

STANDARDIZED PROCEDURE

HIGH RESOLUTION ANOSCOPY (HRA) (Adults, Peds)

I. Definition

High Resolution Anoscopy (HRA) is the visualization of the anus and perianus anal mucosa through a colonoscope using acetic acid and Lugol's solutions. The purpose of HRA is to identify squamous epithelial lesions that may require biopsy to determine the diagnosis for treatment triage. Anal biopsy is the removal of a sample of rectal anal mucosal tissue for pathology evaluation via anoscopy. Practitioners must be experienced HRA providers and/or have completed a colonoscopy training in HRA prior to approval of this standardized procedure. HRA training may include an HRA course, and observed preceptorship of 50 HRA exams. Competency will be determined by an experienced UCSF HRA attending (> 5 years experience).

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 verbal 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 experienced UCSF HRA attending physician with > 5 years HRA experience, who works directly with the supervising physician and is authorized to supervise the AHP.

The AHP will notify the physician immediately upon being involved in any emergency or resuscitative events, or under the following circumstances:

1. If the patient has disease that is clinically suspicious for cancer;
2. If the histology results are unclear;
3. If the histology diagnosis is cancer;
4. If the patient requires follow up that deviates from the clinical protocols;
5. If hemostasis cannot be achieved following the biopsy, or
6. If a patient calls in complaining of uncontrolled bleeding or symptoms of infection following a biopsy.

C. Indications

Clinical indications for HRA include: an abnormal anal Papcytology (>ASCUS), patients considered to be in a high-risk population for anal cancer, presence of an abnormal or suspicious lesion, presence of an anal rectal mass, bleeding, hemorrhoids, fissures, or per Clinical Research protocol or for follow-up of any of these conditions.

STANDARDIZED PROCEDURE
HIGH RESOLUTION ANOSCOPY (HRA) (Adults, Peds)

D. Precautions/Contraindications

Patients with known neutropenia, platelet counts below 60,000, patients receiving anti-coagulant therapy, and patients with coagulation disorders will be examined but not biopsied. Patients with a history of mitral valve prolapse, heart murmurs, or recipients of artificial heart valves will receive prophylactic antibiotic therapy if indicated prior to a biopsy. The AHP will consult with the supervising physician if clarification is needed.

Other precautions/contraindications include:

1. Clinical instability (for example, uncontrolled high blood pressure or psychiatric states which preclude informed consent) will be referred for appropriate care and not examined.
2. Untreated rectal infection with copious discharge or severe pain will be treated presumptively after STI testing or referred for treatment and HRA will be deferred. If appropriate, the HRA will be performed and biopsies deferred until the infection is treated. STI testing will be performed as defined by the research protocol in advance of the biopsy procedure.
3. Presence of internal hemorrhoids, ulcerations, and/or lesions or masses that preclude the ability to insert an anoscope. In most cases these patients will be referred to colo-rectal surgery for evaluation.

III. Materials

A. Equipment

1. Colposcope
2. Biopsy forceps and punch

B. Exam supplies

1. Polyester swabs, cytobrushes, liquid cytology medium
2. 3-5% Acetic Acid
3. Lugol's Solution
4. Monsel's Solution (for hemostasis)
5. Cotton tip applicators and scopettes
6. 4X4 gauze pads
7. Biopsy specimen bottles with fixative
8. Silver Nitrate applicators (for hemostasis)
9. 30 gauge needle with syringe for administering injectable Lidocaine
10. 1-2% injectable Lidocaine HCL injection single dose vial with and without Epinephrine
11. Liquid Nitrogen
12. Trichloroacetic Acid 85%
13. 2-5% Lidocaine cream or gel

STANDARDIZED PROCEDURE
HIGH RESOLUTION ANOSCOPY (HRA) (Adults, Peds)

IV. Anal High Resolution Anoscopy (HRA)

A. Pre-treatment evaluation

Patients will be questioned and history will be reviewed for prior abnormal cytology or diagnosis and treatment of anogenital disease (e.g. condyloma, intra-epithelial lesions of the lower genital tract, or cancers), HPV testing, or HPV vaccination.

Patient's history will be reviewed for general health, comorbid conditions such as HIV infection or other immunosuppression, medications, and allergies, especially iodine.

Patients with iodine or shellfish allergies will not have Lugol's solution used.

There should be a negative pregnancy test if born female.

B. Set up

Room will be cleaned and colposcope disinfected with Cidex prior to each exam. Forceps will be sterilized in central supplies according to current standards.

Clean area with clean gloves, 4X4 gauze, lubricant, scopettes, anoscope, sterile biopsy punch, toothpicks, specimen medium.

C. Patient Preparation

Explain HRA rectal biopsy/anoscopy procedure to participant.

Have patient undress from waist down and cover with drape. Position on side.

Patients will be examined initially in the left lateral position. Occasionally the patient requires repositioning to the right lateral, lithotomy, or prone position.

D. Procedure

1. Cytology specimen: A Dacron or polyester swab will be inserted 2-3 inches into the anal canal and rotated while removing it. The swab will be placed in a liquid cytology specimen container. Adjunctive clinical HPV testing will be performed using the cytology specimen if indicated.
2. HPV testing if needed per research protocol: A second Dacron or polyester swab will be inserted 2-3 inches into the anal canal and rotated while removing it. The swab will be placed in a culture medium for HPV testing. Separate HPV testing is performed only if clinically indicated or by study protocol.
3. If STD cultures are indicated the appropriate swabs will be performed. The clinician will refer the patient to their primary care provider or Public Health Clinic for rapid testing if indicated, but are not provided by the study protocol.
4. A digital anal rectal examination will be performed using lubrication.

5. The anoscope will be inserted into the anus with additional lubrication. The obturator will be removed and followed by the insertion of a gauze pad wrapped around a q-tip and soaked in 3-5% acetic acid. The gauze swab with acetic acid will be left in place for one to two minutes after the anoscope is removed. The gauze swab with acetic acid will then be removed and the anoscope re-inserted.
6. The HRA examination will be performed using the colposcope for lighting and magnification. Acetic acid will be continually applied to the anal mucosa using

STANDARDIZED PROCEDURE

HIGH RESOLUTION ANOSCOPY (HRA) (Adults, Peds)

cotton swabs to visualize all aspects of the anal canal. Lugol's solution will be used as needed to further identify and characterize lesions.

7. Lesions with the colposcopic appearance of LSILLGAIN, HGAINSIL or cancer may be biopsied if there is no contraindication (see above). Generally 1 –3 biopsies will be performed, but occasionally 3-5 biopsies may be taken. Internal intra-anal biopsies will not require anesthesia but external peri-anal lesions will be pre-anesthetized with 1-2% injectable lidocaine. Biopsies will be performed using a surgically sterile forceps or biopsy punch. The specimen will be placed in formalin and cataloged according to location.

E. Post-procedure

If needed, hemostasis will be achieved by applying pressure with a scopette, Monsel's solution or a silver nitrate stick.

Assess the participant for comfort and stability. Observe for signs of vasovagal reaction.

Advise participant to wait 3 days before taking aspirin and anti-inflammatory medications.

Instruct participant patients to put nothing in rectum for 7 days after the procedure or until bleeding stops.

Instruct the participant to observe for abnormal bleeding, signs/symptoms of infection, pain and to call the research clinician or on call pager if any problems arise.

F. Follow-up treatment

Patients will be informed of their results, and recommendations for follow up or treatment will be discussed. If AHP or patient determines it is necessary, the patient will return to clinic for consultation regarding the results. Referring providers will be informed by letter of results. If more urgent communication is deemed appropriate by the AHP, the referring provider will be contacted by telephone or secure email. Patients with newly diagnosed disease will be called with results. Patients with stable unchanged disease will be informed by letter. Patients will be given the AHP or MD pager numbers for backup

1. Research patients will be followed according to approved CHR study protocols.
2. Non-research patients:
 - a. Diagnoses of limited focal SIL, LGAIN, or HGAIN may be treated according to standard protocols using ablative therapy for cervical, vaginal or vulvar dysplasia. This may include Trichloroacetic (TCA) 85% for intra-anal or peri-anal lesions and/or with Liquid Nitrogen for peri-anal lesions. TCA and/or liquid nitrogen will be applied directly to the lesions. Treatments may be repeated up to 4 treatments 3-4 times apart. If there is no response, a different treatment should be used.
 - b. Perianal LGAIN may be treated with self-applied therapies including;
 1. Condylox 0.5% gel applied BID X 3 days then off 4 days and repeated up to 4 weeks. If no response or intolerable inflammation, a different treatment should be used.

STANDARDIZED PROCEDURE
HIGH RESOLUTION ANOSCOPY (HRA) (Adults, Peds)

2. Veregen 15% ointment applied TID continually up to 16 weeks. If no response or intolerable inflammation, a different treatment should be used.
 3. Aldara 5% - apply one packet at night every other day 3 times per week and continue up to 12 weeks. If no response or intolerable inflammation, a different treatment should be used.
- c. Patients with larger intra-anal or peri-anal lesions may be treated with Infra-red coagulation (see IRC protocol).
 - d. Patients with circumferential HGAIN and/or circumferential disease or not considered appropriate for physical ablation may be treated with self-applied Efudex 5% cream in the following protocol: ¼ " applied to each affected area (e.g. intra-anal left, right, Peri-anal left, right). A maximum of 1 " will be applied if all 4 areas have HGAIN. The cream will be applied BID for 5 days, then no treatment for 9 days and continued in two week cycles up to 16 weeks. Patients will be examined after 4 cycles. Patients will discontinue medication if there is severe irritation.
 - e. Patients with LGAIN or HGAIN that is not considered amenable to office ablation or self-applied therapy will be referred to a proctologist or the dysplasia clinic for treatment consultation.
 - f. Patients diagnosed with anal cancer will be referred for appropriate standard of care treatment.
 - g. New therapies for LGAIN and/or HGAIN that become available will be considered in consultation with the supervising physician.

V. Documentation

- A. Written record** reflects prior history relevant to the procedure, description of findings, adequacy of exam (an adequate exam is defined as the entire anal transition transformation zone, distal canal, and perianus visualized), or reason for inadequate exam, location of biopsies, clinical impression of disease status, and recommendations for follow-up, treatment or referral.

Documentation is in the electronic medical record

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1. Documentation of the pretreatment evaluation
 2. Record the time out, procedure, EBL, the outcome, patient tolerance, medications given, and the plan in the note, as well as any teaching and discharge instructions.
- B.** Expected findings can be managed independently per protocols as described above. **All abnormal or unexpected, equivocal, or suspicious for cancer findings** are reviewed with supervising physician.

STANDARDIZED PROCEDURE
HIGH RESOLUTION ANOSCOPY (HRA) (Adults, Peds)

VI. Competency Assessment

A. Initial Competence

1. The Advanced Health Practitioner will have completed a course in High Resolution Anoscopy. AHPs without prior gynecologic colposcopy will also have completed a basic colposcopy course. There is no current national HRA certification at this time. The AHP 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 high resolution anoscopy and 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. Each Advanced Health Practitioner is to directly observe this procedure as per the colposcopy advanced procedure.
4. AHPs with no prior HRA or gynecologic colposcopy experience will complete a colposcopy training program which includes four days of didactic material and a practicum. Additionally, a preceptorship is completed, which involves a supervised performance of at least **50** colposcopic HRA exams and **50** biopsies. AHPs with prior gynecologic colposcopy experience will complete a preceptorship which involves supervised performance of at least **25** HRA procedures and at least **15** biopsies. Supervision will be provided by the supervising or designee, and will be with an experienced attending with >5 years HRA experience. During the supervised preceptorship, the AHP will be given instruction on performing HRA similar to a residency program. At the end of the preceptorship, the AHP will have gained the skills necessary to perform HRA competently at a novice level. At the end of this preceptorship, colposcopists are tested and evaluated for competency.
5. AHPs with HRA experience obtained prior to employment at UCSF will be evaluated per section 6 below. Additional supervised preceptorship will be determined at the discretion of the supervising physician or designee. At the end of this preceptorship, colposcopists are tested and will be evaluated for competency by an experienced HRA attending (more than 5 years experience). The AHP will be evaluated performing **8** HRA procedures, with at least **6** requiring biopsies. This evaluation will determine whether the AHP is considered competent to provide HRA independently at UCSF.
6. Colposcopists must perform at least **50** treatments/procedures under the direct observation of a supervising physician or designee before certification is issued. A minimum of **10** high-grade squamous intraepithelial (HSIL) must be included.
7. Certification in basic colposcopy must be completed within a year of employment.

STANDARDIZED PROCEDURE
HIGH RESOLUTION ANOSCOPY (HRA) (Adults, Peds)

Designee is defined as another attending physician who works directly with the supervising physician and is authorized to supervise the Advanced Health Practitioner and has > 5 years experience in HRA.

A copy of the signed competency certificates will be retained by the practitioner's department for the personnel file and will also be sent to the medical staff office for the credentialing file.

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 Practitioner must perform this procedure at least **sixty** times per year (on average 5/month). 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 documentation of the 60 minimum required procedures per year, and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted. In addition, the AHP will provide an approximate number of total procedures performed per year.
5. The AHP will be observed performing 4 HRA procedures at the discretion of the supervising physician every 2 years to maintain privileges.

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 February 2012 by Subcommittee of the Committee for Interdisciplinary Practice

Reviewed February 2012 by the Committee on Interdisciplinary Practice

Prior revision April 2009

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

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