

**Rapid Communication**

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# A Community-Based Approach to Enhancing Anal Cancer Screening in Hawaii's HIV-Infected Ethnic Minorities

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## Abstract

**Objective:** Disparities in anal cancer incidence among Hawaii's HIV-infected minority population is an emerging health concern. Although anal cytology/anoscopy are effective anal cancer screening tools, social barriers exist that prevent individuals from seeking appropriate care.

**Design:** Community based participatory research (CBPR) principles were applied to develop resources, including testing a self-obtained anal specimen procedure, to increase anal cancer screening among Hawaii's underserved/minority populations.

**Methods:** A team of community members, academic researchers, and health care providers developed culturally-sensitive educational/recruitment materials regarding anal cancer risk targeting underserved/minority HIV-infected individuals. Self- and health care provider (HCP)-obtained anal cancer screening specimens were reviewed for cytology and tested for human papillomavirus DNA. A follow-up evaluation elicited feedback on attitudes and experiences.

**Results:** Community discussion sessions identified key messages about anal cancer, anal cancer screening, and HPV infection for materials and were used, that successfully recruited 46 individuals (38 males/8 females; 9 Native Hawaiians/Pacific Islanders/Asians, 2 Blacks, 6 Hispanics, 6 American Indian/Alaskan Natives, 23 Whites). Concordance in cytology results between self- and HCP-obtained specimens was moderated ( $\kappa=0.37$ ) with the perception that the self-obtained specimen procedure was private (93%), safe (100%), and easy to manage (100%); and a majority (92%) willing to use the self-obtained method again.

**Conclusions:** CBPR was a practical approach in engaging Hawaii's HIV-infected minority participation in anal cancer screening research. Community outreach and recruitment efforts suggested that self-obtained screening specimens could be an acceptable and effective means to reach Hawaii's HIV-infected ethnic minorities.

**Keywords:** Human papillomavirus; Anal neoplasia; Anal dysplasia; Human immunodeficiency virus

## Introduction

Anal cancer rates have risen in the past three decades for both men and women [1,2] with a five-fold increased risk among HIV-seropositive men and women [3,4]. Like cervical cancer, the majority of anal cancers are associated with human papillomavirus (HPV) infection [5-10]. The incidence of anal cancer in men who have sex with men (MSM) before the onset of the HIV epidemic was approximately 35 per 100,000, comparable to cervical cancer incidence in women before the introduction of cervical cytology screening [3,4,10-12]. It is therefore likely that the early detection of anal cancer or anal intraepithelial lesions (AIN) in high-risk, HIV-infected individuals would have tangible public health benefits.

There continue to remain barriers to anal cancer screening within high-risk populations including the need for education about the importance of anal cytology screening among health care providers and their patients, particularly in Hawaii where the HIV/AIDS epidemic disproportionately affects ethnic minorities [13,14]. In Hawaii, the stigma of HIV/AIDS in the Native Hawaiian-Pacific Islander and Asian population remains a major obstacle to seeking appropriate healthcare which is compounded by the segmented Hawaiian Islands' geography, general physician shortages, and rural isolated communities [15].

The Hawaii Center for AIDS with its Community and Scientific

Advisory Boards, representing patients, medical providers, patient advocates and AIDS service organizations and patient navigator determined that information on the importance and availability of anal cancer screening was not being effectively disseminated to Hawaii's underserved Native Hawaiian-Pacific Islanders and Asians at risk for anal cancer. Given this need for education and access to preventive care for anal cancer, the current study was designed to support collaborations between clinical researchers, medical providers, and members of Hawaii's HIV infected community to meet the following three primary research objectives: 1) To enhance community awareness on the importance of anal cancer screening among HIV-infected Native Hawaiian-Pacific Islanders and Asians; 2) To evaluate HPV DNA and anal cytologies from self-obtained and healthcare provider (HCP)-

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obtained specimens to compare the two specimen collection methods; and 3) To determine whether a self-obtained anal specimen procedure might reduce barriers to anal cancer screening within Hawaii's multiethnic and multicultural population. The diverse ethnicities found in Hawaii and the cultural sensitivities of these populations regarding HIV infection necessitated the identification of specific, sensitive, and appropriate communication strategies to build broad awareness about anal cancer risks and screening. We hypothesized that self-obtained cytology specimens would minimize a patient's self-consciousness and fear of discomfort associated with anal specimen collection. While previous studies demonstrated that self-obtained cytology samples from MSM were adequate for cytological examination and comparable in quality to those obtained from clinicians [16,17], the demographic profile of the 'at-risk' population in Hawaii diverged substantially from participants in previous studies who were already accustomed to routine cytological testing or were mainly Caucasians [16,17]. This study sought to understand patients' perceptions and attitudes concerning self-obtained cytology samples as compared with those collected by a health care provider.

## Methods

### Community-based participatory research (CBPR)

CBPR methods were used to promote mobilization and education within Hawaii's HIV-infected community about anal cancer risks and the adoption of anal cancer screening [18]. The research team was comprised of representatives from the University of Hawaii Cancer Center and the Hawaii Center for AIDS and the patient navigator as part of the NCI-funded AIDS Malignancy Consortium. This group convened the Hawaii Center for AIDS Community and Scientific Advisory Boards as a first step towards engaging Hawaii's HIV-infected community with the study [18]. The Community and Scientific Advisory Board study team consisted of twelve members that included HIV-infected patients, community physicians, public policy personnel, and health care professionals caring for HIV-infected clients in Hawaii. The Community and Scientific Advisory Boards were previously established to provide advice and input for other clinical translational research involving HIV-infected patients. These combined groups of researchers, clinical providers, patient navigator, and members of Hawaii's HIV-infected community served as the research study team [18].

The community-academic research team met bi-annually throughout the course of the study. During the first meetings, the community-academic team served as key-informants to identify salient messages that could be used to inform the community about anal cancer screening and which could be used to recruit participants to the study [19]. A list of potential anal cancer educational messages was developed from a review of the scientific literature and from current patient education resources used at clinics elsewhere and were reviewed by the research team selecting a set using nominal group process [20]. A survey was developed and administered to the research study team members to evaluate the selected messages with HIV-infected individuals in the community [21].

A guided discussion session was subsequently held with HIV-infected individuals at the Life Foundation, a non-profit AIDS-service organization assisting people who are living with HIV and AIDS in Hawaii [19]. These sessions were designed to evaluate information forwarded by the community-academic research team with HIV-infected individuals in Hawaii about: 1) the importance of anal cancer

screening; 2) the use of anal cytology for screening, and; 3) the key educational messages selected to promote anal cancer screening and recruitment. Analysis of survey data was conducted using SPSS Version 19 (SPSS, Inc., 2010, Chicago, IL). Discussion group data was coded and analyzed using Grounded Theory [22]. The study was reviewed and approved by the University of Hawaii Institutional Review Board and patients underwent an informed consent process prior to participation.

### Participant recruitment and specimen collection for anal cytology

Recruitment of participants was accomplished by organizing information sessions at community forums, through recruitment materials at public events and clinic offices, through information dissemination by the patient navigator at neighbor island AIDS service organizations, and referrals by community physicians. Participants were recruited to compare self-obtained- versus HCP-collected anal specimens for cytology during the same research clinic visit using a modified protocol [23]. Consented participants who met the inclusion criteria (HIV-seropositive, male or non-pregnant female  $\geq 18$  years old, ability to perform daily activities) collected an anal cytology specimen himself or herself following instructions provided by the HCP who was not present during the self-obtained procedure. The HCP subsequently collected a second anal cytology specimen, as well as additional research specimens. The self-collection process included a kit consisting of a tube containing CytoThinPrep sample collection medium (Cytoc Corp., Boxborough, MA), a Dacron swab that was prepared with a marking tape on the swab handle 3 inches from the tip, and latex gloves. After applying gloves, the subject moistened the Dacron swab with tap water in a cup before inserting it 2-3 inches into the anal canal. A taped marking on the handle was used to indicate the three inch limit. With gentle pressure to the walls of the anal canal, the patient withdrew the swab from the anal canal with a spiral motion over a 10-second period and placed the swab into the CytoThinPrep medium. The swab was agitated vigorously in the medium for 10 seconds and discarded in an appropriate waste container and the collection tube covered. The HCP repeated the same procedure with the second swab placed in a separate medium container. Both containers were sent to a CLIA-certified laboratory, processed, and the cytology reviewed by the same pathologist (JK) according to the Bethesda system and anal intraepithelial neoplasia (AIN) system [24,25]; and categorized as: 1) Negative if no cellular changes could be detected or if cellular changes were caused by inflammation or reparative process; or 2) Low- or high grade squamous intraepithelial lesions (LGSIL/HGSIL) for simple HPV changes and AIN I or AIN II and III, respectively. Concordance was defined if the HCP- and subject-obtained specimens which had similar AIN I/II/III or negative cytologies.

### HPV genotyping

DNA from a separate anal specimen was extracted using commercial reagents (Qiagen Inc, Valencia CA) and analyzed for the presence or absence of HPV DNA by PCR using a modified version of the PGMY09/PGMY11 primer system [26]. HPV DNA-positive specimens were then genotyped using a reverse line blot detection method for 37 different HPV types including high-risk (HR) types 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73, and 82; low-risk (LR) types 6, 11, 42, 54, 61, 72, 84, and CP6108; and undetermined risk types 55, 62, 67, 71, 83, and 84 (Roche Molecular Systems, Pleasanton, CA) [26-28]. HPV-positive specimens that were subsequently found to be negative in the genotyping assay were considered to be unclassified HPV-positive

	All		Males		Females	
	N	%	n	%	n	%
Number of subjects	46	100	38	83	8	17
Mean age (SE)	49 (1.2)		49 (1.4)		50 (1.7)	
Race/ethnicity						
Non-Hispanic White	23	50	18	47	5	62
Hispanic/Latino	6	13	5	13	1	12
African American	2	4	1	3	1	12
Asian	4	9	3	8	1	12
Native Hawaiian/Pacific Islander	5	11	5	13	0	0
American Indian/Alaska Native	6	13	6	16	0	0
HPV test result*						
Negative	17	37	12	32	5	62
Positive	29	63	26	68	3	38
Oncogenic HPV genotype†						
Negative	24	52	18	47	6	75
Positive	22	48	20	53	2	25
HCP-specimen cytology						
Negative	28	61	22	58	6	75
AIN I/II/III**	18	39	16	42	2	25
Subject-specimen cytology						
Negative	26	56	20	53	6	75
AIN I/II/III**	20	44	18	47	2	25

Key: n, number; SE, standard error; HPV, Human Papillomavirus; HCP, health care provider

\*Positive for any HPV type

†Positive for oncogenic HPV type(s) only

\*\*AIN I/II/III: Anal intraepithelial neoplasia Grade I (mild changes in abnormal cells); Grade II (moderate changes in abnormal cells); Grade III (severe changes in abnormal cells)

**Table 1:** Participant Demographics.

A. All subjects			B. Males			C. Females		
Subject Cytology	HCP Cytology		Subject Cytology	HCP Cytology		Subject Cytology	HCP Cytology	
	Negative	Atypical		Negative	Atypical		Negative	Atypical
Negative	20	6	Negative	15	5	Negative	5	1
Atypical	8	12	Atypical	7	11	Atypical	1	1
$\kappa$ : 0.37 (95% CI: 0.10, 0.64)			$\kappa$ : 0.36 (95% CI: 0.07, 0.66)			$\kappa$ : 0.33 (95% CI: -0.41, 1.00)		

**Table 2A:** Concordance of Anal Cytology Results: Subject versus Health Care Provider (HCP).

specimens. All specimens were tested for the human  $\beta$ -globin gene as an internal control for sample sufficiency. Specimens testing negative for  $\beta$ -globin were considered insufficient and excluded from analyses.

### Self-obtained anal cytology specimen evaluation

A questionnaire was administered to assess perceptions about self-obtained anal cytology specimens. The questionnaire was adapted by the community-academic research team from an instrument originally created to assess self-obtained specimens for Chlamydia [29]. Study participants were contacted and those who agreed to participate in the survey were given the questionnaire with arrangements to have the completed survey returned to study personnel.

### Statistical analysis

Concordance between subject- and HCP-collected specimens was evaluated using Cohen's Kappa statistic ( $\kappa$ ) [30]. Logistic regression was used to assess the association between oncogenic HPV genotype and a positive cytology result [31]. Chi-square test was used to analyze by collection methods.

## Results

### Community-based participatory research

Fourteen of the 32 (43%) discussion session attendees completed the survey that sought to identify key messages about anal cancer, anal cancer screening, and HPV transmission and infection. The themes that were identified confirmed the primary importance of providing information about anal cancer risks and screening to HIV-infected individuals in Hawaii. Key messages were used to create recruitment materials including posters, flyers, and brochures to educate Hawaii's HIV-infected community about the importance of anal cancer screening and to encourage participation in the study. The patient navigator led discussion sessions and assisted participants through the study. These sessions enhanced study recruitment, particularly in Hawaii's rural communities including the neighbor islands.

### Anal cancer screening participants

Forty-six participants were recruited including 38 men and 8 women (Table 1). The patient navigator and community-vetted promotional materials recruited HIV-positive individuals from rural areas and diverse ethnic groups throughout the Hawaii. Six of seven study participants recruited from rural areas in Hawaii joined as a result of outreach efforts by the patient navigator. Participant demographics included Asians (9%), Native Hawaiians and Pacific Islanders (11%), Hispanics (13%), African-Americans (4%), and American Indians and Alaskan Natives (13%). Seven participants (15%) resided in neighboring (non-Oahu) Hawaiian Islands (Table 1). All of the subjects participated in the self- and HCP-obtained anal collection process.

### Anal cytology and HPV genotyping

The anal cytology results from HCP- versus self-obtained specimens showed moderate concordance,  $\kappa=0.37$  with no difference in concordance between genders (Table 2A). Concordance was defined if both HCP- and subject-obtained specimens had similar AIN I/II/III or negative cytology results. For HPV genotyping, all specimens initially screened for good quality DNA using  $\beta$ -globin primers. HCP- and subject-collected anal cytologies with AIN I/II/III showed moderate concordance for the presence of oncogenic HPV in the same specimens,  $\kappa=0.31$ , with HCP-obtained AIN I/II/III specimens being 3.6-fold more likely to be associated with an oncogenic HPV type than specimens with a normal cytology ( $p=0.04$ ) (Table 2B). The p-value tests whether the odds ratio (OR) is statistically significantly different from 1.0 (null). A p-value of less than 0.05 indicates that there is a statistically significant association for the different oncogenic types versus the reference group. In contrast, among subject-obtained specimens, no significant association of AIN I/II/III with oncogenic

A. HCP-Obtained Specimens		n	OR	95% CI	p-value***
Non-oncogenic HPV only / negative		24	1	Reference group	
Any oncogenic HPV type(s)		22	3.6	1.0, 12.5	0.04
B. Subject-Obtained Specimens		n	OR	95% CI	p-value***
Non-oncogenic HPV only / negative		24	1	Reference group	
Any oncogenic HPV type(s)		22	2.4	0.7, 7.9	0.15
C. HCP or Subject-Obtained Specimens		n	OR	95% CI	p-value***
Non-oncogenic HPV only/negative		24	1	Reference group	
Any oncogenic HPV type(s)		22	3.7	1.1, 12.9	0.04

**Table 2B:** Association of AIN I/II/III\* with the Risk of Oncogenic HPV Genotype by HCP\*- or Subject-Obtained Specimen.



A. HCP-Obtained Specimens	n	OR	95% CI	p-value***
Non-HPV-16/18 or negative	33	1	Reference group	
HPV-16 and/or -18	13	3.7	1.0, 14.1	0.06
B. Subject-Obtained Specimens	n	OR	95% CI	p-value***
Non-HPV-16/18 or negative	33	1	Reference group	
HPV-16 and/or -18	13	2.8	0.7, 10.5	0.13
C. HCP- or Subject-Obtained Specimens	n	OR	95% CI	p-value***
Non-HPV-16/18 or negative	33	1	Reference group	
HPV-16 and/or -18	13	6.6	1.3, 34.5	0.02

\*AIN I/II/III: Anal intraepithelial neoplasia Grade I (mild changes in abnormal cells); Grade II (moderate changes in abnormal cells); Grade III (severe changes in abnormal cells)

\*\*HCP: healthcare provider

\*\*\*p-value tests whether the odds ratio (OR) is statistically significantly different from 1.0 (null); a p-value of <0.05 suggests that the association for the different oncogenic types versus the reference group is statistically significant

**Table 2C:** Association of AIN I/II/III with Risk of HPV-16 and/or -18.

HPV was found; although for any AIN I/II/III specimen regardless of who collected the specimen there was a 3.7-fold increased likelihood of association with an oncogenic HPV type ( $p=0.04$ ) (Table 2B). Similar findings were noted when the analyses were focused on AIN I/II/III and only oncogenic HPV genotypes 16 and 18 (Table 2C).

### Self-obtained anal cytology specimen evaluation

Among the 46 participants, 31 (67%) consented to complete the follow-up questionnaire. Participants preferred to be evaluated in the Hawaii Center for AIDS clinic (42%) or given the option of having a self-obtained (45%) anal cancer screening procedure rather than to have an anal screening test performed by their private physician (13%). This preference was not influenced by concordance with the HCP-obtained sample (overall,  $p=0.80$ ) or with the presence of oncogenic HPV (overall,  $p=0.39$ ). There was also no difference in preference between the patient preferring to obtain his/her own specimen versus someone else (either the HCP or private physician),  $p=0.40$ . However, given the three options of collecting the anal specimen (self, HCP, private physician), self-obtain collection was preferred,  $p=0.01$ , but the small sample size limits the interpretation of the analysis. No differences were observed in preference by who obtained the anal specimen based on gender ( $p=0.81$ ) or by ethnic minority background ( $p=0.86$ ). There was a trend towards non-Caucasians finding the self-obtained collection more comfortable compared to Caucasians; and overall, the age group 40-60 years described the self-obtained procedure to be uncomfortable.

The self-obtained anal cytology specimen procedure was perceived by participants as being private (93%), safe (100%), and easy to manage (100%), regardless of concordance with the HCP-obtained sample or the HPV result. The majority of participants (92%) stated that they would use the self-obtained anal specimen collection method again and would prefer to collect their own specimen even if the results were inconsistent with those obtained by the HCP or were found to be HPV positive. To determine if any of the preferences were different based on ethnicity was not possible because the post-study survey was administered without any asking for any personal identifying information.

### Discussion

Community engagement and input provided an opportunity to disseminate culturally-appropriate and culturally-sensitive information to complement recruitment efforts by the patient navigator in the anal cancer screening study among HIV-infected Native Hawaiians, Pacific Islanders, Asians, disadvantaged, and rural populations in Hawaii including populations on neighboring Hawaiian Islands. The rich ethnic

and racial diversity in Hawaii set the foundation to implement CBPR principles for enhancing anal cancer screening among HIV-infected minority populations. To achieve our objectives community members, AIDS service organizations, health care practitioners, the Hawaii State Department of Health and other community stakeholders assisted with the study's implementation and promotion. Engagement of community advisory groups and Hawaii's AIDS service organizations allowed for interactive feedback which fostered a sense shared responsibilities that served to support and refine the study design, methods and resources, and facilitated the dissemination of research findings. The action orientation of the study enhanced anal cancer screening among HIV-infected men and women while building the knowledge and skills of community members and researchers.

Our results demonstrated substantial ethnic minority participation in anal cancer screening, including active involvement from rural Hawaiian island communities that have been traditionally underserved. Community outreach with the patient navigator visiting the neighbor island AIDS service organization disseminated information about the importance of anal cancer screening. Among the seven study participants from Oahu's neighbor islands, six had their first anal cancer screening through enrollment in the study.

A long-term research objective was to design an anal cytology self-collection home kit for HIV-infected populations in Hawaii who continue to experience barriers to anal cancer screening in a healthcare setting. The results of the current study demonstrated reasonable concordance between subject- and HCP-obtained anal cytology specimens, although the agreement in our study was lower than anticipated from published research [16,23]. One possible explanation for the less than expected concordance between cytology results from subject- versus HCP-obtained anal specimens is that the anal cancer screening was the first experience for 72% of the participants and the limited exposure and experience on the methodology and process. Laboratory differences in interpreting cytology results are less likely sources of variation because the same pathologist (JK) reviewed all of the cases.

The follow-up survey of the study participants demonstrated overwhelming satisfaction with the ease of the self-obtained anal cytology specimen collection method. There was also no significant difference in whether patients preferred to obtain their own specimen versus having a specimen obtained by either the HCP in the research clinic or their private physician. These data served to design a follow up study of a self-obtained home sampling kit that would be an option for anal cancer screening that could minimize an individual's consciousness and fear of discomfort associated with anal cytology collection in the clinical setting. The small sample size is a limitation of the study and validation of the results is needed in a larger study. The study was also not designed to evaluate the cost-effectiveness of implementing self-obtained anal cytology collection. This would be important to assess in future studies.

Native Hawaiians account for an increasing proportion of AIDS cases in Hawaii, thus education and information dissemination regarding HIV-associated anal cancer and its relation to HPV infection is an emerging public health priority [32,33]. Our results underscore the potential of the CBPR approach to increasing anal cancer screening among Hawaii's underserved populations. The study results demonstrated that building alliances with key community partners to engage populations at high-risk for anal malignancy was effective in disseminating information and participating in anal cancer screening of Hawaii's HIV-infected community.

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