

# Guidance on the use of paclitaxel in the treatment of ovarian cancer

Technology appraisal guidance

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[www.nice.org.uk/guidance/ta55](http://www.nice.org.uk/guidance/ta55)

## Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

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This guidance replaces TA3.

This guidance is partially replaced by TA91.

# 1 Recommendations

- 1.1 It is recommended that paclitaxel in combination with a platinum-based compound or platinum-based therapy alone (cisplatin or carboplatin) are offered as alternatives for first-line chemotherapy (usually following surgery) in the treatment of ovarian cancer.
- 1.2 The choice of treatment for first-line chemotherapy for ovarian cancer should be made after discussion between the responsible clinician and the patient about the risks and benefits of the options available. In choosing between treatment with a platinum-based compound alone or paclitaxel in combination with a platinum-based compound, this discussion should cover the side-effect profiles of the alternative therapies, the stage of the woman's disease, the extent of surgical treatment of the tumour, and disease-related performance status.

## 2 Clinical need and practice

- 2.1 Ovarian cancer is a significant cause of early death, resulting in approximately 5,000 deaths in the UK each year.
- 2.2 Early stages of the disease are often asymptomatic, and as a result most women are diagnosed with advanced disease. This gives a relatively poor prognosis, and 5-year survival rates are reported to be around 30% in the UK and up to 40% in some European countries.
- 2.3 Surgery is usually the first intervention used to treat the disease. However, in most women it is not possible to remove the tumour completely. Radiotherapy is usually of limited effectiveness and has side-effects on other abdominal organs.
- 2.4 Platinum-based chemotherapy has been the established therapy in ovarian cancer for some time. However, as research evidence emerged, paclitaxel (Taxol) was added in combination with platinum. It is estimated that 75% of women with ovarian cancer currently receive a paclitaxel/platinum combination as first-line therapy.
- 2.5 Although most patients (70% to 80%) initially respond to first-line chemotherapy, most responders eventually relapse (55% to 75% within 2 years). Responses can occur when first-line chemotherapy is repeated for a second and sometimes a third time, although they occur proportionately less frequently and do not last as long. A complete response is defined as malignant disease not detectable for at least 4 weeks, and a partial response is defined as tumour size reduced by at least 50% for more than 4 weeks.
- 2.6 Women who initially respond to first-line therapy are also more likely to respond to second and subsequent courses of therapy. The 2 factors shown to be predictive of second and subsequent response to first-line therapy are the length of the progression-free interval and the extent of the relapse (that is the number of tumour sites involved and their volume). Current best practice for women who initially respond to first-line therapy is to give second and possibly subsequent courses of the same treatment at some point.

- 2.7 Once re-treatment with first-line therapies has failed, second-line therapies can be offered. These may alleviate symptoms, but may also prolong survival. At the same time, however, they are likely to have a different range of adverse effects.
- 2.8 Seven chemotherapy agents are licensed for second-line treatment of ovarian cancer: paclitaxel, carboplatin, chlorambucil, treosulfan, hexamethylmelamine (altretamine), topotecan, and pegylated liposomal doxorubicin hydrochloride (PLDH).
- 2.9 Choice of second-line therapy is influenced by the effectiveness of the different agents and the patient's response to first-line therapy regimens.
- 2.10 In May 2000, NICE issued the following guidance:
- Paclitaxel in combination with a platinum-based therapy (cisplatin or carboplatin) should be the standard initial therapy for patients with ovarian cancer following surgery.
  - The use of paclitaxel/platinum combination therapy in the treatment of recurrent (or resistant) ovarian cancer is recommended if the patient has not previously received this drug combination. If the patient has already received both drugs, the combination of paclitaxel and platinum-based therapy in recurrent (or resistant) ovarian cancer is not recommended, outside the context of clinical trials.

It was recommended that the NICE guidance should be reviewed once full results from a further study (ICON3) were available. The present document has been prepared as part of that review.

## 3 The technology

- 3.1 Paclitaxel (Taxol) is a cytotoxic anticancer drug and belongs to the taxane group of drugs. It has the following licensed indications for ovarian cancer in the UK:
- primary ovarian cancer in combination with cisplatin (a platinum drug) in patients with advanced disease or residual disease after initial surgical treatment
  - metastatic ovarian cancer where standard platinum-containing therapy (cisplatin or carboplatin) has failed (that is, paclitaxel as monotherapy).
- 3.2 Paclitaxel is usually administered at a dose of 175 mg per m<sup>2</sup> body surface area, in a 3-hour intravenous infusion, followed by a platinum compound, at 3-weekly intervals. The paclitaxel infusion is usually undertaken on an outpatient basis, with drug costs of approximately £1,100 per cycle. Patients normally receive 6 cycles, with a total drug cost of approximately £6,600, excluding costs of platinum drugs, pre-medication, wider outpatient or inpatient care, the cost of treating side effects, and value added tax (VAT).
- 3.3 While paclitaxel is licensed in combination with cisplatin for first-line therapy, both carboplatin and cisplatin are licensed for monotherapy in ovarian cancer and there is good evidence of their equivalent efficacy. However, carboplatin is recognised as being less toxic and resulting in fewer side effects. Consequently, in UK clinical practice, paclitaxel is usually provided in combination with carboplatin.

## 4 Evidence

The [appraisal committee](#) reviewed the evidence from a [number of sources](#).

### 4.1 Clinical effectiveness

#### First-line treatment

- 4.1.1 Four randomised controlled trials (RCTs) provide the main evidence base for the consideration of paclitaxel as first-line therapy in ovarian cancer. Full results from the ICON3 trial and updated results from 2 others (GOG111, OV10) have become available since NICE issued its last guidance on the use of paclitaxel in the treatment of ovarian cancer.
- 4.1.2 The GOG111 trial compared combination treatments of paclitaxel (135 mg/m<sup>2</sup>)/cisplatin (75 mg/m<sup>2</sup>) and cisplatin (75 mg/m<sup>2</sup>)/cyclophosphamide (750 mg/m<sup>2</sup>) in 410 women. All had severe disease (as defined by the International Federation of Gynaecology staging system, FIGO stage 3 or 4) and sub-optimal tumour reduction following surgery. No statistically significant difference in overall tumour response (that is, complete and partial response) was found (relative risk = 1.19, 95% confidence interval [CI] = 0.95 to 1.5). However, median progression-free survival was statistically significantly longer for patients receiving the paclitaxel/cisplatin combination (18 months versus 13 months, relative risk = 0.7, 95% CI = 0.5 to 0.8, p<0.001). Overall survival was also statistically significantly longer in these patients (38 months versus 24 months, relative risk = 0.6, 95% CI = 0.5 to 0.8, p<0.001). Estimates from updated longer-term study results suggest that the death rate is 30% less among those treated with the paclitaxel-containing regimen (relative hazard: 0.7, 95% CI = 0.57 to 0.87). No statistically significant difference in performance scores was found between the 2 groups.
- 4.1.3 The OV10 trial also compared the combinations of paclitaxel (175 mg/m<sup>2</sup>)/cisplatin (75 mg/m<sup>2</sup>) and cisplatin (75 mg/m<sup>2</sup>)/cyclophosphamide (750 mg/m<sup>2</sup>). The 680 women had optimal or sub-optimal tumour reduction following surgery, and 93% had FIGO stage 3 or 4 disease. A statistically significant difference in overall tumour response (that is, complete and partial response) in favour of the



paclitaxel combination was found (relative risk = 1.92, 95% CI = 1.52 to 2.42). Like GOG111, the study also found statistically significantly longer median progression-free survival for the paclitaxel combination (15.3 months versus 11.5 months, hazard ratio = 0.74, 95% CI = 0.63 to 0.88,  $p=0.0005$ ). Overall survival was also statistically significantly higher in this group (35.6 months versus 25.8 months, hazard ratio = 0.73, 95% CI = 0.60 to 0.89,  $p=0.0016$ ).

- 4.1.4 The GOG132 trial included comparison of combination paclitaxel (135 mg/m<sup>2</sup>)/cisplatin (75 mg/m<sup>2</sup>) with cisplatin (100 mg/m<sup>2</sup>) alone. All 424 women had FIGO stage 3 or 4 disease and sub-optimal tumour reduction following surgery. No statistically significant difference in overall tumour response (that is, complete and partial response) was found between the group receiving cisplatin alone and those receiving the paclitaxel/cisplatin combination (relative risk = 0.97, 95% CI = 0.86 to 1.09). However, unlike GOG111 and OV10, no statistically significant differences were found in progression-free survival (14.1 months versus 16.4 months, hazard ratio = 1.06, 95% CI = 0.86 to 1.30), and overall survival (26.6 months versus 30.2 months, hazard ratio = 0.99, 95% CI = 0.80 to 1.23). The difference between the findings of the trial and those reported for the GOG111 and OV10 studies may be explained by the extent of patient cross-over between treatments before the disease progressed. However, it is unlikely that this is sufficient to explain such markedly different findings.
- 4.1.5 The most recent trial, ICON3, compared a different combination of paclitaxel (175 mg/m<sup>2</sup>)/carboplatin (5 AUC) with either carboplatin (5 AUC) alone or a combination of cyclophosphamide (750 mg/m<sup>2</sup>)/doxorubicin (75 mg/m<sup>2</sup>)/cisplatin (75 mg/m<sup>2</sup>; CAP). The trial differs from the others, in that patients had a wider range of residual tumour following surgery (54% had optimally reduced tumours), and a smaller proportion (80%) had FIGO stage 3 and 4 disease. Of the total 2,074 women recruited, 1,421 were randomised to receive the paclitaxel/carboplatin combination or carboplatin alone. The findings of the ICON3 trial after more than 3 years' follow-up also differ from those of the GOG111 and OV10 studies. No statistically significant difference was found between the groups receiving the paclitaxel/platinum combination or carboplatin alone, in terms of progression-free survival (17.1 months versus 16.1 months, hazard ratio = 0.94, 95% CI = 0.84 to 1.05,  $p=0.24$ ) or overall survival (37.6 months versus 36.1 months, hazard ratio = 0.96, 95% CI = 0.84 to 1.09,  $p=0.53$ ). Also, no statistically significant differences were found in anxiety and depression scores. It is possible

that the recruitment of more patients with less severe disease could have diluted the effect of paclitaxel treatment, but sub-group analyses by FIGO stage and extent of residual tumour did not show any trend supporting this. The trial design allowed choice of the control arm before randomisation, and although some suggest that this could also have diluted any treatment effect, it may be that this may better reflect clinical practice in some respects.

- 4.1.6 The 4 trials showed consistently that treatment with paclitaxel in combination with platinum leads to more side effects. Over the 4 trials statistically significantly higher rates of neutropenia, allergic reactions, cardiovascular problems, hypersensitivity, neuromotor and neurosensory problems, fever and alopecia were reported in patients receiving the paclitaxel/carboplatin combination compared with the control treatments.
  
- 4.1.7 While design differences between the 4 trials, in terms of severity of disease of included patients, differences in treatment and control drugs and doses, length of follow-up, and the extent of cross-over (before and after disease progression), may hamper statistical pooling of results, meta-analyses have been undertaken by the Medical Research Council (MRC) and Bristol-Myers Squibb (BMS). These take account of statistical heterogeneity as far as possible, and their results appear consistent, reporting that the findings for progression-free survival (hazard ratios = 0.84, 95% CI = 0.70 to 1.02 [MRC] and 0.87, 95% CI 0.72 to 1.05 [BMS]) and overall survival (hazard ratios = 0.82, 95% CI 0.66 to 1.01 [MRC] and 0.82, 95% CI 0.68 to 1.00 [BMS]) across the trials do not show statistically significant differences between paclitaxel/platinum and the alternatives.

## Second-line treatment

- 4.1.8 Four published RCTs on the second-line use of paclitaxel (monotherapy) in the treatment of ovarian cancer were identified. However, 2 of these studies compared paclitaxel with unlicensed treatments, and 1 compared different dosing schedules of paclitaxel itself.
  
- 4.1.9 In the remaining RCT, paclitaxel was compared with topotecan in 235 women who had been previously treated with a platinum-based compound (they had not been previously treated with paclitaxel). The trial found no statistically significant

differences in overall tumour response, progression-free survival or overall survival. The incidence of neutropenia, anaemia, thrombocytopenia, leukopenia, nausea and vomiting was significantly lower among patients receiving paclitaxel than among those receiving topotecan. However, there was a significantly higher incidence of alopecia among the paclitaxel-treated group.

## 4.2 Cost effectiveness

- 4.2.1 Eleven cost-effectiveness analyses and 3 cost-utility analyses were available as evidence on the first-line use of paclitaxel. All were based on trials favouring paclitaxel (that is, GOG111 or OV10), and therefore found the paclitaxel/platinum combination to be more costly and more effective than control treatments. Three of the analyses could be directly applied to the UK.
- 4.2.2 Two published UK cost-effectiveness analyses found that the incremental cost per life-year gained for paclitaxel/platinum ranged between £7,173 and £12,417, depending on the effectiveness trial results and drug doses applied. One of the studies reported the incremental cost per progression-free life-year gained to be between £20,084 and £22,021, again depending on the trial results applied.
- 4.2.3 One published UK cost-utility analysis was available, but its methods were not well reported, and its results need to be interpreted with caution. An incremental cost-utility estimate based on this analysis, for paclitaxel/platinum compared with carboplatin alone, showed the incremental cost per quality-adjusted life year to be £5,273.
- 4.2.4 A cost-effectiveness analysis undertaken by the manufacturer of paclitaxel was also available. The analysis was based on resource use and outcomes from GOG111, though carboplatin was substituted as the control treatment, as this better reflects UK practice. Consequently, the analysis assumed equivalent efficacy between carboplatin and cisplatin in combination with paclitaxel. UK unit costs were incorporated from routine sources, and included: chemotherapy drugs, pre-medication, drug administration, management of febrile neutropenia, and other inpatient and outpatient care. For the paclitaxel/carboplatin combination versus carboplatin alone, the analysis reported an incremental cost of £7,074 per life-year gained and £10,808 per progression-free life-year gained.

- 4.2.5 Given that this analysis was based on the survival in the most favourable survival findings available (that is, a hazard ratio of 0.61 in favour of paclitaxel/platinum combination for overall survival), sensitivity analyses were undertaken by NICE to indicate the likely magnitude of effect on the cost-effectiveness ratio of changing the survival gains attributed to paclitaxel/platinum. Simply adjusting the manufacturer's analysis to the survival difference reported by ICON3 (hazard ratio of 0.96) suggests an incremental cost per life-year gained in the region of £45,000. However, other analyses undertaken by NICE suggest that the cost per life-year gained could be much higher.

## 4.3 Consideration of the evidence

- 4.3.1 Having carefully considered the design and full findings of ICON3 in conjunction with the 3 other published (updated) RCTs, the committee concluded that all of the trials contribute to the understanding of the clinical effectiveness of paclitaxel in the first-line treatment of ovarian cancer.
- 4.3.2 The committee noted that the availability of the full ICON3 evidence meant that 2 of the 4 published trials favoured paclitaxel in combination with a platinum-based compound, whereas 2 trials failed to show a significant difference in survival between the combination and a platinum-based compound alone. The combination of these findings in meta-analyses suggested that there was no statistically significant survival advantage for one of these therapeutic approaches over the other. In addition, cost-effectiveness estimates varied considerably with the assumed magnitude of the survival difference.
- 4.3.3 The committee took account of this range of trial evidence as well as other factors that would differentiate between the 2 regimens including the side-effect profiles of the treatments, and the broad range of cost-effectiveness estimates presented. On this basis the committee considered that paclitaxel/platinum combination treatment should no longer be recommended exclusively as standard therapy for women receiving first-line chemotherapy for ovarian cancer. As a consequence, the committee considered that both platinum therapy alone and a combination of paclitaxel and a platinum compound were appropriate first-line treatments for women with ovarian cancer.

- 4.3.4 The committee discussed pathways of care for women with ovarian cancer. It was recognised that women with a good initial response to first-line therapy will be offered additional courses of the chosen treatment, and will be offered second-line treatment options once the tumour fails to respond to the chosen first-line regimen.
- 4.3.5 In view of the limited evidence available on the clinical effectiveness of paclitaxel in second-line treatment, the committee concluded that paclitaxel should be considered as an option for second-line treatment only for women who do not receive it as part of their first-line therapy. For such women, it should be offered as one option alongside other drugs that are licensed for second-line treatment of ovarian cancer.

## 5 Implications for the NHS

- 5.1 In May 2000, NICE's guidance indicated that the total annual cost of adding paclitaxel to platinum therapy in England and Wales was approximately £28 million (assuming that 4,000 patients were treated at a cost of £7,000 each).
- 5.2 Given that the guidance set out in [section 1](#) promotes informed choice between the available treatments, it is difficult to estimate the likely current resource impact on the NHS. However it appears unlikely that the guidance will result in an increase in the resources required to treat ovarian cancer. In fact, since women who do not receive paclitaxel in combination as first-line chemotherapy may receive the drug later as second-line therapy, the total number receiving paclitaxel at some point in their treatment may remain approximately unchanged, as may the total cost of chemotherapy for ovarian cancer.

## 6 Further research

6.1 Research would be beneficial to examine the following aspects of effectiveness and cost effectiveness of paclitaxel:

- whether paclitaxel/platinum combination therapy is of particular benefit to identifiable clinical sub-groups
- the optimal sequencing of paclitaxel therapy with other ovarian chemotherapy compounds – that is, paclitaxel/platinum combination versus platinum followed by paclitaxel in sequence.

## 7 Implementation

- 7.1 Section 7 of the [National Institute for Health and Care Excellence \(Constitution and Functions\)](#) and the [Health and Social Care Information Centre \(Functions\) Regulations 2013](#) requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication.
- 7.2 Chapter 2 of [Appraisal and funding of cancer drugs from July 2016 \(including the new Cancer Drugs Fund\) – a new deal for patients, taxpayers and industry](#) states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or fast track appraisal), at which point funding will switch to routine commissioning budgets. The [NHS England and NHS Improvement Cancer Drugs Fund list](#) provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.
- 7.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.
- 7.4 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has ovarian cancer and the healthcare professional responsible for their care thinks that paclitaxel is the right treatment, it should be available for use, in line with NICE's recommendations.
- 7.5 Clinicians with responsibility for treating women with ovarian cancer should review their current practice in line with the guidance set out in [section 1](#).



- 7.6 Local guidelines, protocols or care pathways on the care of women with ovarian cancer should incorporate the guidance set out in section 1.
- 7.7 To measure compliance locally with the guidance, the following criteria can be used. Further details on audit criteria are presented in the [section on details on criteria for audit](#).
  - 7.7.1 First-line chemotherapy (usually following surgery) in the treatment of ovarian cancer includes the options of paclitaxel in combination with a platinum-based compound or platinum-based therapy alone.
  - 7.7.2 The choice of treatment for first-line chemotherapy for an individual woman with ovarian cancer is based on discussion between the woman and the responsible clinician regarding the risks and benefits of the options available. The following issues should be discussed: side-effect profiles of the alternative therapies, the stage of the woman's disease, the extent of surgical treatment of the tumour, and disease-related performance status.
  - 7.7.3 Additional courses of treatment with the chosen chemotherapy regimen are offered to women following relapse after the initial (or subsequent) course of first-line treatment, if the extent and duration of the initial (or previous) response is adequate.
  - 7.7.4 Paclitaxel is considered as second-line (or subsequent) treatment for women with ovarian cancer only if they have not received the drug previously as part of first-line treatment.
  - 7.7.5 Only oncologists specialising in ovarian cancer supervise the provision of chemotherapy in ovarian cancer.
- 7.8 Local clinical audits on the management of ovarian cancer also could include measurement of compliance with accepted clinical guidelines or protocols or with the measures for the treatment of ovarian cancer that are suggested in Improving Outcomes in Gynaecological Cancers, Guidance on Commissioning Cancer Services.

## 8 Appraisal committee members

The appraisal committee is a standing advisory committee of NICE. Its members are appointed for a 3-year term. A list of the committee members appears below. The appraisal committee meets twice a month other than in December, when there are no meetings. The committee membership is split into 2 branches, with the chair, vice-chair and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If there is a conflict of interest, the member is excluded from participating further in that appraisal.

The [minutes of each appraisal committee meeting](#), which include the names of the members who attended and their declaration of interests, are posted on the NICE website.

### **Professor R L Akehurst**

Dean, School of Health Related Research, Sheffield University

### **Professor David Barnett (Chair)**

Professor of Clinical Pharmacology, University of Leicester

### **Professor Sir Colin Berry**

Professor of Morbid Anatomy St Bartholomew's and Royal London School of Medicine

### **Dr Sheila Bird**

MRC Biostatistics Unit, Cambridge

### **Professor Martin Buxton**

Director of Health Economics Research Group  
Brunel University

### **Dr Karl Claxton**

Lecturer in Economics  
University of York

### **Professor Sarah Cowley**

Professor of Community Practice Development  
Kings College, London

**Mr Chris Evennett**

Chief Executive  
Mid-Hampshire Primary Care Group

**Professor Terry Feest**

Clinical Director and Consultant Nephrologist  
Richard Bright Renal Unit and Chairman of the UK Renal Registry

**Professor Gary Ford**

Professor of Pharmacology of Old Age / Consultant Physician  
Wolfson Unit of Clinical Pharmacology University of Newcastle

**Mrs Sue Gallagher**

Chief Executive  
Merton, Sutton and Wandsworth Health Authority

**Dr Trevor Gibbs**

Head, Global Clinical Safety & Pharmacovigilance  
GlaxoSmithKline

**Mr John Goulston**

Director of Finance  
Barts & the London NHS Trust

**Professor Philip Home**

Professor of Diabetes Medicine  
University of Newcastle

**Dr Terry John**

General Practitioner  
The Firs, London

**Dr Diane Ketley**

Research into Practice Programme Leader  
NHS Modernisation Agency

**Dr Mayur Lakhani**

General Practitioner, Highgate Surgery, Leicester and Lecturer, University of Leicester

**Mr M Mughal**

Consultant Surgeon

Chorley and South Ribble NHS Trust

**Mr James Partridge**

Chief Executive

Changing Faces

**Professor Philip Routledge**

Professor of Clinical Pharmacology

University of Wales

**Professor Andrew Stevens (Vice Chairman)**

Professor of Public Health

University of Birmingham

**Dr Cathryn Thomas**

General Practitioner

Senior Lecturer

Department of Primary Care and General Practice

University of Birmingham

## 9 Sources of evidence considered by the committee

The following documentation and opinion were made available to the committee:

Assessment Report prepared by the NHS Centre for Reviews and Dissemination, University of York. An update of a rapid and systematic review of the effectiveness and cost-effectiveness of the taxanes used in the treatment of advanced ovarian cancer, March 2002.

Manufacturer or sponsor submissions:

- Bristol-Myers Squibb.

Professional or specialist and patient group submissions:

- CancerBACUP
- Ovacome
- Marie Curie Cancer Care
- MRC Clinical Trials
- National Cancer Research Institute (formerly UKCCCR)
- Royal College of Obstetricians and Gynaecologists

External expert and patient advocate submissions:

- Dr Martin Gore, Consultant Oncologist, Royal Marsden Hospital, London
- Dr Ganesan, Consultant Medical Oncologist, ICRF Medical Oncology Unit, Oxford Radcliffe Hospital, Oxford
- Louise Bayne, Chair, Ovacome
- Martin Ledwick, Senior Cancer Information Specialist, CancerBACUP
- Joanne Rule, Chief Executive, CancerBACUP

## 10 Details on criteria for audit of the use of paclitaxel in the treatment of women with ovarian cancer

### 10.1 Possible objectives for an audit

An audit on the treatment of ovarian cancer could be carried out to ensure that:

- paclitaxel is used appropriately
- women with ovarian cancer participate in making the choice concerning their therapy
- chemotherapy for women with ovarian cancer is supervised by an appropriate specialist.

### 10.2 Patients to be included in an audit

All women undergoing treatment for ovarian cancer over a reasonable time period, for example, 1 year. For measures 3 and 4 below, it may be useful to include women who were diagnosed and begun on chemotherapy sufficiently long ago that relapses and second-line therapy may have occurred.

### 10.3 Measures that can be used as a basis for audit

The measures that can be used in an audit are described in **table 1**.

**Table 1. Measures that can be used as a basis for audit**

Criterion	Standard	Exception	Definition of terms
1. Paclitaxel in combination with a platinum-based compound or platinum-based therapy alone is offered for first-line chemotherapy	100% of women with ovarian cancer	None	First-line = usually following surgery. Platinum-based compound = cisplatin or carboplatin
2. The choice of treatment for first-line chemotherapy is based on discussion between the patient and the responsible clinician	100% of women with ovarian cancer	None	Local specialists should agree on how discussion with the woman about the risks and benefits of the options available is documented, for audit purposes. Reference should be made to side-effect profiles of the alternative therapies, the stage of the woman's disease, the extent of surgical treatment of the tumour, and disease-related performance status

Criterion	Standard	Exception	Definition of terms
3. Additional courses of treatment with the chosen chemotherapy regimen are offered to women following relapse after initial (or subsequent) courses of first-line chemotherapy, if the extent and duration of the initial response is adequate	100% of women with ovarian cancer who received first-line chemotherapy and who have experienced a relapse	A. Inadequate or too short a duration of initial response B. The woman declines treatment following discussion with the responsible clinician	Local specialists should agree on how to judge the adequacy and duration of initial response, for audit purposes
4. Paclitaxel is considered as second-line (or subsequent) treatment	0% of women with ovarian cancer	A. The woman has not received paclitaxel previously as part of first-line treatment	
5. The provision of chemotherapy is supervised by an oncologist specialising in ovarian cancer	100% of women with ovarian cancer	None	Local specialists should agree on what constitutes supervision, for audit purposes

## Calculation of compliance with the measures

Compliance with the measure described in the table is calculated as follows.

Numerator divided by the denominator, multiplied by 100.



Numerator: Number of patients whose care is consistent with the criterion plus the number meeting any applicable exceptions

Denominator: Number of patients in the audit to which the criterion and exception(s), where applicable, apply

Clinicians should review the findings of measurement, identify if practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that desired improvement is being achieved.

# Update information

## Minor changes since publication

**March 2014:** Implementation section updated to clarify that paclitaxel is recommended as an option for treating ovarian cancer.

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