Australian Government

Cancer Australia
National Centre for
Gynaecological Cancers

NATIONAL BREAST
AND OVARIAN
CANCER CENTRE

Summary Report

Development of a Minimum Data Set - Gynaecological Cancers

June 2008

CONTENTS

Background

There is a lack of consistency in the collection of data about gynaecological cancers in Australia. Inconsistent data hinder the establishment of evidence-based national benchmarks and comparative analyses of data from different collections for service planning, evaluation, quality assurance and research. At the first meeting of the National Working Group for Gynaecological Cancers held in June 2007, advice was provided to Cancer Australia that priority should be given to the development of a national data set for gynaecological cancers. It is envisaged that this will result in greater national consistency in the collection of gynaecological cancer statistics by specialists in Australia.

In September 2007, National Breast Cancer Centre* was contracted by the National Centre for Gynaecological Cancers (NGCC), Cancer Australia, to develop data sets for ovarian, cervical and endometrial cancer.

Ovarian, cervical and endometrial cancers have been selected as they represent the three most common gynaecological cancers in women in Australia and are responsible for most of the deaths from gynaecological cancer.

** In February 2008 National Breast Cancer Centre (NBCC) changed its name to become National Breast and Ovarian Cancer Centre (NBOCC).*

Role of minimum data set for gynaecological cancers

The data items are intended for clinical rather than population-based cancer registration. The primary purpose behind the development of the data items is monitoring patterns of care against guidelines for best practice, although clinical and translation research applications would also apply. If a uniform set of agreed data items is used for collection, this will improve quality assurance practice and facilitate benchmarking.

The intention of the project was to avoid duplication of existing datasets in gaining national imprimatur for a sub-set of specialist data items. The sub-set of specialist data items are intended to supplement the existing minimum data set for clinical cancer data collections, developed under the aegis of the National Cancer Control Initiative (NCCI). In developing these data items the need to only include those items considered critical, and thereby provide a minimum data set was recognised.

Approach
National Breast and Ovarian Cancer Centre sourced staff from the project from current employees, with input to the drafting of the data definitions from an external data manager.

A multidisciplinary Working Group, representing national interests and expertise, was established to oversee the development of the data items. The Group was chaired by Professor David Roder. In consultation with Cancer Australia, A consumer representative was also chosen, as well as representatives from relevant disciplines, including gynaecological oncology, medical oncology, radiation oncology and pathology, were invited to join the Working Group. In addition, representatives from other groups that have also undertaken work in developing data items for gynaecological cancers were included, to promote efficiencies and to avoid duplication. (A list of Working Group members and the terms of reference are provided as Appendices 1 and 2).

Data items
In developing the data items, a number of documents were reviewed in order to avoid duplication and to ensure consistency in data collection. These included:

- The existing generic data items developed for clinical cancer data collections by the National Cancer Control Initiative (NCCI)
- The International Federation of Gynaecology and Obstetrics (FIGO) data items
- The NSW Clinical Cancer Data Extensions – Gynaecology Oncology
- Technical report – NBCC Consistency of Ovarian Cancer Clinical Databases Survey, 2007

For the first meeting of the Working Group held in Sydney on 27 November 2007, 102 data items were reviewed for possible inclusion. After input from members, and further review, a draft minimum data set of 26 items was identified. These 26 items were sent to members for further review and sign off. The draft list of data items for stakeholder review was agreed at a teleconference held in February 2008, subject to subsequent comparison with items developed by FIGO to ensure that no relevant FIGO items had been omitted.

The amended draft data items were made available to identified key stakeholders for review. (See Appendix 3 for a list of stakeholders). Comments were sought using a standardised feedback form. (See Appendix 4). Comments from the stakeholder review were considered by working group members at a meeting held in Sydney in April 2008.

Following comments received from radiation oncologists around the proposed radiotherapy data item, it was agreed by the working group that additional feedback from radiation oncologists would be sought.

The purpose of the additional consultation was to seek input about suggestions put forward during the consultation process. Six radiation oncologists from across Australia were canvassed as part of this review. (See Appendix 3). The Chair also undertook additional individual consultations to inform the development of the data definition for the radiotherapy data item. The final list of data items, agreed by members, is provided as Appendix 5.

Data dictionary definitions

Following agreement on the specialist data items for ovarian, cervical and endometrial cancers, draft data dictionary definitions were developed. Where data definitions existed these were incorporated; where no definitions existed, these were developed, with feedback from Working Group members.

Feedback provided as part of the review process and working group discussion indicated that the forthcoming review of the existing generic minimum data set should consider the following data items:

- Indigenous status
- Method of detection/diagnosis of first recurrence/relapse
- Organ site for distant recurrence/relapse

Feedback from the review of proposed radiotherapy data item(s) from radiation oncologists indicated some issues around the fields and definitions that should also be considered as part of the generic data set review. The radiotherapy item included in the specialist minimum data set covers only targeted sites. The dose for each site can be included in the revision of the generic clinical data collection.

The data dictionary definitions are provided as Appendix 6.

Pilot process

While the piloting of the data items and data definitions did not fall within the scope of this project, it was agreed that NBOCC provide some information about how a pilot may be undertaken, and identify possible issues that may impact on the pilot. Additional work on data dictionary definitions and piloting may be undertaken as a subsequent project by Cancer Australia in 2008-2009. At the meeting held in Sydney in April 2008, working group members were invited to comment on issues around the implementation of the minimum data set.

Possible issues arising from pilot

One of the key issues in any discussion about data collection and standardisation is resources, in particular funding to support data managers. There is no universal or standard approach to the funding of data managers for clinical databases. Some centres have funding available for data managers; and others do not. In some cases, a data manager is funded for a specific study or pilot but not on an on-going basis. A lack of clinical expertise may also impact on data collection if there is insufficient clinician time available to ensure accuracy of data.

The Victorian Cancer Outcomes Network (VCON) has been running a pre-trial pilot to test capacity around the collection and analysis of additional clinical treatment information based on the National Health Data Dictionary Version 12 Supplement Data Set Specification Cancer (Clinical) (DSSC) at the Royal Women's Hospital (RWH) in Melbourne. The interim report from the pre-trial has identified issues around resourcing and funding. The amount proposed by the Ministerial Task Force for Cancer for funding of RWH for the pre-trial pilot was $50,000, of which $30,000 was allocated for data management. [2]

Data from the pre-trial pilot at RWH also shows data management support of 0.6 FTE is required to fully capture the DSSC data for gynaecological cancer cases at one hospital. Results indicate that the expected recurrent data management support costs to fully capture the complete DSSC data for gynaecological cancer at one hospital site is approximately $55,000 per annum. [2]

System issues are also likely to impact on data collection, with a lack of consistency in software systems and formats. In the longer term, issues around the transfer of data and the move from individual to a national system will need to be addressed.

Other issues include:

- Lack of information/data transfer across sectors e.g. private and public systems
- Lack of information/data transfer across locations e.g. metropolitan, regional or remote locations
- Ambiguity in data items or unclear data definitions
- Lack of synoptic reporting

Outcome measures
Outcome measures of interest from the pilot process may include:

- Percentage completion for each data item
- Comparison of completion rates between sub-set of specialist gynaecological cancer data items and existing generic items
- Feedback on lack of completeness to identify barriers to completion
- Analysis of data completeness by location e.g. by state, area or gynaecological cancer centre

APPENDICES

Appendix 1
Gynaecological Cancer Data Items - Working Group

Professor David Roder (Chair)	Manager, Population Health National Breast and Ovarian Cancer Centre
Ms Stephanie Alvarez	Consumer Representative, Western Australia
Mr Neville Board	Clinical Information Manager, Cancer Institute NSW, NSW
Professor Jonathan Carter	Gynaecological oncologist, Area Head Gynaecology and Gynaecological Oncology Services, Sydney South West Area Health Service, NSW
Associate Professor Margaret Davy AM	Gynaecological oncologist, Director, Department of Gynaecological Cancer, Royal Adelaide Hospital, SA
Dr Anna de Fazio	Head, Gynaecological Oncology Research Group, Westmead Institute for Cancer Research, Westmead Hospital, NSW
Professor Tom Dodd	Head, Tissue Pathology, Institute of Medical and Veterinary Sciences, Adelaide, SA
Professor Neville Hacker	Gynaecological oncologist, Director, Centre for Gynaecological Cancer, Royal Women's Hospital, Sydney, NSW
Professor Ian Olver	Medical oncologist, CEO, Cancer Council Australia, National
Dr Greg Robertson	Gynaecological oncologist, Chair, Cancer Institute NSW Gynaecological Cancer Data Items Working Group, NSW
Ms Margot Osinski	Data Manager, Oncology/Dysplasia Unit, Royal Women's Hospital, Parkville, VIC. Past Chair of the ANZGOG Data Manager Group,
Professor Michael Quinn	Gynaecological oncologist, Member, National Working Group, National Centre

	for Gynaecological Cancers, Cancer Australia
Dr John Ward	Director, Radiation oncology, Royal Hobart Hospital, TAS
Dr Penny Webb	Epidemiologist, Senior Research Fellow, Queensland Institute of Medical Research
NBOCC staff	
Dr Helen Zorbas	Director
A/Professor Christine Giles	General Manager
Ms Jane Francis	Program Co-ordinator
Ms Ornella Care	Senior Project Officer
National Gynaecological Cancer Centre (NCGC) staff Ms Bernadette Loughrey	Project Manager

Appendix 2
Terms of reference for the Gynaecological Data Items Working Group

Background

The National Breast Cancer Centre has been contracted by Cancer Australia to develop data sets for ovarian, cervical, and endometrial cancer. The development of these data sets will result in greater national consistency in the collection of gynaecological cancer statistics for specialists in Australia.

Terms of reference

Terms of reference are to:

- provide input into the development of a draft set of ovarian, cervical and endometrial cancer specific data items
- provide advice about the number of data items that should be included and propose the most appropriate items
- provide input into the development of data dictionary definitions for these items.

Appendix 3
Stakeholder consultation
List of stakeholders

Cancer Australia Research Group

State and territory cancer councils

The Cancer Council Australia

Australasian Association of Cancer Registries (AACR)

State Cancer Registries

Queensland Cancer Control Analysis Team: Shoni Colquist

AIHW Health Register and Cancer Monitoring Unit

WA Cancer Services Task Force

Cancer Institute NSW (Professor Jim Bishop)

The National Safety and Quality Commission in Health Care-Professor Chris Baggoley

The Australasian Biospecimen Network (Anna de Fazio)

The Royal Australian and New Zealand College of Gynaecologists and Obstetricians (RANZCOG)

Australian New Zealand Gynaecological Oncology Group (ANZGOG) (Professor Michael Friedlander- retiring Chair)

The Royal Australian and New Zealand College of Radiologists (RANZCR)

Royal College of Pathologists Australasia (RCPA)

Cancer Nurses Society Australia (CNSA)

Medical Oncology Group of Australia (MOGA)

Clinical Oncological Society of Australia (COSA)

All Certified Practising Gynaecological Oncologists

OvCa Australia

Gynaecological Awareness Information Network (GAIN)

Cancer Australia consumer group

Current stakeholders of Cancer Victoria GOP

Dr Danny Rischin, Peter MacCallum Cancer Centre

Stakeholders who requested to review data items or provided comment

Cancer Registries

Western Australian Cancer Registry

Consumers

Margaret E Heffernan (member of the Cancer Australia WGGC)

Data Managers

Dan Jackson, QLD

Nurses

Helen Green, WA

Radiation oncologist

Dr Mike Poulsen, QLD

Associate Professor Andrew Miller, NSW

Dr Maitham Mathlum, VIC

Dr Shalini Vinod, NSW

Gynaecological oncologist

Dr Russell Hogg, NSW

Dr Christopher Dalrymple, NSW

Dr Christine Tippett, President RANZCOG

Additional radiation oncologist review

Dr David Bernshaw, VIC

A/ Professor Kailash Narayan, VIC

Dr Robyn Cheuk, QLD

Dr Viet Do, NSW

Dr Chris Milross, NSW

Dr Colin Bull, NSW

Appendix 4
Stakeholder Consultation

National Breast and Ovarian Cancer Centre (NBOCC) and National Centre for Gynaecological Cancers Gynaecological (NCGC) minimum data set

Stakeholder consultation

Briefing note for stakeholders

National Breast and Ovarian Cancer Centre (NBOCC) would like to invite you to provide comment on the NBOCC and NCGC proposed national gynaecological minimum data set.

What is the purpose of the stakeholder consultation?

The purpose of the stakeholder consultation is to ensure the proposed national minimum data set for gynaecological cancers encompasses all relevant areas and data items.

What is the purpose/intention of the gynaecological minimum data set?

The intention for the data set is to create national consistency in the collection of gynaecological cancer statistics. National consistency in clinical cancer registration data will facilitate establishment of evidence-based national benchmarks and comparative analyses of data from different collections for service planning, evaluation, quality assurance and research.

The data items are intended to be clinical rather than population–based and the primary purpose of the data set is not for research, although it may be useful in some instances, such as monitoring patterns of care.

Once the items are finalised, data dictionary definitions will be developed. A process will then be implemented for piloting the items and data dictionary definitions.

How was the gynaecological minimum data set developed?

In 2007, NCGC, Cancer Australia, contracted NBOCC to develop data sets for ovarian, cervical, and endometrial cancer. A national multidisciplinary working group has been established consisting of gynaecological oncologists, medical oncologist, pathologists and consumer representation.

In developing the minimum data set, a number of documents have been reviewed in order to avoid duplication and to ensure consistency in data collection including the existing NCCI generic data items and the International Federation of Gynaecology and Obstetrics (FIGO).

FEEDBACK FORM

Thank you for agreeing to review the proposed gynaecological minimum data set. Please complete the following details to assist the National Breast and Ovarian Cancer Centre (NBOCC).

Reviewer details

Name _____ Discipline _____

Organisation _____

State _____ Phone_____

Email_____

Following review of the proposed minimum data set, please answer the following questions (you are welcome to write comments on the data set and return to the NBOCC).

1. Are there any ambiguous items in the data set? ☐ Yes ☐ No

Please comment:

_____

_____

_____

2. Are there any omitted areas or gaps? ☐ Yes ☐ No

Please comment:

_____

_____

_____

3. Do you have any significant issues or concerns regarding the proposed minimum data set?

   ☐ Yes ☐ No

Please comment

_____

_____

_____

4. Any other comments?

_____

_____

_____

_____

_____

Many thanks for your consideration of this request; we look forward to receiving your comments.

Please forward your comments to:

Ms Ornella Care, Senior Project Officer by COB Monday 31 March 2008 either by

e-mail: ornella.care@nbocc.org.au, or fax: 02 9357 9477.

Appendix 5
Final data items for ovarian, cervical and endometrial cancer

The list of final data items are as follows:

CANCER RELATED:

- Cytology result (corpus uteri/cervix)
- Lymphovascular invasion
- FIGO stage
- Distant metastatic site(s)
- Depth of myometrial involvement/invasion of cervical cancer (corpus uteri/cervix)
- Tumour size outside ovary (ovary)
- Synchronous primary tumour
- Tissue locator

TREATMENT RELATED:

- Surgeon type
- Residual post-surgery

- Radiotherapy- targeted by sites
- Treatment complications (primary course):
    - Surgical
    - Radiotherapy
    - Systemic therapy
- First recurrence treatment:
    - Surgery
    - Radiotherapy
    - Chemotherapy
    - Hormone therapy
    - Other
    - Treatment outcome

FOLLOW-UP:

- Date of last contact

Generic data items plus proposed data items (in brackets)

Provider data:

Establishment number

Patient data:

Person id number

Family name, given name(s)

Medicare card number

Residential address

Birth date

Death date

Cause of death (ICD 10)*

Diagnostic data:

Diagnosis date

Performance status at diagnosis – ECOG*

Most valid basis of diagnosis

Primary site of cancer

Laterality

Morphology of cancer (ICDO)

(Cytology result (corpus uteri/cervix)

(Lymphovascular invasion)

(FIGO Stage)

(Distant metastases(s))

Staging basis – clinical/surgical

Staging scheme source and source edition number

(Depth of myometrial involvement/invasion of cervical cancer (corpus uteri/cervix))

Histopathological grade

Tumour size

(Tumour size outside ovary (ovary))

Number of regional lymph nodes examined

Number of regional lymph nodes positive

Oestrogen receptor assay status

Progesterone receptor assay status

(Synchronous primary tumour)

(Tissue locator)

Treatment data (primary course):

(Surgeon type)

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

Surgery:

Date

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

Procedure – ICD10 procedure code

Target site

(Surgery outcome:

(Residual post-surgery)

Radiotherapy:

Starting date

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

Type – external beam/brachytherapy/unsealed radioisotopes

Target site

Dose – e.g., as indicated by ICRU50 (photon)/ICRU58^ (brachytherapy)

(Radiotherapy by targeted sites)

Completion date

Systemic therapy:

Starting date

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

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

Completion date

(Treatment complications (primary course):

- Surgical
- Radiotherapy
- Systemic therapy)

Outcome of initial treatment:

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

First recurrence/relapse:

Date of detection/diagnosis

Region (local/regional/distant

Treatment data (for first recurrence of cases gaining complete remission following primary course of care)

(First recurrence treatment:

- *Surgery*
- *Radiotherapy*
- *Chemotherapy*
- *Hormone therapy*
- *Other*
- *Treatment outcome)*

Follow-up:

(Last contact :)

(Date of last contact)

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

^ Note this should read ICRU38

APPENDIX 6
Data definitions

Data Definitions

Cancer related

Cytology (corpus uteri/cervix)	
Metadata type: Data element	
Definition: Cytology is the microscopic analysis of cells.	
Justification: Collected for survival analysis and to help define the proportion of cancer morphologically verified.	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	00 Unknown/not available 01 Negative 02 Positive
Guide for use	

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology & Obstetrics 2003, 83(Supp 1): 1-230.

Lymphovascular invasion - corpus uteri and cervix	
Metadata type: Data element	
Definition: Tumour invasion of the lymphatic vascular space	
Justification: Invasion of lymphatic vascular space is a predictor of lymph node metastasis and recurrence.	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	00 No lymphovascular invasion present 01 Lymphovascular invasion present 09 Not known
Guide for use	

Reference:

GMCT Gynaecology Oncology Information Management Group.

FIGO surgical stage Cervical cancer (Carcinoma of the Cervix Uteri)	
Metadata type: Data element	
Definition: Defines the surgical staging for cervical cancer	
Justification: Stage is an important prognostic indicator.	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Stage Ia 02 Stage Ib 03 Stage Ic 04 Stage IIa 05 Stage IIb 06 Stage IIIa 07 Stage IIIb 08 Stage IIIc 09 Stage IVa 10 Stage IVb 11 Not available
Guide for use	**FIGO stage should be filled out according to 1994 definitions. Data on patients affected by Stage 0 disease will not be collected.** **Stage I The carcinoma is strictly confined to the cervix (extension to the corpus would be disregarded).** Ia Invasive carcinoma which can be diagnosed only by microscopy. All microscopically visible lesions – even with superficial invasion – are allotted to Stage 1B carcinomas. Invasion is limited to a measured stromal invasion with a maximal depth of 5.0mm and a horizontal extension of not >7.0mm. Depth of invasion should not be> 5.0mm taken from the base of the epithelium of the original tissue – superficial or glandular. The involvement of vascular spaces – venous or lymphatic – should not change the allotment. Ia1 Measured stromal invasion of not >3.0mm in depth and extension of >7.0mm

	Ia2 Measured stromal invasion of >3.0mm and not>5.0mm with an extension of not >7.0mm Ib Clinically visible lesions limited to the cervix uteri or preclinical cancers greater than Stage 1a. Ib1 Clinically visible lesions not >4.0mm. Ib2 Clinically visible lesions >4.0mm. **Stage II Cervical carcinoma refers to lesions that have invaded beyond the uterus, but not to the pelvic wall or to the lower third of the vagina.** IIa No obvious parametrial involvement IIb Obvious parametrial involvement **Stage III The carcinoma has extended to the pelvic wall. On rectal examination, there is no cancer-free space between the tumour and the pelvic wall. The tumour involves the lower third of the vagina. All cases with a hydronephrosis or non-functioning kidney should be included, unless they are known to be due to other cause.** IIIa Tumour involves lower-third of the vagina, with no extension to the pelvic wall IIIb Tumour has extended to the pelvic wall and/or there is hydronephrosis or a non-functioning kidney **Stage IV The carcinoma has extended beyond the true pelvis or has involved (biopsy-proven) the mucosa of the bladder or rectum. A bulbous edema, as such, is insufficient evidence for a case to be allotted to Stage IV.** IV a Spread of the growth to adjacent organs IVb Spread to distant organs

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology & Obstetrics 2003, 83(Supp 1): 1-230.

FIGO surgical stage Endometrial cancer (Carcinoma of the Endometrium)	
Metadata type: Data element	
Definition: Defines the surgical staging for endometrial cancer	
Justification: Staging is an important prognostic indicator	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Stage Ia 02 Stage Ib 03 Stage Ic 04 Stage IIa 05 Stage IIb 06 Stage IIIa 07 Stage IIIb 08 Stage IIIc 09 Stage IVa 10 Stage IVb 11 Not available
Guide for use	**FIGO stage should be filled out according to the 1988 definitions (surgical staging)** Stage Ia Tumour limited to endometrium Stage Ib Invasion <½ myometrium Stage Ic Invasion to >½ myometrium Stage IIa Endocervical glandular involvement only Stage IIb Cervical stromal invasion Stage IIIa Tumour invaded the serosa of the corpus uteri and/or adnexae and/or positive peritoneal cytological findings Stage IIIb Vaginal metastases

	Stage IIIc Metastases to pelvic and/or paraortic lymph nodes Stage IVa Tumour invasion of bladder and/or bowel mucosa Stage IVb Distant metastases, including intra-abdominal and/or inguinal lymph nodes

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology & Obstetrics 2003, 83(Supp 1): 1-230.

FIGO surgical stage Ovarian cancer (Carcinoma of the ovary)	
Metadata type: Data element	
Definition: Defines the surgical staging for ovarian cancer	
Justification: Staging is an important prognostic indicator	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Stage Ia 02 Stage Ib 03 Stage Ic 04 Stage IIa 05 Stage IIb 06 Stage IIc 07 Stage IIIa 08 Stage IIIb 09 Stage IIIc 10 Stage IV 11 Not available
Guide for use	**The FIGO stage section should be filled out according to the 1988 definitions (surgical staging)** **Stage I (Growth limited to the ovaries)** Ia Tumour limited to one ovary; no ascites present containing malignant cells. No tumour present on external surface; capsule intact Ib Tumour limited to both ovaries; no ascites containing malignant cells; No tumour on external surface; capsule intact Ic* Tumour meets criteria for Stage Ia or Ib, but with tumour on surface of one or both ovaries, or with capsule ruptured, or with ascites present containing malignant cells, or with positive peritoneal washings **Stage II Tumour involving one or both ovaries with pelvic extension**

	IIa Extension and/or metastases to the uterus and/or tubes IIb Extension to other pelvic tissues IIc* Meets criteria for Stage IIa or IIb, but also with tumour on surface of one or both ovaries; or with capsule(s) ruptured; or with ascites present containing malignant cells or positive peritoneal washings **Stage III Tumour involving one or both ovaries with histologically confirmed peritoneal implants outside the pelvis and/or positive retroperitoneal or inguinal nodes. Superficial liver metastases apply for Stage III. Tumour is limited to the true pelvis, but with histologically proven malignant extension to the small bowel or omentum.** IIIa Tumour grossly limited to the true pelvis with negative nodes, but with histologically confirmed microscopic seeding of abdominal peritoneal surfaces, or histologically proven extension to the small bowel or mesentery IIIb Tumour of one or both ovaries with histologically confirmed implants, peritoneal metastasis of abdominal peritoneal surfaces, none exceeding 2 cm in diameter; nodes are negative IIIc* Peritoneal metastasis beyond the pelvis > 2 cm in diameter and/or positive retroperitoneal or inguinal nodes **Stage IV Tumour involving one or both ovaries with distant metastases. If pleural effusion is present, there must be positive cytology to allot a case to Stage IV. Parenchymal liver metastases indicate Stage IV.**

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology & Obstetrics 2003, 83(Supp 1): 1-230.

Distant metastatic site(s)	
Metadata type: Data element	
Definition: The presence or absence of distant metastases/metastatic sites.	
Justification: For assessing predictive effects on survival	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Lung 02 Liver 03 Bowel 04 Bone 05 Brain 06 Other (specify) 07 Not present
Guide for use	Ovary – Stage IV applies when one or both ovaries have cancers with distant metastases. Parenchymal liver metastases indicate Stage IV. Endometrium – Distant metastases are those occurring outside the uterine serosa, including those in the vagina, adnexae, bladder/bowel mucosa or intra-abdominal, inguinal lymph nodes.

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology & Obstetrics 2003, 83(Supp 1): 1-230.

Depth of myometrial involvement	
Metadata type: Data element	
Definition: Defines the level of myometrial invasion	
Justification: Depth of myometrial invasion is a prognostic factor for endometrial cancer	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Histologically negative myometrial invasion 02 Myometrial invasion < or = ½ 03 Myometrial invasion > ½
Guide for use	

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology & Obstetrics 2003, 83(Supp 1): 1-230.

Depth of invasion - cervical cancer	
Metadata type: Data element	
Definition: Defines depth of invasion of tumour	
Justification: A prognostic indicator for cervical cancer	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	Depth of invasion in millimetres (two digit number)
Guide for use	All macroscopically visible lesions, even with superficial invasion, are allocated to Stage Ib carcinomas.

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology & Obstetrics 2003, 83(Supp 1): 1-230.

Tumour size outside ovary	
Metadata type: Data element	
Definition: Size of the tumour outside the ovary at the opening of the abdomen.	
Justification: Although extra-ovarian tumour size is not used the staging process is a major prognostic factor.	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	00 No macroscopic disease 01 < or = 2 cm 02 between 2 cm and 10 cm 03 > or = 10 cm
Guide for use	Applies to patients treated initially with surgery.

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology & Obstetrics 2003, 83(Supp 1): 1-230.

Synchronous primary tumour	
Metadata type: Data element	
Definition: Simultaneous primary tumours at different sites.	
Justification: A prognostic indicator	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Synchronous primary tumour present 02 No synchronous primary tumour 03 Not known
Guide for use	

Reference:

Commission on Cancer. Facility Oncology Registry Data Standards (FORDS). Revised for 2007.

Tissue locator	
Metadata type: Data element	
Definition: Submission of tissue specimen to tissue bank.	
Justification: For research information	
Representation	
Data type	Alpha/Numeric
Field size	Numeric Min: 2 Max: 2 Alpha -characters as required
Representational format	NN plus alpha for tissue bank site
Data Domain:	01 Tissue sent to tissue bank Tissue bank location(specify)_____ 02 No tissue sent to tissue bank 03 Not known
Guide for use	Location of tissue bank to be specified

Reference:

Treatment related

Surgeon type	
Metadata type: Data element	
Definition: Specialty of surgeon performing initial surgery	
Justification: Provides data about patterns of care/management.	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Gynaecological oncologist 02 Gynaecologist 03 General surgeon 04 Other 05 Not available
Guide for use	**Gynaecological oncologist:** A specialist in obstetrics and gynaecology, awarded the Fellowship of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), having completed a formal three-year training program in gynaecological cancer care and passed the examination for the Certificate of Gynaecological Oncology CGO). **Gynaecologist:** A specialist in obstetrics and gynaecology awarded the Fellowship of RANZCOG, having completed advanced training prescribed or approved by the Council and who furnish to the Council satisfactory evidence of completion of such advanced training. **General Surgeon:** A specialist in surgery, having satisfactorily undertaken the Royal Australasian College of Surgeons (RACS) Fellowship Examination to ensure that attainment of Fellowship standards. **Other:** Other medical practitioners with no specialist surgical/gynaecological cancer training

Reference:

Australian Cancer Network and National Breast Cancer Centre. Clinical practice guidelines for the management of women with epithelial ovarian cancer. NBCC. 2004

Royal Australasian College of Surgeon (RACS) and Royal Australian College of Obstetricians and Gynaecologists

Tumour residual post-surgery	
Metadata type: Data element	
Definition: Tumour residual remaining after initial surgery	
Justification: A prognostic indicator.	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	00 No microscopic residual disease 01 Microscopic but no macroscopic residual disease 02 Residual tumour < 0.5 cm 03 Residual tumour between 0.5 cm and 1 cm 04 Residual tumour between 1 cm and 2 cm 05 Residual tumour > 2 cm 06 Not applicable 07 Not known/not able to be assessed
Guide for use	Based on diameter of largest residual implants For ovarian cancer and stage IV endometrial cancer but not for cervical cancer.

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology & Obstetrics 2003, 83(Supp 1): 1-230.

Radiotherapy - dose by site	
Metadata type: Data element	
Definition: Primary site of radiotherapy	
Justification: Used to record information about site and dose to reflect contribution of radiotherapy in treatment and outcomes based on treatment.	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Primary site only 02 Primary site and pelvis 02 Pelvis and para-aortics 04 Whole abdominal radiotherapy (WART) 05 Other
Guide for use	

Reference:

Feedback from radiation oncologists as part of stakeholder review

Commission on Cancer. Facility Oncology Registry Data Standards (FORDS). Revised for 2007. American College of Surgeons.

Treatment complications - surgical	
Metadata type: Data element	
Definition: Critical events within 30 days of primary surgery	
Justification: For monitoring side effects of surgical treatment	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Unplanned return to theatre 02 Death within 30 days of surgery 03 Post-operative fistula 04 Intra-operative haemorrhage (>6 units of transfusion) 05 Pulmonary embolism 06 Unplanned transfer to ICU 06 Post-operative stay >21 day 07 Other (specify)
Guide for use	More than one item may be selected.

Reference:

Gynaecology Oncology Subspecialty Practice Improvement Critical Project (GO SPICE)

Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG).

Treatment complications - radiotherapy	
Metadata type: Data element	
Definition: Short-term toxicity/complications from primary course of radiotherapy	
Justification: For monitoring side effects of radiotherapy in 30 days post-treatment.	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Bowel obstruction requiring surgery 02 Fistula requiring stoma formation 03 Pelvic insufficiency 04 Other (specify) 05 No complications
Guide for use	More than one item can be selected.

Reference:

Treatment complications - Systemic therapy	
Metadata type: Data element	
Definition: Complications from systemic therapy given as a primary course of treatment	
Justification: Collected to record short-term complications from systemic treatment.	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Bone marrow suppression requiring dose change 02 Bone marrow suppression requiring delay in treatment 03 Toxicity requiring admission 04 Other (specify) 05 No complications
Guide for use	Systemic therapy encompasses - chemotherapy, hormone therapy and immunotherapy.

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology and Obstetrics 83 (supp 1): 1-230. 2003

Commission on Cancer. Facility Oncology Registry Data Standards (FORDS). Revised for 2007. American College of Surgeons.

Treatment - first recurrence	
Metadata type: Data element	
Definition: Therapy used to treat first recurrence of tumour	
Justification: To assess outcomes by treatment of first recurrence	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	00 No treatment 01 Surgery 02 Chemotherapy 03 Radiotherapy 04 Hormone therapy 06 Surgery plus chemotherapy 07 Surgery plus radiotherapy 08 Chemotherapy plus radiotherapy 07 Other (specify)
Guide for use	For first recurrence of cases gaining complete remission following primary course of care

Reference:

Pecorelli, S. 25th Annual Report on the Results of Treatment in Gynecological Cancer. International Journal of Gynecology and Obstetrics 83 (supp 1): 1-230. 2003

Based on FIGO field for treatment at relapse.

Outcome of treatment for first recurrence	
Metadata type: Data element	
Definition: Defines response to treatment for first recurrence (defined as cases gaining complete remission following primary course of care)	
Justification: Collected for analysis of outcome by treatment	
Representation	
Data type	Numeric
Field size	Min: 2 Max: 2
Representational format	NN
Data Domain:	01 Complete response 02 Partial response 03 Stable disease 04 Progressive disease 05 Not assessable 06 Unknown
Guide for use	Complete response - no measurable or evaluable disease for at least four weeks. No new lesions or new evidence of disease. Partial response - A decrease of at least 50% of the sum of the products of the maximum diameter of all measurable lesions for at least four weeks. No new lesions or worsening of evaluable disease. Stable disease - No change in measurable lesions qualifying as partial response or progression and not evidence of new lesions Progressive disease - An increase of at least 25% of the sum of the products of the maximum diameter and a perpendicular diameter of any measurable lesion or appearance of new lesions (measurable or palpable). Not assessable - not assessable

Reference:

NSW Clinical Cancer Registry: Gynaecology Draft Data Set

Follow up

Date of last contact	
Metadata type: Data element	
Definition: Date of last contact with patient.	
Justification: For assessing survival and other clinical outcomes	
Representation	
Data type	Numeric
Field size	Min:8 Max: 8
Representational format	DDMMYY
Data Domain:	Valid date
Guide for use	Date must be greater than date of last follow up.

Reference:

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

Notes:

Data item format

Data items have been described defining characteristics. The components included under these section headings are based on NHDD standards as described below:

Defining characteristics

Metadata Type

Data items in this dictionary are presented as Data Elements – a unit of data for which the definition, identification, representation and permissible values are specified by means of a set of attributes.

Definition

A statement that expresses the essential nature of a data element and its differentiation from all other data elements.

Justification

The reason for collecting this data element.

REPRESENTATION:

Data type

The type of symbol or character, or other designation used to represent the data element. For example numeric, alphanumeric or integer.

Field size: Min: Max:

The minimum and maximum number of characters allowable to represent the data element.

Representational format

A generic example of what the data element should look like in the unit record. For example, dates should be represented in the format of DDMMYYYY where DD represents, the day, MM represents the month, and YYYY represents the four-digit numeric for the year.

Data Domain

The set of possible values for the data item. This may take the form of a code set, or a description of the possible values. Domain values are only specified where size of the code set is small enough to be reasonably reproduced in the document.

Guide for use

Additional comments or advice on the interpretation or application of the attribute 'data domain' (this attribute has no direct counterpart in the ISO/IEC Standard 11179 but has been included to assist in clarification of issues relating to the classification of data elements).

ADMINISTRATION:

Source document(s)

Documents listed here have been used as references when designing the specified item. The item as it is presented in this document is not necessarily identical to the item in the source document.

Source organisation(s)

The name of the organisation(s) that developed the source document(s) or provided advice on the data item.

References

1. Technical report – National Breast Cancer Centre Consistency of Ovarian Cancer Clinical Databases Survey, National Breast Cancer Centre, 2007.

2. Victorian Cancer Outcomes Network (VCON). Royal Women's Hospital Pre-Trial Pilot. Interim Report. April 2007. Meng Tuck Mok and Adam Chapman. Department of Human Services, Victoria. The Cancer Council Victoria).