



VIRTUAL
2020 NATIONAL
RYAN WHITE
CONFERENCE ON
HIV CARE & TREATMENT

Anal Dysplasia Program From Dream to Reality & Lessons Learned

Yvonne G. Newberry, MSN, FNP-BC

Lauren Woodberry, MSN, FNP-C, ACRN

Laura Quass-Ferdinand, MPH, BSN, RN



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I have no disclosures

Objectives



- Review Human papillomavirus (HPV) infection and sequelae
- Review unofficial anal cancer screening recommendations
- Discuss current UVA Ryan White High Resolution Anoscopy (HRA) Clinic recommendations for anal cancer prevention, screening, evaluation, treatment, and follow-up
- Discuss the process for establishing a High Resolution Anoscopy (HRA) Clinic
- Share lessons learned from our experience in the UVA Infectious Diseases (ID) Ryan White HRA Clinic

Human Papillomavirus (HPV)

Human Papillomavirus (HPV) Related Cancers are Preventable



Every year in the United States, 34,800 women and men are estimated to be diagnosed with a cancer caused by HPV infection.

Although cervical cancer is the most well-known of the cancers caused by HPV, there are five other types of HPV cancer that are on the rise.

Cervical cancer is the only type of HPV cancer with a proven screening test to detect it at an early stage.

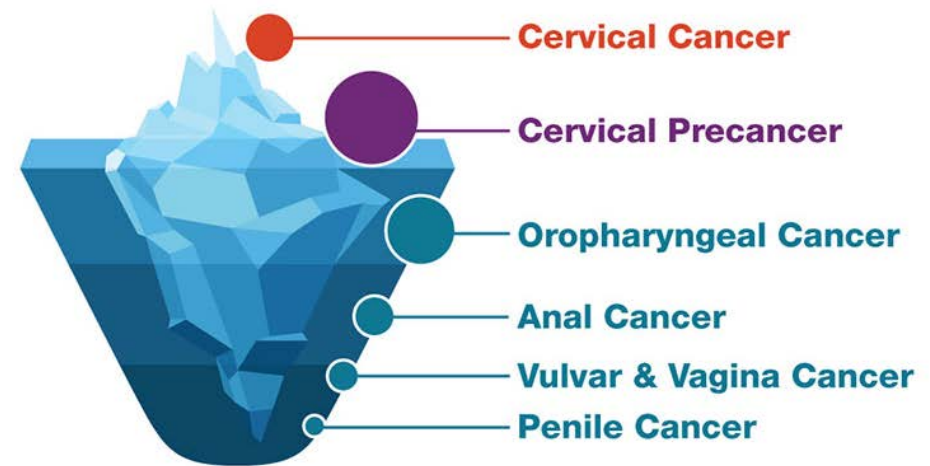
Anal Cancer has the ANAL PAP as a screening test but the guidelines do not have the scientific evidence to support the screening test at this time.

Vulvar, Vaginal, and Penile cancers may be found when screening for cervical and anal cancers.

Unfortunately, there are no screening tests available at this time for oropharyngeal cancers until they cause health problems.

HPV vaccination could prevent more than 90% of cancers caused by HPV—estimated to be 32,100 cases ever year—from ever developing.

Screening Won't Protect Your Patients from Most HPV Cancers



Every year in the U.S., there are:

13,500 Oropharyngeal Cancer cases

6,200 Anal Cancer cases

3,400 Vulvar & Vaginal Cancer cases

800 Penile Cancer cases

Who Gets HPV?



- Human papillomavirus (HPV) is a very common STD/STI
- Estimated 80 percent of sexually active people contract HPV at some point in their lives
- HPV can infect anyone who has ever had a sexual encounter-oral/anal/vaginal/penile
- HPV is the cause of genital warts which usually appear in the groin area-these are low risk HPV types 6 and 11 that typically do not progress into cancers
- HPV strains 16 and 18 and other high risk strains are more likely to cause cancer in the cervix, vagina, vulva, penis, anus, and oropharynx.
 - **High-risk HPV types** (constantly evolving) include **types 16, 18, 31, 33, 34, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68, and 70.**
 - Most cervical/vaginal/anal HPV typing includes **16/18/45** at this time
- Many people who become infected with HPV will not have symptoms and will clear the infection on their own.
- However, **HIV positive people or people who are immunocompromised** may take longer to clear the HPV infection or may never clear the virus regardless of how well their HIV is controlled, thus increasing their risk of developing HPV related cancers.

How is HPV transmitted?



- HPV is a STD or STI
- HPV can be passed from person to person, even when there are no signs of infection.
- Although condoms do reduce the chance of infection, they don't offer complete protection against the virus since HPV can be easily spread by skin-to-skin contact with areas of the body not covered by condoms.
- Because HPV is spread through skin-to-skin contact, both men and women who are sexually active are at risk for getting HPV.
- **MYTH: One has to have anal sex to acquire ANAL HPV!**

Is there a cure for HPV?



- Unfortunately, we have no cure for HPV at this time.
- The **good news** is that people with an intact immune system who become infected with HPV often clear the virus on their own (which means that the virus won't cause them any long term harm).
- The **bad news** is men and women with HIV or any immunocompromising process have a harder time clearing HPV thus exposing them to persistent HPV and increasing their risk of developing HPV related pre-cancers (dysplasia) or cancers.
- Once HPV causes cellular changes such as dysplasia, we are able to treat the lesions caused by HPV to decrease the viral burden and increase their chances of clearing of the virus and preventing the progression to cancer.
- **The key to controlling HPV in the population is prevention with the HPV vaccine prior to becoming sexually active!**

ANAL PAP Screening Recommendations

Why not just start ANAL PAP's Like Cervical PAP's?



- Screening to prevent cervical cancer in women began in the 1950s without any proof whatsoever that PAP smears and treatment of cervical dysplasia would help prevent cancer.
- But....Cervical Cancer rates have decreased dramatically due to PAP SMEAR screening and treatment of dysplasia.
- We live in a very different health care environment today. To integrate a new screening test or procedure into routine health care guidelines there must be **evidence-based** clinical trials.
- Hence the **ANCHOR STUDY**

The ANCHOR Study



- **ANCHOR** stands for
 - **Anal Cancer HSIL Outcomes Research**
 - **Began in April 2015**
 - **High Grade biopsies with HRA Randomized to observation/electrocautery/5-Fluorouracil cream**
- The researchers involved in the ANCHOR study have been stuck in a “catch-22 situation”.
- They know that the precursor lesion High Grade Squamous Intraepithelial Lesion (HSIL) exists.
- They know its treatment prevents cervical cancer, but the research funders, insurers and health care professionals need evidence that we can also prevent anal cancer this way.
- The only way to do this is to randomly assign participants to one of two groups, one treated and the other monitored, to see which group has the most cases of cancer.
- The ANCHOR study was designed to provide this evidence and to establish the standards of care to prevent anal cancer.

Current Recommendations...



- To quote Dr. Joel Palefsky, UCSF, ANCHOR STUDY, Principal Investigator
 - "It's a chicken and egg kind of situation right now. We haven't yet established that the procedures to detect anal pre-cancers and early signs of anal cancer should be standard of care. This is because we don't have firm evidence that they are beneficial. Our approach at UCSF has been to assume that early screening is beneficial until research tells us otherwise."
- This is the premise we assumed at UVA in the Infectious Diseases/Ryan White Clinic when we embarked on operationalizing our dream of a high resolution anoscopy (HRA) clinic.

UVA Infectious Diseases / Ryan White HRA Program

UVA HRA Clinic stats



- **Total number of Active patients in our clinic (as of July 2020): 866**
 - Men: 624
 - Women: 230
 - Transgender MtF: 10
 - Transgender FtM: 1
- **Number of patients that are eligible for ANAL PAP screening (age \geq 30, as of July 2020): 767**
 - Men: 552
 - Women: 206
 - Transgender MtF: 8
 - Transgender FtM: 1
- **Number of patients that have had anal pap screening since the clinic opened (Dec 2017-July 2020): 271**
 - Men: 122
 - Women: 143
 - Transgender MtF: 6
 - Transgender FtM: 0
- **Number of patients that have had ANAL PAP/HPV screening since first recorded in CAREWARE (Nov 2011-July 2020): 739**
 - Men: 527
 - Women: 202
 - Transgender MtF: 10
 - Transgender FtM: 0
- **Number of patients that have had HRA since the clinic opened (Dec 2017-July 2020): 100**
 - Men: 65
 - Women: 33
 - Transgender MtF: 2
 - Transgender FtM: 0
- **Number of patients that have had Hyfreccation since the clinic opened (Dec 2017-July 2020): 35**
 - Men: 29
 - Women: 6
 - Transgender MtF: 0
 - Transgender FtM: 0

UVA Ryan White HRA Clinic Recommendations for Anal Cancer Prevention/Screening/Evaluation/Treatment/Follow-up

Prevention

VACCINATE...VACCINATE!!!



- HPV Vaccine-Gardasil 9
 - 3 injections over 6 month period of time if age 15 or older
 - If younger than 15 only 2 doses
 - Now approved for up to age 45
 - Will not protect against HPV types you already have but not likely that you have **all 7** of the high risk types that it covers
 - Protection is expected to be long-lasting.
 - Effectiveness of the vaccine
 - The vaccine (Gardasil 9) is highly effective.
 - The HPV vaccine provides almost **100% protection** from **nine HPV** types (6, 11, 16, 18, 31, 33, 45, 52 and 58), if all doses are received at the correct intervals, and if it is given before you have an infection with these types.

- Condoms
 - Only protect what they cover
- Keep your immune system as healthy as possible
 - Take your HIV medications to maintain the best possible CD4 and VL
 - Do not smoke tobacco as it weakens the immune system and makes it more difficult to clear HPV





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SCREENING



TABLE 1. Summary of Recommendations

Risk group category	Recommendation ^a
HIV-infected women	<p>Screening for anal cancer with DARE and routine assessment for the development or change in anal cancer symptoms such as pain or bleeding that might suggest cancer, with prompt referrals if positive for either.</p> <p>Given their high incidence of anal cancer, some experts recommend routine screening for, and treatment of, AIN2/3 in this population in an effort to reduce their risk of anal cancer.</p> <p>Screening may include anal cytology with referral for HRA-guided biopsies, followed by treatment of biopsy-proven AIN2/3. The efficacy of this approach to prevent anal cancer has not yet been studied; a clinical trial is in progress to determine if screening and treatment of anal AIN2/3 in this population should become standard of care.</p>
Women with organ transplant	<p>Screening for anal cancer with DARE and routine assessment for the development or change in anal cancer symptoms such as pain or bleeding that might suggest cancer, with prompt referrals if positive for either.</p> <p>Further research is recommended on screening for, and treating AIN2/3 to reduce the risk of anal cancer in this population</p>
Women with systemic lupus erythematosus and Crohn disease	<p>Screening for anal cancer with DARE and routine assessment for the development or change in anal cancer symptoms such as pain or bleeding that might suggest cancer, with prompt referrals if positive for either.</p> <p>Further research is recommended on screening for, and treating AIN2/3 to reduce the risk of anal cancer in this population</p>
Women with vulvar cancer or high-grade VIN	<p>Screening for anal cancer with DARE and routine assessment for the development or change in anal cancer symptoms such as pain or bleeding that might suggest cancer, with prompt referrals if positive for either.</p> <p>Some experts recommend routine screening for, and treatment of, AIN2/3 in an effort to reduce the risk of anal cancer in this population. The efficacy of doing so has not yet been shown in this population and screening is not yet standard of care.</p>
Women with cervical or vaginal cancer or high-grade CIN or VaIN	<p>Screening for anal cancer with DARE and routine assessment for the development or change in anal cancer symptoms such as pain or bleeding that might suggest cancer, with prompt referrals if positive for either.</p> <p>Some experts recommend routine screening for, and treatment of AIN2/3 to reduce the risk of anal cancer in this population. The efficacy of doing so has not yet been shown in this population and screening is not yet standard of care.</p>
Healthy women with none of the risk factors above	<p>No screening for anal cancer or AIN2/3 is recommended at this time.</p> <p>Prompt referral for further diagnostic work-up if symptoms of anal cancer (pain and bleeding) are present.</p>

^aProviders should screen with cytology only if referrals to HRA and HRA-guided treatment are available.

SYSTEMATIC REVIEW, META-ANALYSIS, NARRATIVE REVIEW

Screening for Anal Cancer in Women

Anna-Barbara Moscicki, MD,¹ Tyrone M. Darragh, MD,² J. Michael Barry-Lovstrom, MD,³ Jennifer M. Roberts, MBBCh, FRCPA,⁴ Minnie J. Khan, MD, MPH,⁵ Lori A. Bourdoin, MD, ScM,⁶ Elizabeth Chiao, MD, MPH,⁷ Mark H. Einstein, MD, MS, FACUG, FJCS,⁸ Stephen E. Goldstone, MD,⁹ Naama Jiv, PhD,¹⁰ Wendy M. Liles, PhD, DNSc, APRN-BC,¹¹ Elizabeth A. Sella, MD,¹² Mark L. Wilson, MD, MHCMA,¹³ Dorothy J. Wiley, PhD,¹⁴ and Joel M. Palefsky, MD¹⁵

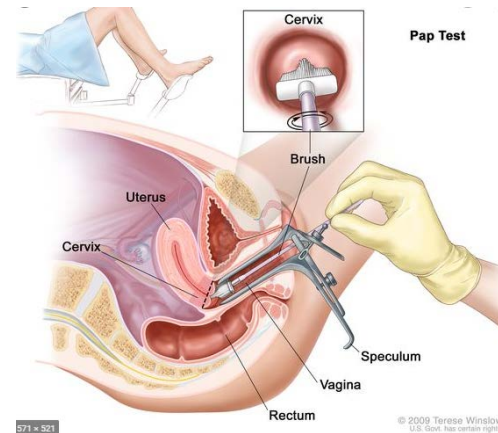
Specific to Women Living with HIV

- **Cervical or Vaginal PAP's**

- Cervical PAP's beginning at age 21 or when HIV diagnosed if younger than 21
- Once have 3 negative PAP's every year x 3 can then repeat every 3 years
- HPV screening with typing of 16/18/non-16/18 can be done with any PAP but not necessarily recommended until age 30 but in our clinic we do **HPV testing with all PAP's on women living with HIV**
- Post Hysterectomy should still continue screening with PAP/HPV at least every 3 years especially if any prior history of HSIL PAP's in past as can get vulvar or vaginal HPV related changes.

- **ANAL PAP & HPV & DARE (digital anorectal exam)**

- Annually beginning at age 30-35
- Regardless of whether ever had anal sex or not
- Cytobrush in anus x 30 seconds
- What we are doing at UVA
 - If 2 negative ANAL PAP's and 3 negative CERVICAL PAP's then repeat ANAL and CERVICAL PAP and HPV every 3 years
 - If abnormal CERVICAL / VAGINAL PAP or ANAL PAP – Repeat both ANNUALLY with HPV



Gonorrhea & Chlamydia Screening in Women



- Three point Gonorrhea and Chlamydia PCR
 - Oral /Anal/Vaginal (or Urine if no pelvic exam)
 - Annually
 - New partner(s)
 - Symptoms

Specific to Men Living with HIV



- ANAL PAP and HPV and DARE (digital anorectal exam)
 - Annually beginning at age 30-35
 - Regardless of whether having anal sex or not
 - MSM
 - Heterosexual
 - Bisexual
 - Transgender
 - At anytime when a patient or clinician finds a lesion either perianal or inside the anus or has anal bleeding or pain.
- Three point Gonorrhea and Chlamydia testing
 - Oral/Anal/Urine
 - Annually
 - New partner(s)
 - Symptoms

Oral HPV Screening



- No current screening options available
- If practice oral sex and have persistent sore throat that does not improve
 - Consider Oral testing for Gonorrhea and Chlamydia
 - Consider seeing an Otolaryngologist or ENT specialist for further evaluation for oral HPV

Evaluation & Treatment

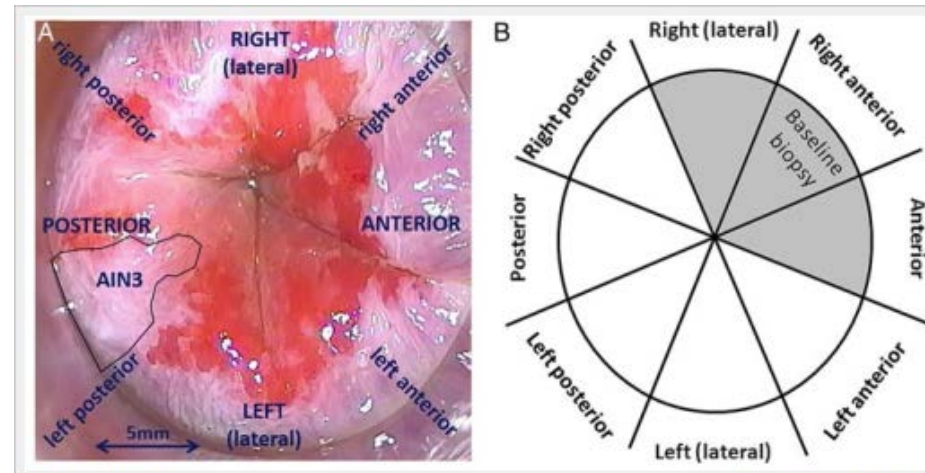
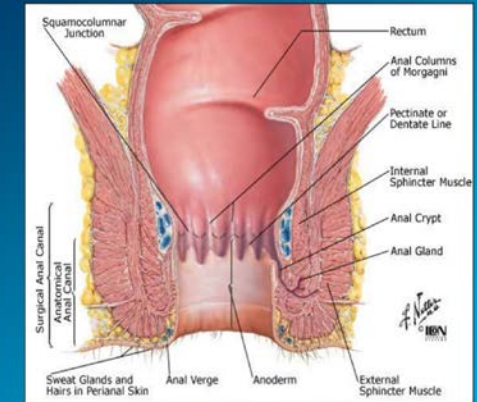
- Abnormal ANAL PAP → HRA
 - PAP/Cytology
 - ASCUS – Atypical Squamous Cells of Undetermined Significance
 - LSIL – Low Grade Squamous Intraepithelial Lesion
 - HSIL – High Grade Squamous Intraepithelial Lesion
 - HPV
 - HRHPV + for 16 or 18 or 16 and 18 or Non 16/18
 - Normal PAP → repeat PAP/HPV in 1 year
 - Abnormal PAP → HRA

High Resolution Anoscopy - HRA

- Office Procedure
- Mild sedation – Xanax or Valium 30 minutes prior to procedure
- Left Lateral Position +/- same as when had ANAL PAP
- Repeat anal Gonorrhea and Chlamydia
- Repeat ANAL PAP
 - If not in last 6 months
- DARE-Digital Anal Rectal Exam
- Insert plastic anoscope
- Place Acetic Acid followed by Lugol's solution
- Look with Colposcope
- Take biopsies of areas of concern
- Examine all 8 octants if possible



Anatomy



Treatment



- If biopsies are negative/normal → repeat ANAL PAP/HPV in 12 months
- If biopsies are low grade → repeat ANAL PAP/HPV and HRA in 12 months
- If biopsies are high grade → HRA with Hyfrecation/Ablation or Topical (5-FU or Aldara)
- Hyfrecation/Ablation
 - Office procedure as long as
 - Patient is open to having procedure in office
 - Patient is not overly anxious
 - Extensive perianal lesions are not present
 - If not an office candidate, the procedure is done in the outpatient surgery center
 - Mild Sedation – Xanax or Valium
 - Local anesthesia prior to treating
 - 1% lidocaine with epi (0.8cc) + 8.4% Sodium Bicarbonate (0.2cc)
 - 1 cc syringe with 1.25” 27 gauge needle
 - Use of electrocautery to destroy abnormal cells
 - Does not cure HPV but may destroy some of the cells that contain HPV so less HPV burden



Follow-up after Treatment



- Repeat HRA in **3-6 months**
 - If all octants with high grade biopsies are treated can f/u in 6 months
 - If too extensive to treat all octants with high grade biopsies may need to f/u in 3 months
 - If patient cannot tolerate HRA long enough to treat all octants may f/u in 3 months
- Once all octants have been treated - usually repeat HRA every **6 months** until biopsies are consistently low grade or negative and then can extend f/u interval to **12 months**
- At repeat HRA's will often repeat biopsies of prior octants and treat in same session

Topical Treatments



- When to use
 - Pt does not desire ablation
 - Pt has extensive high grade disease requiring debulking prior to ablation
 - Pt has perianal lesions

Imiquimod/Aldara



- Apply one packet to a gloved finger and apply intra-anally
- Repeat the process immediately with the opposite hand
- Treat once a day on M/W/F for 16 weeks
- Do a non-HRA "check-in" around 4-8 weeks just to be sure that they are doing OK
- Anal irritation is a side effect and sometimes they can get flu-like symptoms if they use too much and put it too far in (although almost never counsel against this because almost no one goes too far in and tons of people don't go far enough!)
 - Amount to dispense: (\$173/box of 24 packets from pharmacy)
 - 24 packets per month/8 weeks with refill x 1
 - 48 packets for entire 16 weeks

5-Fluorouracil/Efudex



- Can be used to treat perianal and intra-anal warts and dysplasia.
- Use the cream twice daily for five days, and then you will have nine days off (no treatment). This is a two week cycle. You may experience some pain and irritation, if this is the case then please call and we will adjust your treatment regimen.
- On treatment days, place one inch of cream on a gloved finger.
- Insert cream into anus up to your second knuckle and spread it all around in the inside.
- Do this once in the morning and once at night.
- If any warts on the outside then apply 1/4 inch of cream to these.
- Avoid rubbing the cream onto normal skin.
- Use zinc oxide (diaper rash cream) to protect the skin.
- One “cycle” of therapy lasts for two weeks.
- The following Monday start at the top and begin treatment again, this would be the beginning of “cycle two”.
- After four cycles (or eight weeks) of therapy, stop treatment, then come back for a repeat HRA examination two weeks after being off of therapy.
- Cost of one 40 gram tube ranges from \$99 - \$287 (not including insurance coverage or Good Rx coupon)

Sinecatechins



- We do not use as cost prohibitive at this time
 - Cost of one 30 gram tube ranges from \$1600 - \$1709 (without insurance or Good Rx coupon)
 - Even with Good Rx coupon the cheapest price is \$1327.

IMIQUIMOD vs 5-FU vs SINECATECHINS



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- Cost is an obvious consideration
- If there is a fair amount of concurrent condyloma-imiquimod may be better.
- If the patient has trouble with the 5-FU "on/off" schedule go with imiquimod
- If the CD4 count is low (<200) avoid imiquimod as does not work as well

Process for Setting Up HRA Clinic



- Apply for and secure Ryan White Grant Funding
- Visit one of the ANCHOR Study Sites
 - Meet with staff
 - Observe in the clinic
 - Discuss available support for you as you begin to establish your clinic
- Join appropriate Societies
 - ASCCP - American Society for Colposcopy and Cervical Pathology
 - IANS – International Anal Neoplasia Society
- Identify Providers
 - Provider Credentials
 - Education – MD/NP/PA
 - Specialty - ID/Colorectal Surgery/OB-GYN
- Training of Providers
 - ASCCP or IANS HRA course(s)
 - Practical experience – Anchor Study Site Providers
 - Explore credentialing in the institution
- Space
 - Identify a room large enough to easily and safely accommodate your equipment

- Equipment
 - Table (adjustable height with stirrups)
 - Chair for provider (with back and adjustable height)
 - Cart on wheels (with lock for storage of supplies)
 - Mayo Stand
 - Board (to rest on top of table stirrup to support patient's legs)
 - Hyfrecator
 - Smoke Evacuator
 - Colposcope (needs ability to take and save photos)
 - Monitor for Colposcope
 - Monitor for Comparison Photos from prior HRA's
- Instruments
 - Mini-Tischler forceps
 - Nasal polyp forceps
 - Punch biopsy (2/3/4mm)
 - Forceps
 - Iris scissors



- Supplies-non-pharmacological
 - Cytology and Surgical Pathology containers
 - Cytobrushes (or dacron swabs if choose to use instead of cytobrush)
 - Gonorrhea/Chlamydia collection swabs
 - Anoscopes (plastic disposable)
 - 1 ml syringes
 - 1.25 inch 27 gauge needles
 - Sharps safety devices
 - Scopettes
 - 4x4 gauze pads (non-sterile)
 - Small cotton-tipped applicators
 - Vaginal Applicators
 - use to place lidocaine cream in anus after procedure
 - use to place Surgifoam in anus after procedure if needed
 - Blue pads
 - Pillows x 3 (2 for legs and 1 for head)
 - Gowns (non-sterile/waterproof)
 - N95 masks
 - Goggles
 - Non-sterile gloves
 - Suture material (in case needed)

- Supplies-pharmacological
 - 5% acetic acid
 - Lugol's Solution
 - 1 % lidocaine with epinephrine
 - 8.4% sodium bicarbonate
 - 4% lidocaine cream
 - Lubricating jelly
 - Monsel's solution
 - Silver nitrate sticks
 - Sodium Chloride
 - Xanax (0.5mg and 1 mg)
 - Oxycodone
 - Ibuprofen

- Cytology/Pathology Support
 - Talk with your pathologist who will be evaluating the ANAL PAP's and Biopsies
 - If they are not comfortable, have them reach out to the pathologist at one of the ANCHOR sites for guidance
- Patient education and comfort resources
 - Written information for pre- and post-procedure
 - Video for patients to watch prior to procedures
 - English - https://m.youtube.com/watch?v=RZZ5_0Ecd9c
 - Spanish - <https://m.youtube.com/watch?v=P5Y56bxuweo&t=9s>
 - iPad with stand and disposable earbuds for patient use during procedure

Lessons Learned



- Investigate the electrical circuits (especially if your space is an older building) to make sure
 - They will support your equipment
 - Outlets are located so cords reach the outlets easily and safely
- Purchase (in addition to colposcope monitor) a separate monitor to display prior HRA photos from the medical record to compare to current images
- Purchase a custom board for the patient to rest legs on instead of pillow on top of table stirrup
- Purchase iPad with stand and disposable earbuds so patient can listen to music or watch video on iPad during procedure
- Draw up multiple lidocaine/bicarbonate syringes prior to procedure
- Consider using lidocaine/bicarbonate for biopsies as well as ablation
 - Initially did not use lidocaine/bicarb for biopsies but started using as
 - Patient tolerance of biopsies varies
 - Once the patient experiences discomfort, the rest of procedure becomes more anxiety-producing
- Purchase a laser pointer for educating patients and learners regarding images on the monitors.

Room Set-up



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Tray Set-up



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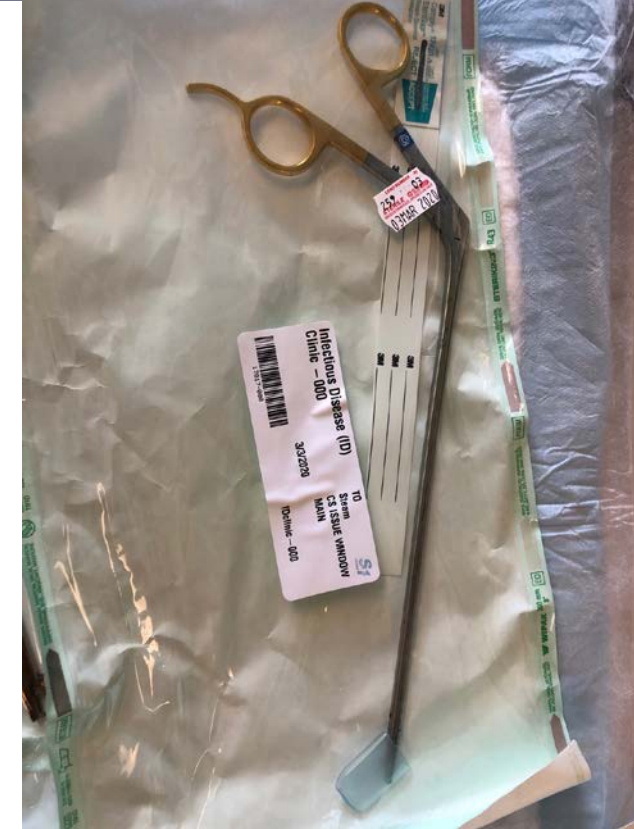
Biopsy/Hyfreccation



**Hyfrecator pencil
smoke evacuator/
suction tubing**



Mini-Tischler biopsy forcep



Nasal polyp forcep

Pharmacologic Agents



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UVA ID Ryan White HRA Team...

It takes a village!



HRA SPECIFIC TEAM

- Providers
 - Yvonne Newberry, FNP (OB/GYN/ID)
 - Tania Thomas, MD (ID)
 - Sook Hoang, MD (Colorectal Surgery)
- Nurses – HRA/OB-GYN
 - Laura Quass-Ferdinand, MPH, BSN, RN
 - Lauren Woodberry, MSN, FNP-C, ACRN
- Consultant
 - Luis Barroso, MD (ID)(ANCHOR SITE @ Wake Forest University)
- UVA Cytology and Pathology
 - Mark Stoler, MD (GYN Pathologist)
- RW Grants & Contracts Administrator
 - Katherine “Kobby” Hoffman, AICP, CRA

CLINIC SUPPORT TEAM

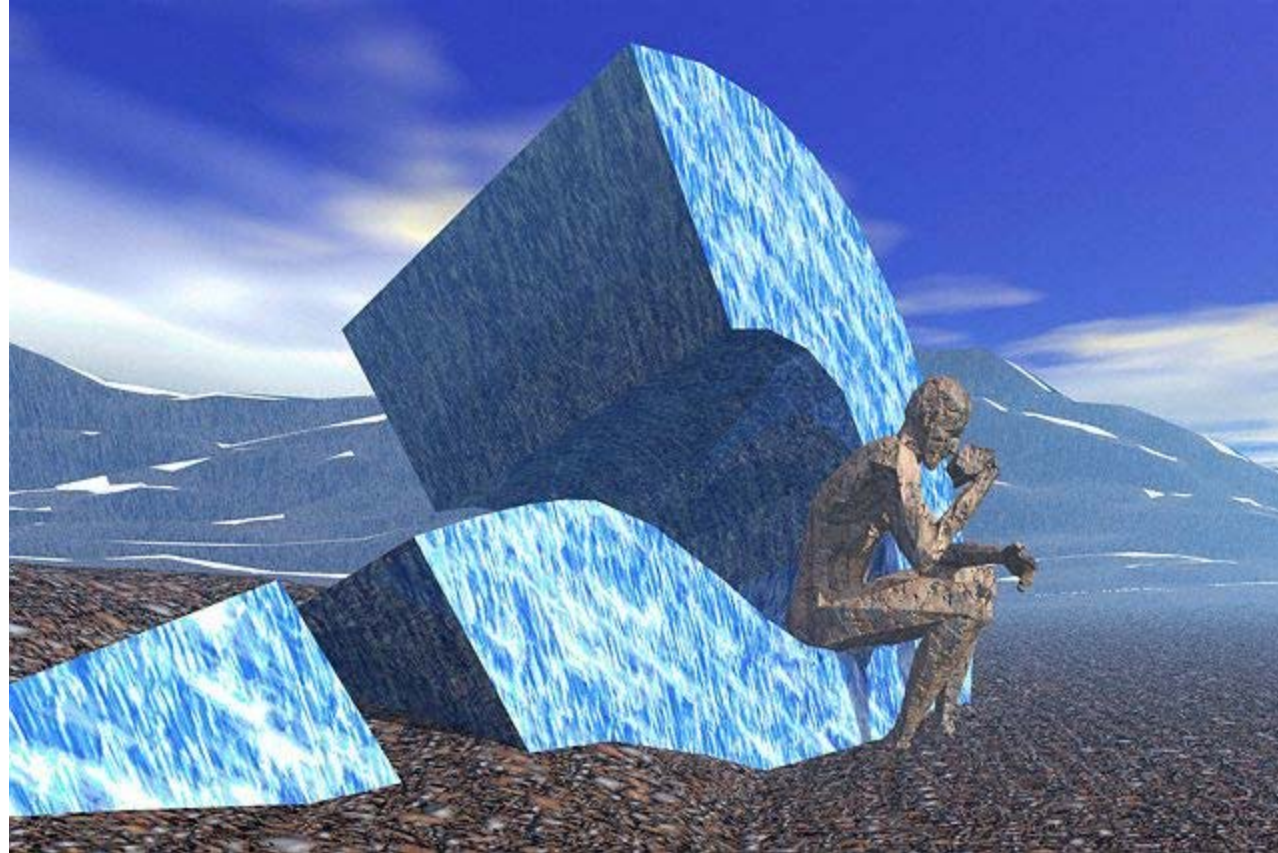
- Case Managers
- Social Workers
- Retention in Care Coordinators
- Psychologists
- Psychiatrists
- Nutritionists
- General ID Nurses
- Front Desk Staff

Thank You ...



- Ryan White Grant funding for making our dream a reality for our patients!
- Colleagues in ID
- Colleagues in Colorectal Surgery
- Colleagues in Pathology
- Colleagues in OB/GYN
- UCSF Anal Dysplasia Team

Questions



Presenters Contact Information



- Yvonne Newberry - YGN7W@hscmail.mcc.virginia.edu
- Laura Quass-Ferdinand - LQ5GH@hscmail.mcc.virginia.edu
- Lauren Woodberry - LAS2KB@hscmail.mcc.virginia.edu