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adjuvant</td>
<td>It is given after potentially curative surgery or chemotherapy.</td>
</tr>
<tr>
<td>2</td>
<td>Radical</td>
<td>It is primary treatment and is given with curative intent.</td>
</tr>
<tr>
<td>3</td>
<td>Palliative</td>
<td>The aim is solely to relieve symptoms.</td>
</tr>
<tr>
<td>95</td>
<td>Patient Refused Radiotherapy</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td>e.g. no external beam radiotherapy given.</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

Related Data Item(s):
Date Treatment Started {Cancer} (Radiotherapy)
Site of External Beam Radiotherapy {Breast Cancer} (1-5)

Notes by Users:
**Site of External Beam Radiotherapy {Breast Cancer} (1-5)**

**Main Source of Data Item Standard:** The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

**Definition:**
The part(s) of the body that receive radiotherapy for breast cancer and may include other sites out-with the breast.

**Field Name:** RADSITE 1  
RADSITE2  
RADSITE3  
RADSITE4  
RADSITE5  

**Field Type:** Integer  
**Field Length:** 2

**Notes for Users:** Required for QPI(s): 9
Radiotherapy sites can include breast (after a wide local excision), chest wall (after mastectomy) and sometimes one or more of the ipsilateral lymphatic areas (supraclavicular fossa, axilla, internal mammary chain). Less commonly, one of the above lymphatic areas may be irradiated without irradiating the breast or chest wall.

In some situations a ‘boost’ dose of radiotherapy is given to the tumour bed after conservation surgery.

IT systems should allow for the recording of multiple sites of external beam radiotherapy.

For the purposes of national audit, only radiotherapy given as part of the primary treatment plan should be recorded. Palliative radiotherapy to other (metastatic) sites is only recorded if part of the initial treatment plan.

**Codes and Values:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Breast</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Chest wall</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Axilla</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Supraclavicular fossa</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Boost</td>
<td>Dose of external beam radiotherapy given at the end of the primary external beam radiotherapy</td>
</tr>
<tr>
<td>3</td>
<td>Internal mammary chain</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td>No External beam radiotherapy given</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td>Includes not recorded</td>
</tr>
</tbody>
</table>

**Related Data Item(s):**
Laterality {Cancer}  
Radiotherapy Course Type

**Notes by Users:**
Date Treatment Started {Cancer} (Radiotherapy)

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The date cancer treatment course commenced.

Field Name: RADDATE
Field Type: Date (DD/MM/CCYY)
Field length: 10

Notes for Users: Required for QPI(s): 9

This is the first fraction of a course of external beam radiotherapy or brachytherapy.

If radiotherapy has not been given or the patient has refused radiotherapy, record as inapplicable, 10/10/1010.

If the date radiotherapy started is unknown, record as 09/09/0909.

For the purposes of national audit, only radiotherapy given as part of the primary treatment plan should be recorded. Palliative radiotherapy to other (metastatic) sites is only recorded if part of the initial treatment plan.

Related Data Item(s):
Radiotherapy Course Type

Notes by Users:
Section 7: Systemic Therapy
**Type of Hormonal Therapy {Breast Cancer}**

**Main Source of Data Item Standard:** The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

**Definition:**
Hormonal therapy is the use of hormones to treat breast cancer. Hormones are ‘chemical messengers’ released by the organs and dispersed by the blood to produce effects on target organs e.g. oestrogens.

**Field Name:** HORMON  
**Field Type:** Integer  
**Field Length:** 2

**Notes for Users:** Required for QPI(s): 3, 6

Some forms of breast cancer depend on oestrogens for continued growth. The use of hormonal therapy can reduce circulating concentrations of oestrogens, or antagonise the effects of oestrogen on the tumour. Hormonal therapy can be given in the form of drugs (anti-oestrogens e.g. Tamoxifen; progestogens e.g. Methoxyprogesterone or aromatase inhibitors e.g. Letrozole) or ovarian ablation-suppression (either by radiotherapy, surgery or drug therapy).

Type of hormonal therapy relates to the treatment intent as below.

Patients may have hormone therapy both before and after surgery. These patients should be recorded under neo-adjuvant Type.

Some patients may receive a short course of treatment for logistical or research reasons. These should be classified as peri-operative i.e.

*If treatment is less than six weeks then record as peri-operative.*
*If treatment is six weeks or more then record as neo-adjuvant.*

If hormonal therapy was not given as part of primary therapy, code as 96.

**Codes and Values:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adjuvant</td>
<td>Additional therapy given after surgery.</td>
</tr>
<tr>
<td>2</td>
<td>Neoadjuvant</td>
<td>Therapy given prior to definitive surgery to reduce tumour</td>
</tr>
<tr>
<td>3</td>
<td>Primary</td>
<td>Given as first line therapy where there is no intention of surgical intervention e.g. due to patient frailty. i.e. if the patient has not proceeded to surgery within one year of diagnosis.</td>
</tr>
<tr>
<td>4</td>
<td>Palliative</td>
<td>Given as first line therapy in patients with metastatic disease at diagnosis.</td>
</tr>
<tr>
<td>11</td>
<td>Peri-operative</td>
<td>This would include patients in peri-operative treatment trials and those commenced on hormone therapy due to a need to delay surgery for patient related reasons e.g. further investigation or social.</td>
</tr>
<tr>
<td>5</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>95</td>
<td>Patient refused hormone treatment</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>
Related Data Item(s):
Date Hormonal Therapy Started (Breast Cancer)
Date of First Definitive Breast Surgery (Breast Cancer)

Notes by Users:
Date Hormonal Therapy Started {Breast Cancer}

Main Source of Data Item Standard: The National Audit Cancer Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This is the first date a patient has taken a hormonal drug or undergone ovarian ablation as part of breast cancer treatment.

Field Name: HORDATE
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users: Required for QPI(s): 3, 6

It is not always clearly documented when hormone therapy starts. In the patient discharge or clinic letter the clinician may ask the GP to prescribe hormone therapy, in this case, record the date as two days from the day the discharge letter or clinic letter was typed.

If the date of clinic letter is not documented, record as 09/09/0909.

If hormonal therapy was not given as part of primary therapy, code as 10/10/1010 (inapplicable).

Related Data Item(s):
Type of Hormonal Therapy {Breast Cancer}

Notes by Users:
Type of Chemotherapy {Cancer} (1-2)

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The type of course of cytotoxic drugs administered for the treatment of the cancer. Cytotoxic drugs are drugs which destroy cells.

Field Name: CHEM 1
          CHEM2
Field Type: Character
Field Length: 2

Notes for Users: Required for QPI(s): 3, 6, 10

Patients may have ongoing chemotherapy both before and after surgery. These patients should be recorded under neo-adjuvant Type. Some patients may have separate completion chemotherapy post-operatively. This may be recorded as two courses neo-adjuvant and adjuvant.

Biological therapy (including Immunotherapy and biological response modifiers) is recorded in a separate standard.

Chemotherapy must be treatment received for initial management and not treatment for recurrence or relapse.

If chemotherapy was not given as part of primary therapy, code as 96 (Not applicable).

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adjuvant</td>
<td>The start of adjuvant chemotherapy is after the date of the first surgery where there is no overt evidence of remaining disease within the breast.</td>
</tr>
<tr>
<td>2</td>
<td>Neoadjuvant</td>
<td>Therapy given prior to first definitive surgery to reduce tumour size.</td>
</tr>
<tr>
<td>4</td>
<td>Palliative</td>
<td>Chemotherapy given for symptom control without curative intent in patients with metastatic disease at time of diagnosis.</td>
</tr>
<tr>
<td>7</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>8A</td>
<td>None – Not clinically indicated</td>
<td>Best practice guidance and/or local protocols do not recommend.</td>
</tr>
<tr>
<td>8B</td>
<td>None – Clinical decision</td>
<td>Patient unfit or clinical assessment indicates other management.</td>
</tr>
<tr>
<td>8C</td>
<td>None – Patient died</td>
<td></td>
</tr>
<tr>
<td>8D</td>
<td>None – Patient refused treatment</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>
Related Data Item(s):
Date Treatment Started {Cancer} (Chemotherapy) (1-2)
Date of First Definitive Breast Surgery {Breast Cancer}

Notes by Users:
**Date Treatment Started {Cancer} (Chemotherapy) (1-2)**

**Main Source of Data Item Standard:** The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

**Definition:**
The date cancer treatment course commenced.

**Field Name:** CHEMDATE1  
CHEMDATE 2  
**Field Type:** Date (DD/MM/CCYY).  
**Field length:** 10

**Notes for Users:** Required for QPI(s): 3, 6, 10

This is the first dose of the first cycle of a course of chemotherapy.

If treatment has not been given, record as inapplicable, 10/10/1010.

If the date treatment started is unknown, record as 09/09/0909.

**Related Data Items(s):**  
Type of Chemotherapy {Cancer} (1-2)  
Date Treatment Completed {Cancer} (Chemotherapy) (1-2)

**Notes by Users:**
Date Treatment Completed {Cancer} (Chemotherapy) (1-2)

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The date cancer treatment course ended.

Field Name: CHEMENDATE1
CHEMENDATE2
Field Type: Date (DD/MM/CCYY).
Field length: 10

Notes for Users: Required for QPI(s): 3, 6

This is the first day of the last cycle of a course of chemotherapy.

It should be noted this can be the same day as the day the therapy started.

If treatment has not been given, record as inapplicable, 10/10/1010.

If the date treatment started is unknown, record as 09/09/0909.

Related Data Item(s):
Type of Chemotherapy {Cancer} (1-2)
Date Treatment Started {Cancer} (Chemotherapy) 1-2

Notes by Users:
Biological Agent {Breast Cancer}

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The type of biological agent administered for the treatment of the cancer.

Field Name: BIOAGENT
Field Type: Integer
Field Length: 2

Notes for Users: Required for QPI(s): 11
Biological therapy must be treatment received for initial management and not treatment for recurrence or relapse.

Biological therapy given directly after adjuvant therapy is still regarded as primary treatment.
If biological therapy was not given as part of primary therapy, code as 96 (Not applicable).

The biological agent can be given in or out-with the context of a clinical trial.

As new treatments are introduced, approval for inclusion of additional codes and values must be sought from ISD.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Anti-HER2 Positive Therapy</td>
<td>e.g. Trastuzumab (Herceptin)</td>
</tr>
<tr>
<td>8</td>
<td>Other – specify</td>
<td>e.g. Non-anti-HER2 positive therapy</td>
</tr>
<tr>
<td>95</td>
<td>Patient refused biological therapy</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Not applicable</td>
<td>No Biological Agent</td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

Related Data Item(s):
Date Treatment Started {Cancer} (Biological Therapy)

Notes by Users:
Date Treatment Started {Cancer} (Biological Therapy)

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition: The date cancer treatment course commenced.

Field Name: BIODATE
Field Type: Date (DD/MM/CCYY).
Field length: 10

Notes for Users: Required for QPI(s): 11

If treatment has not been given, record as inapplicable, 10/10/1010.

If the date treatment started is unknown, record as 09/09/0909.

Related Data Item(s):
Biological Agent {Breast Cancer}

Notes by Users:
Section 8: Clinical Trial Entry
Patient Entered into Clinical Trial {Breast Cancer}

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
An indication of whether or not the patient received treatment within the context of a clinical trial.

Field Name: TRIAL
Field Type: Characters
Field Length: 2

Notes for Users: Required for QPI(s): 9, 10, 11

This relates only to participation in clinical trials which may be national or international multi-centred trials.

The majority of non-commercial multi-centred trials available in Scotland are National Cancer Research Network (NCRN) badged or equivalent.

Some academic and university units may have ongoing local trials which should not be included here. These can be recorded on local trials databases.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>Yes - Radiotherapy</td>
<td>Entered into a clinical trial involving radiotherapy</td>
</tr>
<tr>
<td>1B</td>
<td>Yes - Chemotherapy</td>
<td>Entered into a clinical trial involving chemotherapy</td>
</tr>
<tr>
<td>1C</td>
<td>Yes – Biological therapy</td>
<td>Entered into a clinical trial involving biological therapy</td>
</tr>
<tr>
<td>1D</td>
<td>Yes – More than one modality (including Radiotherapy)</td>
<td>Entered into a clinical trial involving more than one therapy including radiotherapy</td>
</tr>
<tr>
<td>1E</td>
<td>Yes – More than one modality (including Chemotherapy)</td>
<td>Entered into a clinical trial involving more than one therapy including chemotherapy</td>
</tr>
<tr>
<td>1F</td>
<td>Yes – More than one modality (including both Radiotherapy and Chemotherapy)</td>
<td>Entered into a clinical trial involving more than one therapy including radiotherapy and chemotherapy</td>
</tr>
<tr>
<td>1G</td>
<td>Yes – Not known</td>
<td>Entered into a clinical trial but type of therapy not known</td>
</tr>
<tr>
<td>1H</td>
<td>Yes – Hormone therapy</td>
<td>Entered into a clinical trial involving hormone therapy</td>
</tr>
<tr>
<td>2</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

Notes by Users:
Section 9: Follow-up and Death Details
Follow-up Date

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
The date on which the patient was last seen at follow-up.

Field Name: FUDATE
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users: Required for Survival QPI(s): 1, 2

This should be collected annually for a minimum of 10 years.

The follow-up period is calculated from the date of diagnosis to the date of follow-up.

If the exact date is not documented, or data are required for reporting within the year, record as 09/09/0909.

Related Data Item(s):
Follow-up Status

Notes by Users:
Follow-up Status

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
An indicator of the patient’s vital status at follow-up.

Field Name: FUSTATUS
Field Type: Integer
Field length: 2

Notes for Users: Required for Survival QPI(s): 1, 2

IT systems should allow for Follow-up Status to be updated annually.

It is expected that this will be recorded up to 10 years after diagnosis.

It is essential that follow-status has a follow-up date recorded, without which time to relapse cannot be assessed.

Codes and Values:

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Alive and well</td>
<td>Never recurred.</td>
</tr>
<tr>
<td>3</td>
<td>Alive: relapse</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Moved away</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Patient deceased</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Not known</td>
<td></td>
</tr>
</tbody>
</table>

Related Data Item(s):
Follow-up Date.

Notes by Users:
**Date of First Local Recurrence (Breast Cancer)**

**Main Source of Data Item Standard:** The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

**Definition:**
Date of first local recurrence is the date of diagnosis of local recurrence. The date recorded should be the date of the cytological or histological diagnosis, or if not performed, radiological or other diagnostic procedure. If no diagnostic procedure was performed then the first date the doctor records a recurrence is taken.

**Field Name:** FLOCDATE  
**Field Type:** Date (DD/MM/CCYY)  
**Field Length:** 10

**Notes for Users:**
Local disease refers to skin and soft tissue disease occurring in the anatomical area bounded by the ipsilateral clavicle, posterior axillary line, costal margin and mid sternal line, irrespective of the area which may have previously been subjected to local radiotherapy. **This will be defined by the multidisciplinary team (MDT).**

The date of diagnosis of recurrence is taken as the date the procedure was carried out, not the date the report was issued.

Local recurrences are **usually** biopsied and (as at first diagnosis) the date of the biopsy should be used.

Where patients had metastatic disease at diagnosis, or where no surgery was performed, record as inapplicable, 10/10/1010.

If the exact date is not documented, record as 09/09/0909.

**Notes by Users:**
Date of First Regional Recurrence (Breast Cancer)

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
Date of first axillary or supraclavicular recurrence is the date of diagnosis of axillary recurrence. The date recorded should be the date of cytological or histological diagnosis, or if not performed, radiological or other diagnostic procedure. If no diagnostic procedure was performed then the first date the doctor records a recurrence is taken.

Field Name: FREGDATE
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users:

This refers to the first detection of disease recurring in the nodes in the ipsilateral (same side as the breast surgery) axilla, ipsilateral supraclavicular fossa, or in the mammary chain. This will be defined by the multidisciplinary team (MDT).

Regional recurrences are usually biopsied and (as at first diagnosis) the date of the biopsy should be used.

Where patients had metastatic disease at diagnosis, or where no surgery was performed, record as inapplicable, 10/10/1010.

If the exact date is not documented, record as 09/09/0909.

Notes by Users:
Date of First Distant Recurrence

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
Date of distant recurrence is the date of diagnosis of distant recurrence. The date recorded should be the date histological diagnosis was confirmed, or if not performed, radiological or other diagnostic procedure. If no diagnostic procedure was performed then the first date the doctor records a recurrence is taken.

Field Name: FDISTDATE
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users:
Sites of distant spread include contralateral axilla or contralateral supraclavicular fossa. If there is spread to the liver, bone and contralateral breast this is distant relapse. Conversely if a patient develops disease in the contralateral breast (histologically different to the first tumour) and there is no spread to bone, liver etc this is not distant relapse.

The date of diagnosis of recurrence is taken as the date the procedure was carried out, not the date the report was issued.

Some recurrences are never biopsied and therefore there is no histological date so the imaging date is taken. This is particularly the case with distant metastases.

Where patients had metastatic disease at diagnosis, or where no surgery was performed, record as inapplicable, 10/10/1010.

If the exact date is not documented, record as 09/09/0909.

Notes by Users:
Date of Death

Main Source of Data Item Standard: The National Cancer Audit Datasets developed by the regional Cancer Networks supported by Information Services.

Definition:
This is the certified date of death as recorded by the General Register Office (Scotland) (GRO(S)).

Field Name: DOD
Field Type: Date (DD/MM/CCYY).
Field Length: 10

Notes for Users: Required for Survival QPI(s): 1, 2
If the patient is alive use the code 10/10/1010 (inapplicable).
If the exact date is not documented, record as 09/09/0909.

Related Data Item(s):
Primary (Underlying) Cause of Death

Notes by Users: