

STANDARDIZED PROCEDURE

VULVAR BIOPSY

I. Definition

Vulvar biopsy is an office procedure performed using local anesthesia for obtaining a small sample of vulvar epithelium for histologic examination. Methods used for vulvar biopsy in the Ob/Gyn setting are (1) excisional biopsy performed with a cervical biopsy instrument or (2) punch biopsy.

II. Background Information

A. Setting: Select check-off boxes (double click on gray box to select): If Pediatrics are selected make sure Child Life is involved and use age appropriate language and age appropriate developmental needs with care of children

- Adults
- Pediatrics
- Both Adults & Pediatrics

- Inpatient clinical setting
- Outpatient clinical setting
- Both Inpatient & Outpatient clinical setting

B. Supervision: The necessity of this protocol will be determined by the Allied Health Professional in collaboration with the supervising physician or his/her designee. Designee is defined as another attending physician who works directly with the supervising physician and is authorized to supervise the Allied Health Professional.

Direct supervision will not be necessary once competency is determined, as provided for in the protocol. The Allied Health Professional will notify the physician immediately upon being involved in any emergency or resuscitative events or under the following circumstances:

1. Patient decompensation or intolerance to the procedure
2. Bleeding that is not resolved
3. Outcome of the procedure other than expected

C. Indications

Vulvar biopsies may be indicated in the following situations: (1) lesions with thickened skin or color changes; (2) raised, red or pigmented lesions; (3) lesions presumed to be genital warts, particularly those which are not responding to conventional office or home treatment; (4) chronic dermatoses that do not respond to medical therapy; (5) any lesion suspicious for neoplasia, and (6) any lesion with equivocal changes that cannot be reliably diagnosed by visual inspection alone.

Vulvar biopsy may be necessary to differentiate benign from malignant conditions or to establish the diagnosis and proper treatment of acute or chronic vulvar conditions. The decision to biopsy may be instigated by patient symptomatology, such as persistent pain or pruritus, or by the findings of visual or colposcopic lesions. Vulvar lesions that do not spontaneously or therapeutically disappear

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within several weeks or tend to have a chronic course should be followed closely and may need histologic diagnosis.

D. Precautions/Contraindications

Determine if the patient is allergic to Povidone Iodine or either topical or local anesthetic agents.

III. Materials

Mayo stand
Povidone iodine or other topical cleanser
Topical anesthetic such as lidocaine gel
Local anesthetic such as 1% lidocaine drawn up in a 1-3ml syringe with a 27-30 guage needle
Kevorkian or Tischler biopsy forceps or biopsy punches (2-6mm – size determined by size of lesion)
Pick-up forceps
Iris scissors
Guaze sponges
Monsel's solution or silver nitrate sticks
Formalin specimen bottle labeled with patient's name and MRN number

IV. Vulvar Biopsy

A. Pre-treatment evaluation

Identify the area to be biopsied.

B. Set up (if applicable)

See above

C. Patient Preparation

Counsel patient about the procedure: reason for biopsy, determination of any topical allergies, expectations about topical and local anesthesia, care of wound afterward. Answer questions, obtain informed consent, perform timeout .

D. Procedure

1. Clip vulvar hair, if necessary.
2. Apply topical anesthetic, if using.
3. Prepare area with antiseptic solution.
4. Inject tissue with 1% lidocaine or similar local anesthetic to create a small wheal.
5. (Excisional biopsy) Use biopsy forceps to obtain a small segment of tissue.
6. (Punch biopsy) Using the biopsy punch, fix the skin with the nondominant hand and direct the dermatologic punch through the skin into the subcutaneous tissue. The punch is circled in a clockwise fashion until there is release of resistance, indicating that the punch blade is in the subcutaneous tissue. Lift the tissue with the pick-up forceps and use scissors to clip the circular piece of tissue from the subcutaneous area.
7. Cauterize any defect with Monsel's or silver nitrate.
8. Place specimen in labeled formalin container.

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E. Post-procedure

Though unlikely, patient can apply an ice pack if secondary edema occurs. There is generally over the counter analgesics that may be used.

F. Follow-up treatment

Schedule appointment to discuss pathology results and/or future treatment.

V. Documentation

A. Inpatient documentation is in the UCARE procedure note and outpatient will be in the event note.

1. Documentation of the consent, pretreatment evaluation, time out, medications administered, patient tolerance, and follow up care.

B. **All abnormal or unexpected findings are reviewed** with the supervising physician.

VI. Competency Assessment

A. Initial Competence

1. The Allied Health Professional will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.
2. The Allied Health Professional will demonstrate knowledge of the following:
 - a. Medical indication and contraindications of vulvar biopsy
 - b. Risks and benefits of the procedure
 - c. Related anatomy and physiology
 - d. Consent process (if applicable)
 - e. Steps in performing the procedure
 - f. Documentation of the procedure
 - g. Ability to interpret results and implications in management.
3. Allied Health Professional will observe the supervising physician perform each procedure three times and perform the procedure **three** times under direct supervision.
4. Supervising physician will document Allied Health Professional's competency prior to performing procedure without direct supervision.
5. The Allied Health Professional will ensure the completion of competency sign off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.

B. Continued proficiency

1. The Allied Health Professional will demonstrate competence by successful completion of the initial competency.

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2. Each candidate will be initially proctored and signed off by an attending physician. Allied Health Professional must perform this procedure at least **three** times per year. In cases where this minimum is not met, the attending, must again sign off the procedure for the Allied Health Professional. The Allied Health Professional will be signed off after demonstrating 100% accuracy in completing the procedure.
3. Demonstration of continued proficiency shall be monitored through the annual evaluation.
4. A clinical practice outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted.

VII. RESPONSIBILITY

Questions about this procedure should be directed to the Chief Nursing and Patient Care Services Officer at 353-4380.

VIII. HISTORY OF POLICY

Revised Nov 2008 by Subcommittee of the Committee for Interdisciplinary Practice

Reviewed Nov 2008 by the Committee on Interdisciplinary Practice

Approved by Executive Medical Board, Governance Advisory Council
and Chancellor J. Michael Bishop

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