Kent and Medway Cancer Collaborative

The Management of Vaginal and Vulval Cancers

Pathway of Care

Publication date	August 2022
Expected review date	August 2024
Version number	9.0
Version status	Final

Table of Contents

1.0 Pathway Overview

GP decision to refer to first appointment noGPmore than 14 days

Primary Care
Refer if:

- ❒ Any lesions suspicious of vaginal or vulval cancer on clinical examination

2WW Referral

Secondary Care

(Specialist or Affiliated Designated Stand Alone Diagnostic Units)

- ❒ Assessment
- ❒ Diagnosis
- ❒ Imaging

Described in sections 4.2 to 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 all diagnosed Vaginal & Vulval cancers are to be discussed at the Specialist **MDM prior to treatment.**

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

Stand Alone Diagnostic Units

No surgery for Vaginal or Vulval Cancers will be undertaken in the Trusts hosting Stand Alone Diagnostics Units

Specialist MDT

Women with Vaginal or Vulval Cancers will have their surgery undertaken at the Specialist Centre by a core member of the MDT

- ❒ All cases of Vaginal & Vulval 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 10
- ❒ 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

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

2.0 Purpose

To describe the process for ensuring that all Vulval and Vaginal 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 vulval and vaginal cancer management.

3.0 Scope

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

The policy covers the following:

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

4.0 Policy

4.1 Access

All patients with suspected vulval or vaginal cancer to be referred within 24 hours to a **gynaecology rapid assessment clinic via 2ww pathway**, based in each major acute hospital within Kent & Medway. Patients will be seen within 2 weeks of referral. Patients may be seen in the colposcopy suite to facilitate assessment and biopsy.

4.2 Initial Assessment

- Full history and examination
- Vaginal & rectal examination where appropriate
- Colposcopy / Vulvoscopy as appropriate

4.3 Diagnostic Biopsy – Vulval Tumours

To confirm the need for lymphadenectomy, diagnosis and depth of invasion of >1mm must be confirmed.

- Wedge biopsy including tumour margin and normal skin is optimal for lesions >2cm
- Keye's biopsy (4-5mm) may be adequate to confirm diagnosis and depth of invasion
- Excision biopsy to include minimal clearance margin of 1cm may be appropriate for diagnosis and treatment of small lesions of <2cm. Decision for excision must only be taken by the Gynae Oncologist as when performed by referring clinician, it eliminates possibility of sentinel node biopsy.

In some circumstances (unfit patient) a single operation without initial biopsy may be justified.

4.4 Diagnostic Biopsy – Vaginal Tumours

Mode of biopsy depends on tumour site. Punch biopsy with colposcopy biopsy forceps may be adequate to confirm diagnosis.

4.5 Gynaecological Oncology Multidisciplinary Meeting (MDM)

All vulval / vaginal cancer patients should be referred to the Cancer Centre and reviewed at the Multidisciplinary Team Meeting (MDT), where possible prior to undergoing first definitive treatment. Case discussion should include review of:

- Clinical history including performance status
- Histology from biopsy if already performed
- Imaging – CT and MRI

CT is indicated for all patients with more than FIGO Stage 1A disease (i.e. more than 1mm depth of invasion). MRI is indicated for cases where MDT wish to assess extent of local disease progression and evidence of nodal metastases, to help assess operability.

- Discussion of management options (i.e. radical surgery / sentinel node procedure / radiotherapy / chemo-radiotherapy), and discussion of suitability for recruitment into appropriate clinical trials.
- Cases should also be discussed following surgery to review histology and management plan, and in the event of disease recurrence.

4.6 General Investigations

- FBC
- U&E including calcium
- LFTs
- CT chest / abdomen pelvis
- +/- MRI pelvic including groins
- Biopsy of any other suspicious areas that may alter management e.g. FNA suspicious groin nodes.
- Following staging patients may be recruited to trials according to their stage and current trial recognition.

5.0 Imaging

Imaging guidelines can be located in the KMCC agreed document located on the KMCC website on the following link: http://kmcc.nhs.uk/tumour-sites/sub-groups-or-cross-cutting-groups/diagnostics-group/

6.0 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/

7.0 Treatment – Squamous Vulval Cancers

Surgical treatment should be tailored with the aims of local clearance of tumour and without compromising chance of disease cure, minimisation of disfigurement. Each case should be considered on its merits with an agreed plan of management from the Gynaeoncology MDT.

Patients who are to have radical treatment (surgery and / or radiotherapy) should receive advice concerning lymphoedema.

7.1 Stage 1a (Ref: Section 13.1)

Wide local excision to aim for a clear margin of 8mm.

If appropriate excision of dysplastic skin in addition to tumour

7.2 Small Tumours (<4cm) –node negative Stage 1b (Ref: Section 13.1)

7.2.1 Lateral tumours – with medial edge of tumour >1cm from midline

- Radical excision
- Ipsilateral inguinal lymphadenectomy
- Contralateral inguinal lymphadenectomy if positive nodes
- Consider frozen section of suspicious nodes at primary surgery
- Sentinel node assessment with ultrastaging histopathological assessment has been shown to be safe and effective in identifying patients with small primary vulval malignancies (up to 4cm diameter),without multifocal disease, who do not require full inguinofemoral lymphadenectomy. This can now be offered by centres in Kent & Medway which have demonstrated efficacy and safety of the procedure. Patients with a positive sentinel node should undergo full systematic lymphadenectomy or adjuvant radiotherapy as standard management. If a sentinel lymph node is not detected, full systematic lymphadenectomy should be performed in that groin.
- Recruitment into sentinel node GROINSS V II study for patients with vulval cancer is now closed and results are awaited.

7.2.2 Medial tumours – with medial edge of tumour <1cm from midline; or Central tumours.

- Radical excision
- Bilateral inguinal lymphadenectomy
- Consider frozen section of suspicious nodes at primary surgery
- Sentinel node assessment with ultrastaging histopathological assessment has been shown to be safe and effective in identifying patients with small primary vulval malignancies (up to 4cm diameter),without multifocal disease, who do not require full inguinofemoral lymphadenectomy. This can now be offered by centres in Kent & Medway which have demonstrated efficacy and safety of the procedure. Patients with a positive sentinel node should undergo full systematic lymphadenectomy or adjuvant radiotherapy as standard management. If a sentinel lymph node is not detected, full systematic lymphadenectomy should be performed in that groin.

7.2.3 Treatment post Sentinel node procedure.

- When the sentinel lymph node (SLN) is negative after ultrastaging and immuno-histochemistry, the patient will be offered follow up.
- Patients with a positive SLN < / = 2mm will be offered adjuvant radiotherapy.
- Patients with a positive SLN > 2mm should be offered a lymphadenectomy +/- radiotherapy / chemoradiotherapy.
- Consider treatment to the contralateral groin.

7.3 Large Tumours (>4cm)

- Full radical vulvectomy to included bilateral inguinal lymphadenectomy (providing depth of invasion >1mm confirmed on pre-op biopsy or frozen section).
- In very elderly or infirm, systematic bilateral lymphadenectomy may be inappropriate – discuss in MDM to consider options including sentinel node assessment, ultrasound / MRI node surveillance with FNA where indicated
- If incomplete excision margin, for adjuvant radiotherapy; also consider if narrow margin (≤8mm)
  If >1 lymph node +ve or extra-capsular disease, for adjuvant radiotherapy / chemoradiotherapy

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/

7.4 Advanced Disease

- Multidisciplinary discussion to optimise management regime.
- Radiotherapy or palliation for inoperable disease.
- Radiotherapy to confirmed malignant fixed nodal masses (FNA or open biopsy undertaken)
- Appropriate surgery (surgery or combined surgery with plastics / urology / bowel specialists)
- Generally treat with chemoradiotherapy for tumours involving anus / rectum in preference to primary treatment with surgery requiring de-functioning colostomy and sphincter compromise.
- If bulky groin nodes, consider debulking dissection after discussion with MDT and patient prior to adjuvant radiotherapy / chemoradiotherapy.

7.5 Recurrent Disease

- Multidisciplinary discussion to optimise management regime.
- Local radical surgery if appropriate for local recurrence.
- Radiotherapy if not suitable for excision.
- Radiotherapy for palliation for inoperable disease.
- Chemotherapy can be considered in selected cases.

8.0 Treatment – Non-Squamous Vulval Cancers

8.1 Verrucous Carcinoma / Basal Cell Carcinoma

- no risk of metastasis
- radical local excision / vulvectomy as required, but no lymphadenectomy

- radiotherapy if involving anus

8.2 Adenocarcinoma

- e.g. Bartholin's carcinoma – management as per squamous carcinoma. Bilateral inguinofemoral lymphadenectomy should be performed.

8.3 Melanoma

- Vulval Melanoma may be managed in collaboration with the Royal Marsden Hospital (RMH) Melanoma MDT. Vulval and (where appropriate) nodal surgery will normally be performed in the local Gynaecological Cancer Centre. Adjuvant therapy will often also be administered locally after discussion with the RMH team.
- Radical local excision / vulvectomy as required
- No role for systematic lymphadenectomy, sentinel node assessment and excision of enlarged (clinically involved) nodes of doubtful value.

9.0 Treatment – Vaginal Cancers

- Multidisciplinary discussion to optimise management regime
- Generally:
  - upper 1/3 tumours managed as per cervical cancer
    - radical hysterectomy or chemoradiotherapy
  - middle 1/3 managed as per inoperable vulval cancer
    - chemoradiotherapy
  - lower 1/3 managed as per vulval cancer
    - radical excision / vulvectomy with lymphadenectomy or chemoradiotherapy

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/

10.0 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/

11.0 Supportive and 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, 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

12.0 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.

13.0 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.

13.1 Revised FIGO staging (2021)

Stage	Description
I	Tumor confined to the vulva
IA	Tumor size ≤2 cm and stromal invasion ≤1 mm[a]
IB	Tumor size >2 cm or stromal invasion >1 mm[a]
II	Tumor of any size with extension to lower one-third of the urethra, lower one-third of the vagina, lower one-third of the anus with negative nodes
III	Tumor of any size with extension to upper part of adjacent perineal structures, or with any number of nonfixed, nonulcerated lymph node
IIIA	Tumor of any size with disease extension to upper two-thirds of the urethra, upper two-thirds of the vagina, bladder mucosa, rectal mucosa, or regional lymph node metastases ≤5 mm
IIIB	Regional[b] lymph node metastases >5 mm
IIIC	Regional[b] lymph node metastases with extracapsular spread
IV	Tumor of any size fixed to bone, or fixed, ulcerated lymph node metastases, or distant metastases
IVA	Disease fixed to pelvic bone, or fixed or ulcerated regional[b] lymph node metastases
IVB	Distant metastases

- [a] Depth of invasion is measured from the basement membrane of the deepest, adjacent, dysplastic, tumor-free rete ridge (or nearest dysplastic rete peg) to the deepest point of invasion.
- [b] Regional refers to inguinal and femoral lymph nodes.

14.0 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/

15.0 References

1. Improving Outcomes in Gynaecological Cancers: The Research Evidence NHS Exec. DOH, July 1999.
2. Guidance for Purchasers: Improving Outcomes in Gynaecological Cancers – The Manual
3. Clinical Recommendations for the Management of Vulval Cancer; "Setting Standards to Improve Women's Health". The Royal College of Obstericians and Gynaecologists, July 1999
4. NHS Cancer Referral Guidelines HSC2000/013
5. O.Devaja, G.Mehra, M.Coutts et al. A Prospective Study of Sentinel Lymph Node Detection in Vulval Carcinoma. Int J Gynecol Cancer Vol 21 Number 3 April 2011 559- 564.
6. GROINSS-VII (Groningen International Study on Sentinel nodes in Vulval Cancer) Study protocol – amended, July 2010.
7. RCOG / BGCS Guidelines for the Diagnosis and Management of Vulval Carcinoma – May 2104.

16.0 Glossary

Acronyms in common usage throughout KMCC documentation

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)
KMCA	Kent & Medway Cancer Alliance
KMCC	Kent & Medway Cancer Collaborative
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 and advice to the TSSG, KMCC and geographical locations on new drugs)*
PoC	Pathway of Care *(K&M agreed disease site specific clinical guidelines)*
QEQM	Queen Elizabeth the Queen Mother Hospital, Margate (EKHUFT)
QoL	Quality of life
RAT	Research and Trial Group *(Permanent sub-group of the TSSGs with a specific responsibility for taking forward the clinical trials agenda)*
RMH	Royal Marsden Hospital
RNOH	Royal National Orthopaedic Hospital
TSSG	Tumour Site Specific Group
TYA	Teenage and Young Adult
QVH	Queen Victoria Foundation Trust Hospital East Grinstead
UCLH	University College Hospital London
WHH	William Harvey Hospital, Ashford (EKHUFT)
WK	West Kent

17.0 Document Administration

Document Title	The Management of Vaginal and Vulval Cancers – Pathway of Care
Principle author	Omer Devaja/Andreas Papadopoulos/R. Nath
Co-author(s)	J.Waters/C.Tsatsaklas/S.Attard-Montalto
Current version number	9.0
Current status	Final
Original publication date	March 2011
Expected review date by	August 2024

Enquiries:	
[1] Rema Iyer [2] Annette Wiltshire	rema.iyer1@nhs.net annette.wiltshire@nhs.net

Revision History			
Date of revision	New Version Number	Nature of Revision	Confirmation of Accuracy by
30/08/05	0.1	Development of Kent document based on (with grateful thanks) the Yorkshire Cancer Network original	O.Devaja/ R.Nath/ A.Papadopoulos
27/10/05	0.2	Flow chart update based on revised text set out in draft 1	A.Jackson
30/11/05	0.3	Updated text	A.Papadopoulos
01/12/05	1.0	Updates agreed – published	A.Jackson
31/03/06	2.0	Oncology Provision	A.Jackson
March 2009	2.1/2.2	General review – agreed by Gynae DOG	A.Jackson/A.Nordin
March 2009	2.3	Oncology Provision	R.Jyothirmayi/ C.Waters
March 2009	3.0	Published version	A.Jackson/A.Nordin
January 2010	3.1	Updates on FIGO staging	A.Nordin
March 2011	4.1	Published version	Gynae DOG
June 2012	4.2	Draft - changed to new format; updated all weblinks inc. imaging, pathology & contacts; general formatting & content checking	S.Stanley/L.Caine/ C.Tsatsaklas
September 2012	5.0	FINAL/Published – data collection section updated/ Gynae DOG approved 19/09/12 – agreed/published	A.Brittle/Gynae DOG/ C.Tsatsaklas/I.Vousden
May 2014	5.1	Draft – admin text updates (i.e. removal of KMCN, DOGs, replace with KMCC, TSSG etc)	J.Waters/C.Tsatsaklas/ Gynae TSSG
May 2014	6.0	Final – changes made as agreed 1/5/2014 Gynae TSSG	J.Waters/Gynae TSSG
June 2014	6.0	Final/Published – ratified by the Operational & Quality Group (25/6/14)	Operational & Quality Group
August 2017	6.1	Clinical review complete, web links updated. Sent to TSSG for approval	S.Attard-Montalto /N.Aluwalia
October 2017	6.2	Final draft for O&Q Approval	N.Aluwalia
October 2017	7.0	Final Published version	N.Aluwalia/ O&Q Group
February 2020	8.0	Final – published version new Chair	R. Iyer/A. Wiltshire
August 2022	9.0	Final – Revision of document nearing expiry date	R. Iyer /A. Wiltshire