



Standards and datasets for reporting cancers

Datasets for the histopathological reporting of vulval neoplasms (3rd edition)

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Comments	<p>This edition replaces the 1st edition of the <i>Dataset for the histological reporting of vulval biopsy specimens and vulvectomy specimens for vulval cancer</i> (March 2001), and the 2nd edition, <i>Dataset for histological reporting of vulval neoplasms</i> (June 2008).</p> <p>Following a revision by the authors, a statement of proposed key changes for this edition was put on The Royal College of Pathologists' website for an abridged consultation from 18 October to 1 November 2010 (see Appendix D). We received ten emails of approval, three from people who were happy to leave the decision to the authors, and no further comments. The proposed changes have therefore been incorporated into this edition.</p> <p>Dr Peter Cowling Director of Communications</p>

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1 Introduction

This is a revision of the vulval cancer dataset that was published in 2001. There has been an expansion of the clinico-pathological background and bibliography (up to June 2007), providing an evidence base for the expanded reporting proforma. The main changes in the proforma from 2001 are more precise specification of the nature of the submitted specimen, with more detailed measurements, expansion of the resection margin parameters, inclusion of Paget's disease, mention of lichen planus as a risk factor for vulval squamous carcinoma, more detail on nodal involvement and the status of the sentinel node. Basal cell carcinoma is listed.

In the past, TNM and FIGO staging of gynaecological cancers was recommended to allow standardisation of staging across all cancer sites, but surveys carried out on behalf of the British Association of Gynaecological Pathologists (BAGP) and British Gynaecological Cancer Society (BGCS) were overwhelmingly in favour of using FIGO staging alone for all gynaecological cancers, except cervical carcinoma.⁵⁹

In the accompanying text, more guidance has been given on measuring the depth of invasion.

A graphic has been provided to assist identification of the abnormal areas on the request form and to give a format for recording findings (Appendix A).

1.1 Background

Vulval cancer is a rare disease, with 996 cases resulting in 364 deaths in 2002 in the United Kingdom. This is the nineteenth most common cause of death from cancer in women in the UK,¹ with a crude incidence of 0.8 per 100 000. Most (more than 90%) vulval cancers are squamous carcinomas.² In elderly women, squamous carcinoma is usually human papillomavirus (HPV) negative, often associated with lichen sclerosus and squamous hyperplasia,³ and is often accompanied by differentiated VIN.⁴ In younger, usually premenopausal women, squamous carcinoma is often HPV related, associated with Bowenoid (warty) or basaloid VIN and associated with multifocal HPV associated disease of the cervix, vagina, perineum and anus.⁵

Adenocarcinoma of the vulva affects mainly women over 60 years, usually arising from Paget's disease with underlying carcinoma of a skin appendage in up to 10–20% of patients. Around 5% cases will have spread from local malignant disease of the anus, rectum, bladder or cervix.^{6–8}

The prognosis of vulval carcinoma depends on the size of the lesion, depth of invasion,^{9–12} the number of involved lymph nodes, presence or absence of extranodal spread and proportion of node replaced by metastasis^{13,14} and the presence or absence of lymphovascular space involvement (LVSI).^{13,15} The depth of invasion is measured from the epithelial-stromal junction of the adjacent most superficial dermal papillae to the deepest point of invasion by tumour.¹⁶ Tumour grade is of questionable prognostic significance and most squamous carcinomas in elderly women are well differentiated.

30% of patients have lymph node metastasis at presentation. The pattern of lymph node metastasis is well established and predictable,¹⁷ with spread first to the ipsilateral superficial inguinal nodes¹⁸ and then to deep groin nodes, pelvic lymph nodes and distant sites. Five-year survival is affected by the number of nodes involved and whether involvement is unilateral (five-year survival: 60–70%) or bilateral (five-year survival: 25%). Extracapsular spread is an independent variable in two studies and may influence the decision on the type and dosage of post-operative radiotherapy.^{13,14} Midline disease requires bilateral node dissection.¹⁹ Lymphovascular space invasion (LVSI) is not an independent prognostic factor

but is a good marker of groin node metastasis: 88% with LVSI have nodal spread compared to 19% without LVSI.²⁰

Evidence is accruing that sentinel lymph node examination is a reliable indicator of inguinal node involvement,^{21,22} with a negative predictive value of 95–100%. Step/serial sectioning (ultrastaging), with or without immunohistochemistry, is currently under research. It has been shown to increase the yield of involved nodes that were negative on routine examination (4–11%), but as yet there has been no trial to assess the prognostic significance of this and there is no agreement as to whether this should form part of routine assessment.^{23–26} Until there is evidence that ultrastaging is relevant, sentinel nodes should be examined as detailed in the national breast screening recommendations.²⁷

The risk of lymph node metastasis is very low if the depth of invasion is less than or equal to 1 mm (FIGO stage 1a), allowing the option of curative local excision for both squamous and glandular lesions. Lymph node dissection may not be undertaken if invasion is less than 1 mm in a fully excised specimen.^{28–30}

Lichen sclerosus, especially if associated with squamous hyperplasia³¹ and erosive lichen planus,³² are linked to the later development of squamous carcinoma in older, HPV negative women. Recurrent disease is linked to persisting VIN and lichen sclerosus.³³ Recurrence of VIN is associated with involved margins, multifocal disease and genital warts.³⁴ Untreated and recurrent VIN has a high risk of progression to squamous carcinoma.³⁵ Basal cell carcinoma accounts for 2–28% of vulval cancers, depending on the population³⁶ and generally behaves as an indolent, occasionally locally aggressive neoplasm in elderly women (average age 70) with a propensity to recur if incompletely excised; metastasis and death are rare.^{37–41}

1.2 Stakeholder groups

The following organisations have been consulted during the preparation of the dataset:

- Working Group of the British Association of Gynaecological Pathologists (BAGP) comprising BAGP Council and co-opted members
- British Gynaecological Cancer Society (BGCS)
- British Society for the Study of Vulval Diseases.

2 Clinical information required on the specimen request form

- Full patient details, history and the results of previous biopsies.
- The results of ultrasound combined with fine needle aspiration cytology have been shown to be more accurate than computerised tomography (CT) and magnetic resonance imaging (MRI) in evaluating nodal involvement.⁴² However, it may be advisable for results to be made available, although these might not be an accurate predictor of involvement.¹² The results of lymphangiography, including dye injections⁴³ and scintillography^{21, 22} are relevant to sentinel node assessment.
- Comprehensive details of the surgical procedure should be provided. It may be useful to use a diagram of the site of operation/biopsy with orientation markings/sutures (Appendix A).
- The details of surgical specimens from multiple sites should be provided.
- Specimen pots should be labelled to correspond to the specimen details on the request form.

3 Preparation of specimen before dissection

The usual surgical procedures for vulval carcinoma are:

- radical vulvectomy and lymph node dissection (with or without sentinel node dissection)
- partial vulvectomy and lymph node dissection (with or without sentinel node dissection)
- radical or partial vulvectomy
- wide local tumour excision
- diagnostic biopsy.

Preparation of radical vulvectomy specimens will depend upon the size of the vulval tumour and the extent of spread. Margins may require painting with ink/dye prior to block taking. A photographic record and/or schematic graphic of the orientated vulval specimen (Appendix A) may be useful. A vulvectomy specimen may be pinned out and fixed before block taking, but this is not essential. It is advisable to request that the surgeons mark the site of previous biopsy with a suture or ink if no gross lesion is visible.

4 Specimen handling and block selection⁴⁴

Specimens may be fixed and pinned out or, if appropriate, sampled fresh. It might be appropriate to map the lesion(s) on a graphic (Appendix A) or photograph. The tumour must be adequately sampled to allow typing, grading and measurement of depth and width.

Blocks should be taken to document:

- distance to epithelial resection margin
- distance to urethral resection margin (if appropriate)
- distance to vaginal resection margin (if appropriate)
- distance to anal resection margin (if appropriate)
- distance to soft tissue (deep) resection margin
- any grossly normal or abnormal epithelium to identify non-neoplastic epithelial diseases (NNED)
- any incidental cysts or other abnormalities.

All lymph nodes should be sampled from each side. The presence of macroscopic involvement of lymph nodes should be recorded, together with the dimensions of involved nodes. The sentinel node is highly predictive for inguinofemoral node involvement with a negative predictive value of 95–100%.²³ Although step sectioning and immunohistochemistry have been performed in some studies,² there is no evidence that ultrastaging is prognostically significant.

The following is advised for all inguinal (including sentinel) nodes.

- each lymph node must be examined histologically
- resected lymph nodes not obviously involved by tumour must be examined in their entirety
- larger nodes may require more than one block
- nodes larger than 5 mm should be blocked out at 2–3 mm intervals cut perpendicular to the long axis
- nodes smaller than 5 mm can be bisected or embedded whole
- only one block is necessary from any grossly involved node
- levels are only required for clarification of suspicious groups of cells.^{23–26}

In departments where the facility for processing of oversize blocks is available, a good overview of the tumour and resection margins can be obtained, but standard blocks of tumours should also be processed, to enable immunohistochemistry or other special stains to be performed more readily should these be required.

The origin/designation of all tissue blocks should be recorded on the pathology report. This is particularly important should the need for internal or external review arise. The reviewer needs to be clear about the origin, relevant resection margin and laterality of each block.

5 Core histological data items

The following information must be recorded:

- tumour type, according to the WHO classification (see section 7).
- tumour differentiation
- tumour size (in at least two dimensions)
- thickness/depth of invasion
- presence or absence of lymphovascular invasion
- status of all resection margins
- minimum tumour free margins
- presence of associated VIN or Paget's disease
- status of resection margins for VIN or Paget's disease
- minimum distance to margins for VIN or Paget's disease
- presence or absence of non-neoplastic epithelial disease
- presence or absence of lymph nodes metastases
- presence of extranodal spread
- whether nodal metastasis is larger than 5 mm.⁵⁸

5.1 Tumour differentiation

Squamous carcinomas should be graded according to a modified version of Broders system as 'well differentiated' (keratinising), 'moderately differentiated' or 'poorly differentiated'.⁴⁵ There is no agreed grading system for adenocarcinoma, but it is suggested that these tumours be graded according to the FIGO system for endometrial adenocarcinomas.⁴⁶

5.2 Maximum horizontal dimension (width of lesion)

Where a tumour involves more than one adjacent block, a third dimension may be calculated from an estimate of the block thickness. A tumour occupying seven or more adjacent blocks may exceed 20 mm, i.e. the carcinoma may be more than FIGO stage I.⁴⁷ The microscopic maximum horizontal dimension should be correlated with the gross measurements.

5.3 Thickness/depth of invasion

The depth of invasion is defined as the measurement from the epithelial-stromal junction of the adjacent most superficial dermal papilla to the deepest point of invasion. Where this is not easily achievable, an estimate can be made by measuring from the surface to the deepest point of invasion and then subtracting the distance from the surface to the epithelial stromal junction of the most superficial dermal papilla. If the lesion is ulcerated, a maximum tumour thickness may be given. It is important to correlate the macroscopic and microscopic measurements to avoid error and to permit measurements of tumours larger than a standard slide. Vascular space involvement, either venous or lymphatic, does not alter the staging.^{48,49}

5.4 Vulval intraepithelial neoplasia⁵⁰

The following features should be recorded for instances of vulval intraepithelial neoplasia:

- VIN-warty, basaloid, mixed (warty/basaloid) type
- grades I, II, III
- VIN-differentiated type – this is not graded
- Paget's disease
- assessment of margins
- minimum distance from resection margins, where applicable.

5.5 Non-neoplastic epithelial diseases (NNED)⁵¹

Evidence for the following diseases should be sought, and their presence or absence should be recorded:

- lichen sclerosus
- squamous hyperplasia
- mixed lichen sclerosus and squamous hyperplasia
- lichen planus.

5.6 Nodal involvement

The number of identified and involved nodes at each site must be recorded. Extranodal spread or whether any metastasis is larger than 5 mm may indicate increased risk of local recurrence and must be reported if present.^{13,14, 58}

6 Non-core data items

These may be recorded as a separate comment or within a complementary text report. Such items include the presence of human papillomavirus associated features (koilocytosis, epithelial multinucleation, dyskeratosis, parakeratosis, acanthosis, papillomatosis), inflammatory dermatoses or other benign lesions such as cysts. The presence of a fibromyxoid stromal reaction is reported, in one study, to be an indicator of an adverse prognosis and may be recorded as a separate comment.⁵²

7 WHO classification and SNOMED codes of vulvar epithelial tumours and related lesions

Squamous lesions

Intraepithelial neoplasia (vulvar intraepithelial neoplasia VIN 3)	80772
Carcinoma in situ	80702
Squamous cell carcinoma	80703
Keratinizing	80713
Nonkeratinizing	80723
Basaloid	80833
Verrucous	80513
Warty (condylomatous)	80513

Others

Basal cell carcinoma 80903

Glandular lesions

Paget's disease 85423

Bartholin gland tumours

Adenocarcinoma 81403

Squamous carcinoma 80703

Adenoid cystic carcinoma 82003

Adenosquamous carcinoma 85603

Transitional cell carcinoma 81203

Small cell carcinoma 80413

Carcinoma of mammary type gland 85003

Adenocarcinoma of Skene gland 81403

Carcinoma of sweat gland origin 84003

Adenocarcinomas of other types 81403

8 Small biopsies⁴⁴

These may be received as fresh or fixed material. Wide local excisions are treated in a similar manner to vulvectomy specimens. Small diagnostic punch biopsies may be taken for confirmation of malignancy and the site must be clearly identified to allow orientation of margins and sampling of the biopsy site in any subsequent vulvectomy specimen.

The biopsy will vary according to the size of the lesion, and range from small punch biopsies that are up to several millimetres long and 2–4 mm diameter, to larger ellipse biopsies of similar size to skin or vulval excisional biopsies. In some institutions, small biopsies may be mounted onto a card.

Careful handling of these specimens is recommended to prevent surface trauma and disruption or loss of surface epithelium. It is important to search the container and the under surface of its lid to ensure that stray fragments of tissue are recovered. Fragments should be counted and embedded as received. Larger pieces are measured individually.

Punch biopsies are bisected if larger than 3 mm and the epithelium is clearly visible for orientation. Ellipse excisions are embedded as received if narrower than 3 mm, and bisected longitudinally if wider.

Wider or larger biopsies with an identifiable lesion are cut in transverse section to include the nearest resection margins. The blocks containing the end slices are noted; these will usually be the first and last blocks in the sequence. It may be appropriate to ink the margins as orientated by the clinician with marking sutures or pinned to a cork board. Identifiable surface lesions are described and measured and the macroscopic distance from the closest margin noted.

9 Frozen sections

Frozen section assessment is not routinely used for the assessment of margins. Frozen sections have been used for the assessment of sentinel nodes intraoperatively in research studies, but this is not currently recommended for routine practice due to sampling and interpretational errors.^{15,24,25,27}

10 Ancillary investigations

Immunohistochemistry has a limited role in diagnosis and prognostication of vulval cancers. For invasive vulval carcinoma, stage remains the most important prognostic factor. Diffuse p16 positivity may indicate an HPV-associated neoplasm. Neither ploidy, retinoblastoma protein (pRb) or p53 are prognostically significant.⁵³ Neither p53 nor Ki67 can determine prognosis in Paget's disease of the vulva.⁵⁴

Immunohistochemistry for broad spectrum cytokeratins, such as AE1/AE3, can reveal micrometastases in up to 23% of inguinal nodes,^{25,55} but not all studies support this,^{24,56} and the prognostic implications of micrometastases have not been established.²

The differential diagnosis of Paget's disease of the vulva includes malignant melanoma. Paget's disease is often positive for CAM 5.2, CEA, EMA and CK7, with variable positivity for CK20 and GCDFP15 (gross cystic disease fluid protein 15). Although Paget cells may contain melanin, they are negative with the melanoma markers HMB45 and S100; melanoma reacts for HMB45 and S100.²⁹ CK20 positivity in Paget's disease, especially if strong and diffuse, suggests metastatic involvement from the colorectum or urinary bladder, although some primary vulval Paget's disease may be positive with these markers. Similarly, positivity for uroplakin suggest urothelial origin.^{8, 57}

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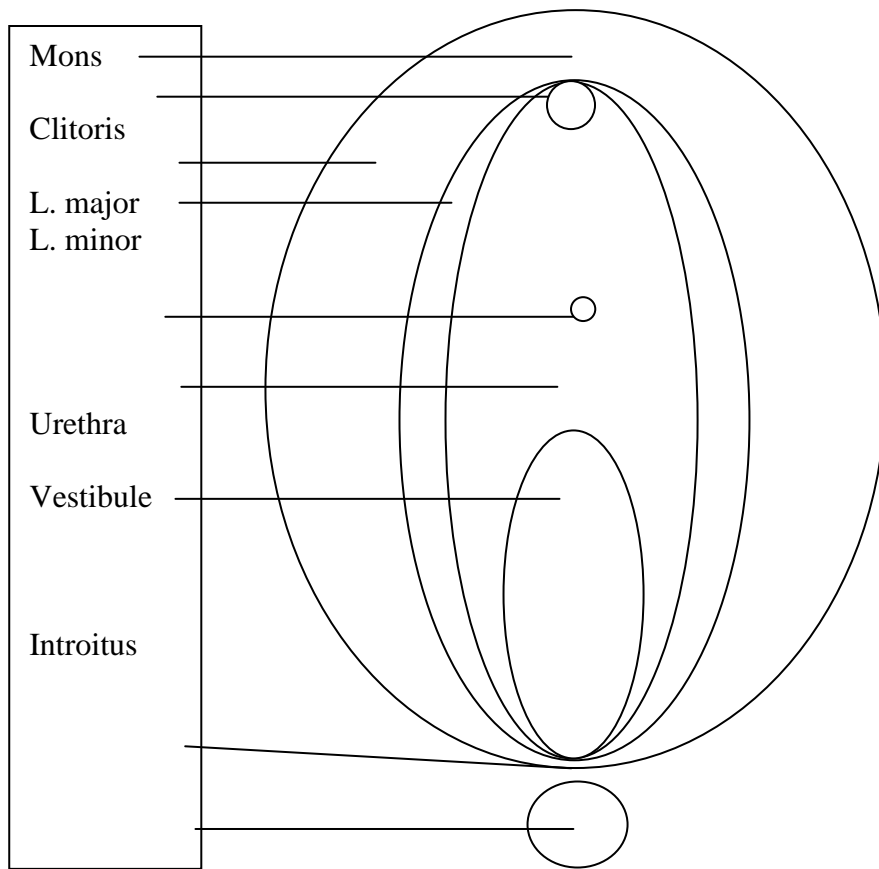
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10 Acknowledgments

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Appendix A Diagram to assist the orientation of specimens and selected blocks



Appendix B FIGO staging of vulval carcinoma

Stage I	Tumour confined to the vulva
Stage I A	Tumour confined to the vulva or perineum, ≤ 2 cm in size with stromal invasion ≤ 1 mm*, negative nodes
Stage I B	Tumour confined to the vulva or perineum, > 2 cm in size or with stromal invasion >1 mm, negative nodes
Stage II	Tumour of any size with extension to adjacent perineal structures (1/3 lower urethra, 1/3 lower vagina, anus), 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
Stage III A	(i) 1 lymph node metastasis (≥ 5 mm) (ii) 1–2 lymph node metastasis(es) (<5 mm)
Stage III B	(i) 2 or more lymph nodes metastases (≥ 5 mm) (ii) 3 or more lymph nodes metastases (<5 mm)
Stage III C	Positive nodes with extracapsular spread
Stage IV	Tumour invades other regional structures (2/3 upper urethra, 2/3 upper vagina), or distant structures
Stage IV A	Tumour invades any of the following: (i) upper urethra and/or vaginal mucosa, bladder mucosa, rectal mucosa, or fixed to pelvic bone or (ii) fixed or ulcerated inguino-femoral lymph nodes
Stage IV B	Any distant metastasis including pelvic lymph nodes

* The depth of invasion is defined as the measurement of the tumour from the epithelial-stromal junction of the adjacent most superficial epithelial papilla to the deepest point of invasion. Vascular space involvement, either venous or lymphatic, does not alter the staging.^{6,7}

Appendix C Reporting proforma for vulval cancer resection specimens

Surname Forenames Date of birth.....
Hospital Hospital no NHS/CHI no
Date of receipt Date of report Report no
Pathologist Surgeon

Nature of vulvectomy specimen

Radical Simple Anterior Posterior
Left hemi Left nodes Right hemi Right nodes
3 part with nodes Y excision with nodes Local excision
Other.....

Gross description

Size of specimen: Length mm Width mm Thickness mm
Size of tumour: Length mm Width mm Thickness mm
Site(s) of tumour (please state):
No macroscopic residual tumour:

Histology

Histological type: Squamous (usual) Verrucous
Adenocarcinoma Basal cell
(For melanoma, use appropriate skin dataset)

Other (please specify)

Histological differentiation: Well Moderate Poor

Tumour size (for staging): Maximum horizontal dimension mm
Thickness/depth of invasion..... mm

(NB Requires correlation of macro/micro measurements)

Lymphovascular invasion: Present Absent

Minimum tumour-free margin

Skin/epithelial..... mm N/A Involved (position).....o'clock
Urethral..... mm N/A Involved
Vaginal mm N/A Involved
Anal mm N/A Involved
Soft tissue mm N/A Involved

VIN 1 VIN 2 VIN 3 Differentiated VIN Paget's
VIN or Paget's excised Yes No

Minimum margin

Skin/epithelial..... mm	N/A <input type="checkbox"/>	Involved <input type="checkbox"/> (position).....o'clock
Urethral..... mm	N/A <input type="checkbox"/>	Involved <input type="checkbox"/>
Vaginal mm	N/A <input type="checkbox"/>	Involved <input type="checkbox"/>
Anal mm	N/A <input type="checkbox"/>	Involved <input type="checkbox"/>

Presence of non-neoplastic epithelial disease (NNED): Yes No

Lichen sclerosus Lichen planus

Squamous hyperplasia HPV-associated features

NNED excised: Yes No

Groin nodes

Sentinel node, if sent – (right) positive Sentinel node, if sent – (left) positive

Total number of nodes (right) Total number of nodes (left)

Total number of positive nodes (right) Total number of positive nodes (left)

Extranodal extension: Yes No

>5 mm metastasis Yes No

Comments/additional information

Provisional FIGO stage **(may change following MDTM discussion).**

SNOMED codes: T..... M.....

Signature..... **Date**...../...../.....

Appendix D Key changes made to this 2010 edition

Minor revisions are proposed to take into account the recent revision of FIGO staging of vulval cancers.

The changes to the dataset include:

1. Replacement of the existing statement in the introduction about TNM and FIGO staging with: "In the past TNM and FIGO staging of gynaecological cancers was recommended to allow standardisation of staging across all cancer sites, but surveys carried out on behalf of the BAGP and BGCS were overwhelmingly in favour of using FIGO staging alone for all gynaecological cancers, except cervical carcinoma."
2. Inclusion of the revised FIGO staging system for vulval carcinoma.
3. Removal of the TNM staging system of vulval carcinoma from the dataset.
4. Modification of the histopathology reporting proforma at the end of the dataset to take into account the revised FIGO staging system.
5. Amendment of the document text to take into account a new core data item (nodal metastasis larger than 5 mm); this replaces a previous core data item (>50% of any one node involved by tumour).

Laurence Brown

21 September 2010