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Overcoming Barriers to Screening for Anal Intraepithelial Neoplasia for Persons Living with HIV

Brandon Hastings
University of San Francisco, bhastings@usfca.edu

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Doctor of Nursing Practice Final Project Report

Brandon Hastings DNPc, FNP-BC, CNL

University of San Francisco

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Abstract

Screening has proven an effective strategy in the management of diseases that plague the population. This technique has proven to be most effective when screening is conducted with those who are most at risk for developing the targeted illness and when the frequency of screening follows set guidelines. Currently there are no nationally recognized screening guidelines for anal intraepithelial neoplasia (AIN). Screening for AIN stands to reduce overall incidence of anal squamous cell carcinoma through destruction of the dysplastic cells before they become cancerous. The goals of this project were to identify the patient population that stands to benefit the most from AIN screening, to identify the existing barriers to screening, and to educate primary care providers on methods to overcome these barriers. The results of this primary care practice improvement project show that with an educational forum for the providers, rates of AIN screening increased by as much as 89%. However, more attention still needs to be paid to the individual biases of providers regarding their views on AIN screening; also, more providers need training in high-resolution anoscopy, as this is the mainstay of follow-up.

Keywords: anal intraepithelial dysplasia, AIN, anal cancer, anal squamous cell carcinoma, human papillomavirus, HPV

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Since human immunodeficiency virus (HIV) has become a chronic disease, the prospect of long-term survival has become a reality for persons living with HIV (PLWH). Those who are started on anti-retroviral therapy (ART) when their CD4 count is above 200 cells/mm^3 have a reasonable expectation to live well past the age of 65 (Schneider et al., 2005). Thus healthcare providers are in the position of not only managing HIV, but they must also be cognizant of other health-related problems PLWH are susceptible to. Many age-related comorbidities affect PLWH at an earlier age, and many forms of cancer have proven widespread in this population as well, specifically anal squamous cell carcinoma (ASCC) (Patel et al., 2008). To best serve PLWH, careful attention must be paid to the increased risk of these age-related comorbidities, ASCC and it precursor, anal intraepithelial neoplasia.

Introduction

Background Knowledge

Historically the United States has been very aggressive in the development of programs to control medical problems that plague its citizens. In 1996 the United States Preventative Services Task Force (USPSTF) recommended screening for colorectal cancer (CRC) in all persons over the age of 50, resulting in a decrease in the overall incidence of CRC (USPTF, 2008; National Cancer Institute Age Adjusted SEER Incidence, n.d.). Similarly, the Papanicolaou (Pap) smear, and the subsequent set of screening guidelines, is credited with a dramatic reduction in the incidence of cervical cancer (Spitzer, 2007). Currently there are no nationally accepted guidelines for

screening patients for AIN, the suspected precursor to ASCC. Rates of ASCC in the general population have historically been low, with an increase in new cases of 2.2% per year over the past 10 years (Patel et al., 2008; National Cancer Institute Age Adjusted SEER Incidence, n.d.). However, this trend has not held true in PLWH, who some estimate have a 40 times greater chance of developing ASCC over those without HIV (Cranston, Hart, Gornbein, Hirschowitz, Cortina & Moe, 2007).

Local Problem

As of December 31, 2013 over 15,900 persons were living with HIV in San Francisco, representing 13% of the total PLWH in the state of California (San Francisco Department of Public Health, 2014). These numbers have continued to rise year after year. Newly diagnosed cases of HIV were 359 in 2013, down from 426 in 2012 (SF Department of Public Health, 2014). The rise is compounded by the fact that the number of deaths in PLWH has been steadily declining (SF Department of Public Health, 2014). This longevity of PLWH has increased their risk of developing other comorbidities.

Aim

The aim of this primary care practice improvement project is to identify and address the existing barriers to screening for AIN, real or perceived, to identify patients most at-risk for ASCC, and to educate primary care providers on methods to overcome these barriers.

Review of the Evidence

During the 1990s, before combined antiretroviral therapy, the incidence of anal

cancer in PLWH was about 20 times that of people without HIV (Patel et al., 2008). Combined antiretroviral therapy, more commonly referred to as highly active antiretroviral therapy (HAART) in the medical literature, was hailed as the solution to these alarming rates of cancer, yet the contrary proved to be true. Patel et al. (2008) examined the rates of invasive anal cancers found in PLWH over three time periods: 1992-1995 (pre-HAART), 1996-1999 (early HAART), and 2000-2003 (later HAART). This study revealed that ASCC increased in incidence from 19.0/100,000 person-years to 48.3/100,000 person-years during the pre-HAART to the early HAART. This alarming increase continued into the later HAART period going as high as 78.2/100,000 person-years over the 3-year later HAART time period. Over the course of the same time frame, the rates of anal cancer in the non-HIV infected general population increased 1.0, 1.2, and 1.3/100,000 person-years respectively (95% CI) (Patel et al., 2008). There have been other studies that have echoed these results. A cohort study in France examined over 100,000 patients from 1992-2008, with HAART readily available for the last 12 of those years, and found that the incidence of invasive anal cancer was 20 times that of the general public (p=.02) (Piketty et al., 2012).

ASCC and cervical cancer. Cervical cancer, and its precursor cervical intraepithelial neoplasia (CIN) are very closely related to ASCC and its suspected precursor AIN. In 2010 the incidence of cervical cancer in the US was 6.7/100,000 person-years, down from 14.8/100,000 in 1975 (National Cancer Institute, n.d.). The use of Pap smear technology is largely to credit for this reduction, along with a clear and unambiguous set of screening guidelines (Spitzer, 2007). The current guidelines replaced the 2003 guidelines as published by the United States Preventative Services Task Force

(USPSTF), demonstrating a continued effort to control, if not eradicate, cervical cancer through screening. The revision includes a more guided approach based on the age of the woman, and also addresses the frequency of screenings in women of all ages (Moyer, 2012). These evolving criteria are being revised in an effort to eliminate unnecessary screenings, while still identifying those most at risk for the disease. In the case of AIN, and the subsequent ASCC, the lack of nationally recognized screening criteria have resulted in many at-risk individuals not being screened at all (Palefsky, 2009).

Both ASCC and cervical cancer have dysplastic cells that serve as precursors to invasive cancer. The anal canal and the cervix both have regions of cells that have active metaplasia called the transformation zone. This is the area where the glandular epithelial cells, or columnar cells, are being replaced with squamous epithelium (Darragh & Winkler, 2011). Not only is the anatomy of the cervical and anal transformation zones similar, but cervical cancer and ASCC also share other similarities; both have a causal relationship with the human papillomavirus (HPV).

HPV. HPV is the most common sexually transmitted disease in the United States, with over 79 million Americans infected with some strain of the virus (Centers for Disease Control and Prevention (CDC), 2013). HPV is a DNA virus that has over 100 subtypes, 40 of which can infect the anogenital tract in humans (CDC, 2012). Of these 40 subtypes, the subtypes 16 and 18 have demonstrated that they are particularly oncogenic; they have shown to be the cause of 70% of cervical cancers and 90% of ASCC (CDC, 2012).

When HPV is introduced to the transformation zone in either the anus or the cervix, the rapidly changing cells presumably allow the virus easy access to the basal cell

layers. Once the basal cell layer has been infected, there is a possibility that the cell cycle will be interrupted, leading to the development of intraepithelial neoplasia (IN) (Moody & Laimins, 2010). The IN is exactly what is being sought with the screening of patients for AIN.

Bethesda system. The cytology reports produced from cervical specimens are reported using the Bethesda system. This system has been slightly modified to accommodate the subtle differences of anal cytology. The modified system ranks cells found on the specimen as either: normal, abnormal squamous cells of unknown significance (ASC-US), low-grade squamous intraepithelial lesion (LSIL), or high-grade squamous intraepithelial lesion (HSIL) (Soloman et al., 2002).

Existing barriers. When a woman is noted to have CIN during screening for cervical neoplasia on her Pap exam, she is referred for follow-up to a provider who can perform colposcopy and biopsy of any area of concern. If the areas biopsied are found to have high-grade lesions, then the cervix is treated using the loop electro-excision procedure (LEEP). Most gynecologists and Nurse Practitioners (NPs) who work in women's health provide colposcopy for CIN and LEEP if indicated. These procedures are taught routinely as part of gynecological residency training for Medical Doctors and also as part of training for NPs as they enter the women's health arena (Moyer, 2012; Palefsky, 2009; Darragh & Winkler, 2011, Bigrigg, Haffenden, Sheehan, Codling & Reed, 1994).

For patients diagnosed with high-grade lesions on anal Papanicolaou smear (Pap), the options are not as plentiful. Ideally, those with HSIL on anal Pap would be referred to a high-resolution anoscopy (HRA) trained provider. HRA is very closely related to

colposcopy and uses magnification to examine the squamous cells of the anal canal in a microscopic fashion, using equipment that has been modified to address the anatomical differences between the cervix and the anus (Goldstone, 2010). In spite of the fact that the techniques are similar, there are very few providers trained in the use of HRA (Oon & Winter, 2010).

The shortage of providers, and lack of screening guidelines, have led to fewer patients being found to have AIN and fewer people being treated with targeted destruction. This limits the ability to thoroughly evaluate efficacy of existing treatments, and limits the development of new treatments. LEEP currently produces a one-year cure rate of 95% when the entire transformational zone is removed (Oon & Winter, 2010). Unfortunately, this approach is not useful in the anal transformation zone; removal of the entire anal transformation zone would lead to mechanical impairment and strictures of the anal canal. Therefore the treatments for lesions found on anal Pap must rely on targeted destruction of the lesions (Gaisa & Goldstone, 2011). While there are many options available for the targeted destructive therapy, the efficacy rates vary widely as to recurrence rates (Gaisa & Goldstone, 2011). Full exploration of the various treatment options extends beyond the scope of this project. The main purpose here is to overcome barriers to screening, allowing a larger data set be used to better determine the most effective screening practices.

Many opponents of AIN screening point to the fact that there are no randomized controlled trials (RCTs) that aid in the determination of the best treatment modalities for AIN. There is also an obvious lack of supporting data linking the treatment of AIN to the reduction in ASCC. With both of these facts known, there is widespread support for an

RCT to examine both. However, an RCT that would examine the link between AIN and ASCC would require a control, or observation group, that could be at risk to develop the invasive form of cancer. This would lead to enormous ethical concerns that are difficult to overcome when designing the RCT. Another strategy would be to use historical controls to limit the ethical complexity of such a study. The abundance of historical data would strengthen the results and provide further evidence that increased screening now could serve a greater purpose in the future. It is also important to note that an RCT examining the relationship between the CIN and cervical cancer has never been done (Palefsky, 2009). Current screening guidelines and treatment recommendations are based on decades of observational data in areas where cervical screening has been implemented. Drastic reductions in the rates of invasive cervical cancers have been demonstrated as a result (Palefsky, 2009). To address the concerns of many medical professionals that cite the lack of hard data linking screening for AIN to a reduction in the numbers of ASCC, Dr. Joel Palefsky of the University of California, San Francisco, began enrollment in April 2014 for a random-assign quasi-experimental study. This study aims to identify over 5000 people with AIN and randomize them into two groups. One group will be treated with targeted destructive therapy while the other closely observed for progression of their HSIL and/or the development of ASCC. The results could illustrate that with screening and subsequent treatment of high-grade AIN; ASCC could be preventable (Colliver, 2013; The ANCHOR Study.org, 2015). Currently they are still recruiting participants at more than 15 sites throughout the country, and are already monitoring over 1000 participants already enrolled (The ANCHOR Study.org, 2015).

Who is at risk. Despite the fact that no RCT has ever been done linking CIN to cervical cancers, there is national acceptance of the screening guidelines currently being used. This is because the observational data has largely overshadowed the need for an RCT. During the process of developing this body of information on AIN screening, and developing the subsequent set of guidelines that will evolve out of it, identifying the proper target population is an integral step. As previously outlined, the rates of ASCC for PLWH were noticed in the 1990s, and when the rates continued to rise in spite of the HAART, researchers began to look at other potential causes for the disproportionate rise in PLWH. It is largely believed that the destruction of the immune system caused by HIV allows HPV to live in the transformation zone longer, thus allowing more time for the virus to cause IN (Palefsky, Holly, Ralston & Jay, 1998). Additionally, men who have sex with men (MSM) have demonstrated rates of ASCC far above rates found in the general population, regardless of HIV status. Anoreceptive intercourse allows the anal mucosa, especially the transformation zone, to come into direct contact with the HPV-infecting source (Palefsky et al., 1998).

Research supports the fact that MSM living with HIV (LWH) are most at risk for the development of AIN and subsequently ASCC. When the practitioner is attempting to stratify the risk profile of their patients, discussion of HIV status is a given in most instances; however, to wholly identify all those who would benefit from AIN screenings, discussion regarding sexual health is necessary. Recent literature has demonstrated that in some cases as many as 29% of patients have not had a discussion with their primary care provider regarding sexual orientation (Petroll & Mosack, 2011). Moreover, MSM require additional risk stratification in the areas of risk reduction, substance abuse and

disease prevention, adding even more importance to this discussion (Gee, 2006; Rosa-Cunha, Cardenas, Dickinson & Metsch, 2010). Rosa-Cunha et al. (2010) also found that just over 33% of patients being treated in a clinic specifically designed for PLWH had any discussion with their provider regarding sexual practices, specifically anoreceptive intercourse.

While MSM, PLWH and MSM-LWH are at the highest risk for AIN, there are other smaller subgroups that should be considered when seeking to identify those who need AIN screening through the anal Pap. Women LWH should be considered for the anal Pap. While the fact that the woman is LWH is not an indicator alone, this should invite a more thorough line of questioning, specifically as to a history of anoreceptive intercourse, or history of HPV. If the woman has a history of either, then she would qualify for AIN screening. Women who have lower genital tract squamous IN are also at increased risk for the development of IN in the anogenital tract (Santoso, Long, Crigger, Wan & Haefner, 2010). All patients who are immunosuppressed for reasons such as organ transplant, and have a documented history of HPV in the genital or anal region, should be considered for screening as well (Collett, Mumford, Banner, Neuberger & Watson, 2010).

Existing guidelines. While not nationally accepted, the New York State Department of Health AIDS Institute (NYDHAI) implemented an AIN screening guideline for practitioners in 2007, and is currently revising to their guidelines to better serve their patients and also to stay current with the data as it grows (New York State Department of Health, 2007). The current NYDHAI guidelines are that PLWH who are: men who have sex with men (MSM), men or women who have a history of anogenital

condylomas, or women with abnormal cervical and/or vulvar histology, should be screened on an annual basis (New York State Department of Health, 2007). Any patient who is found to have ASC-US, LSIL, or HSIL is referred for HRA with biopsy as indicated (New York State Department of Health, 2007). The United States Department of Veterans Affairs (VA) adopted a similar screening guideline in 2009, and subsequently updated it in 2011 to include more PLWH (US Department of Veterans Affairs, 2011). This guideline is similar to the previous one in that a baseline screening is recommended, and then on an annual basis thereafter, with all ASC-US, LSIL and HSIL being referred for HRA and biopsy. However they go somewhat further as to whom they include in the screenings. The VA screens PLWH and who are one of the following: MSM, persons with a history of receptive anal intercourse, persons with a history of anogenital condylomas, women with abnormal cervical and/or vulvar histology, or tobacco smokers (US Department of Veterans Affairs, 2011).

For the purposes of this project, the guideline will be as follows: MSM-LWH or women LWH who have a concomitant history of cervical or vulvar dysplasia. These criteria were chosen in response to the supporting literature highlighting this patient population as the most at risk for the development of ASCC (Palefsky et al., 1998). The main criterion that was omitted from the project screening guidelines was current or historical tobacco smoking, as noted in the VA screening guidelines. This criterion was removed due to the lack of evidence linking tobacco smoking and an increased risk of ASCC or AIN.

Benefits of screening. The definitive standard as to the effectiveness of this cancer-screening program is a reduction in the number of people with the cancer through

targeted destruction of the pre-cancerous lesions. While this may seem like an obvious statement, one can only reach that conclusion after a satisfactory number of screenings have been performed, studied, and then reported back to the scientific community. Unfortunately not enough data exist to support such claims in the case of ASCC. In areas where many, yet not all, high-risk individuals receive anal cancer screening, the rates of anal cancer have remained relatively stable, while in other parts of the country, the rate of ASCC has doubled (Katz, Clarke, Bernstein, Katz & Klausner, 2009). Further study of those rates is required to fully ascertain the connection between rates of screening and rates of invasive cancers. Screening for AIN, and subsequently ASCC, can also be examined from a different perspective. Patients who have anal cancer diagnosed when in situ have an 80% survival rate after 5 years, whereas that number drops to 30% when the cancer has metastasized, emphasizing the point that earlier detection will produce better long-term outcomes (National Cancer Institute SEER, n.d.).

Additionally, the cost savings related to screening for AIN, and the ensuing reduction in the incidence of ASCC are noteworthy. Studies have found that the costs of treating a single patient in the first year after diagnosis of ASCC was over $30,000, but aggressive screening, coupled with targeted destruction, could result in a $16,600 reduction in those costs (Lam, Hoch, Tinmouth, Sano, Rabound & Salit, 2011; Olsen, Jorgenson, Kofoed & Larsen, 2012).

Evaluation of the evidence. A full review of the evidence was also done to determine if the literature provided is of the upmost reliability. As previously mentioned, there is a lack of RCT to support the connection between and AIN and ACSS as well as the link between screening/early detection and improved outcomes for the patients. Therefore

the evidence above is mostly rated as level II or level III evidence. The majority of the studies referenced were cohort studies or case-controlled studies, lacking the randomization required for the highest level of evidence (Newhouse, Dearholt, Poe, Pugh, & White, 2007). In addition to the level II-III, there is evidence referenced that falls in to the level IV and V categories according to the Johns Hopkins model. Many of the observations regarding ASCC have been noted by providers who have had large numbers of PLWH on their patient profile and have led to many of the published works noted above. These providers have also published many case reports that also contribute to the level V evidence (Newhouse et. al., 2007).

Theoretical Framework

The seminal work by Kurt Lewin (1947) was chosen as the theoretical framework for the implementation of this practice change project. It was chosen because the success of this project relies upon healthcare providers discussing this issue with patients deemed at-risk for the development of ASCC. Given the nature of screening, patients can benefit the most have no symptoms of illness or other complaints. Therefore changing the perceptions and actions of the providers is essential.

The Lewin framework uses a three-step process to ensure a successful change in behavior. The first step, unfreezing, is arguably the most important step in the process. During this step, primary care providers in the case of this project must be readied for change. To accomplish this, evidence must be provided illustrating that the 'pros' outweigh the 'cons', and that the change is imminently needed. Lewin (1947) also encourages the use of a force field analysis, or a complete review of all factors, to ensure the change agent has addressed all of the elements currently affecting behavior. After the

force field analysis is complete, the use of unbiased and reliable evidence is used, along with deadlines, to promote the urgency of the change (Connelly, n.d.).

Secondly, this framework calls for the actual change, but more appropriately, the transition, as change is not a single event in time but rather a process (Lewin, 1947; Connelly, n.d.). While the first step in the change model is viewed as the most important, this second step is the hardest. The change agent must combat tradition, fear, skepticism and other emotions that can prevent the change from taking place. To best tackle these potential barriers, frequent communication and support of the primary care providers must be offered. This will serve to not only encourage the change, but also make sure those expected to make the change are aware that others are equally as vested in the change (Connelly, n.d.).

The framework concludes with the third step of refreezing. Lewin (1947) stresses the importance of this step to prevent a circular pattern, referred to by others as regressions to the pre-change state (Connelly, n.d.). Strategies for this include ensuring the change fits into the routine, perhaps a new routine. To further support the refreezing process, ensuring the permanency of the change very early in the change process is important (Lewin, 1947; Connelly, n.d.). To convey the lasting nature of the change, the change agent should ensure that new processes are designed at the outset to enable participants to work through the new process. These new processes should also have feedback mechanisms built in to allow the end-users a way of giving input and lastly support from the leadership in the early stages of the change will create the perception that the change has a more permanent nature (Connelly, n.d.).

Methods

Ethical Issues

The project qualifies as a primary care practice improvement project. The participants were the primary care providers, 2 Medical Doctors, 1 Physicians Assistant and 1 Nurse Practitioner, at each of the two implementation sites along with their support staff of 2 medical assistants at each site. The educational forums took place during the lunch hour, during which time the offices were closed to patients. The overall standards of care and medical decision-making were unaffected by this project; therefore no ethical issues were identified. There was no review of patient medical records, and no patient contact by the project director. The University of San Francisco Doctor of Nursing Practice faculty approved the project as a primary care practice improvement project and approved the project outline as IRB exempt (Appendix A).

Setting

Two clinics were chosen for implementation of the project. Both of these clinics are members of a larger healthcare delivery system that includes a full range of services including outpatient and primary care services, acute care hospital care and a range of post-acute services across Northern California. The importance of this is that both clinics, labeled primary care, have MSM-LWH as the majority of their patient profiles and both providers were considered ‘HIV specialists’ at the time they were acquired by the larger parent organization. The primary doctors at both sites gained the title of HIV specialist during the heat of the AIDS crisis during the 1980’s, leading to a large percentage of patients in the practice that are LWH. This was a title bestowed upon those providers who were willing to treat the AIDS patients at the time, yet no specialized training was obtained. The MD providers were the two primary participants in the

project, but the Physician Assistant (PA) and the NP working alongside the MD providers also agreed to participate and aided in the success of the project. To preserve the anonymity of the providers, the sites will be referred to as Implementation Site 1 (site 1) and Implementation Site 2 (site 2).

Site 1 was noted to have 1 MD provider and 1 PA provider, both with varying numbers of daily visits. Both the providers at site 1 have outpatient appointments, but also manage their patients when they are admitted to the hospital, ranging from 4-14 patients visits per provider per day. Site 2 also has 2 MD and 2 NP providers, however only 1 MD and 1 NP were participants in this project. The MD and NP provider at site 2 also only practice outpatient medicine, thus the number of visits per day was more stable, ranging from 12-14 visits per provider per day.

The implementation sites were also chosen because the majority of their patients are MSM-LWH or PLWH. This information was provided by both of the MD providers at sites 1 and 2, however the exact numbers of MSM-LWH or PLWH is not known. The only way this information could have been obtained was a chart review of all patients, which would require additional IRB approval and consent of each of the patients, neither of which was obtained.

Process. The medical assistants (MA) prescheduled all patients for either an acute concern, a follow-up regarding a past visit or hospitalization, or a wellness visit. All visits were potentially included in the project. Visit length varied from 20-40 minutes depending on the nature of the visit, and visit lengths allowed adequate time to discuss AIN screening with the patients. In each of the implementation sites there were very clear discussions regarding any additional work on the part of the providers, or any

additional time required. After a thorough presentation, all providers agreed that the goals and processes of the project would not add to their workload.

Planning the Intervention

The literature regarding screening supports the fact that well-orchestrated programs can result in lowering the rates of disease. This principle is well defined in the areas of cervical cancer as well as colorectal cancers, yet without a cogent set of nationally accepted guidelines for the screening, many providers opt not to screen patients (National Cancer Institute, n.d.; Spitzer, 2007). During early conversations with the providers regarding this project, there was baseline knowledge of the AIN screening process, and all needed skills and equipment were already present in both clinics. This information shaped the first portion of the project, to gather baseline data on current practices being employed by the providers. Given the existing knowledge of the providers and their accessibility to the equipment required for specimen collection, the second portion of the project was to identify barriers to screening the patients most at risk. The final portion of the project was an educational forum developed for each of the sites consisting of information to overcome barriers, both from the literature and those held by the providers. These barriers included which patients should be selected for screening and follow- up recommendations for the patient with a positive screening. Additionally, providers at both sites 1 and 2 shared that they were hesitant to screen patients for AIN due to questions surrounding billing and reimbursement practices. This additional barrier was also included in the educational forum.

Cost-benefit analysis. The total cost to implement the project was $1824; inclusive of direct costs of $1084 and indirect costs of $740. Some direct costs that could

be avoided should this project be implemented at future sites include the cost of catered lunches provided during the educational forums as well as the informational meetings conducted with the office staff. Factors that aided in keeping the costs down were that the supplies needed for screening, the processes for sending out specimens, and the procedures for securing follow-up were already in place. The benefit to the overall health of PLWH, and cost savings to their care, could be as high as $36,483.00 after the direct costs of the screening process is taken into account (CMS, Oct. 1, 2014; CMS, 2014; Hu & Goldie, 2008). If as little as 5% of the PLWH population in San Francisco were prevented from developing ASCC, the overall healthcare system would see a savings of over $28 million dollars (Hu & Goldie, 2008; SF Department of Public Health, 2014). See Appendix B for cost-benefit analysis.

Responsibilities/communication plan. Communication of the project timeline, milestones, deliverables and the subsequent variances that arose, were organized in the communication matrix (Appendix C). At regular intervals the matrix was discussed with the DNP committee chair, Dr. Stefan Rowniak, during meetings held at the USF Hilltop Campus. Communication regarding implementation was conducted with the primary MD providers at each of the implementation sites, and adjustments to the implementation timeline were largely guided by the providers, as every means was taken to minimize the impact on regular clinic operations.

Implementation of the Project

Implementation of the project began with a meeting with the MA staff in each of the primary care sites. This consisted of an introduction of the project, an overview of the MA responsibilities in the project, and an observation period to ascertain the normal

clinic operations regarding patient scheduling, check-in and rooming processes, and the processes at the conclusion of the visit. This was done at the urging of both providers at site 1 and site 2 to ensure that normal clinic operations would not be interrupted or forced to change. During the initial phase of the project implementation, the MA role consists of placing a survey on each patients chart for the MD, NP or PA provider to review. Up until this point, all communication had been with the MD providers only; consequently some time was taken to address the project with the other providers (NP and PA) at each site, validating their participation and responsibilities. Each of the MD, NP and PA providers were asked to review the survey placed on the chart by the MA, then to determine if the survey was completed, indicating this patient would be selected for AIN screening. The decision to include/exclude the patient was then used to deduce the provider's ability to identify patents at most risk for the development of AIN. At the conclusion of the visit, the initial surveys were left for gathering the baseline information on current screening practices (Appendix D). Development of the survey used for collection of the baseline practices was developed from the data found during the literature review regarding patients most at risk for the development of AIN. For each patient chosen as a potential candidate for AIN screening, and subsequently each survey completed, the goal was to determine what clinical data was used in making the decision to include the patient.

The second portion of implementation was the educational forum for the providers. This forum consisted of: background on the need for AIN screening, types of patients who stood to benefit most from screening, methods for specimen collection, a follow-up algorithm, and solutions to the commonly identified barriers to screening.

Following the forum, each of the providers was given a packet of information for reference (Appendix E). The content of the educational forum, delivered by the project manager, was developed using information gathered during the literature review. This information included the background information on AIN, methods for patient selection and technique for specimen collection. Additionally, the forum included methods to overcome barriers; both those noted in the literature and those identified as unique barriers within the specific implementation sites.

To serve as a visual reminder for the providers to address AIN screening with their patients, signage was placed in each of the exam rooms regarding steps for specimen collection and the follow-up algorithm (Appendices F and G). This information was also provided to ensure that lack of knowledge did not become an additional barrier to AIN screening. After the forum with the providers, the follow-up surveys were left with the MA staff for distribution to the providers at the conclusion of each visit (Appendix H). There was no formal evaluation done of the educational forum, however, following the forum at both sites 1 and 2 the providers were given an opportunity to follow up with the project manager regarding any questions they may have following the forum. The project manager was also present at both sites on a weekly basis to collect the completed surveys and to allow any of the office staff or providers to seek clarification on any aspects of the project.

Planning the Study of the Intervention

Baseline data. The providers collected the baseline data before any education was provided to either site. During the baseline data collection at site 1, the providers were asked to identify patients whom they believed would benefit from AIN screening. This

was done by having the MA staff affix an initial survey (Appendix D) to the after-visit summary at the conclusion of each visit. Initial surveys were affixed to the summaries of all patients who were seen in the site 1 office over the 2-week period of baseline data collection. Upon receiving the survey the provider decided whether to complete it based on clinical data of the patient, and whether the provider felt the patient would benefit from AIN screening. The decision to complete the baseline survey was also used to determine the provider's intention to screen, as without the intention to screen the survey was not completed. The after-visit summaries were chosen as the vehicle to present the providers with each survey since site 1 had converted to an electronic medical record system, thus there was no paper chart following the patient.

During the same 2-week period, baseline data collection at site 2 was slightly different. This office was still using a paper charting system. In this office, the MA staff would affix the initial survey (Appendix D) to the front of the chart upon rooming each pre-scheduled patient. The charts were then given to each provider to review before the visit. At the end of the visit, each provider would also determine whether to complete the survey based again on their existing ideas of which patients should be screened for AIN.

When examining the information obtained with the initial surveys, the goal was to determine if the providers could adequately identify patients most at risk for the development of AIN, and who therefore would benefit most from AIN screening. As previously mentioned, MSM-LWH and women LWH who also have a history of vulvar and/or cervical dysplasia have been identified as the targeted population for AIN screening. As these data were collected at both site1 and site 2, the exact criteria used by each of the providers is unknown. There was no effort to identify the criteria used by

each provider to avoid influencing that baseline practices at each site. This lack of insight on the part of the project director will capture over screening of patients, but may fail to identify the provider who is under screening their patients.

Analysis of this information showed that at implementation site 1, a total of 53 surveys were completed, indicating that providers felt that those 53 patients would benefit from AIN screening (Table1). Further review of these surveys revealed that of the 53 patients, 12 female and 41 male, only 23 met the criteria for AIN screening identified in the literature and also being used for this project. The difference between the females and males who were selected by the providers also provided insight. Female patients were selected based on their HIV status or their history of cervical and/or vulvar dysplasia rather than the presence of both. Only 25% or 3/12 met the criteria of LWH and positive history of dysplasia. In the males selected, the patients' HIV status was the main determining factor, as all were LWH but only 50% or 20/41 were also MSM.

Evaluation of the initial survey results from site 1 not only demonstrated the providers' need for enhanced training on how to identify the at-risk patients, but also revealed their low rates of screening, based on the low number of patients selected. The total number of patients seen at each site is not captured here because all patients were not targeted for inclusion in the project, only MSM-LWH or women LWH and who also have a history of cervical and/or vulvar dysplasia. This stands in contrast to the fact that the office already had all the necessary equipment, and each of the providers stated knowledge of the screening process and steps to specimen collection. The rate of female patients chosen for screening at site 1 were 0/12 for the selected patients and only slightly higher in males where 10% or 4/41 had been screened for AIN in the past year. These

figures point to the fact that aside from patient selection; other barriers exist to AIN screening.

Table 1

Site 1 Baseline Survey Results

Gender	HIV+	HIV-	MSM	Non-MSM	Screened for AIN in past yr.
Male (n=41)	41	0	20	21	4

Gender	HIV+	HIV-	Hx of dysplasia	No hx of dysplasia	Screened for AIN in past yr.
Female (n=12)	9	3	3	9	0

Analysis of the initial surveys from implementation site 2 showed there were 87 patients (11 female and 76 male) chosen by the providers (Table 2). Yet similar to site 1, not all of the patients met the screening criteria targeting those most at risk for the development of ASCC, MSM-LWH or women LWH and a history of cervical and/or vulvar dysplasia. The surveys demonstrated that the female patients were chosen based solely on HIV status; none of the selected female patients had a history of vulvar and/or cervical dysplasia. For male patients, the pervasive selection criteria noted was MSM status, with HIV having no impact on the decision to include a patient as one who would benefit from AIN screening. The providers at site 2 chose 20 male patients, (26% of the males), who were MSM but not infected with HIV. This data reconfirms that patient selection for AIN screening remains a barrier noted in practice, because over screening limits the cost effectiveness of any screening program.

Moreover, there were also low numbers of patients being identified as at-risk for the development of ASCC taking place at site 2. Only 12 of the total 87 patients selected in site 2 for inclusion had been screened in the past year, and all were male. This

information reiterates the fact that this office too has barriers to AIN screening that extend beyond patient selection.

Table 2

Site 2 Baseline Survey Results

Gender	HIV+	HIV-	MSM	Non-MSM	Screened for AIN in past yr.
Male (n=76)	56	20	46	30	12

Gender	HIV+	HIV-	Hx of dysplasia	No hx of dysplasia	Screened for AIN in past yr.
Female (n=11)	11	0	0	11	0

Additional barriers. At the conclusion of the baseline data collection, informal conversations between the project director and the providers at both implementation sites revealed that barriers to AIN screening exist in addition to those noted in the literature. The literature highlights the point that patient selection remains the most substantial issue however that was addressed in the educational forum. The providers noted some personal barriers in their own practices that were standing in their way of increasing the number of patients they screen for AIN.

The first additional barrier identified through these conversations was one of follow-up, more specifically where to obtain the follow-up. Each of the providers was fully informed of the fact that HRA was the next step for a patient with a positive screen, however where and how to access the HRA services was a problem. To combat this barrier, the educational forum included an algorithm currently in use by the Dysplasia Clinic at the University of California San Francisco (UCSF) Cancer Center (Appendix G) (Jay, 2011). All referrals for HRA could be made to the UCSF Dysplasia Clinic, allowing every patient to receive treatment there because the health plan covering all patients at both sites does not employ, or does not identify, HRA providers. The referral

for HRA would be considered a referral for a higher level of treatment and thus coverage would continue at the UCSF Dysplasia Clinic.

Another barrier noted in the baseline data was in obtaining reimbursement for the office procedure. At both sites, all patients were covered by the same private insurance plan, ensuring reimbursement for services rendered by the providers. Post implementation of the Affordable Care Act in January 2014, all preventative care is covered (H.R. 3590, 2009); however it is the responsibility of the primary care provider to determine what is considered preventative for each patient. If the patient has been identified as a high-risk patient but has not previously been screened, the code V76.49 can be used to bill for screening. The V76.49 billing code can also be used for rescreening of the patient if the initial screening revealed normal tissue with no evidence of dysplasia. If the patient has previously been screened and has documented abnormalities, then the following ICD-9 code can be used for billing purposes: 796.70 (ICD9Data.com, 2013) (See Appendix I for full Gap Analysis).

Finalizing the implementation. In the summer of 2013 the project topic was finalized and approval was obtained from the USF DNP Faculty, inclusive of IRB exemption. Following this approval, authorization from both primary care clinics chosen for implementation was obtained during September 2013. At the request of the clinics, actual implementation of the project was delayed until after the start of 2014 in order to avoid the holiday season during which hours at each site were changing and many of the staff were away. Implementation began in February 2014 and continued through May 2014. Final evaluation of the project took place in July and August 2014, and variances

to plan and timeline were documented via the milestone reporting matrix (Appendix J). See appendices K and L for detailed timeline and work breakdown structure respectively.

Methods of Evaluation

After extensive discussions with the DNP committee members throughout the qualifying process, and also to stay in line with the IRB exemption granted, the decision was made to focus on the intention of the providers to screen patients for AIN as the measure of how successful the project was at overcoming barriers. The primary providers also indicated a strong desire for little to no impact to the daily operations or workflow of the clinics due to the busy nature of both sites. This led to the decision to use a survey to collect the information regarding the baseline practices and any changes on the part of the providers following the education on AIN screening. The MA issued the surveys to the provider after the visit had concluded so as to have no impact on existing standards of care or medical decision-making.

All of the participating providers cited existing knowledge at the outset of the project, yet none screened patients in a consistent manner. This highlights the threats to the project to have an intended change in practice and for these changes to persist following the conclusion of the project. Currently, Sutter Health does not have any providers that market themselves as HRA providers. While they do have an extensive network of gynecological providers, who sometimes do perform HRA, there is no way to identify those providers for the purposes of referrals. This has resulted in the need to refer out of the healthcare system for follow-up, causing significant trepidation on the part of the providers (see Appendix M for full SWOT analysis).

Assessment of Change of Practice

The project was analyzed by comparing the baseline practices at each implementation site to practices after the educational forum. These baseline practices were evaluated to ascertain the providers' ability to identify patients in need of AIN screening and to identify those not screened, and the reasons they were not. Following the educational forum with the providers, additional surveys were completed to determine if the providers were now more successful in identifying patients who could benefit from AIN screening (Appendix H). The follow-up surveys focused on provider intention to screen each patient they selected for inclusion, and if there was no intention to screen, the reason for not screening the patient. The secondary portion of the survey served to aid in the identification of barriers that were not successfully overcome. The decision was made to only consider intended rates of screening post-forum to ensure that the project remained in line with the IRB exemption that was granted. However the actual numbers of patients screened is unknown. This would have required specific patient data collected from the medical records, and both sites were resistant to providing that data. Changes were determined using the surveys provided to each primary care provider and completed at the conclusion of each visit.

The surveys used to collect data after the educational forum were distributed to each of the providers in the same fashion as the baseline surveys. In implementation site 1, surveys were attached to the after-visit summary of all patients already scheduled for visits by the MA. At site 2, the surveys were affixed to each medical record of pre-scheduled patients upon rooming by the MA.

Results

Program Evaluation/Outcomes

Project implementation went according to the methods identified in the original project prospectus with one exception. After gathering the data on current screening practices at each site, there was a delay in conducting the educational forum for each of the providers. This delay resulted from the MD at site 2 requesting that the data to be delivered in the forum also be given to each of the providers in printed form for future reference (Appendix E). Development of the hard copy of the information along with securing reproductions for each of the providers delayed the forum for approximately 1 month.

Aside from the slight change in the timeline referenced above, there was success in meeting the objectives found in the project prospectus. The identified barriers, with solutions, were presented to each of the MD, NP and PA providers, who all actively participated in the educational forum. These barriers and solutions are as follows: patient selection, MSM-LWH and female patients LWH who also have a history of cervical and/or vulvar dysplasia; how to follow up on a positive screen, all patients can be referred to the UCSF Dysplasia Clinic for HRA and subsequent targeted destruction as indicated; and how to ensure proper billing and reimbursement, providers were given ICD-9 codes for both initial screenings and follow up or rescreening.

Through the use of the post-forum surveys (Appendix H) completed at each site, there was a noted improvement in patient selection, according the criteria of MSM-LWH or women LWH and a history of either cervical or vulvar dysplasia. As previously noted, the rates of screening for AIN in both sites were low, based on the assumption that the low number of post-forum surveys completed, indicates the provider did not select this

patient as a potential AIN screening candidate. This stands in contrast to the fact that site 2 was actually over-selecting MSM patients without HIV. This highlights the fact that inclusion of information on the most at-risk patients is imperative when seeking to improve rates of AIN.

After each provider at site 1 had participated in the training, and had been provided a hard copy of the most relevant data, the patients identified for AIN screening did increase when compared to the number of patients selected pre-forum. To garner the post-forum data, each provider was again asked to examine the patients already scheduled, and if they met the criteria for AIN screening as noted in the provider packet, to discuss the issue of AIN screening with the patient. This discussion was to investigate if there were any barriers to screening on the part of the patients, which may not have appeared in the literature, or during discussion with providers throughout the project. Distribution of the follow-up surveys (Appendix H) was done in the manner referenced above, in which the providers were issued a survey at the conclusion of each visit during the 2-week post-forum data collection period.

The follow-up surveys demonstrated that 66% or 33/50 of the patients chosen for inclusion by the providers at site 1 would have been screened at the conclusion of their visit (Table 3). However, some patients chosen by the providers did not meet the criteria. There were 3/4 female patients chosen for inclusion that did not meet criteria. Two of these female patients were noted to be LWH, yet lacked any history of cervical and/or vulvar dysplasia; and the other female patient who does have the necessary history of cervical and/or vulvar dysplasia, but was not LWH. The males chosen by the providers, 46 in total, did all meet the criteria of MSM-LWH as outlined in the provider

packet and also discussed during the educational forum. This finding indicates the ongoing need to highlight the differences between men and women when seeking to determine if they would benefit from AIN screening.

Table 3

Site 1 Post-forum Survey Results

Gender	HIV+	HIV-	MSM	Non-MSM	Would be screened	Would not be screened
Male (n=46)	46	0	45	1	29	17*

*16 Refusals, 1 Structural Issue

Gender	HIV+	HIV-	Hx of dysplasia	No hx of dysplasia	Would be screened	Would not be screened
Female (n=4)	3	1	2	2	4	0

As previously noted, only 33 out of the 50 surveys completed at site 1 were noted to have an intention to screen for AIN, yet 94% or 47/50 would have met the criteria for inclusion. Using the additional questions on the survey, it was noted that 16/50 of the patients identified by the providers would refuse actual screening. This information was obtained from each of the providers at the time of the visit through a discussion of AIN screening with each patient. There was an additional patient who was selected by a provider, but not included for intended screening due to a pending loss of insurance, cited as a structural barrier by the provider (Table 3).

Review of the survey results from implementation site 2 provided similar results, however for full analysis, it is important to review the data separately. The baseline data collected during early implementation demonstrated higher rates of AIN screening, but with varying criteria used for inclusion. Following the education provided to both the NP and MD providers in the office, surveys were distributed for all patients by the MA staff. The providers selected 61 patients, 54 male and 7 female, from their already scheduled

appointments to discuss the idea of AIN screening (Table 4). Of those 61 patients chosen for inclusion, 6 females and 2 males did not meet the criteria for AIN screening. These patients, while LWH, had none of the concomitant history. This information does show an improvement in the ability of the providers to identify at-risk patients, but patients were still over-selected based on HIV status alone.

Table 4

Site 2 Post-forum Survey Results

Gender	HIV+	HIV-	MSM	Non-MSM	Would be screened	Would not be screened
Male (n=54)	54	0	52	2	48	6*

*4 Refusals, 2 Lack of evidence

Gender	HIV+	HIV-	Hx of dysplasia	No hx of dysplasia	Would be screened	Would not be screened
Female (n=7)	7	0	1	6	6	1*

*1 Refusal

Further examination of these surveys also revealed that site 2 had an improvement in their ability to identify patients who stand to benefit from AIN screening, when compared to the baseline patient selection. This improvement was greater than what was noted in site 1. The surveys at site 2 showed that the providers intended to screen 89% or 54/61 of the selected patients at the conclusion of the visit. Of the 7 remaining patients, whom the providers did not intend to screen, 5 (4 males and 1 female) stated they would refuse screening. The remaining 2 male patients whom the provider did not intend to screen were not included due to insufficient evidence supporting screening in this patient. Important to note, these 2 patients also did not meet the criteria of MSM-LWH, as both were LWH but have no history of MSM, supporting the provider's assertion that the evidence does not support screening this patient. It is unclear why the provider selected these patients (Table 4).

The results were shared with the providers at both sites during an informal meeting conducted at the conclusion of the project. This meeting also provided an opportunity to gain insight to the perceptions of the providers on AIN screening in general, as it is hypothesized that this had a great impact on shaping the patients perceptions on participation in AIN screening.

As noted, the vast majority of research that has been conducted and published on AIN screening methods, protocols for follow-up and determining the most at-risk groups and more has come out of the work of a relatively small research team; and is credited in both the NYDHAI and the VA guidelines. The knowledge that preceded the implementation of this project allowed each of the providers to develop their own opinions and biases regarding screening for AIN and the subsequent HRA required for follow-up on positive screens. More specifically, the MD at implementation site 1 shared a personal relationship with the two of the lead physicians who have generated much of the AIN research that exists. During the last meeting to discuss the results of the project, it was revealed that this relationship has led the MD at site 1 to develop the opinion that some of the data being generated on the topic lacks the significance required for a change in his practice.

In the post-implementation discussions with the providers, it was also noted that the providers at site 2 discussed the idea of AIN screening with patients as a novel idea that could have positive benefits on their health, while site 1 providers presented the idea as a "project being conducted in the office", thus having a possibly significant influence on the perceived benefit on the part of the patient. The MD provider at site 2 was very forthcoming regarding the fact that this is an element of prevention he eagerly looks

forward to incorporating into the office. This created a situation in which these providers acted as sales agents for the idea of AIN screening. This is an imperative role for primary care providers, to ensure their patients receive the care needed.

In contrast, when meeting with the providers at site 1 and their staff, it was clear there was no intention of implementing an AIN screening program. The MD stated that he was not convinced of the evidence showing patients have anything to gain from screening. While he willingly participated in the project, his views on the topic were quite set. The reluctance on the part of the MD provider at site 1 to accept the evidence supporting AIN screening should have been better assessed during the unfreezing portion of the project. The willingness to participate in the project was misinterpreted on the part of the project manager as readiness to change, but later it became clear that was not the case. More discussion on this is noted under the Limitations section. (See Tables 1-4 for complete results.)

Discussion

Summary

Examination of the results demonstrates that there was success in changing the practice of all of the providers who participated in the project, measured by their ability to select or identify patients in need of AIN screening and also through providing an educational forum, providing resources overcoming barriers to AIN screening. This change was garnered through an evidence-based approach regarding whom to screen, and through a set of strategies to overcome the identified barriers. However, the change in practice also revealed other barriers not yet identified in the literature, or on the part of

the author. In spite of the fact that information on characteristics that place the patient in the highest risk category was delivered to the providers during the educational forum and in the provider packet, this proved to be the area still in need of the most improvement. Each of the participating providers focused on the HIV status of the patient and did not fully consider the required co requisites, MSM in males and a history of cervical or vulvar dysplasia in women.

The results also show that preconceived ideas and opinions of the providers can have a larger than anticipated effect on the rates of intended screenings as well as on the patients' perceptions of what they stand to gain from potential AIN screening. In the case of this project, the providers who viewed AIN screening in a positive light prior to the project were more inclined to present the issue to their patients also in a positive light. The manner of presentation by the provider had an impact on the perception of how useful or beneficial the screening was for the patient.

Evaluation of the Lewin theory as the guiding theory was also done, revealing that the integral step of 'unfreezing' was not fully successful. This assumption was made following the post-implementation meetings conducted with the providers. During these interactions, it became clear that not enough attention was spent on readying the providers for a change of practice as outlined in the Lewin model (1947). Should this project be continued in each of the clinic sites, or at other sites, ensuring the providers' readiness to change will be more carefully examined. The incomplete 'unfreezing' at the outset of the project also threatened the sustainability of the project. As mentioned previously, the project manager was unaware of the unwillingness of the providers at site 1 to sustain the practices following the completion of the project until discussion of the

results were being delivered to the providers. This created a situation where there was little that could be done to change the perceptions of the providers, or increase the chances of a sustained practice change in site 1.

Relation to other evidence

Evidence regarding the benefits of screening is plentiful. Screening programs for both CRC and cervical cancer have proven successful, as previously mentioned (National Cancer Institute Age Adjusted SEER Incidence, n.d.; National Cancer Institute, n.d.). This success has largely been credited to the development of national guidelines for primary care providers, yet there are no nationally recognized guidelines for AIN screening. The results of this project also mirror those found in another study where the feasibility of an AIN screening program in an HIV clinic was tested (Rosa-Cunha et. al., 2011). As in the case of this project and the Rosa-Cunha et. al. (2011) study, full implementation of the AIN screening program could be done with minimal changes to the existing primary care clinic.

Limitations of the project

Initially the implementation was met with few limitations. The clinics and providers chosen for participation were eager to be involved, and there were sufficient numbers of patients in each office that would benefit from AIN screening. Furthermore, one of the leading clinics conducting research and treatment of AIN is located in San Francisco, which was presumed to be a benefit. However, this is what became an obstacle when seeking to fully overcome the barriers to the AIN screening process. The location of the UCSF Dysplasia Clinic and the implementation sites not only proved to be a limitation in the implementation of this project, but will also become a limitation should

this project be replicated at future sites. The close proximity of the UCSF Dysplasia Clinic allowed the MD providers at both sites 1 and 2 to become familiar with the AIN screening process. However, the close proximity also allowed the providers to develop professional relationships with the UCSF clinic staff regarding their work. At subsequent geographical locations, the limitation would be the lack of follow-up for patients who are found to have a positive screen, due to the sporadic supply of HRA providers. The lack of HRA providers is certainly a well known barrier to AIN screening, but will require more of a systems change as opposed to a practice change, as was the focus of this project.

Moreover, there was no pilot done with the initial or post forum surveys. This created gaps in the information gathered by during the project. Both the initial baseline survey and the post forum survey lacked the ability to determine which of the providers (MD, PA or NP) had seen the patient and completed the survey. With this information, a determination could have been made as to how best to address the barriers that may exist on an individual basis, thus enhancing the evaluation of this project. The surveys also were only completed by the providers whom were selected by the providers, rather than being completed on all patients seen at both sites. This limits the ability to evaluate the total numbers of patients being chosen for inclusion, both before and after the educational forum. However, because the target population of this project was MSM-LWH and women LWH who also have a history of cervical and/or vulvar dysplasia, capturing this information would neither add nor detract from the overall project.

Lastly, follow-up with HRA, biopsy and/or targeted destruction of dysplastic tissue was secured at the UCSF Dysplasia Clinic. Many patients conveyed to their

individual provider at the implementation site that they were not interested in moving to another healthcare delivery system. To overcome this limitation an Advanced Practice Nurse could be employed to perform the HRA, biopsy and/or additional treatment as indicated. Advanced Practice Nurses, with training, are ideal candidates to fill this gap in both the Sutter Health system as well as other healthcare systems in the country that may be limited in AIN screening due to the lack of follow-up care.

Interpretation

Upon evaluation of the change in practice, more patients were accurately selected for AIN screening at both sites. This increase implies that many of the barriers were successfully overcome. However, closer examination of the data demonstrates that if additional IRB approval had been obtained, the project director could have reviewed patient's charts. This would allow for patients who were not selected by the providers for AIN screening, but may still benefit, to be identified. With full information on all patients seen during the project timeline, the noted change in practice may have been less significant when compared to baseline practices at each site.

The personal bias of the providers was also determined to have played a larger role than initially thought. In the future, a collaborative effort on the part of the UCSF Dysplasia Clinic and any other primary care clinic could serve to address these preconceived notions, and would be the recommendation for any further projects.

Implications for the future. This practice improvement project did however succeed in raising awareness of AIN screening and did develop an educational process that could easily be replicated for use in other settings, provided the access to HRA providers were in place. Inclusion of AIN, its causes and the consequent HRA required for those who

are determined to have a positive screen could all be addressed in Advanced Practice Nursing programs going forward, given the large potential impact Advanced Practice Nurses could have on the issue.

Additionally, more information should be included in the initial education of the providers to address any existing knowledge or opinion that exists surrounding the issue of AIN screening. If this information were fully available early in the project, steps could have been taken to address these opinions. Another step that could be taken for future projects would be to standardize the conversation that each of the providers has with the patients. This would further reduce the effect of personal opinions to impact the conversation.

Development of the quadrivalent HPV vaccine will also inevitably play a role in the issue of ASCC as well. While the vaccine has now been approved in both boys and girls from the age of 11 years old, the full effects of this will not be felt for many years. Current CDC recommendations are that children receive the vaccine before having their first sexual encounter to ensure there has been no previous HPV exposure (CDC, 2012). In spite of the recommendation, patients are still eligible to receive the vaccine after their first sexual encounter, and the effectiveness of protection after exposure to HPV is unknown. Also long-term efficacy data on the vaccine only extends 10 years. Ongoing research is being conducted to gain better insight into effectiveness after the known 10-year period (CDC, 2012). The work being done to provide better primary prevention for ASCC and other HPV-related cancers is imperative to the overall strategy to fully combat these cancers. However this delay underscores the need for a change in practice regarding AIN screening.

Conclusions

Through a methodical, evidence-based approach, barriers to AIN screening can be overcome. The providers' willingness to screen more of their patients following the educational forum highlights the fact that there is a willingness to change on the part of primary care providers. This project also demonstrates that an AIN screening program can be implemented in primary care clinics, where HRA services are available, with a relatively small amount of money and with minimal impact on the existing operations of the office environment.

Treatment options for PLWH continue to improve, resulting in a lifespan similar to those not living with HIV. This fact means the percentage of the population who stand to benefit from AIN screening is continuously growing. Advanced Practice Nurses are well-poised to fill gaps such as the low number of HRA providers, allowing more primary care providers and PLWH to have access to AIN screening. This project will serve to increase knowledge and awareness of ASCC and its precursor AIN in PLWH and perhaps change the standard of care for these patients.

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Tables

Table 1

Site 1 Baseline Survey Results

Gender	HIV+	HIV-	MSM	Non-MSM	Screened for AIN in past yr.
Male (n=41)	41	0	20	21	4

Gender	HIV+	HIV-	Hx of dysplasia	No hx of dysplasia	Screened for AIN in past yr.
Female (n=12)	9	3	3	9	0

Table 2

Site 2 Baseline Survey Results

Gender	HIV+	HIV-	MSM	Non-MSM	Screened for AIN in past yr.
Male (n=76)	56	20	46	30	12

Gender	HIV+	HIV-	Hx of dysplasia	No hx of dysplasia	Screened for AIN in past yr.
Female (n=11)	11	0	0	11	0

Table 3

Site 1 Post-forum Survey Results

Gender	HIV+	HIV-	MSM	Non-MSM	Would be screened	Would not be screened
Male (n=46)	46	0	45	1	29	17*

*16 Refusals, 1 Structural Issue

Gender	HIV+	HIV-	Hx of dysplasia	No hx of dysplasia	Would be screened	Would not be screened
Female (n=4)	3	1	2	2	4	0

Table 4

Site 2 Post-forum Survey Results

Gender	HIV+	HIV-	MSM	Non-MSM	Would be screened	Would not be screened
Male (n=54)	54	0	52	2	48	6*

*4 Refusals, 2 Lack of evidence

Gender	HIV+	HIV-	Hx of dysplasia	No hx of dysplasia	Would be screened	Would not be screened
Female (n=7)	7	0	1	6	6	1*

*1 Refusal

Appendices

Appendix A: IRB Exemption

Approved.DNP Department 4.19.13

University of San Francisco
School of Nursing and Health Professions
DNP Department

DNP Project Approval: Human Subjects Protection

(Non-research Status Form)

Title of DNP Project: To Screen or Not to Screen: An evidence based tool to assist primary care porviders with the decision to screen or not to screen patients for anal cell dysplasia

Brief Description of Project: There is currently conflicting data regarding the risk factors for the development of anal cell dysplasia, and the majority of the research is coming out of tertiary medical centers with far more resources than a single primary care clinic. The goal of this project will be to develop a tool to be used by PCP's when deciding if their patients should or should not be screened for anal cell dysplasia. The tool will be based on the latest in research that is available, and will not relay on high-resolution anosopy (as this is not available to most clinics) for further treatment decisions. Implementation and evaluation will consist of getting the tool out to primary care clinics, then assessing the level of comfort among the regarding patient care, or patient care decisions is beyond the scope of this project.

To qualify as a QI/ Process Improvement Project, rather than a research project, the criteria outlined in federal guidelines will be used:
(http://answers.hhs.gov/ohrp/categories/1569)

☑ This project meets the guidelines for a Quality Improvement Project as outlined in the Clinical Quality Improvement Checklist (attached) and can be submitted to the USF IRB Committee as QI.

☐ This project involves research with human subjects and must be submitted for full IRB approval.

Comments:

Signature of DNP Committee Chair Stephanie Rowniak 5/30/13 **(date)**

Signature of DNP Student 5/30/13 **(date)**

CLINICAL QUALITY IMPROVEMENT CHECKLIST *

6

Approved.DNP Department 4.19.13

CLINICAL QUALITY IMPROVEMENT CHECKLIST *

STUDENT NAME: Brandon Hastings **DATE:** May 29, 2013 .

DNP COMMITTEE CHAIR: Stefan Rowniak .

Instructions: Answer YES or NO to each of the following statements about QI projects:

Project Title:	YES	NO
The aim of the project is to improve the process or delivery of care with established/ accepted quality standards, or to implement change according to the agency Quality Improvement programs. There is no intention of using the data for research purposes.	X	
The specific aim is to improve performance on a specific service or program and is **a part of usual care.** ALL participants will receive standard of care.	X	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.	X	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	X	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	X	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	X	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	X	
The agency or clinical practice unit agrees that this is a QI project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	X	
If there is an intent to, or possibility of publishing your work, you and your DNP Committee and the agency oversight committee are comfortable with the following statement in your methods section: *"This project was undertaken as a Quality Improvement Initiative at X hospital or agency and as such was not formally supervised by the Institutional Review Board."*	X	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered a Clinical Quality Improvement activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

* Used with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

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Appendix B: Budget and Cost-Benefit Analysis

Direct Costs

Catering		$75/meeting x 4 meetings	$300
Surveys	#1	$100 x 2 sites	$200
	#2	$100 x 2 sites	$200
Signage			
	Algorithm	$24 x 8 exam rooms	$192
	Collection	$24 x 8 exam rooms	$192
		Total Direct Costs	$1,084

Indirect Costs

		Cost per hour x total hrs	
Education	MA	$20 x 4	$80
	NP	$60 x 1	$60
	PA	$60 x 1	$60
	MD	$90 x 2	$180
Meeting Location		$90 per hour x 4 hours	$360
		Total Indirect Costs	$740
		Total Project Costs	$1,824

Cost- Benefit Analysis

Anal cytology (collection and test)	$63	
AIN diagnosis (HRA & biopsy)	$314	
Treatment for HGAIN	$419	
	$793	Source: Medicare Physician Fee Schedule Source: CMS Laboratory Fee Schedule
Invasive anal cancer	$37,276	Source: Hu, Goldie (2008)

Assumed cost savings/prevented ASCC case $36,483

Appendix C: Communication Matrix

Information	**Audience**	**When**	**Method of Communication**	**Provider**
Project Prospectus Approval	DNP Committee	Once, May 2014	Email	B. Hastings
Milestone Report	DNP Chair (Rowniak)	Intermittent, approximately monthly	Meeting	B. Hastings
Project Status	DNP Chair (Rowniak)	Monthly	Meeting/Email	B. Hastings
Variances/Problem resolution	DNP Chair (Rowniak)	As needed	Meeting/Email	B. Hastings
Timeline changes/alterations to schedule	DNP Chair (Rowniak) Providers Clinic Staff	As needed	Meeting/Email	B. Hastings
Project eval./ Write-up Process	DNP Chair (Rowniak)	Monthly	Meeting	B. Hastings

Appendix D: Baseline Data Collection Survey

Is the patient HIV+?
☐ Yes ☐ No

Has the patient been screen for AIN in the past 1 year?
☐ Yes ☐ No

Has the patient EVER been screened for AIN?
☐ Yes ☐ No

Males only:
Is the patient MSM, or has participated in anoreceptive intercourse?
☐ Yes ☐ No

Females only:
Has this patient been screened for CIN in the past 1 year?
☐ Yes ☐ No

Does the patient have a history of abnormal vulvar or cervical cytology?
☐ Yes ☐ No

Appendix E: Provider Packet

2/17/15

Anal Intraepithelial Neoplasia (AIN): Overcoming Barriers to Increase Screening

Brandon Hastings DNPc, FNP-BC, CNL

AIN Background

•Is suspected of the being the pre-cursor to anal squamous cell carcinoma (ASCC), similar to CIN and cervical cancer.

•Also like CIN, is usually found in the active metaplasia zone of anus, the transformational zone.

•Can be identified using the same technology as CIN, the papanicolaou (pap) smear.

•Through the identification and eradication of AIN, ASCC can be prevented.

1

**

2/17/15

Why should we care?

•HIV positive people have rates of ASCC that are 20x greater than the general HIV negative population, 1.3 vs 48.3/100,000 person years.

•The widespread availability and use of ART has not lower the rates of ASCC, actually they continue to rise.

•With the development and use of screening guidelines for CIN, the rates of cervical cancer have been reduced.

•The same can be done for ASCC!

Who should be screened?

Men
•HIV+
•HIV-, with a history of anorecpetive sex
•HIV-, with a history of anogenital condylomas

Women
• HIV+ with a history of abnormal cervical and/or vulvar histology

2

*An error was noted during the educational forum regarding the inclusion criteria to be used in male screening. The error was corrected during the educational forum to reflect the actual goals of project, HIV+ and MSM.

2/17/15

Steps in performing an Anal Cytology Smear

1. Moisten synthetic swab with tap water or saline.
2. Separate buttock gently so anal opening is clearly viewed.
3. Insert swab slowly until it bypasses the internal sphincter; be certain to find the angle that iis not painful or met with immediate resistance; adjust angle and reinsert if needed.
4. Insert at least 2-3 inches, until resistance is met when the swab meets the distal wall of the rectum.

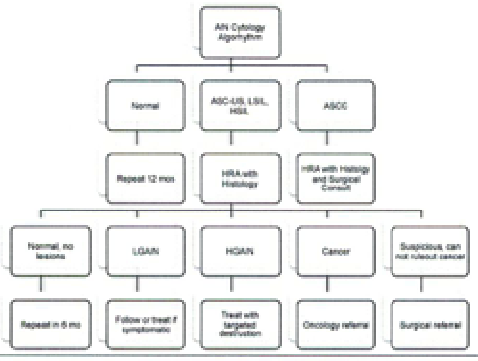
Screening steps, con't

1. Slowly remove the swab in a circular motion to sample all aspects of the anal canal.
2. Count slowly to 10 while removing the swab.
3. When reaching the anal verge (i.e. distal end of the anal canal), release hold on the anal opening so that the verge and perianus are sampled.
4. Place in cytology medium or fixative solution.

3

2/17/15

The results are in …. Now what?



Easily avoidable barriers

Billing and Reimbursement

- All preventative healthcare is no covered as of 1/14 as a result of the ACA
- ICD-9 codes V76.49 (for first time screening) and 796.70 can be used for AIN Screening

Follow up

- UCSF Dysplasia Clinic, 1600 Divisadero St. 4th floor, San Francisco, CA 94143 (if surgical referral is not indicated at the time of screening)
- 415-353-7100, M-F 8am-5pm

4

2/17/15

For any further questions, comments or concerns please don't hesitate to contact me, Brandon Hastings, FNP-BC.

Brandon Hastings
704-473-0500
bhastings@usfca.edu

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Appendix F: Specimen Collection

Steps in Performing an Anal Cytology Smear

1. Moisten synthetic swab with tap water or saline.

2. Separate buttocks gently so anal opening is clearly viewed.

3. Insert swab slowly until it bypasses the internal sphincter; be certain to find an angle that is not painful or met with immediate resistance; adjust angle and reinsert if needed.

4. Insert at least 2-3 inches until resistance is met with the swab abuts the distal wall of the rectum.

5. Slowly remove the swab in a circular motion to sample all aspects of the anal canal.

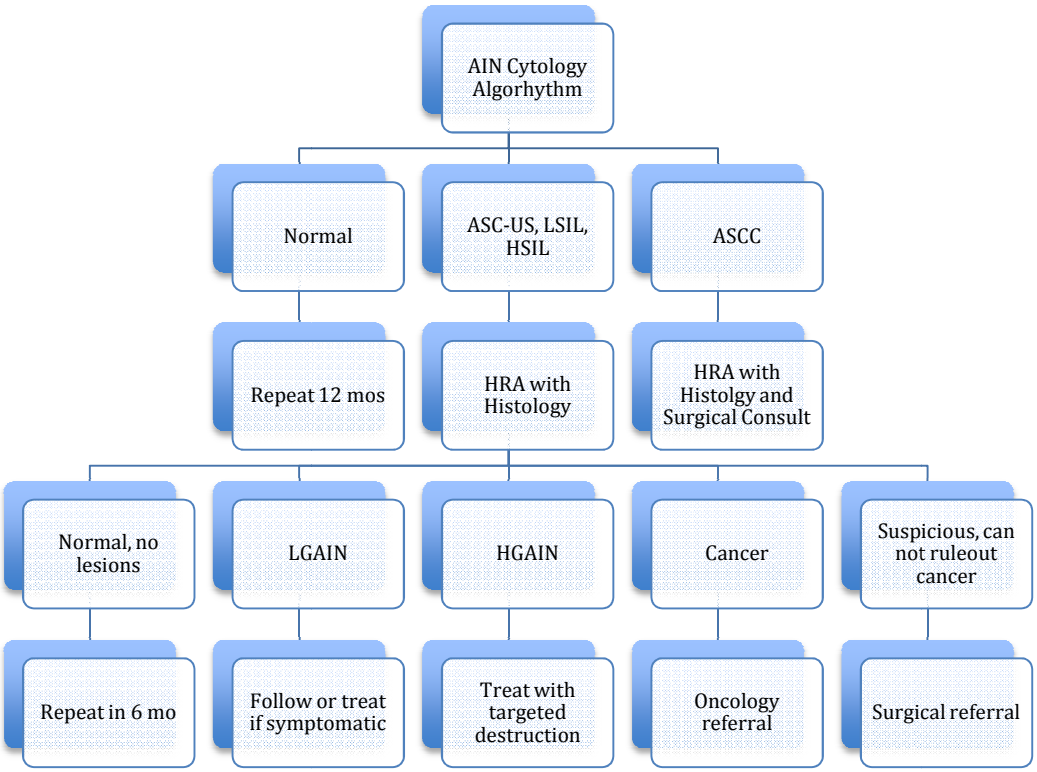
6. Count slowly to 10 while removing the swab.

7. When reaching the anal verge (i.e., distal end of the anal canal), release hold on the anal opening so that the verge and perianus are sampled.

8. Place in cytology medium or fixative solution.

(Jay, 2011)

Appendix G: Follow up Algorithm



Adapted from the University of California San Francisco (UCSF) anal screening algorithm. Note: ASC-US = atypical squamous cells of undetermined significance; LSIL = low-grade squamous intraepithelial lesion; HSIL = high-grade squamous intraepithelial lesion; ASCC = Anal squamous cell carcinoma; HRA = high-resolution anoscopy; LGAIN = low-grade anal intraepithelial neoplasia; HGAIN = high-grade anal intraepithelial neoplasia

Appendix H: Follow-up Survey

Is the patient HIV+?
☐ Yes ☐ No

Males only:
Is the patient MSM, or has participated in anoreceptive intercourse?
☐ Yes ☐ No

Females only:
Has this patient been screened for CIN in the past 1 year?
☐ Yes ☐ No

Does the patient have a history of abnormal vulvar or cervical cytology?
☐ Yes ☐ No

At the conclusion of today's visit, **WOULD** you have screened this patient for AIN?
☐ Yes ☐ No

If no, because of:

☐ Lack of medical evidence supporting screening

☐ Structural or process issues (lack of reimbursement, lack of adequate follow up, etc)

☐ Patient refusal

Appendix I: Gap Analysis

FUTURE STATE	**CURRENT SITUATION**	**NEXT ACTIONS**
Providers will be able to identify patients most at risk for the development of AIN using the most current literature.	Of the implementation sites, one MD provider does not screen patients at all, while the PA in the same office does some screening. The other screens on an ad hoc basis, mostly using sexual behavior as the guiding principle.	1. Increase knowledge base of patients who are most at risk for the development of AIN. 2. Conduct individualized lunch meetings with providers at each implementation site to educate on at-risk patients. 3. Information regarding the most at-risk patients will be developed and given to each of the providers for reference during the educational meetings.
Existing barriers to screening for AIN will be identified and providers will have the ability to address barriers.	Providers are unfamiliar with the proper codes to secure reimbursement for screening. Follow up process post screening is unclear. No existing national guidelines to steer providers with screening.	1. During the first lunch meeting (at the outset of the project) referenced above, perceptions of the providers view on the existing barriers will be gathered. 2. On the subsequent lunch meeting solutions to the provider-identified barriers will be provided to the providers. 3. Additional barriers to AIN screening identified in the literature and by other experts in the

		field will be conveyed to the providers with solutions. 4. Methods to address the barriers will be included in the packet of information provided to the providers for their reference during the project.

Appendix J: Milestone Report

Milestone	Target Date	Final Date	Communicated to DNP chair	Status
Approval of site from primary MD providers	Fall, 2013	1/23/14	Mar. 2014	Completed
Lunch meeting with MA staff in both clinics	Feb., 2014	2/4/14 2/11/14	Mar. 2014	Completed
Collection of current practices surrounding AIN screening	March, 2014	2/4/14 - 2/25/14 2/11/14 – 3/4/14	Mar. 2014	Completed
Lunch meeting with MD, PA and NP to conduct the educational forum	March, 2014	3/18/14 3/25/14	May, 2014	Completed – with variance due to the delay in developing the 'provider packet' for their reference
Second lunch meeting with MA staff to discuss changes in surveys to be distributed	March, 2014	3/20/14 3/27/14	May, 2014	Completed – with variance due to the delay in developing the 'provider packet'
Collection of the AIN screening practices following the forum	Apr., 2014	3/20/14 – 4/29/14 3/27/14 – 5/5/14	May, 2014	Completed
Evaluation of the baseline data and the surveys completed post forum	June, 2014	July, 2014	Aug., 2014	Completed
Final meeting with providers and MA staff, thanking them for participation	June, 2014	7/10/14 7/11/14	Aug., 2014	Completed

and dissemination of the results				
Development of the final project write up	Fall, 2014	Sept. – Oct. 2014	11/1/14	Completed
Dissemination of results to DNP committee	Dec., 2014	Pending	Project sent to committee for review	Pending –

Appendix K: Project Timeline

	2013									2014											
Milestone	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Topic Finalized																					
Secure implementation site																					
DNP Faculty approval																					
Secure IRB exemption																					
Lit. Review																					
Working lunch with MA staff																					
Baseline data collection																					
Complete signs/ check clinic equipment																					
Working lunch with providers																					
Display signage (algorithm and methods)																					
Post-forum data collection																					
Project evaluation																					
Write-up and presentation																					

Yellow = Pre-implementation
Teal = Implementation
Orange = Post-implementation

Appendix L: Work Breakdown Structure
(Each of the following steps was completed at both sites)

1.0 Buy- in for the project from the primary providers at each of the implementation sites

- 1.1 Providers meeting
  - 1.1.1 Introduction of the project to MD providers
  - 1.1.2 Description of roles for each of the provides (MD, NP, PA)
  - 1.1.3 Date determined for meeting with other clinic staff
- 1.2 Clinic staff meeting
  - 1.2.1 Introduction of the project to medical assistants (MA)
  - 1.2.2 Description of the MA role in the project
  - 1.2.3 Assessment of the current MA work flow to ensure minimal impact to daily routines

2.0 Assessment of current AIN screening practices

- 2.1 Surveys provided to MA
- 2.2 Weekly visit to site to collect initial surveys
  - 2.2.1 Volume of at-risk patients also observed on the weekly visits to better determine timeline for implementation

3.0 Project Implementation

- 3.1 Educational forum with providers
  - 3.1.1 Lunch meeting held with both the MD and NP or PA
  - 3.1.2 Information on at-risk patients, benefits and barriers given to each provider for their reference throughout the project
  - 3.1.3 Address questions/concerns of providers
- 3.2 Additional meeting with MA staff

3.2.1 Secondary surveys given to MA staff to be completed by each provider at the conclusion of each visit

3.2.2 Address questions/concerns of MA staff

3.3 Place signage in exam rooms regarding specimen collection techniques and follow-up algorithm

3.4 Weekly visits to site

3.4.1 Collection of completed surveys

3.4.2 Address questions/concerns that have arisen

4.0 Results

4.1 Comparisons made between providers behavior regarding AIN screening before and after the educational forum

4.2 Meeting with providers after synthesis of surveys

4.2.1 Allow providers to explain certain survey results

4.2.1 Allow providers to see results from the other site

4.3 Dissemination

4.3.1 DNP Paper

4.3.2 DNP Presentation

Projected Resource Requirements

1. Locations
    a. Sutter Health, 45 Castro Street
    b. Sutter Pacific Medical Foundation, 45 Castro Street
2. People
    a. Primary Care Providers

i. Site 1 MD

ii. Site 1 PA

iii. Site 2 MD

iv. Site 2 FNP

b. Medical Assistant staff at each site

c. DNP committee members

i. Stefan Rowniak PhD MS FNP – Chair

ii. Susan Prion EdD RN CNE

iii. Gregory Crow EdD RN

3. Tools/Equipment

a. Dacron swabs for specimen collection (already stocked by clinics)

b. Liquid based cytology (already stocked by clinics)

c. Provider reference manual – reproduced for each provider

Appendix M: SWOT Analysis

STRENGTHS	WEAKNESSES
-No costs to clinics for implementation -MD, NP and PA interest in project goals -Infrastructure in place to support increased screening for AIN (medical assistants, physical space for consultations with patients and specimen collection, swabs used to collect specimens, relationships with labs to process specimens, mechanisms to follow up with patients regarding screening results) -Adequate supply of HRA trained providers locally	-Busy practice with forced time constraints. -No follow-up available within the same health care delivery system -Perceived invasive nature of the specimen collection may deter patients -No nationally accepted set of guidelines for providers -Preconceived opinions on the part of the MD, NP and PA providers regarding AIN screening in general
OPPORTUNITIES	**THREATS**
-Build upon the growing body of knowledge that can aid in the development of national guidelines -Providers already trained in the technique needed for specimen collection -Better care for existing patients through early diagnosis and treatment if abnormal cells (or ASCC) is found	-Patients have to follow up with UCSF Dysplasia Clinic -Sustainability – with no national guidelines to follow, no mechanism in place to encourage providers to continue beyond this project -Providers may feel they will lose their patients to the UCSF clinic for primary care as well if their AIN is referred there for treatment