



**NATIONAL BREAST
CANCER CENTRE**

Incorporating the
Ovarian Cancer Program

BREAST CANCER SPECIFIC DATA ITEMS FOR CLINICAL CANCER REGISTRATION

PREPARED BY THE NATIONAL BREAST CANCER CENTRE

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DEPARTMENT OF HEALTH AND AGEING

Breast cancer specific data items for clinical cancer registration

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FOREWORD

The National Breast Cancer Centre was established in 1995 to improve outcomes for women with breast cancer. Through collaborative partnerships and the dedication and commitment of clinical experts and consumers, much progress has been made in the areas of diagnosis and treatment since that time. Our ability to measure and improve care is reliant on quality data. However, there has been no consistent set of clinical indicators on which to assess care and to collect prospective data in breast cancer at a national level.

The National Breast Cancer Centre is grateful for the high quality input into the development of the breast cancer specific data items for clinical registration. A multidisciplinary working group was chaired by Professor David Roder and broad consultation with clinical colleges and cancer organisations was sought to reduce duplication across existing data sets and to engage widespread support for the final data items.

We will work with relevant groups to encourage the adoption of the breast cancer items nationally so that we have a consistent approach to defining and measuring care into the future. Furthermore, we hope this work will provide a model for the development of cancer specific data items in other cancers.

ACKNOWLEDGEMENTS

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This guide was developed with input from a multidisciplinary Working Group with these members:

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Breast Cancer Network Australia
Clinical Oncological Society of Australia
Cancer Institute NSW
National Cancer Control Initiative
New South Wales Breast Cancer Institute
Queensland Cancer Control Analysis Team
Queensland Cancer Fund
Royal Australian and New Zealand College of Radiologists
Royal Australasian College of Surgeons, Breast Section
Royal College of Pathologists of Australia

The Cancer Council Australia
The Cancer Council Australian Capital Territory
The Cancer Council New South Wales
The Cancer Council Northern Territory
The Cancer Council South Australia
The Cancer Council Tasmania
The Cancer Council Victoria
The Cancer Council Western Australia

LIST OF ABBREVIATIONS

ABS	Australian Bureau of Statistics
ACHS	Australian Council of Healthcare Standards
ACN	Australian Cancer Network
AIHW	Australian Institute of Health and Welfare
FORDS	Facility Oncology Data Standards: Revised for 2004 (Commission on Cancer, Chicago)
NBCC	National Breast Cancer Centre
NCCI	National Cancer Control Initiative
NHDD	National Health Data Dictionary (AIHW)
NHMRC	National Health and Medical Research Council
RACS	Royal Australasian College of Surgeons
WHO	World Health Organization
DCIS	Ductal Carcinoma In Situ
LCIS	Lobular Carcinoma In Situ

INTRODUCTION

In its December 1997 report, National Cancer Control and Implementation, the NCCI identified important gaps in cancer-data availability for cancer control in Australia. In response, a consultative process was arranged involving key stakeholders, which resulted in the development of a data set for clinical cancer registration. Data items covered by the data set were subsequently refined and included in Australia's NHDD.

This was a core data set directed at all cancers. It represented a compromise between collecting excessive detail that would be unsustainable, and undue brevity that would not be informative. The purpose was to provide a guide, such that clinical data sets around Australia would include similar items and definitions, thereby facilitating comparative analysis, and where appropriate, data pooling for rare sub-types of cancers.

Version 12 of the National Health Data Dictionary (AIHW, 2004) describes the data items included as core items for clinical cancer care registration. They comprise: (1) person characteristics, such as name, address, gender, date of birth and death; (2) treatment establishment number; (3) diagnostic characteristics, such as primary cancer site, diagnosis date, cancer morphology and grade, laterality, most valid basis of diagnosis, and patient's performance status; (4) stage characteristics, including TNM or equivalent stage, tumour size, regional nodal status, and oestrogen and progesterone receptor status; (5) features of the primary courses of care, such as treatment intent, surgical procedures, radiotherapy types and doses, names of systemic agents, and clinical outcomes; and (6) for the first recurrence, the date of diagnosis and anatomical region involved. Morphology codes were comprehensive, providing for benign and in situ, as well as invasive lesions.

It was not intended in the development of the core data set that it would be sufficient for all clinical applications. In particular, it was anticipated that specialist tumour groups would require additional information. The present report indicates specialist items additional to the core data set that should be considered for specialist breast-cancer registration. Again, the purpose is to provide a guide, such that specialist breast-cancer data sets around Australia may include similar items and definitions, which would facilitate comparative analysis, and where appropriate, data pooling. It is accepted that some groups may choose to exclude certain items, or include additional ones, to better meet their needs.

The items in this guide were developed through a NBCC multidisciplinary Working Group, in consultation with key stakeholders, who have been listed in the Acknowledgements section.

MORPHOLOGY STATEMENT

Specialist breast data collections should record DCIS and invasive cancer, in accordance with ACN pathology guidelines. The proposed guide provides for the recording of these lesions. The guide also would accommodate collection of LCIS data, which would cater for the increasing interest in this condition. Final decisions on the content of individual collections would rest with the local administration, but the content should be sufficient to provide data extractions that comply with ACN pathology guidelines. In particular, tumour morphology should be recorded in sufficient detail to enable appropriate data extractions.

BREAST DATA ITEMS

1. **Indigenous status**
2. **Menopausal status**
3. **Clinical trial enrolment**
4. **Initial presentation**
5. **Presence of ductal carcinoma in situ in adjacent breast tissue**
6. **Lymphatic/vascular invasion**
7. **HER2**
8. **Sentinel lymph node**
9. **Organ sites of distant metastases**
10. **Surgical margin clearance**
11. **Surgical margin involvement**
12. **Radiotherapy targets in primary course of care**
13. **Breast reconstruction**
14. **Arm symptoms**
15. **Last contact**

ADMINISTRATION:

Source documents: National Health Data Committee 2003. National Health Data Dictionary Version 12, AIHW Cat. No. HWI 43. Canberra: AIHW

ABS 1989. Standards for Statistics on Cultural and Language Diversity. Canberra: ABS Catalogue No. 1289.0. Canberra: ABS

Source organisations: AIHW
ABS

Comments: The following definition, commonly known as 'The Commonwealth Definition', was given in a High Court judgement in the case of *Commonwealth v Tasmania* (1983) 46 ALR 625.

'An Aboriginal or Torres Strait Islander is a person of Aboriginal or Torres Strait Islander descent who identifies as an Aboriginal or Torres Strait Islander and is accepted as such by the community in which he or she lives'.

There are three components to the Commonwealth definition:

- Descent;
- Self-identification; and
- Community acceptance.

In practice, it is not feasible to collect information on the community acceptance part of this definition for general purpose statistical and administrative data collections. Therefore, standard questions on Indigenous status generally relate to descent and self-identification only.

2. MENOPAUSAL STATUS

Metadata Type: Data element

Definition: The menopausal status of the woman.

Justification: Treatment recommendations can differ by menopausal status, as for example with ovarian ablation, which generally would not be indicated for postmenopausal patients.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data Domain:

Code	Classification	Description
1	Pre	An individual who has not yet experienced menopause
2	Post	An individual who has experienced menopause and the occurrence of 12 months of spontaneous amenorrhea
3	Peri	An individual who is either in the period just prior to menopause or the subsequent 12 months of amenorrhea following menopause
4	Male	
9	Unknown	Not stated or inadequately described

Guide for Use: Responses would normally be based on self-identification of menopausal status (rather than LH/FSH concentrations which generally would be unknown). If menopausal status is not reported, likely menopausal status could be inferred for statistical purposes from age (eg, premenopausal - <48 weeks; peri-menopausal – 48-55 weeks; and postmenopausal - >55 weeks).

Validation Rule: This data item is for both invasive cancer and in situ lesions

ADMINISTRATION:

Source document: RACS. The National Breast Cancer Audit. Prepared by Australia Safety & Efficacy Register of New Interventional Procedures – Surgical. Updated February 2005

Source organisation: RACS

3. CLINICAL TRIAL ENROLMENT

3.1 CLINICAL TRIAL ENROLMENT STATUS

Metadata Type:	Data element
Definition:	Whether or not the patient is/or is to be enrolled in a clinical trial as part of the anti-cancer treatment. <i>According to WHO, a clinical trial is ' Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes.'</i>
Justification:	The % of patients in a service who are enrolled in a clinical trial is a widely acknowledged indicator of quality of care.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 enrolment not proposed 2 enrolment proposed 3 enrolment occurred 9 not stated/inadequately described

Validation Rule: This data item is for both invasive cancer and in situ lesions.

ADMINISTRATION:

Source organisation: NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration

3.2 CLINICAL TRIAL REGISTRY NUMBER

Metadata Type:	Data element
Definition:	The unique trial number recorded for the trial on the Australian Clinical Trials Registry.
Justification:	The % of patients in a service who are enrolled in a clinical trial is a widely acknowledged indicator of quality of care.

REPRESENTATION:

Data type:	Alphanumeric
Field size:	Min: 1 Max: 40
Representational format:	AN (40)
Data Domain:	Text.
Guide for Use:	Where the clinical trial registry number is not known, the trial name should be recorded instead. Blanks, spaces, hyphens, special characters and punctuation marks are allowed.
Validation Rules:	This item is to be completed only if the data element 'Clinical trial enrolment status' is coded as '3'. This data item is for both invasive cancer and in situ lesions .

ADMINISTRATION:

Source organisation:	NHMRC, Australian Clinical Trials Registry
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4. INITIAL PRESENTATION

Metadata Type:	Data element
Definition:	The initial presentation mode for detection of this breast cancer.
Justification:	Initial presentation mode has prognostic significance and is used in clinical and population health research.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 mammography screen detected 2 other non-symptomatic 3 symptomatic 9 not stated/inadequately described
Guide for Use:	Symptomatic presentation may include a breast lump, nipple discharge, change in breast shape, change in nipple shape, or significant or new pain.
Validation Rule:	This data item is for both invasive cancer and in situ lesions

ADMINISTRATION:

Source organisation:	NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
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5. PRESENCE OF DUCTAL CARCINOMA IN SITU IN ADJACENT BREAST TISSUE

Metadata Type:	Data element
Definition:	Whether or not DCIS is present in adjacent breast tissue.
Justification:	Presence of DCIS in adjacent breast tissue can have prognostic and treatment implications.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 yes 2 no 9 not stated/inadequately described
Validation Rule:	This data item is for invasive cancer only

ADMINISTRATION:

Source documents:	ACN. The Pathology of Reporting Breast Cancer. A Guide for Pathologists, Surgeons and Radiologists. Second Edition, Sydney (2001) RACS. The National Breast Cancer Audit. Prepared by Australia Safety & Efficacy Register of New Interventional Procedures – Surgical. Updated February 2005
Source organisations:	ACN RACS NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration

6. LYMPHOVASCULAR INVASION

Metadata Type:	Data element
Definition:	The presence of tumour cells in endothelium-lined spaces (lymphatics or blood vessels).
Justification:	Lymphovascular invasion is a predictor of lymph node metastasis and recurrence.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 present 2 absent 9 not stated/inadequately described
Validation Rule:	This data item is for invasive cancer only

ADMINISTRATION:

Source documents:	RACS. The National Breast Cancer Audit. Prepared by Australia Safety & Efficacy Register of New Interventional Procedures – Surgical. Updated February 2005 ACN. The Pathology of Reporting Breast Cancer. A Guide for Pathologists, Surgeons and Radiologists. Second Edition, Sydney (2001)
Source organisations:	RACS ACN NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration

7. HER2

7.1 HER2 STATUS

Metadata Type:	Data element
Definition:	<p>HER2 is a gene involved with tumour growth for some cancer cells, including some breast-cancer cells. The name stands for “human epidermal growth factor receptor 2”. HER2 status is assessed either through immunochemistry (IHC) or more recently, in situ hybridisation (ISH). It is measured as positive or negative.</p> <p>IHC tests for the HER2 receptor protein. A test result of 3+ indicates HER2 positivity, i.e., >10% of cancer cells show strong, complete membrane staining without cytoplasmic staining and without staining of the normal breast. A score of 0-1+ indicates the presence of a normal amount of HER2 protein and is classified as HER2 negative. A score of 2+ is equivocal and indicates a need for retesting by ISH.</p> <p>ISH tests assess whether amplification of the HER2 gene is present. Two test types are used, fluorescence in situ hybridization (FISH) and chromogenic in situ hybridization (CISH). The results indicate whether a low (negative) or high (positive) level of HER2 gene amplification is present.</p>
Justification:	HER2 status has been shown to be predictive of tumour response to chemotherapy. The HER2 gene can also be a target for antibody therapy.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 positive 2 equivocal 3 negative 4 ordered but not known 7 not done 9 not known
Validation Rule:	This data item is for invasive cancer only

ADMINISTRATION:

Source document:	ACN. The Pathology of Reporting Breast Cancer. A Guide for Pathologists, Surgeons and Radiologists. Second Edition, Sydney (2001)
Source organisation:	ACN

7.2 HER2 TEST TYPE

Metadata Type	Data element
Definition	HER2 status can be assessed either by immunohistochemistry (IHC), or by in situ hybridization (ISH), which may be either fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH).
Justification	HER2 status has been shown to be predictive of response to chemotherapy. The HER2 gene can also be a target for antibody therapy. Interpretation of test results requires information on the type of test.

REPRESENTATION:

Data type	Numeric
Field size	Min 1 Max 1
Representational format:	N
Data Domain	1 IHC 2 ISH – FISH 3 ISH – CISH 7 ordered but not known 8 not done 9 not known
Validation Rule:	This data item is for invasive cancer only.

ADMINISTRATION

Source document:	ACN. The Pathology of Reporting Breast Cancer. A Guide for Pathologists, Surgeons and Radiologists. Second Edition, Sydney (2001)
Source organisation:	ACN

8. SENTINEL LYMPH NODE

8.1 ATTEMPT TO IDENTIFY SENTINEL LYMPH NODE

Metadata Type:	Data element
Definition:	Whether or not identification of sentinel lymph node attempted
Justification:	Identification and removal of the sentinel lymph node is undertaken to determine nodal status in patients where there is no clinical evidence of nodal involvement. If the sentinel node biopsy shows no tumour cells, an extensive regional lymph node dissection normally would not be undertaken, reducing the potential for lymphoedema and other surgical complications

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 yes 2 no 9 not known
Validation Rule:	This data item is for invasive cancer only

ADMINISTRATION:

Source document:	RACS. The National Breast Cancer Audit. Prepared by Australia Safety & Efficacy Register of New Interventional Procedures – Surgical. Updated February 2005.
Source organisation:	RACS

8.2 METHOD USED IN ATTEMPT TO IDENTIFY SENTINEL LYMPH NODE

Metadata Type:	Data element
Definition:	<p>Method used when attempting to identify the sentinel lymph node</p> <p>Identification of the sentinel node requires lymphatic mapping. Lymphatic mapping techniques include the use of radioactive colloids (isotopes) and blue dyes that are injected into the breast and preferentially enter the lymphatics. These agents are taken up by the sentinel node(s) and facilitate intraoperative identification of the node by the surgeon.</p> <p>Radioactive colloids (isotopes) are injected around the tumour or beneath the areola prior to surgery. Lymphoscintigraphy is then undertaken to identify the position of the sentinel node (axillary, internal mammary or other). During surgery, the sentinel node is identified by the surgeon using a hand held Gamma probe. The sentinel node displays much higher levels of radioactivity than the background tissues.</p> <p>Blue dye is also used to facilitate intraoperative identification of the sentinel node. Patent blue dye is injected into the breast around the tumour or beneath the areola. Axillary nodes that are blue in colour are identified as sentinel nodes.</p>
Justification:	Assists in the evaluation of methodologies for identifying sentinel lymph nodes

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 isotope only (lymphoscintigraphy) 2 blue dye only 3 isotope and blue dye 9 not stated/inadequately described
Guide for Use:	This item is to be completed only if the data element 'Attempt to identify sentinel lymph node' is coded as '1'.
Validation Rule:	This data item is for invasive cancer only

ADMINISTRATION:

Source documents:	ACN. The Pathology of Reporting Breast Cancer. A Guide for Pathologists, Surgeons and Radiologists. Second Edition, Sydney (2001)
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RACS. The National Breast Cancer Audit. Prepared by
Australia Safety & Efficacy Register of New Interventional
Procedures – Surgical. Updated February 2005

Source organisations:

ACN
RACS

8.3 SENTINEL LYMPH NODE IDENTIFICATION

Metadata Type:	Data element
Definition:	Whether or not sentinel lymph node(s) identified and removed intraoperatively, according to nodal site.
Justification:	Identification of the sentinel lymph node is undertaken to permit a biopsy to be undertaken. If the biopsy shows no tumour cells, an extensive regional lymph node dissection normally would not be undertaken, reducing the possibility of lymphoedema and other surgical complications.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 internal mammary 2 axillary 3 both internal mammary and axillary 4 other site 5 no nodes identified 9 not known
Validation Rule:	This data item is for invasive cancer only

ADMINISTRATION:

Source document:	RACS. The National Breast Cancer Audit. Prepared by Australia Safety & Efficacy Register of New Interventional Procedures – Surgical. Updated February 2005.
Source organisation:	RACS

9 DISTANT METASTASES

Metadata Type: Data element

Definition: This data element records the absence or presence of distant metastases, and their location if present.

Justification: For survival analyses adjusting for stage at diagnosis and for assessing patterns of cancer dissemination.

REPRESENTATION:

Data type: Numeric

Field size: Min: 2 Max: 2

Representational format: NN

Data Domain:

Code	Site of distant metastases
00	no distant metastases
01	lung
02	brain
03	bone
04	liver
05	ovaries
06	spinal cord
07	eye
08	peritoneum
98	other
99	not known/inadequately described

Validation Rule: This data item is for invasive cancer only.

ADMINISTRATION:

Source organisation: NBCC, Working Group on Breast Cancer Specific Data Items

11.2 SURGICAL MARGIN INVOLVEMENT (IN SITU COMPONENT)

Metadata Type:	Data element
Definition:	The extent in millimetres (mm) of margin involvement by DCIS. If a re-excision is required, the margin involvement should be the final margin involvement following this secondary procedure.
Justification:	Margin involvement is a prognostic indicator and indicator of treatment needs.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 2
Representational format:	N (N)
Data Domain:	1-10 margin involvement stated in mm 97 a greater involvement than 10 mm 98 not applicable - a complete mastectomy 99 not stated
Guide for Use:	This recording applies where no marginal clearance is recorded for DCIS (i.e., surgical margin clearance is recorded as "0" millimetres for DCIS). Involvement should be recorded as described in the pathology report.
Validation Rule:	This data item is for DCIS

ADMINISTRATION:

Source documents:	RACS. The National Breast Cancer Audit. Prepared by Australia Safety & Efficacy Register of New Interventional Procedures – Surgical. Updated February 2005 ACN. The Pathology of Reporting Breast Cancer. A Guide for Pathologists, Surgeons and Radiologists. Second Edition, Sydney (2001)
Source organisations:	RACS ACN

12 RADIOTHERAPY TARGETS IN THE PRIMARY COURSE OF CARE

Metadata Type: Data element

Definition: This data item records the assigned radiotherapy targets for the primary course of care.

Justification: For patient follow-up and outcome studies.

REPRESENTATION:

Data type: Numeric

Field size: Min: 2 Max: 2

Representational format: NN

Data Domain:

Code	Description
01	breast
02	chest wall
03	axilla
04	supraclavicular fossa
05	internal mammary lymph nodes
97	primary site
98	other
99	not stated/not applicable

Guide for Use: Code all sites targeted.

Validation Rule: This data item is for both invasive cancer and in situ lesions

ADMINISTRATION:

Source organisation: NBCC, Breast Cancer Working Group on Specific Data Items for Clinical Cancer Registration

13.2 DATE OF START OF BREAST RECONSTRUCTION

Metadata Type:	Data element
Definition:	The date when the breast reconstruction was first started.
Justification:	For patient follow-up and outcome studies.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 8 Max: 8
Representational format:	DDMMYYYY
Data Domain:	Valid date
Guide for Use:	This item is to be completed only if the data element 'Breast reconstruction' is coded as '1'.
Validation Rules:	This data item is for both invasive cancer and in situ lesions
Verification Rules:	Date of breast reconstruction start must be: <ul style="list-style-type: none">• Greater than the date of diagnosis• Less than or equal to the date of death

ADMINISTRATION:

Source organisation:	NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
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13.3 INITIAL BREAST RECONSTRUCTION PROCEDURE

Metadata Type:	Data element
Definition:	The initial breast reconstruction procedural type.
Justification:	For patient follow-up and outcome studies.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 implant 2 flap 9 not known/inadequately described
Guide for Use:	This item is to be completed only if the data element 'Breast reconstruction' is coded as '1'.
Validation Rules:	This data item is for both invasive cancer and in situ lesions

ADMINISTRATION:

Source organisation:	NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
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13.4 FLAP TYPE

Metadata Type: Data element

Definition: The type of flap used in the initial breast reconstruction.

Justification: For patient follow-up and outcome studies.

REPRESENTATION:

Data type: Numeric

Field size: Min: 1 Max: 1

Representational format: N

Data Domain:

Code	Description of flap type
1	tram
2	buttock
3	breast
4	back
5	hip
8	other
9	not known/inadequately described

Guide for Use: This item is to be completed only if the data element 'Initial breast reconstruction procedure' is coded as '2'.

Validation Rule: This data item is for both invasive cancer and in situ lesions

ADMINISTRATION:

Source organisation: NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration

13.5 OTHER FLAP TYPE

Metadata Type:	Data element
Definition:	The type of flap used in the initial breast reconstruction where it is listed as 'Other' in the data element 'Flap type'.
Justification:	For patient follow-up and outcome studies.

REPRESENTATION:

Data type:	Alphanumeric
Field size:	Min: 1 Max: 20
Representational format:	AN (20)
Data Domain:	Text
Guide for Use:	This item is to be completed only if the data element 'Flap type' is coded as '8'.
Validation Rule:	This data item is for both invasive cancer and in situ lesions

ADMINISTRATION:

Source organisation:	NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
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14 ARM SYMPTOMS

Metadata Type:	Data element
Definition:	The nature and extent of any discomfort or swelling in the arm(s) associated with the current treatment episode (both surgical and non-surgical) at the review appointment.
Justification:	Lymphoedema and other discomfort may be associated with radiotherapy and axillary node dissection. This data item can be used to investigate the effect of conservative management and/or sentinel node dissection on the incidence of arm symptoms.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	1 no symptoms 2 mild symptoms 3 moderate symptoms 4 severe symptoms 5 extreme symptoms 9 unknown
Guide for Use:	Individual self-reporting of arm symptoms should be used.
Validation Rule:	This data item is for both invasive cancer and in situ lesions

ADMINISTRATION:

Source document:	RACS. The National Breast Cancer Audit. Prepared by Australia Safety & Efficacy Register of New Interventional Procedures – Surgical. Updated February 2005
Source organisations:	RACS NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration

15 LAST CONTACT

15.1 DATE OF LAST CONTACT

Metadata Type:	Data element
Definition:	The date of last contact with the patient.
Justification:	For patient follow-up and outcome studies.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 8 Max: 8
Representational format:	DDMMYYYY
Data Domain:	Valid date
Validation Rule:	This data item is for both invasive cancer and in situ lesions.
Verification Rules:	Date of last contact must be: <ul style="list-style-type: none">• Greater than date of diagnosis• Less than or equal to date of death

ADMINISTRATION:

Source document:	Commission on Cancer, Facility Oncology Registry Data Standards Revised for 2004 (FORDS)
Source organisation:	Commission on Cancer, American College of Surgeons

15.2 CANCER STATUS

Metadata Type:	Data element
Definition:	Records the presence or absence of clinical evidence of the patient's tumour as applying at the date of last contact.
Justification:	For patient follow-up and outcome studies.

REPRESENTATION:

Data type:	Numeric
Field size:	Min: 1 Max: 1
Representational format:	N
Data Domain:	0 no cancer detected 1 local recurrence 2 regional recurrence 3 distant metastasis
Guide for Use:	Code the most advanced recurrence if more than one applies
Validation Rule:	This data item is for both invasive cancer and in situ lesions

ADMINISTRATION:

Source document:	Commission on Cancer, Facility Oncology Registry Data Standards Revised for 2004 (FORDS)
Source organisations:	Commission on Cancer, American College of Surgeons NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration

15.3 DISTANT METASTASIS AT DATE OF LAST CONTACT

Metadata Type: Data element

Definition: The presence or absence of a distant metastasis of the patient's tumour as applying at the date of last contact.

Justification: For patient follow-up and outcome studies.

REPRESENTATION:

Data type: Numeric

Field size: Min: 2 Max: 2

Representational format: NN

Data Domain:

Code	Site of distant metastases
00	no distant metastases
01	lung
02	brain
03	bone
04	liver
05	ovaries
06	spinal cord
07	eye
98	other
99	not know/inadequately described

Guide for Use: Code multiple sites, if applicable.

Validation Rule: This data item is for invasive cancer only

ADMINISTRATION:

Source organisation: NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration

15.4 DATE OF DIAGNOSIS OF DISTANT METASTASIS RECORDED AT LAST CONTACT

Metadata type:	Data element
Definition:	The date a medical practitioner confirms the diagnosis of the distant metastasis recorded at last contact.
Justification:	This item is collected for determining time to distant recurrence and time from distant recurrence to death.

REPRESENTATION:

Data type:	Numeric
Field size:	MIN: 8 Max: 8
Representational format:	DDMMYYYY
Data Domain:	Valid date
Guide for Use:	This data element applies when the response to "Cancer Status" (15.2) is coded as "2"
Validation Rule:	This data item is for invasive cancer only

ADMINISTRATION:

Source organisation:	NBCC, Working Group on Breast Cancer Specific Data Items for Clinical Cancer Registration
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RECOMMENDATIONS FOR RECORDING GENERIC DATA ITEMS IN ASSOCIATION WITH SPECIALIST BREAST CANCER CLINICAL REGISTRATION

When recording the generic core data items in association with specialist breast cancer registration, it is recommended that additional details be provided for hormone receptor status and most valid basis of diagnosis, viz:

- Raw data be provided for oestrogen and progesterone receptor status (i.e., % and intensity of cell staining)
- Most valid basis of diagnosis be recorded as: (1) non-microscopic – clinical only, mammography, ultrasound, exploratory surgery or autopsy, or biochemical or immunological test; (2) microscopic – FNA, core biopsy or open biopsy; (3) death certificate only; and (4) unknown.

APPENDIX 1

EXCERPT FROM THE NATIONAL HEALTH DATA DICTIONARY VERSION 12 SUPPLEMENT¹

DATA SET SPECIFICATION (DSS) CANCER (CLINICAL)

Admin status: CURRENT 04/06/2004 **Version number:** 1

Metadata type: Data Set Specification

Start date: 04/06/2004

Scope: This cancer (clinical) data set specification is not mandated for collection but is recommended as best practice if cancer clinical data are to be collected. The cancer (clinical) data set underpins the evaluation of cancer treatment services and this can occur at a number of levels; i.e., at the individual clinician, the health care institution, and state or territory level, and at a national level. Clinicians use such data for ongoing patient management. The ability to link patient management to outcomes allows treatments or outcomes to be identified and assessed. Institutions can monitor throughput in their centres for planning and resource allocation purposes, in order to obtain optimum return for cancer expenditure. Endpoints can be monitored to ensure that objectives are being met. The principal aim of good quality and consistent data is to provide information that can lead to improved quality and length of life for all patients by providing a systematic foundation for evidence-based medicine, informing quality assurance and improvement decisions, and for guiding successful planning and evaluation of cancer control activities.

Collection methodology: This data set is primarily concerned with the clinical use of cancer data. It can also be used by a wider range of health and health-related establishments that create, use, or maintain records on health-care clients.

Data elements included:

Address line, version 1
Cancer initial treatment — completion date, version 1
Cancer initial treatment — starting date, version 1
Cancer staging — M stage code, version 1
Cancer staging — N stage code, version 1
Cancer staging — T stage code, version 1
Cancer staging— TNM Stage grouping code, version 1
Cancer treatment type, version 1
Cancer treatment — target site, version 1
Date of birth, version 5
Date of death, version 1
Date of diagnosis of cancer, version 1
Date of diagnosis of first recurrence, version 1

¹ Health Data Standards Committee 2004. Data Set Specification, Cancer (clinical), National Health Data Dictionary Version 12, Supplement. AIHW Cat. No. HWI 71. Canberra: Australian Institute of Health and Welfare.

Date of surgical treatment for cancer, version 1
Establishment number, version 4
Family name, version 2
Given name(s), version 2
Histopathological grade, version 1
Intention of treatment for cancer, version 1
Laterality of primary cancer, version 1
Medicare card number, version 2
Morphology of cancer, version 1
Most valid basis of diagnosis of cancer, version 1
Oestrogen receptor assay status, version 1
Outcome of initial treatment, version 1
Person identifier, version 2
Primary site of cancer, version 1
Progesterone receptor assay status, version 1
Radiotherapy treatment type, version 1
Received radiation dose, version 1
Region of first recurrence, version 1
Regional lymph nodes examined, version 1
Regional lymph nodes positive, version 1
Sex, version 4
Staging basis, version 1
Staging scheme source, version 1
Staging scheme source edition number, version 1
Surgical treatment procedure for cancer, version 1
Systemic therapy agent name, version 1
Tumour size at diagnosis – solid tumours, version 1
Tumour thickness at diagnosis – melanoma, version 1

APPENDIX 2

CLINICAL CANCER REGISTRATION DATA ITEMS - BREAST CANCER (INVASIVE CANCER & IN SITU LESIONS)

GENERIC PLUS SPECIALIST ITEMS (IN BRACKETS)

Provider data:

Establishment number

Patient data:

Person id number

Family name, given name(s)

Medicare card number

Residential address

Sex – male/female

Birth date

Death date

Cause of death (ICD 10)*

(Indigenous status)

(Menopausal status – pre/post/peri)

(Presentation data:)

(Initial presentation)

Diagnostic data:

Diagnosis date

Performance status at diagnosis – ECOG*

Most valid basis of diagnosis

Primary site of cancer

Laterality

Morphology of cancer (ICDO)

TNM stage grouping (0-IV, plus subgroups)

T, N, and M codes

(Distant metastases – organ sites)

Staging basis – pathological/clinical

Staging scheme source and source edition number

Histopathological grade

Tumour size

(Presence of DCIS in breast tissue adjacent to invasive cancer)

(Lymphovascular invasion)

(HER2 status/test type)

Number of regional lymph nodes examined

Number of regional lymph nodes positive

(Sentinel lymph node – attempted identification/method used/sentinel node identified/extent of cancer in sentinel node)

Oestrogen receptor assay status

Progesterone receptor assay status

Treatment data (primary course):

(Clinical trial enrolment)

Surgery:

Date

Intent – prophylactic/curative/non-curative (includes palliative)

Procedure – ICD10 procedure code

Target site

(Surgical margin clearance – inv/DCIS)

(Surgical margin involvement – inv/DCIS)

Radiotherapy:

Starting date

Intent – prophylactic/curative/non-curative (includes palliative)

Type – external beam/brachytherapy/unsealed radioisotopes

Target site

Dose – eg, as indicated by ICRU50(photon)/ICRU58(brachytherapy)

Completion date

Systemic therapy:

Starting date

Intent – prophylactic/curative/non-curative (palliative)

Agent – SEER codes (i.e., for hormone therapy/chemotherapy/targeted therapy)

Completion date

Outcome of initial treatment:

Complete response/incomplete response (partial response/stable or static disease/progressive disease)

First recurrence/relapse:

Date of diagnosis

Region (local/regional/distant)

(Breast reconstruction:)

(Starting date)

(Initial reconstruction procedure)

(Flap type)

(Arm symptoms:)

(Symptoms at review appointment – mild/moderate/severe/extreme)

(Last contact:)

(Date of last contact)

(Cancer status – none detected/local/regional/distant)

(Distant metastasis – organ sites)

(Date of diagnosis of distant metastasis recorded at last contact)

* Data item included by NCCI in initial data set but excluded from National Health Data Dictionary