Anal Cancer Screening in a High-Risk Population: A Quality Improvement Initiative

by

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DISSERTATION

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ABSTRACT
Anal Cancer Screening in a High-Risk Population: A Quality Improvement Initiative

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Background: The main risk factor for the development of anal cancer is acquisition of the human papilloma virus (HPV). Individuals infected with the human immunodeficiency virus (HIV) have a higher prevalence of HPV and subsequently developing HPV induced dysplasia. The incidence of anal cancer among HIV positive men who have sex with men (MSM) has been estimated to be approximately twice that of HIV negative MSM with rates as high as 112-144 per 100,000. By relying on similarities between the anus and the cervix, and the established success of cervical cytology screening in reducing the incidence of cervical cancer, anal cancer screening programs have been established to identify pre-cancerous lesions.

Local Problem: A retrospective chart review of anal cancer incidence at Parkland Hospital revealed a significant burden of anal cancer amongst HIV positive patients. As such, Parkland has decided to implement a policy of annual anal cancer screening among all HIV patients via anal cytology screening and referrals to proctology for any abnormal anal cytology samples.

Methods: In order to assess the monthly anal cancer screening rate, we looked at the absolute number of anal cytology samples performed in a 28 day period. The list of anal cytology samples performed was pulled from the Cerner laboratory information system (LIS) and correlated with a quarterly chart review using the electronic medical record (EMR). Utilizing, QI MACROS in EXCEL, we were able to create a run chart to identify trends in anal cancer screening rates over the duration of the project. We used chi-squared test of independence and unpaired t-test to determine statistical significance.

Interventions: We implemented a multi-step process involving over 10 Plan-Do-Study Act (PDSA) cycles for increasing the number of anal cytology samples performed in the clinic. The three most impactful PDSA cycles are discussed in the article.

Results: The primary outcome of monthly anal cancer screening rate increased over the duration of the project from an average of 19.5 in 2015 to 58.6 samples collected per month in 2018, a 199.3% increase relative to baseline ($p < 0.001$). While the interventions implemented were successful in increasing anal cancer screening rates, we were unable to determine which of

the PDSA intervention cycles had the biggest impact on altering the clinic practice. Over the duration of the project, we screened 1908 patients. Of the patients screened, we identified 249 patients with abnormal anoscopy findings. Amongst the patients that had anal lesions on anoscopy, 10 developed anal cancer, 4.0%. When taking a closer look at these individuals and the electronic medical record, 3 patients were found to be completely asymptomatic at the most recent clinic prior to collection of the anal pap and would not have been referred to proctology if it weren't for the screening test, which ultimately resulted in an earlier diagnosis

Conclusion: We were successful in taking previously proven interventions for increasing cervical cancer and adapting them for anal cancer. By increasing awareness to both patients and providers on the risks of anal cancer, instructing providers on the methods to screen for the disease, and providing timely feedback, we were able to increase the anal cancer screening rate in this large urban clinic with limited resources.

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CHAPTER 1
Introduction

Problem Description

A retrospective chart review of the characteristics and outcomes of anal cancer was conducted at Parkland Hospital from 2008-2013. This study revealed a significant burden of anal cancer occurred amongst the local HIV infected patients with 47 (46.5%) of the 101 cases recorded occurring in HIV positive patients. Amelia Court Clinic, the local HIV clinic attached to Parkland Hospital, is the largest HIV clinic in Dallas County. While the clinic has the capability of screening for early anal cancer through anal cytology and referring patients to proctology for anoscopy, it is unclear how frequently the cancer screening was being utilized at the clinic. Due to the high burden of anal cancer seen amongst the HIV infected individuals in this community, Parkland implemented a policy of annual anal cancer screening among all HIV patients via anal cytology screening and referrals to proctology for any abnormal anal cytology samples.

Available Knowledge

Squamous Cell Carcinoma (SCC) of the anal canal is a relatively rare cancer with an incidence rate of 0.5-1.0 per 100,000 women and 0.3-0.8 per 100,000 men with a 2:1 female predominance.[1] Anal cancer typically occurs among patients in their 6^{th} or 7^{th} decade of life, however, it can occur in younger patients, particularly in those with compromised immune systems, such as HIV positive patients. While anal SCC is still a relatively rare disease, the incidence of anal cancer has been increasing in the past decades. Data from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute has demonstrated a threefold increase in the

incidence of anal SCC in the United States from 1 to 3 per 100,000 men.[2,3]

The primary risk factor for the development of anal SCC is acquisition of the human papillomavirus (HPV). There is an established association between several oncogenic HPV strains and many premalignant and malignant lesions of the genital tract, anus, rectum, and mouth. Epidemiologic studies have shown that up to 93 percent of anal SCC is associated with HPV infection, which is a stronger association than what is seen in cervical cancer.[4,5,6] As in cervical cancer, HPV 16 and 19 is the most frequently isolated type in anal malignancies. In contrast, low-grade lesions are associated with other HPV subtypes.[4,6] A complex association exists between human immunodeficiency virus (HIV) and HPV infections. Not only do HIV infected patients have a higher incidence of HPV infection, but they also encompass a heavier burden of HPV-induced dysplasia and cancer due to progressive immune suppression.[7] In addition, the prevalence of high-grade anal intraepithelial neoplasia (AIN) and anal carcinoma is higher in those with concomitant HIV infection compared to those who are HIV negative.[8,9,10] Despite these observations, the overall relationship between HPV and HIV infections and the overall impact that HIV has on the incidence rate of anal cancer remains unclear.[9,11,12] Other risk factors for the development of anal cancer, include chronic immune suppression, such as in transplant patients, cigarette smoking, and high-grade cervical dysplasia in women.[1,13,14,15]

Men who have sex with men (MSM) are at a much higher risk for developing anal SCC compared to the general population. Anal cancer incidence was estimated to be as high as 37 per 100,000 among MSM prior to the HIV epidemic, approaching levels similar to that of cervical cancer in

women prior to the introduction of Papanicolau (Pap) smear screening.[1,9,11,16] The risk of anal cancer increases when multiple risk factors are present. The incidence of anal cancer among HIV positive MSM has been estimated to be approximately twice that of HIV negative MSM with rates as high as 112-144 per 100,000. In these high-risk populations, anal cancer incidence is significantly higher than other cancer, such as lung (57 per 100,000) and prostate cancer (92.1 per 100,000).[17,18,19] In contrast to the other common acquired immune deficiency syndrome (AIDS) defining conditions, such as Kaposi sarcoma, cytomegalovirus, and pneumocystis jirovecii pneumonia, the incidence of anal cancer has not declined in the era of highly active antiretroviral therapy (HAART). The age-adjusted incidence of anal cancer in men 40 to 64 years of age more than quadrupled from the pre-HIV period (1973-1978) to the late 1990's (1996-1999) following the widespread availability of HAART.[20]

Anal cancer screening programs typically rely upon cytology as the initial screening test in high-risk populations. The goal of screening is to identify individuals with abnormal cytology, which includes atypical squamous cells of undetermined significance (ASCUS), atypical squamous cells suggestive of high grade squamous intraepithelial lesions (ASC-H), low grade squamous intraepithelial lesions (LSIL), and high grade squamous intraepithelial lesions (HSIL). Individuals with abnormal cytology are then referred for high-resolution anoscopy to assess the anal canal with biopsy and histopathological evaluation of any suspicious lesions. The results of the biopsy are used to guide treatment of any precursor lesions noted and for definitive diagnosis of anal cancer. As HSIL lesions are true precursor lesions, these lesions are often referred to undergo definitive ablative treatments to reduce the risk of progression to anal cancer.[21] There is

conflicting data regarding the effectiveness of anal cytology as an accurate predictor of the presence of HSIL lesions, regardless of HIV status. Initial studies demonstrated a sensitivity of anal cytology to detect biopsy proven anal squamous intraepithelial lesions in HIV positive and HIV negative MSM is 81 and 50 percent respectively. These percentages are similar to the sensitivity of cervical cytology for the detection of cervical disease.[22,23] Other data suggests that anal cytology is an inaccurate predictor of the presence of HSIL with a sensitivity of 47 percent for detecting HSIL. Taken together, this data suggests that when HSIL is found on anal cytology, there is a high probability of HSIL disease on high-resolution anoscopy guided biopsy.[24] The finding of LSIL or ASCUS, conversely, does not reliably exclude the presence of HSIL on biopsy.

As there are no randomized clinical trials documenting the value in screening for anal dysplasia, the United States Public Health Service has no formal guidelines recommending anal cancer screening. The HIV Medical Association of the Infectious Diseases Society of America, on the other hand, makes a weak recommendation for screening with anal cytology in high risk populations, such as HIV infected patients, MSM, women with a history of abnormal cervical pap results, and those with genital warts.[17]

Rationale

The rationale behind screening for an anal squamous intraepithelial lesion (AIN) in an at-risk population is based upon the similarities between the anus and the cervix, and the established success of cervical cytology screening in reducing the incidence of cervical cancer.[1,19] Indirect evidence supporting the implementation of an anal dysplasia screening program for high-risk

populations includes the high incidence of anal cancer in these populations, the advent of screening modalities which can effectively and reliably diagnose the precursor lesions, and effective treatments to ablate or remove the precursor lesions. In addition, there is a significant morbidity and mortality associated with untreated anal cancer which can be reduced if the SCC is detected and treated at an earlier stage.

Regular screening for cervical, breast, and colorectal cancer can prevent or reduce the mortality and morbidity associated with those diagnoses. While there is no clearly documented clinical trial documenting the benefit of screening for anal dysplasia in preventing anal cancer development, research is actively being conducted in this field. The Anal Cancer/HSIL Outcomes Research (ANCHOR) study is now in progress to determine if treatment of anal HSIL is effective in reducing the incidence of anal cancer. Primary care providers play an important role in screening programs by identifying eligible patients, counseling on the risks and benefits of screening, and offering referrals for performing relevant tests.[25]

Quality improvement initiatives based in primary care practices, such as a local HIV clinic, have been proven effective in increasing cancer screening rates. Interventions which have been effective in the past in increasing cancer screening rates include patient reminders, small media interventions (brochures, pamphlets, flyers, etc.), provider assessment and feedback informing physicians on their personal cancer screening performance, and provider reminders that their patient is due or overdue for a screening test.[25,26] In order to better assess the current anal cancer screening rate in our high-risk population and to improve upon our current screening program,

we decided to implement a quality improvement initiative at the HIV clinic.

Specific Aims

The main objective of this project was to increase and sustain the number of monthly anal cytology screening tests performed at Amelia Court Clinic by 20% by January 2017. Our secondary objectives were to increase the proportion of patients with abnormal anal cytology results that had timely proctology follow up (within 6 months of abnormal results) to greater than 80 percent and to reduce the number of anal cytology samples that were determined to be insufficient for diagnosis to less than 5 percent. Finally, the patient collected samples and the provider collected samples were analyzed to determine the effectiveness of patient provider samples in screening for anal cancer.

CHAPTER 2
Methods

Context

The following project took place at Parkland Health and Hospital System's largest outpatient HIV clinic, Amelia Court Clinic. Amelia Court is also the largest HIV clinic in Dallas County, treating over 5,000 HIV+ patients annually. The project focused specifically on HIV positive MSM and HIV positive females with a history of cervical dysplasia who were 18 years of age or older, and who had attended the Amelia Court Clinic at least once in the previous 12 months. In order to maximize the effectiveness of the project, we assembled a multidisciplinary team composed of key stakeholders including infectious disease, proctology, and pathology.

In order to determine a baseline anal cancer screening rate, we looked at all the anal cytology samples collected from June 22, 2015 to April 11, 2016, a 10 month period. A list of all the patients who received an anal cytology screen was generated from a search through Cerner, the laboratory information system used by pathology at our hospital. We used the generated list to manually search through the electronic medical record (EMR) for the results of the anal cytology specimen and any follow up appointments. We measured the anal cancer screening rate by calculating the absolute number of anal cytology specimens collected over a 28 day time period. Our baseline anal cytology rate was found to be 19.5 tests per 28 days.

The next step in our project was to outline all the steps involved in the anal cancer screening process which can be seen in Figure 1. After establishing the process map, we created an Ishikawa diagram trying to identify all potential causes for the low anal cancer screening rate, which is shown in Figure 2. The most likely cause behind the low cancer screening rate was identified as a general lack of awareness on the importance and the availability of an anal cancer screening program in the clinic. If the provider was not informing patients on the availability of the screening program or if the provider did not educate the patient on the risks and benefits, then the patient was not being screened.

Intervention(s)

During the implementation phase, over 10 Plan-Do-Study-Act (PDSA) cycles were involved in attempting to successfully meet the aim that was previously established. Each PDSA cycle

required significant involvement from our multidisciplinary team with biweekly meetings to evaluate the effect of each PDSA cycle modification. Throughout each PDSA, an extensive record of each anal cytology sample collected by the clinic was recorded and analyzed in order to determine the impact of each modification and to follow the overall progress of the project. Three of the most impactful PDSA cycles are discussed below.

Based on the conclusion that it was a general lack of awareness on the importance and the availability of anal cancer screening in our population, the team decided to generate awareness for the screening program by using some of the strategies proven to be effective in increasing cervical cancer screening. Our first PDSA cycle focused mostly on increasing provider awareness by scheduling time during the monthly provider meeting to re-educate the providers on anal cancer. During the meeting, we re-iterated the importance of anal cancer screening in our population. We created an infographic displaying preliminary results concerning anal cancer in our local population. The infographic also displayed baseline de-identified statistics regarding the performance of each individual provider in the clinic with the plan for subsequent updates every 3-4 months in order to reinforce the efforts of the initial meeting, provide statistical evidence of the effect of the quality improvement project, and receive feedback from the frontline providers with regards to additional barriers that could be addressed.

The second PDSA cycle focused on adding the option for patient self-collected (in addition to provider-collected). In collaboration with the Pathology Department, we set up a system that allowed us to collect and analyze anal cytology specimens that were self-collected by the patients

while they were in clinic. We educated providers at Amelia Court Clinic on the availability of patient self-collected specimens in order to increase patient acceptability of the test and reduce barriers to performing the test. With the aim of maximizing the reliability of self-collected specimens, we provided the providers with a video link that could be played in the clinic room which demonstrated the required steps for self-collected anal cytology specimens. In addition, we ensured that the self-collected specimens were tagged in the Cerner LIS for future comparison with provider collected specimens.

The third PDSA cycle took a slightly different approach to increasing patient and provider awareness. Instead of focusing all of the effort on the provider side of the equation, we decided to appeal directly to the patients themselves and make use of the shared decision model of medicine. We created an informational flyer that was displayed in the waiting room and in the individual clinic rooms that encouraged patients to request cancer screening from their providers.

Study of the intervention

In order to assess the effect of the various interventions on our anal cancer screening rate and evaluate for any roadblocks to implementation, we held quarterly meetings with our core stakeholders. In addition, we formulated a run chart using QI MACROS in EXCEL to assess the effect of the interventions on the central tendency of the process and to help determine if the changes seen in the anal cancer screening rate were due to the interventions. We then performed statistical analysis using chi-squared test of independence and unpaired t-test.

Measures

In order to assess the monthly anal cytology screening rate, we looked at the absolute number of anal cytology specimens collected over a 28 day time period. The other measures analyzed were the percent of anal cytology specimens that were insufficient for diagnosis and the percent of patients who had timely proctology follow up, which were calculated using Equations 1 and 2, respectively. Anal cytology diagnoses were classified using the 2001 Bethesda System. We used chi-squared test of independence and unpaired t-test to determine statistical significance. Statistical significance was considered to be a p value less than 0.05.

Equation 1

$$Percent\ of\ samples\ insufficient\ for\ diagnosis = \frac{count\ of\ insufficient\ samples}{total\ anal\ Paps\ performed} * 100\%$$

Equation 2

$$Percent\ Follow\ Up$$

$$= \frac{count\ of\ patients\ who\ attended\ procto\ within\ 3\ months\ of\ abnormal\ Pap}{count\ of\ patients\ with\ abnormal\ anal\ Pap} * 100\%$$

Analysis

In order to determine the effects of the interventions on the anal cancer screening rate, we first analyzed the run chart of our baseline data, as shown in Figure 3. A run chart is a quality improvement tool used to monitor a process over time. In addition, this tool can be used to differentiate between common cause and special cause variation, a key step when attempting to

effect change to an established process.[27] Common cause variation is defined as random variation inherent to a process and implies that the process is stable and predictable. Special cause variation, on the other hand, is irregular variation caused by an external source or as a result of some change to process.[27] While the special cause variation is present, the process is deemed unstable and in flux. Special cause variation is detected on run charts by noticing certain types of patterns that have been established over the years. A list of the common rules used to identify special cause variation can be seen in Table 1.[28] While there is no limit to the number of tests that can be used to identify non-random patterns in the data, the more tests applied results in an increased false positive rate. As such, we used three tests to search for special cause variation in our data tests: shifts, trends, and abnormal variation. A shift is defined as 6 or more consecutive points above or below the median. A trend is defined as 5 or more consecutive points either increasing or decreasing in value. Abnormal variation is defined as a non-random pattern signaled by too few or too many runs. A run is a series of points in a row on one side of the median. Tabled critical values are used to determine if too many or too few runs exist. Since the three tests were negative for our baseline data, the process was determined to be stable and in control. Following the implementation of our various PDSA cycles, we once again searched for special cause variation to help determine if there was an impact on our process. These steps were then repeated for our secondary aims.

Following analysis of the run charts, additional statistical analysis was performed on the raw data using chi squared and unpaired t tests. Odds ratios with 95% confidence intervals were calculated to assess the relationship between cytology results and the presence or absence of anal lesions.

Furthermore, for those patients who were found to have biopsy proven anal cancer, a search of the electronic medical record was performed to evaluate for the presence of absence of anorectal symptoms at the time of anal cytology screening.

Ethical considerations

The primary ethical consideration in this project was maintaining patient confidentiality given the sensitive nature of a diagnosis of HIV and anal cancer. As such, the utmost care was taken throughout the implementation of this quality improvement project to ensure patient confidentiality was maintained. The secondary ethical consideration in the project revolved around the controversial nature of anal cancer screening. As there are no randomized clinical trials documenting the value in screening for anal dysplasia or in routine follow-up of patients with known anal dysplasia, there was some concern with regards to exposing patients to potentially unnecessary invasive anoscopies. Due to these concerns, all patients were fully informed on the potential risks and benefits before being screened with anal cytology.

CHAPTER 3
Results

The study was performed over a period of 37 months with the initial intervention taking place at the beginning of month 13. Over this time period, we collected 1908 anal cytology specimens with 235 occurring in the pre-implementation period. The patient demographics for the two time periods can be seen in Table 2. There was no statistical difference with regards to patient age or sex between the two groups. The infographic distributed to the providers at the initial provider

re-education and the final patient flyer can be seen in Figure 4 and 5, respectively.

The primary outcome of monthly anal cancer screening rate increased over the duration of the project. The baseline average screening rate prior to implementation of the project was 19.5 per 28 day. After implementation of the various PDSA cycles, the monthly average increased to 58.6 per 28 days, a 199.3% increase relative to baseline ($p < 0.001$). These results are demonstrated in Figure 6. Secondary outcomes included the percentage of samples collected deemed insufficient for analysis and the percentage of patients who had timely proctology follow up. The effects of the quality improvement project on these outcomes are shown in Table 3. The percent of insufficient samples slightly increased from 18.0% to 22.98% ($p = 0.93$), as shown in Figure 7. When comparing the adequacy of provider collected specimens and patient collected specimens, there was no statistical difference between the two groups ($p = 0.478$). Patient collected specimens had a 25.23% insufficiency rate, whereas provider collected specimens had a 23.52% insufficiency rate, which can be seen in Table 4. The percent of timely proctology follow up had a non-statistically significant change from 33.61% to 26.18 ($p = 0.322$), as shown in Figure 8. Analysis of the relationship between anal cytology and the presence or absence of anal lesions revealed an increased likelihood of having an anal lesion with a diagnosis of HSIL as opposed to ASCUS, as shown in Table 5. There was no change in likelihood between the other groups.

CHAPTER 4
Discussion

Summary

By increasing both patient and provider awareness, we were able to achieve a quantitative increase of 199.3% in the number of anal cytology samples performed each month at a large HIV clinic in a limited resource environment. While we were successful at adapting and implementing quality improvement measures in order to meet our primary aim, we are currently unable to determine if the increased screening has had an effect on the prognosis for anal cancer. Comparisons between patients with anal cancer who were detected via the anal cancer screening program and those detected through traditional means needs to be conducted to determine the ultimate effect of anal cancer screening. Our secondary aims of improving proctology follow up and decreasing insufficiency rates were not significantly affected throughout the duration of this project. Further PDSA cycles need to be run focusing on improving these secondary aims. Ultimately, this quality improvement project proved that by utilizing simple measures, it is possible to improve patient participation in quality improvement projects in resource-limited environments.

Interpretation

As a result of this quality improvement initiative, we were able to significantly increase the anal cancer screening rate in a large HIV clinic with limited resources by undergoing successive PDSA cycles aimed at increasing provider and patient awareness of our cancer screening program. This exceeded our aim of increasing anal cancer screening by 20%. We were successful in taking

previously proven interventions for increasing cervical cancer screening and adapting them for anal cancer screening. At this time, we do not have enough data to determine which of the PDSA intervention cycles had the biggest impact on altering the clinic practice. Informal feedback from the providers in the clinic suggests that a large portion of the anal cytology samples performed were patient driven, leading us to believe that the patient flyers have been very successful.

Following the initiation of the project, there was a noticeable increase in the number of anal paps collected. Educating both the patients and the providers on the availability and importance of the screening program had a significant impact on the views expressed towards anal cancer screening resulting in an increase in buy-in from these key stakeholders. It is possible that the Hawthorne effect influenced the numbers represented in the run chart. The Hawthorne effect is a phenomenon described as an alteration in the behavior of the subjects of a study due to their awareness of being observed.[29] The data reflects that during the periods of active observation, there was an increase in the number of paps collected, whereas in periods without observation there were fewer paps collected. However, even in periods without active observation (periods 25-40), there remained a significant increase in the number of anal paps as compared to baseline.

In contrast to the great improvement in our primary aim, we were less successful in improving our secondary aims of decreasing the number of anal paps deemed insufficient for diagnosis and improving our proctology follow up rate. Neither aim demonstrated a statistically significant change from baseline after implementation of our multiple PDSA cycles. There was a non-significant increase in the insufficiency rates, despite attempts on educating both patients and

providers on the best technique for collecting anal paps. Furthermore, when we looked at insufficient rates between patient collected and provider collected specimen, there was no statistical difference between the two groups. Follow-up rates at the proctology clinic showed a non-significant decrease over the duration of the project. As the run chart demonstrated instability due to special cause variation during the period of baseline data collection, we were unable to draw any inferences with regards to this slight decrease.

One unexpected result of this quality improvement project was the degree to which we increased anal cancer screening. As a result of the sudden increase in anal cytology samples, we have experienced an increase in proctology referrals, which has put an increased strain on the proctology clinic in being able to schedule follow up appointments with the patients with abnormal cytologies and has potentially led to longer wait times.

Over the duration of this project, we have identified 850 anal paps that demonstrated abnormal cytological results. Amongst the patients with abnormal cytology results, 606 followed up with the proctology clinic. Of these patients, 249 were found to have an anal lesion on anoscopy and 35.9 % of these lesions were biopsied. Lesions with concerning characteristics, such as size, shape, rate of growth, etc were used in determining if a lesion warranted biopsy. Overall, 10 patients were diagnosed with biopsy proven anal cancer. When taking a closer look at these individuals and the electronic medical record, 3 patients were found to be completely asymptomatic at the most recent clinic prior to collection of the anal pap and would not have been referred to proctology if it weren't for the screening test, which ultimately resulted in an earlier diagnosis.

While we cannot conclusively state that this screening test impacted the staging of the cancer or the ultimate prognosis for the patient, in general we do know that anal cancer diagnosed at an earlier stage has a much better prognosis. Furthermore, there is some evidence that delays in diagnosis might lead to higher cancer stages at presentation and decreased survival.[30]

Limitations

One limitation of this quality improvement project is the metric by which we are calculating the monthly anal cancer screening rate. We calculated the anal cancer screening rate as the absolute number of screens performed in a 28 day cycle. However, this presumes a stable number of patients seen in clinic each month and that the number of eligible patients requiring screening remains the same. As more and more patients get anal screening, less patients would require screening in subsequent months and years. Future iterations of the project should calculate the screening rate that takes into account these considerations to ensure more accurate month to month comparison. Another limitation is that the current project utilizes a manual EMR search to collect the relevant data for analysis. This limits the sustainability of the project in the long term. As this quality improvement project was conducted in a setting with a large population of HIV patients in an urban setting, it may not be generalizable to other settings.

A vast majority of the patients who took part in this study were male. The local HIV clinic, on the other hand, has a population distribution of approximately 70% male and 30% female. The low female participation in the project might be a result of providers being less comfortable performing both cervical and anal pap smears on women or women being more uncomfortable

with anal paps. Regardless, the low female participation limits the generalizability of this project to this population.

Conclusions

In this quality improvement initiative, we implemented repeated PDSA cycles in order to increase awareness to both patients and providers on the increasing incidence of anal cancer in a high-risk population and the presence of an anal cancer screening program. By increasing both patient and provider awareness, we were able to achieve a quantitative increase in the number of anal cytology samples performed each month at a large HIV clinic in a limited resource environment. Over the duration of this project we were able to detect several cancers in patients who were otherwise asymptomatic, thus decreasing their time to diagnosis. While we were able to improve the time to diagnosis, it is unclear at this time if this has had a positive impact on treatment and prognosis for these patients. Next steps in this project involve transferring to an automated and sustainable method for collecting information on our anal cancer screening and in analyzing the impact earlier detection has on anal cancer prognosis.

LIST OF TABLES

Table 1:

Table 1. Special Cause Variation Rules.

Test	Rule
1	1 point is outside the control limits (three standard deviation lines)
2	8 of 9 consecutive points on the same side of the center line
3	6 consecutive points are increasing or decreasing
4	14 consecutive points are alternating up and down
5	2 of 3 consecutive points are between the second and third standard deviation lines in the same direction
6	4 of 5 consecutive points are between the first and second standard deviation lines in the same direction
7	15 consecutive points are within 1 standard deviation of the central tendency line
8	8 or more consecutive points on either side of the central tendency line

Table 2:

Table 2. Epidemiological data regarding the patients who received anal cancer screening.

	Pre-implementation	Post-Implementation	P-value
Age	42.68	43.09	0.621
Sex			0.082
Male	226 (96.17)	1639 (97.97)	
Female	9 (3.83)	34 (2.03)	

Table 3:

Table 3. Results of the quality improvement project on the anal cancer screening rate, the insufficiency rate, and the timely proctology follow up rate

	Pre-Implementation	Post-Implementation	P-Value
Average Monthly Anal Pap Rate	19.3	58.61	0.0000002
Insufficiency Rate			0.103
Insufficient	44 (18.72)	393 (23.49)	
Adequate	191 (81.28)	1280 (76.51)	
Timely Follow Up Rate			0.322
Within 6 Months	79 (33.61)	438 (26.18)	
Not Within 6 Months	156 (66.39)	1235 (73.82)	

Table 4:

Table 4. Analysis of patient collected versus provider collected anal cytology samples

	Patient Collected	Provider Collected	P-Value
Insufficient	109 (25.23)	266 (23.52)	0.478
Adequate	266 (74.77)	865 (76.48)	
Total	432	1131	

Table 5:

Table 5. Odds Ratios for having an anal lesion based on cytology results

Cytology Category	Abnormal Anoscopy	Normal Anoscopy	Odds Ratio (95% CI)
HSIL	17	13	1.0[a]
ASC-H	13	23	2.31 (0.86-6.23)
LSIL	146	171	1.53 (0.72-2.15)
ASCUS	66	155	3.07 (1.41-6.68)

a. Reference category

LIST OF FIGURES

Figures 1:

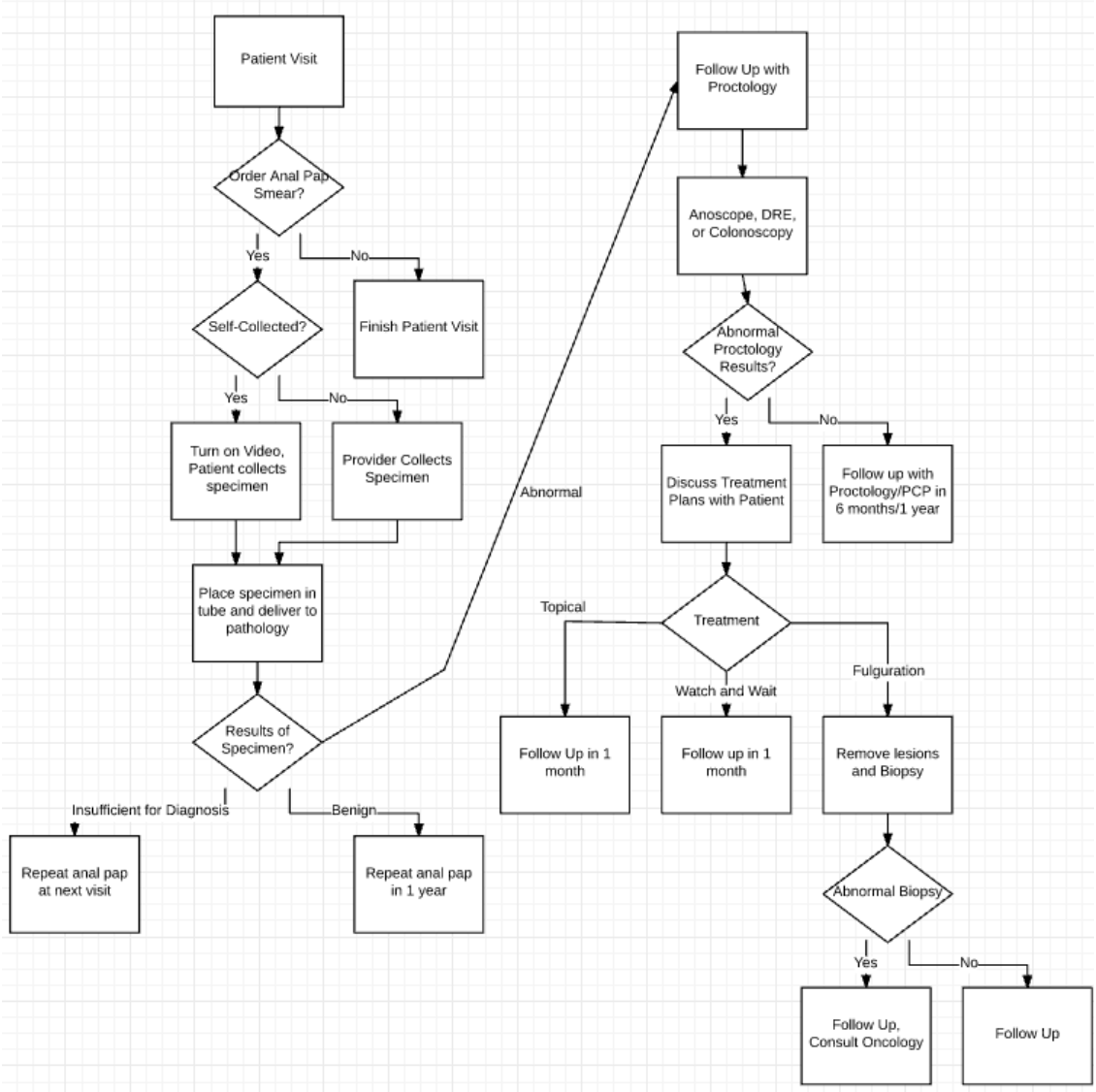


Figure 1. Process map of the anal cancer screening program

Figure 2:

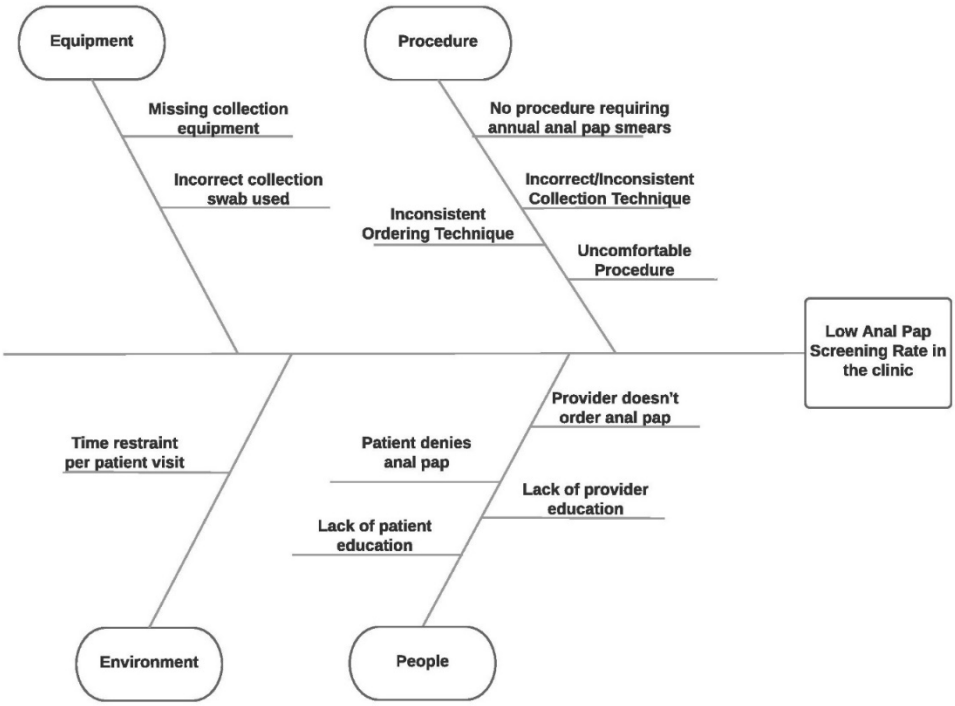


Figure 2. Ishikawa diagram focusing on low anal cancer screening rate

Figure 3:

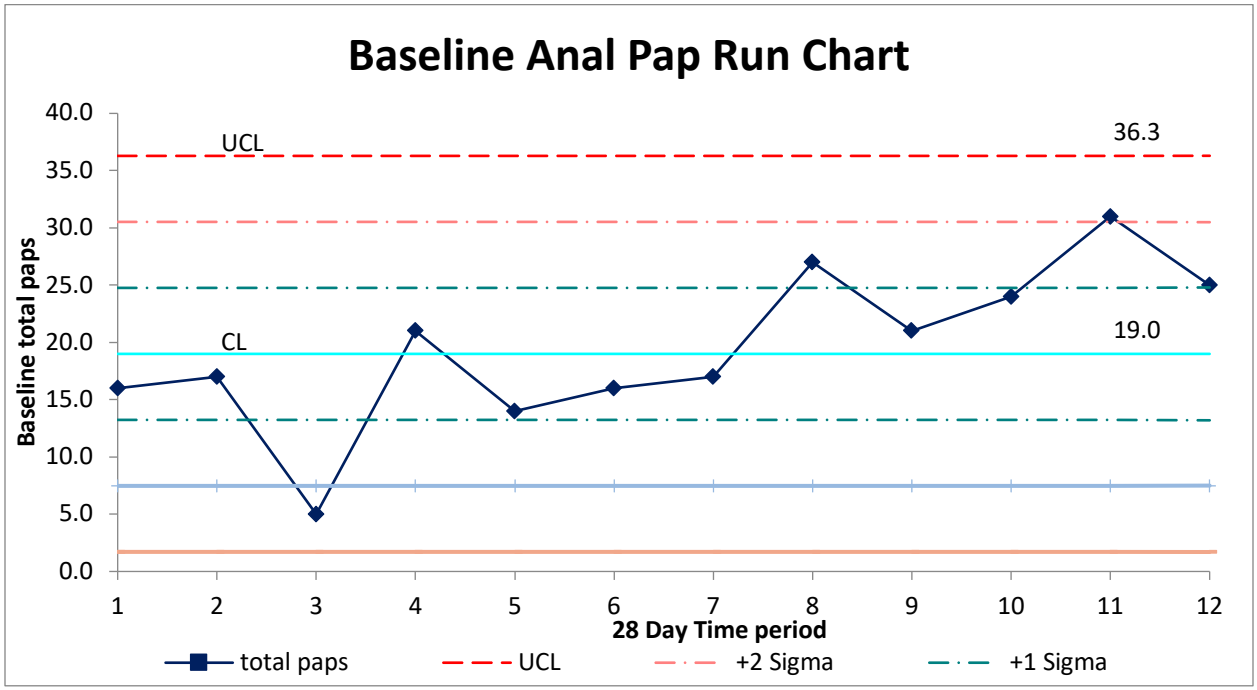
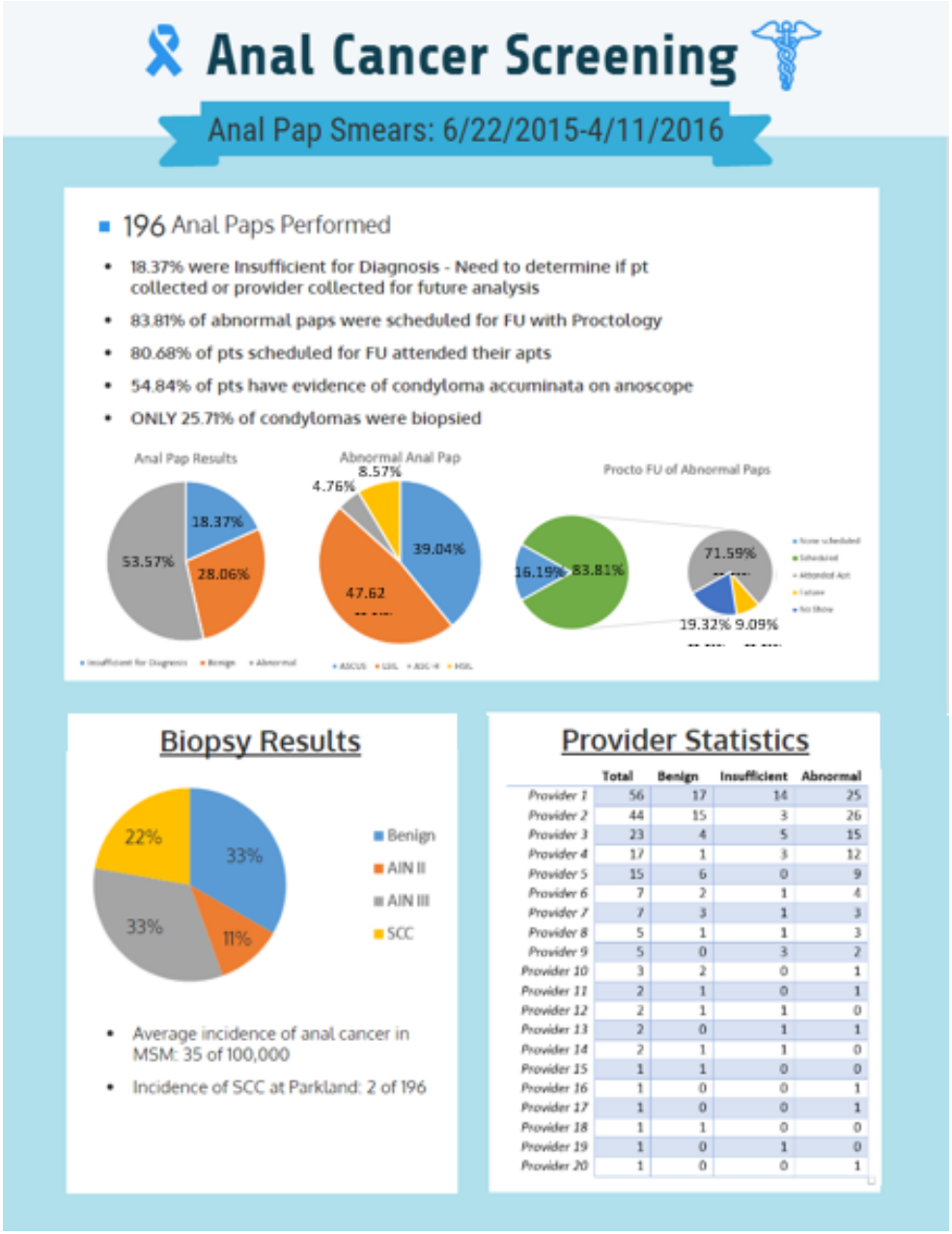


Figure 3. Run chart displaying the baseline anal pap results prior to implantation of the PDSA cycles

Figure 4:



	Total	Benign	Insufficient	Abnormal
Provider 1	56	17	14	25
Provider 2	44	15	3	26
Provider 3	23	4	5	15
Provider 4	17	1	3	12
Provider 5	15	6	0	9
Provider 6	7	2	1	4
Provider 7	7	3	1	3
Provider 8	5	1	1	3
Provider 9	5	0	3	2
Provider 10	3	2	0	1
Provider 11	2	1	0	1
Provider 12	2	1	1	0
Provider 13	2	0	1	1
Provider 14	2	1	1	0
Provider 15	1	1	0	0
Provider 16	1	0	0	1
Provider 17	1	0	0	1
Provider 18	1	1	0	0
Provider 19	1	0	1	0
Provider 20	1	0	0	1

Figure 4. Flyer distributed at the provider re-education meeting. Top shows the current statistics for anal cancer screening and proctology follow up. Lower Left shows the statistics on biopsies performed on screened patients. Lower right shows the de-identified statistics for anal cytology samples performed by provider.

Figure 5:

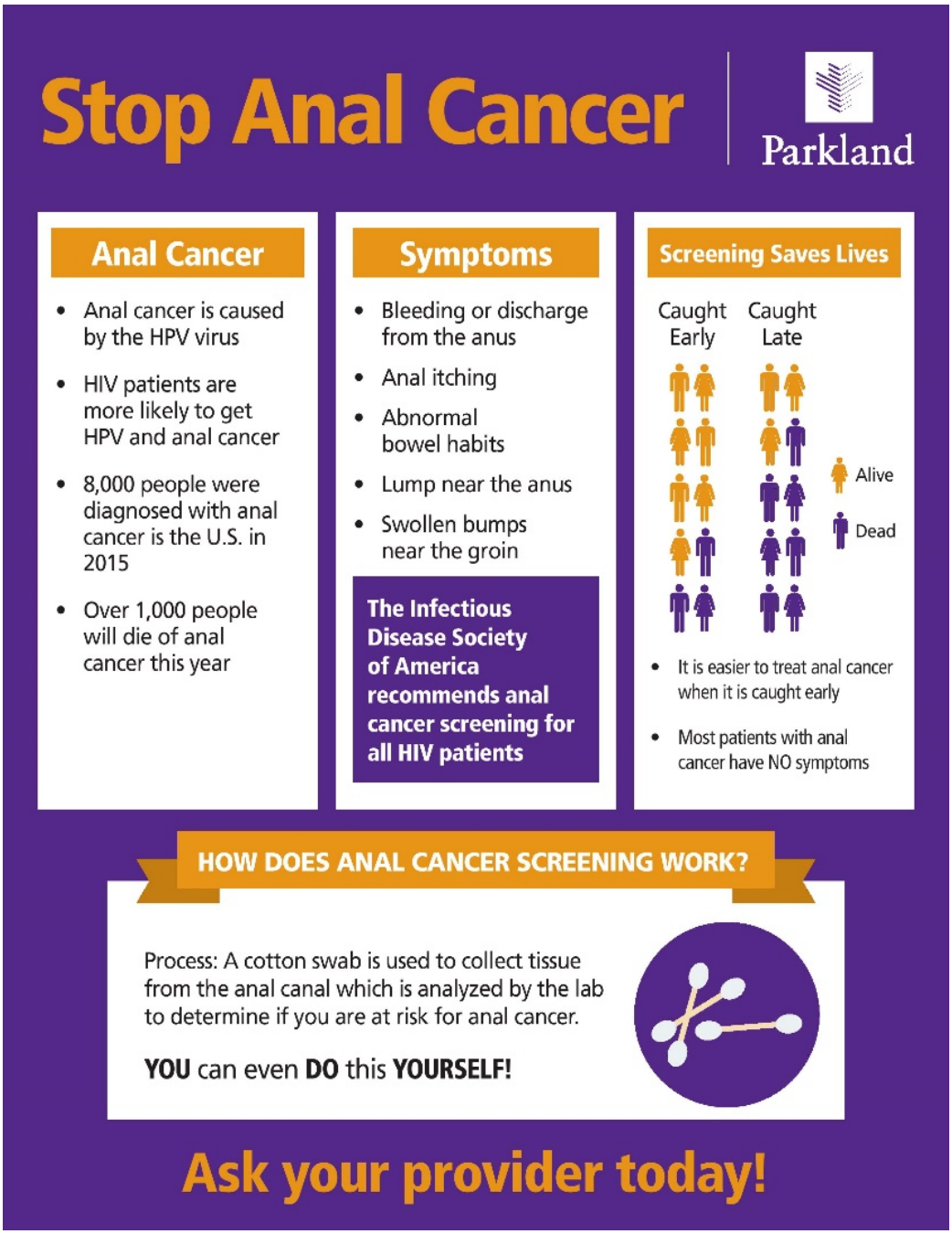


Figure 5. Flyer displayed in patient rooms encouraging patients to request anal cancer screening from their providers

Figure 6:

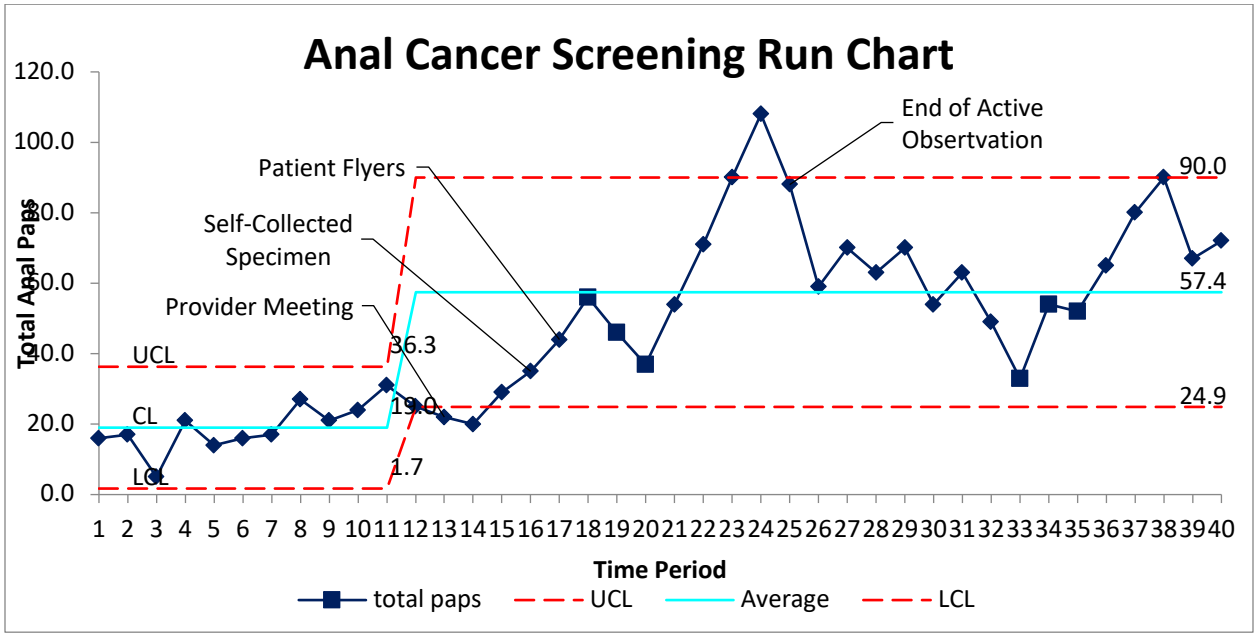


Figure 6. Run chart displaying the effects of the QI initiative on the average number of anal cytology samples collected per 28 day period. Key PDSA cycles are annotated on the chart. Beginning in period 25 and continuing through period 40, active observation of anal cytology rates was paused.

Figure 7:

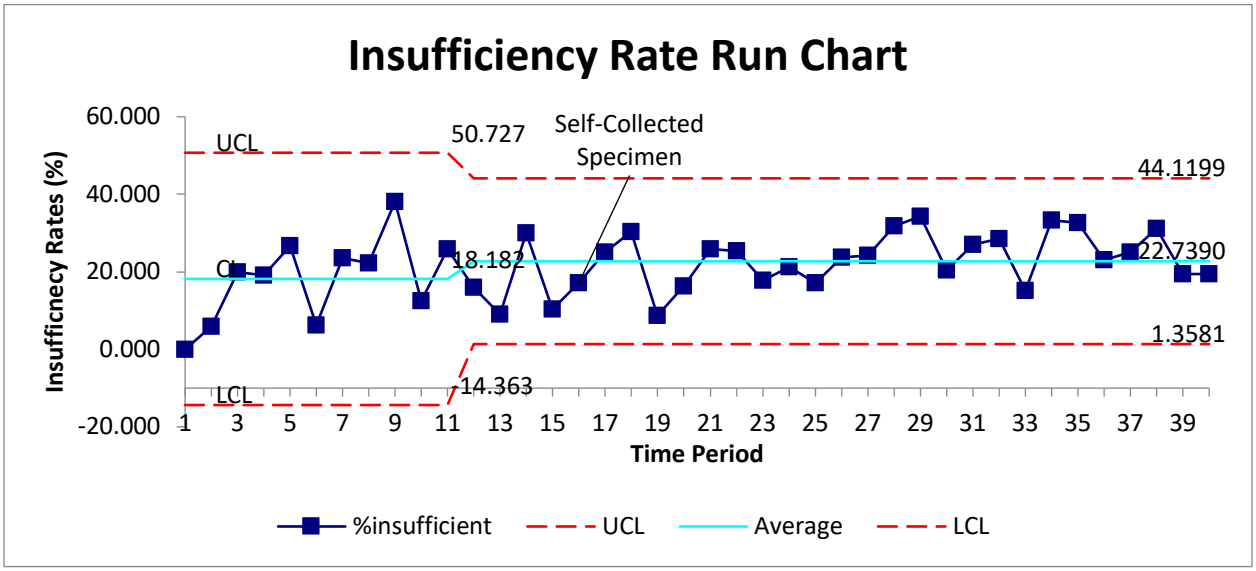


Figure 7. Run chart displaying the effects of the QI initiative on the insufficiency rates for the anal cytology samples collected

Figure 8:

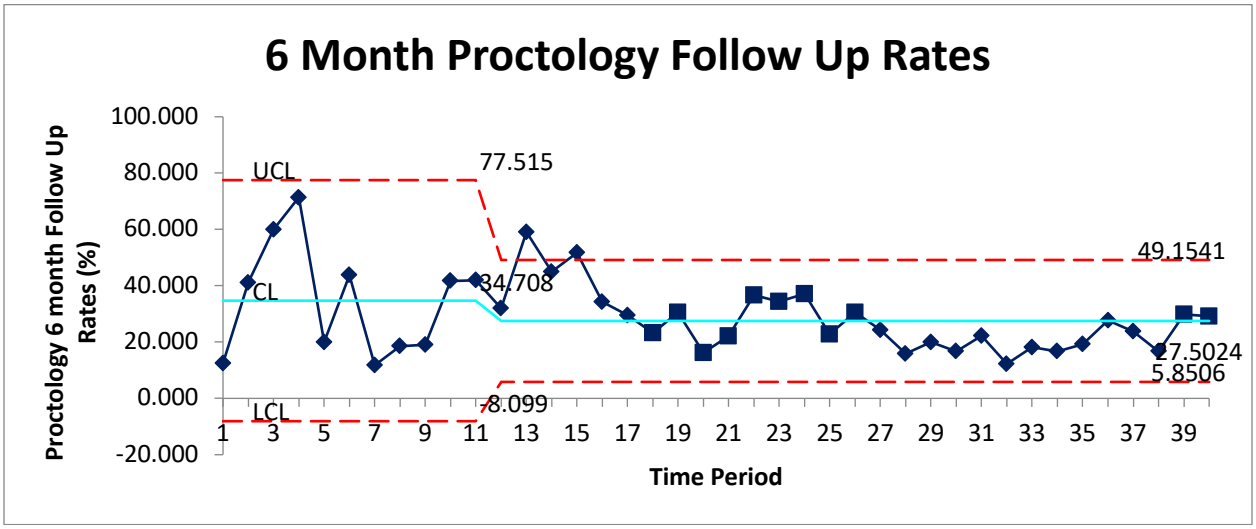


Figure 8. Run chart displaying the effects of the QI initiative on the proctology follow up rates

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VITAE

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