



Feidhmeannacht na Seirbhise Sláinte
Health Service Executive



INSTITUTE OF OBSTETRICIANS
& GYNAECOLOGISTS
ROYAL COLLEGE OF PHYSICIANS OF IRELAND

NATIONAL CLINICAL GUIDELINE

INVESTIGATION AND MANAGEMENT OF OVARIAN CYSTS IN POSTMENOPAUSAL WOMEN

Institute of Obstetricians and Gynaecologists,
Royal College of Physicians of Ireland
and the

Clinical Strategy and Programmes Division,
Health Service Executive

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1. Revision History

Version No.	Date	Modified By	Description
1.0	23/9/16	Vicky O'Dwyer	

2. Key Recommendations

- Women with a postmenopausal ovarian cyst should have a CA 125 level and transvaginal ultrasound performed.
- Women with a postmenopausal ovarian cyst should have a risk of malignancy index calculated to decide on management.
- Simple, unilateral ovarian cysts, <5 cm in diameter can be managed conservatively with monitoring of CA 125 level and ultrasound surveillance.
- Aspiration is not recommended for management of postmenopausal ovarian cysts.
- Laparoscopic oophorectomy is appropriate management for women with a low risk of malignancy index who do not fit the criteria for conservative management. This may be performed by a general gynaecologist.
- Consider performing salpingectomy or bilateral salpingo-oophorectomy for women undergoing laparoscopic management of postmenopausal ovarian cysts.
- Women with a moderate risk of malignancy index should undergo laparoscopic bilateral salpingo-oophorectomy.
- Women with a moderate or high risk of malignancy index should be managed by a gynaecological oncologist in a cancer centre.

3. Purpose and Scope

The purpose of this guideline is to provide information for healthcare professionals on the investigation and management of ovarian cysts in postmenopausal women.

The guideline is intended to be used by healthcare professionals working in the area of women's health, which includes gynaecologists, nurse sonographers, radiographers, radiologists and general practitioners. This guideline aids clinical judgement and does not replace it. In individual cases a gynaecologist may, after careful consideration, decide not to follow the guideline if it is deemed to be in the best interests of the woman.

4. Background and Introduction

The cornerstone of management of postmenopausal ovarian cysts is identification and treatment of ovarian malignancy in the appropriate setting. Ovarian cancer is the fifth commonest malignancy in women. It usually occurs in women after the age of 50 years. Ovarian cancer often presents late, (stage 3-4), with a high mortality rate.

Management of postmenopausal cysts includes surveillance and surgery, which may be performed by either a general gynaecologist or by a gynaecological oncologist in a cancer centre depending on the risk of malignancy.

Risk factors for ovarian cancer include:

- prolonged exposure to Estrogen, for example, early menarche and late menopause
- polycystic ovarian syndrome
- nulliparity
- genetic mutations; BRCA 1, BRCA 2; Lynch syndrome
- personal history of breast cancer
- family history of breast or ovarian cancer
- obesity
- smoking

- never having used the oral contraceptive pill
- fertility treatment
- hormone replacement therapy

5. Methodology

This guideline was written after Medline, EMBASE and Cochrane Database of Systematic Reviews were searched using the terms 'menopause', 'ovarian cyst', 'ovarian mass' and 'ovarian cancer'. Searches were limited to humans and restricted to the titles of English language articles published between August 1992 and August 2015.

Relevant meta-analyses, systematic reviews, intervention and observational studies were reviewed.

The principal guideline developer was Dr Vicky O'Dwyer.

The guideline was reviewed by: Dr William Boyd (Gynaecologist, Rotunda), Dr Donal O'Brien (Obstetrician, NMH), Dr Tom D'Arcy (Obstetrician & Gynaecologist, CWIUH), Dr Michael Gannon (Obstetrician & Gynaecologist, Mullingar), Dr Matt Hewitt (Obstetrician & Gynaecologist, CUMH), Dr John Birmingham (Obstetrician, Waterford), Dr Katharine Astbury (Obstetrician & Gynaecologist, Galway), Dr Ulrich Bartels (Obstetrician & Gynaecologist, Mayo General).

6. Clinical Guideline on Ovarian Cysts in Postmenopausal Women

6.1 Investigation - CA125 and ultrasound

To decide on the appropriate management of a postmenopausal ovarian cyst it is necessary to firstly estimate the risk that the cyst is malignant (Curtin 1994). This involves checking a serum CA125 and performing an ultrasound. CA125 is raised in over 80% of ovarian cancers and, if a cut-off of 30 u/ml is used, the test has a sensitivity of 81% and specificity of 75% (Jacobs et al, 1990). However, CA125 will only be raised in 50% of stage 1 ovarian cancers.

Ultrasound is also well established, achieving a sensitivity of 89% and specificity of 73% when using a morphology index (DePriest et al, 1994). Ovarian cysts should normally be assessed using transvaginal ultrasound, as this appears to provide more detail and greater sensitivity than transabdominal ultrasound (Leibmann et al, 1988). Larger cysts may also need to be assessed by transabdominal ultrasound.

The roles of magnetic resonance imaging (MRI), computed tomography (CT) and positron emission tomography (PET), in the diagnosis of ovarian cancer have yet to be clearly established (Kurtz et al, 1999; Grab et al 2000). These imaging modalities are generally used for staging once a cytological or histological diagnosis of cancer has been made.

6.2 Risk of malignancy index

Risk of malignancy index should be used to decide which women are managed by a general gynaecologist, or by a gynaecological oncologist in a cancer centre. The best prognosis for women with ovarian cancer is obtained if a laparotomy and full staging procedure is carried out by a gynaecological oncologist. (Junor et al, 1999)

$$RMI = U \times M \times CA125$$

$U = 0$ (for ultrasound score of 0); $U = 1$ (for ultrasound score of 1); $U = 3$ (for ultrasound score of 2–5). Ultrasound scans are scored one point for each of the following characteristics:

multilocular cyst

bilateral lesions

evidence of solid areas

evidence of metastases

presence of ascites

$M = 1$ for premenopausal women and 3 for postmenopausal women

CA125 is serum CA125 measurement in u/ml

6.3 Management of ovarian cysts

Management of postmenopausal ovarian cysts includes both surveillance and surgery.

6.3.1 Conservative management

Simple, unilateral ovarian cysts, less than 5 cm in diameter, have a low risk of malignancy. In the presence of a normal serum CA125 level, they can be managed conservatively (Goldstein et al, 1989). The risk of malignancy for these type of cysts is less than 1%. Over 50% of these cysts will resolve spontaneously within three months, Thus, it is reasonable to manage these cysts conservatively, with a follow-up ultrasound scan in three months (Oveles et al, 2002).

Persistent ovarian cysts should be reviewed at 3 months and then every 6 months thereafter on a selected basis. The American College of Obstetrics and Gynecology (ACOG) recommends annual transvaginal ultrasounds for 3 years and CA 125 for 5 years from diagnosis (Farghaly, 2014). This is due to the fact that postmenopausal simple unilocular ovarian cysts are common, have low malignant potential and are likely to remain stable or resolve without surgical intervention (Nardo et al, 2003). An increase in cyst size or rising CA 125 level should prompt the clinician to consider surgical management.

6.3.2 Surgical management

Aspiration

Cytological examination of ovarian cyst fluid is poor at distinguishing between benign and malignant tumours, with sensitivities in most studies of around 25%. Cyst rupture in the setting of unexpected malignancy results in upstaging and an adverse effect on survival rates. Aspiration, therefore, has no role in the management of ovarian cysts in postmenopausal women.

Laparoscopic oophorectomy

It is recommended that a 'risk of malignancy index' should be used to select women for laparoscopic surgery. The laparoscopic management of benign adnexal masses is well established. However, when managing ovarian cysts in postmenopausal women, it should be remembered that the main reason for operating is to exclude an ovarian malignancy. If an ovarian malignancy is present then the appropriate management in the postmenopausal woman is to perform a laparotomy and a total abdominal hysterectomy, bilateral salpingo-oophorectomy, infracolic omentectomy, pelvic washings +/- appendicectomy. The laparoscopic approach should, therefore, be reserved for those women who are not eligible for conservative management but still have a relatively low risk of malignancy. In a postmenopausal woman, the appropriate laparoscopic treatment for an ovarian cyst, which is not suitable for conservative management, is oophorectomy, with removal of the ovary intact in a bag without cyst rupture into the peritoneal cavity.

Robotic assisted laparoscopic management

An alternative to traditional laparoscopic surgery is robotic assisted laparoscopic surgery. A recent American study reviewed these two methods of management of presumed benign ovarian masses and it found that the traditional laparoscopic approach was preferable to robotic surgery due to quicker operating time. There was no difference in complications or length of hospital stay between the two groups (Khlouly et al, 2014).

Laparoscopic salpingectomy

Recently it has been suggested that ovarian carcinomas, which are most commonly high-grade serous carcinomas, arise from high-grade intraepithelial

serous carcinomas in the fallopian tube which then spread to the ovary. This is in contrast to the original theory that all ovarian cancer develops from a surface lesion of the ovary which then undergoes metaplastic change and develops into a stromal cancer. (Kirman & Shih, 2010). Therefore, it has been suggested that prophylactic salpingectomy should be performed as a risk reducing procedure in addition to oophorectomy.

In a Canadian study, salpingectomy for sterilisation or at the time of hysterectomy was found to be a safe procedure with no increase in operating time, blood transfusion or other peri/postoperative complications (McAlpine et al, 2014).

Laparoscopic bilateral salpingo-oophrectomy

The clinician should consider bilateral salpingo-oophrectomy (BSO) as an alternative to oophorectomy to reduce the chance of further benign or malignant ovarian cysts and need for further surgery. Laparoscopic BSO should also be performed in women with a moderate risk of malignancy index. These women should have their surgery performed by a gynaecological oncologist in a cancer centre. Women at intermediate risk undergoing laparoscopic oophorectomy should be counselled preoperatively that a full staging laparotomy will be required if evidence of malignancy is revealed.

Surgery of suspected ovarian malignancy

If an ovarian cancer is discovered at surgery or on histology, a subsequent full staging procedure is likely to be required. A full staging procedure should also be performed for women with a high risk of malignancy index. This includes a midline laparotomy, cytology (either ascites or pelvic washings), hysterectomy, bilateral salpingo-oophorectomy and infracolic omentectomy. Biopsies should be taken from suspicious areas and bilateral selective pelvic and para-aortic lymphadenectomy performed. Appendicectomy is performed in all suspected mucinous cystadenocarcinomas.

6.4 Management algorithm

Low risk

- Management in a general gynaecology unit.
- Simple cysts less than 5 cm in diameter with a normal serum CA125 level may be managed conservatively.
- Conservative management should include ultrasound scans and serum CA125 measurement every three months for two years.
- If the cyst does not fit the above criteria or if the woman requests surgery then laparoscopic oophorectomy is acceptable.

Moderate risk

- Management in a cancer centre by a gynaecological oncologist.
- Laparoscopic bilateral salpingo-oophorectomy is acceptable in selected cases.
- If a malignancy is discovered then a full staging procedure should be undertaken.

High risk

- Management in a cancer centre by a gynaecological oncologist.

GP referral pathway for symptomatic high risk women

- Appendix 1
- Appendix 2

7. References

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Kurtz AB, Tsimikas JV, Tempany CM et al. (1999) 'Diagnosis and staging of ovarian cancer: comparative values of Doppler and conventional US, CT, and MR imaging correlated with surgery and histopathologic analysis: report of the Radiology Diagnostic Oncology Group'. *Radiology*, 212: 19–27.

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McAlpine JN, Hanley MMM, Tone AA et al. (2014) 'Opportunistic salpingectomy: uptake, risks, and complications of a regional initiative for ovarian cancer prevention'. *American Journal of Obstetrics & Gynecology*, 210 (5): 471

Nardo LG, Kroon ND, Reginald PW. (2003) 'Persistent Unilocular Ovarian Cysts in a General Population of Postmenopausal Women: Is There a Place for Expectant Management?' *Obstetrics & Gynecology*, 102 (3): 589-93.

Oyelese Y, Kueck AS, Barter JF et al. (2002) 'Asymptomatic postmenopausal simple ovarian cyst'. *Obstetrical & Gynecological Survey*, 57(12): 803-9.

8. Implementation Strategy

- Distribution of guideline to all members of the Institute and to all maternity units.
- Distribution to the Directorate of the Acute Hospitals for dissemination through line management in all acute hospitals.
- Implementation through HSE Obstetrics and Gynaecology Programme local implementation boards.
- Distribution to other interested parties and professional bodies.

9. Qualifying Statement

These guidelines have been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. Clinical material offered in this guideline does not replace or remove clinical judgement or the professional care and duty necessary for each pregnant woman. Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources and expertise.

This Guideline does not address all elements of standard practice and assumes that individual clinicians are responsible for:

- Discussing care with women in an environment that is appropriate and which enables respectful confidential discussion.
- Advising women of their choices and ensure informed consent is obtained.
- Meeting all legislative requirements and maintaining standards of professional conduct.
- Applying standard precautions and additional precautions, as necessary, when delivering care.
- Documenting all care in accordance with local and mandatory requirements.

10. Appendices

Appendix 1: Ovarian cancer GP referral for symptomatic women



OVARIAN CANCER GP REFERRAL FOR SYMPTOMATIC WOMEN



Ovarian cancer is the main cause of death from gynaecological cancer. Around 370 women are diagnosed each year; 80% are over 50 years of age. Most have advanced disease at presentation. Fewer than one-third have stage I or stage II disease at diagnosis. Survival in Ireland is poor - less than 40% at 5 years.

Data Source: National Cancer Registry Ireland

Factors that increase risk: Increasing age - most cases are post-menopausal; Lifestyle (overweight, smoking) is associated with 20%; Genetic mutations account for 10% (e.g. a woman with a first degree relative with ovarian cancer has a 3-4 fold increased risk. The known mutations, BRCA1 and BRCA2, explain less than 40% of the excess risk of familial cancer); Nulliparity; Prolonged HRT use (e.g. for more than 5 years); Unintentional infertility or use of fertility drugs.

Factors that decrease risk: Interruption of ovulation (e.g. pregnancy, oral contraceptive use, tubal ligation).

**Screening of well women for ovarian cancer does not reduce mortality. It is not recommended.
Ovaries are not palpable in post-menopausal women. If they are felt, consider malignancy.**

Symptoms of ovarian cancer

Ovarian cancer has few specific symptoms.

Consider ovarian cancer in women (especially aged over 50 years), who present with the following persistent and frequent symptoms (i.e. more than 12 times per month):

- Abdominal distension
- Early satiety
- Loss of appetite
- Pelvic or abdominal pain
- Increasing urinary urgency or frequency
- New onset Irritable Bowel Syndrome (IBS)

Consider ovarian cancer in women who present with unexplained:

- Ascites
- DVT
- Change in bowel habit
- Weight loss
- Fatigue

CA125

- Should not be ordered if a woman has no symptoms.
- Can be elevated in ovarian and other cancers and in many benign conditions.
- Is not an adequate ovarian cancer detection tool when used alone.
- Is raised in 80% of epithelial ovarian cancer but raised in only 50% of early stage disease.

Pelvic Ultrasound (US)

- A pelvic US is required to evaluate an ovarian mass.
- An urgent US is needed where CA125 is elevated in a symptomatic woman.
- Pre-menopausal ovarian cysts are common; almost all are benign.

A woman should be referred directly to gynae-oncology:

- If clinical findings reveal a pelvic mass or unexplained ascites (not obviously uterine fibroids)
- If an ultrasound (US) is suspicious for ovarian cancer. Please include details of where the US was carried out and a copy of the report
- If CA125 > 200kU/L
- If CA125 > 35kU/L and continues to rise on retesting but pelvic ultrasound is normal

Who can refer to gynae-oncology?

You, the GP, when the patient meets the criteria in this guideline.

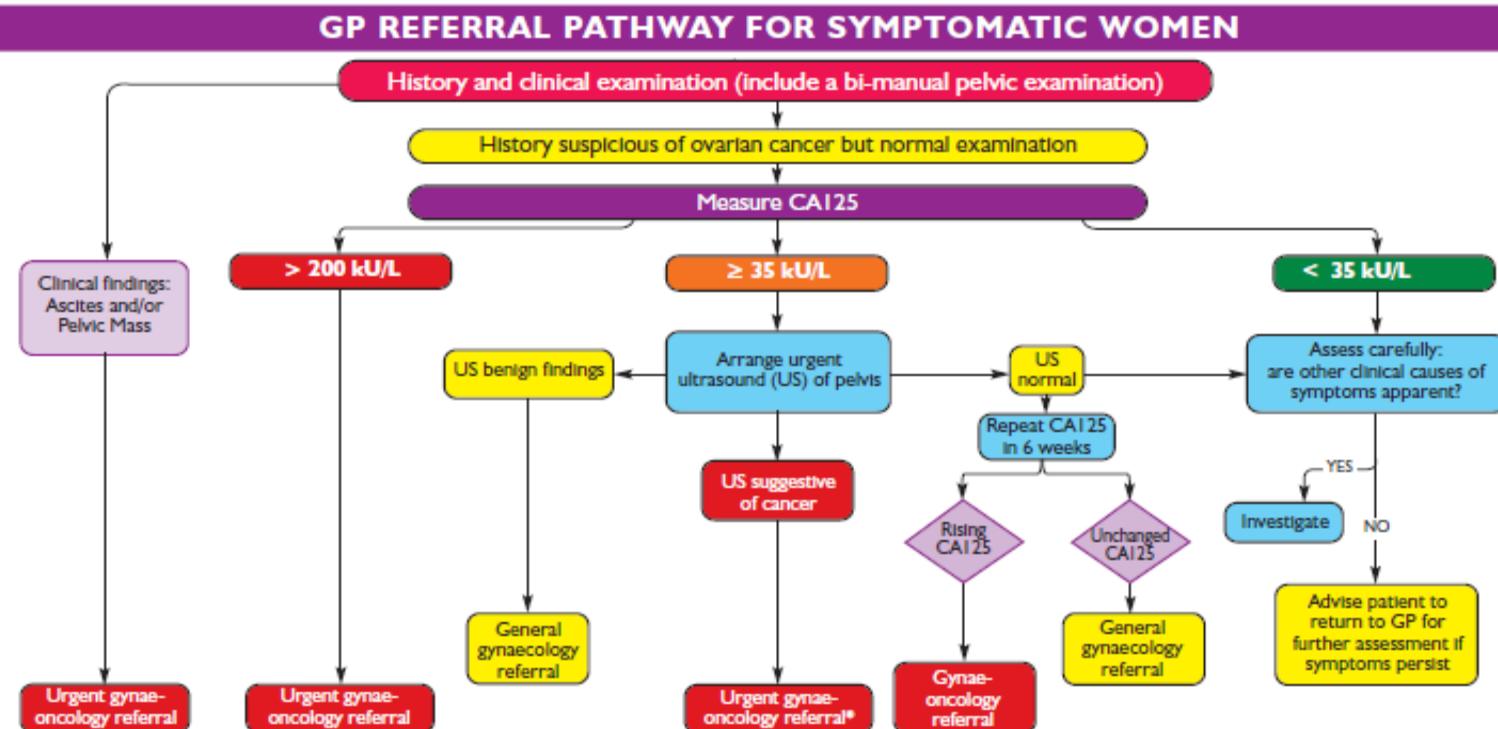
Another hospital-based clinician (e.g. from the Emergency Department or Radiology).

When is a referral to gynae-oncology not appropriate?

If a patient has benign gynaecological conditions referral should be to the general gynaecology service.

This guideline represents the view of the NCCP, which was arrived at after consideration of evidence. Health professionals are expected to take it fully into account when exercising their clinical judgment. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to each patient. This guideline will be reviewed as new evidence emerges.

NCCP-COM-009-01(b) V14: May 2016

**General Recommendations**

This referral guideline is to prioritise women with suspected ovarian cancer. You can make a referral using the ovarian cancer referral form to one of these gynaec-oncology centres.

Post-menopausal bleeding (1 year after last period) requires an urgent referral to any general gynaecology clinic in your area.

Women with other gynaecology symptoms should be referred routinely to a general gynaecology clinic in your area.

Gynaec-oncology centre contact details

<input type="checkbox"/> Cork University Hospital	[To be confirmed]	
<input type="checkbox"/> Galway University Hospital	Tel: 091 544529	Fax: 091 542044
<input type="checkbox"/> University Hospital Limerick	Tel: 061 482311	Fax: 061 485305
<input type="checkbox"/> St Vincent's University Hospital	Tel: 01 2216594 [Mon/Tues/Wed]	Fax: 01 221 4318
<input type="checkbox"/> St James's Hospital Dublin 8	Tel: 01 2213055 [Thurs/Fri]	
<input type="checkbox"/> Mater University Hospital	Tel: 01 803 4448	Fax: 01 805 6282
<input type="checkbox"/> University Hospital Waterford	Tel: 051 842778	Fax: 051 842132

Appendix 2: National Ovarian Cancer GP Referral for symptomatic women

<h1 style="margin: 0;">NATIONAL OVARIAN CANCER GP REFERRAL FOR SYMPTOMATIC WOMEN</h1> <p>This referral form should ONLY be used where ovarian cancer is suspected. Other gynaecological conditions that require specialist consultation can be referred in the usual manner to any general gynaecology clinic.</p> <p>Please follow the referral guideline and insert the required clinical information on this form to refer a patient to:</p> <p>A) ANY radiology department for an ultrasound or B) directly to ONE gynaec-oncology centre.</p>	 <p>HSE Health Service Executive National Cancer Control Programme</p>																
<p>For direct gynaec-oncology referrals please POST OR FAX this FORM to ONLY ONE of the Hospitals listed below to avoid duplication</p>	<table border="0"> <tr> <td><input type="checkbox"/> Cork University Hospital [To be confirmed]</td> <td><input type="checkbox"/> St James's Hospital Dublin 8</td> <td>Tel: 01 4162239</td> <td>Fax: 01 410364</td> </tr> <tr> <td><input type="checkbox"/> Galway University Hospital Tel: 091 544529 Fac: 091 542044</td> <td><input type="checkbox"/> Mater University Hospital</td> <td>Tel: 01 8024446</td> <td>Fax: 01 8056282</td> </tr> <tr> <td><input type="checkbox"/> University Hospital Limerick Tel: 061 482311 Fac: 061 485305</td> <td><input type="checkbox"/> University Hospital Waterford Tel: 051 842778</td> <td>Tel: 051 842132</td> <td>Fax: 051 842132</td> </tr> <tr> <td><input type="checkbox"/> St Vincent's University Hospital Tel: 01 2216594 [Mon-Fri] Tel: 01 2213055 [Thurs-Fri]</td> <td></td> <td></td> <td></td> </tr> </table>	<input type="checkbox"/> Cork University Hospital [To be confirmed]	<input type="checkbox"/> St James's Hospital Dublin 8	Tel: 01 4162239	Fax: 01 410364	<input type="checkbox"/> Galway University Hospital Tel: 091 544529 Fac: 091 542044	<input type="checkbox"/> Mater University Hospital	Tel: 01 8024446	Fax: 01 8056282	<input type="checkbox"/> University Hospital Limerick Tel: 061 482311 Fac: 061 485305	<input type="checkbox"/> University Hospital Waterford Tel: 051 842778	Tel: 051 842132	Fax: 051 842132	<input type="checkbox"/> St Vincent's University Hospital Tel: 01 2216594 [Mon-Fri] Tel: 01 2213055 [Thurs-Fri]			
<input type="checkbox"/> Cork University Hospital [To be confirmed]	<input type="checkbox"/> St James's Hospital Dublin 8	Tel: 01 4162239	Fax: 01 410364														
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<input type="checkbox"/> St Vincent's University Hospital Tel: 01 2216594 [Mon-Fri] Tel: 01 2213055 [Thurs-Fri]																	
<p>PATIENT DETAILS</p> <p>Surname: _____ First Name: _____ DOB: _____ Address: _____ Tel evening: _____ Hospital No. (if known): _____ First language: _____ Interpreter needed: <input type="checkbox"/> Yes Wheelchair assistance: <input type="checkbox"/> Yes</p>	<p>GENERAL PPA CITIZENSHIP DETAILS</p> <p>Name: _____ Address: _____ Telephone: _____ Mobile: _____ Fax: _____ GP Signature: _____ Date of referral: _____ Medical Council Registration No: _____</p>																
<p>REFERRAL INFORMATION</p> <p>Is this referral for pelvic ultrasound? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes what is the CA125 result: _____ kU/L In what hospital was the CA125 test analysed: _____ Date of CA125 test(s): _____</p>	<p>Is this a referral to gynaec-oncology? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes does the patient have: <ul style="list-style-type: none"> • Unexplained ascites / pelvic mass <input type="checkbox"/> Yes <input type="checkbox"/> No • US suggestive of ovarian cancer (attach report) <input type="checkbox"/> Yes <input type="checkbox"/> No • CA125>200kU/L <input type="checkbox"/> Yes <input type="checkbox"/> No • Elevated CA125 (>35kU/L) that on repeat testing <input type="checkbox"/> Yes <input type="checkbox"/> No after 6 weeks continues to rise (attach report(s)) </p>																
<p>PAST MEDICAL / FAMILY HISTORY</p> <p>Please tick as appropriate</p> <p>Family history:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Ovarian cancer <input type="checkbox"/> Hysterectomy <input type="checkbox"/> On HRT for _____ years <p>Menopausal status:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Post-menopausal (>1 yr since LMP) <input type="checkbox"/> Hysterectomy <input type="checkbox"/> On HRT for _____ years <p>Reason patient did not accept first appointment offered: _____</p>	<p>Previously seen by Gynaecologist? <input type="checkbox"/> Yes <input type="checkbox"/> No Consultant name: _____ Location: _____ Year: _____ Diagnosis if known: _____</p> <p>Allergies? <input type="checkbox"/> Yes <input type="checkbox"/> No Anticoagulants? <input type="checkbox"/> Yes <input type="checkbox"/> No Medication? <input type="checkbox"/> Yes <input type="checkbox"/> No List Medication: _____ _____ _____</p>																
<p>FOR HOSPITAL USE:</p> <p>Gynaec-oncology Triage Team <input type="checkbox"/> Urgent Referral for gynaec-oncology <input type="checkbox"/> Routine Referral (related to routine gynaecology clinic) Triaged by: _____</p>	<p>Date of referral received: _____ Date of appointment offered: _____</p>																
<small>The form will be reviewed at new evidence emerges.</small>																	
<small>NCCP May 2004</small>																	