Opening an Anal Cancer Screening Service for a Unique HIV Positive Patient Population in a Small to Medium-Sized City: Lessons Learned

Standard 4.7 Studies of Quality

The Purpose of the Study.

Studies of anal dysplasia and carcinoma in human immunodeficiency virus (HIV) infected patients are increasingly appearing in relevant literature with needs for and impacts of anal cytology screening programs being reported from several health care centers. As an historical perspective / comparison, exfoliative cytology of the female genital tract (cervix and vagina) has been employed as a routine cancer screening test in North America for decades. This testing is now standard of care and has resulted in a significant diminution in the number of invasive cervical squamous carcinomas through early detection and subsequent management of precursor lesions. Prior to implementation of broad scale screening, cervical cancer was the number one cause of cancer mortality for women in the United States. Today, invasive cervical cancers are less commonly encountered, and this disease now falls outside of the "top ten" most frequently diagnosed and most commonly fatal malignancies for women.[1] It is well known that most / nearly all cervical cancers are HPV mediated.[2,3] As the incidence and frequency of death from invasive cervical cancer has decreased, the incidence and frequency of death from anal cancer (another HPV mediated condition) has increased for both men and women.[4,5] Anal cancer precursors (like cervicovaginal dysplasias) are often asymptomatic, and because population based screening for anal neoplasia is not practiced, it is not uncommon for persons with HPV mediated anal disease to be diagnosed with mass lesions by digital anal exam or to present with symptoms such as bleeding. Certain specific populations may be predisposed to developing anal warts, dysplasias and carcinomas. Perhaps the most widely studied populations include HIV infected persons and men who have sex with men (whether HIV positive or not).[6-11] Availability of anal cytology screening is currently variable, and as anal dysplasia clinics open, some are reporting their findings.[12] Most currently operating anal dysplasia screening programs are located in urban/highly populated geographies. Herein, we report our experiences with opening an anal cytology screening program for HIV infected persons in Everett, Washington (a medium-sized Pacific Northwest community with a population of approximately 100,000 people). It is our hope that targeted screening of patient cohorts who are at highest risk of developing HPV mediated anal neoplasia may stem the tide of increasing disease incidence, ideally preventing both morbidity and mortality.

1. Setting the Study Topic.

An electronic medical record retrieval for first time anal cytology screening tests (CellNetix Pathology and Laboratories, Everett, Washington, U.S.A.) was performed for the two year period 03/2011 through 03/2013. All anal cytology samples were collected by one physician (S.A.D., Internal Medicine, HIV Specialist, American Academy of HIV Medicine) working in an outpatient clinic (The Everett Clinic, Harbour Pointe, U.S.A.). All samples were collected using Dacron swabs. The employed collection technique was based upon the instructional video *Anal Pap Smear A Simple, Fast & Easy Procedure HRSA Grant #6 H4AHA006002, 2004, Johns Hopkins University School of Medicine, Infectious Disease Division*. During the first seven months of the twenty-four month period, the samples were submitted in SurePath vials (Becton Dickinson Company). During the last seventeen months, the samples were submitted in ThinPrep vials (Hologic). Samples were processed per product guidelines. Cytomorphologic interpretation was based upon The Bethesda System for Reporting Cervical Cytology, Second Edition.[13] HPV DNA testing was not performed. Results of the retrieval were entered into a spread sheet for data organization and were correlated with a review of the electronic clinical / laboratory medical records of each of the identified patients. Data points gathered for spread sheet entry for each patient included age at time of cytology sample collection, gender, HIV viral load (measured within preceding six months), CD4+ cell count (measured within preceding six months), documentation of current use of highly active antiretroviral therapy (HAART), and cytologic interpretation. All patients interpreted to have squamous intraepithelial lesions on cytology were referred to high resolution anoscopy. Follow up information (12/2013, with time frames ranging from a minimum of 9 months to a maximum of 33 months) was also recorded in spread sheet columns. Follow up data points included all subsequently available cytology or histology interpretations and corresponding chronologic intervals from the time of primary entry into the screening program. Institutional review board (IRB) approval for this retrospective project was sought and granted by Western IRB, Olympia, WA, letter dated 08/30/2013.

2. Define Criteria for Evaluation.

The anatomic pathology laboratory information system data retrieval identified 138 patients who underwent first-time anal cytology testing in the initial two years of the screening program at The Everett Clinic. All patients were HIV positive. The majority of patients were male (60%), and all patients were adults. Patient ages ranged from 20 to 72 years with a mean age of 44 years. (See Table 1 for demographic data). The majority (88%) of patients was receiving combination antiretroviral therapy at the time of anal cytology screening, and the majority of patients (75%) had viral loads that were undetectable by polymerase chain reaction testing. The mean CD4+ cell count was 595 cells/uL. Of the 138 patients who underwent anal cytology screening, 62 (45%) were identified with abnormal squamous epithelial findings. (See Table 2 for cytology interpretations and subsequent follow up results). Thirty patients (22%) were interpreted to have atypical squamous cells of undetermined significance (ASC-US). Three patients (2%) were interpreted to have atypical squamous cells, cannot exclude high grade squamous intraepithelial lesion (ASC-H). Twenty-six patients (19%) were interpreted to harbor a low grade squamous intraepithelial lesion (LSIL). Three patients (2%) were interpreted to have high grade squamous intraepithelial lesions (HSIL). No invasive carcinomas were identified. Of the patients with lesional (ASC and above) interpretations, 41 (66%) had either additional cytology or histology follow up. Histologic follow was made possible through routine processing of high resolution anoscopic biopsies. The majority of patients without follow up were those in the ASC-US category. The percentages of patients with HSIL, anal intraepithelial neoplasia (AIN) 2/3, on follow up were 100% for those patient's with HSIL cytology, 67% for those patients with ASC-H cytology, 42% for those patients with LSIL cytology, and 3% for those with ASC-US cytology.

3. Conducting the QI Study According to the Identified Measures.

The retrospective data points were collected by CellNetix Pathology and Laboratory technical staff from the laboratory information system. The information was reviewed and collated by PRCP cancer liaison physician and pathologist, Charles D. Sturgis, M.D. Clinical correlative data was garnered from the electronic medical record by Sheryl A. Dreyer, M.D.

4. Prepare a Summary.

See Tables 1 through 3 and Figures 1 through 3 below followed by explanatory paragraphs.

Table 1

Demographics

Number of patients for first time anal cytology screening	**138**
Male	83 (60%)
Female	55 (40%)
Youngest age (years)	20 years
Oldest age (years)	72 years
Mean age (years)	44 years
Lowest absolute CD4+ cell count (cells/uL)	86
Highest absolute CD4+ cell count (cells/uL)	1253
Mean CD4+ cell count (cells/uL)	595
Lowest viral load (copies / ml)	0 (75%)
Highest viral load (copies / ml)	148,000
Mean viral load (copies / ml)	3,105
Currently on HAART	121 (88%)
Currently not on HAART	17 (12%)
Number of patients with lesional (ASC & above) cytology	**62 (45%)**
Number of lesional patients with no follow up	21 (34%)
Number of lesional patients with cytology follow up	21 (34%)
Number of lesional patients with biopsy follow up	20 (32%)

HAART = highly active antiretroviral therapy, ASC = atypical squamous cells

Table 2

Cytology and Follow Up

Interpretive Category	%	#	HSIL (AIN 2/3) Follow Up #	HSIL (AIN 2/3) Follow Up %
Unsatisfactory	1	1		
NILM	54	75		
ASC-US	22	30	1	3
ASC-H	2	3	2	67
LSIL	19	26	11	42
HSIL	2	3	3	100
Totals:	100%	138	27	20%

NILM = negative for intraepithelial lesion / malignancy, ASC-US = atypical squamous cells of undetermined significance, ASC-H = atypical squamous cells cannot exclude high grade dysplasia, LSIL = low grade squamous intraepithelial lesion, HSIL = high grade squamous intraepithelial lesion, AIN = anal intraepithelial neoplasia.

Table 3

Follow Up HSIL by Gender

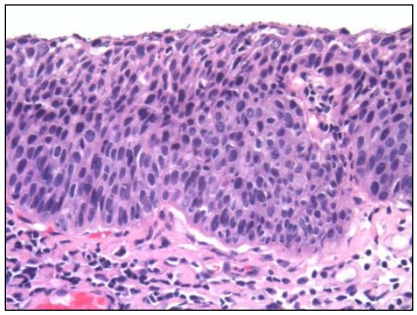
	Undergoing Primary Anal Cytology Screening	Follow Up (9 to 33 Months) of HSIL (AIN 2/3) by HRA Biopsy
Men	83/138 (60%)	14/16 (87%)
Women	55/138 (40%)	2/16 (13%)

HSIL = high grade squamous intraepithelial lesion, AIN = anal intraepithelial neoplasia, HRA = high resolution anoscopy.

Figure 1.

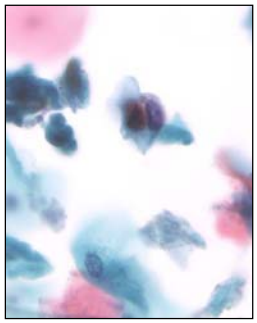
Koilocytes identified in initial anal screening cytology from a 57 year-old, HIV+, male patient. Anal cytology interpreted as LSIL (low grade squamous intraepithelial lesion). Papanicolaou stain, 630X.

Figure 2.



Moderate to severe squamous dysplasia (anal intraepithelial lesion [AIN 2/3], high grade squamous intraepithelial lesion [HSIL]) in a histologically processed high resolution anoscopic biopsy from a 57 year-old, HIV+, male (same patient as Figure 1) whose screening cytology was originally interpreted as low grade squamous intraepithelial lesion (LSIL). Hematoxylin and eosin, 400X.

Figure 3.



Rare cells of high grade squamous intraepithelial lesion (HSIL) in a 57 year-old, HIV+, male patient (same patient as in Figures 1 and 2) were identified on retrospective review for cyto-histologic correlation. Papanicolaou stain, 630X.

Contrary to the noted decreasing trends of preinvasive and invasive squamous tumors of the cervix and vagina, age-adjusted incidence rates for preinvasive and invasive squamous anal malignancies are significantly increasing over time.[4] The incidence of anal cancer is known to be elevated in HIV infected men who have sex with men compared to the general population, and anal HSIL has clear potential to progress to invasive disease in this group.[6,11] The goal of clinical management of patients with HPV mediated lesions of the lower anogenital tract should be to identify and treat patients with high grade precursor lesions (HSIL) to decrease the risk of developing invasive cancers.[14] Some investigators have suggested that risk factor assessment / stratification in HIV infected patients may help to disentangle the influences of anal exposure to HPV, immunodeficiency, tobacco smoking, and combined antiretroviral therapy.[15,16] Such stratification might allow for development of algorithms as to which subpopulations are in greatest need of anal cytology screening. No clear correlations could be made with CD4+ cell counts or with measurable viral loads in our study; however, our "n" is low, and this is a limitation of this investigation. Some authors suggest annual screening for all patients with HIV, and this is our preferred approach.[7]

One unique characteristic of the population in our current retrospective review is the percentage of female patients presenting for first time screening and follow up (40%). The female patients in this cohort acquired their HIV infections through heterosexual practices and/or through intravenous drug use. It is uncertain what percentage of these women engaged in receptive heterosexual anal intercourse. While women represented 40% of the patients initially screened, they represented only 13% of the patients who were ultimately found to harbor high grade squamous intraepithelial lesions (AIN 2/3) on high resolution anoscopy with biopsy over the average of 21 months of follow up time. (See Table 3 for HSIL follow up by gender). The comparatively large percentage of female patients with HIV in this study may be one explanation for the somewhat lower fractions of patients with abnormal cytology in comparison to other reports.

Another lesson learned from this retrospective review is that cytology appears to underestimate the grade of dysplasia when compared to results of corresponding anoscopically guided biopsy histology. The sensitivity and specificity of a single anal cytology specimen have been reported to be comparable with those for a single cervical cytology test; however, lesional severity does not always correlate between the two modalities, and high resolution anoscopy with biopsy and histologic interpretation is most often viewed as the gold standard.[6,17-18] In the current review, 42% of patients (mostly men) interpreted to have LSIL on screening cytology were subsequently found to have HSIL on biopsy follow up. This figure is more than four times higher than the 10% that we see in our geographically identical general cervical screening program (for all women of all ages and all immune statuses). The practice pattern in our local pathology professional group is one in which the cervicovaginal and anal cytology screening specimen slides are interpreted by all of the anatomic pathologists (non-specialty sign out). In revisiting the cytology and histology slides from all of the patients initially classified as LSIL on cytology, at least three of these patient's could have been originally labeled as HSIL. (See Figures 1, 2 and 3 for a case example of a patient interpreted with LSIL whose follow up revealed HSIL and retrospective cytology review confirmed rare overlooked HSIL cells in the original screening cytology). While it cannot be said with absolute certainty, it may be that assigning these anal cytology cases to a focused group of pathologists with cytopathology expertise might result in greater accuracy and reproducibility. The literature on this topic suggests moderate to good agreement between cytopathohlogists evaluating anal cytology specimens from HIV positive men who have sex with men.[19] A recent College of American Pathologists Interlaboratory Comparison Program in Nongynecologic Cytology showed poor performance on anal cytology, especially with regard to correct identification of HSIL, and indicated a need for continued education about anal cytology.[20]

Currently, there are no national guidelines or organizationally approved recommendations for anal cytology screening. This lack of published guidelines results in many "unanswered" questions about which patients should be screened and at what screening intervals testing should be performed. There seems likely to be little argument that persons living with HIV and men who have sex with men may benefit from anal screening, and some authors suggest that patients in these categories who are screened and are interpreted to have atypical squamous cells (ASC) or worse should be referred to high resolution anoscopy.[17] In our practice in Everett, Washington, following this paradigm would result in a 45% anoscopy referral rate. It is important to remember that screening for screening's sake alone is of no value, and patients who are discovered to have ASC or worse on cytology need to be examined by a well trained anoscopist. In establishing our program in Everett, we were limited in that no such person exists in our community. We do have the good fortune of being located within 40 miles of two high quality clinician anoscopists, and patients with abnormal findings are triaged to these providers in the Seattle metropolitan area for anoscopy with biopsy and relevant follow up. In communities without high resolution anoscopy services, it is of paramount importance to establish clinical connections with a referral anoscopist prior to starting a screening service.

Because the prevalence of anal HPV infection in HIV infected men is high (more than half of patients in many studies), we chose not to reflex atypical cytology results to HPV DNA testing in designing our triage approach.[21-25] There is a literature to suggest that commercially available DNA tests are valid for use in liquid based anal cytology samples.[26] It is possible that HPV DNA testing might have utility in centers where anal cytology screening is performed on patient populations other than men who have sex with men and those with HIV. Other populations in which anal cytology screening might be considered are patients who are solid organ transplant recipients and well (non-immunocompromised women) who are known to have high grade squamous intraepithelial neoplasia (HSIL) of the cervix.[27,28] Broad scale outcomes studies that systematically assess the efficacy of anal cancer screening programs in reducing the incidence and morbidity and mortality of invasive anal cancers are needed.[29]

5. Compare with National Benchmarks.

See NCDB benchmark reports below for age groups and gender trends in anal cancer in Everett in comparison to Washington State. References for text follow the NCDB data.

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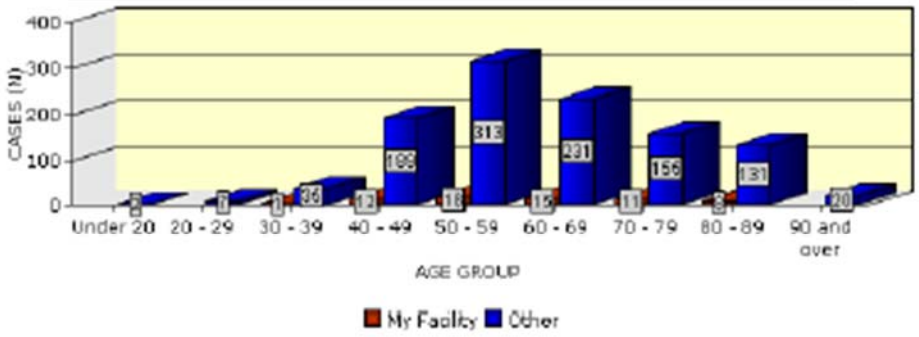
NCDB
BENCHMARK REPORTS

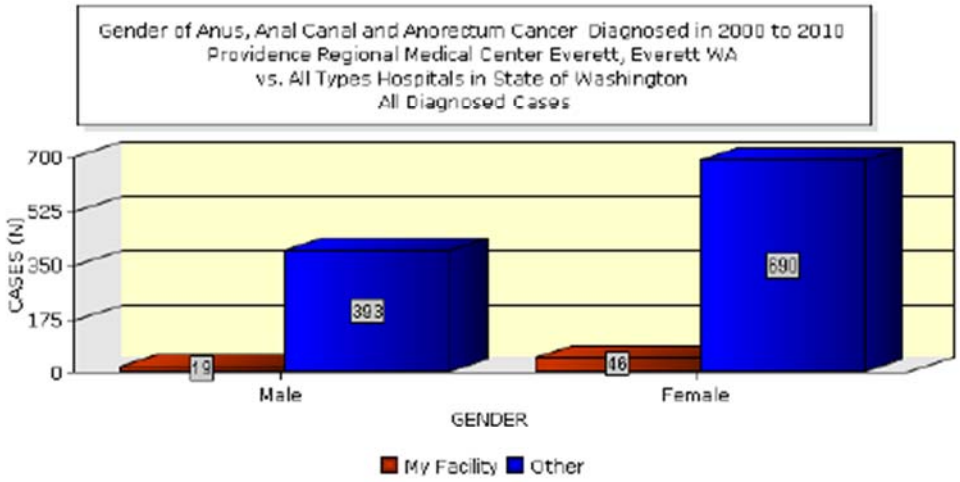
Age Group of Anus, Anal Canal and Anorectum Cancer Diagnosed in 2000 to 2010
Providence Regional Medical Center Everett, Everett WA
vs. All Types Hospitals in State of Washington
All Diagnosed Cases



	Under 20	20 - 29	30 - 39	40 - 49	50 - 59	60 - 69	70 - 79	80 - 89	90 and over
My Facility			1	12	18	15	11	8	
Other	2	7	35	189	313	231	155	131	20

Age Group of Anus, Anal Canal and Anorectum Cancer Diagnosed in 2000 to 2010
Providence Regional Medical Center Everett, Everett WA
vs. All Types Hospitals in State of Washington
All Diagnosed Cases

#	Age Group	My (N)	Oth. (N)	My (%)	Oth. (%)
1.	Under 20	.	2	.	0.18%
2.	20 - 29	.	7	.	0.65%
3.	30 - 39	1	35	1.54%	3.23%
4.	40 - 49	12	189	18.46%	17.45%
5.	50 - 59	18	313	27.69%	28.9%
6.	60 - 69	15	231	23.08%	21.33%
7.	70 - 79	11	155	16.92%	14.31%
8.	80 - 89	8	131	12.31%	12.1%
9.	90 and over	.	20	.	1.85%
	Col. TOTAL	65	1083	100%	100%



	Male	Female
My Facility	19	46
Other	393	690

Gender of Anus, Anal Canal and Anorectum Cancer Diagnosed in 2000 to 2010

Providence Regional Medical Center Everett, Everett WA
vs. All Types Hospitals in State of Washington
All Diagnosed Cases

#	*Gender*	My (N)	Oth. (N)	My (%)	Oth. (%)
1.	Male	19	393	29.23%	36.29%
2.	Female	46	690	70.77%	63.71%
	Col. TOTAL	65	1083	100%	100%

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6. Action Plan Based on the Evaluation.

Anal cancer screening in the high risk populations identified (HIV+ patients and men who have sex with men) will continue in the hopes of preventing the development of cancers in those screened. Dr. Sturgis will continue to give public discussions (including a "grand rounds" at PRCP") to educate and inform clinical colleagues as to the benefits of this screening and to possibly expand such screening to other potential higher risk groups such as women with known high risk HPV infections of the female genital tract and/or documented HSIL of the female genital tract and other people with immune compromise.

7. F/U Steps to Monitor.

We will continue to monitor anal cancer trends via NCDB data and to monitor this disease in our community. We will also keep abreast of new peer reviewed studies on this topic.

8. Monitoring the Effectiveness of the Studies Action Plan.

Our results compare similarly to those seen in the references. Ongoing monitoring will follow. We may consider conducting a similar review of "well women" at high risk of anal cancer if our clinical care community opts to screen this population going forward.

C.D. Sturgis, M.D.
12/28/13