

# Follow up of women with epithelial ovarian cancer

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**A CLINICAL PRACTICE GUIDELINE DEVELOPED BY CANCER AUSTRALIA\***

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\* In July 2011, National Breast and Ovarian Cancer Centre (NBOCC) amalgamated with Cancer Australia to form a single national agency, Cancer Australia, to provide leadership in cancer control and improve outcomes for Australians affected by cancer.



## Key points

- Reasons for providing follow-up care to women post-treatment for *epithelial ovarian cancer* include identification of relapse and managing side effects of treatment. Possible options for follow-up and their implications and consequences should be discussed with the woman prior to establishing the format and schedule of follow-up appointments
- Clinicians should be aware that follow-up appointments are a cause for concern and anxiety for women, and that consideration should be given to strategies to lessen anxiety
- It is important that a clear and mutually agreed care plan be offered to women who have been treated for epithelial ovarian cancer
- The decision to initiate re-treatment requires careful consideration based on the individual woman's situation, and factors including the nature of the *recurrence* and the wishes of the woman.
- Women should be fully informed of the pros and cons of routine measurement of CA125 during follow-up and supported to make an informed decision, considering the findings of the randomised controlled trial on follow-up after *ovarian cancer*.

## Background

In 2004, National Breast Cancer Centre (NBCC)\* and Australian Cancer Network (ACN) developed the *Clinical practice guidelines for the management of women with epithelial ovarian cancer*. Clinical practice guidelines are a key component of Cancer Australia's leadership in information provision. Ensuring currency of guidelines is essential to ensuring timely, evidence-based information is available.

In September 2009, a meeting of the Ovarian Cancer Steering Committee was convened to identify and prioritise topic areas for revision within the guidelines. The selected topics were circulated among key stakeholders for further prioritisation. Three topics were identified for updating, including Follow-up for women with *epithelial ovarian cancer*. This updated chapter was developed for health professionals involved in the management of women after initial treatment for *epithelial ovarian cancer*.

A systematic review was undertaken by Cancer Australia of literature published between January 2003 and January 2010<sup>1</sup> and informed the revision of this chapter, with input from a multidisciplinary working group. This chapter replaces information about follow-up (pages 127-129) in the *Clinical practice guidelines for the management of women with epithelial ovarian cancer*.

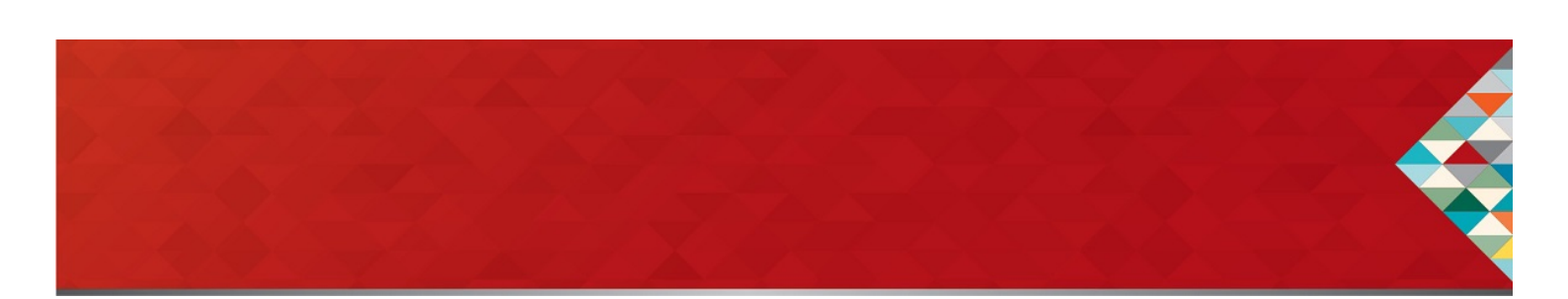
\* In February 2008, National Breast Cancer Centre incorporating the Ovarian Cancer Program (NBCC) changed its name to National Breast and Ovarian Cancer Centre (NBOCC). On 30 June 2011, NBOCC amalgamated with Cancer Australia to form a single national agency, Cancer Australia

## Epithelial ovarian cancer

Information in this chapter is limited to epithelial tumours, which account for approximately 84% of primary *ovarian cancers*, and represents the common usage of the term 'ovarian cancer'.<sup>2</sup> The chapter does not include information about the follow-up for borderline tumours (also known as low malignant potential tumours). Borderline tumours are less common than invasive disease and include a number of different subtypes which behave differently.

For the majority of women treated for *epithelial ovarian cancer*, there is a high likelihood of recurrence;<sup>3</sup> approximately 60-70% of patients will experience relapse.<sup>4</sup> The median time to relapse ranges from 11 to 29 months.<sup>5</sup> The risk





of relapse is associated with the *stage*, histologic type and tumour *grade*.<sup>6</sup> The pelvis and abdomen are the most common sites of *recurrences*.<sup>6</sup>

The median survival time for women with recurrent ovarian cancer ranges from 12 to 24 months.<sup>4</sup> The longer the interval between treatments, the more likely the disease is to respond to re-treatment with the same drugs. The typical prognosis of recurrent ovarian cancer is increasingly shorter remissions, followed eventually by disease that is resistant to available *chemotherapy* agents.<sup>3</sup>

### Follow-up post-treatment in women with epithelial ovarian cancer

Follow-up supports the physical and emotional needs of women following treatment. There are a number of reasons for providing follow-up care to women post-treatment for *epithelial ovarian cancer*, including the identification of relapse and managing side effects of treatment.<sup>7</sup> It can establish a conduit through which a woman can communicate with a health professional about her current health status, including issues such as *menopausal symptoms*, *lymphoedema*, fatigue, psychological issues, and the experience of the cancer journey. A definitive program is useful in providing this level of support. Women with *ovarian cancer* expect such a program to offer continuity and support, regardless that the disease *stage* at diagnosis is predominantly advanced, and that the ultimate prognosis is usually poor.

While the optimal method of follow-up is not yet established, possible options for follow-up and the implications and possible consequences of these options, should be discussed with the woman at the completion of primary treatment. Some women will decide that the psychological trauma of follow-up is too unsettling and opt to attend follow-up visits only if they have symptoms. Some women may opt out of specialist follow-up. Others will be kept for surveillance – even though some may experience anxiety prior to the follow-up visits.<sup>8</sup>

#### Key point:

- **Reasons for providing follow-up care to women post-treatment for epithelial ovarian cancer include identification of relapse and managing side effects of treatment. Possible options for follow-up and their implications and consequences should be discussed with the woman prior to establishing the format and schedule of follow-up appointments.**

### Survivorship/Psychosocial issues

Some women who survive *ovarian cancer*, or who are living with ovarian cancer, have reported positive changes such as a new appreciation of life, a strengthening of relationships or family ties, or a more “live for the moment” philosophy.<sup>9</sup> However, many women report issues related to survival. A study of 18 Canadian women living with ovarian cancer found that the most significant challenges faced by women with ovarian cancer could be grouped into three main themes: living with uncertainty, the stigma of cancer, and facing death.<sup>10</sup>

The members of the treatment team should be aware that follow-up visits are a source of anxiety for women,<sup>8</sup> with concerns about the testing involved and the possibility of a *recurrence* being diagnosed. Consideration should be given as to how anxiety might be lessened, such as scheduling tests before the visit so that test results are available for discussion at the time of the follow-up visit.<sup>11</sup> A pilot study of nurse-led follow-up found providing information, practical advice and coping strategies improved women’s wellbeing.<sup>12</sup>

Women surveyed about their experiences of recurrent disease have described the experience of waiting for a recurrence as frightening, and the follow-up appointments were anticipated with fear that their ovarian cancer had

recurred. Tumour markers such as CA125 were a signal that their cancer was recurring and they found the periods of waiting difficult. A rising CA125 had significant meaning, and women reported profound fear and devastation knowing it meant a recurrence of the cancer.<sup>10</sup>

In a study of women with *stage* I and II ovarian cancer who had survived 5 years or more after completion of treatment, survivors reported significant amounts of distress related to fear of a second cancer, recurrence of the cancer, and future diagnostic tests. In relation to specific survivorship stressors, 18% reported continuing distress since the completion of treatment, and distress related to changes in their appearance as a result of the cancer and/or treatment.<sup>13</sup>

#### Key point:

- **Clinicians should be aware that follow-up appointments are a cause for concern and anxiety for women, and that consideration should be given to strategies to lessen anxiety**

## Timing of follow-up consultations

### Common program

Women should be offered the opportunity to have regular follow-up. Discussion with the woman about follow-up could incorporate a schedule of follow-up appointments, including the possibility of no formal follow-up schedule, based on the identified needs and wishes of the individual. A woman may be reviewed by either a *gynaecological oncologist* or *medical oncologist*. If it is convenient for the woman, she may see her gynaecological oncologist and medical oncologist at alternate visits. Communication with a woman's GP should be maintained throughout follow-up.<sup>14</sup>

There is no recommended frequency of follow-up consultations, but a clear and mutually agreed arrangement should be negotiated with the woman, tailored according to risk and to individual patient characteristics, which acknowledges the benefits of an ongoing relationship and the opportunity to deal with issues as they arise.

Women residing in rural and regional areas face additional challenges of access to specialist clinicians for follow-up appointments. Individual circumstances should be considered when establishing a follow-up schedule.

A common follow-up program reported in guidelines and publications in the systematic review is:<sup>11,15-20</sup>

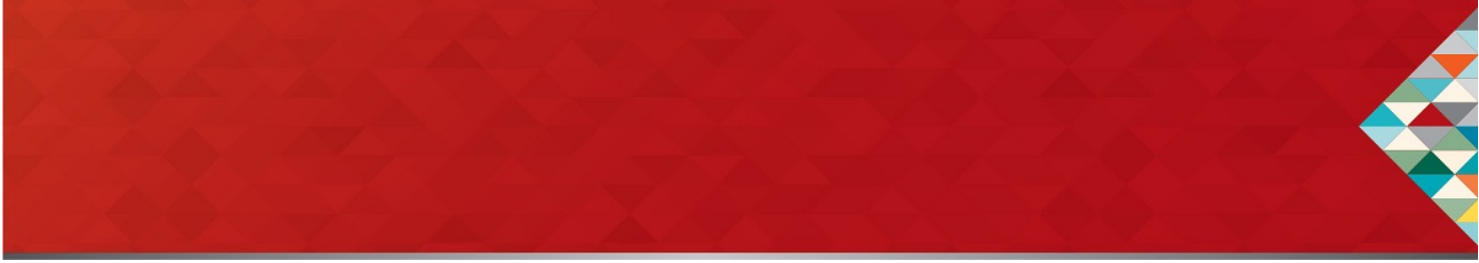
- Review every three months for 2 years then;
- Review every four-six months for the next 2 years and;
- Review six monthly for a year before moving to annual review.

#### Key point:

- **It is important that a clear and mutually agreed care plan be offered to women who have been treated for *epithelial ovarian cancer*.**

## Format for follow-up consultations

The basic format of consultation is to update the patient history, assess psychosocial and supportive care needs, and undertake physical examination, which may include pelvic examination. Studies have shown that the rates of



*recurrence* detected through physical examination vary significantly. In a patient with symptoms or other reason to suspect recurrence, physical examination alone may not be sufficient.<sup>20,21</sup>

There should be time provided for the woman and her clinician to discuss the implications of monitoring progress and initiating treatment based on CA125 levels. Women can be advised that they have the option to have CA125 levels tested at agreed intervals, or not at all. Women who choose to have CA125 levels measured should be informed that CA125 levels may fluctuate due to individual and laboratory assay variations, and the implications of stable, fluctuating and rising levels should be discussed.

The woman's report to the clinician about how she feels will often contain the best index of recurrence for the clinician. Women should be encouraged to report a range of symptoms, including nausea, vomiting, abdominal distension, cramping pain and shortness of breath.<sup>16</sup>

Radiological imaging should not be done routinely, but should be performed if there is clinical or CA125 evidence of recurrence.<sup>21</sup> The rationale for not undertaking routine imaging should be discussed with the woman.

## The asymptomatic women with a rising CA125

Around 60-90% of asymptomatic women will have a rising CA125 that precedes detection of a clinical *recurrence* by 3-5 months.<sup>5</sup> Where an asymptomatic woman has rising CA125 levels but no evidence of disease, for example on imaging, and where her reported quality of life is good, there is good reason to delay the initiation of any treatment based on the findings of Rustin *et al.*<sup>22</sup> The decision to initiate re-treatment requires careful consideration based on the individual woman's situation, and factors including the eventual nature of the recurrence and the wishes of the woman.

## CA125 in follow-up

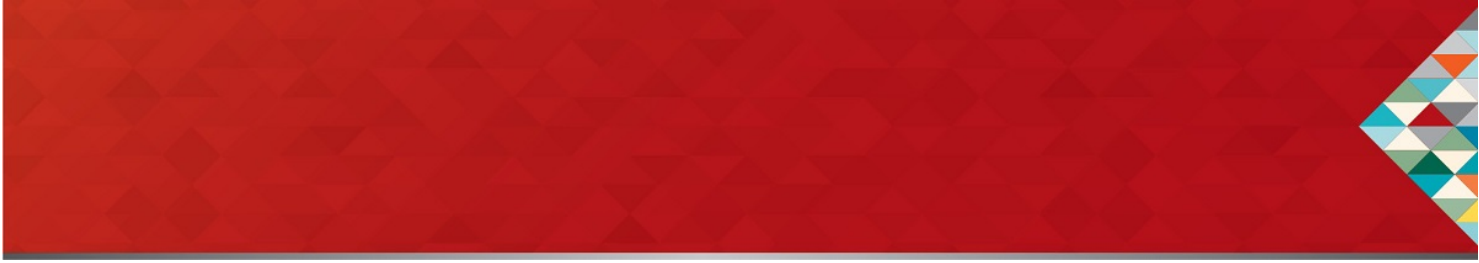
The trial by Rustin *et al* in women with *ovarian cancer* in complete clinical remission following primary treatment, found no evidence that early initiation of *chemotherapy* for *recurrence* based on rising CA125 concentrations improves survival or quality of life, compared with delaying chemotherapy until clinical or symptomatic recurrence is evident (median follow-up of 57 months from randomisation).<sup>22</sup>

In this multicentre study of over 1,400 women recruited from the UK, Europe and South Africa between 1995–2005, clinical examination and CA125 measurement was undertaken every three months. The strength of this study was that it was a prospective randomised trial, however some limitations of the study have been noted.<sup>23-25</sup> Patients and clinicians were blinded to CA125 results which were monitored by coordinating centres. Once CA125 levels were elevated beyond twice the upper limit of normal, 529 patients were randomised to either early treatment (n=265) or treatment delayed until clinical or symptomatic recurrence was evident (n=264).

Fifty three percent and 79% of women were recruited within 12 and 24 months of completion of first line chemotherapy respectively. Nineteen percent of the study population had originally been diagnosed with early *stage* disease (FIGO I or II). Data on optimal debulking rates from primary surgery were not provided. Subgroup analysis adjusted for stratification and prognostic factors showed no difference in treatment effect by treatment group. However the study was not sufficiently powered to analyse the effect of time from first-line treatment to randomisation, or timing to second-line treatment.

In assessing quality of life, the study by Rustin *et al*<sup>22</sup> found that women in the delayed treatment arm reported good global health scores for longer than those in the early treatment arm (for 9.2 months compared to 7.2 months).





Subgroup analyses using components of the EORTC QLQ-C30 subscales showed deterioration in scores for almost all subscales occurred sooner for women in the early treatment arm compared to the delayed group. There was evidence of significant disadvantage for role, emotional, social and fatigue measures for women in the early treatment arm compared to women in the delayed treatment arm.<sup>22</sup>

The routine measurement of CA125 during follow-up for all women treated for ovarian cancer has pros and cons. Rustin's study<sup>22</sup> questions the routine use of CA125 in surveillance, and challenges the widespread belief that early treatment of recurrent disease must be better. For women who encounter early relapse of their cancer, routine CA125 measurement is not beneficial. There are however concerns that it is premature to conclude that surveillance of all women using CA125 should be abandoned.<sup>25</sup> It is suggested that some women with ovarian cancer may benefit from the detection of subclinical recurrence, particularly those who are eligible for secondary cytoreductive surgery.

The key findings of the Rustin study include:

- There is no evidence of survival benefit for women who commenced early chemotherapy for first relapse based on raised CA125 levels alone
- Less deterioration in quality of life was reported among women who delayed chemotherapy until clinical or symptomatic recurrence was evident

Complete cytoreduction at the time of surgery for recurrence is strongly linked to improved survival.<sup>26,27</sup> The Desktop II study prospectively validated a scoring system predicting complete *secondary cytoreduction* in women with recurrent ovarian cancer. Predictive factors included women with platinum sensitive recurrent disease, without *ascites*, in whom complete resection of disease was obtained at first line surgery and who have a good performance status.<sup>28</sup> The AGO-OVAR Desktop III randomised trial aims to evaluate the role of secondary cytoreductive surgery for recurrent ovarian cancer.

The key findings of the Desktop II study support that:

- Some women may benefit from routine measurement of CA125, including those who are eligible for secondary cytoreductive surgery,

Defining women who are likely to benefit from measurement of CA125 is challenging and in the absence of data it is suggested women who are eligible for secondary cytoreductive surgery at relapse, should continue to be offered CA125 follow-up. Other women who may benefit from routine CA125 measurement are those taking part in *clinical trials* and those for whom intensive clinical follow-up is not practical.<sup>25</sup>

A qualitative study of 20 Australian women with *advanced ovarian cancer* found that women apply different meanings to CA125 surveillance results, including as an indicator of cancer recurrence; as an indicator of the effectiveness of treatment and/or self-care; and as an indicator of wellness. These meanings may support or challenge the woman's experience of her symptoms, and may complicate communication and decision-making about resuming treatment.<sup>3</sup>

Jordens *et al* noted the psychological burden of awareness of subclinical recurrent disease. Delaying subsequent chemotherapy until clinical or symptomatic recurrence is evident enables the woman to extend her experience of remission and delay her experience of recurrence.<sup>3</sup>

### Key points:

- **The decision to initiate re-treatment requires careful consideration based on the individual woman's situation, and factors including the nature of the recurrence and the wishes of the woman.**



- **Women should be fully informed of the pros and cons of routine measurement of CA125 during follow-up and supported to make an informed decision, considering the findings of the randomised controlled trial on follow-up after ovarian cancer.**

## Models of follow-up care

The use of alternate models of follow-up care for women with *ovarian cancer*, such as GP or nurse-led follow-up, telephone follow-up and patient initiated care is an area for future research. Some of the issues that would need to be addressed in any future studies include patient and clinician preferences, the effectiveness and cost effectiveness of the alternate models and the ability of health services to support them.

## Areas of further research

Areas of further research identified below may be addressed in ongoing trials. As new treatments become available for recurrent *ovarian cancer*, the methods of follow-up may need to be reassessed.<sup>29</sup>

- The evaluation of follow-up interventions on survival, quality of life and psychosocial effects, and cost effectiveness
- The evaluation of interventions during follow-up to reduce anxiety and promote the return to normal functioning for asymptomatic women

Prospective trials evaluating hospital-based follow-up versus other models of follow-up, including telephone follow-up, patient-initiated follow-up, and follow-up led by a nurse or general practitioner

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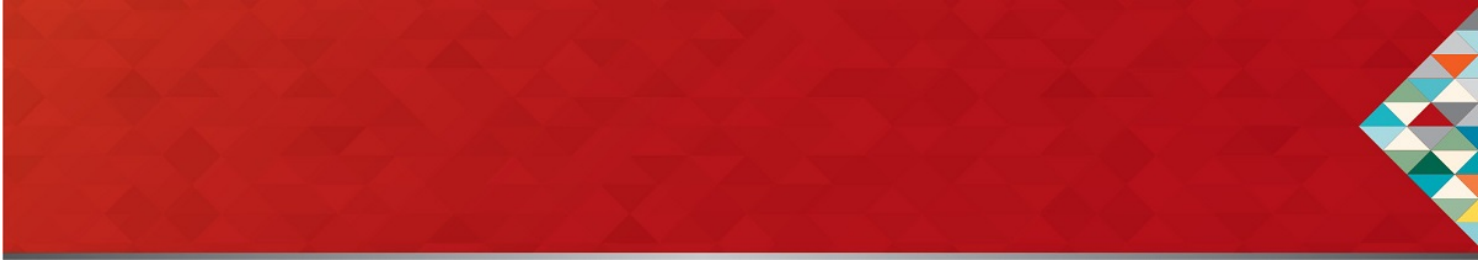
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## External review

Cancer Australia acknowledges those who gave their time to provide comment on the chapter revision as part of the external review process.

## Topic-specific guideline development process





Priority topic areas for guideline development were determined in consultation with key stakeholders including experts in relevant disciplines and consumer representatives. A specific multidisciplinary Working Group, including consumer representatives, was established for each topic identified and was involved in all aspects of guideline review and development. A systematic evidence review was undertaken for each topic. All members were asked to declare any conflicts of interest and these declarations are recorded. The content of this revised chapter is not influenced by any external funding body, and is reviewed externally by key stakeholders and the wider community.

\* In July 2011, National Breast and Ovarian Cancer Centre (NBOCC) amalgamated with Cancer Australia to form a single national agency, Cancer Australia, to provide leadership in cancer control and improve outcomes for Australians affected by cancer.

## Additional information

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