

Protocol for the Examination of Specimens From Patients With Carcinoma of the Vagina

Protocol applies to all invasive carcinomas of the vagina.

Based on AJCC/UICC TNM, 7th edition, and FIGO 2009 Annual Report

Protocol web posting date: January 2016

Procedures

- Biopsy
- Excisional biopsy
- Vaginectomy
- Radical Vaginectomy

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CAP Vagina Protocol Revision History

Version Code

The definition of version control and an explanation of version codes can be found at www.cap.org (search: cancer protocol terms).

Version: Vagina 3.2.0.0

Summary of Changes

The following changes have been made since the December 2013 release.

Biopsy

The following data elements were modified:

- Histologic Type
- Additional Pathologic Findings

The following data element was deleted:

- Tumor Type

Excisional Biopsy, Resection

The following data elements were modified:

- Histologic Type
- Margins
- Lymph-Vascular Invasion
- Regional Lymph Nodes
- Distant Metastasis (changed to required only if confirmed pathologically)
- Additional Pathologic Findings

The following data element was added:

- FIGO Stage (not required)

The following data element was deleted:

- Tumor Type

Surgical Pathology Cancer Case Summary

Protocol web posting date: January 2016

VAGINA: Biopsy

Note: Use of case summary for biopsy specimens is optional.

Select a single response unless otherwise indicated.

+ Procedure (Notes A through C)

- + Incisional biopsy
- + Other (specify): _____
- + Not specified

+ Tumor Site

- + Upper third
- + Middle third
- + Lower third
- + Not specified

+ Histologic Type (select all that apply) (Note D)

- + Superficial invasive squamous cell carcinoma (SISCCA)
- + Squamous cell carcinoma
 - + Keratinizing
 - + Nonkeratinizing
 - + Basaloid
 - + Verrucous
 - + Warty
- + Adenocarcinoma
 - + Clear cell
 - + Mucinous
 - + Endometrioid
 - + Mesonephric
 - + Intestinal type
- + Adenosquamous carcinoma
- + Undifferentiated carcinoma
- + Other (specify): _____

+ Histologic Grade (Note E)

- + Not applicable
- + GX: Cannot be assessed
- + G1: Well differentiated
- + G2: Moderately differentiated
- + G3: Poorly differentiated
- + G4: Undifferentiated
- + Other (specify): _____

+ Microscopic Tumor Extension

- + Cannot be assessed
- + Stromal invasion
- + Muscle invasion

+ Data elements preceded by this symbol are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

+ Margins

- + ___ Not applicable
- + ___ Cannot be assessed
- + ___ Uninvolved by tumor
- + ___ Involved by tumor
 - + Specify site: _____

+ Additional Pathologic Findings (select all that apply) (Note F)

- + ___ None identified
- + ___ High grade squamous intraepithelial neoplasia
- + ___ Low grade squamous intraepithelial neoplasia
- + ___ Vaginal intraepithelial neoplasia, differentiated type
- + ___ Condyloma accuminatum
- + ___ Adenocarcinoma in situ
- + ___ Atypical adenosis
- + ___ Other (specify): _____

+ Comment(s)

Surgical Pathology Cancer Case Summary

Protocol web posting date: January 2016

VAGINA: Excisional Biopsy, Resection (Vaginectomy, Radical Vaginectomy)**Select a single response unless otherwise indicated.****Procedure**

- Excisional biopsy
 Partial vaginectomy
 Radical vaginectomy
 Other (specify): _____
 Not specified

Tumor Site (select all that apply)

- Upper third
 - + Circumferential
 - + Anterior
 - + Posterior
 - + Left lateral
 - + Right lateral
- Middle third
 - + Circumferential
 - + Anterior
 - + Posterior
 - + Left lateral
 - + Right lateral
- Lower third
 - + Circumferential
 - + Anterior
 - + Posterior
 - + Left lateral
 - + Right lateral
- Not specified

Tumor Size

- Greatest dimension: ___ cm
 + Additional dimensions: ___ x ___ cm
 Cannot be determined (explain): _____

Histologic Type (select all that apply) (Note D)

- Superficial invasive squamous cell carcinoma (SISSCA)
 Squamous cell carcinoma
 - Keratinizing
 - Non-keratinizing
 - Basaloid
 - Verrucous
 - Warty

- Adenocarcinoma
 - Clear cell
 - Endometrioid
 - Mucinous
 - Mesonephric
 - Intestinal type
- Adenosquamous carcinoma
- Undifferentiated carcinoma
- Small cell neuroendocrine carcinoma
- Large cell neuroendocrine carcinoma
- Other (specify): _____

Histologic Grade (Note E)

- Not applicable
- GX: Cannot be assessed
- G1: Well differentiated
- G2: Moderately differentiated
- G3: Poorly differentiated
- G4: Undifferentiated
- Other (specify): _____

Margins (select all that apply)

- Cannot be assessed
- Uninvolved by invasive carcinoma
 - Distance of invasive carcinoma from closest margin: ____ mm
 - Specify margin, if possible: _____
- Involved by invasive carcinoma
 - Specify margin(s), if possible: _____
- Uninvolved by high grade squamous intraepithelial lesion (VAIN 2-3)
- Involved by high grade squamous intraepithelial lesion (VAIN 2-3)
- Uninvolved by vaginal intraepithelial neoplasia, differentiated type
- Involved by vaginal intraepithelial neoplasia, differentiated type
 - Specify margin(s): _____

Lymph-Vascular Invasion

- Not identified
- Present
- Cannot be determined

Pathologic Staging (pTNM) (Note H)

TNM Descriptors (required only if applicable) (select all that apply)

- m (multiple primary tumors)
- r (recurrent)
- y (posttreatment)

Primary Tumor (pT)

- pTX: Cannot be assessed
- pT0: No evidence of primary tumor
- pTis: Carcinoma in situ
- pT1: Tumor confined to vaginal wall
- pT2: Tumor invades paravaginal tissues but not the pelvic wall
- pT3: Tumor extends to pelvic wall
- pT4: Tumor invades mucosa of bladder or rectum and/or extends beyond true pelvis

+ Data elements preceded by this symbol are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

Regional Lymph Nodes (pN) (select all that apply)

+ *Modifier*

- + ___ (sn)
- + ___ (sn)(i-)
- + ___ (sn)(i+)

Category (pN)

- ___ pNX: Cannot be assessed
- ___ pN0: No regional lymph node metastasis
- ___ pN1: Pelvic or inguinal lymph node metastasis

___ No nodes submitted or found

Inguinal lymph nodes:

___ No inguinal nodes submitted or found

Number of Inguinal Lymph Nodes Examined

Specify: ___

___ Number cannot be determined (explain): _____

Number of Inguinal Lymph Nodes Involved

Specify: ___

___ Number cannot be determined (explain): _____

Other lymph nodes:

Specify site: _____

Number of Other Lymph Nodes Examined

Specify: ___

___ Number cannot be determined (explain): _____

Number of Other Lymph Nodes Involved

Specify: ___

___ Number cannot be determined (explain): _____

+ Number of lymph nodes with isolated tumor cells (<0.2 mm): _____

+ Number of lymph nodes with micrometastasis (>0.2 mm to 2 mm): _____

Distant Metastasis (pM) (required only if confirmed pathologically in this case)

___ pM1: Distant metastasis

Specify site(s), if known: _____

+ FIGO Stage

- + ___ I: Carcinoma is limited to the vaginal wall
- + ___ II: Carcinoma has involved the sub-vaginal tissue but has not extended to the pelvic wall
- + ___ III: Carcinoma has extended to the pelvic wall
- + IV: Carcinoma has extended beyond the true pelvis or has involved the mucosa of the bladder or rectum
(bullous edema as such does not permit a case to be allotted to stage IV)
- + ___ IVA: Tumor invades bladder and/or rectal mucosa and/or direct extension beyond the true pelvis
- + ___ IVB: Spread to distant organs

+ Data elements preceded by this symbol are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

+ Additional Pathologic Findings (select all that apply) (Note F)

- + None identified
- + Low-grade squamous intraepithelial lesion (VAIN 1)
- + High-grade squamous intraepithelial lesion (VAIN 2-3)
- + Vaginal intraepithelial neoplasia, differentiated type
- + Condyloma acuminatum
- + Adenocarcinoma in situ
- + Atypical adenosis
- + Other (specify): _____

+ Comment(s)

Explanatory Notes

A. Prenatal DES Exposure

Prenatal exposure to diethylstilbestrol (DES) or related synthetic drugs was relatively common in the United States and other countries until 1971, when its relation to clear cell adenocarcinomas of the vagina and cervix led to proscriptioin of these drugs by the Food and Drug Administration. From the 1970s to the turn of the 21st century, most patients with clear cell adenocarcinoma of the vagina had a history of DES exposure.¹ As this cohort ages, the diagnosis has been less common, and most women with this diagnosis currently have no DES exposure history. Furthermore, it has been reported that these patients have significantly worse outcomes than do patients with history of DES exposure and patients with squamous cell carcinoma.² A bimodal age peak for DES-related carcinoma has, however, been recently reported, and therefore a history of this type of prenatal drug exposure should alert the pathologist to the possible presence of those tumors and associated lesions.^{3,4}

B. Prior Tumors and Operations

A history of dysplasia, carcinoma in situ, or invasive carcinoma of the cervix as well as knowledge of the tumor's microscopic features may be essential in the determination whether a subsequent vaginal tumor is a recurrent or new tumor. Also, a history of a carcinoma higher in the female genital tract may influence the interpretation of a neoplasm that is detected in a specimen from the vagina. Prior pathology slides and reports should be obtained and reviewed if a review is deemed essential by the clinician or pathologist for optimal pathologic evaluation of the present specimen.

C. Clinical Findings and DES Exposure

Naked-eye examination, colposcopy, and iodine staining of the cervix and vagina may disclose a variety of changes highly suspicious of prenatal DES exposure, such as cervical hypoplasia, pseudopolyp, or coxcomb deformity,⁴ and vaginal adenosis or ridge, any of which should alert the pathologist to look carefully for DES changes.⁴

D. Histologic Type

The World Health Organization (WHO) classification and nomenclature of vaginal tumors is recommended because of its wide acceptance.⁵ The most common subtype is squamous cell carcinoma. However, when such tumor simultaneously involves the cervix or the vulva and the vagina, the tumor is considered to originate from the cervix or vulva, with secondary extension to the vagina. Also, when an adenocarcinoma is present in the vagina, it is important to keep in mind that many of those tumors represent secondary involvement either by direct extension or metastases, more commonly from the endometrium, colorectal, ovary, vulva, urethra, and urinary bladder. Although not included in the current WHO classification, primary intestinal type adenocarcinoma has recently been described in the vagina.⁶ These tumors usually arise in a background of benign adenomatous lesion. Awareness of this new subtype is necessary to avoid misdiagnosis of a metastatic colorectal adenocarcinoma.⁶⁻⁸

WHO Classification⁵

Precancerous Lesions and Carcinomas of the Vagina (Modified)

Epithelial Tumors

Squamous tumors and precursors

Squamous intraepithelial lesions (SIL)	Vaginal intraepithelial neoplasia (VAIN)	
Mild dysplasia	VAIN 1	Low-grade SIL (LSIL)
Moderate dysplasia	VAIN 2	High-grade SIL (HSIL)
Severe dysplasia	VAIN 3	HSIL
Carcinoma in situ	VAIN 3	HSIL
Vaginal intraepithelial neoplasia, differentiated type		
Squamous cell carcinoma, not otherwise specified		
		Keratinizing
		Nonkeratinizing
		Basaloid
		Verrucous

- Warty
- Glandular tumors
 - Clear cell carcinoma
 - Endometrioid adenocarcinoma
 - Mucinous adenocarcinoma
 - Mesonephric adenocarcinoma
- High-grade neuroendocrine carcinoma
 - Small cell neuroendocrine carcinoma
 - Large cell neuroendocrine carcinoma
- Other epithelial tumors
 - Adenosquamous carcinoma
 - Adenoid cystic carcinoma
 - Adenoid basal carcinoma
 - Undifferentiated carcinoma

E. Histologic Grade

No specific grading system for vaginal cancers is recommended. For the sake of uniformity, however, it is suggested that 3 grades be used, as shown below, with grades 1 to 3 assigned to carcinomas showing squamous or glandular differentiation.

Grade X	Cannot be assessed
Grade 1	Well differentiated
Grade 2	Moderately differentiated
Grade 3	Poorly differentiated
Grade 4	Undifferentiated

F. Other Lesions

Squamous dysplasia or carcinoma in situ, adenocarcinoma in situ, or atypical adenosis, particularly if such changes are at the resection margin, may increase the frequency of recurrent tumor. Also, few cases of primary invasive carcinoma of vagina have been reported to occur in association with severe vaginal prolapse.⁹⁻¹¹

G. Staining of Mucosal Surface

Schiller's or Lugol's solutions stain glycogenated epithelium brown. Therefore, they stain glycogenated squamous epithelium and well-glycogenated tumors. The stains are useful in identifying sites of nonstaining vaginal adenosis or immature squamous metaplasia of adenosis in patients exposed to DES, which may not be detectable before staining.

H. TNM and FIGO Stage Groupings

The TNM staging system for vaginal cancer endorsed by the American Joint Committee on Cancer (AJCC) and the International Union against Cancer (UICC),^{12,13} and the parallel system formulated by the International Federation of Gynecology and Obstetrics (FIGO)¹⁴ are recommended.

By AJCC/UICC convention, the designation "T" refers to a primary tumor that has not been previously treated. The symbol "p" refers to the pathologic classification of the TNM, as opposed to the clinical classification, and is based on gross and microscopic examination. pT entails a resection of the primary tumor or biopsy adequate to evaluate the highest pT category, pN entails removal of nodes adequate to validate lymph node metastasis, and pM implies microscopic examination of distant lesions. Clinical classification (cTNM) is usually carried out by the referring physician before treatment during initial evaluation of the patient or when pathologic classification is not possible.

Pathologic staging is usually performed after surgical resection of the primary tumor. Pathologic staging depends on pathologic documentation of the anatomic extent of disease, whether or not the primary tumor has been completely removed. If a biopsied tumor is not resected for any reason (eg, when technically unfeasible) and if the highest T and N categories or the M1 category of the tumor can be confirmed microscopically, the criteria for pathologic classification and staging have been satisfied without total removal of the primary cancer.

TNM and FIGO Staging Systems for Vaginal Carcinoma**Primary Tumor (T)**

TNM	FIGO	Definition
Category	Stage	
TX	(--)	Primary tumor cannot be assessed
T0	(--)	No evidence of primary tumor
Tis	0	Carcinoma in situ
T1	I	Tumor confined to vaginal wall
T2	II	Tumor invades paravaginal tissues but not the pelvic wall [#]
T3	III	Tumor extends to pelvic wall
T4	IVA	Tumor invades mucosa of bladder or rectum and/or extends beyond the true pelvis (bullous edema is not sufficient to classify a tumor as T4)
(M1)	IVB	Distant metastasis (excludes peritoneal metastasis)

[#] Pelvic wall is defined as muscle, fascia, neurovascular structures, or skeletal portions of the bony pelvis.

Microinvasive/early carcinoma is not, currently, a recognized entity in the vagina, in contradistinction to the cervix, and the term is therefore not used. Superficially invasive tumors which invade 3 mm or less without lymphovascular invasion (LVI) have a low incidence of lymph node metastasis.¹⁵

Regional Lymph Nodes (N): TNM

NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Pelvic or inguinal lymph node metastasis

Although N0(sn)(i-) and N0(sn)(i+) are not explicitly mentioned in the vagina chapter of the AJCC 7th edition, AJCC acknowledges use of (sn) and (i) modifiers for cancers other than breast cancer. This nomenclature is currently being adopted and used by pathologists for vaginal cancer.

Distant Metastasis (M): TNM

M0	No distant metastasis
M1	Distant metastasis

Stage Groupings

AJCC/UICC TNM				FIGO
Stage 0	Tis	N0	M0	Stage 0
Stage I	T1	N0	M0	Stage I
Stage II	T2	N0	M0	Stage II
Stage III	T1	N1	M0	Stage III
	T2	N1	M0	
	T3	N0, N1	M0	
Stage IVA	T4	Any N	M0	Stage IVA
Stage IVB	Any T	Any N	M1	Stage IVB

TNM Descriptors

For identification of special cases of TNM or pTNM classifications, the “m” suffix and “y,” “r,” and “a” prefixes are used. Although they do not affect the stage grouping, they indicate cases needing separate analysis.

The “m” suffix indicates the presence of multiple primary tumors in a single site and is recorded in parentheses: pT(m)NM.

The “y” prefix indicates those cases in which classification is performed during or following initial multimodality therapy (ie, neoadjuvant chemotherapy, radiation therapy, or both chemotherapy and radiation therapy). The cTNM or pTNM category is identified by a “y” prefix. The ycTNM or ypTNM categorizes the extent of tumor

actually present at the time of that examination. The “y” categorization is not an estimate of tumor prior to multimodality therapy (ie, before initiation of neoadjuvant therapy).

The “r” prefix indicates a recurrent tumor when staged after a documented disease-free interval, and is identified by the “r” prefix: rTNM.

The “a” prefix designates the stage determined at autopsy: aTNM.

Additional Descriptors

Residual Tumor (R)

Tumor remaining in a patient after therapy with curative intent (eg, surgical resection for cure) is categorized by a system known as R classification, shown below.

RX	Presence of residual tumor cannot be assessed
R0	No residual tumor
R1	Microscopic residual tumor
R2	Macroscopic residual tumor

For the surgeon, the R classification may be useful to indicate the known or assumed status of the completeness of a surgical excision. For the pathologist, the R classification is relevant to the status of the margins of a surgical resection specimen. That is, tumor involving the resection margin on pathologic examination may be assumed to correspond to residual tumor in the patient and may be classified as macroscopic or microscopic according to the findings at the specimen margin(s).

Lymph-Vascular Invasion (LVI)

LVI indicates whether microscopic lymph-vascular invasion is identified. LVI includes lymphatic invasion, vascular invasion, or lymph-vascular invasion. By AJCC/UICC convention, LVI does not affect the T category indicating local extent of tumor unless specifically included in the definition of a T category.

Regional Lymph Nodes: Isolated Tumor Cells

Isolated tumor cells (ITC) are single cells or small clusters of cells not more than 0.2 mm in greatest dimension. Lymph nodes or distant sites with ITC found by either standard histologic examination, immunohistochemical stains (eg, cytokeratin), or nonmorphological techniques (eg, flow cytometry, DNA analysis, polymerase chain reaction [PCR] amplification of a specific tumor marker) should be so identified. There is currently no guidance in the literature as to how these patients should be coded; until further studies are available, they should be coded as “N0(i+)” with a comment noting how the cells were identified.

Sentinel Lymph Nodes

The sentinel lymph node is the first node to receive drainage from a primary tumor. There may be more than 1 sentinel node for some tumors. If a sentinel node contains metastatic tumor, it indicates that other more distant nodes may also contain metastatic disease. If sentinel nodes are negative, other regional nodes are less likely to contain metastasis.

I. Cervical Abnormalities

Ectropion (erosion, eversion) of the cervix, which is characterized by the appearance of glandular (columnar) epithelium outside the external os of the cervix, is seen in approximately 90% of women exposed to DES in utero (but is often seen in nonexposed women as well). Approximately one-third of patients exposed to DES have 1 or more gross structural abnormalities of the cervix.^{1,4}

J. Fallopian Tubes

The fallopian tubes are abnormal in some women exposed to DES in the form of hypoplasia or defects demonstrated on hysterosalpingographic examination.⁴

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