Treatment Guidelines

Gynaecology SELCN

June 2012
## SELCN Treatment Guidelines - Agreement Sheet

The Gynaecology SELCN Treatment Guidelines have been agreed by:

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<td>8th June 2012</td>
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**TWG members agreed Treatment Guidelines on:** 8th June 2012

**Treatment Guidelines Review Date:** 7th June 2013

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1.0 Introduction

In 1995, the then government published the Calman Hine review “A Policy Framework for Commissioning Cancer Services” which signalled the start of a national focus on the strategic development of cancer services. This report focused on the management of cancer with the development of cancer services on a number of general principles, which included:

- Access to a uniformly high quality of care;
- Public and professional education to help early detection;
- Clear information for patients, carers and their families;
- Patient centred service development;
- Excellent and seamless communication between organisations involved in patient care.

In order to deliver on these recommendations a new structure was established based on a network of expertise in cancer care reaching from primary care through Cancer Units in district hospitals to Cancer Centres. Through this, an Expert Advisory Group aimed to ensure that the benefits of specialised care were available to all patients either close to their homes or, when necessary, by referral to special Centres, including the Joint Cancer Centre of Guy’s, Kings College and St Thomas’ Hospital.

The thrust of the Gynaecological Improving Outcomes Guidance (IOG) Advisory Group is the centralisation of all major surgery for any form of gynaecological malignancy. Thus it suggests that all ovarian cancers, most cervical and more advanced and aggressive endometrial cancers as well as all vulval and vaginal cancers should be operated on and managed within the environment of a Cancer Centre. Within the South East London Cancer Network, there is the Joint Cancer Centre of Guy’s, King’s College and St Thomas’ Hospitals (GKT). In discussion and agreement within the Centre, the base for gynaecological cancer surgery became the St Thomas’ Hospital site.

A review of the annual activity for gynaecological cancer surgery reveals that full implementation of the Gynaecological IOG would result in a transfer of 242 cases from the current site at Kings as well as the surrounding Cancer Units – University Hospital, Lewisham (UHL), Queen Elizabeth Hospital, Woolwich (QE), Queen Mary’s’ University Hospital (QMUH), Sidcup and Princess Royal University Hospital Bromley, (PRUH).
1.1 Cancer Centres and Cancer Units

1.1.1 Cancer Units

Cancer Units are usually located in district hospitals with a full range of supportive services; they have arrangements for the close integration of primary and secondary care and the identification of appropriate rapid referral patterns for patients with symptoms indicating a high risk of a malignancy. Cancer Units have site-specific consultations in clinics led by consultant specialists.

1.1.2 Cancer Centres

Cancer Centres form part of large general hospitals providing services for patients with commoner cancers in the same way as the Cancer Unit, as well as an additional range of specialized services, which are provided in support of Cancer Units on a Network basis. The Cancer Centre provides a full range of cancer treatments encompassing treatment programmes for less common and rare cancers and those treatment regimens, which are too specialised, technically demanding or capital intensive to be provided in the Cancer Unit.

Cancer Centres are responsible for the coordination and conduct of clinical and basic research projects in the area of gynaecological and other malignancies. To this end partnership with and membership of local, national and international organisations are sought.

1.2 South East London Cancer Network

The South East London Cancer Network (SELCN) serves a local resident population of 1.5 million although for specialist and less common cancers it has a larger catchment population. The Network comprises the Joint Cancer Centre of GKT with associated cancer units at PRUH, QEH, QMH, UHL.

The Network oversees the strategic development of cancer services, the setting, implementation and monitoring of evidence based protocols as well as the establishment of network wide policies and systems, communication and high quality network wide research and development.

1.2.1 SELCN Gynaecological Cancer Group

There is a specific sub group of the SELCN, which is devoted to the development of gynaecological cancer management within the Network. This group meets on a quarterly basis. All members of the GKT Joint Cancer Centre Gynaecology Multi-disciplinary team are members of this group together with representation from all cancer units in the network, the Primary Care Trusts and the Network cancer management team.
1.3 Gynaecological Clinical Outcomes Guidance

Since the initial publication of the Calman Hine Service Framework (1995), a number of specialist reference groups were drawn together to look at care models for specific cancer types. These groups each made recommendations based on the Cancer Network model as to how care should be organised and which services should be provided at the various care levels within the Network. The specific guidance looking at gynaecological cancers was first published in July 1999.

The SELCN Gynaecological Cancer Group was set up to oversee the strategic and operational development of services for gynaecological cancers and as such has been responsible for agreeing a model of care to support the implementation of the Gynaecological Improving Outcomes Guidance (IOG). This group of cancers includes cancer of the ovary, endometrium, cervix, vagina and vulva.

1.4 Key Recommendations of the Gynaecological IOG

The key recommendations of the Gynaecological IOG were as follows:

That dedicated diagnostic and assessment services should be established in Cancer Units, to which all women with possible or suspected Gynaecological cancers should be referred.

There should be specialist multi-professional gynaecological oncology teams based in Cancer Centres responsible for the management of all women with gynaecological cancer with the exception of stage 1a1 carcinoma of the cervix and low risk, grade 1, stage 1a and 1b, endometrial carcinoma.

The specialist gynaecological oncology and palliative care teams in each Cancer Centre and associated Cancer Units should agree clear local policies for the management of women with advanced or progressive disease. These policies should be designed to ensure the co-ordination of high quality care between Cancer Centres, Cancer Units, palliative care, primary care and community services.

There should be rapid and efficient communication systems for liaison and cross-referral between all levels of service. Audit should take place across the entire service delivery network, including the Cancer Centre and all related Units.

The translation of this to the services that should be provided at the cancer unit or cancer centre is shown in the next sections.

1.4.1 Services provided by the Cancer Unit

Cancer units should provide rapid assessment services for patients with pelvic masses or post-menopausal vaginal bleeding, a dedicated colposcopy service for the evaluation of abnormal cervico-vaginal cytology, and systems for data collection and audit within the 31 day cancer waiting times guidance for patients referred within the two week wait system.
1.4.2 Responsibilities of the Cancer Unit

These responsibilities relate to the initial diagnostic procedures such as clinical examination, biopsies of endometrial, cervical, vaginal and vulval lesions, ultrasound scanning and tumour marker assays. In addition, the designated lead gynaecologist should normally carry out surgery for early (stage Ia or b, grade 1) endometrial carcinoma, early cervical carcinoma (stage Iai) and for pelvic masses where the risk of malignancy, based on the Risk of Malignancy Index, is low (less than 250).

1.4.3 Linked services at the Cancer Unit

Pathology: Biopsy specimens and pathology reports should be sent to the Cancer Centre when women are referred there from the Cancer Unit.

Chemotherapy: may only be given within the Cancer Centre.

Psychosocial and psychosexual counselling: The extent to which these are provided at Cancer Units will depend on local circumstances. Where they are not available, there should be easy access to these facilities at a Cancer Centre.

Clinical Nurse Specialist Gynaecological Oncology. All patients with the diagnosis of Gynaecological Malignancy should have access to nurses with specialist knowledge (see nursing support section).

Stoma care: Patients should have access to specialist nurses who can offer assistance with stomas.

Lymphoedema treatment: Nurses or therapists with specialist knowledge of lymphoedema should be available at Cancer Units.

Palliative care: All Cancer Units are responsible for delivery of local in-patient palliative care.

1.4.4 Services Provided by the Cancer Centre

Women with gynaecological cancers that are less common or more difficult to treat (ovarian cancers, later stage and aggressive histological subtype endometrial cancers, cancers of the cervix, vulva or vagina) should be managed by a specialist multi-professional Gynaecological Oncology Team based at a Cancer Centre. This core team should liaise closely with designated lead gynaecologists at the Cancer Unit level. All members of the Cancer Centre core team should have a special interest in gynaecological cancer with one member taking lead managerial responsibility for the service as a whole.

The specialist gynaecological oncology team meets weekly to discuss the management of individual patients. There are joint or parallel clinics involving different disciplines, so that individual patients can be seen and discussed by two or more team members together. More than one person may be required to fulfil each role in the team, depending on workload. The team must maintain close contact with other professionals who are actively involved in supporting the patient or carrying out...
the management strategy decided by the team. Throughout the care of each patient and her family there should be a named clinician to whom she principally relates. Such arrangements should be explicit and clearly understood by patients and health care professionals, including the primary care team.

1.5 Guidelines for the Management of Individual Tumour Sites

These Guidelines have been developed to assist healthcare practitioners and providers in making appropriate decisions of care for patients in specific clinical circumstances. The objective is to come as close as possible to an optimal outcome for the individual patient.

Guidelines are designed based on current research evidence and thus their need to be updated annually. Statements in these guidelines are not designed to be prescriptive regarding treatment decisions as these are ultimately taken by senior personnel within the Gynaecology-Oncology team.

Although the detailed focus of these guidelines is on the surgical aspect of care of the patient with a gynaecological malignancy, its relationship to the components of non-surgical care is described.

All clinical and medical oncology interventions will take place at the cancer centre. Protocols regarding the preoperative checklist, preoperative preparation and postoperative care are mandatory; any deviation needs to be discussed with senior personnel within the Gynaecology-Oncology team. The ultimate decisions for the care of the patient rests with that of the individual consultant concerned.

1.6 General Guidance for Referrals

Primary care referrals of patients with symptoms suspicious of gynaecological cancer should be made using the 2-week wait proforma. These patients will be seen at the next available Gynae Oncology clinic. Other patients with such symptoms referred to other clinics or gynaecologists will be triaged by the unit Gynae team and redirected to the next available Gynae Oncology clinic.

Tertiary referrals should be made to the Department of Gynaecological Oncology 12th floor St Thomas’ Hospital C/O the administrator who will ensure that patients receive timely appointments in the Wednesday Combined Gynae Oncology clinic and are reviewed with their referral problems, original pathology, imaging and histology/cytology in the MDM. Please refer to the Gynaecology MDT Operational Policy for guidelines on how to refer.

1.6.1 Emergency Care

Emergency referrals from other specialities, within each unit, should be referred to the Unit Gynaecology Oncology team, who will assess the patient before re-referring as appropriate. If required the patient will be presented and discussed at the Centre MDM Meeting.
1.7 Gynaecology MDT Patient Pathway
2.0 Cancer of the Cervix

2.1 Staging
(Reference: UICC: TNM Classification of Malignant Tumours 5th Edition pp.141-6.)

The two major international systems of classification of gynaecological cancers by their anatomic extent are respectively the FIGO (Fédération Internationalé de Gynécologie et d’Obstétrique) system, specific for gynaecological malignancies, and the TNM (Tumour, Node, Metastasis) system applicable to all sites and adopted by the UICC (International Union Against Cancer) and the AJCC (American Joint Committee on Cancer).

Both classifications may be utilized in the same patient as long as the general principles of staging are understood and strictly adhered to. The FIGO system is utilized for the purposes of these guidelines.

The staging should be based on careful clinical examination before any definitive therapy. It is desirable that the examination be performed by an experienced examiner (Consultant Gynae-Oncologist or Gynae-oncology Sub-specialist registrar) with input from a non-surgical gynaecologist/ oncologist and under anaesthesia. The clinical staging must under no circumstance be changed on the basis of subsequent findings. When it is doubtful to which stage a particular case should be allotted the case must be referred to the earlier stage. Only if the rules for clinical staging are strictly observed will it be possible to compare results of different clinics and modes of therapy.

2.1.1 Post surgical pathological staging
[TNM classification]

Such findings may reveal unsuspected extent of disease. This should not change the clinical staging but should be recorded. Similarly, if hysterectomy has been carried out for other reasons and an unsuspected cancer if found, such stages cannot be clinically staged but should be recorded separately. Additionally, restaging should not be carried out at the time of disease recurrence.
### Stage

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
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<tbody>
<tr>
<td>X</td>
<td>The primary tumour cannot be assessed</td>
</tr>
<tr>
<td>0</td>
<td>Carcinoma in situ, intra-epithelial carcinoma. Cases of Stage 0 should not be included in any therapeutic statistics for invasive Carcinoma</td>
</tr>
<tr>
<td>I</td>
<td>The carcinoma is strictly confined to the cervix</td>
</tr>
<tr>
<td>Ia</td>
<td>Invasive carcinoma identified only microscopically. All gross lesions even with superficial invasion are stage Ib cancers. Invasion is limited to measured stromal invasion with maximum depth of 5mm and no wider than 7mm.</td>
</tr>
<tr>
<td>Ia1</td>
<td>Measured invasion of stroma no more than 3mm in depth and no wider than 7mm.</td>
</tr>
<tr>
<td>Ia2</td>
<td>Measured invasion of stroma more than 3mm and less than 5mm in depth, and no wider than 7mm.</td>
</tr>
<tr>
<td>Ib</td>
<td>Clinical lesions confirmed to the cervix or pre-clinical lesions greater than stage Ia.</td>
</tr>
<tr>
<td>Ib1</td>
<td>Clinical lesions no greater than 4cm in greatest dimension.</td>
</tr>
<tr>
<td>Ib2</td>
<td>Clinical lesions more than 4cm in greatest dimension.</td>
</tr>
<tr>
<td>II</td>
<td>The carcinoma extends beyond the cervix, but has not extended to the pelvic wall. The carcinoma involves the vagina, but not as far as the lower third.</td>
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<tr>
<td>IIa</td>
<td>No parametrial involvement.</td>
</tr>
<tr>
<td>IIb</td>
<td>With parametrial involvement.</td>
</tr>
<tr>
<td>III</td>
<td>The carcinoma has extended to the pelvic wall. On rectal examination there is no cancer-free space between the tumour and pelvic wall. Or the tumour involves the lower third of the vagina. All cases with hydronephrosis or non-functioning kidney are included, unless they are known to be due to other causes.</td>
</tr>
<tr>
<td>IIIa</td>
<td>The tumour involves the lower third of the vagina but not the pelvic sidewall.</td>
</tr>
<tr>
<td>IIIb</td>
<td>Extension to the pelvic wall and/or hydronephrosis or non-functioning kidney.</td>
</tr>
<tr>
<td>IV</td>
<td>The carcinoma has extended beyond the true pelvis or has clinically involved the mucosa of the bladder or rectum. The presence of bullous oedema does not permit a case to be allotted to stage IV.</td>
</tr>
<tr>
<td>IVa</td>
<td>Spread of the growth to adjacent organs.</td>
</tr>
<tr>
<td>IVb</td>
<td>Spread to distant organs.</td>
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2.2 Investigations

Inspection/palpation of the tumour

Colposcopic assessment and biopsy and/or examination under anaesthetic with/without biopsy

If stage 1a suspected, a loop excision to provide a cone biopsy in a single piece should be performed

Endocervical curettage

Hysteroscopy

Cystoscopy +/- bladder biopsy

Proctoscopy +/- biopsy

Intravenous urogram

Chest x-ray

Full blood count

Urea, electrolytes, creatinine

LFT’s, bilirubin, albumin

Because the following investigations are not universally available, they cannot be used to alter the clinically determined stage of disease but they may be of benefit in planning treatment

Laparoscopy

Pelviabdominal ultrasound

MR scan of the abdomen and pelvis with intravenous and oral contrast

CT scan of the chest
2.3 Treatment

2.3.1 Treatment by stage

Microinvasion: The diagnosis of IA1 or IA2 disease can only be made on the basis of a cone biopsy specimen, with negative margins, or on a trachelectomy or hysterectomy specimen. If cone biopsy margins are positive, a second cone should be obtained, or the patient treated as for stage IB disease [1].

Stage 1a1. No lympho-vascular space involvement
Retain fertility - cone biopsy
Completed family - total / vaginal hysterectomy [2].

Stage 1a2
Modified radical hysterectomy and pelvic lymphadenectomy. If there is no lymphovascular invasion in the biopsy specimen consider extrafascial hysterectomy and pelvic lymphadenectomy.
Consider Trachelectomy and pelvic lymphadenectomy, the latter by laparoscopy if preferred, if retention of fertility is required [3,4].

Early stage disease can be equally well controlled by surgery or radiotherapy [6,7]. When modalities are combined morbidity is usually increased, therefore, primary treatment should seek to avoid planned use of both radical surgery and radiotherapy.

Stage Ib1
<2cm in diameter – radical hysterectomy with pelvic lymphadenectomy or consider radical trachelectomy and extraperitoneal lymphadenectomy if patient is young and wishes to preserve fertility.

Stage 1b and IIa

Primary tumour <4cm in diameter
well or moderately differentiated squamous cell carcinoma. No lymph-vascular space involvement
Radical hysterectomy with pelvic lymphadenectomy (+ BSO if >45 years)

Consider ovarian transposition, in younger patients where postoperative radiotherapy is likely.

Also consider radical vaginal hysterectomy.

Primary tumour <4cm in diameter Poorly differentiated and/or lymph-vascular space involvement
Radical hysterectomy with pelvic lymphadenectomy OR
radical radiotherapy and concomitant chemotherapy

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Primary tumour >4cm in diameter. Poorly differentiated and/or lymph-vascular space involvement

Radical radiotherapy and concomitant chemotherapy

Consider also, primary chemoradiotherapy [14], radical surgery followed by radiotherapy, or neoadjuvant chemotherapy followed by radical surgery +/- adjuvant radiotherapy/chemotherapy [15]

Unfit for radical surgery Radiotherapy.
Consider concomitant chemotherapy if performance status 0-1

Stage IIb, IIIa, IVa and IVb

Radical Radiotherapy + concomitant chemotherapy

Adenocarcinoma of the cervix should be treated stage for stage as for squamous carcinoma.

Stage Ib or IIa post-Radical hysterectomy.

Surgical Group Node +ve or positive margins in parametrium

Adjuvant Radiotherapy +/- concomitant chemotherapy

Primary tumour >4cm in diameter Poorly differentiated And/or Lymph-vascular space involvement

Radical Radiotherapy + concomitant chemotherapy
2.4 Surgery

2.4.1 Radical hysterectomy and pelvic node dissection
(Wertheim Hysterectomy)

This involves removal of the uterus and the adjacent parametrium and paracolpos. The cardinal and uterosacral ligaments are sacrificed to a varying degree depending on the type of radical hysterectomy (see Piver et al for details). In addition, the upper one third of the vagina approximately is removed. A bilateral pelvic lymphadenectomy is performed.

The lymphadenectomy may be performed first; any suspicious nodes being sent for frozen section analysis. If positive the procedure is abandoned and chemo-radiation or radiation alone given.

Ovarian preservation is discussed with the patient.

2.4.2 Radical trachelectomy and pelvic node dissection

This involves amputation of the cervix with removal of a 1cm cuff of vagina, and clearance of the pelvic nodes extra-peritoneally.

Indications:

Management of disease with the following patient or tumour characteristics:

A strong desire for child bearing without contraindications for adequate fertility; and understands that a caesarean section would be necessary.
Age sufficient to support childbearing (preferably <40yrs).
Compliant with intensive follow up.
Compliant with the recommendation that a full TAH be performed post completion of family.
Stage Ia1+LVSI
Stage Ia2.
Up to Stage Ib1 providing the cervical lesion is 2cm or less.

Pre-operative preparation:
The preoperative preparation and investigations are similar to that for a simple hysterectomy, except that 2 units of blood are held in reserve, after cross matching.

Consent:
Radical Trachelectomy and extraperitoneal lymph node dissection and uterine suture insertion.

Factors to be discussed at consent:

Drains (One to each pelvic side wall), and a bladder catheter usually 24-48 hrs.
Post-operative management:
Local Trust guidelines to be referred to for routine post op care.

Follow Up Adjuvant Treatment Required:

No further treatment if:
IA1
IA2 – no lymph nodes metastases, not poorly differentiated, no LVSI.

Adjuvant Chemo-Radiotherapy if:
IA2 and lymph node involvement.
IA2 and poorly differentiated and/or LVSI
All of these patients must be referred to the Clinical Oncology team via MDM by a member of the Gynaecological Oncology team, and discussed at the MDT meeting.
Please refer to Gynaecology MDT Operational Policy for referral guidelines.

Follow Up where NO Adjuvant Treatment is Required:
The first appointment to follow MDM decision regarding management.
The patient is then seen at 3 monthly intervals for the first year, and 4 monthly for the second. A colposcopy and smear will be performed at each visit.
Subsequent follow up will be at 6 monthly intervals for 5 years. The patient should be seen by the Gynaecological Oncology Consultant if she conceives and as soon as she has a positive pregnancy test.

2.4.3 Pelvic exenteration

In a carefully selected group of women pelvic exenterative surgery may be used with curative intent for central locally recurrent uterine malignancy where radiation therapy has previously been used. In the absence of recurrent disease exenterative procedures have on rare occasions also been carried out for radiation necrosis, where the quality of the patient's life would be improved. Exenterative procedures may be anterior, posterior or total. They may also be of the supra or infralevator type depending upon the distribution of the disease. A multi disciplinary approach will be employed involving the active participation of colorectal and urological surgeons as appropriate in the management of these patients.

Incidental finding of cervical cancer
This refers to the finding of invasive disease following simple hysterectomy for a presumed benign condition. Before commencing treatment a pelviabdominal CT or MR scan and chest Xray should be performed to assess disease extent. Treatment choice depends upon histological and radiological findings.

For radiological stage Ia1 disease, no further treatment is required.
For stages Ia2 and beyond, further treatment should be as follows:
If margins are positive, or if there is deep stromal or lymphvascular space invasion, pelvic radiotherapy +/- concurrent chemotherapy should be given.
2.5 Cervical cancer during pregnancy

In general the principles are the same as in non-pregnant women. However, cone biopsy should only be considered if cytology/biopsy/colposcopy suggest possible invasion because of the problems of haemorrhage, abortion or premature labour. All management plans should be decided on after full discussion with the woman and her partner and their wishes must be respected.

There is no evidence that the mode of delivery in women with Ia1 disease influences outcome.

For all other stages of disease, management must be individualised and is influenced by stage of disease and gestation.

If the diagnosis is made before 20 weeks gestation, the disease should be treated without delay. Radical surgery may be performed with the foetus in situ. Spontaneous abortion will usually occur in patients treated with chemo/radiotherapy. If diagnosed after 28 weeks, foetal viability should be achieved before treatment is initiated. If the diagnosis is made between 20 and 28 weeks, treatment delay is an option for patients with Ia2 and Ib1 disease. For more advanced disease, the effect of treatment delay on patient survival is unknown.
Management of Cervical Cancer after EUA, CT scan to assess stage

- **IA1**
  - Local excision:
    - LLETZ
    - KCB
    - TAH/VH

- **IA2**
  - Fertility Desired
    - ≤ 2cm
      - KCB
      - Radical Trachelectomy
      - Extra pelvic lymph node dissection
  - Radiotherapy alone
    - Radical Hysterectomy*
      - Lymph nodes +ve
        - EBRT
        - No LVSI – ve Lymphnodes

- **IA2-IIA**
  - No Surgery
    - IIA - IV

- **IB1**
  - Follow up
  - Poorly Differentiated
  - LVSI
    - Chemo

* Radicality of hysterectomy is tailored to the stage of disease.
** Adjuvant chemotherapy for patient with poorly differentiated SCC after RHPLD

If: Hydronephrosis
- For stenting/nephrostomy insertion
- Check renal function before deciding treatment

Routine follow up
2.6 Radiotherapy

Histology: The majority of cases are squamous cancers however a small number will be adenocarcinomas. The treatment for both histological types is the same.

Post-operative radiotherapy:

Stage Ia (micro-invasive). Patients have usually had TAH or vaginal hysterectomy and cervical carcinoma found incidentally on pathological examination of cervix.

Treatment category: Standard treatment planning and start i.e. within 4 weeks of request. Treatment category 2, i.e. prolong overall treatment time by resting on service days and holidays.

Pelvic radiotherapy: 45 Gy in 25 fractions in 5 weeks.

Planning target volume: To cover upper half of vagina, obturator, internal and lower common iliac nodes and uterine bed. The volume need not cover the uterosacral ligaments posteriorly unless the primary tumour was more advanced.

Stage Ib or IIa post-Wertheim’s hysterectomy. Patients either node-positive or positive margins in parametrium or large (> 4cm diameter) poorly differentiated tumour. (1)

Treatment category: Standard treatment planning and start i.e. within 4 weeks of request. Treatment category 1 i.e. treatment time should not be prolonged and patients should be treated over public holidays and on machine service days.

Pelvic radiotherapy: 45 Gy in 25 fractions in 5 weeks.

Planning target volume: To cover upper half of vagina, obturator, internal and lower common iliac nodes and uterine bed. The volume need not cover the uterosacral ligaments posteriorly unless the primary tumour was more advanced.

Stage Ib or IIa post-Wertheim’s hysterectomy. Patients with positive vaginal margins.

Treatment category: Standard treatment planning and start i.e. within 4 weeks of request. Treatment category 1 i.e. treatment time should not be prolonged and patients should be treated over public holidays and on machine service days.

Pelvic radiotherapy: extended pelvis plus vaginal ovoids. Intracavity boost to give 20 Gy at a point 0.5 cm from the surface of the ovoids

Non-operated patients ie those having radical radiotherapy alone.

Treatment Category: Urgent treatment planning and start date
i.e. start within 2 weeks of request date.
Treatment category 1 i.e. treatment time should not be prolonged and patients should be
treated over public holidays and on machine service days.

Stage Ib (radical radiotherapy): Either 2 intracavity insertions (tube and ovoids) to give 60 Gy to point A OR whole pelvis 45 Gy in 25 fractions in 5 weeks followed 2 weeks later by Selectron insertion (tube and ovoids) to give 25 Gy to point A. Maximum rectal dose from the entire treatment 60Gy.
If the tumour is large and friable and there may be difficulty dilating the cervical canal safely consider giving 20 Gy in 10 fractions in 2 weeks to the uterus and cervix followed by 2 intracavity insertions as above, reducing the intracavity dose as appropriate to maintain a safe rectal dose.

Stage IIa, IIb, and III: Pelvic radiotherapy: extended pelvis fields as above. Preferably plan using CT planning or virtual simulation to ensure accurate coverage of the primary tumour and nodes (2). 50.4 Gy in 25-28 fractions in 35-37 days then MDR Selectron insertion after 7-10 day gap to give 22.5-25.0 Gy to point A. Maximum rectal dose from the entire treatment 64Gy.

Para-aortic nodes if involved either surgically or on CT scan: 45 Gy in 25 fractions in 35 days with parallel opposed pair then cone down to treat planned volume to 50-55 Gy in a further 6-8 fractions.

Stage IV: Treatment in cases of advanced disease needs to be individualised, however it should be remembered that up to 25% of patients presenting with Stage IV disease will be alive 5 years after radical radiotherapy.
Pelvic radiotherapy; Usually a parallel opposed pair to encompass the local disease. 50 Gy in 27-30 fractions in 37-42 days followed after a 2-week gap by intracavity caesium 22.5 Gy to Point A or further planned volume to treat primary tumour with external beam radiotherapy to total of 60Gy.
2.7 Chemotherapy

Concomitant chemotherapy: There is now good level 1 evidence (3-5) that the addition of platinum-based chemotherapy improves both local control and survival in patients treated with radical radiotherapy and in high-risk patients with early stage disease treated postoperatively with radiotherapy. Both acute and long term toxicity of the treatment are increased and patients must have adequate renal function and performance status to tolerate the addition of chemotherapy. It must be recognised that radiotherapy is curative treatment and additional treatment should not compromise the radiotherapy by extending the overall time or causing dose reductions.

Concomitant weekly cis-platin:
Serum creatinine < 100 µmol/L
Exclusions:
Contraindication to cisplatin (e.g. deafness, intolerance to fluid load, neuropathy) any small cell component ECOG status = 3
Tests:
Baseline and before each treatment (on treatment day or within two previous days, attempt to coordinate with routine radiation therapy tests): fbc & diff, creatinine, electrolytes
Prehydration:
1000 mL 2/3 D5W-1/3 NS with 20 mEq potassium chloride and 2 g magnesium sulphate over 2 hours, prior to cisplatin
Premedication:
Granisetron 3 mg PO 30 minutes prior to cisplatin
dexamethasone 6 mg PO 30 minutes prior to cisplatin
Treatment: note: Since cisplatin is used in this protocol as a radio-sensitizing agent, it is to be administered on a day on which radiation therapy is delivered, preferably on day 1 or 2 of the 5-day radiation. If radiation therapy is cancelled, do not give cisplatin that day; postpone until radiation therapy resumes.

Cis-platin 40 mg/m2 IV in 500 mL NS with 30 g mannitol and 2 g MgSO4, over 1 hour
Repeat weekly x 4 cycles
Posthydration:
1000 mL 2/3 D5W-1/3 NS with 20 mEq potassium chloride and 2 g magnesium sulphate over 2 hours, after completion of cisplatin

Anti-emetics post-cisplatin:
dexamethasone 4 mg PO 12 hours after cisplatin, then 4 mg PO q12h x 2 days (3 days if necessary) domperidone 20mg tds for 2-3 days

Precautions:
1. Renal Toxicity: Nephrotoxicity is common with cisplatin. Encourage oral hydration. Avoid nephrotoxic drugs such as aminoglycosides.
2. Neutropenia: Fever or other evidence of infection must be assessed promptly and treated aggressively.
2.8 Follow up

2.8.1 Surgery

Surgical patients will receive a follow-up appointment at the Centre six weeks post-operatively. If surgery has been the only treatment, the patients will then be followed up at the Unit with vault smears:

3 monthly intervals for the first year
6 monthly in the second year
annually until 5 years

2.8.2 Chemoradiation

Chemo-radiation patients will receive a follow-up appointment at the Centre six weeks after the end of treatment. Thereafter, follow-up will remain at the Centre. Smears not routinely taken:

3 monthly intervals for the first year
4 monthly in the second year
6 monthly for 5 years (after 3 years can be followed up in Unit)
2.9 References


3.0 Cancer of the Ovary

3.1 Staging

The FIGO Gynaecological Oncology committee recommended that the clinical staging of primary carcinoma of the ovary should be based on findings at laparotomy as well as on the usual clinical examination and imaging studies. Although laparoscopy may be used to delineate the site of disease, to assess whether surgical resection is possible and to obtain biopsies, staging surgery is usually performed by laparotomy.

3.1.1 Staging laparotomy

A staging laparotomy for suspected ovarian malignancy should involve:

- Laparotomy via midline incision
- Careful evaluation of all peritoneal surfaces
- Washings (or ascites) of the peritoneal cavity
- Infracolic omentectomy
- Biopsy and/or resection of any suspicious lesions, masses and any adhesions
- Total abdominal hysterectomy and bilateral salpingo-oophorectomy
- Selected lymphadenectomy of the pelvic and para-aortic nodes
- Appendicectomy for mucinous tumours

The operation note should record the size, site and number of tumour nodules, and the volume of ascites. A record should be made of the size and site of residual disease.

The histopathology and cytology findings after surgery are to be considered in the staging process (1).
3.2 Emergency management

Guidelines for Management of Ovarian cancer presenting as an emergency

Wherever possible a provisional diagnosis of ovarian cancer should be made prior to surgical intervention. Urgent investigations should include
1. Ca125, ca 199 and CEA estimation
2. Imaging to include at least USS and if possible CT scan of the chest, abdomen and pelvis.
3. Cytological examination of ascitic or pleural fluid to confirm a diagnosis of malignancy.

The Guys and St Thomas’ Gynaecological cancer Centre does not have a 24-hour on-call service for emergencies. Ideally patients should be resuscitated and stabilised and then transferred to the cancer centre on the next working day so that surgery can be carried out at the cancer centre. The transfer should be arranged by telephoning one of the surgical gynaecological oncologists or the medical oncologist (if the patient is to have chemotherapy) personally between 0900 and 1700 Monday to Friday.

If the patient is felt to be too ill to transfer, and requires surgery for bowel obstruction, surgery should be carried out at the Unit, by the local bowel team for that unit (the unit lead clinician should be informed).
Carcinoma of the ovary – FIGO and TNM staging (1)

Stage I (T1) Growth limited to the ovaries.

<table>
<thead>
<tr>
<th>Stage</th>
<th>T1a</th>
<th>T1b</th>
<th>T1c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia</td>
<td>Growth limited to one ovary, no malignant cells in the peritoneal washings or ascites. No tumour on the external surfaces, capsule intact.</td>
<td>Growth limited to both ovaries, no malignant cells in the peritoneal washings or ascites. No tumour on the external surfaces, capsule intact.</td>
<td>Tumour either stage Ia or Ib, but with: tumour on the surface of one or both ovaries or with capsule ruptured or with positive malignant cells in the peritoneal washings or ascites.</td>
</tr>
<tr>
<td>Ib</td>
<td>Ic</td>
<td></td>
<td></td>
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</tbody>
</table>

Stage II (T2) Growth involving one or both ovaries with pelvic extension.

<table>
<thead>
<tr>
<th>Stage</th>
<th>T2a</th>
<th>T2b</th>
<th>T2c</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIa</td>
<td>Extension and/or metastases to the uterus and/or tubes. No malignant cells in the ascites or peritoneal washings</td>
<td>Extension to other pelvic organ. No malignant cells in the ascites or peritoneal washings.</td>
<td>Tumour either Stage IIa or IIb, with positive malignant cells in the ascites or peritoneal washings.</td>
</tr>
<tr>
<td>IIb</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIc</td>
<td></td>
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</tbody>
</table>

Stage III (T3) Tumour involving one or both ovaries with microscopic confirmed peritoneal metastasis outside the pelvis and/or regional lymph nodes metastasis.

<table>
<thead>
<tr>
<th>Stage</th>
<th>T3a</th>
<th>T3b</th>
<th>T3c</th>
<th>T3cN1</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIIa</td>
<td>Microscopic peritoneal metastasis beyond the pelvis</td>
<td>Macroscopic peritoneal metastasis beyond the pelvis 2cm or less in greatest dimension</td>
<td>Peritoneal metastasis beyond pelvis more than 2cm in diameter</td>
<td>Regional lymph node metastasis (with any T)</td>
</tr>
<tr>
<td>IIIb</td>
<td>T3b</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIIc</td>
<td>T3c</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIlc</td>
<td>T3cN1</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Stage IV (M1) Distant metastasis (excluding peritoneal metastasis) beyond the peritoneal cavity
3.3 Central referral guidelines

The decision whether to treat at unit level or refer to the cancer centre will be based on calculation of the risk of malignancy index (RMI) for all patients with an ovarian cyst or mass. The RMI score remains the method of choice in determining whether an ovarian mass is benign or malignant. Patients with RMI of 250 or greater are designated high risk of ovarian cancer and should be referred to the centre for further management.

Women referred to the centre should be discussed in the MDM when their history and co morbidities should be presented together with results of their investigations. Imaging and/or pathology will be reviewed and a decision made on appropriate management.

**Calculate a risk of malignancy index I (RMI I) score (after performing an ultrasound) and refer all women with an RMI I score of 250 or greater to the specialist multidisciplinary team.**

Calculating the RMI (2)

\[
RMI = U \times M \times CA_{125}
\]

Ultrasound

\[
U = 0 \text{ for ultrasound score 0} \\
1 \text{ for ultrasound score 1} \\
3 \text{ for ultrasound score 3-5}
\]

Ultrasound scans score 1 for each of the following characteristics:

- Multilocular cysts
- Evidence of solid areas
- Evidence of metastases
- Ascites
- Bilateral Lesions

Menopausal Status

\[
M = 3 \text{ for all menopausal women, 1 for pre-menopausal}
\]

CA 125 measured in u/ml
3.4 Investigations

Initial Investigations – All Stages

Full blood count

Urea, electrolytes, creatinine

LFT’s, bilirubin, albumin

Tumour markers Ca – 125, CEA, Ca – 199 (for suspected germ cell tumours in women under the age of 40, alpha fetoprotein, serum beta HCG and LDH should be performed)

Trans vaginal ultrasound – to identify a pelvic mass and evidence of metastases

CT scan of the chest, abdomen and pelvis with intravenous and oral contrast is indicated if there is evidence of metastases on the ultrasound. This is better at assessing the extent of disease particularly in the retroperitoneum, omentum and peritoneum.

If the imaging is suggestive of ovarian cancer, but the RMI score is less than 250, then the patient should be discussed at the centre MDM.

If offering cytotoxic chemotherapy to women with suspected advanced ovarian cancer, first obtain a confirmed tissue diagnosis by histology (or by cytology if histology is not appropriate) in all but exceptional cases.
3.5 Treatment

Surgery in all cases, irrespective of stage, where ovarian cancer is suspected based on the RMI should take place in the centre by a designated gynaecological oncologist. A review of the role of surgery in ovarian carcinoma can be found in reference 17.

Initial treatment may be surgical or medical based on individual circumstances following discussion by the MDT.

Pre-operative management

Patients listed for surgery should undergo a pre-assessment visit at GSTFT prior to surgery where their bloods, cross match, ECG and imaging (if indicated) can be performed.

Patients for surgery should not routinely undergo bowel preparation unless the history, clinical findings or imaging reveal advanced disease where bowel involvement is present. If bowel preparation is given based on these findings, then the patient should see a trained stoma nurse prior to surgery for counselling and stoma site marking.

Patients undergoing surgery for ovarian cancer are at increased risk of venous thromboembolism (3) and should undergo prophylaxis with the use of TED stockings and the administration of low molecular weight heparin. The low molecular weight heparin should be given as extended prophylaxis in the community (4).

Patients are at increased risk of infection and should receive antibiotic prophylaxis.

Intra-operative management

Use of frozen section
At operation, malignant disease may be obvious by the appearance and pattern of spread of disease. However the diagnosis may not be evident where pre-operative investigations have revealed a complex ovarian cyst with no macroscopic metastatic disease, or where a suspicious looking lesion is identified and the nature of this may alter the type of surgery performed (e.g. fertility sparing surgery). The use of intraoperative frozen section analysis may be used to identify malignant disease and reduce the need for a second staging procedure (5). This technique has its limitations however and may not reliably differentiate between borderline and benign disease, and is more difficult to interpret with mucinous tumours (5).
3.6 Surgery

3.6.1 Early-stage epithelial disease

Stage 1
Surgery for stage 1 disease is as follows: the unilateral ovarian lesion should be removed and sent for frozen section to confirm a diagnosis of malignancy. For confirmed malignant lesions a staging laparotomy should be performed (Peritoneal Washings, TAH, BSO, Omentectomy, Node Biopsy (pelvic and para aortic node sampling) and selected biopsies e.g. peritoneal biopsy where indicated) (6).

Fertility preserving surgery
In women where reproductive capacity is of priority conservative surgery may be carried out. When counselling women for such surgery however, a plan needs to be made of what surgery to perform if intra operative frozen section of any suspicious lesions reveals evidence of metastatic disease. In addition, the patient should be aware that there is a risk of recurrence of her disease (up to 9% in one study (7)).

Criteria for considering conservative surgery in Epithelial Ovarian Cancer:
Apparent Stage IA following optimal surgical staging procedures.
Favourable histopathologic subtype (will not be known until pathology is reviewed).
Negative peritoneal washings.
No invasion through the tumour capsule.
No lymph node involvement.

Conservative surgery consists of:
Unilateral Salpingo-Oophorectomy
Peritoneal washings
Biopsy of the other ovary (if this looks abnormal or suspicious)
Omentectomy.

A methodical exploration of the whole abdomen, with multiple peritoneal biopsies from any suspicious areas including the diaphragm, para-colic gutters and pelvis. The retroperitoneal, para-aortic and pelvic lymph nodes should be carefully inspected and sampled. Any suspicious lesions should be sent for intra operative frozen section analysis, and if these reveal malignant disease then fertility sparing surgery may not be possible (this event should be clearly explained to the patient at the time when the consent is obtained).

Perform retroperitoneal lymph node assessment as part of optimal surgical staging in women who appear to have stage I ovarian cancer.

Do not include systemic retroperitoneal lymphadenectomy (block dissection of lymph nodes from the pelvic side walls to the level of the renal veins) as part of standard surgical treatment in women with suspected ovarian cancer whose disease appears to be confined to the ovaries (that is, who appear to have stage I disease).
3.6.2 Locally-advanced epithelial disease

If performing surgery for women with ovarian cancer, whether before chemotherapy or after neoadjuvant chemotherapy, the objective should be complete resection of all macroscopic disease.

Stage 2 and 3 Cytoreductive Surgery
A thorough staging laparotomy as described previously is performed and cytoreductive surgery carried out. If the disease is confined to the pelvis (i.e. apparent stage 2 disease) then nodal samples from the pelvic and para aortic nodal chain should be obtained for staging. Ideally cytoreductive surgery should not leave any residual disease (8). It consists of:
- Bilateral salpingo-oophorectomy
- Total hysterectomy
- Infracolic or total omentectomy
Bowel surgery may be performed if:
- There is evidence of impending bowel obstruction or
- If resection of large or small bowel will result in optimum cytoreduction. In cases of small bowel or prepared large bowel involvement a direct anastomosis without an ileostomy or colostomy may be performed.

Interval Debulking (cytoreductive) Surgery Protocol
This surgery is defined as a surgical procedure performed in women whose tumour mass has decreased following three to four courses of chemotherapy who have previously undergone surgery that was unsuccessful at optimally cytoreducing the disease. These women should show evidence of a response to chemotherapy as determined by CA 125 and imaging.

IDS may be performed as part of a trial (e.g. CHORUS) or where at initial surgery it was not possible to optimally debulk the disease (9).

Delayed Primary Surgery
Some women may present with poor performance status at initial presentation or have evidence of Stage 4 disease. These women may receive neo-adjuvant chemotherapy and at the end of 3 to 6 cycles of treatment may be shown to have evidence of a response to treatment (reduction in CA 125 and radiological response). In these women delayed primary surgery may be considered (10).

Second Look Surgery
This is a surgical reevaluation of asymptomatic ovarian cancer patients who have no clinical evidence of tumour after primary cytoreductive surgery and adjuvant chemotherapy. Disease may be identified in more than 50% of women undergoing this surgery (11), and if completely resected can result in a survival improvement (12). However the use of second look surgery is not advocated because earlier initiation of chemotherapy when recurrent disease was found has not been demonstrated to show a survival benefit (13, 14).

Secondary cytoreductive surgery
This is defined as a subsequent surgical debulking after primary treatment and a treatment free interval. Patients who progress on first line chemotherapy are unlikely to benefit from such surgery (15). An improvement in survival is most likely to be seen in women who had complete resection of recurrent disease with secondary debulking surgery (16) and whose treatment-free interval was greater than 12 months (11).

2.6.3 Malignant germ cell tumour suspected

Fertility sparing surgery is possible in the majority of patients with a suspected germ cell tumour. The involved ovary should be sent for frozen section analysis, and standard surgical staging should be performed (18).

2.6.4 Borderline ovarian disease

The management of borderline ovarian disease (19) very much depends on the age and fertility status of the patient. All patients with this disease should undergo staging surgery consisting of:

- Thorough exploration of the entire abdominal cavity
- Peritoneal washings
- Infracolic omentectomy
- Removal of all macroscopic suspicious peritoneal lesions
- Multiple peritoneal biopsies
- Appendicectomy (for mucinous tumours)

For women with apparent stage 1 disease and a desire to preserve fertility, the uterus and part of one ovary may be preserved. The patient should be counselled pre operatively that there is a higher chance of recurrence after conservative surgery (particularly if a cystectomy is performed). If there is bilateral ovarian disease or a history of previous unilateral salpingo oophorectomy, it is reasonable to perform a cystectomy (if this is feasible, however in the presence of gross bilateral disease this may not be possible). If the disease only involves one ovary (and the other appears normal) then this should be removed. There is no need to perform systematic biopsies from the contralateral normal looking ovary (20). Once fertility has been achieved it is reasonable to offer completion hysterectomy and removal of the residual ovary (if the patient wishes this be performed).

For women who have no desire to retain fertility the standard surgery in addition to staging should include total abdominal hysterectomy, bilateral salpingo-oophorectomy.

If conservative (fertility sparing) surgery is performed and histology reveals evidence of invasive implants then the patient should undergo second surgery to remove the uterus and residual ovary (21).

As there is no difference in recurrence or survival rate when performing lymphadenectomy for early or advanced disease, there is no need to perform this procedure (22).
If borderline ovarian disease is diagnosed as an unexpected finding for surgery for benign disease, then restaging should be performed if there is no description in the operation note of the abdominal cavity or peritoneal surfaces (omentum involved in 39% of cases, 9% invasive implant rate (23)).

3.7 Chemotherapy

Guidelines According to Stage

All chemotherapy will be given at the cancer centre. For patients who are not eligible for primary surgery and are treated outside clinical trials the recommended treatment includes:

Stage Ia + b: no chemotherapy
(except clear cell, poorly differentiated EOC, and Germ cell tumours)

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

Stage Ic: (any Stage I clear cell, any endometrioid, or poorly differentiated):
single agent Carboplatin AUC 6-7 x 6 courses

Offer women with high-risk stage I disease (grade 3 or stage Ic) adjuvant chemotherapy consisting of 6 cycles of carboplatin.

Discuss the possible benefits and side effects of adjuvant chemotherapy with women who have had suboptimal surgical staging and appear to have stage I disease.

Stage IIa, b and c:
single agent Carboplatin AUC 6-7 x 6-8 courses
OR Carboplatin AUC 5 + Taxol 175mg/m² every 3 weeks x 6-8 courses

Stage IIIa, b, c and IV:
Carboplatin AUC 6-7 x 6-8 courses
OR Carboplatin AUC 5 + Taxol 175mg/m² every 3 weeks x 6-8 courses

(If at all possible patients should be entered into all clinical trials)

At point of relapse the MDM will decide on most appropriate second or third time chemotherapy.

Do not offer intraperitoneal chemotherapy to women with ovarian cancer, except as part of a clinical trial.
3.8 Follow up

Stage 1 (observation policy)
3 monthly appointments for years 1 and 2
Ca 125 every 3 months
CT scan (or ultrasound if fertility preservation) every 6 months

Annual appointments from 3 years on
Annual Ca 125 from 3 years on
CT scan (Only if clinically indicated)

Stage 2, 3, and relapsed 1

3 monthly, post chemotherapy, for years 1 and 2
Ca 125 before each appointment (from start of treatment), CT scans if Ca 125 is elevated.

6 monthly with Caa125, (CT if Ca 125 is elevated) for years 3 to 5
Annual appointments, with Ca 125, CT only if clinically indicated from 6 years onward
(If Ca 125 was not initially elevated, CT scans at 6 and 12 months then yearly for 5 years

3.9 Support needs of 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.
3.10 References


4. GSTFT Guideline on thromboprophylaxis. Dr B Hunt


SELCN Gynaecology Treatment Guidelines 2012


22 Seidman JD and Kurman RJ. Ovarian serous borderline tumours: A critical review of the literature with emphasis on prognostic indicators. Hum Pathol 2000; 31: 539 – 557

4.0 Cancer of the Fallopian Tube

4.1 Staging

Diagnostic Criteria (to distinguish from metastatic spread)
The tumour should arise from the tubal epithelium, with the majority of the cancer in the tube.
Histological features should resemble a tubal pattern.
There should be a demonstrable area of transition between normal and malignant endosalpinx.
The ovaries and endometrium should be normal, or at least contain less tumour than the tube.
Staging

Stage 0  Carcinoma in situ (limited to tubal mucosa)
Stage I  Growth limited to fallopian tubes.
  Ia  Growth limited to one tube with extension into the submucosa and/or muscularis but not penetrating the serosal surface; no ascites
  Ib  Growth is limited to both tubes with extension into the submucosa and/or muscularis but not penetrating into the serosal surface; no ascites
  Ic  Tumour either stage Ia or Ib with tumour extension through or onto the tubal serosa; or with ascites present containing malignant cells or with positive peritoneal washings
Stage II  Growth involving one or both fallopian tubes with pelvic extension
  Iia  Extension and/or metastases to the uterus and/or ovaries
  Iib  Extension to other pelvic tissues
  Iic  Tumour either Stage Iia or Iib and with ascites present containing malignant cells
Stage III  Tumour involves one or both fallopian tubes with peritoneal implants outside of the pelvis and/or positive retroperitoneal or inguinal nodes.  Superficial liver metastases equals Stage III.  Tumour appears limited to the true pelvis but with histological proven malignant extension to the small bowel or omentum
  IIIa  Tumour is grossly limited to the true pelvis with negative nodes but with Histologically confirmed microscopic seeding of abdominal peritoneal surfaces
  IIIb  Tumour involving one or both tubes with histologically confirmed implants of abdominal peritoneal surfaces none exceeding 2cm in diameter.  Lymph nodes are negative.
  IIIc  Abdominal implants greater than 2cm in diameter and/or positive retroperitoneal or inguinal nodes
Stage IV  Growth involving one or both fallopian tubes with distant metastases.
  If pleural effusion is present, there must be positive cytology to the stage IV.
  Panrenchymal liver metastases equals Stage IV

Note: Staging for fallopian tube carcinoma is based on pathology and operative findings prior to tumour debulking.
4.2 Investigations

Initial Investigations – All Stages

Full blood count

Urea, electrolytes, creatinine

LFT’s, bilirubin, albumin

Tumour markers Ca – 125, CEA, Ca – 199

Chest XR

CT scan of the abdomen and pelvis with intravenous and oral contrast or review of outside films + or – chest x-ray. Or ultrasound if indicated

Cystoscopy with/without Sigmoidoscopy

4.3 Treatment

Treatment guidelines are the same as those for cancer of the ovary.

4.4 Follow up

Follow up guidelines are the same as those for cancer of the ovary.
5.0 Cancer of the Uterus

5.1 Introduction

The aim of this guideline is to ensure that all patients within the South East London Cancer Network region with suspected endometrial carcinoma are appropriately referred and investigated and any patient with confirmed endometrial carcinoma receives care and treatment in accordance with the best possible evidence based practice available within the Network.

The policy covers the following:

- Access
- Initial Assessment and investigations
- Gynaecological oncology multidisciplinary meeting
- Surgical and non-surgical treatment.
- Recurrent disease and follow up

5.2 Policy

Access
All patients with suspected endometrial cancer to be referred within 24 hours to a gynaecology rapid assessment clinic (RAC), based in each major acute hospital within the Network. Patients will be seen within 2 weeks of decision to refer.

Initial Assessment
- Full history and pelvic examination
- Assessment of endometrial thickness by TVS (abdominal scan if transvaginal scan TVS is not possible)
- Endometrial assessment and biopsy (TVS/ outpatient hysteroscopy/ pipelle)

Diagnostic Biopsy Of The Endometrium
- Hysteroscopy and/or endometrial sampling can be performed as an outpatient procedure if the endometrial thickness is more than 5mm. If the cavity view is suboptimal or the biopsy inadequate, this procedure can be repeated under a general anaesthetic.

Gynaecological Oncology Multidisciplinary Meeting
All grade 2 and above, and ideally all, endometrial cancer patients should be referred to the Centre and reviewed at the MDT meeting prior to undergoing first definitive treatment. Case discussion should include review of:
- Histology from biopsy if already performed
- Imaging – CXR, CT, MRI
- Discussion of management options (i.e. surgery/ chemotherapy/ radiotherapy), and discussion of suitability for recruitment into clinical trials
Cases should also be discussed following surgery to review histology and management plan, and in the event of disease recurrence.
5.3 Investigations
- FBC
- U&E
- LFTs
- +/- Ca 125

5.3.1 Imaging
The aim of imaging is to define the depth of myometrial invasion and to assess for extra-uterine disease. Imaging is organized in referral Unit and is dependent on histology grade (endometrial adenocarcinoma) and subtype:
- Endometrial adenocarcinoma Grade 1-3: MRI of pelvis/ abdo
- Mixed Mesodermal tumour (MMMT), Clear Cell tumours: MRI of pelvis/ abdo
- Papillary serous: MRI of pelvis/ abdo and CT chest
- Leiomyosarcoma; MRI of pelvis/ abdo and CT chest
- Imaging guided biopsy where appropriate.
All imaging is to be reviewed at the MDM prior to surgery.

5.3.2 Pathology
All grade 2 and above, and ideally all, endometrial biopsies should be referred to the Cancer Centre and reviewed at the MDT meeting. Grade alone will determine whether treatment is to be undertaken at the Centre or Unit unless examination and/or radiology demonstrate obvious stage greater than I (e.g. cervical extension or uterine fixity on pelvic examination). Hence if grade>1 then surgery will be undertaken at the Centre. Pathology specimens will be processed and reported in accordance with the guidelines set out RCP minimum data set.
5.4 Staging

The FIGO Committee on Gynaecologic Oncology revised the surgical staging of endometrial cancer in 2009.

**FIGO Stages of Cancer of the Corpus Uteri (Revised 2008)**

<table>
<thead>
<tr>
<th>Stage I -- confined to the corpus uteri.</th>
<th>Stage II -- the corpus and the cervical stroma is involved, but no extension outside the uterus.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia Tumour limited to endometrium and/or invasion to &lt; ½ myometrium</td>
<td></td>
</tr>
<tr>
<td>Ib Invasion to ≥ ½ myometrium</td>
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<tr>
<td>Stage III -- extension outside of the uterus but confined to the true pelvis.</td>
<td></td>
</tr>
<tr>
<td>IIIa Tumour invades serosa and/or adnexae</td>
<td></td>
</tr>
<tr>
<td>IIIb Vaginal metastases</td>
<td></td>
</tr>
<tr>
<td>IIIC Metastases to pelvic and/or para aortic lymph node</td>
<td></td>
</tr>
<tr>
<td>IIIC1 positive pelvic nodes</td>
<td></td>
</tr>
<tr>
<td>IIIC2 positive para-aortic nodes with or without positive pelvic nodes</td>
<td></td>
</tr>
<tr>
<td>Stage IV -- involvement of the bladder or bowel mucosa or metastasis to distant sites.</td>
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</tr>
<tr>
<td>IVa Tumour invasion of the bladder and/or bowel mucosa</td>
<td></td>
</tr>
<tr>
<td>IVb Distant metastases including intra abdominal and/or inguinal lymph node</td>
<td></td>
</tr>
</tbody>
</table>
5.5 Policy for low risk endometrial cancer patients

Patients with well differentiated (grade 1) stage 1a endometrioid adenocarcinoma of the endometrium may be treated at the Unit. All other patients must be referred to the Centre for surgery. Imaging before surgery should be used to define depth of myometrial invasion.

5.6 Treatment

5.6.1 Surgery

The aim of surgical treatment is stage the disease and to achieve local clearance of the disease.

According to FIGO, nodal status must be known in order to stage the patient. However patients with well differentiated endometrioid tumours have a minimal chance of nodal disease and therefore do not need to undergo lymphadenectomy. These patients can be treated at the Unit provided that the histology and imaging has been centrally reviewed and confirmed grade 1 disease that is radiologically stage 1. However, for all other grades and stage 2 and above, the surgery must be carried out at the Centre and the following should be carried out:

- Detailed inspection of the abdominal-pelvic cavity, contents and retroperitoneum
- Peritoneal washings
- Total abdominal hysterectomy and bilateral salpingo-oophorectomy
- Pelvic lymphadenectomy, not node sampling (para-aortic node sampling if suspicious)
- Omentectomy – serous or clear cell histology

The need for postoperative radiotherapy will be decided by the degree of differentiation, the cell type, the presence of vascular space involvement, the depth of myometrial invasion, and the presence or absence of lymph node metastasis.

5.6.2 Radiotherapy

Post-operative Adjuvant Radiotherapy

Risk factors for local recurrence:
- Poorly differentiated adenocarcinoma, clear cell carcinoma or serous carcinoma.
- Invasion of the outer half of the myometrium.
- Involvement of endocervix.
- Lymph vascular space involvement
- Positive washings

Low risk of local recurrence i.e. none of the above risk factors: No further treatment.
High risk of local recurrence i.e. any of the above risk factors: adjuvant radiotherapy.
5.6.3 Chemotherapy

Patients with clear cell and serous papillary endometrial carcinoma may also require chemotherapy.

5.7 Follow up

The purposes of follow-up are as follows:
- Detection of disease recurrence
- Symptom management
- Patient reassurance
- Outcome data
- Benefit of clinician

In the absence of quality evidence, the Network believes that we should not dispense with the strategy of routine regular follow-up clinic reviews for the majority of endometrial cancer patients.
## Endometrial Telephone Follow Up 4-6 months post surgery

<table>
<thead>
<tr>
<th>Patient name:</th>
<th>Telephone number:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital Number:</th>
<th>Date and time of call:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Questions:

#### CANCER DIAGNOSIS AND TREATMENT

<table>
<thead>
<tr>
<th>How are you feeling?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Do you have any questions about your treatment?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How have you been managing your daily life since your treatment (getting out and about, work, etc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No problems □</td>
</tr>
<tr>
<td>Difficulty with activities of living □</td>
</tr>
<tr>
<td>Pre existing difficulties □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

#### VAGINAL BLEEDING

<table>
<thead>
<tr>
<th>Have you had any bleeding since your treatment?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No bleeding □</td>
</tr>
<tr>
<td>Mild bleeding/spotting □</td>
</tr>
<tr>
<td>Post coital bleeding □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>All vaginal bleeding needs investigating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

#### VAGINAL DISCHARGE

<table>
<thead>
<tr>
<th>Have you had any discharge from your vagina since your treatment?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No problems □</td>
</tr>
<tr>
<td>Offensive vaginal loss □</td>
</tr>
<tr>
<td>If discharge what colour?</td>
</tr>
</tbody>
</table>

| Pruritis/itch □                                                |
|                                                              |

| No Action □                                                   |
|                                                             |
| Emotional support □                                           |
| Advice □                                                      |

| Medical Advice □                                              |
|                                                             |

#### PAIN

<table>
<thead>
<tr>
<th>Do you experience any pain?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No problems □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severity, location and nature of pain. Present analgesia and effectiveness -</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No Action □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional support □</td>
</tr>
<tr>
<td>Advice □</td>
</tr>
<tr>
<td>GP □</td>
</tr>
<tr>
<td>District Nurse □</td>
</tr>
<tr>
<td>Community Macmillan □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medical Advice □</th>
</tr>
</thead>
</table>

### Actions

- □ No Action
- □ Advice
- □ Welfare rights/social worker ref
- □ OT ref

---

SELCN Gynaecology Treatment Guidelines 2012
<table>
<thead>
<tr>
<th>Questions:</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LYMPHOEDEMA</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Have you noticed any new swelling of your legs or pubis? | Discuss with Medical team □  
Refer to lymphodema nurse □  
For medical review and management to exclude DVT □ |
| **BLADDER/BOWELS** | |
| How is going to the toilet, passing urine, opening your bowels? | No Action □  
Advice/Info given □  
Dietician □  
medical advice □  
GP □  
Continence ref □ |
| **SEXUAL HEALTH** | |
| No problems □  
Body image issue □  
Relationship issues □  
Previous medical / emotional conditions □  
Fertility Concerns □  
Hormonal concerns □ | No Action □  
Ask GP to ref to sex therapist □  
Fertility Concern noted and Plans Made □  
GP for hormonal advice □  
Ref menopause clinic □ |
| **PSYCHOLOGICAL STATE:** | |
| Do you have any worries following your treatment? | No Action □  
Advice/support □  
Coping strategies □  
Problem solving □  
Specialist psychological intervention □  
Community Macmillan ref □  
Previous experience of cancer - |
Future Follow up pathway for non complex cancer treatment:
This will be for all patients who have not had adjuvant treatment (surgical only endometrial)

- Referred for additional support
- Patient Information Day

- Assessment Questionnaire
- Concerns checklist

Patient Triggered Follow up
Patient phones CNS to report any worrying symptoms. These are discussed and patient brought in for review as appropriate.
5.7.1 Surgery

Surgical patients will receive a follow-up appointment at the Centre post-operatively to be informed of the result and whether there is need for adjuvant treatment. If surgery has been the only treatment, the patients may be followed up at the Unit.

Clinical examination:
3 monthly intervals for the first year
6 monthly in the second year
annually until 5 years then discharge

5.7.2 Radiotherapy

Patients will receive a follow-up appointment at the Centre six weeks after the end of treatment. Thereafter, follow-up will remain at the Centre for first three years.

Smears not routinely taken:
3 monthly intervals for the first year
6 monthly for 1 year
Unit for annual follow-up year 3-5 then discharge
5.8 Uterine Sarcoma

These cases are uncommon and represent less than 5% of all malignant tumours of the uterine corpus. They may be either pure monophasic neoplasms (e.g. Leiomyosarcoma and endometrial stromal sarcoma) or biphasic when mixed with epithelial elements (e.g. Carcinosarcoma, the most common uterine sarcoma). They present frequently as a rapidly enlarging pelvic mass (leiomyosarcoma in particular) with post-menopausal bleeding (carcinosarcoma), or with a combination of both.

5.8.1 Staging

There is no internationally accepted staging system for uterine sarcomas. By convention the FIGO system for endometrial carcinoma has been adopted. There are however limitations to this current method of using another tumor staging system, particularly for leiomyosarcomas, where a depth of myometrial invasion is not relevant.

Table The FIGO staging system adopted for uterine sarcoma.

<table>
<thead>
<tr>
<th>FIGO stage (Revised 2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage I -- confined to the corpus uteri.</td>
</tr>
<tr>
<td>Ia  Tumour limited to endometrium and/or invasion to &lt; ½ myometrium</td>
</tr>
<tr>
<td>Ib  Invasion to ≥ ½ myometrium</td>
</tr>
<tr>
<td>Stage II -- the corpus and the cervical stroma is involved, but no extension outside the uterus.</td>
</tr>
<tr>
<td>Stage III -- extension outside of the uterus but confined to the true pelvis.</td>
</tr>
<tr>
<td>IIIa  Tumour invades serosa and/or adnexae</td>
</tr>
<tr>
<td>IIIb  Vaginal metastases</td>
</tr>
<tr>
<td>III C Metastases to pelvic and/or para aortic lymph node</td>
</tr>
<tr>
<td>IIIC1 positive pelvic nodes</td>
</tr>
<tr>
<td>IIIC2 positive para-aortic nodes with or without positive pelvic nodes</td>
</tr>
<tr>
<td>Stage IV -- involvement of the bladder or bowel mucosa or metastasis to distant sites.</td>
</tr>
<tr>
<td>IVa  Tumour invasion of the bladder and/or bowel mucosa</td>
</tr>
<tr>
<td>IVb  Distant metastases including intra abdominal and/or Inguinal lymph node</td>
</tr>
</tbody>
</table>
5.8.2 Investigations

Initial Investigations – All Stages

Colposcopic assessment and biopsy and/or examination under anaesthetic with/without biopsy

If stage 1a suspected, a loop excision to provide a cone biopsy in a single piece should be performed

Full blood count

Urea, electrolytes, creatinine

LFT’s, bilirubin, albumin

Chest XR

CT scan of the abdomen and pelvis and chest with intravenous and oral contrast or review of outside films. OR ultrasounds

Cystoscopy with/without Sigmoidoscopy

5.8.3 Treatment

The current most effective therapy for sarcomas (otherwise known as malignant mesenchymal tumors of the uterus) is surgery. Nearly all patients with gross or microscopic residual disease after primary surgical extirpation of their tumor will succumb to their disease.

There are no set criteria for surgical staging. Because of the propensity for retroperitoneal lymph node spread, para-aortic and pelvic lymph node sampling may help in optimising the choice of postoperative adjuvant therapy, as may an omental biopsy. Sampling of normal appearing peritoneum as in ovarian carcinoma is probably of little value.

Adjuvant Therapy → to be discussed at MDM and patient referred to a Specialist Centre such as the sarcoma unit at the Royal Marsden Hospital.

There is good level 2 evidence that adjuvant pelvic radiotherapy improves the disease-free survival and overall survival in uterine carcinosarcoma, and level 1 evidence that pelvic radiotherapy improves loco-regional control but not overall survival in other uterine sarcomas. Radiotherapy protocols are as for uterine carcinomas.

There is no evidence that adjuvant chemotherapy is of any benefit in this group of patients.

5.8.4 Follow up

See endometrial carcinoma schedule for follow-up.
### 6.0 Cancer of the Vagina

#### 6.1 Staging

<table>
<thead>
<tr>
<th>TNM</th>
<th>FIGO</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCis</td>
<td>0</td>
<td>Carcinoma in situ, intraepithelial carcinoma (VAIN)</td>
</tr>
<tr>
<td>T1</td>
<td>I</td>
<td>The carcinoma is limited to the vaginal wall</td>
</tr>
<tr>
<td>T2</td>
<td>II</td>
<td>The carcinoma has involved the subvaginal tissues but has not extended onto the pelvic wall</td>
</tr>
<tr>
<td>T3</td>
<td>III</td>
<td>The carcinoma has extended beyond the true pelvis or has clinically involved the mucosa of the bladder or rectum. Bullous oedema as such, does not permit a case to be allotted to stage IV</td>
</tr>
<tr>
<td>T4</td>
<td>Iva</td>
<td>Spread of the growth to adjacent organs and/or direct extension beyond the true pelvis</td>
</tr>
<tr>
<td></td>
<td>Ivb</td>
<td>Spread to distant organs</td>
</tr>
</tbody>
</table>

TNM System: Regional Lymph Nodes (Pelvic and Inguinal)

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nx</td>
<td>Regional lymph nodes cannot be assessed</td>
</tr>
<tr>
<td>No</td>
<td>No regional lymph node metastasis</td>
</tr>
<tr>
<td>N1</td>
<td>Regional lymph node metastasis</td>
</tr>
</tbody>
</table>

M: Distant Metastasis

<table>
<thead>
<tr>
<th>Metastasis</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mx</td>
<td>Distant metastasis cannot be assessed</td>
</tr>
<tr>
<td>Mo</td>
<td>No distant metastasis</td>
</tr>
<tr>
<td>M1</td>
<td>Distant metastasis</td>
</tr>
</tbody>
</table>
6.2 Investigations

Initial Investigations – All Stages

Colposcopic assessment and biopsy and/or examination under anaesthetic with/without biopsy

Excision or wedge biopsy as appropriate

Full blood count

Urea, electrolytes, creatinine

LFT’s, bilirubin, albumin

Chest XR

CT scan of the abdomen and pelvis with intravenous and oral contrast or review of outside films

Cystoscopy with/without Sigmoidoscopy

6.3 Treatment

Treatment planning should take place initially at the MDT Conference followed by joint review and discussion with the patient.

Radiotherapy (Radiation Therapy):

Radiotherapy is the most widely used primary treatment modality for all stages of the disease.
Stage I lesions <2cm in dimension with no lymph-vascular space involvement and grade 1-2 may be treated with brachytherapy alone or wide local excision provided the depth if invasion is <3 mm.

Other cases of cancer of the vagina require external beam therapy to the vagina, paracolpium and pelvis in addition to brachytherapy. Cases involving the lower one-third of the vagina or with suspicious or positive groin nodes require the addition of external beam therapy to the groins.

In more advanced disease chemotherapy should be considered with radiation therapy.

Radiation is indicated post-surgery when poor prognostic features such as positive nodes are present or when there are close/involved margins.

Radical surgery may be considered for primary treatment of lesions other than in paragraph 1. Stage I and II small lesions involving only the vault of the vagina with no or early parametrial involvement may be treated with radical vaginectomy/hysterectomy and pelvic and paraaortic node dissection. For lesions that lie adjacent to the bladder or rectum, radiation therapy should be considered; however, some may require exenteration. Where the lower one-third of the vagina is involved or there are suspicious or positive groin nodes then radical vulvectomy and groin node dissection may be considered.

Local recurrence in the vagina or central pelvis following radiotherapy may be treated by exenteration.
6.4 Follow up

At end of treatment six week follow-up appointment at Centre.

3 monthly follow-up for the first year
6 monthly follow-up for next four years

All Centre follow-up
## 7.0 Cancer of the Vulva

### 7.1 Staging

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (Tis, N0, M0):</td>
<td>This is a very early cancer found in the surface of the skin of the vulva only. It is also known as carcinoma in situ, and as Bowen disease.</td>
</tr>
<tr>
<td>I (T1, N0, M0):</td>
<td>The cancer is in the vulva or the perineum (the space between the rectum and the vagina) or both. The tumour is 2 cm or less (about 3/4 inch) in diameter and has not spread to lymph nodes or distant sites.</td>
</tr>
<tr>
<td>IA: T1a:</td>
<td>These are stage I cancers with invasion no deeper than 1 mm (about 1/25 inch).</td>
</tr>
<tr>
<td>IB: T1b:</td>
<td>These are stage I cancers that have invaded deeper than 1 mm.</td>
</tr>
<tr>
<td>II (T2, N0, M0):</td>
<td>The cancer is in the vulva or perineum or both, and the tumour is larger than 2 cm. It has not spread to lymph nodes or distant sites.</td>
</tr>
<tr>
<td>III (T3, N0-N1, M0, or T1-T2, N1, M0):</td>
<td>The cancer is growing into the anus, vagina, or lower urethra. It may have spread to nearby lymph nodes on 1 side of the groin. It has not spread to distant sites (T3, N0-N1, M0). OR Cancer is found in the vulva or perineum or both and has spread to nearby lymph nodes on 1 side of the groin. It has not spread to distant sites. (T1-T2, N1, M0)</td>
</tr>
<tr>
<td>IVA (T1-3, N2, M0, or T4, any N, M0):</td>
<td>Cancer has spread to lymph nodes on both sides of the groin (N2) or it has spread beyond nearby tissues to the upper part of the urethra, bladder, rectum, or pelvic bone (T4). It has not spread to distant sites.</td>
</tr>
<tr>
<td>IVB (any T, any N, M0):</td>
<td>Cancer has spread to distant organs or lymph nodes. This is the most advanced stage of cancer. Recurrent: The cancer has come back after treatment.</td>
</tr>
</tbody>
</table>

#### Tumour extent (T)
- **Tis**: The cancer is not growing into the underlying tissues.
- **T1**: The cancer is growing only in the vulva or perineum and is smaller than 2 cm. (about 0.8 inches).
- **T1a**: The cancer has grown no more than 1 mm into underlying tissue.
- **T1b**: The cancer has grown more than 1 mm into underlying tissue.
- **T2**: The cancer is growing only in the vulva or perineum and is larger than 2 cm. (about 0.8 inches).
- **T3**: The cancer is growing into the anus, vagina, or lower urethra (the tube that drains urine from the bladder).
- **T4**: The cancer is growing into the upper urethra, bladder or rectum or into the pubic bone.

#### Lymph node spread of cancer (N)
- **N0**: No lymph node spread
- **N1**: Cancer has spread to lymph nodes on the same side as the tumour
- **N2**: Cancer has spread to lymph nodes in both groin regions

#### Distant spread of cancer (M)
- **M0**: No distant spread
- **M1**: The cancer has spread to distant sites (includes spread to pelvic lymph nodes)
7.2 Treatment

Surgery for Stage I Vulval Lesions:

Investigation
Biopsy, CT scan chest abdomen and pelvis, MRI pelvis

Stage I lesions <2cm in dimension with no lymph-vascular space involvement and grade 1-2 may be treated with brachytherapy alone or wide local excision provided the depth if invasion is <3 mm.

Other cases of cancer of the vagina require external beam therapy to the vagina, paracolpium and pelvis in addition to brachytherapy. Cases involving the lower one-third of the vagina or with suspicious or positive groin nodes require the addition of external beam therapy to the groins.

In more advanced disease chemotherapy should be considered with radiation therapy.

Radiation is indicated post-surgery when poor prognostic features such as positive nodes are present or when there are close/involved margins.

Radical surgery may be considered for primary treatment of lesions other than in paragraph 1. Stage I and II small lesions involving only the vault of the vagina with no or early parametrial involvement may be treated with radical vaginectomy/hysterectomy and pelvic and paraaortic node dissection. For lesions that lie adjacent to the bladder or rectum, radiation therapy should be considered; however, some may require exenteration. Where the lower one-third of the vagina is involved or there are suspicious or positive groin nodes then radical vulvectomy and groin node dissection may be considered.

Local recurrence in the vagina or central pelvis following radiotherapy may be treated by exenteration. Adjuvant post-operative radiotherapy for carcinoma vulva.

Radical surgery is curative in a high proportion of patients who are node negative and in whom the surgical clearance at the primary site is more than 1cm (10mm). No adjuvant treatment is indicated in these cases.
Ensure patients who need plastics reconstructive surgery are referred for assessment in plastics surgery clinic preop.

Primary tumour: Where the surgical margin of clearance is less than 1cm there is a high risk of recurrence (1) and adjuvant radiotherapy is indicated, either with EBRT or brachytherapy.

Lymph nodes: After inguinal node dissection the risk of inguinal failure and pelvic nodal recurrence increases as the number of involved groin nodes increases (2). Evidence from a randomised controlled trial shows that adjuvant radiotherapy to the inguinal and deep pelvic nodes both improves local control and survival in patients with one or more involved nodes at surgery(3).
7.3 Radiotherapy

Radiotherapy techniques

The planning target volume includes the inguinal, internal and external iliac and obturator nodes on both sides of the pelvis. If the margins of excision of the primary lesion were positive (or less than 10mm) the vulval region must be included. This is a necessarily large volume with the superior border extending to approximately the mid-sacro-iliac joints. Virtual simulation or CT planning allows the possibility of shielding rectum and a small amount of central small bowel, and ensures coverage of all the nodal areas. Morbidity of treatment may be reduced if the perineum can be treated by a direct perineal field to the site of the primary lesion. It may be possible to encompass the perineum and nodal areas with a 4-field plan which allows the possibility of some rectal shielding. Alternatively a parallel pair should be used which may be weighted 2:1 to the anterior.

The tumour dose is 45Gy in 25 fractions in 5 weeks with a boost to the primary site or to the groins to 55-60Gy if there are postive margins or extensive extra-capsular spread of disease.

Pre-operative Chemo-radiation for Advanced Vulval carcinoma

Pre-operative radiotherapy given concomitantly with cis-platin and 5-f-u has been shown to significantly reduce tumour bulk and allow curative surgery in patients presenting with T3 or T4 primary tumours and/or unresectable fixed or ulcerating groin nodes (4,5). 45 Gy in 25 fractions in 5 weeks are given to the primary tumour and nodes together with 2 courses of cis-platin 50mg/m2 day I and 29 and 5-fluoro-uracil 1Gm/m2 daily on days 1-4 and 29-32 of radiotherapy. Surgery should then be carried out 4-6 weeks after completion of radiotherapy. This is very toxic and aggressive treatment with a significant morbidity and mortality and should only be considered in younger and very fit patients.

If there is a poor response to treatment and surgery is not feasible then the involved nodes and the primary site should be boosted to 60 Gy with direct fields.

Palliative radiotherapy for advanced inoperable vulval cancer

If patients are unfit for radical chemo radiotherapy there is no role for palliative radiotherapy apart from the use of 1-2 fractions of 6-8Gy to treat persistent bleeding. The toxicity of radiotherapy is high and the duration of response short. The quality of life of these patients is generally not improved by palliative radiotherapy, even to high doses. (6)
7.4 Follow up

3 monthly follow up for the first year and 6 monthly follow up for four year.
Centre Follow-up

7.5 References

8.0 Gestational Trophoblastic Disease

All cases of Gestational Trophoblastic Disease should be referred to Charing Cross Hospital.
9.0 Nursing and Supportive Care for Patients with Gynaecological Malignancy

1.0 The nursing care that cancer patients receive has a direct impact on their ability to adjust to a cancer diagnosis, to cope with cancer treatments and interventions and to maintain high quality of life as far as possible. Without the support of a robust nursing team, it would not be possible to ensure the highest standards of gynaecological cancer care that SELCN aims to provide.

(i) Nursing recruitment, workforce planning and nurse education within acute and primary settings should reflect the complex needs of women with gynaecological malignancy.

(ii) The importance of specialist cancer and women’s health qualifications should be recognised for nurses working with this patient group. Networking, mentoring, succession planning and coaching should be established in order to ensure a sustainable and appropriately experienced nursing workforce.

2.0 Prompt and appropriate referral to the Clinical Nurse Specialist can also significantly improve the patients’ experience of cancer and its treatments.

(i) Patients receiving a new diagnosis of cancer within the SELCN should be accompanied by a Clinical Nurse Specialist or designated link nurse, who will be able to provide support after the consultation. If no nurse is available the patient should be given the contact details of the CNS/link nurse.

(ii) All patients with a diagnosis of gynaecological malignancy should have access to Clinical Nurse Specialist support. Where a post is vacant a designated link nurse should be nominated.

(iii) Printed information on the Role of the CNS and contact details of the Unit and Centre CNS’s within SELCN, should be given to all patients with a diagnosis of gynaecological malignancy.

3.0 Recent Government and Multi-agency guidance recommend that patients receive streamlined and coordinated cancer treatment. Clinical Nurse Specialists are in an ideal position to facilitate this.

(i) The Clinical Nurse Specialist will endeavour, (through close liaison with their multidisciplinary teams, nursing colleagues and leaders), to ensure a seamless patient pathway throughout the Network for those patients with gynaecological malignancy.

(ii) Network CNS’s will work collaboratively to:
provide patients with consistent printed and verbal information about their disease, treatments and support available.
establish excellent communication on nursing care between and within Units, Centre, Primary Care, treatment modalities and palliative / supportive care.

SELCN Gynaecology Treatment Guidelines 2012
support and advise nursing colleagues in Acute and Primary Care settings on integrating most up-to-date gynaecological oncology evidence based nursing practice.

Routine referrals will be contacted within 2 working days to arrange an assessment. For urgent referrals, direct contact with palliative care team is needed to discuss each situation individually.

Criteria for Referral
Most patients will have an advanced, progressive disease, where the focus of care will have changed from curative to palliative and the prognosis is limited. Some patients, who have complex specialist needs, can be referred at an earlier stage, from diagnosis onwards. Patients may be discharged if their condition stabilises.

A demonstrable need for specialist palliative care services must be established. Appropriate reasons for referral may include potential / existing difficulties with the following:
- Pain and Symptom management
- Meeting the psycho-social needs of the patient & their family, and/or significant others
- Terminal Care/Dying
  Where possible, the patient, and if not, the carer, should be informed and in agreement with the referral
- Any Health Care Professional can refer to the Specialist Palliative Care Team, but acceptance must be with the agreement of the GP/inpatient Consultant

Criteria for Urgent Referral: needing advice/assessment within 1-2 working days.
- Difficult psychological/physical symptoms causing distress and not responding to current management
- Rapidly deteriorating condition
Clinical Nurse Specialist (CNS) Referral Pathway

1. Referrals for CNS support can be made via: telephone, email or fax.

2. Referrals are either self-referrals or can be made with the consent of the patient via:

   Relative/carer
   Medical staff
   Nursing staff
   Primary care
   Professions Allied to Medicine (P.A.M.’s)

3. Appropriate criteria for referral include:

   New diagnosis of cancer
   Recurrent or new metastatic disease
   Planned surgery which could have significant impact on body image, sexuality, self-esteem, sexual health or fertility
   Women with complex psychosocial needs
   Women demonstrating strong, negative reactions or difficulties in coping/adapting
   Where there is a need for further information, advice and psychological support regarding decision making and treatments i.e. moving between treatment modalities, changes to or withdrawal of treatment.
   Women’s health issues relating to life after cancer treatment i.e. premature menopause, hormone replacement therapy, HRT alternatives, sexual health.
   Need for possible onward referral to other areas of expert help, such as: counselling, psychosexual counselling, symptom control, lymphoedema management, financial and/or social support
   Complex and unusual problems

4. Information to include in referral:

   Patient contact details
   Name
   Age
   Hospital number
   Diagnosis or suspected diagnosis
   Reason for referral
5. Seamless Network Wide CNS support

The Centre and Unit CNS’s will work jointly to support patients who have a diagnosis of gynaecological malignancy. Primary responsibility, whilst patients are receiving active treatment at the Centre, will be with Centre CNS’s, unless otherwise arranged and agreed with Unit CNS. Patients will be informed which CNS’s are responsible for them.

6. CNS Documentation

CNS’s will write in the medical notes summaries of information given, assessment of identified needs and plan for follow-up. Also any information needs to be shared with the team in order to support the way in which women wish to be treated. We will also keep our own CNS notes, to document telephone conversations or confidential matters (see below).

7. Patient Confidentiality

CNS’s discuss confidentiality with the patients. Current patient needs, should be discussed with the whole team to achieve consistent care. Women will be told that we document interactions in the medical notes. When patients request confidentiality between us, we will respect this as long as we feel it does not compromise the patients’ safety.