



**NATIONAL BREAST
CANCER CENTRE**

Incorporating the
Ovarian Cancer Program

Clinical practice guidelines for the management of women with epithelial ovarian cancer

Approved by



Australian Government

National Health and Medical Research Council



Clinical practice guidelines for the management of women with epithelial ovarian cancer

Prepared by the Australian Cancer Network and
the National Breast Cancer Centre
(incorporating the Ovarian Cancer Program)

Funded by the Department of Health and Ageing
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These guidelines were approved by the National Health and Medical Research Council at its 152nd Session on 18 March 2004, under section 14A of the National Health and Medical Research Council Act 1992. Approval for the guidelines by NHMRC is granted for a period not exceeding five years, at which date the approval expires. The NHMRC expects that all guidelines will be reviewed no less than once every five years. Readers should check with the National Breast Cancer Centre for any reviews or updates of these guidelines.

The strategic intent of the NHMRC is to provide leadership and work with other relevant organisations to improve the health of all Australians by:

- fostering and supporting a high quality and internationally recognised research base;
- providing evidence based advice;
- applying research evidence to health issues thus translating research into better health practice and outcomes; and
- promoting informed debate on health and medical research, health ethics and related issues.

This document is a general guide to appropriate practice, to be followed subject to the clinician's judgement and the patient's preference in each individual case.

The guidelines are designed to provide information to assist decision-making and are based on the best evidence available at the time of publication.

This is the first edition of the *Clinical practice guidelines for the management of women with epithelial ovarian cancer*.

It is planned to review this Clinical Practice Guideline in 2009. For further information regarding the status of this document, please refer to the NHMRC web address: <http://www.nhmrc.gov.au>

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FOREWORD

“The ovary is small, homely, and innocuous at first glance, but its tumors of gigantic proportion and exotic appearance continually widen the eye of the most jaded gynecologist as they exert fascinating effects upon his patient. Such an organ deserves respect”, wrote Kraus in his 1967 textbook of pathology.¹

The lifetime risk of ovarian cancer for Australian women to age 74 is one percent (1%),² but the impact on society is far greater than this figure implies. Ovarian cancer is the most common cause of death from gynaecological malignancy. For the majority of women who develop ovarian cancer, it will ultimately be lethal. This is due to a large extent to our current inability to readily diagnose ovarian cancer at an early stage, where cure might be achievable. No algorithm for early detection has yet been developed. The symptoms are frequently vague and non specific, so that in about three-quarters of cases, diagnosis is only made when the disease is advanced, thus overall outcomes are poor.

There is a distinct lack of awareness, both on the part of women and also health professionals, about symptomatology and triage for women who might have ovarian cancer. In spite of the high mortality rate, the majority of women do not receive optimal staging or treatment.^{3,4}

We are eagerly awaiting the results of several large international studies on population screening. These will not be available for another year or so at the earliest. Meanwhile routine screening has not been proven to be efficacious, at this stage, for the general population. (*See chapter 3 – Screening for ovarian cancer.*)

Interpretation of the histological findings is crucial to determining prognosis, and thus influences treatment decisions. Expert pathology review is a vital component of the overall management process. (*See chapter 5 – The biology and pathology of ovarian cancer and chapter 6 – Multidisciplinary management of women with ovarian cancer.*)

There is evidence that prognosis is directly related to the training of the treating surgeon, who understands the natural history of the disease, and is also trained formally to deal with any situation which might be found at the time of surgery. The Certified Gynaecological Oncologist has a three year post-specialty training in this area. (*See chapter 6 – Multidisciplinary management of women with ovarian cancer.*) Incomplete staging gives incomplete information about the extent of the disease. If staging is not complete then there is a strong chance that the woman will not be adequately treated and the chance of subsequent death is increased.

These guidelines, based upon a review of evidence-based information, have been specifically confined to the dominant group of ovarian malignancies - the so-called epithelial tumours. This group accounts for over 90% of primary ovarian cancers and represents the common usage of the term ‘ovarian cancer’. Neither germ cell malignancies nor sex cord stromal tumours have been addressed. These groups, which account for less than 10% of primary ovarian cancers, have very different patterns of pathogenesis, epidemiology, clinical management and outcomes and have therefore not been included.⁵

The guidelines are formulated with the aim of closing the gap on information for clinicians (both specialists and general practitioners) and other health professionals, so that awareness of ovarian cancer is raised and the possibility of earlier diagnosis and optimal treatment is realised. Consumers and consumer groups frequently show interest in the clinical document, however, it is planned to subsequently develop a consumer guide, based on the evidence in the guidelines.

The best available evidence has been collated and while much of it is level IV, there is a substantial component of level III evidence, with some level II and level I evidence. As the levels of evidence are low for most situations, more research is required. We have included suggestions for where research can be directed to improve the evidentiary base (*See Appendix 6*).

Dr Margaret Davy AM

Chair, Working Party

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EXECUTIVE SUMMARY

- Cancer of the ovary is a significant malignancy in Australian women, being the eighth most common cancer and the sixth most common cause of death. It is the most common cause of death from gynaecological malignancy.
- In Australia in 1999 the age-standardised incidence rate was 10.6 per 100,000 female population. There has been a decline in mortality since 1983, most notable for women less than 55 years of age. Possible explanations for the trend include differences in histological types and prognosis of tumours occurring in the younger age groups, protective effects of oral contraceptive use and improvements in treatment.
- The established risk factors for ovarian cancer are strongly related to family history and increasing age, neither of which is readily modifiable through prevention strategies.
- Specific strategies may be considered to reduce the risk of ovarian cancer for women with one of the familial cancer syndromes.
- Protective factors for ovarian cancer include increasing parity, hysterectomy, tubal ligation and oral contraceptive use.
- The issues around screening for ovarian cancer are not yet resolved and the results of three large randomised, controlled trials are awaited.
- The vagueness of initial symptoms of ovarian cancer requires that clinicians be alert to their significance during examination and investigation.
- The surgical approach is the cornerstone of all subsequent treatment and management of ovarian cancers, as the careful and accurate surgical procedure will determine the true stage. Optimal benefits result when all gross malignancy can be excised safely. Chemotherapy is available for the treatment of any residual disease.
- Radiation therapy may be used in certain circumstances.
- Accurate histopathological and clinical staging provide prognostic indices for gynaecological oncologists and women.
- To achieve best outcomes for women with ovarian cancer the ideal is that they be treated by a multidisciplinary team that includes a gynaecological oncologist.
- Attention to psychosocial issues, quality of life and palliative care is an essential part of multidisciplinary care.
- Better outcomes have been reported for those cancer patients taking part in clinical trials.
- Emphasis must be placed on optimal use of available resources and the collection of comprehensive and consistent data to plan future strategies in prevention and to achieve a reduction in mortality.

SUMMARY OF GUIDELINES

Guideline	Level of Evidence	Chapter/Reference number	Page
Familial aspects of ovarian cancer		Chapter 4	
Bilateral risk reducing salpingo-oophorectomy in carriers of BRCA1 and BRCA2 mutations reduces the risk of epithelial ovarian cancer by at least 90%. It is the only proven method of reducing the risk of ovarian cancer and cancer of the fallopian tube. It may also halve the risk of breast cancer in mutation carriers. Ideally, risk reducing surgery should always be discussed with women at potentially high risk of ovarian cancer.	III-2	26,27,28	37
The biology and pathology of ovarian tumours		Chapter 5	
It is recommended to sample several areas from any suspected borderline ovarian tumour (eg highly complex cystic tumours), to reduce sampling error; especially for tumours that are, or appear to be, mucinous or which are over 1 kg.	III-3	7	45
The use of the Universal Grading System is recommended and addresses some of the limitations of other methods for histological grading. There is good predictive power across most stages and types.	III-3	11,12	47
When considering the prognostic indicators for serous borderline tumours, surgical pathological stage and sub-classification of extra-ovarian disease into invasive and non-invasive implants are the most important indicators.	IV	18	49

Guideline	Level of Evidence	Chapter/ Reference number	Page
Use of the term 'high grade proliferating' as an alternative to 'carcinoma in situ' or 'intraepithelial carcinoma' within a borderline neoplasm is recommended for mucinous tumours with no evidence of stromal invasion, if they show more than four layers of nuclei and marked nuclear atypia.	IV	24	50
The multidisciplinary management of women with ovarian cancer		Chapter 6	
There is a growing body of evidence to suggest that outcomes for a woman with ovarian cancer are improved if she is referred to be managed under the care of a Multidisciplinary Care team. The ideal situation is for referral of the woman to a centre where all aspects of management, including surgery, pathology review, chemotherapy and on-going psychosocial support are available.	IV	1,7	58
Survival for women with ovarian cancer has been shown to be improved when the initial surgery has been done by a gynaecological oncologist. The surgical care of women with ovarian cancer is best directed, whenever possible, by a gynaecological oncologist.	IV	2,4,5,13,15	61

Guideline	Level of Evidence	Chapter/ Reference number	Page
Management of a pelvic mass		Chapter 8	
<p>Surgical staging for ovarian cancer always includes:</p> <ul style="list-style-type: none"> • peritoneal washings for cytology; • exploration of all peritoneal surfaces including the diaphragm, bowel serosa and Pouch of Douglas; • biopsy of any suspicious nodules; • infracolic omentectomy, multiple peritoneal biopsies; and • at least adequate sampling of pelvic and para-aortic lymph nodes. 	IV	7,8,9	73
<p>In premenopausal women, with invasive adenocarcinomas, early disease and favourable pathology (Grade I or Grade II, Stage IA or IB tumours) fertility-preserving surgery in association with appropriate follow-up can be safely undertaken, if child bearing is desired.</p>	IV	10-13	74
<p>In the event of an unexpected diagnosis of ovarian cancer at the time of surgery for other purposes:</p> <ul style="list-style-type: none"> • diagnosis should be confirmed with a biopsy; • minimal additional surgery should be undertaken; • postoperative referral to a gynaecological oncology unit for definitive treatment should be arranged. 	IV	14	75
The management of borderline ovarian tumours		Chapter 9	
<p>There is no role for adjuvant therapy for Stage I borderline ovarian tumours.</p>	I	7	79

Guideline	Level of Evidence	Chapter/ Reference number	Page
Surgery for invasive ovarian cancer		Chapter 10	
Primary cytoreduction is considered the initial treatment of choice for women with ovarian cancer and typically includes: <ul style="list-style-type: none"> • total abdominal hysterectomy; • bilateral salpingo-oophorectomy; • omentectomy; and • resection of metastatic lesions from the peritoneal surfaces or from the bowel. 	IV	1,2,3	81
Neoadjuvant chemotherapy and interval cytoreduction may be considered if optimal primary cytoreduction was not achieved.	II	13	83
Surgery has no place for women who develop progressive disease during their initial chemotherapy program.	IV	15,16	84
Chemotherapy - Early ovarian cancer		Chapter 11	
Adjuvant chemotherapy with a platinum agent is recommended for patients with high grade or clear cell histology because they are known to have a higher relapse rate.	II	1	90
Patients with stage IA or IB well or moderately differentiated tumours do not require adjuvant chemotherapy because their risk of relapse is low, and the toxicity not justified.	II	2	90
Adjuvant chemotherapy is not indicated in patients with borderline tumours (unless invasive implants are confirmed histologically).	II	3	90

Guideline	Level of Evidence	Chapter/ Reference number	Page
Platinum-based adjuvant chemotherapy improves recurrence-free and overall survival in women with surgically resected early ovarian cancer who are at high risk of relapse.	II	6,7	90
Chemotherapy - Advanced ovarian cancer		Chapter 11	
The first line treatment of advanced ovarian cancer ideally should include a platinum compound.	I	9	91
It is currently recommended that standard first line chemotherapy should be a combination of carboplatin (AUC × 6) and paclitaxel (175 mg/ m ²) given every three weeks.	II	10,12	93
In patients unsuitable for combination therapy (on the basis of either concurrent medical conditions, performance status or by patient preference) single agent carboplatin is an effective and acceptable treatment for advanced ovarian cancer.	II	14	93
Although intraperitoneal chemotherapy is not recommended as standard therapy its use may be considered on an individual patient basis at a designated cancer centre.	II	27	95
The use of chemotherapy protocols utilising high dose therapy should only be offered as part of an appropriately designed clinical trial.	IV	34	96
The use of maintenance or consolidation chemotherapy should only be offered as part of an appropriately designed clinical trial.	II	38,39	97

Guideline	Level of Evidence	Chapter/ Reference number	Page
Patients relapsing more than 6 months after a confirmed response to initial treatment with platinum compounds should be considered for re-treatment.	IV	40,41	98
Radiation therapy		Chapter 12	
Whole Abdominal Radiation Therapy (WART) should be considered in Stage III ovarian cancer patients with complete surgical and pathologic remission at second-look laparotomy.	II	12	105
Symptomatic relief and palliation in women with metastatic or recurrent disease can be achieved with radiation therapy.	IV	15,16, 17	106
Quality of life and psychosocial issues		Chapter 13	
Psychosocial interventions can result in lower rates of anxiety and depression, reduced mood disturbances, nausea and vomiting and enhanced knowledge for cancer patients.	I	9	109
Psychosocial interventions that can improve physical, functional and psychological adjustment and may be considered for women with ovarian cancer; include: <ul style="list-style-type: none"> • Counselling and relaxation therapy • Education programs to improve pain control • Cognitive behavioural interventions 	I II III-2	9 16 17	110

Guideline	Level of Evidence	Chapter/ Reference number	Page
Alternative and complementary therapies		Chapter 14	
Relaxation therapy has been shown to be effective and non-harmful in managing patients with cancer pain.	I	5	121
Palliative care		Chapter 16	
Specialist palliative care services can improve outcomes in relation to patient satisfaction, patients being cared for in their place of choice, family satisfaction and control of pain, symptoms and family anxiety.	I	4	132
Clinical trials		Chapter 17	
Cancer patients who participate in clinical trials may have better outcomes than those given the same treatment outside a clinical trial setting. It is appropriate for clinicians to discuss participation in clinical trials with women who have ovarian cancer.	III- I	4	140

INTRODUCTION

Research has shown that clinical practice guidelines can be effective in bringing about change and improving health outcomes.¹ In November 2000, the Australian Cancer Network established a multidisciplinary working party to develop clinical practice guidelines for the management of women with epithelial ovarian cancer. With the establishment of the National Ovarian Cancer Program in 2001, the National Breast Cancer Centre worked collaboratively with the Australian Cancer Network to develop, revise and complete the guidelines.

The working party comprised representatives from the disciplines of:

- Gynaecological Oncology
- Medical Oncology
- Pathology
- Radiation Oncology
- Nursing
- General Practice
- Epidemiology; and
- Consumers

The *Clinical practice guidelines for the management of women with epithelial ovarian cancer*, aim to:

- improve the quality of healthcare for women;
- educate those involved in the care of women with epithelial ovarian cancer;
- assist the decision-making process by women with epithelial ovarian cancer and their doctors; and
- facilitate the optimal treatment of women with epithelial ovarian cancer.

In the first chapter of these guidelines, *Ovarian cancer in Australian women*, the data provided covers all types of ovarian cancer. In the following chapters, the information provided will be for epithelial ovarian cancer (borderline and invasive) only. Most information will be about invasive epithelial ovarian cancer.

The *Clinical practice guidelines for the management of women with epithelial ovarian cancer* are based on the best available evidence, and readers can judge the level of the evidence on which assertions are based.

The process employed to develop the guidelines is described in Appendix 6.

These guidelines are not rigid procedural paths. They are one element of good medical decision-making, which takes account of patients' preferences and values, clinicians' experience, and the availability of resources.²

The guidelines use a rating system to identify the evidence base for key recommendations. The rating system is recommended by the Quality of Care and Health Outcomes Committee (QCHOC) and has been adapted from the system developed by the US Preventive Services Task Force and recommended by the National Health and Medical Research Council (NHMRC).²

- Level I** evidence obtained from a systematic review of all relevant randomised controlled trials.
- Level II** evidence obtained from at least one properly designed randomised controlled trial.
- Level III-1** evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
- Level III-2** evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies, or interrupted time series with a control group.
- Level III-3** evidence obtained from comparative studies with a historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
- Level IV** evidence obtained from case series, either post-test or pre-test and post-test

Level I evidence represents the gold standard.

'Guidelines' are boxed throughout the text and are summarised at the beginning under 'Summary of Guidelines'. These are all evidence-based and the level of evidence and appropriate references are denoted.

There are also 'Key points' to draw the reader's attention to other issues of importance that may be of interest, but which are not clinical practice recommendations. Levels of evidence were able to be attributed for some of these, while others refer to areas for which there is no 'hard' evidence, but which the working party nevertheless considered to be worthy of consideration by clinicians.

These guidelines highlight areas of established knowledge, but also areas where knowledge is poor. They provide guidance for research. The guidelines will be evaluated to determine their impact and their effects on patient outcomes.

A consumer booklet will be developed by the Ovarian Cancer Program of the National Breast Cancer Centre, based on the clinical practice guidelines. This booklet will be for use by women with epithelial ovarian cancer and their families, as well as for discussion between the woman and her doctor.

STAGING

Management decisions are made based on the diagnosis and prognostic indices. The guidelines used for staging are presented here for reference and should be used in conjunction with the information provided in the chapter on *Management of a Pelvic Mass* (Chapter 7). Ovarian cancers are staged surgically, based on the extent of growth of the disease. Guidelines for staging have been established by the *Federation Internationale de Gynecologie et d'Obstetrique (FIGO)*. The *Annual Report on the Results of Treatment in Gynaecological Cancer* is published triennially to coincide with the scientific meeting of FIGO. This is a collection of data from many countries world-wide to give a world picture of the incidence and the outcomes of treatment in gynaecological malignancies. The concept began in 1928 when Heyman, Lacassagne and Voltz were given the task to explore a system to give uniform statistical information on the results of radiation therapy in cervix cancer. Their system was adopted in 1929. It was not until 1973 in the 15th Annual Report that ovarian cancer was included.³

Stage I Growth limited to ovaries

- Ia Growth limited to one ovary; no ascites present containing malignant cells. No tumour on external surface; capsule intact.
- Ib Growth limited to both ovaries; no ascites present containing malignant cells. No tumour on external surfaces; capsules intact.
- Ic* Tumour either 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 Growth 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* Tumour either stage IIa or IIb, but with tumour on the surface of one or both ovaries; or with capsule(s) ruptured; or with ascites present containing malignant cells or with 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 equals Stage III. Tumour is limited to the true pelvis, but with histologically proven malignant extension to 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 small bowel or mesentery.
- IIIb Tumour of one or both ovaries with histologically confirmed implants, peritoneal metastases of abdominal peritoneal surfaces, none exceeding 2cm in diameter; nodes are negative.

IIIC Peritoneal metastases beyond the pelvis >2cm in diameter and /or positive retroperitoneal or inguinal nodes.

Stage IV Growth 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 equal Stage IV.

* In order to evaluate the impact on prognosis of the different criteria for allotting cases to Stage Ic or IIc, it would be of value to know if rupture of the capsule was spontaneous, or caused by the surgeon; and if the source of the malignant cells detected was peritoneal washings, or ascites.

The role of surgical staging is the cornerstone of all subsequent treatment discussions in ovarian cancer. Careful and accurate surgical procedure will determine the true stage. (*See chapter 10 on Surgery for invasive ovarian cancer*). The task forces of FIGO endorse the histologic typing of ovarian tumours, as presented by the World Health Organization (WHO). (*See Appendix 2*).

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