

STANDARDIZED PROCEDURE

DYSPLASIA ASSESSMENT AND TREATMENT (Adult, Peds)

I. Definition:

Dysplasia is an abnormal change in the cells of the cervix which is detectable by routine Pap smear, and represents a precursor of invasive squamous carcinoma. Dysplasia is graded according to the degree of abnormality. The natural history of the disease is unpredictable in a single patient; it may regress, persist at one level, or progress to malignancy.

The Bethesda System is the current method of classifying Pap tests. It gives detailed descriptive information and uses the terms atypia (ASC) low grade squamous intraepithelial lesion (LSIL) for CIN1 and high grade squamous intraepithelial neoplasia (HSIL) for CIN2 and CIN3. In addition, ACG is used for atypical glandular cells.

The following nomenclature is used for grading dysplasia:

Atypical Squamous Cells (ASC): Cellular changes that are more marked than those attributable to reactive changes, but that are short of a definitive diagnosis of squamous intraepithelial lesion (SIL). These are subdivided into two categories:

ASC – US: Atypical Squamous Cells of Undetermined Significance

ASC – H: Atypical Squamous Cells, can't exclude a high-grade squamous intraepithelial lesion.

Mild dysplasia: cervical intraepithelial neoplasia 1 (CIN1)

Moderate dysplasia: cervical intraepithelial neoplasia 2 (CIN2)

Severe dysplasia and carcinoma-in-situ: cervical intraepithelial neoplasia 3 (CIN3)

Dysplasia may develop in the vaginal and vulvar tissue also, and is graded according to the same criteria:

Vaginal intraepithelial neoplasia 1-3 (VAIN 1-3)

Vulvar intraepithelial neoplasia 1-3 (VIN 1-3)

The current theory is that the etiology of dysplasia is multifactorial, but that a dominant agent, the human papilloma virus (HPV) is nearly always present. This virus is sexually transmitted and is also known to cause genital warts (condylomata acuminata). It is felt that other cofactors may be involved in the development of dysplasia, including other vaginal and cervical infections, cigarette smoking and other environmental carcinogens.

Colposcopy:

Patients with abnormal cells on Pap smear, genital warts, and/or other suspicious genital lesions, may be referred for colposcopic examination, endocervical curettage, and directed biopsy. Colposcopy is an examination of the involved

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tissue with a high powered microscope (colposcope). 3-5% acetic acid is first applied to the tissue; this causes the abnormal areas to become more prominent. These abnormal areas are then viewed through the colposcope and biopsied.

II. Background Information

A. Setting: The setting (inpatient vs outpatient) and population (adults vs pediatrics) for the Advanced Health Practitioner (AHP) is determined by the approval of the privileges requested on the AHP Privilege Request Form. If the procedure is being done on a Pediatric patient, make sure Child Life is involved and use age appropriate language and age appropriate developmental needs with care of children, as appropriate to the situation.

B. Supervision:

The necessity of the procedure will be determined by the AHP in collaboration with the attending physician or his/her designee. Direct supervision will not be necessary once competency is determined, as provided for in the procedure. At that time, general or indirect supervision is acceptable.

Designee is defined as another attending physician who works directly with the supervising physician and is authorized to supervise the AHP.

The Advanced Health Practitioner 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
4. Pregnant patient with dysplasia;
5. Atypical vessels of cervix;
6. Any patient with cells suggesting malignancy or invasive cancer on cytology;
7. Any patient with clinical findings consistent with malignancy or invasive cancer.

C. Indications:

Patient requiring biopsy with suspicious lesion.

III. Review patient's chart to evaluate eligibility

Subjective Data:

1. Age, parity, birth control method, last menstrual period, desire for present/future pregnancy
2. Gynecology history: (allergies, date of last Pap smear, DES exposure, history of abnormal Pap smears, history of vulvar, vaginal, or cervical dysplasia,

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history of gyn surgery (including laser, LEEP and cryotherapy), HPV testing, HPV vaccination.

3. Medication history, allergies, blood dyscrasias
4. Sexual history: age at first intercourse, number of sexual partners, history of genital warts in patient or any past or present partners, history of other sexually transmitted infections.
4. Personal/Social history: cigarette smoking, drug or alcohol abuse.

Objective Data

1. External genitalia: note erythema, discharge, gross lesions including condylomata, herpes, leukoplakia;
2. Speculum exam: note discharge, erythema, gross lesions of vagina and cervix, characteristic DES changes (see DES protocol)
3. Colposcopic exam (should be done prior to and after application of 3-5% acetic acid): note lesions of cervix and vagina (white epithelium, mosaic, punctuation, and atypical vessels). Note characteristic DES changes. Note location of the squamo-columnar junction. If it is not visible on the exocervix, an endocervical speculum should be used. Lugol's solution may be used in addition to acetic acid in patients not allergic to iodine.

Assessment

1. Presence of vaginitis/cervicitis and causative agent.
2. Presence of condylomata acuminata, herpes and other STDs.
3. Presence of dysplastic-appearing lesion of the vulva, vagina and cervix.
4. Location, extent and type of lesion.
5. Location of squamo-columnar junction.
6. Presence of characteristic DES changes.

IV. Precautions:

Coagulopathy, active infection present, allergy to iodine

V. Materials

Gloves, biopsy kit, culture supplies, povidone iodine, Monsel's paste, Silver Nitrate, Lidocaine solution, and appropriate solutions for the procedure, such as 3-5% acetic acid and Lugol's solution.

VI. Procedure

A. Pre-treatment evaluation:

Review current laboratory data and evaluate need for procedure.

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B. Set up:

Gather all necessary materials.

C. Patient preparation

Explain procedure and obtain informed consent

D. Perform the Procedure:

1. Diagnostic

- a. Cultures for gonorrhea and chlamydia as indicated, wet prep and treatment of infection as indicated.
- b. Cultures for herpes as indicated.
- c. Repeat Pap smear.
- d. Endocervical sampling when indicated (selected patients with dysplasia on Pap smear, and selected patients after treatment for dysplasia).
- e. Possible biopsy of abnormal areas of vulva, vagina and cervix. Any biopsies of the vulva or lower 1/3 of the vagina should be performed after injection of 1% lidocaine to the area and cleansing with Povidone Iodine solution. Hemostasis of biopsy sites may be achieved with silver nitrate or Monsel's paste.

2. Treatment:

- a. 80% trichloroacetic acid 1-2 x/week to verrucous condylomata of vulva (generally the first treatment of choice), or
- b. 0.5% Podofilox (Condylox) BID x 3 days then off x 4 days up to 4 weeks for verrucous condylomata of vulva (to be applied by patient), or
- c. 5% 5-Fluorouracil (Efudex) cream applied sparingly to flat condylomata of vulva once weekly x 10 weeks (to be applied by patient)
- d. 5% 5-Fluorouracil (Efudex) cream: ½ applicator to vagina nightly x 4 nights, with silicone-based protective ointment to vulva (for biopsy-proven vaginal condylomata)
- e. Cryotherapy to biopsy proven cervical condylomata or dysplasia. (Squamo-columnar junction must be visible, ECC benign, and lesion smaller than 2 quadrants.)
- f. Laser vaporization to biopsy proven condyloma or dysplasia. (Squamo-columnar junction must be visible and ECC benign).
- g. Excisional procedure with LEEP, laser, when colposcopy is unsatisfactory or cold knife cone biopsy when glandular abnormality or microinvasion is present.

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- h. Management of medication as appropriate to clinical expertise.

E. Post-procedure

Referral to MD as needed for patients requiring laser treatment, LEEP, and cervical conization.

Patient/Family Education

In verbal and/or written format, the Advanced Health Practitioner explains to the pertinent party or parties involved the disease process, pertinent signs and symptoms, therapeutic modalities and appropriate follow-up, including but not limited to the following:

- Possible pre-malignant nature of disease and need for close and continuous follow-up;

- Discussion of sexual transmission and need to use condoms;

- Referral of male partners for colposcopic exam to rule out genital warts;

- Discussion of possible relationship of cigarette smoking and other risk factors to dysplasia.

F. Follow-up treatment

- a. Patients with benign colposcopy of vulva, vagina or cervix should return in 6 months for repeat Pap and for some patients, colposcopy. After 2 benign exams, patient may return to schedule of Pap every 6 months-1 year. National guidelines dictate the time appropriate intervals.

- b. Patients who have been treated will have the following post-treatment visits:

- Pap smears every 6-to-12 months.

- When the surgical margins are positive, an ECC may be added to the follow-up exam.

The guidelines and algorithms for follow-up and management of the post treated patient are reviewed and updated regularly with evidence based recommendations. These detailed recommendations and algorithms are available on the ACOG and ASCCP websites and are too detailed to include in this document.

- c. Non compliant patients not keeping follow-up appointments will be telephoned once, then sent two letters urging that they receive follow-up care.

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VII. Documentation

- A. Documentation is in the electronic medical record
1. Documentation of the pretreatment evaluation and any abnormal physical findings.
 2. Record the time out, indication for the procedure, procedure, EBL, the outcome, how the patient tolerated the procedure, medications (drug, dose, route, & time) given, complications, and the plan in the note, as well as any teaching and discharge instructions, as well as the follow-up plan.
- B. **All abnormal or unexpected findings are reviewed** with the supervising physician.

VIII. Competency Assessment

A. Initial Competence

1. The Advanced Health Practitioner will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.
2. The Advanced Health Practitioner will demonstrate knowledge of the following:
 - a. Medical indication and contraindications of Dysplasia Assessment and Treatment
 - 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. Advanced Health Practitioner will observe the supervising physician perform each procedure three times and perform the procedure **three** times under supervision if colposcopy procedure is not involved. See colposcopy procedure if colposcopy is needed.
4. Supervising physician will document Advanced Health Practitioner's competency prior to performing procedure without supervision.
5. The Advanced Health Practitioner 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.

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B. Continued proficiency

1. The Advanced Health Practitioner will demonstrate competence by successful completion of the initial competency.
2. Each candidate will be initially proctored and signed off by an attending physician. Advanced Health Practitioners must perform this procedure at least **three** times per year if colposcopy is not involved. See colposcopy procedure if colposcopy is needed.
In cases where this minimum is not met, the attending, must again sign off the procedure for the Advanced Health Practitioner. The Advanced Health Practitioner 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 PROCEDURE

Revised March 2012 by Subcommittee of the Committee for Interdisciplinary Practice

Reviewed March 2012 by the Committee on Interdisciplinary Practice

Prior revision Sept 2009

Approved March 2012 by the Executive Medical Board and the Governance Advisory Council.

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