East Midlands
Strategic Clinical Networks and Senate

GYNAECOLOGY
NETWORK SITE SPECIFIC GROUP

CLINICAL GUIDELINES
AND OPERATIONAL POLICY

(11-1A-204 to 209 inclusive)

Ratified by:	**EM Gynaecological Cancer ECAG**
Endorsed by:	**Chair – Mr Quentin Davis**
Updated:	**July 2013**
Review Date:	**Next Review July 2014**
Distributed to:	**All Trust Management Teams and Directorates**

CONTENTS

1.0 General Information

1.1 Cancer waiting times targets

The Calman-Hine Report (1995) set up a framework for commissioning Cancer Services and provided guidance for purchasers and providers. It led to the creation of Cancer Networks made up of Cancer Centres (Derby) and Cancer Units (Burton) and published general principles of good cancer care, to ensure uniformly high standards nationally. Guidance is published in the form of Improving Outcomes Guidance and Cancer Standards. The Government has also set targets for the treatment of cancer patients:

- No more than 14 days between GP referral for suspected cancer (known as two-week wait) and date that patient is first seen in the acute setting.
- No more than 62 days between GP referral and first definitive treatment for patients referred under the two-week wait system.
- No more than 31 days between the date of decision to treat and the date of the first definitive treatment for all patients, however referred.

The team works against the background of these targets together with booking and trials recruitment targets, and their own objectives.

The 14-day target has been in force for some time and 100% adherence is generally achieved.

31 and 62-day waits

Cancer Teams nationally are working towards targets for treatment laid down by the Department of Health, namely:-

No more than 31 days between “decision to treat” date and “first definitive treatment” for all cancer patients, however referred.

No more than 62 days between “urgent GP referral” and “first definitive treatment” for all patients referred via the two-week wait system.

“Decision to treat” is defined as the day on which the patient is given their diagnosis and the treatment plan is agreed between patient and doctor.

“First definitive treatment” is defined as the day on which the patient is given treatment to either shrink or remove the tumour, or is given palliative treatment, or a decision is made for “no treatment” or “watch and wait”.

“Urgent GP referral” is defined as the day on which the GP faxes to the Trust the two-week wait pro-forma indicating suspicion of cancer.

The Trust is monitored against adherence to these targets.

The Cancer Plan 2000 included a number of waiting times standards, now referred to as classic standards, that the NHS was expected to achieve:

Two week standard from urgent GP referral for suspected cancer to first hospital assessment:

- 31 day standard from diagnosis/decision to treat to first treatment;

- 62 day standard from urgent GP referral for suspected cancer to first treatment.

The Cancer Reform Strategy (2007) recognised the excellent progress made on the classic cancer waiting times standards but also that there was a need to widen the entry gate to the cancer pathways and to change the monitoring to be in line with 18 week no pause model. As a result of this:

- The existing 31 day standard has been expanded to cover subsequent treatments for all cancer patients including those diagnosed with a recurrence – Surgery and drug Treatment by **December 08** and Radiotherapy and other treatments by **December 2010**
- There are two additional entry points for the 62 day standard: referral from NHS Cancer Screening Programmes (breast, cervical and bowel) or a consultant upgrade following a non-urgent referral by **December 08**
- The existing two week standard has been expanded so that any patient with breast symptoms will be referred and seen within two weeks whether cancer is suspected or not by **December 2009**

Performance standards have been reset to take account of the changes in monitoring. These are now:

Classic standards	Extended standards
2 week wait 93% 31 day first definitive treatment 96% 62 day referral to treatment 85%	2 week wait for symptomatic breast patients 93% 31 day subsequent treatments ♦ Surgery ♦ Drugs 98% ♦ Radiotherapy 94% 62 day to treatment for patients referred via screening 90% 62 days to treatment for patients upgraded by a consultant – to be confirmed

1.2 General referral guidance

A patient who presents with symptoms suggesting gynaecological cancer should be referred to a team specialising in the management of gynaecological cancer, depending on local arrangements.

1.3 Specific referral guidance

The first symptoms of gynaecological cancer may be alterations in the menstrual cycle, intermenstrual bleeding, postcoital bleeding, postmenopausal bleeding or vaginal discharge.

When a patient presents with any of these symptoms, the primary healthcare professional should undertake a full pelvic examination, including speculum examination of the cervix. In patients found on examination of the cervix to have clinical features that raise the suspicion of cervical cancer, an urgent referral should be made. A cervical smear test is not required before referral, and a previous negative cervical smear result is not a reason to delay referral. Patients with an abdominal mass should be offered CA125 as per the guidance.

Ovarian cancer is particularly difficult to diagnose on clinical grounds as the presentation may be with vague, non-specific abdominal symptoms alone (bloating, constipation, abdominal or back pain, urinary symptoms). In a woman presenting with any unexplained

abdominal or urinary symptoms, abdominal palpation should be carried out. If there is significant concern, a pelvic examination should be considered if appropriate. Any woman with a palpable abdominal or pelvic mass on examination that is not obviously uterine fibroids or not of gastrointestinal or urological origin should have an urgent ultrasound scan. If the scan is suggestive of cancer, or if ultrasound is not available, an urgent referral should be made. Woman should also be offered a CA125 Test as indicated in the guidelines

When a woman who is not on hormone replacement therapy presents with postmenopausal bleeding, an urgent referral should be made. When a woman on hormone replacement therapy presents with persistent or unexplained postmenopausal bleeding after cessation of hormone replacement therapy for 4 weeks, an urgent referral should be made. Tamoxifen can increase the risk of endometrial cancer. An urgent referral should be made when a woman taking tamoxifen presents with postmenopausal bleeding.

An urgent referral should be considered in a patient with persistent intermenstrual bleeding and a negative pelvic examination.

When a woman presents with vulval symptoms, a vulval examination should be offered. If an unexplained vulval lump is found, an urgent referral should be made. Vulval cancer can also present with vulval bleeding due to ulceration. A patient with these features should be referred urgently.

Vulval cancer may also present with pruritus or pain. For a patient who presents with these symptoms, it is reasonable to use a period of 'treat, watch and wait' as a method of management. But this should include active follow-up until symptoms resolve or a diagnosis is confirmed. If symptoms persist, the referral may be urgent or non-urgent, depending on the symptoms and the degree of concern about cancer.

1.4 Onward Referral Guidelines

All new gynaecological cancer patients must be discussed at a gynaecology MDT. This will, in the first instance, almost always be in the Trust receiving the first referral. This is for the purpose of this guideline 'the *First MDT'*.

Referrals from first MDT to second MDT within or out with the East Midlands Cancer Network by reason of referral as follows:

1. Further consideration of a complex case

(e.g. borderline decision for surgery due to extensive co-morbidity, rare tumour, diagnostic uncertainty, etc.)

All cases in this category must be discussed by the second MDT. The second MDT decisions would usually supercede the decisions of the first MDT. The second MDT will take lead responsibility in this case

2. Second opinion requested by patient or first MDT

All such cases will be discussed at the second MDT. The two sets of views will be considered in the decision making with the patient.

3. Referral to another specialist for further tests/treatment

Many staff participate in more than one MDT. It is not therefore necessary to discuss straightforward cases again at a second MDT. However these patients may be discussed if the clinician receiving the referral feels it would be of advantage or it is second MDT policy.

Lead responsibility will remain with the first MDT.

4. Communication and waiting times

Good and rapid communication between the MDTs involved is vital. The MDT co-ordinator for each MDT should have a list of all fax numbers for MDT co-ordinators across the network(s). Referrals should be faxed in the first instance.

2.0 East Midlands Gynaecological Cancer Pathway for Teenage and Young Adult Patients

2.1 Initial management: (11-7A-213)

2.1.1 Patients aged 13-18 years:

- All patients between the ages of 13-18 with suspected gynaecological cancer living within the East Midlands (East Midlands region as part of the East Midlands Cancer Network boundaries) to be referred to the East Midlands Children's and Young Persons' Integrated Cancer Service

  (Principal Treatment Centre at Nottingham University Hospitals, Queen's Medical Centre Campus (Nottingham Children's Hospital) and University Hospitals of Leicester, Leicester Royal Infirmary site).
- This service is accessed by contacting the Paediatric Oncology Consultant on-call at Queens Medical Centre in Nottingham when a patient is judged likely to have cancer. The contact number for this service is 0115 849 3302.
- These patients are treated as part of the paediatric pathway. The paediatric pathway requires the centralisation of diagnostic investigations, surgery and the most intensive chemotherapy to QMC but most patients from Leicestershire, Rutland and Northamptonshire will receive most or all of their treatment in Leicester. There is also a shared care arrangement with the paediatric team at Northampton General Hospital.
- The Paediatric team would welcome a discussion about patients in this age group in case a specific patient needs an individualised pathway.

2.1.2 Patients aged 18 years (but <19y)

- Need to be treated in an age-specific cancer facility but depending on education/employment/diagnosis/trial availability etc it may be appropriate for them to be treated by the Paediatric or the Adult site-specific pathway (in age-appropriate facilities).
- A discussion between the Paediatric team and the Site-specific consultant about patients in this age group helps to ensure that patient's needs are best served.
- This decision will be made on a patient-by-patient basis but the location of care should be in an age specific environment.
- The *East Midlands Children's and Young Persons' Integrated Cancer Service* currently provides this service within a predominantly paediatric setting in the Leicester Royal Infirmary and at Queens Medical Centre in Nottingham. This is being upgraded in order to enhance the teenage age-specific cancer facilities.

2.1.3 Patients aged 19-24 years

- All patients in this age range will be offered the choice of being:

1) referred to a young adult age-specific cancer facility
2) accessing local adult cancer services

(Please also refer to the National Guidance for GPs: Clinical Practice for the assessment of Young Women aged 20-24 with Abnormal Vaginal Bleeding)

- The East Midlands will have young adult (19 – 24y) age-specific cancer facilities at the following sites:

  - Leicester Royal Infirmary, University Hospitals of Leicester (13-24 years)
  - Nottingham City Hospital, Nottingham University Hospitals (19-24 years)
    (Nottingham Children's Hospital, Queen's Medical Centre Campus
    (Nottingham University Hospitals – City Hospital Campus (13-18 years))

The young adult age-specific inpatient, day care and outpatient facility is under development and until this is in place the additional age-specific support that these patients will be able to access in Leicester and Nottingham will be limited to an on-site teenage and Young Adult Activity Coordinator/Development Officer, Social Worker and TYA Clinical Nurse Specialist. As soon as the facilities are completed all Site - Specific MDTs will be informed.

2.2 MDT Discussion

2.2.1 Patients aged 13-24 Years

- All patients diagnosed with cancer between the ages of 13-24, living within the East Midlands (East Midlands region as part of the East Midlands Cancer Network boundaries) are to be discussed at the TYA MDT and relevant Site Specific MDT or Paediatric Cancer MDTs.
- The TYA MDT will discuss the treatment plan forwarded from the (Site Specific MDT/Paediatric Cancer MDT) and discuss the patients psychosocial care needs.
- Please refer to the East Midlands TYA Multidisciplinary Operational Policy for the referral process *(referral information outlined in brief below)*

2.3 Referral Process

2.3.1 Referral general points:

- Referrals to the TYA MDT will need to on the agreed referral form
- This referral form can be obtained from the Trust Cancer Centre, East Midlands Cancer Network website www.eastmidlandscancernetwork.nhs.uk or the Principal Treatment Centre.

2.3.2 Referral routes:

The following referral routes have been identified:

- Site Specific MDTs (MDT Coordinator) 19-24 years
- Paediatric Cancer MDTs (MDT Coordinator)
- Surgeon at Biopsy stage of the pathway
- Childrens and Young Persons' Integrated Cancer Service 13-18 years
- Via Pathology Department
- Via Alert System

- In exceptional circumstances trusts/Departments i.e. other medical departments or psychosocial/psychological service providers
- In exceptional circumstances by GP/Dentist referral

2.3.3 Responsibility for making the referral:

- Responsibility for making the referral will lie with local MDT Coordinators, Consultants, Cancer Centres and Clinical Nurse Specialists
- All referral forms accompanied with relevant information relating to the patient will either be faxed to the Principal Treatment Centre or electronically using the nhs.net email address or via post. Contact details can be found by telephoning UHL 0116 2586721 and NUH 0115 9691169 ext 54550 and asking for assistance relating to the TYA MDT.
- All patients aged 15-24 years will need to be registered with the TYAC Registration Process; this will be completed via the TYA MDT.

2.4 Treatment Responsibilities:

- All cases even those who choose to be treated outwith either the PTC or a designated hospital MUST be registered with the PTC and discussed at both the site specific and TYA MDTs
- The treatment plan is jointly agreed by the site specific and TYA MDT and will reflect the relevant network or national clinical guidelines
- Final diagnostic responsibility for TYA patients lies with the site specific MDT
- Arrangements for age specific support lies with the TYA MDT
- Follow up will be as per the appropriate disease guideline

3.0 2 WEEK WAIT REFERRAL GUIDELINES

GYNAECOLOGY 2 WEEK WAIT REFERRAL GUIDELINES

Referral Code	Symptom
5A	Lesion suspicious of cancer on cervix or vagina on speculum examination.
5B	Lesion suspicious of cancer on clinical examination of the vulva.
5C	Palpable pelvic mass not obviously fibroids.
5D	Suspicious pelvic mass on pelvic ultrasound.
5E	More than one or a single episode of post menopausal bleeding in women aged over 55 years who are not on HRT. **or** any woman with post-menopausal bleeding not on HRT
5F	Postcoital bleeding in women over 35 years that persists for more than 4 weeks.
5G	Unexpected or prolonged bleeding persisting for more than 4 weeks after stopping HRT.

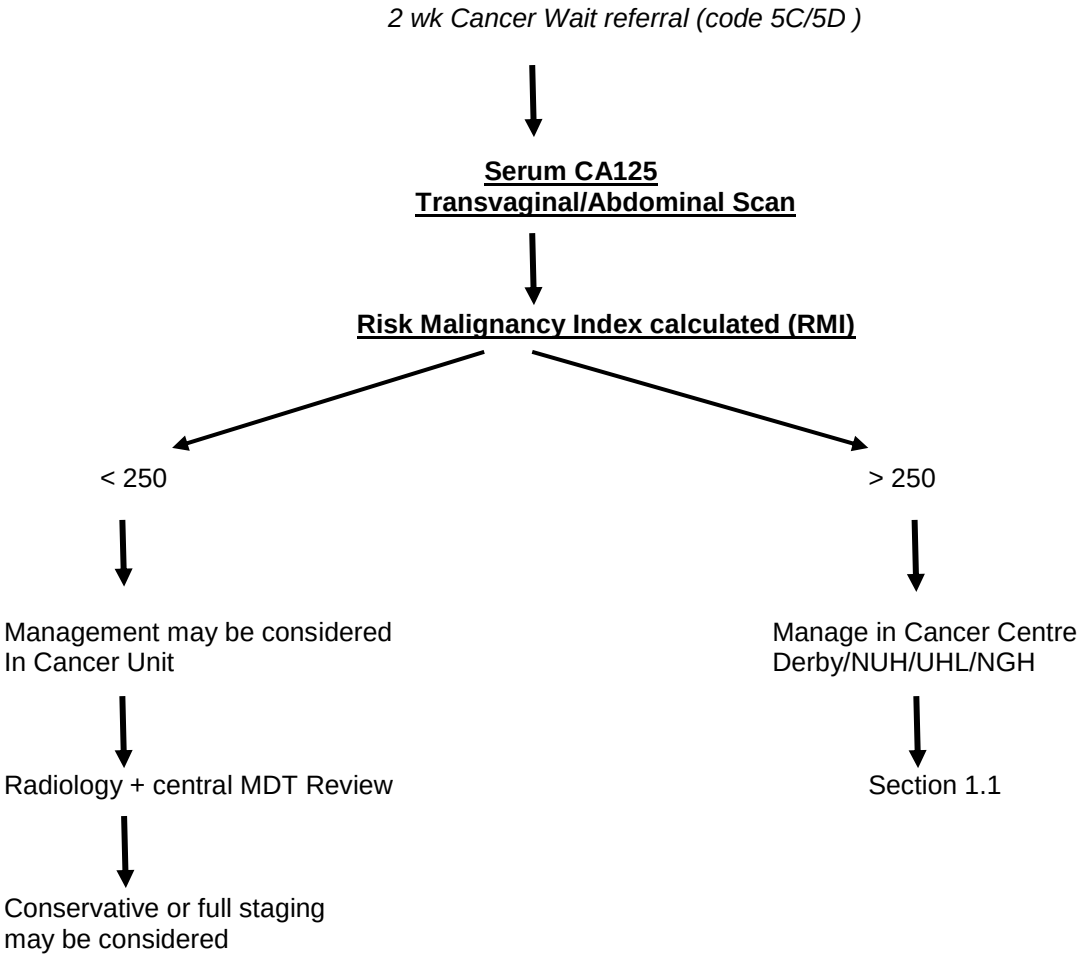
4.0 EMCN Gynaecological Cancer NSSG Ovarian Cancer Guidelines (11-1A-205e)

Signed: Mr Quentin Davis
Chair of East Midlands Cancer Network – Gynaecology Site Specific Group
Dated: 12.07.2013

Signed:
Dated:

Date of Next Review January 2014

Suspected epithelial ovarian malignancy



If at any stage concerns regarding malignancy refer to cancer centre

RMI Calculation (Jacobs and Oram 1990)

RMI = U x M x Serum CA125 level

Ultrasound (1 pt for each characteristic)	**Ultrasound score (U)**
Multilocular cyst	0 for 0 points
Evidence of solid areas	1 for 1 point
Evidence of metastases	3 for 2-5 points
Presence of ascites	
Bilateral lesions	
Menopausal status	**Menopausal status score (M)**
Pre-menopausal	1
Post-menopausal	3

Section 1.1

Suspected ovarian malignancy
RMI >250

Site of tumour obviously ovarian

Yes

No

If Age <40
Serum hCG / AFP / CEA / CA125

If Age > 40
Serum CEA / CA125

Serum hCG / AFP / CEA / CA19.9 / CA 15.3

CT Abdomen/Pelvis
Chest X-ray

(If non-ovarian malignancy suspected or associated bowel symptoms other investigation (e.g. Barium studies) need to be considered on individual basis)

Radiology + MDT Review

Ovarian malignancy still considered

Yes

No

Laparotomy + Debulking surgery
or
Image guided Biopsy + Neoadjuvant Chemotherapy

(Patients management decided at MDT and
Consideration given to open trials e.g. CHORUS)

Management guided by MDT

Ovarian Cancer

General:

The flow diagrams enclosed act as a guide for referral and management of patients with suspected ovarian cancer. Specific referrals relate to primary care team to hospital base and from unit level to cancer centre.

Ovarian carcinoma is the commonest malignant condition in gynaecological cancers, with about 75% of women presenting with advanced disease, which has an associated 5 year survival of around 35%. The main histological type is epithelial carcinoma.

Primary Care Team Management:

- Patient suspected of ovarian malignancy would be referred on a 2-week cancer wait form, codes 5c/5d.

- If patients have had an ultrasound scan as part of their assessment in the primary care, then a copy of the scan result is to accompany the patient.

Hospital Assessment:

- A transvaginal / transabdominal ultrasound scan

- Tumour markers:
    - CA125, CEA
    - AFP / HCG < 40yrs
    - CA15.3 / CA19.9 < If primary tumour considered to be non ovarian

- The Risk of Malignancy Index **(RMI)** is calculated and appropriate referrals as shown on the flow diagram to the cancer centre are then made. Those with an RMI >250 have a high risk of ovarian malignancy.

- CT scan if RMI > 250.

- All patients suspected of ovarian cancer should have:-

    - Chest x-ray
    - FBC
    - U&Es
    - LFTs
    - Tumour Markers as above and according to flow diagram.

Staging:

- Staging is according to the FIGO classification. At the MDT discussion, each patient will be managed individually whether a laparotomy/diagnostic biopsy is taken to confirm the diagnosis. Staging is normally undertaken at laparotomy, but may be presumed by imaging if only biopsy is considered.

Surgical Management:

- Laparotomy – The aim is to achieve optimal debulking (less than 1cm residual disease visible).
    - Midline abdominal incision.
    - Thorough laparotomy for staging.
    - Peritoneal washings
    - where possible, total abdominal hysterectomy with bilateral salpingo-oopherectomy and omentectomy
    - Consider biopsy of suspicious nodes and peritoneal surfaces particularly if apparent stage 1 disease. Otherwise the role of lymphadenectomy remains unclear.
    - If tumour extensive remove as much tumour as is deemed safe. Record the site and size of the residual disease in the operation notes.
    - Fill in the list of operative findings.

- In advanced disease – neoadjuvant therapy on Specialist MDT discussion/decision.

- Conservative surgery – The standard treatment of epithelial ovarian cancer is T AH/BSO, but the pros and cons of conservative surgery should be discussed with women who may not have completed childbearing and at patient request. In particular, the possibility of requiring further surgery in the future will need to be covered.

    - Consider frozen section especially with possible germ cell tumours
    - Remove affected ovary
    - Do wedge biopsy of contralateral ovary only if there is any suspicion of metastatic seedling
    - Take peritoneal biopsies and washings
    - Omentectomy
    - Remove suspicious nodes.

Chemotherapy:

- Patients with tumours of borderline malignancy do not require any adjuvant chemotherapy.

- Stage 1a / Grade 1 tumours – chemotherapy is discussed and offered to all patients although debate remains regarding this, if patients have been fully staged with pelvic and para-aortic lymphadenectomy

- > Stage 1a disease – chemotherapy using Carboplatin/Paclitaxel or Carboplatin single agent as per NICE guidelines recommended.

Radiotherapy:

Is the treatment of choice in selected cases of recurrence but not used as adjuvant treatment.

Recurrence:

- Persistent disease following surgery/chemotherapy is defined as disease remaining or presenting within 6 months from the end of chemotherapy. The role of novel agents may be considered, and in very selective cases surgery can be used to alleviate symptoms. Each case should be discussed at the MDT.

- In relapsed disease (after 6 months) there is no consensus opinion as to the correct course of action. A disease free interval of 12 months is associated with a greater likelihood of further response to platinum agents. Again, each case should be discussed at the MDT, to ensure an appropriate utilisation of both chemotherapy and surgery.

Follow Up:

Refer to Appendix A

Trials:

- Refer to Trials Portfolio

Emergency: 11-1A-205e: Ovarian Cancer presenting as emergency under Generalists:

Recommendations: Stabilise patient
Seek telephone advice from gynaecological oncologist/ unit lead for gynaecological oncology
Advice regarding appropriate investigations including tumour markers and CT
Scanning
Review at MDT
Plan appropriate consultation/ treatment with the patient

Germ Cell Tumours Ovarian Cancer:

- These are extremely sensitive to chemotherapy with over 80% cure rates. Unilateral oophorectomy followed by careful monitoring of tumour markers in stage 1A disease (fully staged and histologically proven by multiple biopsy and CT/MRI scan to exclude pulmonary and liver metastasis).

- Chemotherapy (BEP combination, bleomycin to be discontinued after 3 cycles) is usually required. Chemotherapy is given for 2 further cycles (as consolidation) after achieving a complete response on markers and scans.

- Surgery and occasionally radiotherapy is necessary to eliminate residual tumour.

- Preservation of fertility is important in these patients. Cryopreservation of ovarian tissue should be offered.

FIGO staging:

Stage 1A:	Tumour limited to 1 ovary; capsule intact, no tumour on ovarian surface. No malignant cell in ascites or peritoneal washings.
Stage 1B:	Tumour limited to both ovaries, capsules intact, no tumour on ovarian surface. No malignant cells in ascites or peritoneal washings.
Stage 1C:	Tumour limited to 1 or both ovaries with any of the following: capsule ruptured, tumour on ovarian surface, malignant cells in ascites or peritoneal washings.
Stage IIA:	Extension and/or implants on the uterus and/or fallopian tubes. No malignant cells in ascites or peritoneal washings.
Stage IIB:	Extension to and/or implants on other pelvic tissues. No malignant cells in ascites or peritoneal washings.
Stage IIC:	Pelvic extension and/or implants (stage IIA or IIB) with malignant cells in ascites or peritoneal washings.
Stage IIIA:	Microscopic peritoneal metastasis beyond pelvis 2cm or less in greatest dimension.
Stage IIIB:	Macroscopic peritoneal metastasis beyond pelvis 2cm or less in greatest dimension.
Stage IIIC:	Peritoneal metastasis beyond pelvis more than 2cm in greatest dimension and/or regional lymph node metastasis.
Stage IV:	Tumour involving 1 or both ovaries with distant metastasis. If pleural effusion is present, there must be positive cytological test results to designate a case to Stage IV. Parenchymal liver metastasis equals Stage IV.

5.0 EMCN Gynaecological Cancer NSSG Cervical Cancer Guideline (11-1A-206e)

Signed: Mr Quentin Davis
Chair of East Midlands Cancer Network – Gynaecology Site Specific Group
Dated: 12.07.2013

Signed:
Dated:

Date of Next Review January 2014

Suspected Cervix malignancy

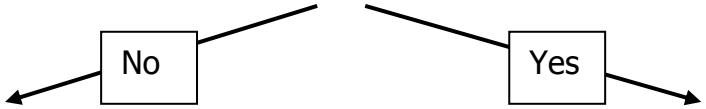
(PCB, PMB etc)

General Examination
Pelvic Examination
+/- cervical smear

2 wk Cancer Wait form codes 5E/5G- GP

Refer to cancer unit or cancer centre

Suspicious of malignancy in cancer unit



Colposcopy + directed biopsy

Prompt referral to cancer centre
(See section 1.2)

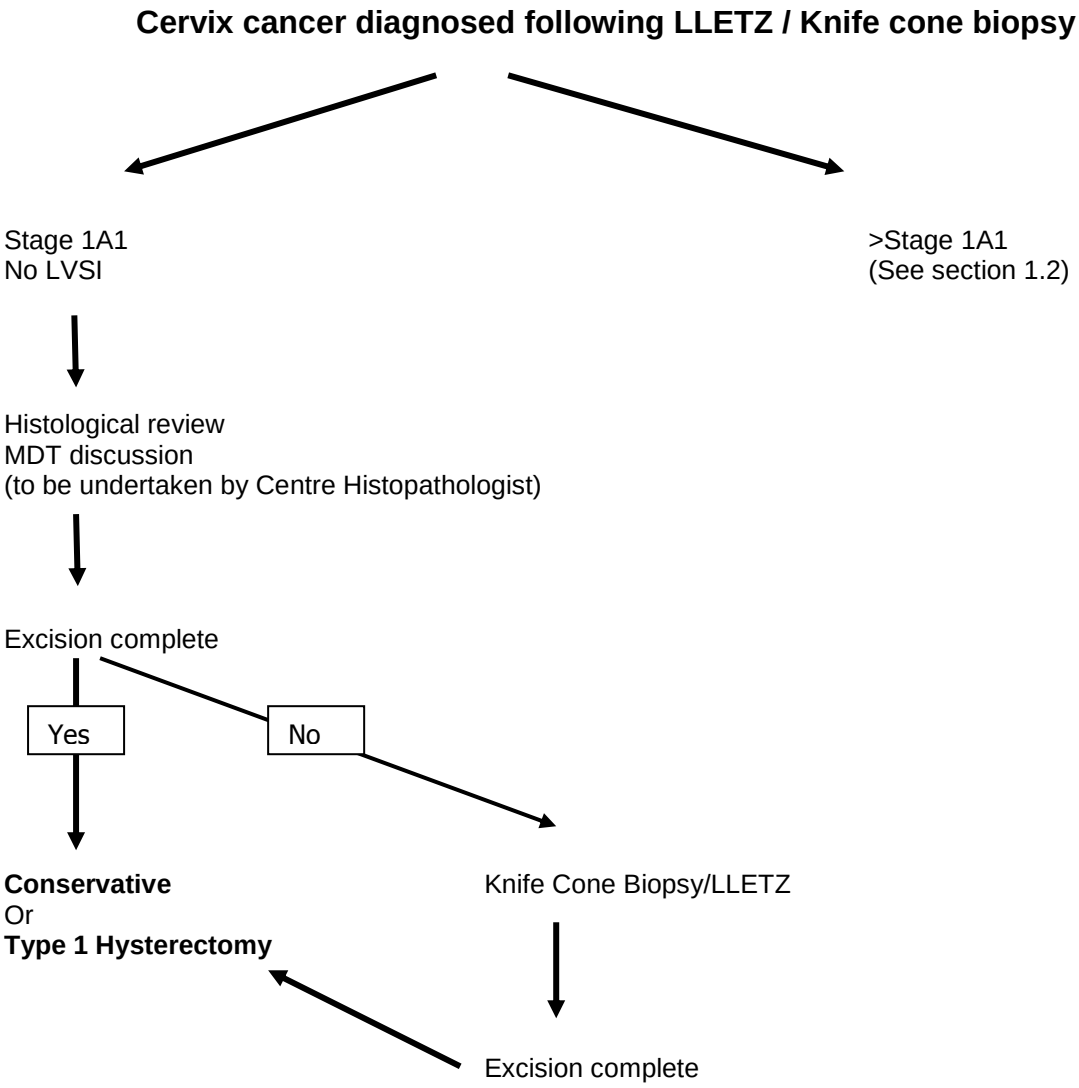
Malignant

Benign

Management continues in cancer unit – Kettering, Burton, United Lincolnshire and Sherwood Forest

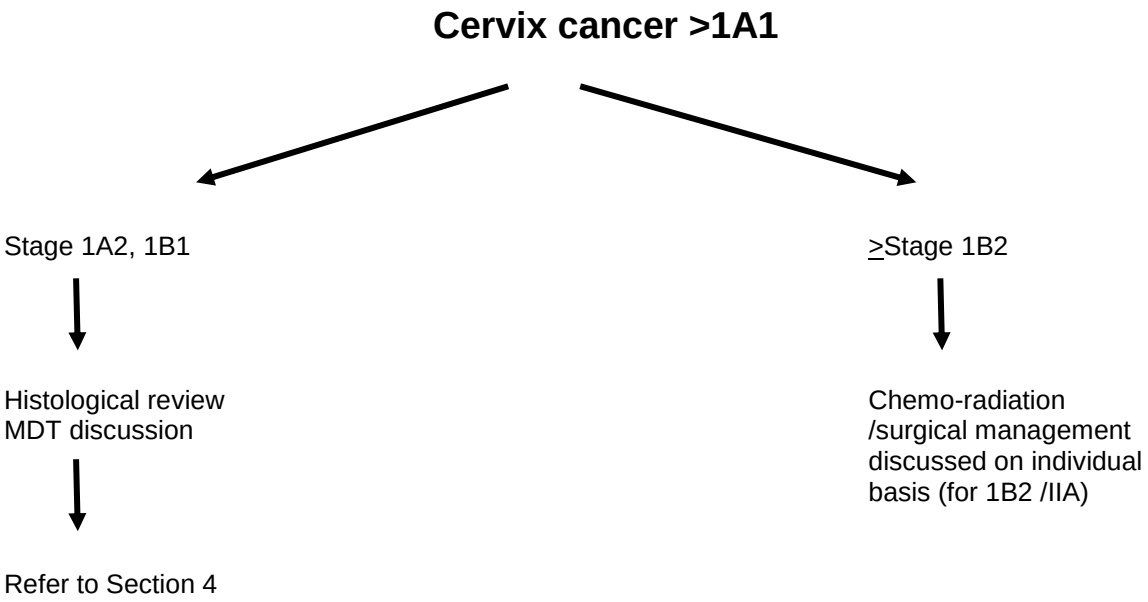
If at any stage concerns regarding malignancy refer to cancer centre

Section 1.1



Management of stage 1A1 cervix cancer can be considered in cancer unit - Kettering, Burton, United Lincolnshire and Sherwood Forest

Section 1.2



For all cases of cervix cancer pathology should be reviewed by the Centre Histopathologist.

Management in the Cancer Centres – Derby, Nottingham, Leicester and Northampton

Cervical Cancer:

General:

Cervical cancer remains a common malignancy worldwide although the incidence in developed countries is falling due to an effective cervical cancer screening program. There is a wide variation in the incidence and the lifetime risk of cervical cancer across different parts of the world. In England, the incidence of cervical cancer fell from 4467 new cases in 1985 to 2424 in 2000. The peak incidence for invasive cancer is 45-50 years, although there has been a rise in the 25-34 year age range. Currently, the mortality rate from cervical cancer is falling by almost 7% annually in the UK and this has been attributed mainly to the success of the cervical screening program. Squamous cell carcinoma is the main histological subtype although there has been a significant rise in the proportion of cases of adenocarcinomas and adeno-squamous carcinomas. There is now overwhelming evidence that HPVs are the main cause of both pre-invasive and invasive squamous cell carcinoma of the cervix in nearly 100% of cases. HPV vaccination is now being implemented in the UK.

The flow diagrams enclosed act as a guide for referral and management of patients with suspected ovarian cancer. Specific referral relate to primary care team to hospital base and from unit level to cancer centre.

Primary Care Team Management:

- Patient with suspected cervix cancer should be referred on the 2-week cancer wait form (Codes 5F/5G). All patients with intermenstrual, postcoital or postmenopausal bleeding should have a general examination, pelvic examination and cervical smear if indicated.

- Patients referred from colposcopy should be done so in an urgent inter-hospital manner.

Hospital Assessment:

- In suspected cases of cervix cancer, a staging EUA + cervical biopsies should be undertaken as part of the initial assessment and staging of this disease. If cancer confirmed, patient will need to have:-

    - Chest x-ray
    - MRI

Staging:

- Staging for this disease is clinical base imaging and with MRI.

- Histological staging should include:-
    - Differentiation of tumour
    - Histological sub-type

- Presence of nodal metastases
- Accurate measurement as to the dimensions of the tumour

Surgical Management:

- Stage 1A1 disease.
    - Cone biopsy may be performed in patients wishing to preserve fertility. Lymph node dissection is not performed.
    - Simple hysterectomy can be offered to this patient if family complete and invasive and pre-invasive disease has been completely removed.
- Stage 1A2 disease to 1B1
    - If patient wishing to preserve fertility, and tumour fulfils criteria to be suitable for cone biopsy + bilateral pelvic lymph node dissection or radical trachelectomy + bilateral pelvic lymph node dissection, then consideration should be given to this form of treatment.
    - If patient does not wish to have fertility preserved, then consider radical Wertheim's hysterectomy with bilateral pelvic lymph node dissection. If on the basis of MRI any lymph nodes that are deemed to be suspicious they should be removed first and sent for frozen section analysis. If these are positive the procedure should be abandoned and patient considered for chemo-radiotherapy.
    - Primary radiotherapy +/- chemotherapy
- Stage 1B2 and Advanced Disease.
    - All patients should be referred to the clinical oncologist for consideration of chemo-radiation.
    - Selected cases of 1B2 / IIa disease may be offered radical surgery +/- neoadjuvant chemotherapy.

Radiotherapy +/- chemotherapy:

- Offered to all patients with 1B and above
- Chemo-Radiation is considered in all patients if renal function satisfactory otherwise radical radiotherapy as single modality
- Weekly Cisplatin concurrent with pelvic radiotherapy x6 in the dose of 40mg/m^2. Pelvic radiotherapy 45 – 50 Gys to pelvis 3 to 4 field technique followed by 2 to 3 insertions of HDR Brachytherapy (7 or 8 Gy per fraction x 3)
- Parametrial/Pelvic boost can be considered if persistent parametrial/pelvic disease (8Gy/4# or 10.8Gy/6#)

Recurrent Disease:

- All cases of recurrent disease should be discussed at the Multi-Disciplinary Team Meeting.

- Those with central recurrence and no evidence of metastases should be considered for exenterative surgery. This will include input from the colorectal surgeons and urologists.

- If inoperable palliative chemotherapy considered

Follow Up:

Refer to Appendix

Miscellaneous:

- Cervix cancer diagnosed in pregnancy. Each case should be promptly referred to the multi-disciplinary meeting and managed on an individual basis.

Trials:

- Refer to Trials Portfolio

FIGO Staging for Carcinoma of Cervix Uteri

Stage I	The carcinoma is strictly confined to the cervix (extension to the corpus would be disregarded)
IA	Invasive carcinoma which can be diagnosed only by microscopy, with deepest invasion $\leq$ 5mm and largest extension $\geq$ 7mm
IA1	Measured stromal invasion of $\leq$ 3.0mm in depth and extension of $\leq$ 7.0 mm
IA2	Measured stromal invasion of > 3.0 mm and not > 5.0 mm with an extension of not > 7.0 mm
IB	Clinically visible lesions limited to the cervix uteri or pre-clinical cancers greater than stage 1A
IB1	Clinical visible lesion $\leq$ 4.0 cm in greatest dimension
IB2	Clinically visible lesion > 4.0 cm in greatest dimension
Stage II	Cervical carcinoma invades beyond the uterus but not to the pelvic wall or to the lower third of the vagina
IIA	Without parametrial invasion
IIA1	Clinically visible lesion $\leq$ 4.0 cm in greatest dimension
IIA2	Clinically visible lesion > 4 cm in greatest dimension
IIB	With obvious parametrial invasion
Stage III	The tumour extends to the pelvic wall and/or involves lower third of the vagina and/or causes hydronephrosis or non-functioning kidney
IIIA	Tumour involves lower third of the vagina with no extension to the pelvic wall
IIIB	Extension to the pelvic wall and/or hydronephrosis or non-functioning kidney
Stage IV	The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum. A bullous edema, as such, does not permit a case to be allotted to Stage IV
IVA	Spread of the growth to the adjacent organs
IVB	Spread to distant organs

6.0 EMCN Gynaecological Cancer NSSG Endometrial Cancer Guideline

Signed: Mr Quentin Davis
Chair of East Midlands Cancer Network – Gynaecology Site Specific Group
Dated: 12.07.2013

Signed:
Dated:

Date of Next Review January 2014

Post Menopausal Bleeding

2 wk cancer wait referral (code 5E/5G)

Transvaginal Scan

Endometrium ≤ 5mm	Endometrium >5mm≤10mm	Endometrium >10mm
Reassure #	Pipelle Biopsy *	Hysteroscopy / D&C

Non-Cancer	Hyperplasia	**Cancer**
Treat accordingly	See Section 1.1	Imaging as considered appropriate

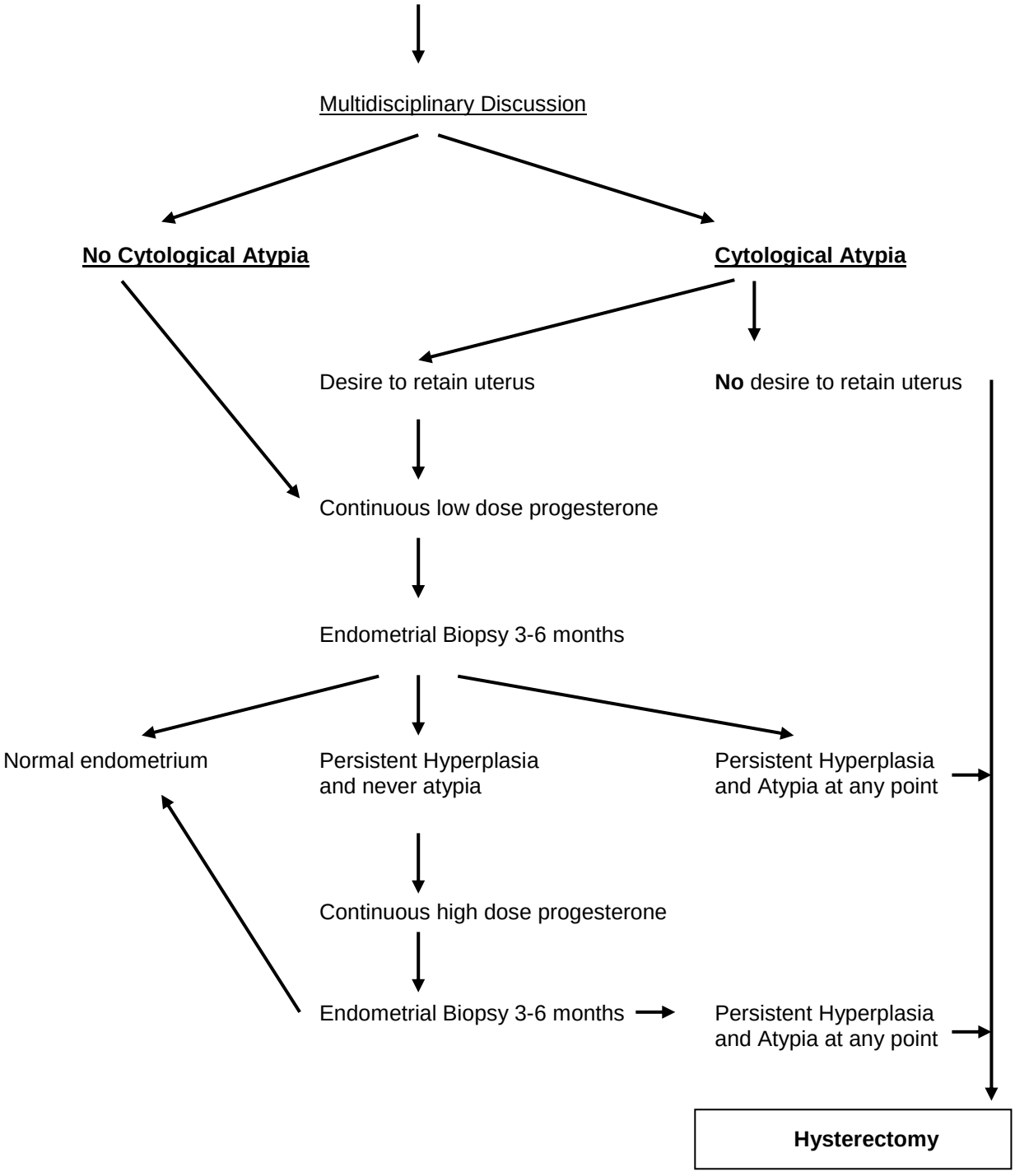
	GI / GII <50% Myometrial Invasion (Stage ≤IB)	GIII Non-Endometrioid >50% Myometrial Invasion (Stage ≥IB)
	Manage at Unit Level	**Refer to Cancer Centre**
	Hysterectomy / BSO / Peritoneal washings	Section 1.2

Persistent bleeding – Hysteroscopy / D&C
* Unable to perform Pipelle / Insufficient – Hysteroscopy / D&C

- If suspicious of polyp recourse directly for Hysteroscopy / D&C
- If on Tamoxifen recourse directly for Hysteroscopy / D&C

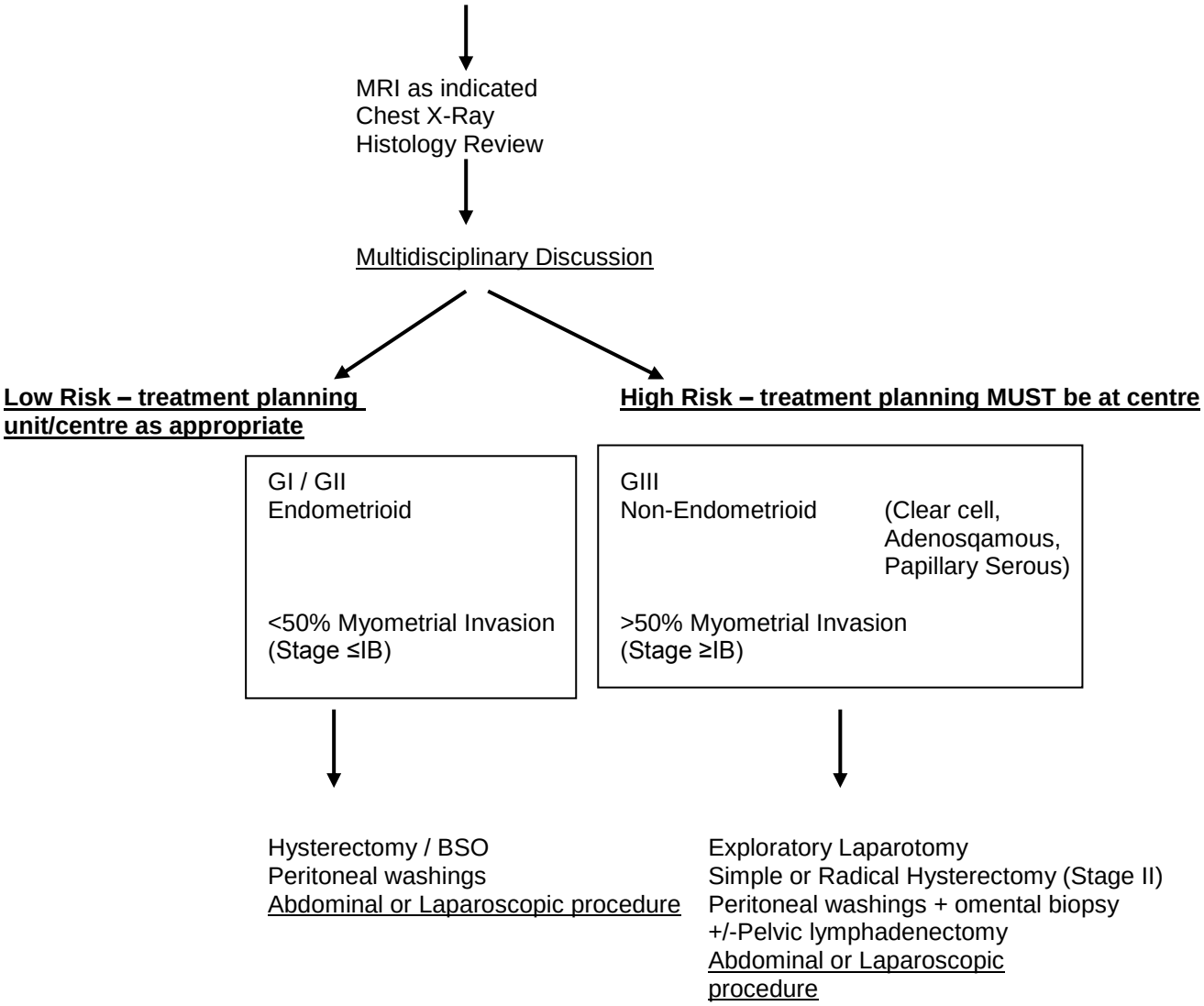
Section 1.1

Endometrial Hyperplasia



Section 1.2

Endometrial cancer



Endometrial Cancer:

General:

The incidence of endometrial cancer in England and Wales is 14.3/100,000 (OPCS, 1989) with an overall five year survival of approximately 70%. The disease affects mainly post-menopausal Women with the peak incidence in the 7th decade of life, though 4.2% of cases occur in women <45 years of age (OPCS, 1989). The majority of women present with post-menopausal bleeding (PMB) and all women with this complaint require investigations to rule out endometrial malignancy. As such, screening is targeted towards this sub-group, with no method of generalised popu!ation-based screening is available presently. In early stage disease, surgical intervention affords cure for a significant proportion of women. In advanced disease, radiotherapy forms the basis of management.

The flow diagrams enclosed act as a guide for referral and management of patients with suspected endometrial cancer. Specific referrals relate to primary care team to hospital base and from unit level to cancer centre.

Primary Care Team Management:

- All patients with postmenopausal bleeding should be referred as an urgent 2-week referral on the appropriate forms, Code 5E/5G, for gynaecological assessment. Transvaginal / Transabdominal ultrasound scan will be organised will be organised to coincide with the patients' appointment.

Hospital Assessment:

- If on transvaginal scan the endometrial thickness (ET) < 5mm but no other suspicious features and the patient has had one episode of post menopausal bleeding, the patient can be reassured without further investigations being necessary. If the ET >5mm but <10mm, a pipelle biopsy should be attempted at the outpatient clinic unless otherwise indicated. If the ET >10mm the patient will be booked for either an outpatient or inpatient hysteroscopy, dilatation and curettage.

- All patients requiring hysteroscopy and D&C as an inpatient will required to have pre-operative assessment and other investigations arranged as per individual basis (for example chest x-ray, ECG).

- If endometrial cancer is diagnosed by curettage, the patient should have:-

    - Chest x-ray
    - MRI as indicated
    - FBC, U&Es, LFTs as indicated

Staging:

- Staging for endometrial cancer is primarily surgical according to FIGO classification.

- The histological report will contain

    - Histological type and differentiation.
    - Depth of invasion
    - Lymph node status (if lymphadenectomy has been performed).

- Cytological report on peritoneal washings.

Surgical Management:

- Most patients with endometrial cancer will undergo surgery as the mainstay of treatment. Surgery includes:
    - Hysterectomy
    - bilateral salpingo-oophorectomy
    - peritoneal washings
    - Selective pelvic / para-aortic lymph node dissection

- The MRC ASTEC Study is now closed and the role of routine pelvic lymph node dissection does not influence outcome. It should only be undertaken once discussed at the Multi-Disciplinary Meeting and clinically investigated.

Radiotherapy:

- Radiotherapy is generally not considered in patients found to have a low risk or recurrence. These include patients with grade I or grade II endometrioid adenocarcinomas $\leq$ stage 1b with no lymphomascular space involvement.

- Adjuvant radiotherapy is discussed with all patients with tumour stage $\geq$1C or grade G3. ASTEC and PORTEC2 results are available and they should lead to and increased in the use of Brachtherapy only (21 Gy HDR in 3 fractions, or 30 Gy LDR)I n the following patients

    - Stage IA and IB grade 3
    - Stage IC all grades
    - Papillary serous, clear cell, stage ≤IIB and grades

Primary Radiotherapy:

- This is indicated for those patients technically or medically inoperable with the disease confined to the pelvis. It will consist of external beam radiotherapy followed by intrauterine and vaginal vault radiotherapy.

Chemotherapy:

- Adjuvant chemotherapy using Carboplatin, Paclitaxel or CAP (Cisplatin, Adriamycin, Cyclophosphamide) is offered to patients with clear cell or serous papillary carcinoma, what stages? Evidence to support this?.

Recurrence:

- Local pelvic recurrence, radiotherapy to the whole pelvis with vaginal boost if no previous irradiation given.

- Chemotherapy Carboplatin single agent or in combination with Paclitaxel or CAP regime with palliative intent.

- Provera 200 mg tds can be used for local and or systemic recurrence.

Follow Up:

- Refer to Appendix

Miscellaneous:

- Endometrial Hyperplasia – details of how to manage this condition are shown in the flow diagram.

- Uterine Sarcoma – total abdominal hysterectomy, bilateral salpingo-oopherectomy, omentectomy and pelvic lymph node dissection. Patient is discussed at the MDT - CT chest, abdomen and pelvis organised followed by adjuvant radiotherapy / chemotherapy as indicated for high-grade cases.

- Tamoxifen users – all patients presenting with PMB on Tamoxifen should have hysteroscopy and D&C irrespective of endometrial thickness.

Trials:

- Refer to NSSG Trials Portfolio

FIGO staging for Carcinoma of the Endometrium

Stage I	Tumour confined to the corpus uteri
IA	No or less than half myometrial invasion
IB	Invasion equal to or more than half of the myometrium
Stage II	Tumour invades cervical stroma but does not extend beyond the uterus
Stage III	Local and/or regional spread of the tumour
IIIA	Tumour invades the serosa of the corpus uteri and/or adnexae
IIIB	Vaginal and/or parametrial involvement
IIIC	Metastases to pelvic and/or para-aortic lymph nodes
IIIC1	Postivie pelvic nodes
IIIC2	Positive para-aortic lymph nodes with or without positive pelvic lymph nodes
Stage IV	Tumour invades bladder and/or bowel mucosa and/or distant metastases
IVA	Tumour invasion of bladder and/or bowel mucosa
IVB	Distant metastases including intra-abdominal metastases and/or inguinal lymph nodes

7.0 EMCN Gynaecological Cancer NSSG Vulva Cancer Guidelines (11-1A-207e)

Signed: Mr Quentin Davis
Chair of East Midlands Cancer Network – Gynaecology Site Specific Group
Dated: 12.07.2013

Signed:
Dated:

Date of Next Review January 2014

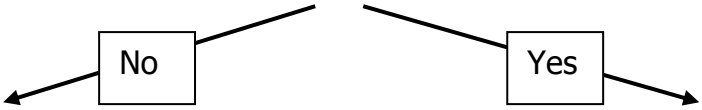
Suspected vulva malignancy

(vulva swelling/polyp/lump/ulcer/suspicious groin nodes etc)

General Examination
Pelvic Examination
2 wk Cancer Wait form coded 5B - GP

Refer to cancer unit or cancer centre

Suspicious of malignancy in cancer unit



In or Outpatient biopsy
+/- Colposcopy

Prompt referral to cancer centre
(See section 1.1)

Malignant

Benign

Management continues in cancer unit – Kettering, Burton, United Lincolnshire, Sherwood Forest

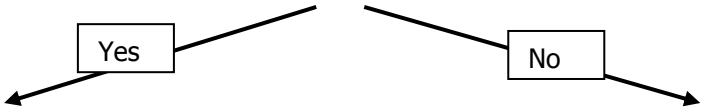
If at any stage concerns regarding malignancy refer to cancer centre – Derby, Nottingham, Leicester, Northampton

Suspicion of vulva malignancy

Outpatient biopsy or inpatient biopsies +/- mapping
+/- cystoscopy or Sigmoidoscopy if necessary

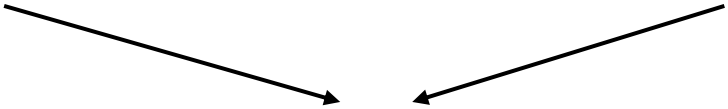
Detailed diagram
Consider photography

Lesion < 2cm in maximum diameter
Free of any midline structure



Excision biopsy with 15mm margin

Consider representative mapping biopsies prior to definitive treatment



Histological Review
MDT Discussion

Stage 1A	Groin node dissection unnecessary
> Stage 1A	Imaging preferable (USS groins +/- CT pelvis) Extent of surgery/chemoradiation determined by stage of tumour.

Unilateral vulva lesions (> 10mm from midline) require ipsilateral inguino-femoral node dissection (if ipsilateral nodes positive consider contralateral inguino-femoral node dissection

Central vulva lesions require bilateral inguino-femoral node dissection

Complication rates of inguino-femoral node dissection are high (eg lymphoedema) especially when radiotherapy is required as well. Primary radiotherapy to groins should be considered if there is positive fine needle aspirate of suspicious nodes by USS or excision of suspicious node(s) is positive.

Vulva Cancer:

General:

Vulva cancer is uncommon. Approximately 800 new cases are registered in the UK each year. Ninety per cent of all vulva cancers are squamous in origin. The histology is, however, important as it represents a variable in determining the likelihood of lymph node involvement. The five year survival in cases with no lymph node involvement is in excess of 80%. This falls to less than 50% if the inguinal nodes are involved and 10-15% if the iliac or other pelvic nodes are involved. Overall, about 30% of operable patients have nodal spread. The surgical management of vulva cancer has become more individualised although the need for adequate resection margins (15 mm) and groin node dissection remain important basic principles. Reconstructive surgery has a significant role in the management of these cancers. Radiotherapy, in combination with chemotherapy, may help in avoiding surgery that may lead to damage of the anal sphincter or urethra. Several conditions are thought to be possible precursor lesions. These include squamous vulval intraepithelial neoplasia (VIN), the maturation disorders and Paget's disease.

The flow diagrams enclosed act as a guide for referral and management of patients with suspected ovarian cancer. Specific referral relate to primary care team to hospital base and from unit level to cancer centre.

Primary Care Team Management:

- All patients with suspected vulva cancer should be referred on the 2-week wait form (Code 5B).

- Suspicious features of vulva cancer include:
    - Swelling, lump, polyp
    - Ulcer
    - Elevation or irregularity of surface contour
    - A clinical wart in postmenopausal women

Hospital Assessment:

- All patients with perceived vulva cancer should have an outpatient biopsy or an examination under anaesthesia with appropriate biopsies. If possible the lesion should be photographed and following this the case discussed at the Multi-Disciplinary Team Meeting. Specific details of how large the biopsy should be are represented in the flow diagram enclosed.

- All women diagnosed with vulva cancer require:
    - Chest x-ray
    - Ultrasound scan of groins
    - CT scan if inguinal nodes appear suspicious.

Staging:

- The staging of vulva cancer is according to FIGO classification. It is predominantly surgical.

- Full histological assessment should include:-

    - Histological sub-type of cancer.
    - Grade of tumour.
    - Exact dimensions of tumour, including accurate measurements of disease free margins.

Surgical Management:

- Surgery should be considered the mainstay of treatment for this disease, irrespective of the age and medical condition of the patient involved.

- Vulva cancers require radical wide local excision with a minimum 15 mm surgical margin around the tumour. Biopsies and removal of suspicious areas should be considered at that time.

- If invasion is greater than 1mm in depth, then appropriate inguinal femoral lymphadenectomy should be performed. The laterality of the lymphadenectomy will be decided upon at the Multi-Disciplinary Team Meeting.

Radiotherapy:

- Neo-adjuvant chemo radiation may be preferable in a few selected cases of vulva cancer. These cases need to be discussed in length and detail at the Multi-Disciplinary Team Meeting.

- Adjuvant radiotherapy (pelvis and inguinal areas) is possibly considered when:-

    - Surgical margins close after possible re-excision.
    - When 2 or more lymph nodes are involved with metastatic disease.
    - Advanced disease, concurrent chemo- radiation to vulva and lymphatic drainage areas given

Recurrent Disease:

- Local recurrence is usually managed by further local excision. Radiotherapy may be considered with a wide recurrent lesion if no radiotherapy previously given.

- Groin recurrence may be managed by both surgery and radiotherapy (if not previously used).

Follow Up

- Refer to Appendix F

Miscellaneous

- The use of sentinel lymph node biopsy is likely to become practice in the next decade but is currently being evaluated in several centres

Trials

- Refer to NSSG Trials Portfolio

FIGO Staging for Vulval Cancer:

Stage I	Tumour confined to the vulva
IA	Lesions $\leq$ 2 cm in size confined to the vulva or perineum and with stromal invasion $\leq$ 1.0 mm, no nodal metastasis
IB	Lesions > 2 cm in size or with stromal invasion > 10 mm, confined to the vulva or perineum with negative nodes
Stage II	Tumour of any size with extension to adjacent perineal structures (1/3 lower urethra, 1/3 lower vagina, anus) with negative nodes
Stage III	Tumour of any size with or without extension to adjacent perineal structures (1/3 lower urethra, 1/3 lower vagina, anus) with positive inguino-femoral lymph nodes
IIIA	(i) with 1 lymph node metastasis ($\geq$ 5 mm), or (ii) 1-2 lymph node metastasis(es) (< 5 mm)
IIIB	(i) with 2 or more lymph node metastases ($\geq$ 5 mm), or (ii) 3 or more lymph node metastases (< 5 mm)
IIIC	With positive nodes with extracapsular spread
Stage IV	Tumour invades other regional (2/3 upper urethra, 2/3 upper vagina), or distant structures
IVA	Tumour invades any of the following:- (i) upper urethral and/or vaginal mucosa, bladder mucosa, rectal mucosa, or fixed to pelvic bone, or (ii) fixed or ulcerated inguuino-femoral lymph nodes
IVB	Any distant metastasis including pelvic lymph nodes

8.0 Vaginal Cancer (11-1A-207e)

Signed: Mr Quentin Davis
Chair of East Midlands Cancer Network – Gynaecology Site Specific Group
Dated: 12.07.2013

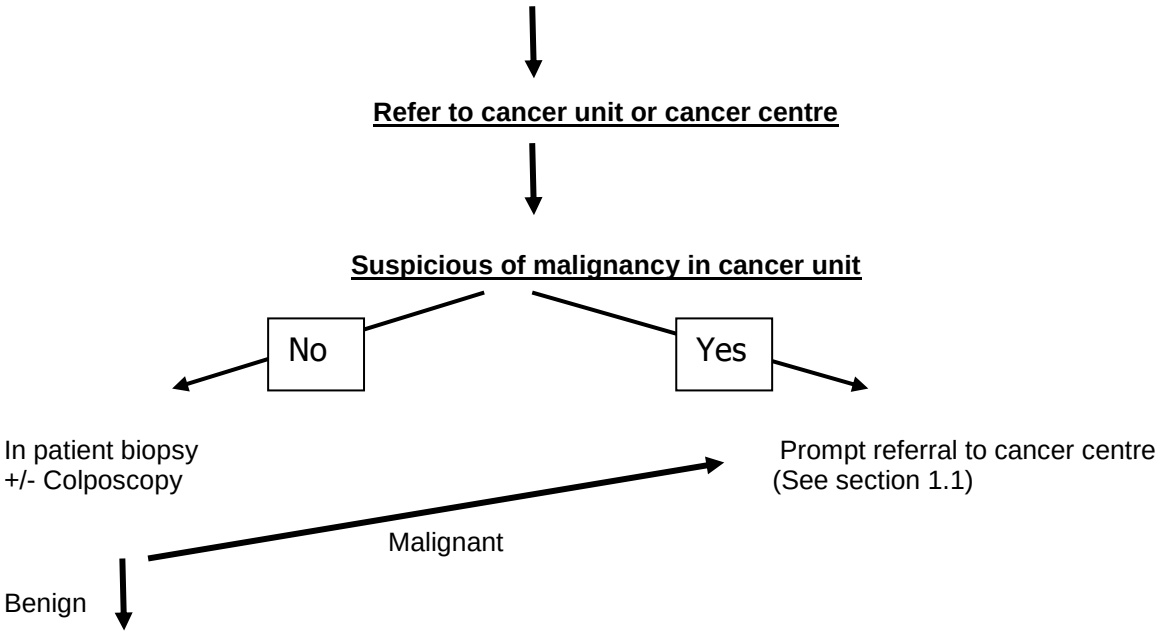
Signed:
Dated:

Date of Next Review January 2014

Suspected vaginal malignancy

(Abnormal vaginal bleeding, lump, ulcer)

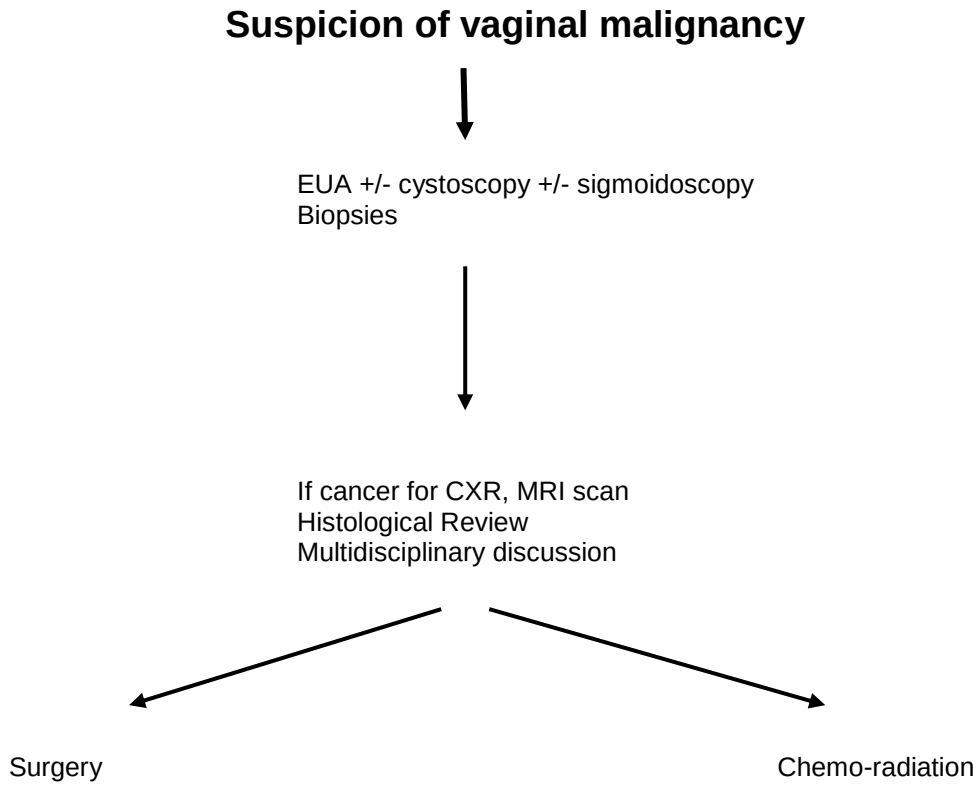
2 wk Cancer Wait form coded (5a) - GP



Management continues in cancer unit – Kettering, Burton, United Lincolnshire, Sherwood Forest

If at any stage concerns regarding malignancy refer to cancer centre – Derby, Nottingham, Leicester and Northampton

Section 1.1


Suspicion of vaginal malignancy
EUA +/- cystoscopy +/- sigmoidoscopy
Biopsies
If cancer for CXR, MRI scan
Histological Review
Multidisciplinary discussion
Surgery
Chemo-radiation

Vaginal Cancer:

General:

The flow diagrams enclosed act as a guide for referral and management of patients with suspected ovarian cancer. Specific referral relate to primary care team to hospital base and from unit level to cancer centre.

Primary Care Team Management:

- All patients with suspected vaginal cancer should be referred on the 2-week wait form (Code 5B).

- Suspicious features of vaginal cancer include:
  - Abnormal vaginal bleeding
  - Presence of lump, ulcer or swelling in vagina

Hospital Assessment:

- All patients with perceived vaginal cancer should have an examination under anaesthesia with appropriate biopsies followed by discussion at the Multi-Disciplinary Team Meeting.

- All women diagnosed with vaginal cancer require:-
  - Chest x-ray
  - MRI scan of pelvis
  - FBC, U&E's, LFT's

Staging:

- The staging of vaginal cancer is according to FIGO classification. It is predominantly surgical.

- Full histological assessment should include:-
  - Histological sub-type of cancer.
  - Grade of tumour.

Surgical Management:

- Surgery rarely considered in cases of vaginal cancer.

FIGO stages I and II can consider TAH + partial or total vaginectomy + bilateral pelvic or groin node dissection.

Chemo-Radiotherapy Options

- **Stage 1: Brachtherapy (intracavitary or intersticial) +/-chemotherapy**
- **Stage>1: Pelvic and inguinal EBRT + Brachytherapy (intracavitary or interstitial) Boost**

9.0 EMCN Gynaecological Cancer NSSG Guideline for Recurrent Gynaecological Cancer

Signed: Mr Quentin Davis
Chair of East Midlands Cancer Network – Gynaecology Site Specific Group
Dated: 12.07.2013

Signed:
Dated:

Date of Next Review January 2014

Signed: Mr A Bali
Chair of East Midlands Cancer Network – Gynaecology Site Specific Group
Dated: 10.07.09

Signed: Mr T Rideout
Chair of Network Board
Dated: 21.07.09

Date of First Review: January 2010

Date of Second Review: January 2011

Date of Next Review: January 2012

Recurrent Gynaecological Cancers:

General:

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- Any patient with suspected recurrent cancer should be referred to a gynaecologist / oncologist within the Gynaecological Cancer Team

- Treatment should be individualised taking into account tumour site, prospect of cure, symptoms and patient wishes.

- Many recurrences are not curable and early palliative care input should be considered in all cases.

- Patients with recurrent disease experience high levels of physical and psychological morbidity.

- Treatment options for recurrent disease may include surgery, radiotherapy, chemotherapy or a combination.

Principles of assessing patients with recurrent gynaecological cancer:

- When recurrence has been diagnosed, all attempts must be made to search for evidence of systemic spread as this will affect prognosis and treatment.

- Histological confirmation of recurrence is not always essential prior to a management plan, e.g., vulval cancer and ovarian cancer.

- Suggested investigations include:
    - CXR – all patients.
    - Serum tumour markers, e.g. Ca 125 – recurrent ovarian cancer.
    - CT/MRI – recurrent cervical/endometrial/ovarian cancer.
    - Bone scan if indicated – recurrent cervical and endometrial cancer.

- Surgery may be potentially curative for some patients e.g.:
    - pelvic exenteration for central pelvic recurrences of cervical or endometrial cancer.
    - wide local excision (+/- plastic reconstruction) of a locally recurrent vulval cancer.

- Surgery may be used to palliate symptoms e.g.:
    - excision of symptomatic masses i.e. isolated groin nodes in recurrent vulval cancer or symptomatic pelvic recurrences in ovarian cancer.
    - bowel/urinary by-pass procedures for obstruction or fistula.
    - peritoneal venous shunts for recurrent ascites.

- Radiotherapy may be potentially curative for some patients e.g.:
    - radical radiotherapy for localised recurrence of cervical or endometrial cancer after primary surgical therapy.

    - Radical radiotherapy in recurrent vulval cancer in combination with chemotherapy.

- Radiotherapy may be used to palliate symptoms e.g.:
    - vaginal/rectal bleeding and/or pain due to pelvic cancer recurrence.
    - Symptomatic bone, brain, nodal metastases.

- Chemotherapy may be used to palliate symptoms e.g.:
    - Recurrent ascites in ovarian cancer.
    - Hormone treatment eg progestogens in endometrial cancer

All patients should be discussed within the MDT.

Recurrent cervical cancer:

Symptoms:

- Vaginal bleeding or discharge.
- Fistulation causing faecal or urinary incontinence.
- Pain from metastatic spread.
- Dysuria and haematuria.

Signs:

- Friable tumour at vault with contact bleeding.
- Pelvic mass.
- Evidence of fistula.
- Left supraclavicular lymphadenopathy

Investigations:

- Histological confirmation is usually necessary.
- CXR
- MRI – to assess nodal spread and extent of pelvic disease.
- EUA, cystoscopy.

Treatment considerations:

- Patients with recurrent pelvic disease previously treated with surgery alone can be potentially cured with chemo irradiation.

- Consideration should be given to treating symptomatic metastases with radiotherapy e.g. bone metastases for symptom relief.

- Chemotherapy produces low response rates (5-10%) in recurrent disease, but can be considered in fit patients.

- By-pass procedures for urinary/bowel fistulation can be considered in fit patients.

- Pelvic exenteration can be considered in patients with central pelvic disease who have been treated with surgery and radiotherapy previously. Salvage hysterectomy is rarely used in patients with recurrent disease because of the high risk of urinary tract injury in irradiated patients.

Recurrent ovarian cancer:

Symptoms:

- Abdominal bloating/distension
- Change in bowel/bladder habit
- Asymptomatic – raised Ca 125 level
- Vaginal bleeding

Signs:

- Ascites
- Pelvic mass
- Pleural effusion

Investigations:

- CXR
- Ca 125
- CT/USS
- Histological diagnosis is not essential prior to treatment

Treatment considerations:

- Recurrent ovarian cancer is not curable. Second line chemotherapy can palliate symptoms e.g., recurrent ascites and can produce remission rates of 20-30%. Toxicity is a problem however and decisions on treatment depends on previous treatment, time interval since treatment or whether patient enters clinical trial.

- The optimal time to start to palliative chemotherapy in asymptomatic patients who have a recurrence based on a raised Ca 125, remains to be defined. MRC OVO5 trial will hopefully address the value of Ca 125 follow-up in the future.

- The type of chemotherapy required depends on the remission duration. Patients should be entered into trials if possible. Options include Cisplatin, Carboplatin, Topotecan, VP 16, Caelyx, PLDH (pegylated liposomal doxyrubicin) and Paclitaxel.

- Surgery can be considered in patients with isolated recurrences where the disease free interval has been greater than 12 months.

Recurrent endometrial cancer:

Symptoms:

- Vaginal bleeding or discharge.
- Fistulation.
- Pain from metastatic spread.
- Dysuria
- Abdominal distention due to ascites
- Dyspnoea due to pulmonary metastases

Signs:

- Friable tumour seen at vault.
- Pelvic mass.
- Distant spread e.g., lung disease.

Investigations:

- Histological confirmation is usually necessary.
- CXR.
- MRI to assess regional nodal spread and pelvic disease.

Treatment considerations:

- There is no evidence that any treatment in recurrent, inoperable disease after initial radiotherapy can be curative. Palliation of symptoms is main aim. Localised pelvic recurrences in the pelvis can be cured by surgery or radiotherapy.

- Pelvic radiotherapy can help palliate vaginal bleeding.

- Chemotherapy (eg Cisplatin and Paclitaxol combinations) can produces 70% response rates in recurrent disease, but has not been shown to improve survival. Toxicity in the elderly population is a problem. Progestogens have a response rate of 30% and should be used as first line as they have low toxicity.

- Surgery is not usually indicated, but a palliative hysterectomy can be considered in patients with intractable vaginal bleeding.

Recurrent vulva cancer:

Symptoms:

- Vulval pain, bleeding or pruritus.
- Groin swelling or vulval lump.

Signs:

- Local recurrence – tumour is usually obvious.
- Groin recurrence – hard, fixed node in groin. Ulceration in advanced recurrences.

Investigations:

- CXR – essential.
- Small local recurrences (<2cm) do not need any further imaging, but consideration should be given to CT/MRI in large lesions where the chance of regional spread is higher.
- Histological confirmation is essential in all patients undergoing exenterative or reconstructive procedures.

Treatment considerations:

- With small local recurrences a wide local excision can be potentially curative. Surgery should aim to remove the lesion with at least a 1-2cm margin of disease free tissue.

- Defects that are not amenable to a primary closure can be covered with either a local skin graft (eg rhomboid) or regional (eg gracilis, rectus abdominus) skin flap in conjunction with the plastic surgeons.

- Exenterative surgery may be considered in those patients with low vaginal/vulval recurrences where previous treatments have included radical surgery and radiotherapy. It is usually reserved for cases where there is sphincter or urinary tract involvement.

- Chemotherapy produces low response rates (5-10%) in recurrent disease.

- Irradiation of the vulval area is poorly tolerated by patients because of skin desquamation.

- Groin node metastases is often a sign of incurable disease. Treatment at this stage produces no survival advantage, but can palliate symptoms. In such patients, early palliative care input is essential. Pelvic nodal disease can produce severe limb pain through sacral plexus compression. Fatal haemorrhage from femoral vessel involvement can occur.

10. EMCN Gynaecological Cancer NSSG Gestational Trophoblastic Disease

Signed: Mr Quentin Davis
Chair of East Midlands Cancer Network – Gynaecology Site Specific Group
Dated: 12.07.2013

Signed:
Dated:

Date of Next Review January 2014

Gestational trophoblastic disease:

General:

Gestational trophobastic disease is rare in the UK, with a calculated incidence of 1.54 per 1000 live births. In the UK there is an effective registration and treatment programme.

Diagnosis:

- Ultrasound - Increased use of Ultrasound in early pregnancy has lead to earlier diagnosis of molar pregnancy.

- Whilst complete molar pregnancy is reliably diagnosed by ultrasound. partial molar pregnancy is more complex and ultrasound has more limited value.

- In twin pregnancies with a viable fetus and a molar pregnancy, the pregnancy can be allowed to proceed. These pregnancies are associated with a reduced live birth rate of 25%, and are at increased risk of complications, particularly pre-eclampsia and haemorrhage. The subsequent need for chemotherapy (around 20%) is the same whether the pregnancy is terminated or allowed to proceed to term.

Evacuation of molar pregnancy:

- Suction evacuation is method of choice

    - There are areas of concern around the use of oxytocics and prostaglandins. Use of these agents may increase the need for subsequent chemotherapy.
    - Cervical preparation prior to suction evacuation should be avoided where possible and oxytocic infusions should only be commenced once evacuation has been completed.
    - Pre-operative haemorrhage may require some degree of control of the condition with these agents if the clinical condition requires their use.

Partial molar pregnancies:

- Where possible suction evacuation should be employed. If the size of fetal parts deters the use of suction curettage, medical termination can be used. These women may be at increased risk for requiring chemotherapy for the treatment of persistent trophoblastic disease, although the risk of requiring chemotherapy with partial moles is low (0.5%).

Histological Examination of RPOC:

- Retained products of conception (RPOC) from evacuations of incomplete miscarriage and, after any repeat evacuations for persisting symptoms after

miscarriage or pregnancy, should be sent for histology to exclude trophoblastic disease.

Registration:

- Women with the following conditions should be registered with a Trophoblastic Tumour Screening Centre:
  - complete hydatidiform mole
  - partial hydatidiform mole
  - twin pregnancy with complete or partial mole
  - limited macroscopic or microscopic molar changes judged to require
  - follow up.

- The local screening and treatment centres are:

Trophoblastic Tumour Treatment & Screening Centre Weston Park Hospital Whitham Road Sheffield S10 2SJ Tel: 0114 226 5202 Fax:0114 226 5511 Registration forms can be obtained from the centre	Trophoblastic Tumour Screening Centre Charing Cross Road Fulham Palace Road Hammersmith London W6 9NT Tel: 020 8846 1234 Registration forms can be obtained from the centre

Follow-up:

- The screening centre will determine the length of follow up. Urine samples will be requested directly from the patient. At certain intervals blood samples will be requested by the screening centre.
- If hCG levels are of concern the screening centre will discuss management with the clinician concerned.

Management of persisting symptoms after evacuation of a molar pregnancy:

- There is no indication for use of second routine evacuation
- If symptoms persist consult the screening centre

Future pregnancy and Contraception:

- Women should be advised not to conceive until they have had normal hCG levels for six months
- The risk of future molar pregnancy is low (1 in 74)
- After the conclusion of any further pregnancy, further samples are requested to exclude disease recurrence
- Combined oral contraceptives can be used once hCG levels have returned to normal

These guidelines are operationalised by the relevant MDTs.

11.0 Guidelines for PET CT in Gynaecological Cancer

A PET scan may be indicated for:

Primary cancers:

1. High risk cervical cancers
2. Staging in primary suspected advanced cervical cancers where MRI suggest advanced disease or there are suspicious nodes on conventional CT
3. Any gynaecological cancer where lung nodules or other imaging suggest metastases
4. Any case discussed at the MDT where a PET is felt to be essential in guiding management

Recurrent tumours:

1. Recurrent cervical cancers
2. All Recurrent tumours where exenterative surgery is being considered
3. Recurrences where conventional imaging (CT / MRI) are unable to confidently differentiate between recurrence and scarring/ radiotherapy changes
4. Selected cases of ovarian cancer where raising CA125 and negative CT
5. Any case discussed at the MDT where a PET is felt to be essential in guiding management

12.0 Follow Up Guidelines for Gynaecological Cancer (Measure 11-1A-208e)

Patients should have their first post-operative follow up appointment with the treating team. For patients referred from local to specialist centres for primary treatment, the responsibility for subsequent follow up should be as determined by the MDT and according to patient risk and choice, on a case by case basis.

(i) Cancer of the cervix

Surgery only – TAH or radical hysterectomy
Follow up in specialist surgical Gynae/Gynae Oncology clinic six weeks
- three-four monthly for first two years
- six monthly for third year
- annually fourth and fifth year

Vaginal or rectal examination would normally be performed. Two smears should be performed after treatment for cervical cancer and then as clinically indicated.

If combined surgery and radiotherapy or chemo-radiotherapy is treatment of choice:

Follow up should be as above but in the combined Gynae Oncology clinic.

(ii) Cancer of the vulva

Follow up should be as for CA cervix and should be at least for five years but some clinicians may follow up indefinitely. VIN should also be followed up for at least five years if the patient is suitable to visit the

clinic. Specialist teams at NGH and UHL, Derby and Nottingham

(iii) Cancer of the endometrium
Follow up should be as for cervical cancer. Multi-disciplinary follow up is necessary for those receiving adjuvant therapy.

(iv) Cancer of the ovary
Most will be late stage disease and will be followed up in the Multi-disciplinary clinic. This is likely to be in the local MDT but with links for advice to the specialist teams. Vaginal or rectal examination +CA 125 should normally be performed in clinic. Scan would be performed as indicated on the basis of clinical findings.

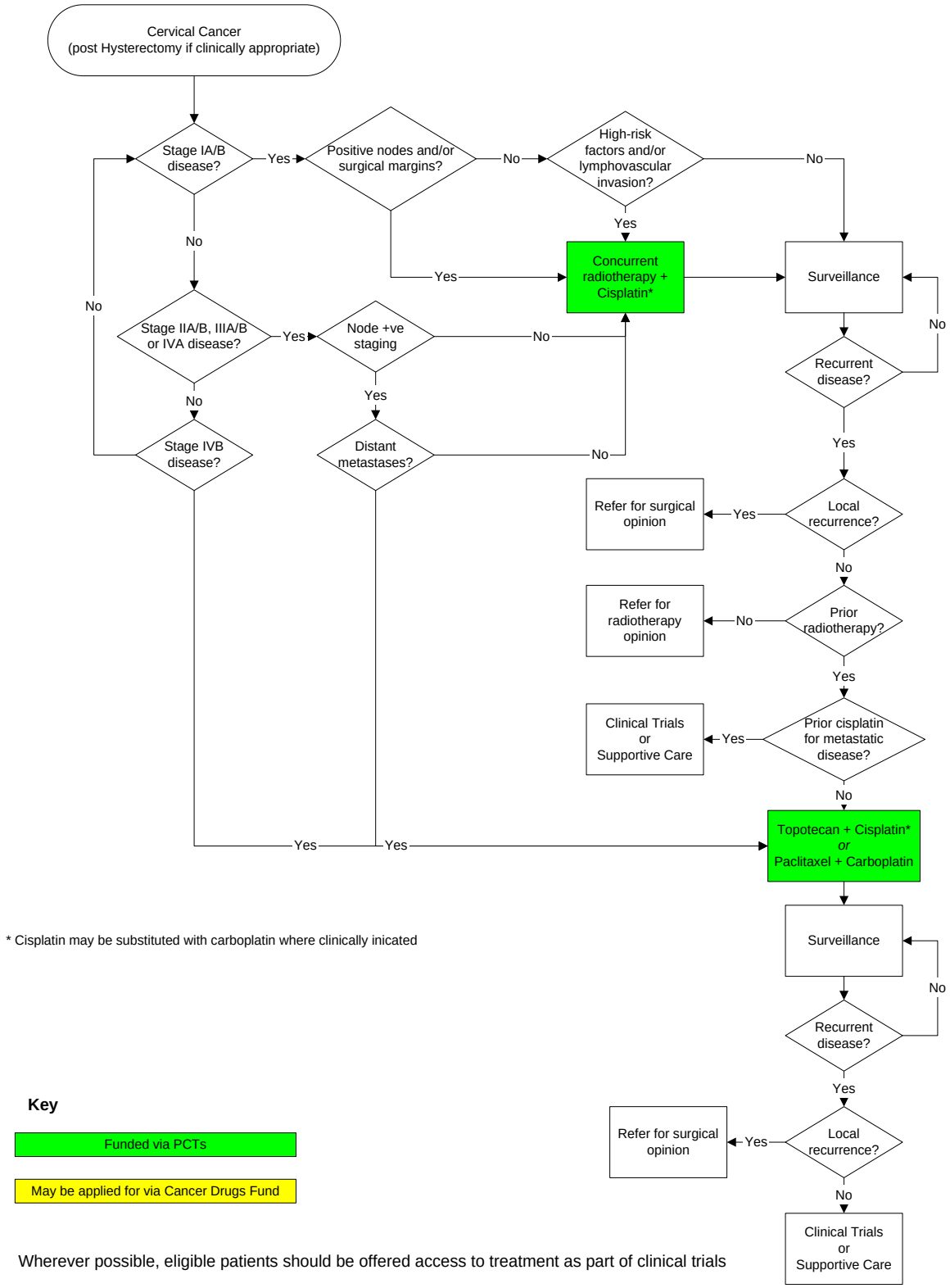
(v) Borderline ovarian tumours
Should be followed up as for ovarian cancers.

(vi) Rarer Tumours – eg fallopian tube
Follow up intervals as above.

All of the above are subject to three yearly review and follow up should be adapted according to the individual needs of the patient. Some patients will wish to have longer follow up than five years and this should be instituted either if the patient strongly desires longer follow up or if it is felt to be clinically indicated.

13.0 Chemotherapy Algorithms (11-1A-208e)

Cervical



* Cisplatin may be substituted with carboplatin where clinically inicated

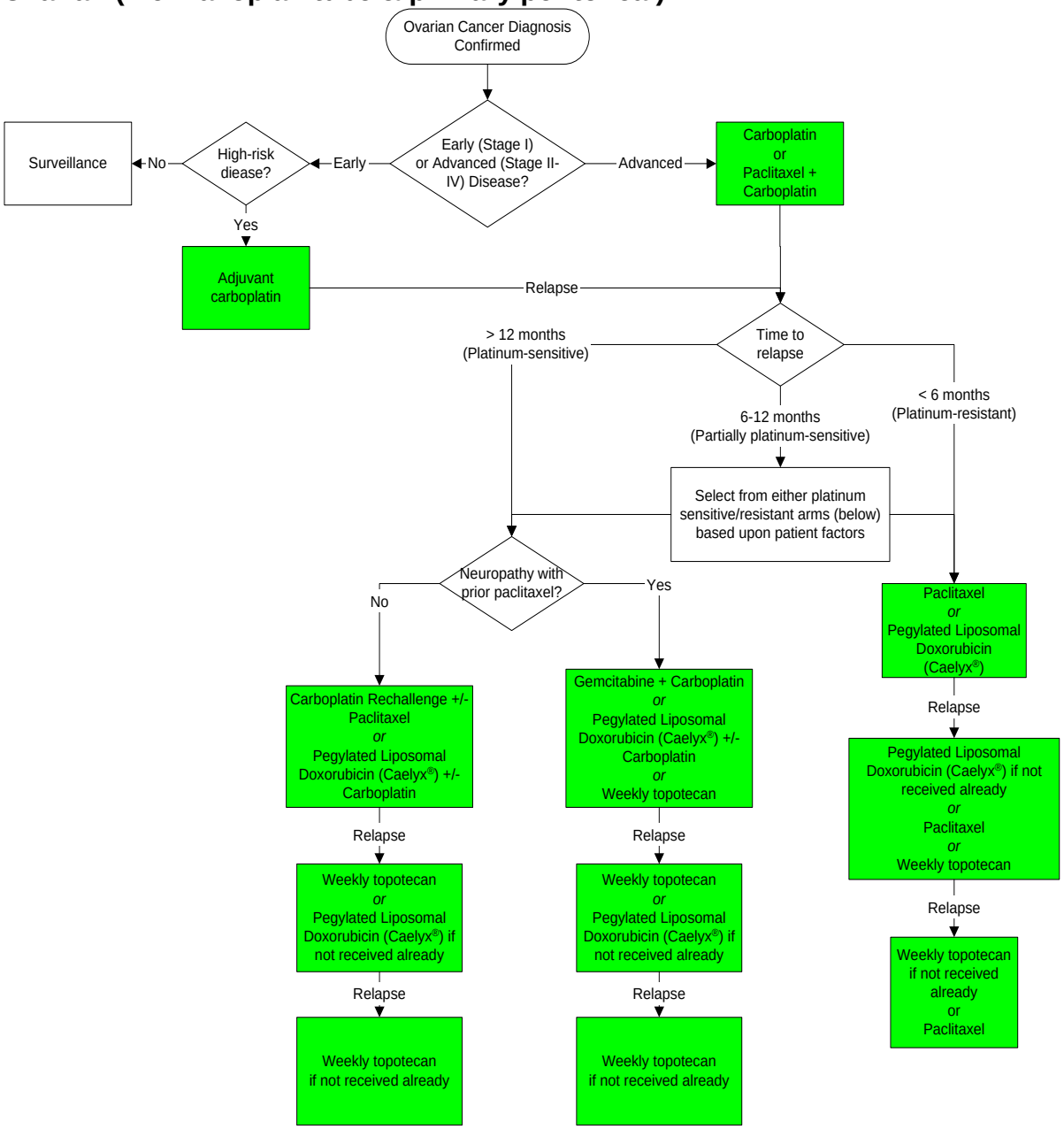
Key

Funded via PCTs

May be applied for via Cancer Drugs Fund

Wherever possible, eligible patients should be offered access to treatment as part of clinical trials

Ovarian (Incl. fallopian tube & primary peritoneal)



Key

Funded via PCTs

May be applied for via Cancer Drugs Fund

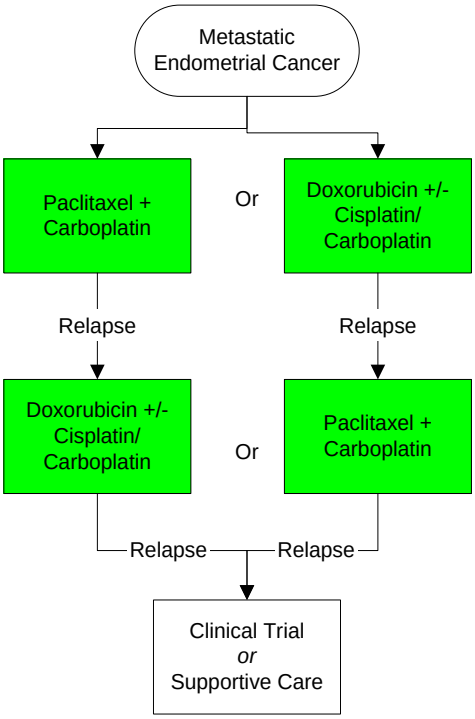
Wherever possible, eligible patients should be offered access to treatment as part of clinical trials

Endometrial

- Adjuvant

  Treat as part of clinical trials

- Metastatic



Key

Funded via PCTs

May be applied for via Cancer Drugs Fund

Wherever possible, eligible patients should be offered access to treatment as part of clinical trials

Uterine Sarcoma

See Sarcoma Network Site Specific Group Clinical Guidelines And Operational Policy

Adult Germ Cell

See Testicular Network Site Specific Group Clinical Guidelines And Operational Policy

APPENDIX A

EMCN Gynaecological Cancers Chemotherapy Regimens

GYNAECOLOGICAL CANCERS CHEMOTHERAPY REGIMENS		TRUSTS USING REGIMEN
Carboplatin		DHFT QHB NUH SFH ULHT UHL NGH KGH
Day 1	Carboplatin (AUC=5-6) intravenous infusion	
Cycle Frequency: every 21 days **Number of cycles:** Maximum 6 cycles		
Cisplatin (with radiotherapy)		DHFT NUH ULHT UHL NGH
Day 1	Cisplatin 40mg/m^2 intravenous infusion (**Maximum** 70mg)	
Cycle Frequency: every 7 days **Number of cycles:** Maximum 6 cycles		
Doxorubicin		DHFT QHB NUH SFH ULHT UHL NGH
Day 1	Doxorubicin 50-60mg/m^2 intravenous bolus	
Cycle Frequency: every 21 days **Number of cycles:** Maximum 6 cycles		
Doxorubicin + Carboplatin		DHFT QHB NUH SFH ULHT UHL NGH
Day 1	Doxorubicin 50mg/m^2 intravenous bolus Carboplatin (AUC=5-6) intravenous infusion	
Cycle Frequency: every 21 days **Number of cycles:** Maximum 6 cycles		
Doxorubicin + Cisplatin		DHFT QHB NUH SFH ULHT UHL NGH
Day 1	Doxorubicin 50mg/m^2 intravenous bolus Cisplatin 60mg/m^2 intravenous infusion	
Cycle Frequency: every 21 days **Number of cycles:** Maximum 6 cycles		
Gemcitabine + Carboplatin		DHFT QHB NUH SFH ULHT UHL NGH
Days 1 & 8 Day 1	Gemcitabine 1000mg/m^2 intravenous infusion Carboplatin (AUC=5-6) intravenous infusion	
Cycle Frequency: every 21 days **Number of cycles:** Maximum 6 cycles		

GYNAECOLOGICAL CANCERS CHEMOTHERAPY REGIMENS	TRUSTS USING REGIMEN
Paclitaxel + Carboplatin Day 1 Paclitaxel 175mg/m^2 intravenous infusion Day 1 Carboplatin (AUC=5-6) intravenous infusion **Cycle Frequency:** every 21 days **Number of cycles:** Maximum 6 cycles	DHFT QHB NUH SFH ULHT UHL NGH KGH
Weekly Paclitaxel + Carboplatin Day 1, 8 & 15 Paclitaxel 80mg/m^2 intravenous infusion Day 1, 8 & 15 Carboplatin (AUC=2 intravenous infusion **Cycle Frequency:** every 28 days **Number of cycles:** Maximum 6 cycles	DHFT QHB NUH SFH ULHT UHL NGH
Paclitaxel Day 1 Paclitaxel 175mg/m^2 intravenous infusion **Cycle Frequency:** every 21 days **Number of cycles:** Maximum 6 cycles	DHFT QHB NUH SFH ULHT UHL NGH KGH
Pegylated Liposomal Doxorubicin (Caelyx®) Day 1 Liposomal Doxorubicin (Caelyx®) 40-50mg/m^2 intravenous infusion **Cycle Frequency:** every 28 days **Number of cycles:** until disease progression	DHFT QHB NUH SFH ULHT UHL NGH
Pegylated Liposomal Doxorubicin (Caelyx®) + Carboplatin Day 1 Liposomal Doxorubicin (Caelyx®) 40-50mg/m^2 intravenous infusion Day 1 Carboplatin (AUC=5-6) intravenous infusion **Cycle Frequency:** every 28 days **Number of cycles:** until disease progression	DHFT QHB NUH SFH ULHT UHL NGH
Weekly Topotecan Days 1, 8 & 15 Topotecan 4mg/m^2 intravenous infusion **Cycle Frequency:** every 28 days **Number of cycles:** until disease progression	DHFT QHB NUH SFH ULHT UHL NGH

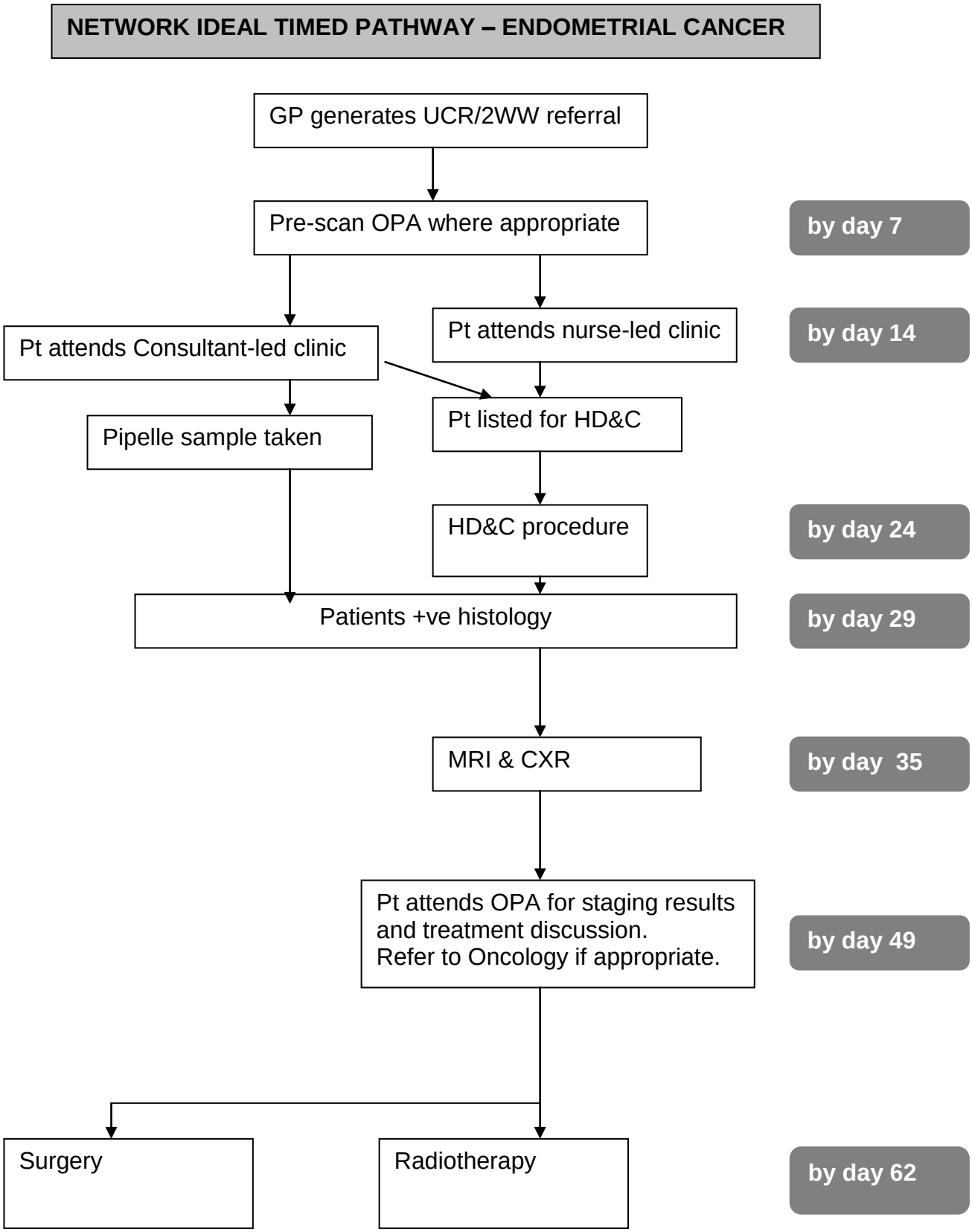
GYNAECOLOGICAL CANCERS CHEMOTHERAPY REGIMENS		TRUSTS USING REGIMEN
Topotecan + Cisplatin		DHFT QHB NUH SFH ULHT UHL NGH
Days 1-3	Topotecan 0.75mg/m^2 intravenous infusion	
Day 1	Cisplatin 50mg/m^2 intravenous infusion	
Cycle Frequency: every 21 days Number of cycles: Maximum 6 cycles		

Delivery Sites:

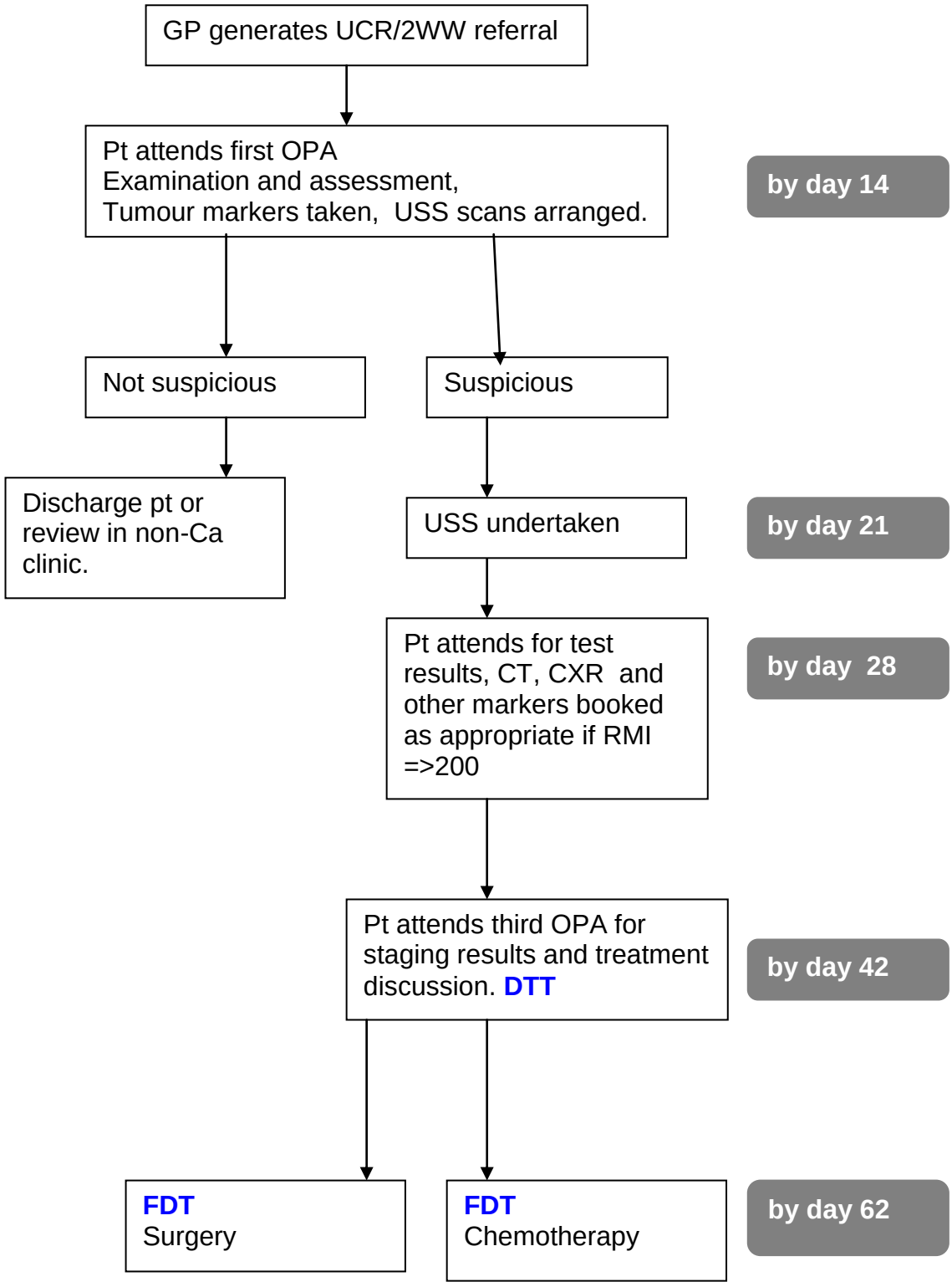
At present the majority of the gynaecological cancer chemotherapy regimens – particular the longer regimens and repeated platinum exposures (rechallenges) are currently delivered in the Cancer Centres – Lincoln County, Nottingham University Hospitals, Royal Derby Hospital, University of Leicester Hospitals and Northampton General Hospital. This is historical rather than risk based.

As part of the implementation of both NCAG and Care Closer to Home this is under review to see where protocol based delivery and/or oncology outreach supervision could repatriate care.

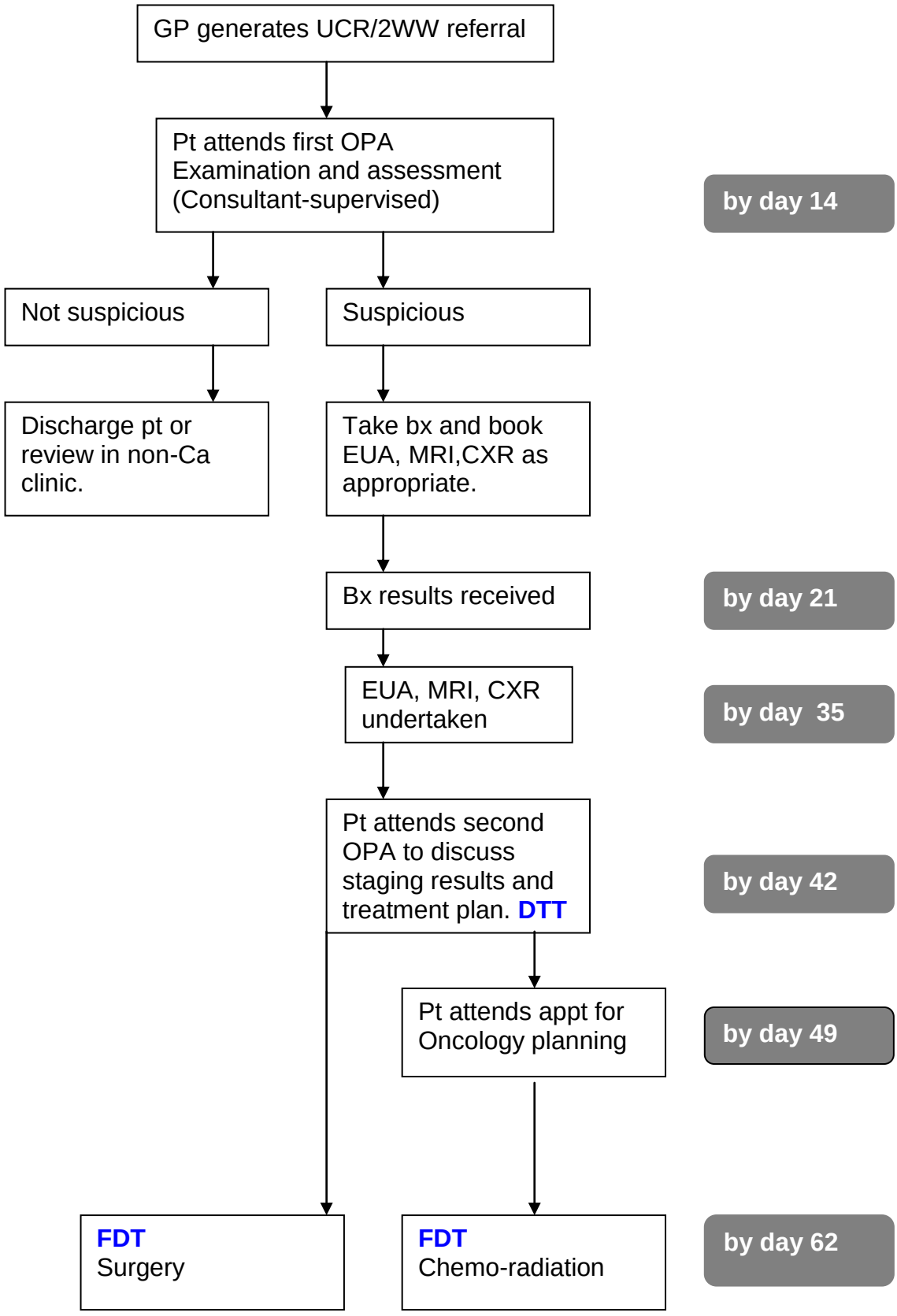
APPENDIX B


NETWORK IDEAL TIMED PATHWAY – ENDOMETRIAL CANCER
GP generates UCR/2WW referral
Pre-scan OPA where appropriate
by day 7
Pt attends Consultant-led clinic
Pt attends nurse-led clinic
by day 14
Pipelle sample taken
Pt listed for HD&C
HD&C procedure
by day 24
Patients +ve histology
by day 29
MRI & CXR
by day 35
Pt attends OPA for staging results and treatment discussion.
Refer to Oncology if appropriate.
by day 49
Surgery
Radiotherapy
by day 62

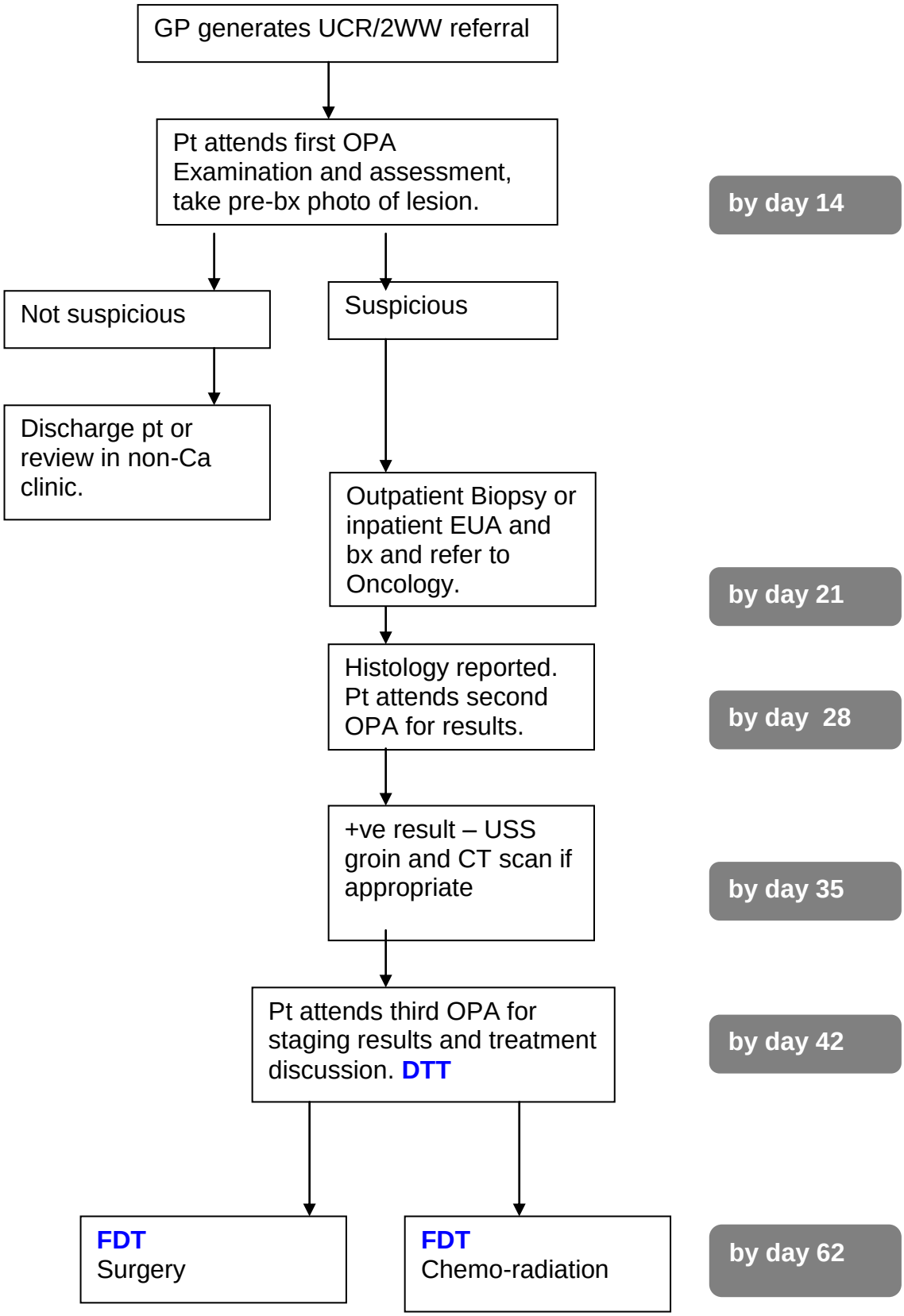
NETWORK IDEAL TIMED PATHWAY – OVARIAN CANCER



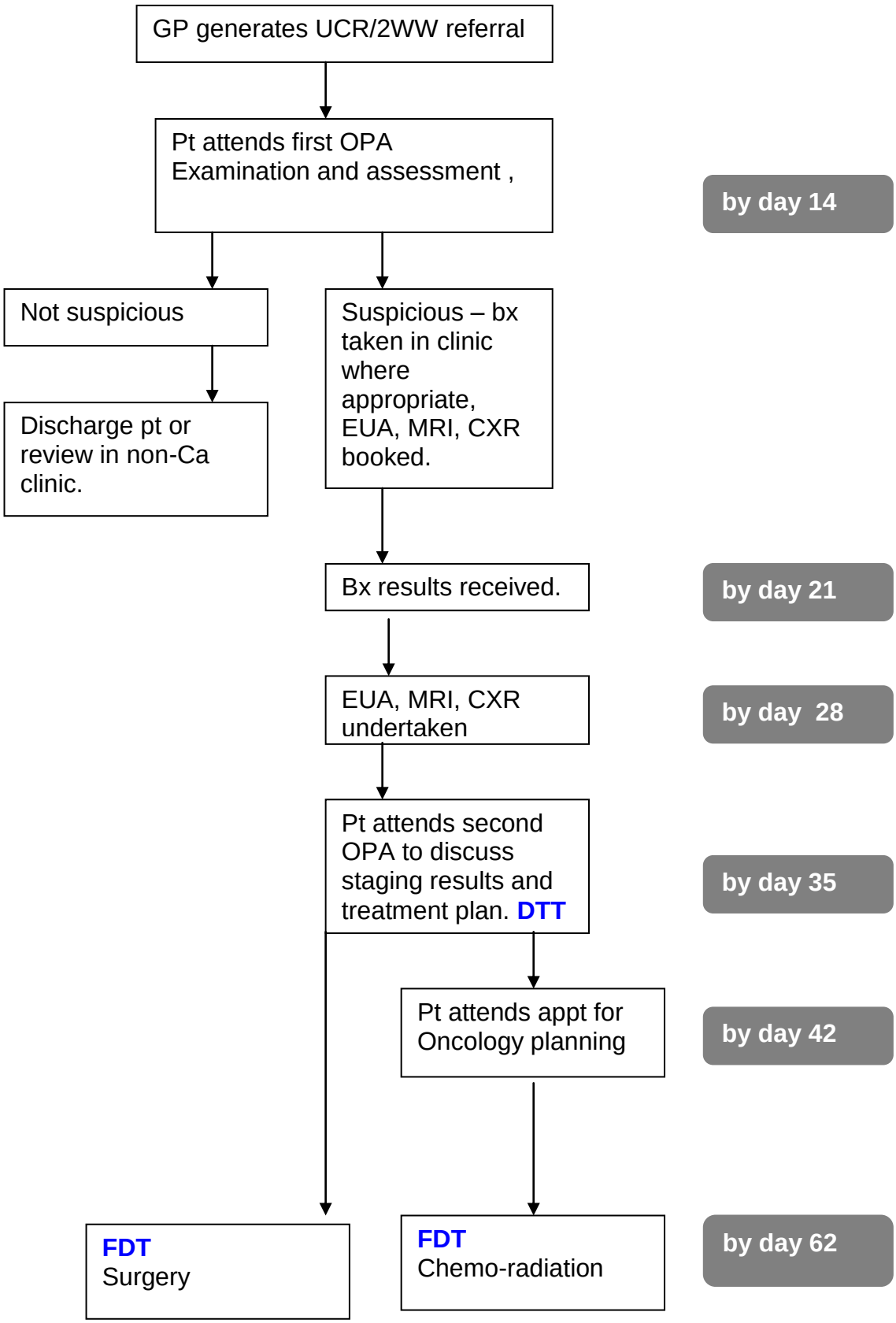
NETWORK IDEAL TIMED PATHWAY – CERVICAL CANCER



NETWORK IDEAL TIMED PATHWAY – VULVAL CANCER



NETWORK IDEAL TIMED PATHWAY – VAGINAL CANCER



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