3rd Annual Cancer Disparities Virtual Symposium: Challenges in Cancer Care for Sexual and Gender Minorities

Saturday, September 18, 2021
Virtual

ANAL CANCER AND NOVEL SCREENING STRATEGIES

Alan G. Nyitray, PhD
Pronouns: he/they
Clinical Cancer Center
Center for AIDS Intervention Research
Medical College of Wisconsin
FINANCIAL DISCLOSURES

National Institutes of Health
   National Institute for Allergy and Infectious Disease
   National Cancer Institute

Medical College of Wisconsin
OBJECTIVES

Review HPV and HPV-associated disease

Discuss PAC Study protocols

Review initial PAC Study data
HUMAN PAPILLOMAVIRUSES ARE COMMON

• HPV is common, but transient.
  • E.g., 82% 2-year period prevalence in heterosexual couples

• Low-risk types may cause anogenital condylomas (e.g., 6 & 11).

• More than a dozen cause cancers like cervical cancer, anal cancer, and oral cavity cancer (e.g., 16 & 18).

• Globally, HPV is responsible for about 5% of all cancers.
Annual age-adjusted incidence per 100,000 persons

USA 6.2
Canada 5.5

THE LEGACY OF THE CERVICAL CANCER SCREENING MODEL

THE LEGACY OF THE CERVICAL CANCER SCREENING MODEL

Estimated age-standardized incidence rates (World) in 2020, cervix uteri, females, all ages, Africa

Annual age-adjusted incidence per 100,000 persons

Nigeria 18.4
Kenya 31.3
Tanzania 62.5
Zimbabwe 61.7

THE LEGACY OF THE CERVICAL CANCER SCREENING MODEL

Estimated age-standardized incidence rates (World) in 2020, cervix uteri, females, all ages, Europe

Annual age-adjusted incidence per 100,000 persons

Romania 22.6
Hungary 17.2

AGE-ADJUSTED CERVICAL CANCER INCIDENCE IN WISCONSIN, 2014-2018

PER 100,000 FEMALES

- Black: 11.4
- American Indian: 13.6
- Asian/Pacific Islander: 10.2
- Latino: 8.3
- White: 6.2

ANAL CANCER INCIDENCE IS INCREASING

Age-adjusted Incidence of Invasive Anal Cancer in US Females and Males 1975-2015

National Cancer Institute, SEER, 2018
Anal cancer risk scale
Clifford et al., IJC 2020, 148(1):38-47
US Preventive Services Task Force recommendations for anal cancer screening do not exist

Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV

Specialists recommend:

- Digital Anal Rectal Examination-DARE (moderate recommendation)
- Anal Pap or high-resolution anoscopy (optional recommendation)

2021 CDC STI Treatment Guidelines

- DARE should be performed in 1) persons with HIV and 2) MSM without HIV who have a history of receptive anal sex

HRSA, Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV
https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Adult_OI.pdf

Centers for Disease Control and Prevention, Sexually Transmitted Infections Treatment Guidelines, 2021
Natural history of anal HPV infection

Uninfected anal canal → infection → HPV-infected anal canal and persistence → progression → Precancer (AIN3) → invasion → Cancer

Screen here for anal precancers? (a cervical cancer screening model)

And/or screen here for early anal cancer? (DARE)

Adapted from Schiffman & Wentzensen, 2010
Problems with the cervical cancer model and DARE for anal precancer or cancer screening

• Cervical Model
  • It’s expensive
  • There is no proven treatment for anal precancerous lesions
  • Anal precancerous lesions often regress spontaneously
  • Infrastructure for high-resolution anoscopy is poor

• DARE
  • Likely useful only after invasion
Mean anal canal tumor size at presentation 3.6 cm in diameter

66 French women and men with early invasive anal cancer (≤1 cm tumors): 5-year disease-specific survival was 100%

Ortholan et al., 2005

15 PLWH with T1N0M0 cancer of the anal verge (below the dentate line): 4-year disease-specific survival was 100%

Alfa-Wali et al., 2016
Prevent Anal Cancer Study

Both PAC studies

• seek to detect cancer earlier when it is more treatable

• address barriers to screening including embarrassment, cost, and lack of health care infrastructure

• target communities at highest risk for anal cancer
PREVENT ANAL CANCER STUDY – TWO APPROACHES

Uninfected anal canal → infection → HPV-infected anal canal and persistence → progression → Precancer (lesions) → invasion → Cancer

Self-swabbing → Prevent Anal Cancer Study → PAC Study → Palpation
Prevent Anal Cancer Study – Two Approaches
PAC Self-Swab Study Objectives

1) Determine compliance with annual anal HPV DNA specimen collection and high-resolution anoscopy.

2) Determine factors associated with annual screening compliance.

3) Assess the performance of two molecular markers: HPV DNA persistence and host/viral DNA methylation.
PAC Self-Swab Study Randomization

400 MSM and transpersons who have sex with men randomized 1:1
- 200 in self-swabbing arm at home (PAC Pack)
- 200 in clinician-swabbing arm at a clinic
  - Persons can choose from one of five clinics in the city

- ≥ 25 years of age
- Milwaukee MSA residence
- Not on anti-coagulants, e.g., Plavix
- No diagnosis or hemophilia, cirrhosis with bleeding varices, or thrombocytopenia
- Remain in Milwaukee for at least 1 year
PERSISTENCE BIOMARKER PAC SELF-SWAB STUDY

Uninfected anal canal → infection → HPV-infected anal canal and persistence → progression → Precancer (lesions) → invasion → Cancer

- Baseline swabbing → HPV 16 methylation
- 12 month swabbing → HPV 16 methylation

Screen with high-resolution anoscopy
Prevent Anal Cancer Study – Two Approaches

- Uninfected anal canal
  - Infection
  - HPV-infected anal canal and persistence
    - Progression
    - Precancer (lesions)
      - Invasion
      - Cancer

Prevent Anal Cancer Study (PAC Study)

Self-swabbing

Palpation
PAC PALPATION STUDY ASSESSES THE ABILITY OF PERSONS TO RECOGNIZE AN ANAL ABNORMALITY

Since most anal cancers have a tumor that can be felt with a finger...

Can MSM and transpersons palpate an anal abnormality?

400 Chicago and 400 Houston participants
PAC Palpation Study Objectives

1) Estimate the anal self-exam and anal companion exam sensitivity and specificity.

2) Determine factors associated with concordance between self/companion-exams and clinician’s exam.

3) Estimate the impact of the exams on quality of life and evaluate cost-effectiveness.
PAC Self-Swab Cumulative Participant Accrual

Accrual resumes
COVID-19 suspension

Eligible | Ineligible | Consented
--- | --- | ---
Jan-20 | 49 | 19 | 16
Feb-20 | 70 | 30 | 25
Mar-20 | 80 | 34 | 34
Apr-20 | 80 | 34 | 34
May-20 | 81 | 34 | 34
Jun-20 | 81 | 34 | 34
Jul-20 | 87 | 34 | 34
Aug-20 | 81 | 34 | 34
Sep-20 | 82 | 34 | 34
Oct-20 | 87 | 34 | 34
Nov-20 | 116 | 44 | 51
Dec-20 | 118 | 51 | 48
Jan-21 | 128 | 51 | 48
Feb-21 | 147 | 52 | 38
Mar-21 | 185 | 58 | 56
Apr-21 | 185 | 61 | 58
May-21 | 204 | 78 | 72
Jun-21 | 281 | 104 | 92
Jul-21 | 303 | 104 | 92
Aug-21 | 319 | 161 | 144
### PAC Study enrollment
January 3, 2020 – August 17, 2021

<table>
<thead>
<tr>
<th></th>
<th>total</th>
<th>PAC Self-Swab MKE</th>
<th>PAC Palp CHI + HTX</th>
</tr>
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<td>375</td>
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<td><strong>144</strong></td>
<td>282</td>
</tr>
</tbody>
</table>
PAC Self-Swab Study (n=144)

Recruitment Source

- Social media
- Flyer
- Clinic
- Friend
- Other/unknown
# PAC Self-Swab Study

<table>
<thead>
<tr>
<th>Age, years</th>
<th>Median (range)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-34</td>
<td>46 (31.9)</td>
<td></td>
</tr>
<tr>
<td>35-44</td>
<td>23 (16.0)</td>
<td></td>
</tr>
<tr>
<td>45-54</td>
<td>29 (20.1)</td>
<td></td>
</tr>
<tr>
<td>55-64</td>
<td>38 (26.4)</td>
<td></td>
</tr>
<tr>
<td>≥65</td>
<td>8 (5.6)</td>
<td></td>
</tr>
</tbody>
</table>
### PAC Self-Swab Study

<table>
<thead>
<tr>
<th>Gender identity</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Man</td>
<td>136</td>
<td>(94.4)</td>
</tr>
<tr>
<td>Trans woman</td>
<td>4</td>
<td>(2.8)</td>
</tr>
<tr>
<td>Non-binary</td>
<td>3</td>
<td>(2.1)</td>
</tr>
<tr>
<td>Another</td>
<td>1</td>
<td>(0.7)</td>
</tr>
</tbody>
</table>
## PAC Self-Swab Study

<table>
<thead>
<tr>
<th>Sexual orientation</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gay</td>
<td>121</td>
<td>(84.6)</td>
</tr>
<tr>
<td>Bisexual</td>
<td>16</td>
<td>(11.2)</td>
</tr>
<tr>
<td>Queer</td>
<td>5</td>
<td>(3.5)</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>1</td>
<td>(0.7)</td>
</tr>
</tbody>
</table>
# PAC Self-Swab Study

<table>
<thead>
<tr>
<th>Race and ethnicity</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>103 (72.0)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>32 (22.4)</td>
</tr>
<tr>
<td>Asian American</td>
<td>0</td>
</tr>
<tr>
<td>Another</td>
<td>8 (5.6)</td>
</tr>
<tr>
<td><strong>Hispanic/Latinx ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>16 (11.2)</td>
</tr>
<tr>
<td>No</td>
<td>127 (88.8)</td>
</tr>
</tbody>
</table>
PAC Self-Swab Study

<table>
<thead>
<tr>
<th>HIV</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>35</td>
<td>(24.3)</td>
</tr>
<tr>
<td>Negative</td>
<td>109</td>
<td>(75.7)</td>
</tr>
</tbody>
</table>
### PAC Self-Swab Study

<table>
<thead>
<tr>
<th>Medical condition*</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>34</td>
<td>(23.8)</td>
</tr>
<tr>
<td>No</td>
<td>109</td>
<td>(76.2)</td>
</tr>
</tbody>
</table>

* Here is a list of medical conditions that may make it harder to use the swab. Has a doctor ever said that you have any of the following?(check all that apply)

Arthritis, carpal tunnel syndrome, obesity, diabetes, fibromyalgia, chronic lower back pain, stroke, cerebral palsy, motor neuron diseases, movement disorders, multiple sclerosis, spina bifida, spinal cord injury, visual impairment, deafness
PAC Self-Swab Study - Randomization

n = 73

or

n = 71

Currently, there are no differences by study arm regarding age, race, ethnicity, or HIV status.
PAC Self-Swab Study (n=144)

Pain associated with swabbing by study arm

<table>
<thead>
<tr>
<th></th>
<th>PAC Pack</th>
<th>Clinician</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>A little pain</td>
<td>0.4</td>
<td>0.4</td>
</tr>
<tr>
<td>A lot of pain</td>
<td>0.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

p = 0.71
# PAC Self-Swab Study (n=144)

<table>
<thead>
<tr>
<th>How much bleeding after the swabbing?</th>
<th>n (%)</th>
<th>Total</th>
<th>Clinician</th>
<th>PAC Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>No bleeding</td>
<td>99 (94.3)</td>
<td>43 (91.5)</td>
<td>56 (96.6)</td>
<td></td>
</tr>
<tr>
<td>A little</td>
<td>1 (1.0)</td>
<td>0</td>
<td>1 (1.7)</td>
<td></td>
</tr>
<tr>
<td>A lot of bleeding</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>I don’t know</td>
<td>5 (4.8)</td>
<td>4 (8.5)</td>
<td>1 (1.7)</td>
<td></td>
</tr>
</tbody>
</table>

p=0.18
PAC Self-Swab Study (n=144)

How would you rate your experience?
(by study arm)

- Mostly positive
- Neutral
- Mostly negative
- I don't know

P = 0.55
Was it hard to position your body to insert the swab?

PAC Self-Swab Study – Use of the PAC Pack by age (n=73)

- 25-34 yrs
  - No, it wasn’t hard: 0.4
  - It was a little hard: 0.2
  - It was moderately hard: 0.1
  - It was very hard: 0.2

- 35-44 yrs
  - No, it wasn’t hard: 0.8
  - It was a little hard: 0.2
  - It was moderately hard: 0.1

- 45-54 yrs
  - No, it wasn’t hard: 0.6
  - It was a little hard: 0.3
  - It was moderately hard: 0.1

- 55-71 yrs
  - No, it wasn’t hard: 0.7
  - It was a little hard: 0.2
  - It was moderately hard: 0.1

p = 0.50
PAC Self-Swab Study – Use of the PAC Pack by medical condition* (n=73)

Was it hard to position your body to insert the swab?

<table>
<thead>
<tr>
<th>Difficulty Level</th>
<th>Medical condition</th>
<th>No medical condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not hard</td>
<td>60%</td>
<td>65%</td>
</tr>
<tr>
<td>A little hard</td>
<td>27%</td>
<td>30%</td>
</tr>
<tr>
<td>Moderately hard</td>
<td>13%</td>
<td>5%</td>
</tr>
<tr>
<td>Very hard</td>
<td>0%</td>
<td>0%</td>
</tr>
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</table>

*p = 0.54

*Arthritis, carpal tunnel syndrome, obesity, diabetes, fibromyalgia, chronic lower back pain, stroke, cerebral palsy, motor neuron diseases, movement disorders, multiple sclerosis, spina bifida, spinal cord injury, visual impairment, deafness
PAC Self-Swab Study – High-resolution anoscopy (n=15)

<table>
<thead>
<tr>
<th>Highest grade lesion identified by biopsy, n (%)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Histologically normal</td>
<td>7</td>
<td>(46.7)</td>
</tr>
<tr>
<td>Histologically abnormal</td>
<td>8</td>
<td>(53.3)</td>
</tr>
<tr>
<td>LSIL</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>HSIL/AIN2</td>
<td>5</td>
<td>(33.3)</td>
</tr>
<tr>
<td>HSIL/AIN3</td>
<td>3</td>
<td>(20.0)</td>
</tr>
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LSIL - Low-grade squamous intraepithelial lesions
HSIL - High-grade squamous intraepithelial lesions
AIN - Anal intraepithelial neoplasia
CrossPAC Data
Milwaukee + Chicago + Houston

Where possible, survey and clinical data collection were standardized across all three cities to support investigations with larger sample sizes.
CrossPAC Data

**Survey data**

- Anal cancer
  - Knowledge
  - Worry
  - HPV vaccination
  - Screening motivation and intentions
  - Self-screening
  - Cost-effectiveness
- Anal pathology history
- DARE, Pap cytology, high-resolution anoscopy history
- Medical conditions, HIV and cancer
- Social support
- Sexual behavior
- Sexual satisfaction
- ATOD use
- COVID-19 experiences

**Clinical data**

- Anal pathology
- DARE practice
PAC Study enrollment  
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CrossPAC Data, Medical conditions (>5%) by age, (n=526)

Overall prevalence of any medical condition = 31.3%

Prevalence of any medical condition among ≥55 years = 47.1%
## CrossPAC Data, Cancer by age, n (%)

<table>
<thead>
<tr>
<th></th>
<th>Total n=526</th>
<th>25-34 yrs</th>
<th>35-44 yrs</th>
<th>45-54 yrs</th>
<th>55-81 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Any cancer</strong></td>
<td>28 (5.3)</td>
<td>1 (0.6)</td>
<td>2 (1.8)</td>
<td>1 (0.9)</td>
<td>24 (17.0)</td>
</tr>
<tr>
<td><strong>Skin</strong></td>
<td>23 (4.4)</td>
<td>1 (0.6)</td>
<td>2 (1.8)</td>
<td>0</td>
<td>20 (14.2)</td>
</tr>
<tr>
<td><strong>Prostate</strong></td>
<td>6 (1.2)</td>
<td>0</td>
<td>0</td>
<td>1 (0.9)</td>
<td>5 (3.6)</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td>1 (0.2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td><strong>Colorectal</strong></td>
<td>1 (0.2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (0.7)</td>
</tr>
</tbody>
</table>

**Bold** indicates an association between cancer and age, p<0.05.
CrossPAC Data, Reasons to screen for anal cancer by age, n (%)

<table>
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<th>Suggested by</th>
<th>Total n=526</th>
<th>25-34 yrs</th>
<th>35-44 yrs</th>
<th>45-54 yrs</th>
<th>55-81 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>A doctor</td>
<td>401 (76.4)</td>
<td>124 (77.5)</td>
<td>80 (72.1)</td>
<td>94 (83.2)</td>
<td>103 (73.1)</td>
</tr>
<tr>
<td>A community health worker</td>
<td>211 (40.2)</td>
<td>74 (46.3)</td>
<td>47 (42.3)</td>
<td>43 (38.1)</td>
<td>47 (33.3)</td>
</tr>
<tr>
<td>A partner</td>
<td>167 (31.8)</td>
<td>68 (42.5)</td>
<td>35 (31.5)</td>
<td>38 (33.6)</td>
<td>26 (18.4)</td>
</tr>
</tbody>
</table>

Bold indicates statistical significance by chi square using a 0.05 alpha standard.
CrossPAC Data, Reasons why some won’t screen for anal cancer by race (n=526)

Asterisk indicates statistical significance by chi square using a 0.05 alpha standard.
CrossPAC Data, Reasons why some won’t screen for anal cancer by gender identity

The doctor might be rude to them because they’re transgender.

- man (n=503)
- non-binary (n=23)

p value < 0.05
CrossPAC Data, Clinical visits

• Digital Anal Rectal Examinations are part of each clinical visit in both PAC Studies (n=377)
CrossPAC Data, Clinically observed lesions, n (%)  

<table>
<thead>
<tr>
<th>Lesion</th>
<th>total n=377</th>
<th>Referred for follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anal canal</td>
<td>49 (13.0)</td>
<td>16 (32.7)</td>
</tr>
<tr>
<td>Perianal region</td>
<td>118 (31.3)</td>
<td>14 (11.9)</td>
</tr>
</tbody>
</table>

Lesion includes any abnormality: enlarged hemorrhoids, skin tag, scar, condyloma, suspicious mass, etc.
CrossPAC Data, Clinically observed lesions by age, (n=377)

Prevalence of any lesion at anal canal (n=49) or perianus (n=118)
CrossPAC Data, Clinically observed lesions

<table>
<thead>
<tr>
<th>Lesion size</th>
<th>median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anal canal</td>
<td>0.2 cm (0.1 cm-1.5 cm)</td>
</tr>
<tr>
<td>Perianus</td>
<td>0.3 cm (0.1 cm-3.0 cm)</td>
</tr>
</tbody>
</table>

DARE can detect very small lesions.
CrossPAC Data, Virtual health care (n=468*)

* Question added after start of COVID-19 pandemic.
Hypothesis: fear of COVID-19 would be inversely associated with worry about cancer.

COVID-19, HIV, and Sexuality Study
-Cohort design
-5 online surveys over 10 months
-Inclusion: residence in Milwaukee, Chicago, Houston, Minneapolis, or Detroit MSAs

n=437 at enrollment

March 2020. Stay-at-home. Studies suspended. How might the pandemic affect our studies and anal cancer screening?
TAKE AWAY

• Anal cancer is rare overall, but common among MSM, especially MSM with HIV
• There are no uniform guidelines for anal cancer screening
• Medical conditions are very common in this population and should be assessed in self-screening for anal cancer
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