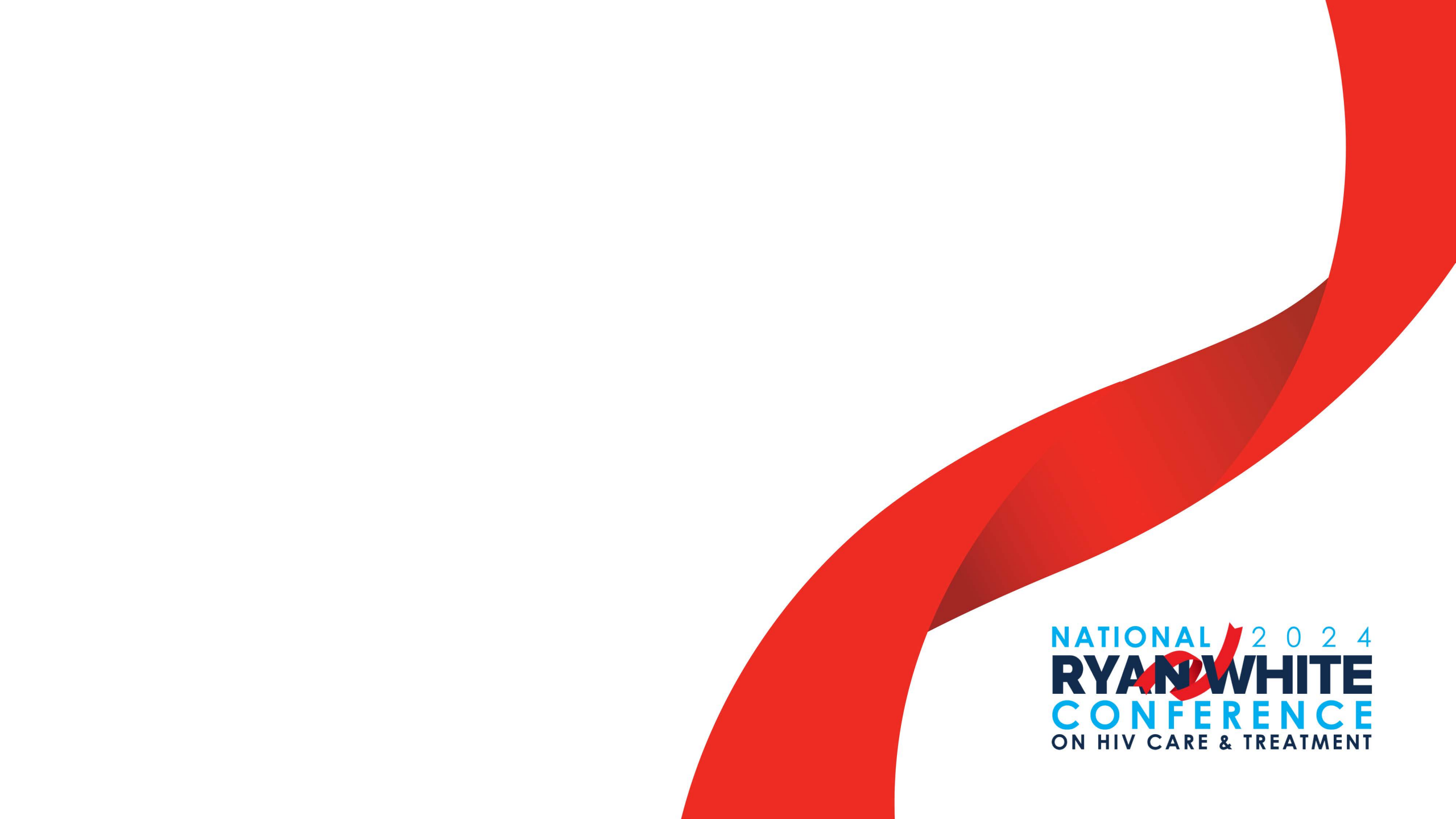
NATIONAL 2024
RYAN WHITE
CONFERENCE
ON HIV CARE & TREATMENT

Implementation of High Resolution Anoscopy (HRA) Anal Cancer Screening for People with HIV at FQHCs

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Disclosures

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- International Anal Neoplasia Society (IANS)
- Oregon AETC

Learning Objectives

At the conclusion of this activity, participants will be able to:

1. Describe why implementation of HRA should be upscaled in Federally Qualified Health Centers (FQHCs)to address gaps in HIV services.
2. Describe training and education resources utilized for building provider capability to support the implementation of HRA in FQHCs.
3. Explain key steps involved in implementing HRA at an FQHC.

Anal Cancer HSIL Outcomes Research (ANCHOR) Study

- Phase 3 trial at 25 U.S. sites
- 4446 people with HIV, 35 years of age or older with HSIL and without a history of anal cancer received either HSIL treatment until complete resolution (e.g., office-based ablation, ablation or excision under anesthesia, or topical therapies) or active monitoring without treatment.

"No one knew that cervical cancer was preventable before the use of Pap smears became widespread in the 1960s and cut the incidence of the disease by 80 percent."

- Dr. Joel Palefsky, Principal Investigator

https://www.nejm.org/doi/full/10.1056/NEJMoa2201048

Anal Cancer HSIL Outcomes Research (ANCHOR) Study 2

- "Among participants with biopsy-proven anal HSIL, the risk of anal cancer was significantly lower with treatment for anal HSIL than with active monitoring."
- "The results may not be generalizable to settings in which high-resolution anoscopy (HRA) and treatment are performed by clinicians with less training and support."

June 2022

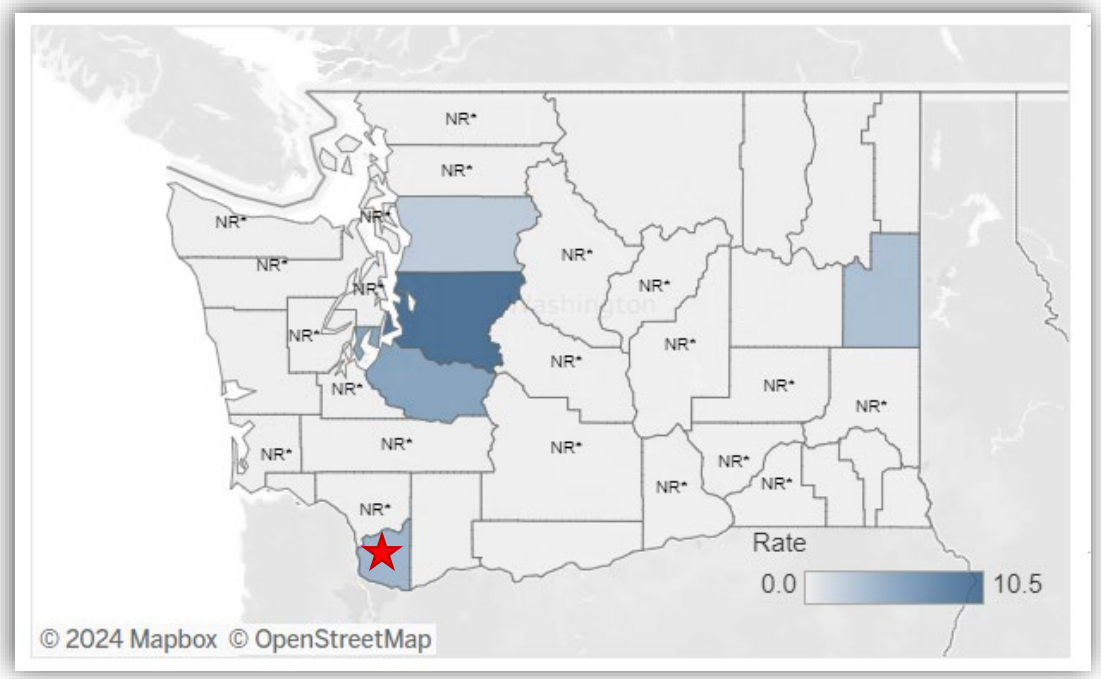
https://www.nejm.org/doi/full/10.1056/NEJMoa2201048

What is HRA?

High Resolution Anoscopy (HRA) is the visualization of the anus and perianus through a colposcope using acetic acid and Lugol's solutions. The purpose of HRA is to identify pre-cancerous lesions that may require treatment to prevent anal cancer. HRA uses biopsy to identify precancerous lesions which are then treated with chemical ablation, thermal ablation, or infrared coagulation.

Sea Mar Salmon Creek

- Sea Mar Salmon Creek is a Federally Qualified Health Center (FQHC) receiving Ryan White Part B and C Funding in Clark County, WA.
- Sea Mar has an established Rapid ART program, with onsite pharmacy, providing HIV care to 100 patients.
- Clark County, WA ranks **third** out of all Washington Counties for HIV incidence, **fourth** for prevalence.



WA HIV Incidence, 2018

https://doh.wa.gov/data-statistical-reports/washington-tracking-network-wtn/hiv/dashboard

Practice Transformation Project (PTP)

- Sea Mar Salmon Creek is a Practice Transformation Project Site of the MWAETC supported by Ryan White Part F – AIDS Education and Training Centers
- Practice Transformation is defined by the Centers for Medicare & Medicaid (CMS) as “a process that results in observable and measurable changes to practice behavior.”
- Through coaching and practice facilitation, the goal is for the AETC’s to assist partner community health centers in enhancing outcomes along the HIV care continuum.

Content Courtesy: Kathryn Burklund, MAETC

2023 PTP Questions

In anticipation of HRA guidelines for people with HIV…

- What would it take to build a provider's capacity to integrate HRA into HIV clinical practice?
- What is the impact of HRA integration on health systems?

Provider Capacity

Provider Champion

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JD Armstrong, MD

- Personal interest in addressing anal cancer among his patient panel.
- Clinical Background:
  - Family Medicine
  - Maternal Child Health Fellowship
  - AAHIVM HIV Specialist Certification
- Relevant Post Residency Training:
  - Shadowing and Proctoring in HRA

HRA Provider Initial Education

- Participate in IANS Virtual Standard HRA Course offered by the International Anal Neoplasia Society (IANS)
- Complete shadowing and proctoring opportunities in HRA
- Attend annual IANS National Conference

HRA Preceptorships

- **Preceptorships**
  - Naomi Jay, RN, NP, PhD at University of California at San Francisco, Principal Investigator for the Anchor Study
  - Hillary Dunlevy, MD, MPH, at Colorado University at Anschutz
  - Michele Babaie, MD, at Multnomah County HIV Health Services Center
- **Reverse Preceptorships**
  - Michele Babaie, MD joined JD Armstrong, MD at his clinic to support the initial exams and provide onsite feedback as JD was establishing his HRA practice.
- **Virtual Proctoring**
  - Michele Babaie, MD has supported JD through reviewing JD's recorded HRA exams and provided feedback as JD gains experience.

Provider HRA Training Checklist

HRA provider confidence and skill is impacted not only by education/training, but also by direct experience and observation of HRA exams.

- Participate in IANS Virtual Standard HRA Course offered by the International Anal Neoplasia Society (IANS)
- Attend at least two HRA Preceptorships
- Establish a Reverse Preceptorship to have an experienced provider (>5 years experience) observe your process
- Where possible engage in virtual proctoring where you record the HRA exam and share with an experienced provider for feedback
- Track your data to ensure you eventually achieve standard quality metrics
- Maintain photo documentation of all HRA exams for review

Building Health System Capacity

Pre-Implementation

Pre-Implementation

- Provider Readiness
- Assessing for Unmet Need for HRA in Your Jurisdiction
- Clinic Readiness
- Cost Benefit Analysis
- Technology Considerations

Assessing for Need

Sea Mar Salmon Creek

- Clark County HIV Prevalence 2022: 868 cases
- Prior to expanding HRA capacity at Sea Mar Salmon Creek, WA Medicaid patients had only one option for accessing high resolution anoscopy in the state: Harborview Medical Center in Seattle, WA (158 miles away/6 hour bus ride).
- WA patients with other health insurances can access HRA in Portland, OR through the Multnomah County HIV Clinic and Kaiser IDC.

Assessing for Need

Integration of HRA is most effective when the patient population in need of screening is large enough to support ongoing need. It is recommended to ensure there are enough patients to **complete at least 50 HRA exams per year** to maintain provider competency in your clinic and to justify the initial costs of program establishment.

- Utilize local epidemiology to determine what percentage of people with HIV reside in your jurisdiction and assess access to HRA.
- Assess current state of anal cancer screening in your area.
  - Are there HRA providers in your area?
  - Are any providers doing anal paps or digital anorectal exams for anal cancer screening?
- Utilize EHR to Identify patients eligible for HRA in your system

Clifford, et al meta-analysis: A meta-analysis of anal cancer incidence by risk group: Toward a unified anal cancer risk scale

Clinic Readiness Assessment

- Does your patient population reflect the prevalence and risk factors for anal dysplasia and cancer?
- Do you have a clinical champion(s) willing to engage in the HRA certification process?
- Does your institutional leadership support this work?
- Do you have funding to pay for HRA related medical equipment and software?
- Do you have funding to pay for staff training which may include time away from clinic, travel, and registration fees?
- Is there a dedicated examination room or space for scope & HRA encounters?
- Have you ensured your lab has procedures for processing anal pap smears?
- Is your IT/ electronic medical record team aware you are integrating HRA in order to download software & add billing codes proactively?
- Does your clinic have access to surgery and oncology consultation?
- Is there ongoing funding to ensure clinicians providing HRA can maintain professional memberships and have access to imaging banks for ongoing clinical support?

Equipment List

- One Seiler 955 Colposcope Video Package:
  - 955 colposcope
  - 50/50-80/20 beam splitter
  - video camera adapter
  - video cables
  - high resolution HD color camera, and
  - 22” LCD Flat Panel Monitor)
- Six Baby Tischler Biopsy Forceps
- 100 Disposable anoscopes
- 12 pack of Ebanel 5% lidocaine topical numbing cream
- Hyfrecator 2000 Electrosurgical system
- 5- fluorouracil
- Imiquimod

Please see the High Resolution Anoscopy Standardized Procedures from UCSF for a more detailed equipment list. It is important to note, clinics should **purchase polyester-tipped swabs** (Dracon and Rayon are two examples). Cotton swabs are inadequate for anal pap smears.

Cost Benefit Analysis

- Investment Cost is around $25,000
- Investment expenses can usually be recouped through HRA billing in 17 weeks (4 anoscopies scheduled in one half day clinic per week) or 68 exams.

HRA CPT CODES

46601 HRA

46606 Anoscopy with Biopsy (do this one because it's reimbursed better, HRA is not)

46607 HRA with biopsy

46600 Standard anoscopy

46900 Chemical destruction of lesions

46910 Electrodessication

46916 Cryosurgery

99213 Medical Evaluation/Management (20 – 29 min)

99214 Office or Other Outpatient Visit

FQHC Considerations

- FQHC encounter rate is limiting and potentially disincentivizes taking on more expensive/complicated patients.
- HRA encounters take more time, so it looks like the provider is less productive with decreased number of encounters in a given day, even if the insurance billing could be higher.
- FQHCS should consider asking their value-based payor and negotiate a carve out for all services/procedures that should be excluded from the value-based pay encounter rate.
  - Service that should fall within the encounter rate

Technology Considerations

Alert IT and those working with the electronic health record (EHR) at your site early in the process since your organization may require prior authorization to download software. You will likely require software and support for programs such as Second Opinion, OBS Studio, Epic-Pen. Additionally, CPT codes for HRA with and without biopsy and destruction of anal lesions will need to be integrated into the EHR. Remember integration of billing codes should precede any patient procedures.

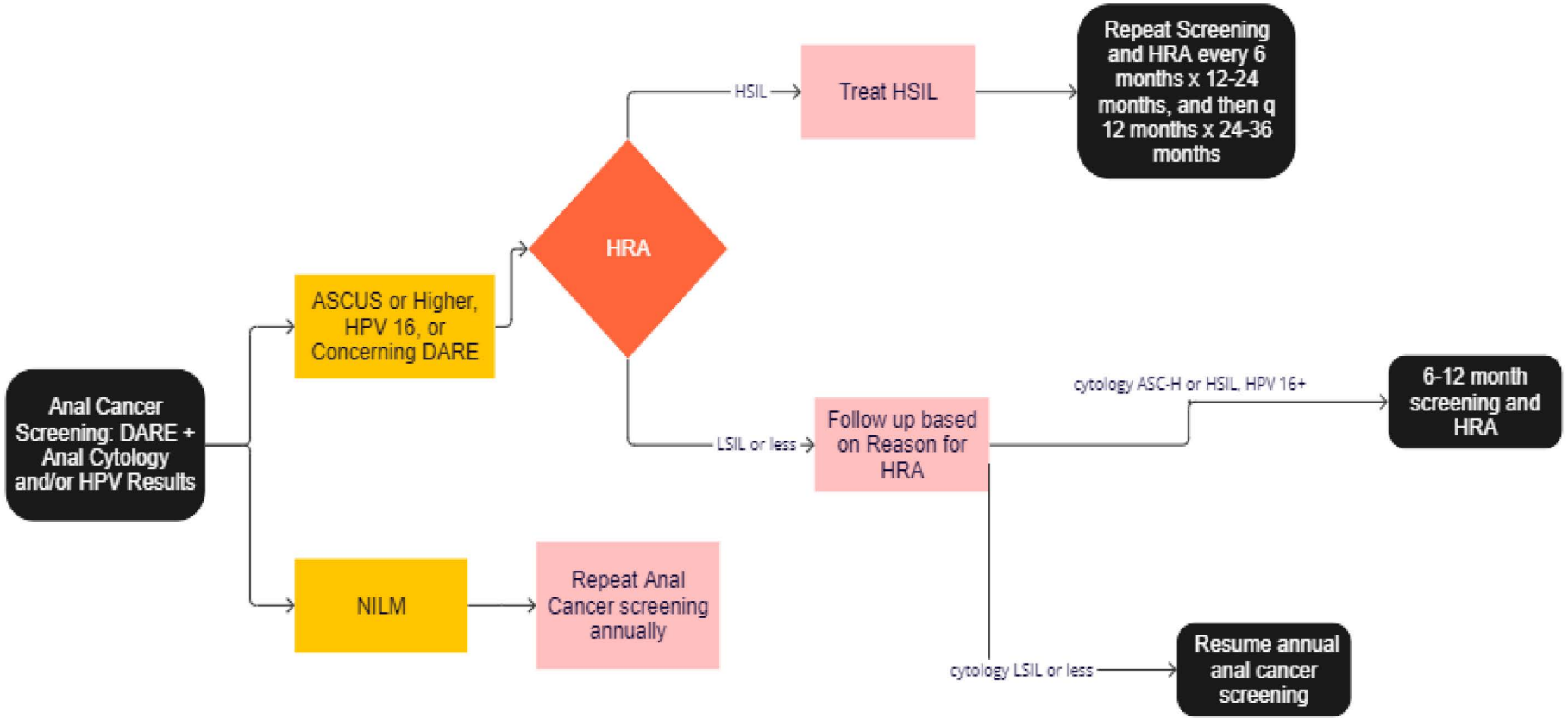
Building Health System Capacity

Implementation

Implementation

- Develop Workflows
- Standardized Protocols for Screening, Linkage, and Referral
- Virtual Proctoring: Recording HRA procedures to send to an experienced professional for external review

Clinic Workflow



Engaging Primary Care
Anal Pap Smears

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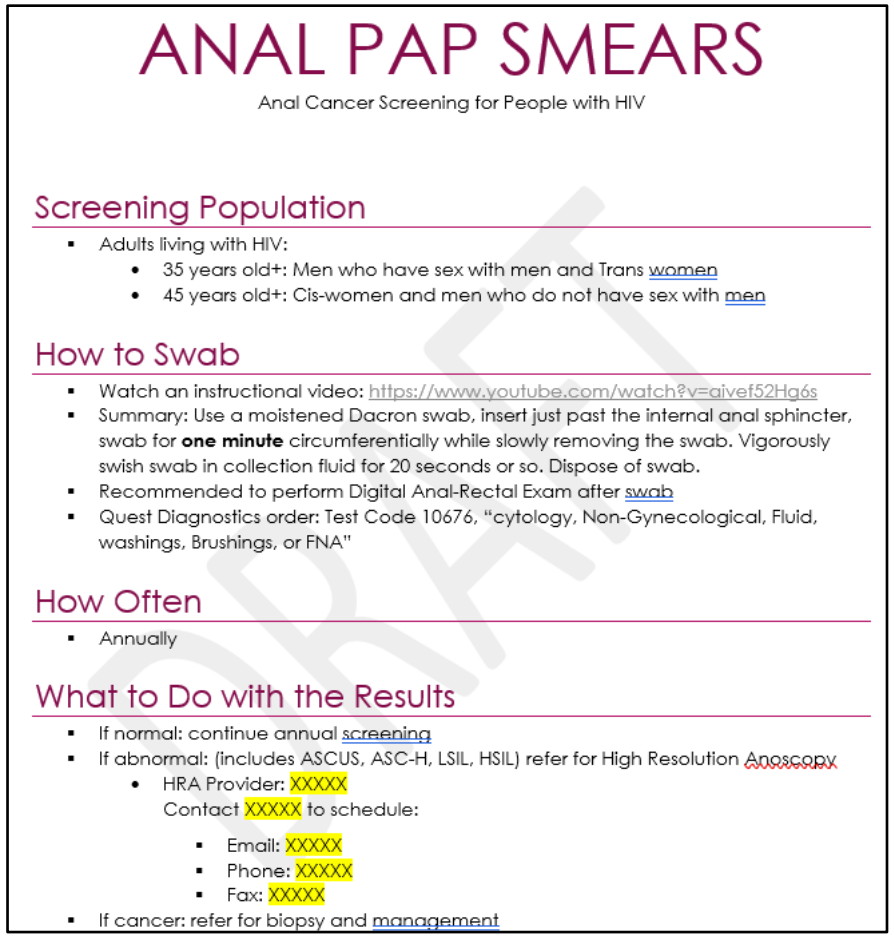
- Make sure you have tools to support routine anal pap smears for primary.
- Train primary care providers on “How to Swab”
  - https://www.youtube.com/watch?v=aivef52Hg6s
- Make sure primary care knows what to do with the swabs prior to increasing clinic wide screening.



ANAL PAP SMEARS

Anal Cancer Screening for People with HIV

Screening Population

- Adults living with HIV:
  - 35 years old+: Men who have sex with men and Trans women
  - 45 years old+: Cis-women and men who do not have sex with men

How to Swab

- Watch an instructional video: https://www.youtube.com/watch?v=aivef52Hg6s
- Summary: Use a moistened Dacron swab, insert just past the internal anal sphincter, swab for **one minute** circumferentially while slowly removing the swab. Vigorously swish swab in collection fluid for 20 seconds or so. Dispose of swab.
- Recommended to perform Digital Anal-Rectal Exam after swab
- Quest Diagnostics order: Test Code 10676, “cytology, Non-Gynecological, Fluid, washings, Brushings, or FNA"

How Often

- Annually

What to Do with the Results

- If normal: continue annual screening
- If abnormal: (includes ASCUS, ASC-H, LSIL, HSIL) refer for High Resolution Anoscopy
  - HRA Provider: XXXXX
    Contact XXXXX to schedule:
    - Email: XXXXX
    - Phone: XXXXX
    - Fax: XXXXX
- If cancer: refer for biopsy and management

DRAFT

Referrals to Surgery and Oncology

Build surgery and oncology referral networks for identified cancer or dysplasia lesions that would be inappropriate to treat in a primary care office setting to ensure continuity of care for patients. This referral relationship should be supported by minimal delays to care.

Building Health System Capacity

Sustainability

Sustainability

- Integration of HRA into primary care medical homes
- Ongoing Provider Education
- Quality Improvement

Patient Centered Medical Home (PCMH)

- Expanding the role of Federally Qualified Health Centers to meet the needs of people with HIV where they live
- Anoscopy is not a procedure patients are jumping at the opportunity to have, so having trust with the provider/ medical home where the procedure is performed can really improve adherence to anal cancer screening

Ongoing Provider Education

HRA Providers within Primary Care Should…

- ***Meet regularly with mentor, submit virtual exams for review***
- Attend periodic IANS sponsored online lectures
- Attend annual IANS Scientific Meeting Conference
- Renew IANS membership annually
- Compile and review HRA best practice data within your own practice

Quality Metrics

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TABLE 8. High-Resolution Anoscopy Performance Metrics

Code	Metric	Recommendation
C.1	Entire SCJ, AnTZ, distal anal canal and perianus fully visualized	>90%
C.2	Average number of biopsies performed per procedure for new patients[1]	>1
C.3	Detection of histological HSIL within 3 months after initial cytological HSIL	>90%
C.4	% perianal biopsies[2]	≥5%

SCJ indicates squamocolumnar junction; AnTZ, anal transformation zone; HSIL, high-grade squamous intraepithelial lesions.[1]
[1]Will depend on mix of patients, such as referral practices, new or return, high risk or treatment experience.
[2]Depending on % of anal cancers that are perianal in local population.

TABLE 9. Patient Experience Metrics

Code	Metric	Recommendation
D.1	Duration of HRAs[1]	90% <15 minutes >90% lasting ≥5 mins
D.2	Problematic pain[2]	≤10%
D.3	Problematic bleeding[3]	≤10%

Hillman, Richard John, et al. "2016 IANS International Guidelines for Practice Standards in the Detection of Anal Cancer Precursors". *Journal of Lower Genital Tract Disease.* Volume 20, No 4, October 2016.

Quality Improvement

- Reassess number of HRA exams required to sustain the program
- Collaborate with community partners to promote HRA service delivery and linkage to care
- Identify process improvements to improve the patient experience

Sample Timeline

Pre-Implementation
Sample Timeline

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Timeline	Items for Timeline
Month 1 (Pre-implementation)	• Assess need for HRA for people with HIV in your community • Engage with health center leadership and community partners • Identify a provider champion
Month 2 (Pre-implementation)	• Provider champion completes IANS virtual standard HRA course • Develop a clinic workflow and identify key staff • Evaluate EHR functionality and draft dot phrases to facilitate HRA documentation/charting • Establish a QI process to evaluate efficiency and effectiveness of the workflow; modify as appropriate
Month 3 – 5 (Pre-implementation)	• Provider champion completes anal pap smear training • Provider champion attends preceptorships to increase competency in HRA • Order HRA equipment • Order exam supplies including polyester-tipped swabs like Dacron or Rayon • Establish a protocol for the image library • Provider champion begins preparing to perform anal pap smears by contacting the lab to confirm how to properly submit orders. For example, you may be requested to order “Cytology, Non-Gyn” as “Anal Pap Smear” may not be an order. • Use EHR to identify patients eligible for HRA in your system • Conduct a cost-benefit analysis to demonstrate the potential benefit of implementing HRA (use CPT codes to determine physician reimbursement fees for related services ie HRA with and without biopsy and destruction of anal lesions) • Train support staff on patient education, scheduling, and preparation for HRA procedures • Modify workflow as needed

Implementation
Sample Timeline

Month 5 – 7 (Implementation)	• Standardized protocol for patient selection, screening and follow-up. This includes defining referral criteria for HRA considering factors ie abnormal anal cytology or persistent high-risk HPV infection Create patient education materials explaining the purpose, benefits and potential risks of HRA • When equipment arrives, begin providing limited HRA through a reverse preceptorship • Record HRA procedures and send to an experienced professional for review • Implement strategies to promote adherence to HRA appointments such as reminder calls, community education campaigns and navigation services
Month 9 – 10 (Implementation)	• Initiate Anal pap smear screening for people with HIV at your clinical site to facilitate referrals. • Promote anal pap smears in surrounding clinics by providing guidance on anal pap smears and referral pathways to your clinic • Schedule HRA visits through protected time (if possible) • Monitor progress through quarterly data feedback reports

Sustainability
Sample Timeline

Ongoing (Sustainability)	• Meet regularly with mentor, submit virtual exams for review • Attend periodic IANS sponsored online lectures • Assess number of HRA exams required to fund the program • Collaborate with community partners to promote HRA service delivery
Annually (Sustainability)	• Attend annual IANS Scientific Meeting Conference • Renew IANS membership • Compile and review HRA best practice data within your own practice

Impact

Case Discussion

Outcomes at Sea Mar

- Between April and December 2023, 23 patients with HIV have received an anal pap smear
- Of the 9 HIV+ patients with abnormal anal cancer screening results, 6 opted for HRA
- 4 out of 6 patients biopsied during the process had lesions
- One patient was positive for HSIL and received treatment onsite and the repeat biopsy was negative

Next Steps

Populations Meriting Screening May 2024
(Anal Pap Smear)

Population	Starting	Rationale
HIV+: MSM and Transwomen	35 years old+	High anal cancer incidence: ~85 (per 100,000 person years)
HIV+: non-MSM men, transmen, cis women	45 years old+	High anal cancer incidence: ~22-32
Persons with history of Vulvar HSIL or Vulvar Cancer	Within 1 year of diagnosis/treatment	High anal cancer incidence: ~48 for vulvar cancer
Solid organ transplant recipients	10 years post transplant	High anal cancer incidence: ~24-50
People with history of cervical or vaginal cancer	≥45 years old with Shared Decision Making	Modestly higher anal cancer incidence
People with history of cervical HSIL	≥45 years old with Shared Decision Making	Modestly higher anal cancer incidence

IANS Consensus Guidelines: https://pubmed.ncbi.nlm.nih.gov/38297406/

Resources

Resources 2

- International Anal Neoplasia Society's consensus guidelines for anal cancer screening May 2024
- Standardized Procedures High Resolution Anoscopy (Adults, Peds)
- Screening for Anal Dysplasia and Cancer in Adults with HIV, Bruce Hirsch, MD, FACP, FIDSA, Steven M. Fine, MD, PhD; Rona M. Vail, MD; Joseph P. McGowan, MD, FACP, FIDSA; Samuel T. Merrick, MD; Charles J. Gonzalez, MD; Christopher J. Hoffmann, MD, MPH, Medical Care Criteria Committee
- High Resolution Anoscopy, J Michael Berry and Naomi Jay
- Best Practices for Monitoring….2016 Paper in HRA Toolkit
- High-resolution anoscopy in HIV-infected men: Assessment of the learning curve and factors that improve the performance, Papillomavirus Research, Karin Neukam, Yusnelkis Milanés Guisado, María Fontillón, Laura Merino, César Sotomayor, Nuria Espinosa, Luis F. López-Cortés, Pompeyo Viciana,
- 2016 IANS International Guidelines for Practice Standards in the Detection of Anal Cancer Precursors

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