Kent & Medway Cancer Collaborative

The Management of Ovarian Cancer

Pathway of Care

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1.0 Pathway Overview

GP decision to refer to first appointment no more than 14 days

NICE Guideline (NG12) 2015 - 'suspected cancer: recognition and referral' recommends the following in primary care to screen for suspected ovarian cancer in women aged 18 or over (1)

1. Refer the woman urgently if physical examination identifies ascites and/or a pelvic or abdominal mass (which is not obviously uterine fibroids).

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

3. Consider carrying out tests in primary care if a woman reports unexplained weight loss, fatigue or changes in bowel habit.

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

5. Carry out appropriate tests for ovarian cancer in any woman of 50 or over who has experienced symptoms within the last 12 months that suggest irritable bowel syndrome (IBS), because IBS rarely presents for the first time in women of this age.

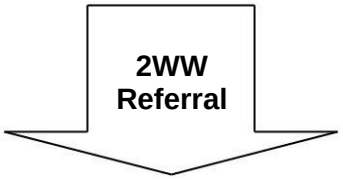
6. Measure serum CA125 in primary care in women with symptoms that suggest ovarian cancer

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

8. If the ultrasound suggests ovarian cancer, refer the woman urgently for further investigation.

9. For any woman who has normal serum CA125 (less than 35 IU/ml), or CA125 of 35 IU/ml or greater but a normal ultrasound:

- assess her carefully for other clinical causes of her symptoms and investigate if appropriate
- if no other clinical cause is apparent, advise her to return to her GP if her symptoms become more frequent and/or persistent



Date of decision to treat to date of first treatment – no more than 31 days

GP Decision to refer to first treatment no more than 62 days

Secondary Care

(Specialist or Affiliated Designated Stand Alone Diagnostic Units)

- ❒ Assessment
- ❒ Diagnosis
- ❒ Imaging

Described in sections 4.2, 4.3, 4.5 & 4.6 below

- ❒ The CNS should always be present when bad news is given
- ❒ Regardless of whether diagnostic assessments are undertaken in a specialist or designated stand alone units <u>all</u> diagnosed Ovarian cancers are to be discussed at the Specialist **MDM**

Stand Alone Diagnostic Units	**Specialist MDT**
Low risk ovarian masses (unlikely to be malignant in origin based on clinical and ultrasound findings) may be operated on by gynaecologists based in the trust hospital hosting a Stand Alone Diagnostic Unit however the cases should be discussed at the Centre MDM prior to undertaking surgery.	Women with an ovarian mass (considered likely to be malignant based on clinical and ultrasound findings) must be operated on at the Specialist Centre by a core member of the Specialist Team

- ❒ Regardless of where surgery is undertaken any post surgical upstaging must be discussed at the Specialist MDM and treatment plans modified if appropriate
- ❒ All cases of ovarian cancer to be considered for entry into an appropriate clinical trial
- ❒ Patients will be followed up according to the Gynae TSSG agreed protocols set out in section 7
- ❒ Women with recurrent/metastatic disease will have their cases reviewed by the MDT in order to optimise their treatment options
- ❒ Women who fall into the age categories specified by the Children's and Young Peoples IOG will be managed in association with designated CYP MDTs

2.0 Purpose

To describe the process for ensuring that all Ovarian Cancer cases diagnosed within the Kent & Medway region are managed by the East and West Kent Gynaecological Oncology Centres, achieving a coordinated seamless patient pathway in accordance with the best possible evidence based practice and to facilitate advancement in the specialty in the field of ovarian cancer management.

3.0 Scope

This Pathway of Care (PoC) applies to all cases and suspected cases of primary ovarian malignancy within Kent & Medway. The Kent & Medway Cancer Collaborative (KMCC) Ovarian Cancer specification of delivery of care requires all Trusts within the region to adopt an agreed policy. The policy relates to the expected PoC / treatment regimes for patients diagnosed with ovarian cancer.

The policy covers the following:

- Access
- Initial Assessment
- Investigations
- Gynaecological oncology multidisciplinary meeting (MDM)
- Surgical and non-surgical treatment.
- Genetics assessment
- Recurrent disease
- Follow up

4.0 Policy

4.1 Access

All patients with suspected ovarian cancer to be referred within 24 hours to a Consultant led **gynaecology rapid assessment clinic**, based in each major acute hospital within Kent & Medway (K&M). Patients will be seen within 2 weeks of decision to refer.

4.1.1 Patients admitted as an emergency

If the patient is admitted as an emergency and the clinical situation permits, her condition should be stabilised and then she should be transferred to the care of the Gynaecological Oncologist.

4.2 Initial Assessment

- Full history and examination
- Vaginal examination
- Pelvic ultrasound (trans vaginal scan unless contraindicated), Ca125.
- CEA and Ca199 (as indicated by the MDT)

Clinicians in the Gynae Oncology Centres who perform surgery for low risk pelvic masses will complete a Risk of Malignancy Index (RMI) calculation to determine whether referral to gynae oncology team is appropriate. Regardless of RMI, Clinicians are encouraged to refer cases with imaging for discussion in the Cancer Centre MDT where clinical or radiological features are suspicious of ovarian malignancy or indeterminate in nature. The MDT will triage these cases and identify low risk cases for surgery by the general Gynaecologist outwith the

Cancer Centre, whilst women with pelvic masses considered likely to be malignant due to clinical and ultrasound findings will be managed by the specialist team at the Cancer Centre.

4.2.1 Table: RMI Calculations

RMI – U x M x Ca-125

U = Ultrasound score: 0 (if none present), 1 (if only one feature present), 3 (if u/s features 2 – 5)

Ultrasound features:	Multiple cysts
	Solid areas
	Bilateral lesions
	Ascites
	Metastases
M = 1 if pre-menopausal	= 3 if post-menopausal

Patients with an RMI ≥ 200 should be referred for MDT discussion

4.3 General Investigations (where malignancy suspected):

- FBC
- U&E
- LFTs, calcium
- CA125 + CEA / Ca19.9
  - if patient <40 years old with partly / wholly solid tumour, add AFP / HCG / LDH
  - if possibility of primary bowel pathology, add CEA
  - if possibility of disseminated upper GI malignancy, add Ca19.9
  - CT chest, abdomen and pelvis

- **If ascites / pleural effusion:**
  - Consider tap for cytology ?/- symptomatic relief
- **If suspicious change in bowel habit (or low Ca125:CEA ratio)**
  - Barium studies / colonoscopy / colorectal clinician's opinion
- If considering neo adjuvant chemotherapy, requires cell block cytology with IHC or histological confirmation of disease by tissue biopsy

4.4 Imaging

Full details of the Collaborative imaging guidance can be found on the KMCC website:- http://kmcc.nhs.uk/tumour-sites/sub-groups-or-cross-cutting-groups/diagnostics-group/

4.5 Pathology

All KMCC reporting pathologists follow The Royal College of Pathologists Histopathology Reporting on Cancers guidelines – a copy of which is available through the KMCC website:- http://kmcc.nhs.uk/tumour-sites/sub-groups-or-cross-cutting-groups/pathology-group/

Pathology specimens will be processed and reported in accordance with the guidelines set out RCP minimum data set.

4.6 Gynaecological Oncology Multidisciplinary Meeting

All ovarian cancer patients should be discussed at Cancer Centre MDT meeting, where possible prior to undergoing first definitive treatment. Case discussion should include review of:

- Imaging – CT and MRI/US
- Cytology from ascites / pleural fluid if performed
- Histology from scan guided biopsy if performed - if considering adjuvant chemotherapy histological confirmation of diagnosis is required

Cases should also be discussed following surgery to review histology and management plan, and in the event of disease recurrence.

5.0 Treatment / Management

5.1 Primary Surgery / Neoadjuvant Chemotherapy and Interval Debulking

- All cases of advanced ovarian cancer should be discussed in the MDT with review of all relevant imaging and histology / cytology if available, to determine whether up front debulking surgery should be performed, or whether the patient should be advised to undergo neoadjuvant chemotherapy and interval debulking surgery. Optimal debulking should be the aim of surgery, with no residual tumour load. Otherwise clearance with minimal residual disease should be performed.
- Laparotomy via longitudinal incision.
- Peritoneal washings / ascites for cytology.
- Hysterectomy, Bilateral Salpingo-Oophorectomy (BSO) as routine.
- Omental biopsy if omentum grossly appears normal or de-bulking supra/infracolic omentectomy if involved with metastatic disease.
- Pelvic +/- para-aortic lymphadenectomy (PELND and PALND respectively) may be indicated for completion of staging of apparent low stage disease, or for debulking of “bulky” nodal disease.
- The advice / assistance of colorectal surgeons should be available and readily sought.
- When optimal debulking is not possible at the time of initial surgery, a second attempt may be appropriate after 3 or 4 cycles of chemotherapy.
- Where frozen section service available, advise use during surgery for indeterminate masses; if confirming (apparent low stage) ovarian cancer, then consider full staging to include PALND + PELND

5.2 Ultra-radical debulking surgery for advanced ovarian cancer

Where ultra-radical surgery involving a multi-disciplinary surgical team is offered to patients with advanced epithelial ovarian cancer, the patient should be counselled about the potential increased morbidity and uncertain long term benefit from the procedure. In addition, alternative treatment options and their benefits and risks compared with extended radicality of debulking surgery including multiple visceral and peritoneal resection should also be discussed.

Patients should be provided with clear written information about the procedure and given options regarding the radicality of surgery where feasible and appropriate.

Data on all patients having this procedure should be submitted to the national register when it becomes available, and subjected to local audit.

5.3 Adjuvant Treatment

If adjuvant treatment is considered by the MDT to be the appropriate course of action, management will be in accordance with the protocols and polices set out in the KMCC Document:

Oncological Treatment of Gynaecological Cancers

Note: Full details of the KMCC oncology guidance can be found on the KMCC website:
http://kmcc.nhs.uk/tumour-sites/tumour-site-specific-information/gynae-tssg/

5.4 Recurrent Disease

- Discussion in Gynaecological Oncology Multidisciplinary Meeting.
- Surgery may be appropriate if localised mass.
- Referral to Oncologist for palliative chemotherapy.
- Palliative radiotherapy may be indicated for symptom control.

6.0 Oncological Provision

All patients will be considered for entry into a clinical trial where possible.

The non surgical oncological management of ovarian cancers is described in the KMCC Document:

Oncological Treatment of Gynaecological Cancers

Note: Full details of the KMCC Oncology Guidance "Oncological Treatment of Gynaecological Cancer" can be found on the KMCC website:-
http://kmcc.nhs.uk/tumour-sites/tumour-site-specific-information/gynae-tssg/

It is the responsibility of the Non Surgical Oncology Sub Group (NOG) of the Gynae TSSG to describe and maintain the Chemotherapy, Radiotherapy and Brachytherapy protocols employed in the management of Ovarian Cancers.

Note: The Terms of Reference for the NOG can be found on the KMCC website:-
http://kmcc.nhs.uk/tumour-sites/terms-of-reference/

7.0 Genetics Assessment

A family history of malignancy should be obtained from all patients diagnosed with epithelial ovarian cancer, however it is now recognised that a significant proportion of women who are diagnosed with ovarian cancer without a relevant family history harbour a genetic variant that predisposes to malignancy. Studies suggest an incidence of BRCA 1 and 2 germ-line mutations to vary from 3-27% in women with ovarian cancer. (4)

It is recommended that all women diagnosed with an epithelial ovarian cancer are counselled regarding the possibility of being a carrier of a genetic fault that has pre-disposed them to develop the cancer.

It is recommended that all women with a primary ovarian/tubal/peritoneal epithelial non-mucinous carcinoma be referred to the regional genetics service at Guy's and St Thomas' Hospital for further counselling, assessment and genetic testing.

8.0 Follow Up

Note: Please see gynaecological follow up guidelines which can be found on the KMCC website:- http://kmcc.nhs.uk/tumour-sites/tumour-site-specific-information/gynae-tssg/

The MRC OV05 trial did not show a survival advantage for patients undergoing routine Ca125 surveillance during follow-up, despite earlier diagnosis and subsequent treatment of recurrent disease. Therefore, patients will not routinely be offered CA125 surveillance. However, following full discussion of the issues included potential disadvantages; routine Ca125 monitoring can be offered if requested by the patients.

9.0 Staging: FIGO 2013 (TNM stages)

9.1 Stage 1: Tumour limited to ovaries or fallopian tubes (T1-N0-M0)

- 1A Tumour limited to one ovary (capsule intact) or fallopian tube: no tumour on ovarian or fallopian tube surface; no malignant cells in ascites or peritoneal washings (T1a-N0-M0)
- 1B Tumour limited to both ovaries (capsules intact) or fallopian tubes: no tumour on ovarian or fallopian tube surface; no malignant cells in ascites or peritoneal washings (T1b-N0-M0)
- 1C Tumour limited to one or both ovaries or fallopian tubes with any of the following:
    - 1C1: Surgical spill (T1c1-N0-M0)
    - 1C2: Capsule ruptured before surgery or tumour on ovarian surface (T1c2-N0-M0)
    - 1C3: Malignant cells in ascites or peritoneal washing (T1c3-N0-M0)

9.2 Stage 2: Tumour involves one or both ovaries and/or fallopian tubes with pelvic extension (below pelvic brim) or primary peritoneal cancer (T2-N0-M0)

- 2A Extension and / or implants on uterus and /or fallopian tube(s) and/or ovaries (T2a-N0-M0)
- 2B Extension to other pelvic intraperitoneal tissues (T2b-N0-M0)

9.3 Stage 3: Tumour involves one or both ovaries or fallopian tubes, or primary peritoneal cancer, with cytologically or histologically confirmed peritoneal metastasis outside the pelvis and / or retroperitoneal lymph node metastasis

- 3A1: Positive retroperitoneal lymph nodes only (cytologically or histologically proven) (T1/T2-N1-M0)
    - 3A1(i) Metastasis up to 10mm in greatest dimension
    - 3A1(ii) Metastasis > 10mm in greatest dimension
- 3A2: Microscopic extrapelvic (above the pelvic brim) peritoneal involvement with or without positive retroperitoneal lymph nodes (T3a2-N0/N1-M0)
- 3B: Macroscopic extrapelvic (above the pelvic brim) peritoneal involvement up to 2cm in greatest dimension with or without positive retroperitoneal lymph nodes (T3b-N0/N1-M0)
- 3C: Macroscopic extrapelvic (above the pelvic brim) peritoneal involvement > 2cm in greatest dimension with or without positive retroperitoneal lymph nodes (T3c-N0/N1-M0)

9.4 Stage 4: Distant metastasis (excludes peritoneal metastasis) (Any T-Any N-M1)

- 4A: Pleural effusion with positive cytology
- 4B Parenchymal metastases and metastases to extra-abdominal organs (including inguinal lymph nodes and lymph nodes outside the abdominal cavity)

10.0 Supportive & Palliative Care

Palliative care provision should be made for all patients:
- Hospital teams, including the Clinical Nurse Specialists for gynae cancer patients.
- Primary Health Care Team would provide for palliative care at home.
- General Practitioner should be informed of management decision changes as soon as possible.

The management of symptoms, psychological, social and spiritual issues, and the communication of the diagnosis and any associated problems, should be within the domain of all health care professionals.

Open and frank discussions with patients should take place with patients at all stages of their journey so that patients are not confused about their prognosis or have unrealistic expectations of any of the forms of treatment offered to them.

Relatives and carers will need to be appropriately supported and given appropriate information. However, in accord with the recommendations set out in various revised Improving Outcomes Guidance (IOG), relatives and carers should not be given information different to that given to the patient.

Referral to specialist palliative care services should be considered when these issues have not been resolved and in particular for patients with:
- Complex symptom management issues, which are difficult to manage
- Difficulties in adjusting to the diagnosis or disease progression
- Psychological and family issues – such as communication problems within the family
- Spiritual issues – such as the challenging of belief system/faith/cultural values as a result of the cancer

Consideration of specialist palliative care or support should be given throughout the patient pathway, particularly:
- At the Multidisciplinary Team Meeting
- When no active treatment is considered
- After active treatment
- At relapse
- In the terminal stages

11.0 Data Collection

Collection of data at each stage of the pathway is the responsibility of the team looking after the patient at that time. The minimum dataset agreed by the TSSG will be a combination of those data items that meet national requirements, and additional items as agreed by the TSSG.

National data requirements will include:

- Cancer Waiting Times monitoring, including Going Further on Cancer Waits. The data items required will be as defined in ISB0147 at the time of referral and/or treatment.

  Details of the Cancer Waiting Times dataset are available from:
  http://www.datadictionary.nhs.uk/data_dictionary/messages/clinical_data_sets/data_sets/national_cancer_waiting_times_monitoring_data_set_fr.asp

  Cancer Waiting Times data will be submitted according to the timetable set out in the National Contract for Acute Services.

- The Cancer Outcomes and Services Dataset. The data items will be as defined in ISB1521, and any subsequent versions, at the time of diagnosis and/or treatment. The requirement will include those fields listed in the “Core” section of the dataset, and any additional tumour site specific sections, as applicable.

  Details of the COSD are available from:
  http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd.aspx

Cancer Registration and Cancer Outcomes and Services (COSD) data will be submitted according to the timetable set out by the National Cancer Registration Service.

- Where applicable, teams will also collect additional data items as defined in any corresponding National Clinical Audit Support Programme (NCASP) audit dataset.

  Details of these datasets are available from: http://www.ic.nhs.uk/services/national-clinical-audit-support-programme-ncasp/cancer

  Data for NCASP audits will be submitted, where applicable, according to timetables as agreed by the TSSG, and within the overall submission deadlines for each audit.

Submission of data to meet these national requirements will be the responsibility of each individual Trust.

Note that these standards are subject to variation from time to time, and where these requirements change, the data items required to be collected by the team will also change in line with national requirements.

Local data requirements will include any additional data items as agreed by the TSSG. These must be selected to avoid overlap with any existing data items, and where possible must use standard coding as defined in the NHS Data Dictionary.

Where possible and applicable, InfoFlex will be used for the collection and storage of data.

Additional areas of the COSD, relating to pathology, radiotherapy, SACT, diagnostic imaging and basic procedure details will feed into the dataset from other nationally mandated sources. It is the responsibility of each team to ensure that the whole of the relevant dataset is collected, and it is acknowledged that this may come from a variety of sources.

12.0 Children, Teenagers and Young Adults

Children and Young People (CYP) and Teenage and Young Adults with Gynaecological Cancers will be treated in accordance with principles set out in the CYP & TYA IOG.

All children and Young People up to 18 years + 364 days must be referred to the CYP Principal Treatment Centre (PTC) which for KMCC is based at the Royal Marsden Hospital.

Referral to a CYP / TYA Principal Treatment Centre does not necessarily mean that treatment will be undertaken at that centre; shared care management protocols may allow some treatments to be undertaken locally.

All Young Adults between 19 and 24 years of age must be offered a referral to the TYA Principal Treatment Centre which for KMCC is the Royal Marsden Hospital.

13.0 Personnel and Contact Information

A comprehensive, up to date list of MDM contact details can be found on the KMCC website via the following link: http://kmcc.nhs.uk/tumour-sites/terms-of-reference/

14.0 References

1. Improving Outcomes in Gynaecological Cancers: Research Evidence NHS Exec. DOH, July '99.
2. Suspected cancer: recognition and referral: NICE guideline (NG12) June 2015
3. Guidance for Purchasers: Improving Outcomes in Gynaecological Cancers – The Manual
4. BRCA Mutation Frequency and Patterns of Treatment Response in BRCA Mutation–Positive Women With Ovarian Cancer: A Report From the Australian Ovarian Cancer Study GroupJ Clin Oncol. 2012 Jul 20; 30(21): 2654–2663.
5. Federation Internationale de Gynecologie et d'Obstetrique (FIGO)
6. NHS Cancer referral Guidelines HSC 2000/013

15.0 Glossary

Acronyms in common usage throughout KMCC documentation:

BSO	Bilateral Salpingo-Oophorectomy
CNB	Cancer Network Board
CYP	Children & Young People (in relation to the IOG)
DCCAG	Diagnostic Cross Cutting Advisory Group
DOG	Disease Orientated Group (NSSG/TSSG/TWG)
DVH	Darent Valley Hospital
EK	East Kent
EKHUFT	East Kent Hospitals University Foundation Trust
HoP	High Level Operational Policy
IOSC	Improving Outcomes: A Strategy for Cancer
K&C	Kent & Canterbury Hospital, Canterbury, (EKHUFT)
KMCN	Kent & Medway Cancer Network
KMCC	Kent & Medway Cancer Collaborative
KMCRN	Kent & Medway Cancer Research Network
LSESN	London & South East Sarcoma Network
MFT	Medway Foundation Trust
MTW	Maidstone & Tunbridge Wells NHS Trust
NOG	Non Surgical Oncology Group *(Permanent oncologist sub group of the TSSGs with a specific responsibility for chemo/rad pathways & advice to the TSSG, KMCC and geographical locations on new drugs)*
NIHR	National Institute of Health Research
PoC	Pathway of Care *(KMCC agreed disease site specific clinical guidelines)*
QEQM	Queen Elizabeth the Queen Mother Hospital, Margate (EKHUFT)
QoL	Quality of life
RMH	Royal Marsden Hospital
RNOH	Royal National Orthopaedic Hospital
TSSG	Tumour Site Specific Group
TYA	Teenagers & Young Adults
QVH	Queen Victoria Foundation Trust Hospital East Grinstead
UCLH	University College Hospital London
WHH	William Harvey Hospital, Ashford (EKHUFT)
WK	West Kent

16.0 Document Administration

Document	The Management of Ovarian Cancer – Pathway of Care
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