Ovarian cancer: the recognition and initial management of ovarian cancer

NICE guideline

Draft for consultation, September 2010

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.

Contents

This guidance updates and will replace recommendation 1.7.4 in ‘Referral guidelines for suspected cancer’ (NICE clinical guideline 27; published June 2005).

Introduction

Ovarian cancer is the leading cause of death from gynaecological cancer in the UK, and its incidence is rising. It is the fifth most common cancer in women, with a lifetime risk of about 2% in England and Wales.

The outcome for women with ovarian cancer is generally poor, with an overall 5-year survival rate of less than 35%. This is because most women who have ovarian cancer present with advanced disease. The stage of the disease is the most important factor affecting outcome. The woman's general health at the time of presentation is also important because it affects what treatments can be used. Most women have had symptoms for months before presentation, and there are often delays between presentation and specialist referral. There is a need for greater awareness of the disease and also for initial investigations in primary and secondary care that enable earlier referral and maximisation of treatment options.

Despite the relatively poor overall survival rates for ovarian cancer, there has been a two-fold increase in survival over the last 30 years. This has coincided with the advent of effective chemotherapy, and the introduction of platinum-based agents in particular, as well as the increased use of radical cytoreductive surgery. More recently, there has been a significant shift towards greater specialisation in the delivery of care, resulting from the implementation of the cancer service guidance 'Improving outcomes in gynaecological cancers'[1]. It is likely that some or all of these changes have contributed to the improved survival rates, emphasising the need to ensure that women with diagnosed ovarian cancer are treated in specialist centres that can provide comprehensive cancer care.

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

[1] Improving outcomes in gynaecological cancers. Cancer service guidance (1999). Department of Health, National Cancer Guidance Steering Group

Patient-centred care

This guideline offers best practice advice on the care of women with ovarian cancer.

Treatment and care should take into account patients' needs and preferences. Women with ovarian cancer should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent (available from www.dh.gov.uk/consent) and the code of practice that accompanies the Mental Capacity Act (summary available from www.publicguardian.gov.uk). In Wales, healthcare professionals should follow advice on consent from the Welsh Assembly Government (available from www.wales.nhs.uk/consent).

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

Awareness of symptoms and signs

- Carry out tests in primary care (see section 1.1.2) if a woman (especially if 50 or over) reports having any of the following symptoms on a persistent or frequent basis – particularly more than 12 times per month:
  - persistent abdominal distension (women often refer to this as 'bloating')
  - difficulty eating and/or feeling full (early satiety)
  - pelvic or abdominal pain
  - increased urinary urgency and/or frequency. [1.1.1.2]

- Carry out appropriate assessments for ovarian cancer (see section 1.1.2) in any woman of 50 or over who has symptoms that suggest irritable bowel syndrome (IBS)[2] because IBS rarely presents for the first time in women of this age. [1.1.1.5]

Asking the right question – first tests

- Measure serum CA125 in primary care in women with symptoms that suggest ovarian cancer (see recommendations 1.1.1.2 and 1.1.1.3). [1.1.2.1]
- If serum CA125 is greater than 35 IU/ml, arrange an ultrasound scan of the abdomen and pelvis. [1.1.2.2]
- Advise any woman who has normal serum CA125, or CA125 greater than 35 IU/ml but a normal ultrasound, to return to her GP for re-assessment if her symptoms persist. [1.1.2.4]

[2] See 'Irritable bowel syndrome in adults' (NICE clinical guideline 61).

Malignancy indices

- Calculate a risk of malignancy index I (RMI I) score[3] (after performing an ultrasound; see recommendation 1.2.3.1) and refer all women with an RMI I score of 200 or greater to a specialist multidisciplinary team. [1.2.2.1]

Tissue diagnosis

- Obtain a confirmed tissue diagnosis before offering cytotoxic chemotherapy to women with suspected advanced ovarian cancer in all but exceptional cases (see recommendation 1.2.4.2). [1.2.4.1]

Staging: the role of systematic retroperitoneal lymphadenectomy

- Do not include systematic retroperitoneal lymphadenectomy as part of the standard surgical treatment of suspected ovarian cancer in women whose disease appears to be confined to the ovaries (that is, who appear to have stage I disease). [1.3.1.1]

Adjuvant systemic chemotherapy in stage I disease: patient selection

- Do not offer adjuvant chemotherapy to women who have had optimal surgical staging[4] and have low-risk stage I disease (grade 1 or 2, stage Ia or 1b). [1.3.2.1]

Support needs for women with newly diagnosed ovarian cancer

- Offer all women with newly diagnosed ovarian cancer information about their disease, including psychosocial and psychosexual issues, that:
  - is available at the time they want it
  - includes the amount of detail that they want and are able to deal with
  - is in a suitable format, including written information if possible. [1.5.1.1]

[3] See appendix D for details of how to calculate an RMI I score.

[4] Optimal surgical staging constitutes: midline laparotomy to allow thorough assessment of the abdomen and pelvis; a total abdominal hysterectomy, bilateral salpingo-oophorectomy and infracolic omentectomy; biopsies of any peritoneal deposits; random biopsies of the pelvic and abdominal peritoneum; and retroperitoneal lymph node assessment [Winter Roach BA, Kitchener HC, Dickinson HO (2009) Adjuvant (post-surgery) chemotherapy for early stage epithelial ovarian cancer. Cochrane Database of Systematic Reviews issue 3: CD004706].

1 Guidance

The following guidance is based on the best available evidence. The full guideline ([hyperlink to be added for final publication]) gives details of the methods and the evidence used to develop the guidance.

1.1 Detection in primary care

Recommendations in this section update and will replace recommendation 1.7.4 in 'Referral guidelines for suspected cancer' (NICE clinical guideline 27).

1.1.1 Awareness of symptoms and signs

1.1.1.1 Refer the woman urgently[5] if physical examination identifies a pelvic or abdominal mass and/or ascites.

1.1.1.2 Carry out tests in primary care (see section 1.1.2) if a woman (especially if 50 or over) reports having any of the following symptoms on a persistent or frequent basis – particularly more than 12 times per month:

- persistent abdominal distension (women often refer to this as 'bloating')
- difficulty eating and/or feeling full (early satiety)
- pelvic or abdominal pain
- increased urinary urgency and/or frequency.

1.1.1.3 Consider carrying out tests in primary care (see section 1.1.2) if a woman reports having abnormal vaginal bleeding, unexplained weight loss, abdominal distension, fatigue or changes in bowel habit.

1.1.1.4 Advise any woman who is not suspected of having ovarian cancer to return if her symptoms become more frequent and/or persistent.

[5] An urgent referral means that the woman is seen by a specialist member of the multidisciplinary team within the national target in England and Wales for referral for suspected cancer, which is currently 2 weeks.

1.1.1.5 Carry out appropriate assessments for ovarian cancer (see section 1.1.2) in any woman of 50 or over who has symptoms that suggest irritable bowel syndrome (IBS)[6] because IBS rarely presents for the first time in women of this age.

1.1.2 Asking the right question – first tests

1.1.2.1 Measure serum CA125 in primary care in women with symptoms that suggest ovarian cancer (see recommendations 1.1.1.2 and 1.1.1.3).

1.1.2.2 If serum CA125 is greater than 35 IU/ml, arrange an ultrasound scan of the abdomen and pelvis.

1.1.2.3 If the ultrasound suggests ovarian cancer, refer the woman urgently[7] for further investigation.

1.1.2.4 Advise any woman who has normal serum CA125, or CA125 greater than 35 IU/ml but a normal ultrasound, to return to her GP for re-assessment if her symptoms persist.

1.2 Establishing the diagnosis in secondary care

1.2.1 Tumour markers: which to use?

1.2.1.1 Measure serum CA125 in secondary care in all women with suspected ovarian cancer, if this has not already been done in primary care.

1.2.1.2 In women under 40 with suspected ovarian cancer, measure levels of alpha fetoprotein (AFP) and beta human chorionic gonadotrophin (beta-hCG) as well as serum CA125, to help identify women with germ cell tumours.

[6] See 'Irritable bowel syndrome in adults' (NICE clinical guideline 61).
[7] An urgent referral means that the woman is seen by a specialist member of the multidisciplinary team within the national target in England and Wales for referral for suspected cancer, which is currently 2 weeks.

1.2.2 Malignancy indices

1.2.2.1 Calculate a risk of malignancy index I (RMI I) score[8] (after performing an ultrasound; see recommendation 1.2.3.1) and refer all women with an RMI I score of 200 or greater to a specialist multidisciplinary team.

1.2.3 Imaging in the diagnostic pathway: which procedures?

1.2.3.1 Perform an ultrasound of the abdomen and pelvis as the first imaging test in secondary care for women with suspected ovarian cancer, if this has not already been done in primary care.

1.2.3.2 If the ultrasound suggests ovarian cancer, perform a CT scan of the pelvis, abdomen and thorax to establish the extent of disease.

1.2.3.3 Do not use MRI routinely for assessing women with suspected ovarian cancer.

1.2.4 Tissue diagnosis

Requirement for tissue diagnosis

1.2.4.1 Obtain a confirmed tissue diagnosis before offering cytotoxic chemotherapy to women with suspected advanced ovarian cancer in all but exceptional cases (see recommendation 1.2.4.2).

1.2.4.2 Offer cytotoxic chemotherapy for suspected advanced ovarian cancer without a confirmed tissue diagnosis only:

- in exceptional cases, after discussion at the multidisciplinary team
- after discussing with the woman the possible benefits and risks of starting chemotherapy without a tissue diagnosis.

Methods of tissue diagnosis other than laparotomy

1.2.4.3 Use biopsy rather than cytology to obtain tissue for diagnosis if surgery has not been performed:

[8] See appendix D for details of how to calculate an RMI I score.

- use percutaneous image-guided biopsy if this is feasible
- use laparoscopy only if percutaneous image-guided biopsy is not feasible or has not produced an adequate sample.

1.3 Management of suspected early (stage I) ovarian cancer

1.3.1 Staging: the role of systematic retroperitoneal lymphadenectomy

1.3.1.1 Do not include systematic retroperitoneal lymphadenectomy as part of the standard surgical treatment of suspected ovarian cancer in women whose disease appears to be confined to the ovaries (that is, who appear to have stage I disease).

1.3.2 Adjuvant systemic chemotherapy in stage I disease: patient selection

1.3.2.1 Do not offer adjuvant chemotherapy to women who have had optimal surgical staging[9] and have low-risk stage I disease (grade 1 or 2, stage Ia or 1b).

1.3.2.2 Discuss the possible benefits and side effects of adjuvant chemotherapy with women who have had suboptimal surgical staging[9] and have stage I disease.

1.3.2.3 Offer women with high-risk stage I disease (grade 3 or stage Ic) six cycles of adjuvant carboplatin (but see also recommendation 1.3.2.4).

1.3.2.4 Consider three cycles of adjuvant carboplatin plus paclitaxel[10] for women with high-risk stage I disease (grade 3 or stage Ic) if they

[9] Optimal surgical staging constitutes: midline laparotomy to allow thorough assessment of the abdomen and pelvis; a total abdominal hysterectomy, bilateral salpingo-oophorectomy and infracolic omentectomy; biopsies of any peritoneal deposits; random biopsies of the pelvic and abdominal peritoneum; and retroperitoneal lymph node assessment [Winter Roach BA, Kitchener HC, Dickinson HO (2009) Adjuvant (post-surgery) chemotherapy for early stage epithelial ovarian cancer. Cochrane Database of Systematic Reviews issue 3: CD004706].

are prepared to accept treatment of shorter duration but increased toxicity.

1.4 Management of advanced (stage II–IV) ovarian cancer

1.4.1 Intraperitoneal chemotherapy

1.4.1.1 Do not offer intraperitoneal chemotherapy to women with ovarian cancer (any stage) except as part of a clinical trial.

1.4.2 Chemotherapy regimens

The recommendations in this section are from 'Guidance on the use of paclitaxel in the treatment of ovarian cancer' (NICE technology appraisal guidance 55).[11]

1.4.2.1 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.

1.4.2.2 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.

1.4.2.3 When relapse occurs after an initial (or subsequent) course of first-line chemotherapy, additional courses of treatment with the chosen

[10] In UK clinical practice, paclitaxel is usually provided in combination with carboplatin (rather than with cisplatin) for treating ovarian cancer, because of the well established lower toxicity of this combination. However, paclitaxel in combination with carboplatin does not have a UK marketing authorisation for treating ovarian cancer, so informed consent should be obtained and documented.

[11] The recommendations from NICE technology appraisal guidance 55 will be incorporated into this guideline subject to a technology appraisal review proposal agreement.

chemotherapy regimen (re-challenge therapy) should be considered if the initial (or previous) response has been adequate in extent and duration. Once the tumour fails to respond adequately to the chosen first-line regimen, different treatment options should be considered as part of second-line therapy (see next recommendation).

1.4.2.4 Paclitaxel is not recommended as second-line (or subsequent) therapy in women with ovarian cancer who have received the drug as part of their first-line treatment. For women who have not received paclitaxel as part of first-line treatment, it should be considered as one option alongside other drugs licensed for second-line treatment of ovarian cancer.

1.4.2.5 Only oncologists specialising in ovarian cancer should supervise the provision of chemotherapy in ovarian cancer.

1.5 Support needs for women with newly diagnosed ovarian cancer

1.5.1.1 Offer all women with newly diagnosed ovarian cancer information about their disease, including psychosocial and psychosexual issues, that:

- is available at the time they want it
- includes the amount of detail that they want and are able to deal with
- is in a suitable format, including written information if possible.

1.5.1.2 Ensure that information is available about:

- the stage of the disease, treatment options and prognosis
- how to manage the side effects of both the disease and its treatments in order to maximise wellbeing
- sexuality and sexual activity
- fertility and hormone treatment

- symptoms and signs of disease recurrence
- genetics, including the chances of family members developing ovarian cancer
- self-help strategies to optimise independence and coping
- where to go for support, including support groups
- how to deal with emotions such as sadness, depression, anxiety and a feeling of a lack of control over the outcome of the disease and treatment.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from www.nice.org.uk/nicemedia/pdf/OvarianCancerFinalScope.pdf

Groups that are covered

- Adult women (18 years and older) with epithelial ovarian cancer.
- Adult women with fallopian tube carcinoma.
- Adult women with primary peritoneal carcinoma.
- Adult women with suspected ovarian or primary peritoneal carcinoma.
- Adult women with borderline ovarian cancer.

Groups that are not covered

- Children (younger than 18 years) with ovarian malignancy.
- Women with pseudomyxoma peritonei.
- Women with relapsed ovarian, fallopian tube or peritoneal cancer.
- Women with germ cell tumours of the ovary.
- Women with sex cord stromal tumours of the ovary.

How this guideline was developed

NICE commissioned the National Collaborating Centre for Cancer to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information about how NICE clinical guidelines are developed on the NICE website (www.nice.org.uk/HowWeWork). A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' (fourth edition, published 2009), is available from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1739).

3 Implementation

NICE has developed tools to help organisations implement this guidance (see www.nice.org.uk/guidance/CG[XX]).

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

4.1 Relationship between duration of symptoms and stage at diagnosis

Further research should be undertaken on the relationship between the duration and frequency of symptoms in women with ovarian cancer before diagnosis, the stage of disease at diagnosis and subsequent survival.

Why this is important

Most women presenting with ovarian cancer have advanced disease and have had symptoms for months. Greater awareness among both women and

healthcare professionals might result in women presenting earlier with less advanced disease, leading to better outcomes. There is insufficient understanding of the factors that influence earlier diagnosis in women with ovarian cancer, especially the relationship between duration of symptoms and stage at diagnosis. Data demonstrating benefits from earlier presentation will justify investment in raising awareness among women and healthcare professionals. This is likely to be a population-based study that records both the duration and frequency of symptoms.

4.2 RMI I threshold

Further research should be undertaken to determine the optimum RMI I threshold that should be applied in secondary care to guide the management of women with suspected ovarian cancer.

Why this is important

Variation exists in the current evidence base as to the optimum RMI I threshold that should be applied in secondary care. The cut-off levels used will have implications for both the management options considered and the number of women who will be referred for specialist treatment. Therefore it is important to establish the relative sensitivities and specificities at the different levels. The research should be a prospective observational cohort study evaluating women referred with suspected ovarian cancer. Diagnostic accuracy, sensitivity, specificity and cost effectiveness should be examined at the different RMI I thresholds.

4.3 Imaging in the diagnostic pathway

Large multicentre case–control studies should be conducted to compare the accuracy of CT versus MRI for staging and for predicting optimal cytoreduction.

Why this is important

Currently most women with ovarian cancer will undergo a CT scan before surgery to assess the extent and resectability of disease. CT and MRI are complementary in their abilities to detect disease, but no adequate studies have been performed that compare their effectiveness in women with

suspected ovarian cancer. No comparative studies have been undertaken evaluating surgical outcome. A prospective study in women undergoing primary surgery would be feasible.

4.4 Systematic retroperitoneal lymphadenectomy

A prospective randomised trial should be undertaken to evaluate the cost effectiveness and associated risks of systematic retroperitoneal lymphadenectomy in women with ovarian cancer whose disease appears to be confined to the ovaries.

Why this is important

Systematic retroperitoneal lymphadenectomy is an untested procedure but is likely to be more accurate than lymph node sampling, with potential benefits to the woman of avoiding chemotherapy. However, increased risks are associated with it. Although there may be no overall survival advantage of this procedure, avoidance of chemotherapy and impact on quality of life may make it attractive to some women as a treatment option. In order to counsel women appropriately it is essential to understand fully the risks associated with this surgery as well as the benefits. Researchers should be encouraged to develop a prospective randomised trial with international collaboration to answer this question in a timely manner.

4.5 The value of primary surgery

Research should be undertaken to determine the effectiveness of primary surgery for women with advanced ovarian cancer whose tumour cannot be fully excised.

Why this is important

Most women with advanced ovarian cancer undergo surgery at some point. Previous studies have shown that surgery after the completion of chemotherapy has no therapeutic value. Studies are being performed to investigate whether the timing of surgery during primary chemotherapy influences outcome. No studies have evaluated whether primary surgery itself has any therapeutic value when compared with chemotherapy alone. The potential advantages of surgery have to be offset against the undoubted

costs, morbidity and occasional mortality. This would be a prospective randomised clinical trial recruiting women who have biopsy-proven advanced ovarian cancer and who are fit enough to receive surgery and chemotherapy. Women would be randomised to either chemotherapy and surgery (conventional arm) or chemotherapy alone (experimental arm). Primary outcome measures would be survival at 1 and 5 years.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'The recognition and initial management of ovarian cancer', contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Cancer and is available from our website (www.nice.org.uk/guidance/CG[XX]/Guidance). **Note: these details will apply to the published full guideline.**

5.2 Quick reference guide

A quick reference guide for healthcare professionals is available from www.nice.org.uk/guidance/CG[XX]/QuickRefGuide

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N[XXXX]). **Note: these details will apply when the guideline is published.**

5.3 'Understanding NICE guidance'

A summary for patients and carers ('Understanding NICE guidance') is available from www.nice.org.uk/guidance/CG[XX]/PublicInfo

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N[XXXX]). **Note: these details will apply when the guideline is published.**

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about ovarian cancer.

6 Related guidance

Published NICE guidance

- Irritable bowel syndrome in adults. NICE clinical guideline 61 (2008). (2005). Available from www.nice.org.uk/guidance/CG61
- Referral guidelines for suspected cancer. NICE clinical guideline 27 (2005). Available from www.nice.org.uk/guidance/CG27
- Improving supportive and palliative care for adults with cancer. Cancer service guidance (2004). Available from www.nice.org.uk/csgsp
- Guidance on the use of paclitaxel in the treatment of ovarian cancer. NICE technology appraisal guidance 55 (2003). Available from www.nice.org.uk/guidance/TA55

Other cancer service guidance

- Improving outcomes in gynaecological cancers. Cancer service guidance (1999). Department of Health, National Cancer Guidance Steering Group. Available from: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4083846.pdf

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

Appendix A: The Guideline Development Group, National Collaborating Centre and NICE project team

Guideline Development Group

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Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

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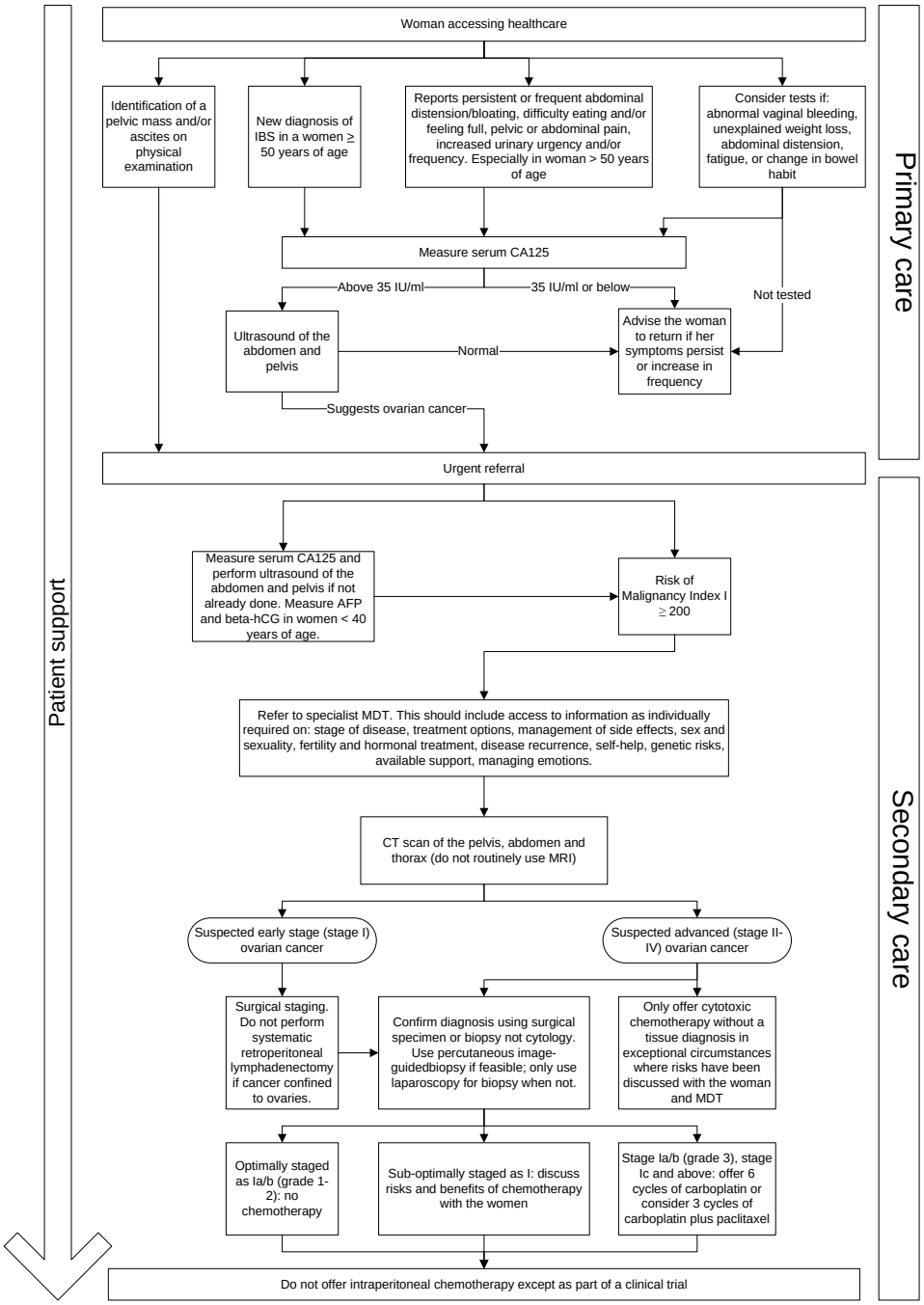
Appendix C: The algorithm

Note: This algorithm includes only the recommendations from the current guideline, and does not represent a complete care pathway for women with ovarian cancer.



Appendix D: Risk of malignancy index (RMI I)

RMI I combines three pre-surgical features: serum CA125 (CA125), menopausal status (M) and ultrasound score (U). The RMI is a product of the ultrasound scan score, the menopausal status and the serum CA125 level (IU/ml).

RMI = U x M x CA125

- The ultrasound result is scored 1 point for each of the following characteristics: multilocular cysts, solid areas, metastases, ascites and bilateral lesions. U = 0 (for an ultrasound score of 0), U = 1 (for an ultrasound score of 1), U = 3 (for an ultrasound score of 2–5).
- The menopausal status is scored as 1 = pre-menopausal and 3 = post-menopausal
- The classification of ‘post-menopausal’ is a woman who has had no period for more than 1 year or a woman over 50 who has had a hysterectomy.
- Serum CA125 is measured in IU/ml and can vary between 0 and hundreds or even thousands of units.