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IMPLEMENTATION OF TELEPHONE SUPPORT TO IMPROVE CERVICAL CANCER  
SCREENING AMONG WOMEN ENROLLED IN A RYAN WHITE CLINIC: AN  
OUTCOMES-BASED PROCESS IMPROVEMENT STUDY

BY

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Degree to be awarded: M.P.H  
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An abstract of  
A Thesis submitted to the Faculty of the  
Rollins School of Public Health of Emory University  
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## Abstract

### IMPLEMENTATION OF TELEPHONE SUPPORT TO IMPROVE CERVICAL CANCER SCREENING AMONG WOMEN ENROLLED IN A RYAN WHITE CLINIC: AN OUTCOMES-BASED PROCESS IMPROVEMENT STUDY

BY

Audrey Wingfield Brown

Purpose: Invasive cervical cancer and its precursor lesions are the most important gynecologic manifestations of human immunodeficiency virus (HIV) infection. Regular Papanicolaou (Pap) testing is accepted as a critical strategy for early detection and timely treatment. A significant gap in adherence to cervical cancer screening exists among HIV positive women enrolled in Georgia's West Central Health District (WCHD) Ryan White Program (RWP). A clinical quality improvement strategy was implemented and its effect on cervical cancer screening was observed. The primary questions addressed were (1) What impact will implementation of a telephone care management system have on client completion of annual cervical cancer screening, and (2) What barriers prevent clients from maintaining up-to-date Pap smears?

Methods: Women identified as overdue for Pap testing received a series of telephone support calls from a trained Prevention Care Manager (PCM) from September 2012 through December 2012. Inclusion and exclusion criteria were determined by the HIV/AIDS Bureau's (HAB) cervical cancer screening performance measure. Patient follow-up continued from January 2013 through December 2013. Data Analysis: Statistical analysis was performed by Minitab 17. The p control chart, or p chart, was used to allow visualization and analysis of process performance during the baseline, intervention, and post-intervention time periods. Patient barriers to Pap testing were assessed by the PCMs during the telephone support calls.

Results: The proportion of women with due or overdue cervical cancer screenings decreased from 49% to 23% during the intervention. During the post-intervention period a steady increase in the proportion of women without documented up-to-date screening occurred, reaching a high of 54%. The most common barriers to maintaining up-to-date Pap status were concerns about cost, (lack of) transportation, and competing priorities. Summary: Intensive recruitment techniques and a combination of tailored strategies have the potential to promote adherence to cervical cancer screening. Patient barriers may be overcome with the implementation of well-designed interventions that are based on the characteristics of the particular patient and provider populations. Further research may be needed to understand the effect of time on persistence of an intervention's impact.

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## **Chapter I**

### **Introduction**

#### **Introduction and rational**

A significant gap in adherence to cervical cancer screening exists among human immunodeficiency virus (HIV) seropositive women enrolled in Georgia's West Central Health District (WCHD) Ryan White Program (RWP). The goal of this project was to implement a clinical quality improvement strategy and observe its effect on increasing the percentage of up-to-date Papanicolaou (Pap) tests within this group. Increasing the use of cervical cancer screening is of great importance in disease prevention and early detection.

#### **Problem Statement**

Today there are more than 1.1 million people living with human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) in the United States and nearly 280,000 of them are women<sup>1</sup>. There were 9,500 new HIV infections among women in 2010, accounting for 20% of the estimated new infections<sup>2</sup>, and greater than 8,400 new AIDS diagnoses were made among women in 2010<sup>3</sup>.

HIV infection is a significant risk factor for human papillomavirus (HPV) infection and the development of HPV associated lesions in the female genital tract<sup>4</sup>. Women infected with HIV not only have a higher prevalence of HPV infection<sup>5,6</sup>, but have also been shown to have persistent infection with HPV<sup>6-8</sup>, infection with multiple types of HPV<sup>9,10</sup>, and increased incidence of cervical cancer precursors<sup>11</sup> than women without HIV infection. HPV is the etiologic agent found in 99.7% of invasive cervical cancers<sup>12</sup>.

Invasive cervical cancer and its precursor lesions are the most important gynecologic manifestations of HIV infection. Women with HIV present with more advanced stages of invasive cervical cancer<sup>13</sup>, have a poorer response to standard treatment<sup>13,14</sup>, higher recurrences and death rates<sup>13</sup>, and a shorter interval to recurrence or death<sup>13,15</sup>. In 1993 the Centers for Disease Control and Prevention (CDC) added invasive cervical cancer to its list of AIDS indicator diseases, emphasizing the importance of integrating gynecologic care into medical services for HIV infected women<sup>16</sup>.

Current guidelines for cervical cancer screening in HIV seropositive women recommend cervical cytology screening twice (every 6 months) within the first year after initial diagnosis. If both tests are normal, annual screening may be resumed. Women with abnormal results should undergo colposcopic evaluation<sup>17</sup>. Several studies have demonstrated that HIV infected women often fail to receive the recommended cervical screening<sup>18-21</sup>. Some of the identified barriers to screening include lack of knowledge about the purpose of the Pap test, fear of the exam, forgetting the appointment, and lack of transportation<sup>22-24</sup>.

Although it has been shown that women receiving care in a Ryan White (RW) funded facility are more likely to receive annual Pap smears<sup>25</sup>, a significant gap in adherence to Pap testing exists in the WCHD's HIV positive women. This RWP has historically failed to meet the HIV/AIDS Bureau's (HAB) cervical cancer screening performance measure. The measure, a quality improvement method created to improve delivery of services, examines the percentage of females with HIV infection who had a Pap screening during the measurement year. The national goal for this measure is 90%<sup>26</sup>. The WCHD's percentage of females with documented Pap results for the past 5 measurement years has been between 42% - 57% per CAREWare, the software used by the RWP to manage and monitor its HIV clinical and supportive care.

## **Theoretical Framework**

The Health Belief Model<sup>27-29</sup> (HBM) was one of the first theories of health behavior and has continued to be a major organizing framework for explaining and predicting acceptance of health and medical care recommendations. This model was developed in the early 1950's by a group of U.S. Public Health Service social psychologists in an attempt to explain the widespread failure of people to participate in programs to prevent and detect disease. They examined factors that encouraged and discouraged people from participating in those programs and theorized that people's belief about whether or not they were susceptible to disease and their perceptions of the benefits of trying to avoid it, influenced their readiness to act.

The HBM is based on the understanding, or assumption, that a person will take a health related action if that person has the desire to avoid illness (or if ill, to get well) and has the belief that a specific health action will prevent or (ameliorate) illness. Four perceptions serve as the main constructs of the model: (1) *perceived susceptibility* – beliefs about the chances of getting a condition; (2) *perceived severity* – beliefs about the seriousness of a condition and its consequences; (3) *perceived benefits* – beliefs about the effectiveness of taking action to reduce risk or seriousness; and (4) *perceived barriers* – beliefs about the material and psychological costs of taking action. These concepts were proposed as accounting for people's readiness to act. Readiness to act is defined in terms of the individual's points of view about susceptibility and seriousness rather than the health care professional's view of reality. An added concept, cues to action, would activate the individual's readiness and stimulate overt behavior. Cues to action are events, people, or things that move people to change their behavior.

In 1988 self-efficacy, or one's own confidence in the ability to successfully perform an action, was added to the original beliefs of the HBM. This concept was added to help the HBM

better fit the challenges of changing habitual unhealthy behaviors, such as being sedentary, smoking, and overeating.

The Health Belief Model's central focus is health motivation, making it a good fit for addressing behaviors that evoke health concerns. Together the six constructs of the HBM (Table 1, Figure 1) provide a useful framework for designing short-term and long-term behavior change strategies.

### **Purpose Statement**

The purpose of this project was to implement a clinical quality improvement strategy and observe its effect on increasing the percentage of HIV positive women with up-to-date cervical cancer screening in the WCHD RWP.

### **Research Questions**

The primary questions addressed were (1) What impact will implementation of a telephone care management system have on client completion of annual cervical cancer screening, and (2) What barriers prevent clients from maintaining up-to-date Pap smears?

### **Significance Statement**

Regular Pap testing is accepted as a critical strategy for early detection and timely treatment of cervical cancer. A low incidence of invasive cervical cancer has been found among HIV infected women participating in a regular prevention program<sup>30</sup>. The potential benefits of routine screening are not being fully realized in the WCHD RWP. Identification of effective intervention strategies could help reduce barriers to early detection of invasive cervical cancer and its precursor lesions among this high risk group of women.

## **Chapter II**

### **Review of the Literature**

#### **Introduction**

This review of the literature begins with an overview of the agencies charged with establishing and promoting quality of care for HIV infected individuals. Studies that examined adherence to the specific quality of care measure, cervical cancer screening, will be presented first. These works will be followed by studies that investigated perceived barriers to Pap screening completion among HIV positive women, and lastly, studies that described interventions used to impact Pap adherence within this group will be presented.

These particular studies were selected because of the specific group of individuals (HIV positive females) and the specific outcome (Pap adherence) examined by the authors.

#### **Literature Review**

##### **Public Health and the Ryan White Program**

The Public Health Service (PHS), the operating division of the U.S. Department of Health and Human Services (HHS), is responsible for promoting the protection and advancement of the American population's physical and mental well-being. Although first established in 1798, it was the Public Health Service Act of 1944 that consolidated and revised almost all legislations relating to public health services.

There are several agencies or operating divisions that fall under the PHS's umbrella. One of these agencies, or divisions, is the Health Resources and Services Administration (HRSA). HRSA is responsible for addressing, within the PHS, issues related to the access, quality, and



cost of healthcare. The administration works with states and communities to help deliver healthcare to underserved areas and groups with special needs.

Since 1990, grants under the Ryan White (RW) Comprehensive AIDS Resource Emergency (CARE) Act have been administered by HRSA. RW funds are provided directly to healthcare facilities through Part C, or Early Intervention Services, grants. Part C (formerly Title III) provides funding for HIV counseling and testing, monitoring of disease progression, treatment of HIV, diagnosis and treatment of related infections, case management and assistance accessing other programs that could provide health and support services to people living with HIV/AIDS. Eligible organizations include Community Health Centers, university affiliated medical centers, hospitals, or other community based health care settings. The HIV/AIDS Bureau (HAB) was created under HRSA in 1997 to streamline the administration of these Ryan White funds.

Through Title XXVI of the PHS Act, as currently amended by the RW HIV/AIDS Treatment Extension Act of 2009 (the fourth amendment and reauthorization of the RW CARE Act), funding to states, cities, and nonprofit organizations is provided to improve the quality and availability of medical care and supportive services for low income, uninsured, and underinsured individuals and families affected by HIV/AIDS. The legislation which provides these funds for HIV care and services also requires that service providers establish quality management programs to assess the extent to which HIV services provided to patients under the grant are consistent with the most recent PHS guidelines for the treatment of HIV/AIDS and related opportunistic infections. With the use of quality improvement methods, such as HAB's performance measures, providers may improve delivery of services.

The HAB HIV Core Clinical Performance Measures are offered as a set of indicators for use in monitoring the quality of care provided to HIV positive persons. One of the performance measures is cervical cancer screening. The U.S. Public Health Guidelines state that “in accordance with the recommendation of the Agency for Health Care Policy and Research, the Pap smear should be obtained twice during the first year after diagnosis of HIV infection and, if the results are normal, annually thereafter”.

#### Cervical Cancer Screening among Women with HIV Infection

Health services use by HIV infected persons has been explored since the early 1990’s. One of the first studies that characterized health service use in this group was performed by Solomon et al.<sup>31</sup> These authors assessed differences in use of health services by a population of HIV seropositive and HIV seronegative women of similar socio-demographic characteristics, but diverse racial and ethnic backgrounds. One of the medical services examined was last gynecologic exam.

The study population consisted of women from four urban centers in the U.S. who volunteered to participate in a longitudinal study of HIV infection. The urban centers were university-affiliated study sites in Baltimore, Detroit, New York, and Providence. Study recruitment was conducted from April 1993 to January 1995. Eligible women were 16-55 years old, without prior AIDS-defining illness, and had recent high risk behavior for HIV acquisition. One thousand two hundred ninety-three women completed the interviewer administered health services use questionnaire at the baseline study visit (865 HIV seropositive, 430 HIV seronegative).

The median age of participants was 35 years old. Fifty-seven percent were African American, 23% white, and 16% Hispanic. Seventy-two percent of the women had a monthly

income of <\$1,000 U.S./month. Fifty-seven percent were on public assistance. Seventy-seven percent had health insurance, but only 11% were privately insured. The authors found that although most women reported going to one doctor or clinic for most of their medical care (85%) and usually saw the same provider at that clinic (85%), HIV infected women were more likely than uninfected women to have a usual clinic (89.4% vs. 74%) and to see the same provider at that clinic (89.7% vs. 74%). (Table 2) In spite of high levels of health care use, almost 30% of HIV positive women had not had a pelvic exam within the last year.

In 2001 Stein et al<sup>32</sup> published a study that examined the socio-demographic, clinical, and organizational factors associated with screening for cervical cancer among HIV infected women in the HIV Cost and Service Utilization Study (HCSUS), a nationally representative cohort of persons receiving care for HIV infection in the contiguous U.S. The reference population was limited to persons at least 18 years old with known HIV infection who made at least one visit to a non-military, non-prison medical provider during the period from January 5 to February 29, 1996. Baseline interviews took place between January 1996 and April 1997. The first follow up interviews that included questions about cervical cancer screening were conducted from December 1996 to July 1997.

There were 624 women who responded to the question about Pap smear testing, representing 43,490 HIV infected women nationally. The analytic weight for each respondent combined a sampling weight, which adjusted for the differential selection probability across subgroups of the population, a non-response weight, and a multiplicity weight to adjust for the fact that some patients had more than one opportunity to enter the sample. This weight, applied in the analysis permitted inference to the national reference population from which the baseline sample was drawn.

Among those women who responded to the question regarding a Pap test in the past 12 months, 54% of the population represented were black and 1 in 5 were Hispanic or another race. Two thirds of the women had public insurance. Two thirds received gynecologic care at the same site as their usual HIV care. Of the eligible women, 81% had had a Pap test in the last year. The high rate of Pap testing was encouraging, but room for improvement was present. The authors make a recommendation for organizing care so that providers may offer gynecologic and general HIV services at the same site to further improve Pap testing rates.

Assessments of quality and adherence to guidelines in Ryan White Programs (RWPs) were also topics of studies during those early years. Kaplan et al<sup>33</sup> evaluated adherence by health care providers in the RW Title III system to guidelines for antiretroviral therapy (ART) and for prevention of opportunistic infections (OIs), including Pap smear testing of women. A pilot study of 50 patients who met eligibility requirements in each of three RW Title III facilities in Maryland was conducted from November 1996 through February 1997. Eligible patients were >13 years old at the time of medical record abstraction, had tested HIV antibody positive at the facility under review or earlier at another facility, had a medical evaluation at the facility within 6 months before record abstraction, and had a CD4 count of <500 cells/ $\mu$ l in their history. The remainder of the study was designed to include 300 study subjects in an urban facility and 150 study subjects in a rural facility in each of three states – New York, Illinois, and Georgia. Additional rural facilities in New York and Illinois were included due to low numbers of eligible cases in some rural areas. The medical records of 1,411 patients at 11 study sites were abstracted during the 11 months of the study. Of the 1,411 patients, 345 were female. During the chart review of the female patients, information was collected on whether a Pap smear had ever been performed.

The authors found that 88% of the 345 women received a Pap smear and concluded that adherence to preventive measures by health care providers was relatively high for measurement of Pap smears. They asserted that this observation attested to the relatively high standard of care in the federally funded facilities sampled in the study.

Sullivan et al<sup>25</sup> sought to provide historical information about the quality of care provided in facilities supported by the RWP to that in non-RWP facilities. The authors used data from the Survey of HIV Disease and Care (SHDC). The SHDC was a pilot project to develop methods for the use of population based sampling of persons receiving care for HIV clinical outcomes surveillance. For each sampled patient, medical records were abstracted for the period January 1 – December 31, 1998. Data were collected on provision of recommended screening tests, among other clinical outcomes. Sampling weights were constructed for each patient by multiplying the sampling weight of the facility by the sampling weight of the patient within the facility. These weights were used to estimate the number of patients in care within the geographic areas, as well as the number of patients in care at facilities supported by HRSA and other facilities. For each geographic area, the proportion of eligible patients receiving care according to treatment guidelines, with 95% confidence intervals, was estimated.

Eight hundred thirty-one patient medical records had information abstracted from them. Thirty percent or 250 patients received their care in facilities supported by the RWP. Using weighted sums of patients in care, the authors estimated that the study made statistical inference to 18,720 (45%, CI 29% - 62%) patients in care for HIV supported by the RWP and 10,230 (55%, CI 37% - 71%) in care at facilities not supported by the RWP. For most clinical care outcomes evaluated, there were no statistically significant differences in the quality of care provided to patients in RW supported and non-RW supported facilities. However, patients

receiving HIV care in RW supported facilities were more likely to receive a Pap smear in 1998 in all of the study areas (Table 3). Even so, the proportions of patients receiving indicated Pap screening were relatively low.

Although Stein et al. and Kaplan et al. observed a high rate of Pap testing, in contrast to the outcomes observed by Solomon and Sullivan there is consensus among the authors of these early studies that Pap screening in this group of high risk women could be improved.

Researchers continued to evaluate adherence to guidelines and the quality of care provided to HIV infected individuals. This next group of studies places emphasis on Pap testing as preventive care in this population.

Sheth et al<sup>34</sup> determined the rates of age appropriate preventive care, including cancer screening, in an urban population followed in an HIV specialty clinic. Two hundred twenty-two patients aged 40 years and over enrolled in John Hopkins Moore Clinic were randomly selected from a computerized database. Patients receiving longitudinal HIV and primary health care who had their most recent clinic visit between April 1999 and August 2002 were included in the analysis. Outpatient medical records were reviewed to collect data. One hundred twenty-four (55.9%) of the patients were female. Over 80% (101) of women were referred for Pap smears in the year prior to their last recorded visit, and 58% (72) actually received the exam. The authors state that HIV care providers may need to give increased consideration to general health maintenance. They suggest that clinics implement methods to familiarize providers with general health maintenance interventions and remind providers of routine screening for their patients, both for in office interventions and for tests that require referrals.

Koethe et al<sup>35</sup> assessed the provision of four preventive health services, including appropriate screening for cervical cancer, to female patients in an urban HIV clinic by board

certified Infectious Disease (ID) specialist physicians and generalist physicians. This was a retrospective cohort study at the Nathan Smith Clinic, an urban HIV clinic affiliated with Yale-New Haven Hospital, located in New Haven, Connecticut. The study cohort consisted of 148 patients eligible for one or both years of the study period (2001 – 2002). All women without documented or reported hysterectomy were included in the study population. Minimum eligibility requirements for inclusion were having a documented primary provider and at least three visits to the clinic during the calendar year in either year under study. The quality of care measure (annual cervical cytological screening) criteria were annual Pap smear performance documented, pathology report in the chart, pap smear offered to the patient but refused, or documentation of Pap smear performed elsewhere.

The highest rate of Pap testing was 64% among patients of ID specialists in 2002 (Table 4). These reported rates of gynecologic exam and Pap testing among both generalist and ID specialist physicians was lower than those reported by Solomon et al. (HIV Epidemiology Research Study/HERS) and Stein et al. (HSCUS). The authors acknowledge that the women with HIV represent a growing challenge for healthcare providers. Provider competency in addressing the primary care needs of HIV clinic patients will only become more crucial.

Oster et al<sup>18</sup> endeavored to determine whether cervical cancer screening was performed as recommended by U.S. Public Health Service and the Infectious Diseases Society of America. This study utilized a cross-sectional interview. HIV infected persons aged 18 years and older were interviewed to collect additional behavioral surveillance information from persons reported as having HIV infection or AIDS. Data were collected in 18 states during 2000-2004.

Analysis was limited to women interviewed from May 2000 – June 2004. A woman was excluded if her HIV diagnosis had been made <1 month before the interview, the interview date was missing, or if the year of her most recent pelvic exam or Pap test was missing.

Two thousand four hundred seventeen women were included in the analysis. Sixty-nine percent were African American and 15% Hispanic. The median age was 39 years old, Fifty-five percent of the women reported household comes of < \$10,000 U.S./year. Eighty-three percent had health insurance. Seventy-four percent received primary HIV care at a community or public clinic. At the time of interview, 556 (23%) had not received a Pap test during the year before the interview. This was believed to be a minimum estimate of the lack of adherence to the Pap screening recommendations. The authors present four recommendations for consideration: (1) HIV providers should ensure that the cervical cancer screening is performed twice in the year after diagnosis and annually thereafter, with special regard for women of increasing age, women with low CD4 counts, and women who receive their gynecologic care at a location other than their usual source of HIV care, (2) primary care providers and gynecologists should be educated about the recommendations for cervical cancer screening for HIV infected women and how they differ from the recommendations for screening in the general population of women, (3) HIV infected women should be informed about current recommendations for annual Pap test, and (4) gynecologic care should be integrated into primary HIV care.

Gynecologic care among HIV infected women has also been found to be unsatisfactory in facilities outside of the U.S. Keiser et al<sup>19</sup> analyzed whether the recommendation for at least one annual gynecologic exam, including a Pap smear, in HIV positive women was followed in Switzerland. This prospective Swiss HIV Cohort Study (SHCS) followed HIV infected individuals aged 16 years old or older who attended 7 outpatient clinics that specialized in



infectious diseases or affiliated outpatient clinics or were seen by private physicians. A questionnaire was introduced in April 2001 asking specifically about gynecologic visits since the last follow up visit and whether a cervical smear had been done. Women with at least one completed gynecologic questionnaire between April 1, 2001 and December 31, 2004 were included in the study. The entire period during which the questionnaires were used was divided into 3 blocks of 15 months (April 1, 2001 – June 30, 2002; July 1, 2002 – September 30, 2003; and October 1, 2003 – December 31, 2004). Two thousand two hundred thirty-nine women had at least one follow up visit in the SHCS, resulting in a total of 11,346 follow up visits. Fifty-three women were excluded from the analysis because a questionnaire had not been completed. A gynecologic exam was reported on 4,594 (44.6%) of the 10,302 SHCS follow up visits. Of those reporting a gynecologic exam, 3,761 (82%) reported having a Pap smear. A total of 1,146 (52.4%) women were followed over the entire study period ( $\geq 2$  SHCS visits in each of the three time periods). With a Pap smear as the outcome, 12.5% never had a gynecologic exam, 61.6% reported an exam at 1 or 2 of the time periods, and 25.9% reported a Pap exam in every period. Patient characteristics are shown in Table 5.

This study is consistent with previous reports from the U.S. demonstrating that HIV infected women often fail to receive necessary gynecologic care. The authors conclude that gynecologic care among HIV positive women in the SHCS is not satisfactory, and recommend that if gynecologic care does not occur, the treating physician should try to elucidate possible reasons and explain to patients why this care is important.

More recent studies underscore the importance of improving access to services and motivating patients to comply with cervical cancer screening. Logan et al<sup>20</sup> examined cervical cancer screening rates and related characteristics of women receiving HIV care in health

department settings. This study was conducted at a RW funded health department that provides care for approximately 1500 patients living with HIV/AIDS. Eligible patients included HIV infected women 18 years or older who had enrolled in the clinic between January 1, 2000 and April 30, 2006 and who had received care for at least 12 months during the study period. Participants in the study were generally of low socioeconomic status and predominantly minorities (Table 6). A list of 464 eligible female patients was generated by the HIV clinic director and 200 were selected by random number generation. A retrospective medical chart review was conducted. One hundred sixty-six females (83%) received one or more Pap smears in their first year after enrollment.

Logan et al.'s findings are consistent with the observations of Kaplan et al. and Stein et al. Logan et al. echo the recommendation of Stein et al. and Oster et al. In order to better meet the cervical cancer screening guideline, they propose making these screening services more conveniently available by providing patients with Pap screening and routine HIV care visits at the same location.

Ranhangdale et al<sup>21</sup> reviewed the frequency of Pap smears in HIV infected women receiving care in an HIV primary care clinic in order to assess the adequacy of provision of primary care to women in this setting. This project was a retrospective cohort study of medical records of HIV infected women obtaining primary care from a public health care clinic, the San Mateo Medical Center, in San Mateo, California. Data were obtained from the HIV database and electronic medical record system. A follow up interval of 18 months was chosen for the Pap smears.

One hundred twenty-five women received care at the clinic between January 1, 2002 and December 31, 2006. The median age at documented first visit was 42 years old. The largest

racial /ethnic group represented in the sample was black women (29 women, 42.6%), followed by Hispanic women (19, 27.9%), and white women (17, 25%). There were 166 total Pap procedures performed over 252.9 person years of time for a rate of 656 Pap smears per 1,000 person years. One hundred eleven (66.9%) of the 166 Pap smears were normal. Eighty-four occurred between 2002 and 2005, allowing for analysis of follow up during the study interval. After excluding 5 women whose follow up could have been outside the study time period, 59.5% (47/79) of the women with normal Pap smears had a follow up Pap smear within 18 months. These study findings indicated that the Pap screening rates for HIV infected women in this region of the U.S. were consistent with other regions of the U.S.

The authors note that although the study shows high numbers of minority women are getting appropriate preventive health screening, there was not consistent follow up of Pap smear screening. They recommend increasing efforts to promote consistent cervical cancer screening, particularly in high risk women with documented abnormal Pap smears.

The most recent study found revisited health service use among HIV women. In an effort to better understand the extent of underutilization of gynecologic healthcare in HIV infected women, Tello et al<sup>36</sup> performed an analysis to determine the prevalence of scheduled visit compliance and to identify factors contributing to or associated with gynecological clinic visit compliance. This study was based on a subset of data collected on women who had at least one visit to the Johns Hopkins HIV Clinic during January 2002 to April 2006. This service provides comprehensive primary and subspecialty medical care, including gynecological care, in a single clinic facility.

There were 1,086 female patients who had at least one visit during the specified period of time. The mean age was 36.6 years with 84% of patients being African American. All of the

patients were either insured or eligible to receive primary and gynecological care paid by the RWP. These women had 26,401 appointments to the two clinics, of which 21,097 (55%) completed HIV primary care clinic visits, and 1,609 (32.2%) completed HIV gynecological clinic visits. By logistic regression accounting for clustering, patients were half as likely to appear for their HIV gynecological clinic appointments as for their HIV primary care visit appointments (OR 0.48, 95% CI 0.44-0.52).

Although there was a relatively low rate of scheduled primary care clinic visit adherence, the rate of gynecological clinic visit adherence was found to be significantly lower. The authors stated that their study showed a low rate of HIV primary care clinic compliance and a dramatically low rate of HIV gynecological clinic visit compliance highlighting the need to examine the barriers to gynecological clinic visit adherence in this population. The authors assert that it will be critical to create appropriate interventions that target barriers to receiving gynecological healthcare among women enrolled in urban HIV clinics.

Cervical cancer screening among women with HIV infection has been examined by researchers since the early 1990's. It is noteworthy that although HIV positive women appear to have high levels of health care use, the proportion of patients receiving consistent Pap smear screening is relatively low. In order to address this health disparity, an examination of barriers to cervical cancer screening within this group will be needed.

#### Barriers to Cervical Cancer Screening among Women with HIV Infection

Limited research examining barriers to cervical cancer screening in HIV infected women was found. One of the earliest studies was performed by Andrasik et al.<sup>24</sup> This group sought to identify cervical cancer screening barriers faced by HIV positive African American women living in poverty. Eligible participants were HIV positive African American women between 18

and 49 years old who were fluent in English and lived in the Liberty City and Overtown neighborhoods of the greater Miami metropolitan area. Participants were identified and recruited through two community based organizations and the Special Immunology Obstetrics and Gynecology Clinic at Jackson Memorial Medical Center from August 2001 through February 2003. Women were excluded from the study if they had had cervical cancer screening in the previous five years or had a hysterectomy. A total of 35 women were selected. The mean age was about 37 years old and 60% of the women were single/never married. The population was characterized as poor since 80% of the women reported being unemployed and 77% reported an income of less than \$10,000/year.

The primary investigator conducted face to face interviews using a semi-structured qualitative instrument with open-ended questions to elicit information on barriers and facilitators to accessing and/or utilizing cervical cancer screening services. Four themes emerged from the women's responses – (1) psychological/emotional barriers, (2) economic/financial barriers, (3) outcome barriers or medical care perceptions and experiences, and (4) enabling resources (Figure 2). The authors assert that this research highlights the need to include both psychological and emotional components in future efforts to contextualize health care perceptions and experiences to account for the development of barriers. In addition, efforts are needed to improve self-esteem and provide education to reduce denial and fear around utilization of cervical cancer screening in prevention and intervention efforts for poor, urban, HIV positive African American women.

Tello et al<sup>22</sup> continued their earlier work by designing a study to determine modifiable barriers to gynecology appointment adherence. A cross-sectional survey, followed by focus groups of women attending the Johns Hopkins HIV Clinic in Baltimore, Maryland was

performed. Two hundred women attending the clinic between February 2008 and June 2008 were recruited. They were recruited from the waiting room and through provider referral. Women were eligible if they were  $\geq 18$  years of age, English speaking, and received both HIV primary and gynecologic care at the Johns Hopkins HIV Clinic. The primary outcome variables included (1) missed gynecology appointments over the past one year, (2) receipt of a cervical or vaginal pool smear within the past one year, and (3) either a missed gynecology appointment or no Pap smear within the past year. The average age of the participants was 46, with 78% of women  $> 40$  years old. Eighty-five percent were African American, and 49% had less than a high school education. Of the primary outcomes, 138 (69%) had missed at least one gynecology appointment in the past year, and 44 (22%) had not had a Pap smear in the past year.

The focus groups revealed four major barriers to care – (1) forgetting the appointment, (2) bad weather, (3) discomfort/pain during the examination, and (4) fear of a bad diagnosis (Table 7). The authors state that providers should be aware of psychosocial and emotional barriers, women's fears, denial, low self-esteem, and competing needs that may contribute to lower appointment adherence. Outreach programs incorporating education, explanation, and peer support are suggested as possible effective methods for addressing the psychosocial and emotional barriers, thereby improving adherence.

These studies demonstrate that there are common barriers that hinder HIV positive women from participating in routine cervical cancer screening. Provider recognition of the presence of psychosocial and emotional barriers, as well as education of the patients, is suggested as a means of improving Pap testing in this group.

#### Interventions to Improve Cervical Cancer Screening among Women with HIV Infection

Only one study was found that investigated the implementation of an intervention in this specific group. Shuter et al<sup>37</sup> described the impact of a computer driven Pap smear reminder system in a large, urban HIV care clinic, the Montefiore Medical Center AIDS Center Infectious Diseases Clinic. This clinic, located in the Bronx, New York City, provides comprehensive outpatient primary care to over 1800 adult patients. The clinic population is 44% female, and 92% of the patients are <55 years of age. Fifty-two percent of patients are Latino, 41% are Black, 6% are White, and 1% from other ethnic groups. Ninety-one percent of patients have incomes that place them below the official poverty line. Routine gynecologic care is provided by the physicians, nurse practitioners, and part-time obstetrician gynecology specialist on site.

Beginning November 2000, a query developed in standard query language, was run weekly that identified the date of the last Pap smear recorded for women with scheduled AIDS Center clinic appointments in the upcoming week. Each week, every clinic provider received a list of scheduled female patients for the upcoming week, with the date of each patient's last Pap smear and a special notation if there was no Pap smear within the preceding year. All clinic visits by female patients between November 11, 2000 and November 10, 2001 were audited by computer. In order to establish a baseline, an identical computer audit was performed retroactively for the eight weeks prior to the beginning of the quality improvement project. A total of 1486 scheduled visits were audited for this time period.

During the baseline period 912/1486 (61.4%) visits were associated with documented up to date Pap smears. In the 52 weeks following the institution of weekly Pap smear reminder lists 7667/10,476 (73.2%) visits were associated with documented up to date Pap smears. The odds ratio (OR) of a given visit being associated with a computer report confirmed up to date Pap smear after the intervention as compared to before the intervention was 1.72 (95% CI 1.53 –

1.93,  $p < 0.001$ ). This represented a 19.2% increase in the proportion of scheduled visits associated with up to date Pap smears. The authors stated that the project suggests that information available in most hospital information systems can fuel a computer-based decision support program capable of improving screening rates in an efficient and inexpensive manner. Additional research in the area of development and implementation of interventions may prove to be beneficial in reducing the gap in adherence to Pap testing in HIV positive women.

### **Summary of Current Problem and Study Relevance**

The reviewed literature contains several studies that have examined cervical cancer screening among HIV infected women. It is recognized that only one of the presented studies (Stein et al.) used a nationally representative cohort of persons receiving care for HIV in the U.S. All others were carried out in specific geographic areas, so it must be acknowledged that results may not generalize to all HIV clinics. It must also be noted that the possibility of bias may exist within some of the works due to the use of volunteers (Sullivan et al., Solomon et al.) and the data collection method used (interview – Oster et al., Stein et al.; questionnaire – Keiser et al.). In addition, it is possible that underreporting of true screening rates may have occurred due to incomplete documentation in patient medical records (Logan et al., Sullivan et al., Koethe et al., Sheth et al.). However, overall, these works do appear to adequately demonstrate the less than optimal adherence to Pap screening in this population.

Research has suggested that HIV positive women are underutilizing gynecologic healthcare, cervical cancer screening in particular. Limited published literature is available that provides an examination of perceived patient barriers to care within this group or interventions to reduce/eliminate this disparity in care. The proposed clinical quality improvement project for the WCHD RWP will build upon the literature by examining the impact of an intervention (a



telephone care management system) on patient completion of annual cervical cancer screening and assessing for barriers that prevent patients from maintaining up-to-date Pap smears.

## Chapter III

### Methodology

#### Introduction

HIV positive women present with more advanced stages of invasive cervical cancer<sup>13</sup>, have a poorer response to standard treatment<sup>13,14</sup>, higher recurrences and death rates<sup>13</sup>, and a shorter interval to recurrence or death<sup>13,15</sup>. Routine screening for cervical cancer is critical for early detection and management of disease. The U.S. Public Health Guidelines recommend that the Pap smear be obtained twice during the first year after diagnosis of HIV infection, and if the results are normal, annually thereafter.

A significant gap in adherence to Pap testing exists among the women enrolled in the West Central Health District's (WCHD's) Ryan White Program (RWP). Published literature<sup>38-40</sup> reveals that a variety of interventions have been developed to increase Pap smear use, but the results have been varied. A selected intervention is likely to be most effective when the provider and patient population characteristics and feasibility of implementation have been considered.

Deitrich et al<sup>41</sup> performed a randomized, controlled trial to evaluate the effect of a telephone support intervention to increase cancer screening rates, including cervical cancer, among minority and low income women. The authors conclude that telephone support can improve cancer screening among women who visit community and migrant health centers and state that the intervention seems well suited to "...other organizations that seek to increase cancer screening rates and to address disparities in care." This telephone support intervention was adapted for use in the WCHD's RWP.

The project was submitted to the Emory University Institutional Review Board (IRB). It was determined that IRB review was not required because the project did not meet the definition of “research” or the definition of “clinical investigation” set forth in Emory policies and procedures and federal regulations. The WCHD’s Executive Management Team and agency IRB reviewed and approved the project.

### **Population and Sample**

The population involved in the project included HIV positive women enrolled in the WCHD’s RWP who were overdue for cervical cancer screening. The health district is comprised of 16 counties in the southwest region of Georgia and includes Chattahoochee, Clay, Crisp, Dooly, Harris, Macon, Marion, Muscogee, Quitman, Randolph, Schley, Stewart, Sumter, Talbot, Taylor, and Webster counties. Clinic sites are located in Crisp, Macon, Muscogee, Randolph, and Sumter county health departments.

The ages of the women receiving services in the program range from 18 – 70+. Inclusion and exclusion criteria for participants were as stated in the HIV/AIDS Bureau (HAB) performance measure. All women  $\geq$  18 years old or who reported a history of sexual activity and had had a medical visit with a provider with prescribing privileges at least once in the measurement year were included in the project. Women were excluded if they were  $<$  18 years old and denied a history of sexual activity or if a hysterectomy had been performed for non-dysplasia/nonmalignant indications.

### **Project Design**

The project was carried out through the use of CAREWare (the RWP’s software for managing and monitoring HIV clinical and supporting care), review of patient charts, and interviews with patients in person and/or via the telephone. Women who were overdue for

cervical cancer screening according to CAREWare and medical record review received a series of telephone support calls from a trained Prevention Care Manager (PCM). Two female PCMs participated in the project. One PCM, a peer counselor, was responsible for working with overdue patients in the Muscogee county clinic. The other PCM worked with those overdue in the Crisp, Macon, Randolph, and Sumter county clinics. This PCM was also the clinic's clerk.

During the first call with the patient, the PCM reviewed screening dates found in the woman's medical record and assessed her readiness to act on completing the screening. Information was provided about the importance of cervical cancer screening in HIV positive women each woman's specific barrier(s) that delayed or prevented screening was responded to. During subsequent calls, the PCM inquired about future appointments and screenings that had been received since the last call and responded to new or ongoing barriers if screening remained overdue. In addition PCM support was demonstrated for the women by provision of accurate information about screenings by mail if requested, scheduling appointments for Pap screenings, prompting the woman with reminder calls and letters, and helping to find a means of transportation to the appointment.

## **Procedures**

The approach used to reach the goals and objectives of the project included the following steps – 1) PCM training, 2) identification of the women overdue for Pap screening and preparation for first contact with the patient, 3) initiation of contact and completion of the follow up plan, and 4) PCM follow up as needed until Pap screening completed or the project ends.

### **PCM Training**

The PCM's training was provided by the program's physician and included background information on cervical cancer screening as presented in a basic patient education pamphlet<sup>42</sup> and

in the most recent edition of the Sexually Transmitted Diseases Treatment Guidelines<sup>17</sup>.

Emphasis was placed on the importance of Pap screening as a means of disease prevention and early detection. Cervical cancer screening goals for the program, as described in the HAB cervical cancer screening performance measure<sup>26</sup>, were also reviewed. Lastly, the prevention care management manual<sup>43</sup> was presented. Its content was reviewed, as well as the various forms that would be utilized during the course of the project.

#### Identification of the Women Overdue for Pap Screening and Preparation for First Contact

A list of women overdue for Pap screening was generated every 4 – 6 weeks from CAREWare by the program coordinator or clerk and shared with the PCMs. A chart review was performed by the PCM to verify the overdue status. If the patient was found to have documentation in the medical record (i.e., Pap report) demonstrating that a Pap had been performed within the past 12 months, the program coordinator or clerk was notified and CAREWare was updated to reflect the correct information. If the patient did not have documentation supporting an up to date Pap status, the record was further reviewed to ensure that the patient met all inclusion criteria as described by the HAB cervical cancer screening performance measure<sup>26</sup>. Women meeting inclusion criteria and who were overdue for Pap screening remained on the list for contact. However if the overdue patient was found to have an abnormal Pap result during the chart review, they were not contacted. Instead, the clinic nurse and/or Program Coordinator were notified and assumed responsibility for following up with the patient.

#### Initiation of Contact and Completion of the Follow up Plan

The PCM's initial contact with the patient accomplished the following objectives - introduction and statement of purpose for the call, verification of Pap status (up to date or

overdue), inquiry about any scheduled Pap appointments, assessment of readiness to act, identification of barriers to completion of cervical cancer screening, and scheduling of a date/time for a follow up call.

When a patient was contacted for the first time, the PCM introduced herself and stated the purpose for the contact using the introductory script.

*“Hello, \_\_\_\_\_? My name is \_\_\_\_\_, and I am a \_\_\_\_\_ at District Clinical Services. In addition to being a \_\_\_\_\_, I am also a Prevention Care Manager, and part of that job is working with women who come to this practice to make sure they are up to date with their cervical cancer screening or Pap test. Do you have 5 minutes to talk to me? According to your medical record, you’re overdue for your Pap test. Dr. Brown thinks it’s very important that you have this test and has asked me to help you obtain it over the next few months.”*

If the patient’s primary or preferred language was one other than English and the PCM could not communicate effectively with the patient, the Program Coordinator would be contacted and asked to assist with finding an interpreter. Once the PCM ascertained that she was able to communicate with the patient, scripts were used along with the Initial Follow up Form to guide the conversation.

The PCM began by reporting the date of the last documented Pap test.

*“Ms. \_\_\_\_\_, I’ve had a chance to look at your chart and found that you had a Pap test in (Month/Year). Is that correct? Have you had a more recent Pap test?”*

If the patient corrected the information from her medical record, the date and location of the test and any pertinent notes were indicated on the Initial Follow up Form. If an upcoming appointment for screening was reported, that information was noted as well.

Patient readiness to act was assessed next.

*“Ms. \_\_\_\_\_, when do you think you would be able to schedule this test? How would you describe your readiness to have your Pap performed?”*

Even if the patient had an upcoming appointment, readiness to act was assessed in order to ascertain if the patient would follow through with the screening. Readiness to act was rated by the PCM using the “A – D scale”. “A” indicated that the patient was ready to take steps now for scheduling; “B” indicated ready to act over the next month, but not today; “C” indicated ready to act at some nonspecific future time; and “D” indicated that the patient was reluctant, ambivalent, or not ready to act.

Barriers were assessed after discussing readiness to act.

*“What is the main reason that you haven’t had a Pap test in greater than one year, Ms. \_\_\_\_\_?”*

The PCMs referred to “Barriers to Cancer Screening Tests and Appropriate Responses” (Appendix D) for a detailed listing of frequently cited barriers to cancer screening tests and appropriate responses to use to help patients overcome these barriers. Even if barriers to screening were not reported, the PCM asked about each of the barriers listed in the table on the follow up form. If at the time of the initial contact the patient reported that she was already scheduled for a test, the PCM still assessed for barriers since the patient might not follow through with the appointment and this information would be helpful in future interactions with the patient.

*“Ms. \_\_\_\_\_, what things do you think would prevent you from getting your Pap smear performed on (Date)?”*

Together with the patient, the PCM developed a strategy of the specific steps needed for the patient to obtain the Pap test.

Lastly the PCM arranged a follow up contact date/time with the patient. This contact would be used to determine if steps had been taken toward completion of the cervical cancer screening. The specific date and time for the call was recorded on the PCM Follow up Plan. At the close of the call the PCM let the patient know that they cared about her preventive care and health and that she would be contacted again. If an appointment for a Pap test had been scheduled, the PCM informed the patient that she would receive a reminder call a few days before the appointment.

*“We really care about your health, Ms. \_\_\_\_\_. We want you to stay up to date with cervical cancer screening by getting your annual Pap test. Is there anything that you would like to add or discuss before we hang up? Remember that I will be calling you again on (Date) to find out when you have scheduled the Pap test (OR I will call you a few days before your scheduled Pap test as a friendly reminder). Thank you for taking the time to speak with me today. I look forward to speaking with you again soon. Have a good day.”*

Once the call was completed the PCM reviewed the form to ensure that all items were completed and consistent. The Follow up Plan and Prevention Care Manger Follow up Plan Worksheet were updated by the PCM after each call and reviewed between calls for the purposes of monitoring the patient’s progress in becoming up to date and ensuring that PCM support tasks were completed in a timely manner.

### **Instruments**

The Initial Contact Form (Appendix A) was used to document the first attempts to contact the patient. This form contains 9 sections that were completed by the PCM. Sections 1 and 2 identify who the contact was initiated by (PCM or patient) and the type of contact (phone or in person). Section 3 is a record of the outcome of all calls leading up to the first contact. The



PCM documented the outcome of each unsuccessful outcome by checking the appropriate box next to the available options – no answer, answering machine, number incorrect, left message, asked to call back, or phone busy. If the patient had a “no telephone contact” request in the medical record, letter mailed was included as an option. The PCM also had the opportunity to write in an outcome if none of the preceding options were accurate. After 8 unsuccessful calls, the PCMs were instructed to find out if the patient was still receiving care at the clinic. Once contact was made, the date of contact was recorded on the form. Section 4 is where the PCM documented some of the patient’s demographic information – primary language, age, race, primary care provider, and type of health insurance. In Section 5, a table is used to display the patient’s last documented date and result of their Pap test. The patient’s up to date status is determined, and the patient may either verify or correct the date of the last test. The corrected date and location of the Pap test are recorded if reported by the patient. Comments may be written as indicated. The PCMs would have to verify the updated Pap information given by the patient in order for them to receive an up to date status. Section 6 documents future appointments of the patient. The next appointment date with the primary care or gynecology provider, as well as the name of the provider, is entered. The date and location of any scheduled Pap test is also recorded if applicable. Next, the PCM assesses readiness to act in Section 7. A check mark was placed by one of the four statements that best describe the patient’s readiness to act. Options include A = ready to take steps now for scheduling, B = ready to act over next month, but not today, C = ready to act at some non-specific future time, and D = reluctant, ambivalent, or not ready to act.

Section 8 explores the barriers identified by the patient that already have or may in the future hinder her from maintaining up to date cervical cancer screening tests. PCMs were to check all

of the listed barriers that applied to that patient and write comments as appropriate. A few examples of the listed barriers include no symptoms, no family history, cost, competing priorities, and access. Finally, the PCM documented the date and time for the next contact.

On subsequent contacts with the patient, the Follow up Form was utilized (Appendix B). This form contains 8 sections that were completed by the PCM. Sections 1, 2, and 3 are identical to Sections 1, 2, and 3 of the Initial Contact Form. Section 4 is for PCM follow up. The PCM documents with a yes/no response if any educational materials were sent to the patient, if the materials were reviewed by the patient, and if the patient had any questions about the information received. Section 5 contains a table that documents Pap test follow up. This section answers the question of whether the patient got screening and scheduled an appointment. Appointment date, appointment location, attendance to appointment (yes/no), and Pap results (normal, abnormal, pending, and unknown) are documented. In addition, the PCM documents whether an appointment was scheduled (yes/no) and the date/time of that appointment. Section 6 documents future appointments of the patient. The PCM writes in the date of the next appointment with the primary care or gynecology provider, as well as the provider's name, and other pertinent comments as needed. Section 7 explores barriers identified by the patient and Section 8 records the date and time of the next contact. These sections are identical to Sections 8 and 9 of the Initial Contact Form.

The Prevention Care Manager Follow up Plan Worksheet (Appendix C) was also used during this project. The purpose of this form was to document the PCM's support tasks. Section 1 asks the PCM to document (yes/no) if urgent abnormal results were found in the chart. This section was not used in this project since those women with abnormal Pap test results were not contacted by the PCM, but instead had arrangements for follow up made by the clinical staff.

Section 2 documented the patient's schedule of appointments. The PCM was able to record who scheduled the appointment (patient or PCM), date/time and location of appointment, date the appointment information was given to the patient or received from the patient, and date of the reminder call. Section 3 was a record of the type of mailings and date sent. Lastly, Section 4 was a listing of the scheduled calls to patient. The planned time of the next call and the date of the actual call were recorded in this section.

### **Plans for Analysis**

Data analysis will be completed using Minitab 17 statistical software. This type of software is useful for analyzing data in quality and process improvement projects. The control chart is the quality tool that will be used for data analysis with this project. A control chart is a graph used to study how a process changes over time. It can differentiate variation that is inherent in every process and due to chance (common cause variation) from variation due to some assignable cause outside the process (special cause variation). These charts can also be helpful in evaluating the effectiveness of a change.

Control charts consist of a central line ( $\bar{x}$ ), an upper control limit (UCL), a lower control limit (LCL), and process values plotted on the chart. Control limits are calculated by estimating the standard deviation,  $\sigma$ , of the sample data, multiplying that number by three and adding that product to the mean for the UCL and subtracting the product from the mean for the LCL. The mathematical formula is control limit (CL) =  $\bar{x} \pm (3 * \sigma\text{-hat})$ . To obtain precise estimates of the limits, enough data must be present. If the amount of data is insufficient, the control limits may be far from the "true" limits due to sample variability. To improve precision of the limits, the number of subgroups can be increased.

The type of data that have been collected and the methods employed will determine which chart to use. Attribute data have been collected in this project. These types of data represent counts of events that can be sorted into discrete groups, e.g. women who have met the performance measure vs. women who have not met the performance measure. The data points will be the proportion of non-conforming units, or women without a documented Pap screening result, during each month of the measurement year. Since the sample sizes will vary each month, a p control chart was selected to analyze the data (Figure 3) <sup>44</sup>.

The p control chart, or p chart, will assess the effectiveness of the implemented program and communicate how the program performs each month. Use of this control chart will also allow monitoring of process variation over time. By comparing current data to historical data, a conclusion may be drawn about whether the process is in control or affected by special causes of variation. The control charts for this project will display defined stages or groups permitting recalculation of the control limits and center line during the different phases. The charts will begin with the baseline which includes January 1, 2012 through August 31, 2012. The intervention phase will be carried out from September 1, 2012 through December 31, 2012. Follow up will conclude with the post-intervention period and cover January 1, 2013 through December 31, 2013.

### **Limitations and Delimitations**

Potential weaknesses identified in this project's design include lack of generalizability of findings, opportunities for missing data, inability to address all barriers to care, and uncertain long term impact of the intervention. This project was carried out in Georgia's WCHD among HIV+ women enrolled in the RWP overdue for cervical cancer screening. Since the intervention's benefit will be to this particular group, generalizable knowledge will not be

developed. Chart review and CAREWare were the sources of outcome data and may not contain a complete record of the Pap tests performed. Pap reports from outside providers may not have been requested, or if requested, may not have been received. In addition, all available Pap results may not have been entered into CAREWare. Not all of the perceived barriers to this population's care could be addressed, thus some women still had obstacles to completing the screening test. Finally, it is uncertain whether the intervention will have a lasting effect on the patient's completion of future Pap screenings.

Several factors narrowed the scope of the project. These factors relate to the selected group of participants and the timeframe for the intervention. The target population was comprised of HIV+ women enrolled in Georgia's WCHD RWP overdue for cervical cancer screening. The inclusion and exclusion criteria used were as stated in the HAB performance measure. All women  $\geq 18$  years old or who reported a history of sexual activity and had had a medical visit with a provider with prescribing privileges at least once in the measurement year were included in the project. Women were excluded if they were  $< 18$  years old and denied a history of sexual activity or if a hysterectomy had been performed for non-dysplasia/nonmalignant indications. The project was conducted from September 1, 2012 through December 31, 2012.

## **Chapter IV**

### **Results**

#### **Introduction**

The purpose of this project was to implement a clinical quality improvement strategy and observe its effect on increasing the percentage of up-to-date Pap tests among women enrolled in the West Central Health District's (WCHD's) Ryan White Program (RWP). The primary questions addressed by this project were (1) What impact will implementation of a telephone care management system have on client completion of annual cervical cancer screening, and (2) What barriers prevent clients from maintaining up-to-date Pap smears? A description of the clinic settings and characteristics of the women that attend will be presented first. This will be followed by information about the intervention implementation, and finally, the findings to the primary questions of the project will be presented.

#### **Findings**

##### **Clinic Settings and Sample Characteristics**

Clinic sites are located in Crisp, Macon, Muscogee, Randolph, and Sumter county health departments. The Muscogee County site is considered the main office for the district's RWP. The other sites are designated as satellite clinics. The main office is staffed full time with 2 clerks, 1 health service technician, 1 nurse practitioner, 1 AIDS certified registered nurse, and 2 medical case managers. The satellite, or county, clinics are covered by traveling staff that maintain a primary office in the Sumter County Health Department. This team consists of 1 clerk, 1 public health nurse specialist, and 1 medical case manager. The county clinics are held on specific days of each month. The largest clinics, Sumter and Crisp, have 5 clinics each month. Macon has 3 clinics and Randolph, the clinic with the fewest patients, has 2 each month.

One physician is employed by the district to serve the RWP patients. This physician provides patient care in each clinic as specified by a pre-established schedule.

Through the use of CAREWare and chart review, a total of 221 women were found to be enrolled in the RWP at the start of the project. The mean age of the women was 46 years old. Greater than 85% of the women were black (Figure 4a). English was identified by the vast majority as their primary language. Most of the population was without insurance (45%), but the majority of those with insurance had either Medicaid (30%) or Medicare (9%) (Figure 4b). Sixty-seven percent of the women reported having a primary care provider (Figure 4c). Inclusion and exclusion criteria as stated in the HIV/AIDS Bureau (HAB) cervical cancer screening performance measure was used to determine eligibility for participation in the project. All women  $\geq 18$  years old or who reported a history of sexual activity and had had a medical visit with a provider with prescribing privileges at least once in the measurement year were included. Women were excluded if they were  $< 18$  years old and denied a history of sexual activity or if a hysterectomy was performed for non-dysplasia/non-malignant indications.

Two hundred twenty-one women were assessed for eligibility at the start of the project. Eighteen women were excluded due to having documentation of hysterectomy for non-dysplasia/non-malignant indications. A total of 203 women met the inclusion criteria. Ninety-nine of the women were found to be due or overdue for a Pap screening at the beginning of the project. Sixteen of this group was found to have an abnormal Pap result on their last documented Pap screening. The names of these women were reported to a nursing staff member for referral and management. Twelve women reached due or overdue status during the months that followed giving the Prevention Care Managers (PCM) an opportunity to work with a total of ninety five women over the 4 month duration of the intervention (Figure 5).

### Intervention Implementation

Of the 95 women that met criteria for inclusion in the intervention group, 59 had confirmed contact by phone and/or mail. Of these, 37 completed Pap screening. There was an average of 2.7 phone calls made to each patient contacted. Educational materials, appointment reminder notes, patient activation cards, and provider recommendation letters were all utilized in communicating with the patients.

The PCMs made telephone contact with 51 women. Forty-six of them expressed readiness to take steps at that time for scheduling Pap screening. Two women reported being ready to act over the next month, two were ready to act at some non-specific future time, and one stated she was reluctant, ambivalent, or not ready to act. Forty-four women identified barriers that hindered them from maintaining up-to-date Pap smears (Table 8). The most common barriers reported were concerns about cost, (lack of) transportation, and competing priorities. These results are similar to the finding of Andrasik et al<sup>24</sup> and Tello et al<sup>22</sup> and affirm the assertion that common barriers hinder HIV positive women from participating in routine cervical cancer screening.

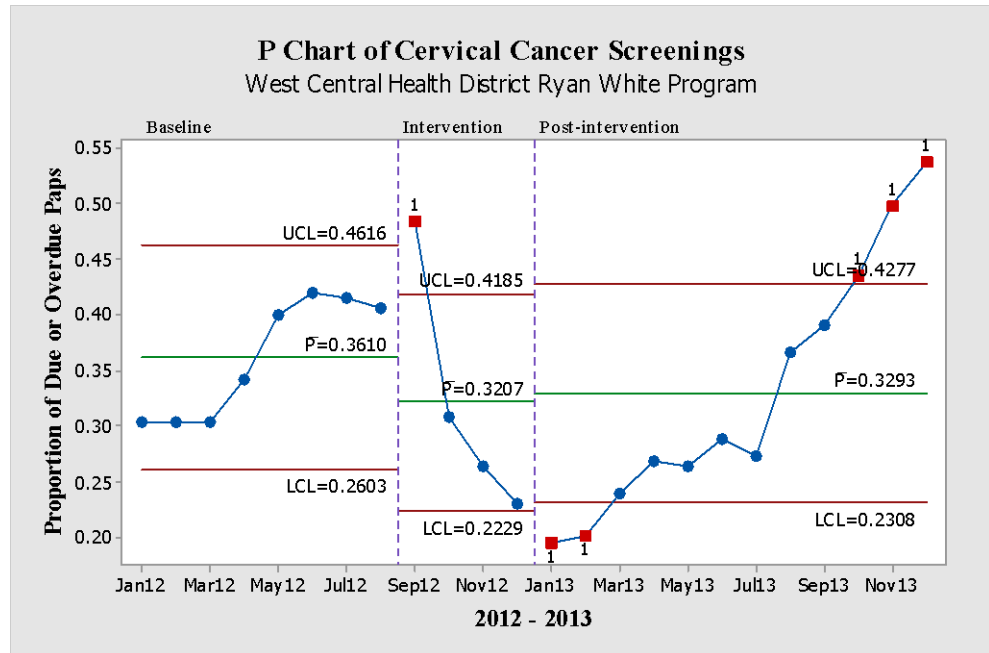
### Intervention Effect

Figure 6 provides baseline or historical, intervention, and post-intervention proportions for due or overdue Pap screenings. The baseline UCL and LCL are set at 46% and 26% respectively. The process average is 36%. During the first quarter (January-March) of the 2012 measurement year, the proportion of women without current screenings is steady at about 30%. The months of April through June show an increase in the number of due or overdue screenings. The last month of the third quarter is notable for a sharp increase, up to 48%, in the proportion of women who are not meeting the HAB cervical cancer screening performance measure.



**Figure 6.** P chart of West Central Health District cervical cancer screenings.

With the implementation of the telephone care management system with PCM support in



September, the fourth quarter demonstrates a decreasing trend in the proportion of women with delinquent Pap screenings. At the conclusion of the project in December, this proportion is at 23%, the lowest of the entire measurement year. During this period a shift in the UCL and LCL can be seen. The UCL moves close to 42% and the LCL to 22%. The process average shifts to 32%. One data point is identified outside of the control limits in the intervention phase. The value for September, 48%, is above the UCL. This point fails Test 1, one of the tests that evaluate process stability in attribute control charts. Test 1 identifies points > 3 standard deviations from the center line and is recognized as necessary for detecting out of control situations. One possible cause for this variation may be the intervention itself. Its implementation and the resulting dramatic decrease in the proportion of due or overdue women caused a downward shift in the UCL and LCL values from baseline. However even without the intervention's implementation, September's proportion would have been above the UCL. Another consideration is that the knowledge of the upcoming project may have contributed to a degree of complacency among the providers. In other words, providers may have been less

aggressive in the recruitment of due or overdue women since the PCMs would be working with them soon.

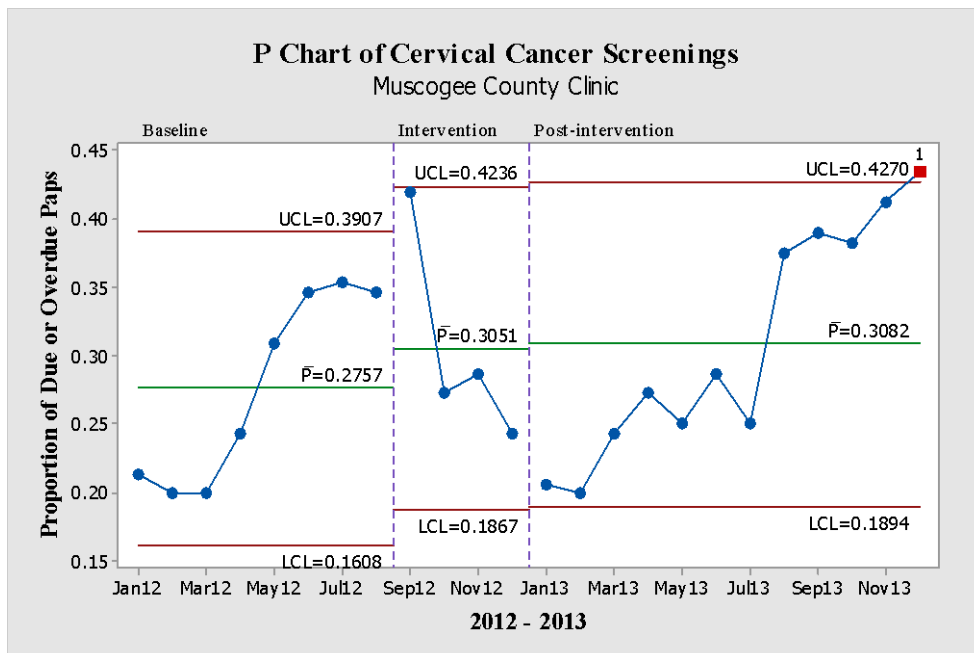
When the telephone support project ended usual care was re-instated. Usual care practices mean that the nurse or physician provider reviews the patient's chart at the time of the visit to determine if the Pap test is up to date. If the patient is found to be due or overdue, a recommendation is made for the patient to schedule an appointment for the screening with her private provider or the RWP nurse if she lacks one. Reassessment for Pap test completion usually occurs at the next clinic visit, typically in 3-4 months, or greater if the appointment is rescheduled or missed.

During the post-intervention period, January 2013 to December 2013, the UCL and LCL remain close to the intervention values. The values are 43% and 23% respectively, and the process mean is 33%. An all-time low of 20% is seen immediately after the intervention, but a gradual increase in the proportion of due or overdue Pap screenings occurs reaching a high of 54% by December. Five data points in this phase failed Test 1; the data points immediately after the intervention (January and February) and the three data points representing the fourth quarter (October through December). January and February 2013 values are at 20% with the LCL at 23%. The most likely cause in this case is continued impact of the intervention. Patients were probably completing Pap screenings that had been scheduled during the final weeks of 2012. October, November, and December 2013 have proportions of 43%, 50%, and 54% respectively. The UCL is calculated to be 43%. Potential causes include the possibility that the improvement in proportions, especially from January through September resulted in a downward shift of the control limits. Prior to the intervention the value for October would have been within the expected variation levels. November and December appear to illustrate the climax of lost ground

since the completion of the intervention. There is one major change in 2013 that may have adversely affected the post-intervention period. In August 2013 the clerk that worked in the satellite clinics found other employment. Changes in available resources and increased duties of the remaining staff likely play a part in reducing attention to maintaining up-to-date Pap tests on the women. Additionally, this is the time of year when the intervention was being carried out in 2012, so a large proportion of women would now be due for repeat screening. Without PCM support and assistance some of the women may not have been motivated to remain current. November and December also represent times of the year when staff is likely to take annual leave, so the number of patients served may have been reduced.

### **Other Findings**

Baseline, intervention and post-intervention proportions of due and overdue Pap screenings in the Muscogee County office and in the satellite clinics were also reviewed. The P chart for the Muscogee County clinic (Figure 7) shows the baseline UCL and LCL set at 39% and 16% respectively. The process average is approximately 28%. First quarter results show the proportion of women without current Pap screenings between 20% - 21%. An increasing trend is noted in the proportion of women due or overdue during the second quarter. The proportion rises from about 24% to 35%. The third quarter demonstrates an increase to 42%. During the intervention a shift in the UCL and LCL occurs. The values are now 42% and 19% respectively with a process mean of 31%.



**Figure 7.** P chart of Muscogee County clinic cervical cancer screenings.

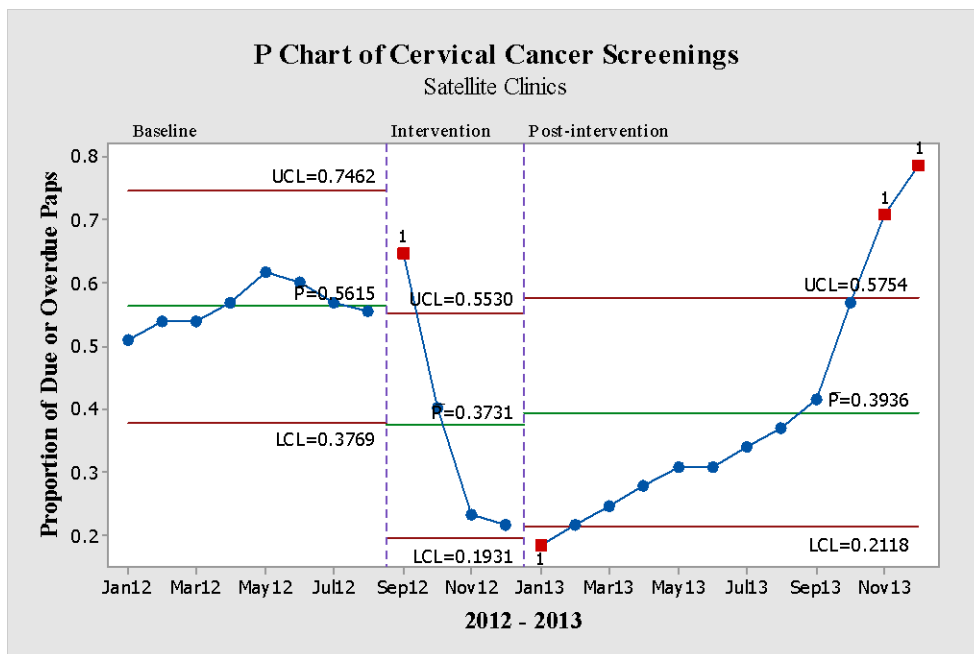
A decline in the proportion of due or overdue Pap screenings from 42% to 24% occurs during this

four month period. The post-intervention period shows an overall increase in delinquent Pap screenings with a high of 43% being reached. The UCL, LCL, and process mean remain stable. One data point, December 2013, is identified outside of the control limits indicating a Test 1 failure. See possible explanation below.

The P chart for the satellite clinics (Figure 8) shows the baseline UCL and LCL set at 75% and 38% respectively. The process average is 56%. During this baseline period, the proportion of women attending the county clinics without a documented Pap screening is consistently >50%. During the intervention, a shift in the UCL and LCL can be seen. The values are 55% and 19% respectively with the process average at 37%. A decline from 65% to 21% in the proportion of due or overdue screenings is demonstrated during these four months. From January 2013 to December 2013, the UCL and LCL remain close to the intervention values. This period has a UCL of 58%, LCL of 21%, and process mean of 39%. Following a low of 18%, a gradual but steady increase in women in need of Pap screening is demonstrated. The post-intervention period culminates in a high of 78%. Four data points, one in the

intervention stage (September) and three in the post-intervention phase (January, November, and December), are identified as Test 1 failures. If not for the intervention effect, September 2012's proportion would have been well within baseline control limits. Immediately after the intervention, an all-time low of 18% is achieved. Again, this is most likely due to patient completion of Pap screenings scheduled during PCM support. The values for November and December 2013 are 71% and 78% respectively. The causes for these test failures are likely similar to those previously stated. A number of those women that benefited from the telephone support intervention are due for repeat screening at this time of the year, and reduction in staff due to holiday leave may have impacted patient access opportunities. Perhaps the most significant contributing factors were the changes in available resources and loss of an employee resulting in increased duties for the remaining staff.

**Figure8.** P chart of satellite clinic cervical cancer screenings.



## **Summary**

The implementation of the telephone support intervention contributed to a clinically significant improvement in the proportion of women with up-to-date Pap smears in the WCHD RWP. However, non-persistence of the intervention's impact is demonstrated. A gradual increase in the proportion of due or overdue Pap tests occurs with the ending of the telephone care management system. We were also able to learn about some of the barriers that prevent this group of women from maintaining up-to-date screenings. The most commonly reported barriers were concerns regarding cost, transportation, and competing priorities.

## Chapter V

### Conclusions, Implications, and Recommendations

#### Introduction

In this final chapter, the major findings of the telephone support intervention will be identified and discussed. A summary of the intervention is followed by a discussion of the project's results, as well as, other considerations such as the cost of quality and the role of statistical process control in the quality improvement of systems. Lastly implications for public health practice and recommendations that may provide clarification or validation of this intervention's results are shared.

#### Summary of Project

The most important gynecologic manifestations of HIV disease are invasive cervical cancer and its precursor lesions. Routine cervical cancer screening is the key to early detection and management of disease. It has been shown that HIV positive women often fail to receive this recommended screening<sup>18-21</sup>. The women enrolled in Georgia's West Central Health District (WCHD) Ryan White Program (RWP) have historically failed to meet the HIV/AIDS Bureau's (HAB) cervical cancer screening performance measure, so the potential benefits of routine screening are not being fully realized in this group. Identification of effective intervention strategies could help reduce barriers to early detection of invasive cervical cancer and its precursor lesions among this high risk population.

Deitrich et al<sup>40</sup> conducted a randomized, controlled trial to evaluate the effect of a telephone support intervention to increase cancer screening rates among minority and low income women. This telephone support intervention was adapted for use in the WCHD's RWP. The primary questions addressed were (1) What impact will implementation of a telephone care

management system have on client completion of annual cervical cancer screening, and (2) What barriers prevent clients from maintaining up-to-date Pap smears?

Through the use of CAREWare, patient chart review, and interviews with patients in person and/or via the telephone, women who were due or overdue for cervical cancer screening were identified. The HAB cervical cancer screening performance measure's inclusion and exclusion criteria were used to determine eligible participants for the project. Those women meeting inclusion criteria received a series of telephone support calls from a trained Prevention Care Manager (PCM). In addition to other tasks, the PCMs shared information about the importance of cervical cancer screening in HIV infected women and responded to each woman's specific barrier(s) that hindered completion of screening.

The intervention was carried out from September 1, 2012 through December 31, 2012. The p control chart was used to assess the effectiveness of this quality improvement project, and a decreasing trend in the proportion of women with delinquent Pap screenings was demonstrated during this period. At its conclusion, the proportion of women failing to meet the HAB cervical cancer screening measure was at 23%, the lowest of the entire measurement year. Follow up continued from January 1, 2013 through December 31, 2013 to assess the intervention's continued impact, and during this period an increase in the proportion of due or overdue Pap screenings was noted. The proportion at the end of December was at almost 54%, higher than at the start of the intervention. It appears that the use of PCM telephone support was helpful in reducing the gap in adherence to Pap testing while being carried out, but the effect waned once the intervention ended. The project also elucidated some of the most common barriers to maintaining an up to date Pap in this population. These included concerns about cost, (lack of) transportation, and competing priorities.



## **Conclusions**

An improvement in Pap smear use is shown with the implementation of the telephone support intervention in the WCHD RWP. Overall, the proportion of due or overdue Pap tests decrease from 48% at the start of the project in September 2012 to 23% at its conclusion in December 2012. This represents a clinically significant improvement. Particularly notable is the decrease in proportion of delinquent screenings among eligible women in the satellite clinics (65% to 22%). The increase in cervical cancer screening has the potential for reducing morbidity, mortality, and health disparities among this high risk group. Goldie et al assert that “over the broadest range of variable estimates, encompassing nearly all reported values in the literature, the screening of HIV-infected women for cervical cancer was associated with projected life expectancy benefits equal to or greater than those provided by other preventive measures in general medicine or in HIV disease”<sup>45</sup>.

The project demonstrates the effectiveness of this type of clinical quality improvement strategy. During the intervention the PCMs employ various approaches in working with the women. These strategies include assessing both patient readiness to act and perceived barriers, telephone follow up, use of educational materials, appointment reminder notes, patient activation cards, and provider recommendation letters. Systematic review findings lend support to the use of these methods. Research shows that women given counseling to promote attendance to a cervical screening program have significantly higher use of screening than those given no counseling or patient prompts alone<sup>40</sup>. Counseling is defined as including a discussion of barriers to screening as well as an educational component and can be performed either face-to-face or on the telephone. The most effective approaches are found to involve the use of access enhancing strategies<sup>38</sup> especially among ethnic minority women. Educational materials are

likely to be important in increasing informed participation in Pap screening<sup>40</sup>, and sufficient evidence also exists to support invitation letters<sup>40</sup> and telephone reminders<sup>39</sup> as adherence improving strategies.

Non-persistence of the intervention's impact is demonstrated over the 2013 year. The proportion of due or overdue Pap tests show a gradual increase and even surpass baseline values. Possible explanations exist for the waning impact of our intervention. The PCMs provided a high degree of personalized attention to the women they contacted. Intensive follow up of this kind could not be maintained by the limited number of providers in the RWP. Additionally, the improvement in the proportion of due or overdue screenings could have contributed to complacency among the providers since the HAB cervical cancer screening measurement was higher than ever before. Finally, without the PCM support and assistance some of the women may not have possessed the resourcefulness or motivation to overcome their perceived barriers to care. Consideration may also need to be given to another possible explanation. Ruffin and Gorenflo<sup>46</sup> state that time since first implementing an intervention has a significant effect. They maintained follow up over a 3 year period after conducting a cancer screening intervention and assert that the effect is of time since implementing, not the intervention, and the effect fades over time. The impact of the intervention seems to fade into the background of the complex setting of the providers' offices.

Integration of a telephone care management system into the established care infrastructure could be beneficial in helping the WCHD RWP meet and maintain the HAB cervical cancer screening performance measure, but the cost of this quality must be considered. Cost of quality is defined as the cost of *not* creating a quality product or service. Total quality costs are equal to the sum of prevention costs, appraisal costs, and failure costs. Prevention costs

cover the cost of all activities designed to prevent poor quality in products or services, including but not limited to, quality education, training, planning and improvement projects. Appraisal costs are costs associated with measuring, evaluating or auditing products or services to assure conformance to quality standards and performance requirements. Failure costs result from products or services not conforming to requirements. For medical outcomes this cost is declared by mortality, morbidity, and the extra medical resources expended in attempts to correct poor outcomes.

Organizations that implement quality improvement are believed to experience a wide range of benefits, namely, improved patient health (clinical) outcomes that involve both process outcomes (e.g. provide recommended screenings) and health outcomes (e.g. decreased morbidity and mortality). By improving processes and outcomes relevant to high-priority health needs, it has been said that an organization may reduce waste and costs associated with system failures and redundancy<sup>47</sup>. In fact, the costs to make the changes are purported to be offset by the cost saving incurred. Others have found that considerable resources are spent to implement quality improvement programs, but organizations may never financially benefit from them<sup>48</sup>. In addition to new administrative costs, higher clinical costs may result because activities related to the initiative are not billable. This financial impact may be especially relevant for health centers with a large proportion of Medicaid and uninsured patients<sup>49</sup>. True bottom-line savings from improved clinical quality rarely materialize. The explanation is believed to lie in the rigid cost structure of the typical health care setting. This cost structure is said to be relatively insensitive to small changes in patient volume, resource use, or severity of patients' health conditions, and instead typically create additional capacity rather than bottom-line savings<sup>50</sup>.

Improvement of healthcare requires making changes in processes and service delivery. Today organizations and providers are challenged to learn from data to improve provision of services and delivery of care. Statistical process control (SPC) is a key approach to quality improvement of systems, processes, and outcomes developed by Walter Shewhart, a statistician, in the 1920's and later expanded and refined by W. Edwards Deming and J.M. Juran. This method is increasingly being used in healthcare to aid in process understanding, assessing process stability, and identifying changes that indicate improvement or deterioration in quality. Control charts are a core tool of SPC and allow visualization and analysis of process performance over time by combining rigorous time series analysis with graphical presentation of data. This type of presentation offers an advantage over classical statistical methods which typically are based on time static statistical tests with all data aggregated into large samples that ignore time order. SPC methods combine the rigor of classical statistical methods with the time sensitivity of practical improvement.<sup>51,52</sup>

### **Implications and Recommendations**

Intensive recruitment techniques and a combination of tailored strategies may have the potential for reaching women who have traditionally been difficult to reach. Patient barriers may be overcome with the implementation of well-designed interventions that are based on the characteristics of the particular patient and provider populations. Further research may be needed to understand the effect of time on persistence of an intervention's impact.

SPC can be a powerful and versatile tool for managing changes in healthcare through quality improvement. The capability to control, improve and design processes, and then to monitor the effects of this work on results is needed to improve performance. Measurement alone may not be sufficient (reference). In addition to its role in helping to manage and

improve healthcare processes, SPC can help clinicians and patients understand and improve the patient's health when directly applied to health indicators. While quality improvement efforts may enhance healthcare, the financial environment in which these programs are being implemented should be understood in order to successfully sustain quality improvement efforts.

## Tables

Table1. The Health Belief Model

<b>Concept</b>	<b>Definitions</b>	<b>Potential Change Strategies</b>
<b>Perceived susceptibility</b>	Beliefs about the chances of getting a condition	<ul style="list-style-type: none"> <li>• Define what population(s) are at risk and their levels of risk</li> <li>• Tailor risk information based on an individual's characteristics or behaviors</li> <li>• Help the individual develop an accurate perception of his or her own risk</li> </ul>
<b>Perceived severity</b>	Beliefs about the seriousness of a condition and its consequences	<ul style="list-style-type: none"> <li>• Specify the consequences of a condition and recommended action</li> </ul>
<b>Perceived benefits</b>	Beliefs about the effectiveness of taking action to reduce risk or seriousness	<ul style="list-style-type: none"> <li>• Explain how, where, and when to take action and what the potential positive results will be</li> </ul>
<b>Perceived barriers</b>	Beliefs about the material and psychological costs of taking action	<ul style="list-style-type: none"> <li>• Offer reassurance, incentives, and assistance; correct misinformation</li> </ul>
<b>Cues to action</b>	Factors that activate "readiness to change"	<ul style="list-style-type: none"> <li>• Provide "how to" information, promote awareness, and employ reminder systems</li> </ul>
<b>Self-efficacy</b>	Confidence in one's ability to take action	<ul style="list-style-type: none"> <li>• Provide training and guidance in performing action</li> <li>• Use progressive goal setting</li> <li>• Give verbal reinforcement</li> <li>• Demonstrate desired behaviors</li> </ul>

Source: Theory at a Glance A guide for Health Promotion Practice. 2 ed 2005.

Table2. Health services use by HIV serostatus among urban women

	All N(%)	HIV seronegative N (%)	HIV seropositive N (%)	p Value
Usual doctor or clinic	1090 (84.4)	319 (74.2)	771 (89.4%)	0.001*
Usually see same provider	920 (85.1)	233 (74)	687 (89.7%)	0.001*
Last gynecologic examination				
<1 year	843 (65.4)	235 (54.6)	608 (70.8)	
1-2 years	279 (21.6)	117 (27.2)	162 (18.9)	
>3 years	129 (10)	62 (14.4)	67 (7.8)	
Never	38 (3)	16 (3.7)	22 (2.6)	0.001**

\* $\chi^2$  unless otherwise indicated

\*\* Mantel-Haenszel  $\chi^2$  test for trend

Source: Solomon L, Stein M, Flynn C, et al. Health services use by urban women with or at risk for HIV-1 infection: the HIV Epidemiology Research Study (HERS). *Journal of acquired immune deficiency syndromes and human retrovirology : official publication of the International Retrovirology Association*. Mar 1 1998;17(3):253-261.



Table3. Estimated proportions of persons in care for HIV infection treated according to guidelines for Pap smear.

	<b>King County N=109 females</b>		<b>Southern Louisiana N=49 females</b>		<b>Michigan N= 106 females</b>	
	RWP Supported n=62	Non-RWP Supported n=47	RWP Supported n=15	Non-RWP Supported n=34	RWP Supported n=22	Non-RWP Supported n=84
<b>Care provided</b>	Treated/ eligible** Estimated % (95% CI)	Treated/ eligible Estimated % (95% CI)	Treated/ eligible Estimated % (95% CI)	Treated/ eligible Estimated % (95% CI)	Treated/ eligible Estimated % (95% CI)	Treated/ eligible Estimated % (95% CI)
Pap Smear*	37/62 61% (49,72)	21/47 40% (24,55)	12/15 81% (42,96)	12/34 41% (24,60)	13/22 62% (32,92)	20/84 19% (5,32)

RWP: Ryan White Program

\*The only exclusions from this analysis were men, and women with a diagnosis of invasive cervical cancer and age 13-17 with non-sexual transmission mode.

\*\*Treated/eligible = number of persons receiving care/number of persons eligible for care

Source: Sullivan PS, Denniston M, Mokotoff E, Buskin S, Broyles S, McNaghten AD. Quality of care for HIV infection provided by Ryan White Program-supported versus Non-Ryan White Program-supported facilities. *PloS one*. 2008;3(9):e3250.

Table4. Comparison of generalist and ID specialist physicians by quality measure

<b>Proportion of patients meeting quality measure</b>				
Quality measure	Generalist physicians	ID specialist physicians	Adjusted odds ratio	95% confidence interval
Pap test 2001	0.55	0.47	1.26	0.78 – 1.90
Pap test 2002	0.59	0.64	0.88	0.44 – 1.80

Source: Koethe JR, Moore RD, Wagner KR. Physician specialization and women's primary care services in an urban HIV clinic. *AIDS patient care and STDs*. May 2008;22(5):373-380.

Table5. Characteristics of women followed over the entire study period

<b>Report of Gynecologic Examination*</b>				
	<b>Never (n=85)</b>	<b>Sometimes (n=657)</b>	<b>Always (n=404)</b>	<b>P Value</b>
Median age (IQR), (y)	40 (37-45)	37 (33-42)	37 (33-40)	<0.001
Ethnicity (n, %)				0.17
White	68 (80%)	471 (71.7%)	285 (70.5%)	
Nonwhite	17 (20%)	185 (28.2%)	118 (29.2%)	
Unknown	0	1 (0.1%)	1 (0.2%)	
Treating infection disease specialist located in SHCS hospital	52 (61.2%)	439 (66.8%)	288 (71.3%)	0.05
Other outpatient clinic and private practice	33 (38.8%)	218 (33.2%)	116 (28.7%)	

\* Only persons who were followed over the whole study period of 45 months in the SHCS are included (n=1146). The p value is based on a test for trend.

Source: Keiser O, Martinez de Tejada B, Wunder D, et al. Frequency of gynecologic follow-up and cervical cancer screening in the Swiss HIV cohort study. *Journal of acquired immune deficiency syndromes (1999)*. Dec 15 2006;43(5):550-555.

Table6. Patient demographic characteristics

Demographic variable	Frequency
Mean age (range)	38 (19 to 80)
Mean annual income	\$8,180 (\$0 - \$71,105)
Race and ethnicity White, non-Hispanic African American Hispanic	39 (19.8%) 113 (57.4%) 45 (22.8%)
Insurance Private Need-based county plan Medicaid Medicare/Medicaid None (Ryan White only)	1 (0.5%) 32 (16.2%) 48 (24.4%) 5 (2.5%) 105 (53.3%)

Source: Logan JL, Khambaty MQ, D'Souza KM, Menezes LJ. Cervical cancer screening among HIV-infected women in a health department setting. *AIDS patient care and STDs*. Aug 2010;24(8):471-475.

Table 7. Reasons women give for missing gynecology appointment

	Number (% of 200)
Forgot about appointment	121 (61)
Sick	104 (52)
Bad weather	83 (42)
Could not get to clinic	61 (31)
Afraid of bad news	27 (14)
Had to take care of someone	12 (6)
No child care	8 (4)
Afraid of pelvic examination	8 (4)
Don't like the clinic	8 (4)
Feel violated by pelvic examination	6 (3)
Don't like the doctor	3 (1.5)

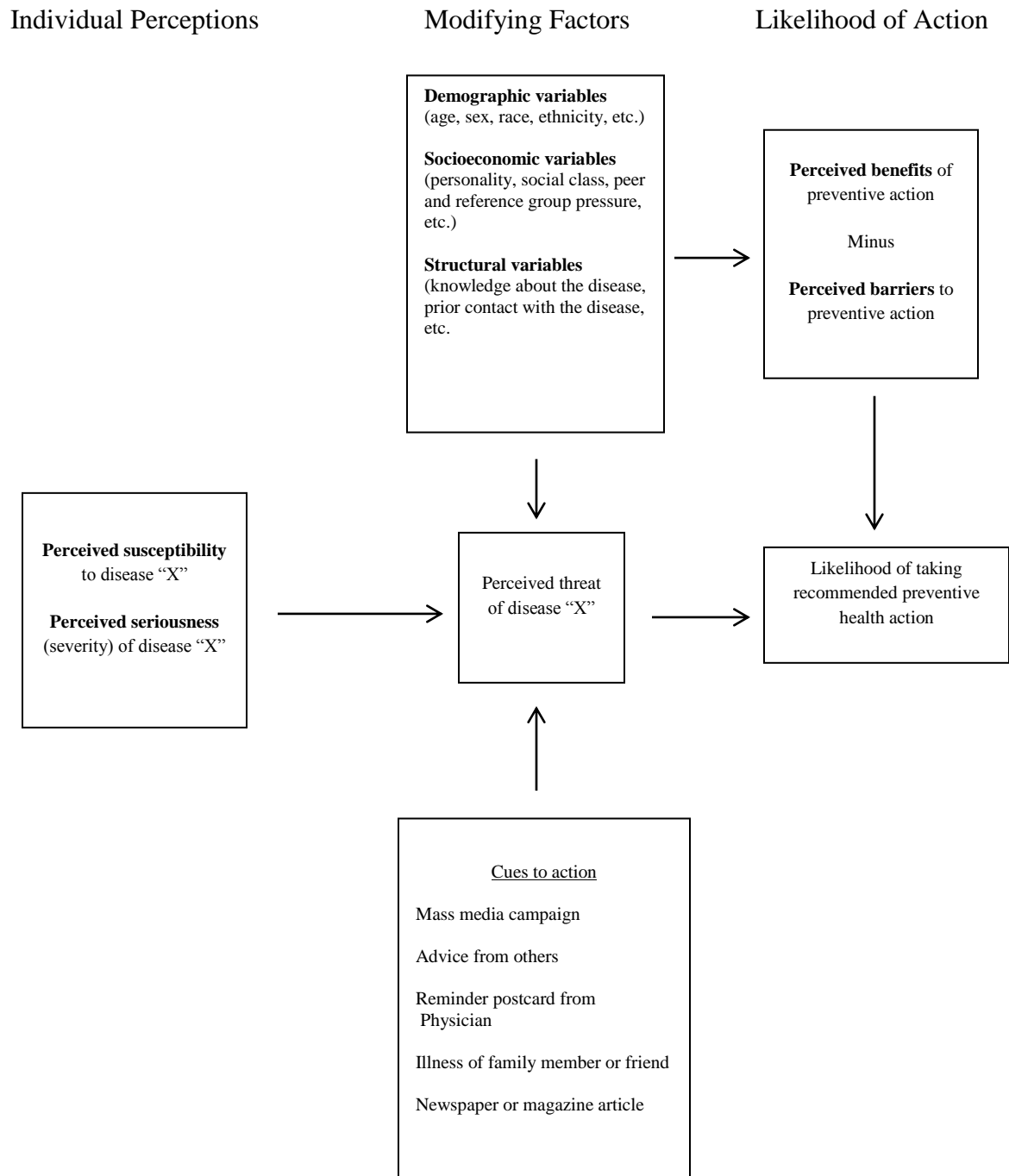
Source: Tello MA, Jenckes M, Gaver J, Anderson JR, Moore RD, Chander G. Barriers to recommended gynecologic care in an urban United States HIV clinic. *Journal of women's health* (2002). Aug 2010;19(8):1511-1518.

Table8. Barriers to maintaining up-to-date Pap smears

	Number (% of 44)
Cost/No insurance	10 (23)
Transportation (lack of)	9 (20.5)
Competing priorities	8 (18)
Provider related issues (needed a provider)	7 (16)
Not motivated	4(9)
Forgot	3 (7)
Didn't know test was needed	2 (4.5)
Nervous about test	1(2)

## Figures

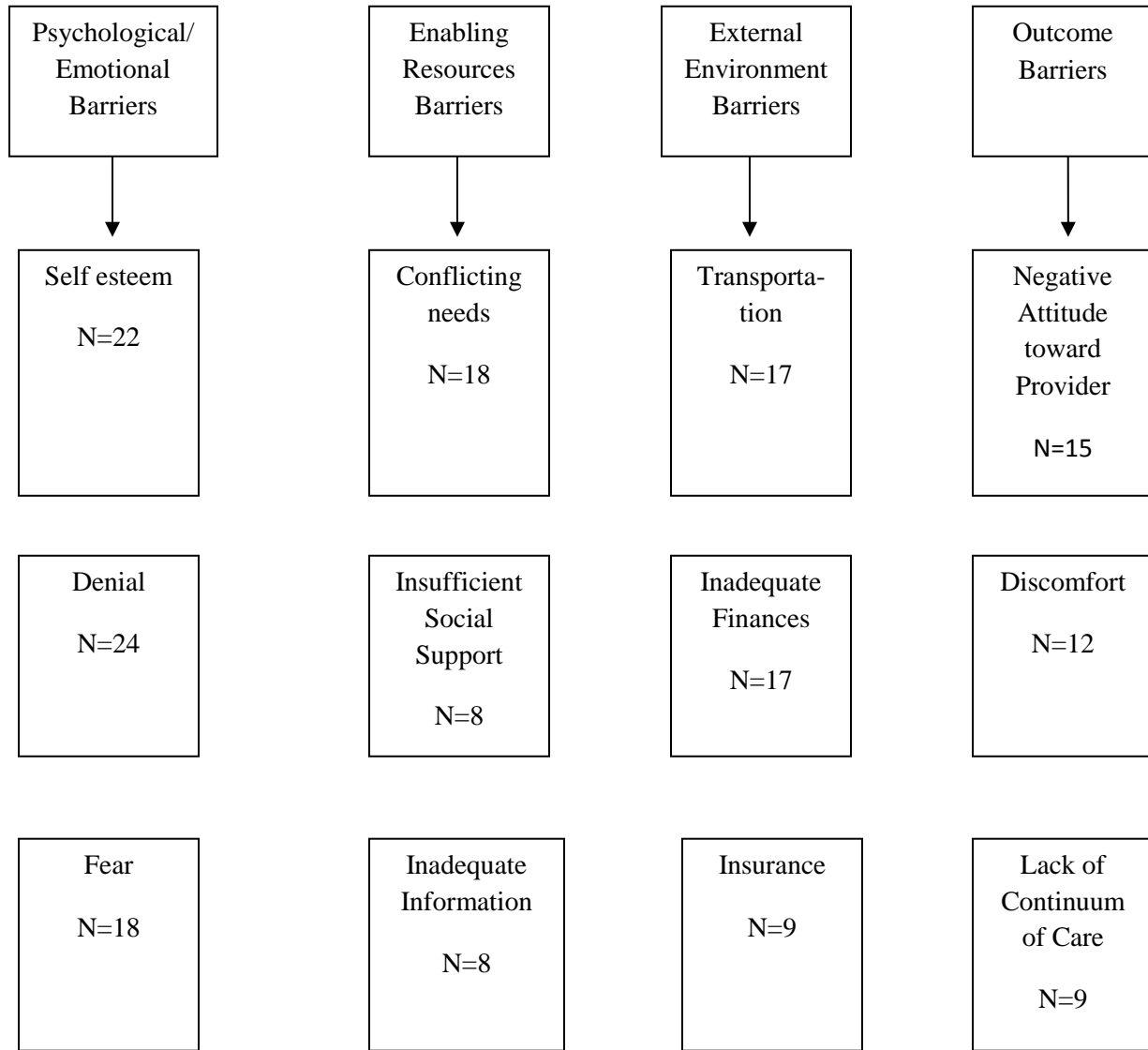
Figure1. The Health Belief Model



Source <http://ninds.nih.gov/img/barch1.jpg>



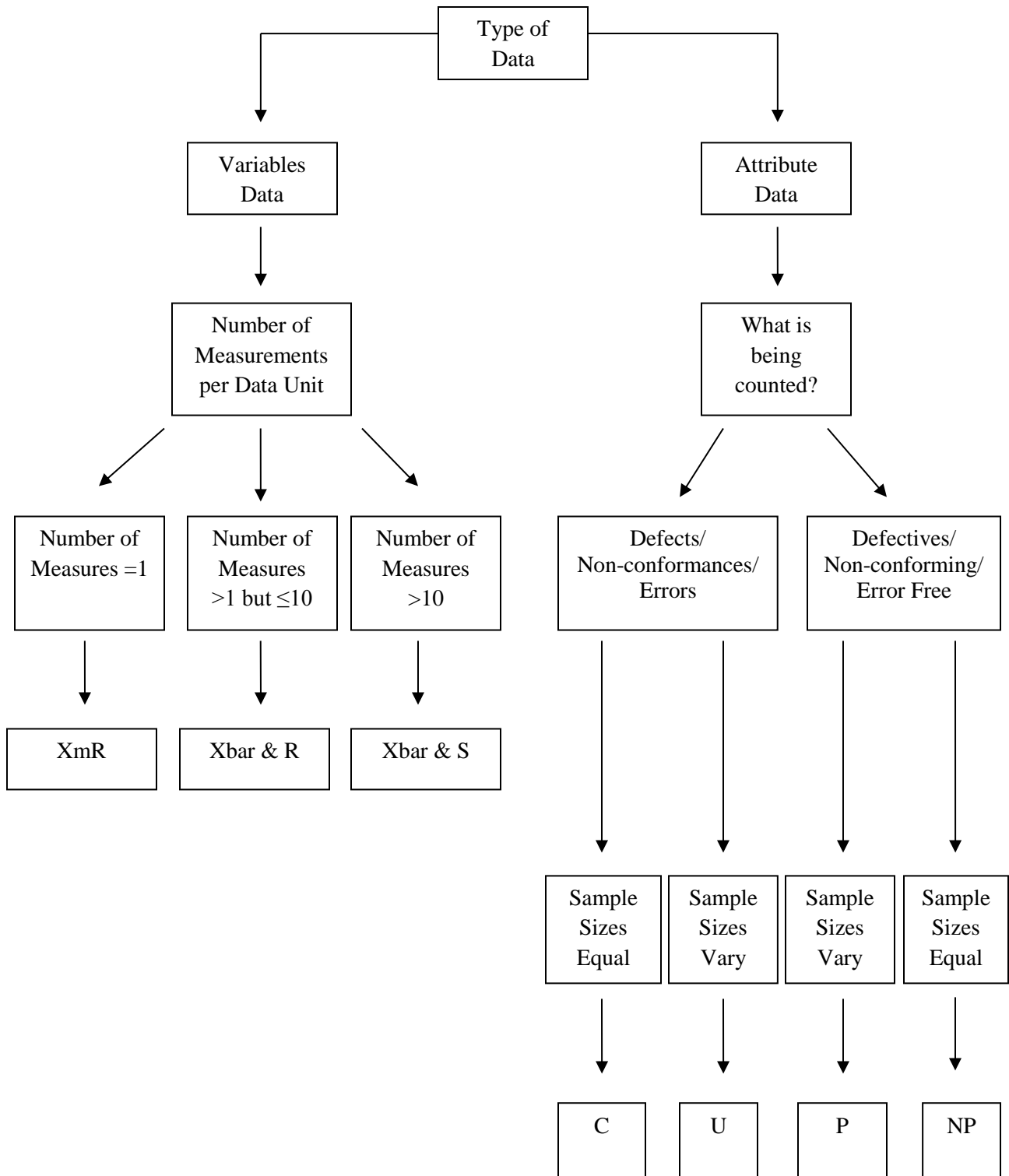
Figure2. Barriers to HIV+ African American women's access and connection to cervical cancer screening



N=the total number of women citing the variable as a barrier

Source: Andrasik MP, Rose R, Pereira D, Antoni M. Barriers to cervical cancer screening among low-income HIV-positive African American women. *Journal of health care for the poor and underserved*. Aug 2008;19(3):912-925.

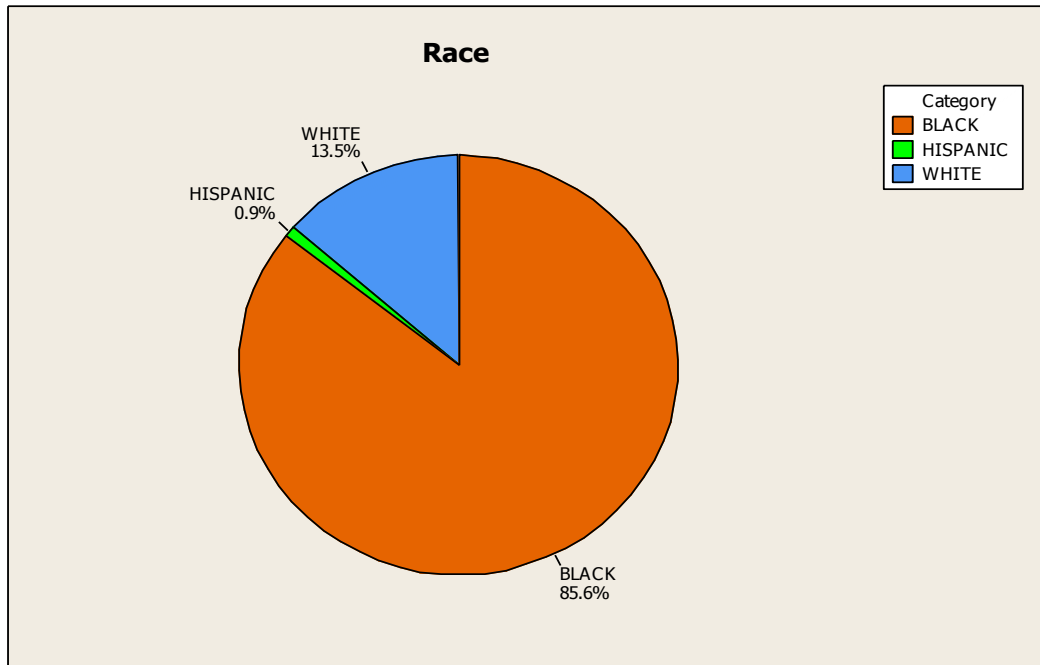
Figure3. Control chart selection decision guide



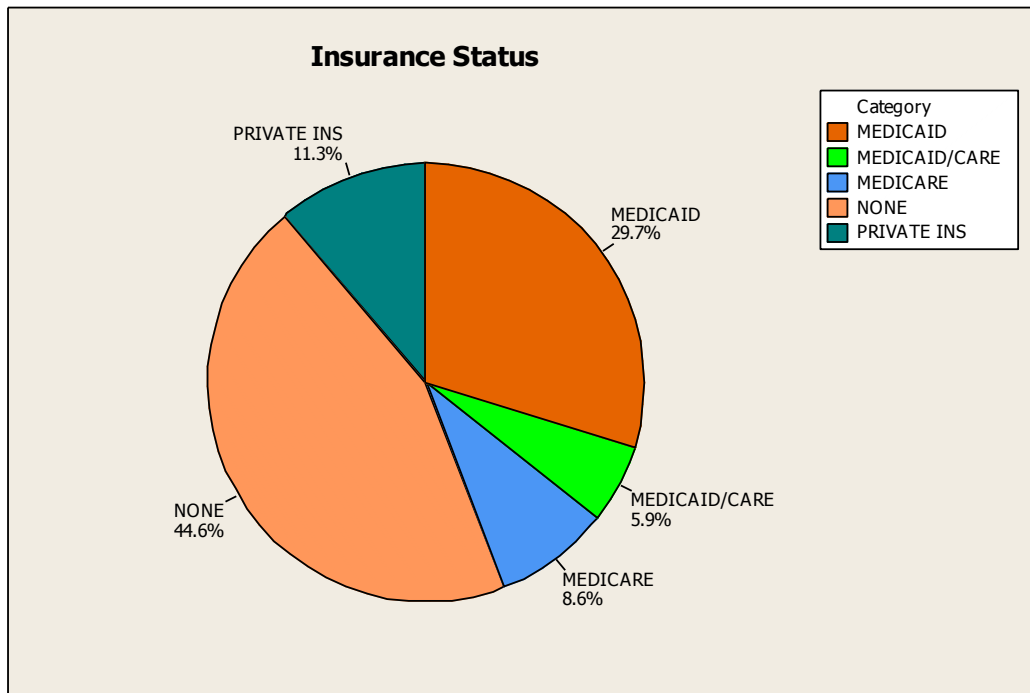
Source: Amin SG. Control charts 101: a guide to health care applications. *Quality management in health care*. Spring 2001;9(3):1-27.

Figure4. Patient demographic characteristics

4a. Race



4b. Insurance status



4c. Primary care provider status

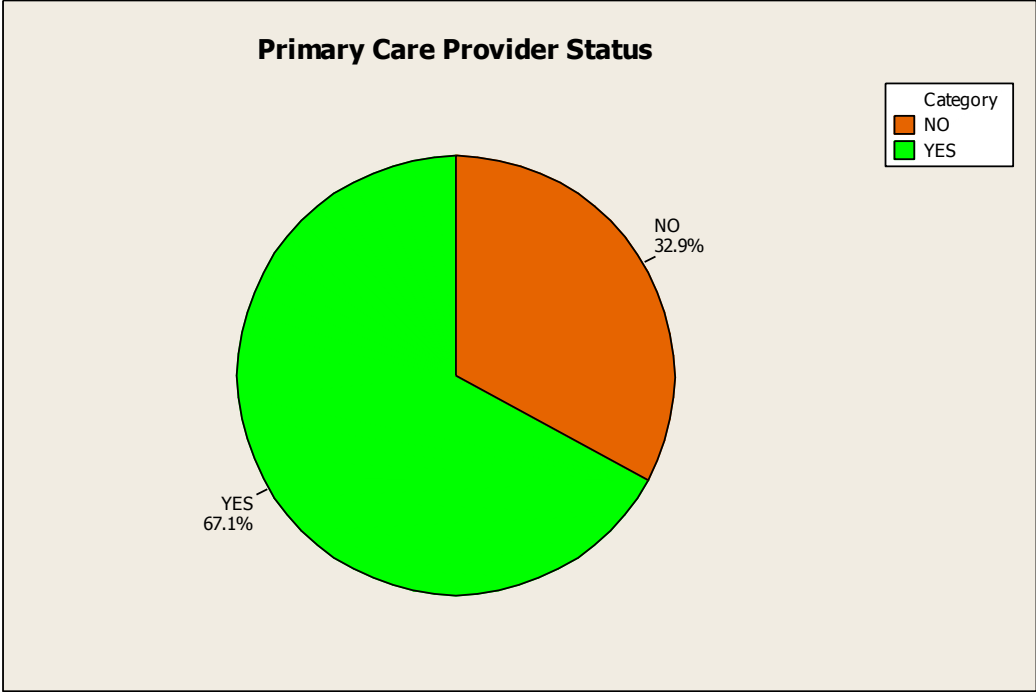
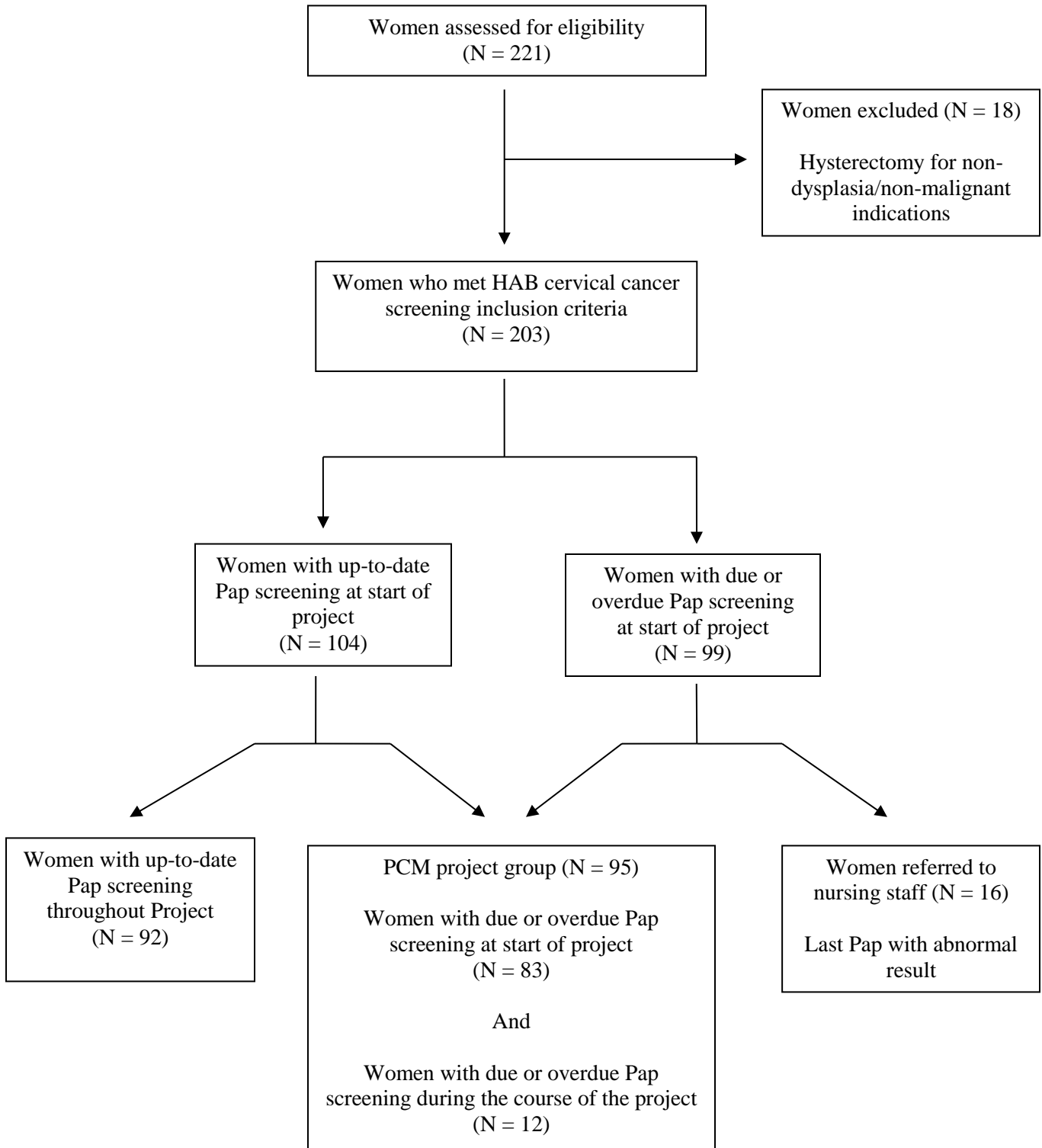


Figure 5. Project participant eligibility assessment and selection



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## Appendix

Appendix A  
 Telephone Support Project – Cervical Cancer Screening  
**Initial Contact Form – page 1**

Patient ID # \_\_\_\_\_ Prevention Care Manager \_\_\_\_\_

1. Contact Initiated by: (circle one) PCM      Patient

2. Type of contact: (circle one) Phone      In person

3. Outcome of call

Record date of all *unsuccessful calls* and place a check mark in appropriate box to indicate outcome of call

Outcome <i>Date</i>	Call #1	Call #2	Call #3	Call #4	Call #5	Call #6	Call #7	Call #8
No answer								
Answering machine								
Number incorrect								
Left message								
Asked to call back								
Phone busy								
No contact – Letter mailed								
Other (specify)								

\*\*After 8 unsuccessful calls, check with provider to find out if patient is still receiving care at clinic

Date of *contact*: \_\_\_\_\_

4. Patient Information

a. Did the patient agree to receive PCM support? (circle one) Agreed      Refused

b. Primary language of patient (circle one) English      Spanish  
 Other (specify \_\_\_\_\_)

c. Age \_\_\_\_\_

Telephone Support Project – Cervical Cancer Screening  
**Initial Contact Form – page 2**

Patient ID # \_\_\_\_\_ Prevention Care Manager \_\_\_\_\_

d. Race (circle one)    Black/African-American                      Caucasian            Mexican            Cuban  
 Other (specify) \_\_\_\_\_

e. Primary care provider \_\_\_\_\_

f. Type of health insurance \_\_\_\_\_

5. Report up-to-date status to patient and confirm or modify (Use the Centers for Disease Control (CDC) Sexually Transmitted Diseases Treatment Guidelines to determine patient’s up-to-date status)

Service	Record date of last test			If patient corrects date of last test, record date as per patient with location of test	
	Date of last test and result	Up-to-date? (circle one)	Overdue date	Date	Location/Notes
Pap test		Yes    No			

Comments: \_\_\_\_\_  
 \_\_\_\_\_

6. Future Appointments

a. Next appointment date with primary care/gyn provider: \_\_\_\_\_

Name of provider: \_\_\_\_\_

c. Does the patient have any scheduled appointments for a Pap test? (circle one) Yes No

If yes, list date and location of Pap. \_\_\_\_\_

d. Comments: \_\_\_\_\_  
 \_\_\_\_\_

Telephone Support Project – Cervical Cancer Screening  
**Initial Contact Form – page 3**

7. Assess readiness to act

Place a check mark by the statement that best describes patient’s readiness to act

- \_\_\_\_\_ A = ready to take steps now for scheduling
- \_\_\_\_\_ B = ready to act over next month, but not today
- \_\_\_\_\_ C = ready to act at some non-specific future time
- \_\_\_\_\_ D = reluctant, ambivalent, or not ready to act

8. Explore barriers identified by patient and comment on barriers below

Check all that apply. For each item that is checked, please comment.

Barriers (check all that apply)	Comments
<input type="checkbox"/> No MD recommendation	
<input type="checkbox"/> No knowledge of test	
<input type="checkbox"/> Misconceptions about test	
<input type="checkbox"/> No symptoms	
<input type="checkbox"/> No family history	
<input type="checkbox"/> Cost	
<input type="checkbox"/> Lack of family support	
<input type="checkbox"/> No social support	
<input type="checkbox"/> Competing priorities	
<input type="checkbox"/> Worry about test	
<input type="checkbox"/> Chronic condition	
<input type="checkbox"/> Access	
<input type="checkbox"/> Other (specify)	
<input type="checkbox"/> Other (specify)	

Additional comments \_\_\_\_\_

\_\_\_\_\_

9. Date and time for next contact \_\_\_\_\_

Appendix B  
 Telephone Support Project – Cervical Cancer Screening  
**Follow-up Form – page 1**

Patient ID # \_\_\_\_\_ Prevention Care Manager \_\_\_\_\_

1. Contact Initiated by: (circle one) Prevention Care Manager (PCM) Patient
2. Type of contact: (circle one) Phone In person
3. Outcome of call  
 Record date of all *unsuccessful calls* and place a check mark in appropriate box to indicate outcome of call

Outcome Date	Call #1	Call #2	Call #3	Call #4	Call #5	Call #6	Call #7	Call #8
No answer								
Answering machine								
Number incorrect								
Left message								
Asked to call back								
Phone busy								
No contact – Letter mailed								
Other (specify)								

**\*\*After 8 unsuccessful calls, check with provider to find out if patient is still receiving care at clinic**

Date of *contact*: \_\_\_\_\_

4. PCM Follow up

Script for introduction – *Hi Ms. \_\_\_\_\_, my name is \_\_\_\_\_. I am the Prevention Care Manager at DCS/Dr. Brown’s office. We spoke recently, and I am calling to follow up as we agreed. I have been looking forward to talking with you again.*

- Were educational materials sent to patient? (circle one) Yes No  
 If yes, were materials reviewed by patient? (circle one) Yes No  
 Did patient have any questions about the educational materials? (circle one) Yes No

Telephone Support Project – Cervical Cancer Screening  
**Follow-up Form – page 2**

Patient ID # \_\_\_\_\_ Prevention Care Manager \_\_\_\_\_

Appointment and Follow up Information

5. Service follow-up (See previous follow up forms to record appointment dates)

Service	Did patient get screening?				Did patient schedule appointment?	
	<u>Appointment Date</u>	<u>Appointment Location</u>	<u>Appointment Attended?</u> (circle one)  Yes / No	<u>Results</u> (circle one)  Normal Abnormal Pending Unknown	<u>Appointment Scheduled?</u> (circle one)  Yes/No	<u>Date/Time</u>
Pap test						

6. Future Appointments

a. Next appointment date with primary care/gyn provider: \_\_\_\_\_

Name of provider: \_\_\_\_\_

b. Comments \_\_\_\_\_  
 \_\_\_\_\_

7. Explore barriers identified by patient and comment on barriers below.

Check all that apply. For each item that is checked, please comment.

Barriers (check all that apply)	Comments
<input type="checkbox"/> No MD recommendation	
<input type="checkbox"/> No knowledge of test	
<input type="checkbox"/> Misconceptions about test	
<input type="checkbox"/> No symptoms	
<input type="checkbox"/> No family history	
<input type="checkbox"/> Cost	
<input type="checkbox"/> Lack of family support	
<input type="checkbox"/> No social support	
<input type="checkbox"/> Competing priorities	
<input type="checkbox"/> Worry about test	
<input type="checkbox"/> Chronic condition	
<input type="checkbox"/> Access	
<input type="checkbox"/> Other (specify)	



Telephone Support Project – Cervical Cancer Screening  
**Follow-up Form – page 3**

Patient ID # \_\_\_\_\_ Prevention Care Manager \_\_\_\_\_

Additional comments \_\_\_\_\_

\_\_\_\_\_

8. Date and time for next contact \_\_\_\_\_

Appendix C  
 Telephone Support Project – Cervical Cancer Screening  
**Prevention Care Manager Follow up Plan Worksheet – page 1**

Patient ID # \_\_\_\_\_ Prevention Care Manager \_\_\_\_\_

**Date of first call:** \_\_\_\_\_

**PCM Support Tasks**

1. Urgent abnormal results found in chart?      Yes      No  
 If yes, send abnormal results letter to provider – date sent \_\_\_\_\_

2. Schedule of appointments

<u>Appointments made</u>	<u>Who scheduled appointments?</u> (circle one)	<u>Date of appointment</u>	<u>Time of appointment</u> (indicate a.m. or p.m.)	<u>Location of appointment</u>	<u>Date appointment information given to patient or received from patient</u>	<u>Date of appointment reminder call</u>
#1	Patient PCM					
#2	Patient PCM					
#3	Patient PCM					
#4	Patient PCM					
#5	Patient PCM					
#6	Patient PCM					

3. Mailings to patient

	Date sent #1	Date sent #2	Date sent #3	Date sent #4
Educational materials				
Appointment reminder note				
Patient activation card				
Provider recommendation letter				

Telephone Support Project – Cervical Cancer Screening  
**Prevention Care Manager Follow up Plan Worksheet – page 2**

Patient ID # \_\_\_\_\_ Prevention Care Manager \_\_\_\_\_

4. Scheduled calls

Scheduled call	Time of next call (circle beginning, middle or end and indicate month)	Date call completed
#1	Beginning Middle of _____ End	
#2	Beginning Middle of _____ End	
#3	Beginning Middle of _____ End	
#4	Beginning Middle of _____ End	
#5	Beginning Middle of _____ End	
#6	Beginning Middle of _____ End	

Comments

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## Appendix D

### **Barriers to Cancer Screening Tests and Appropriate Responses**

There are many reasons a woman might not get a particular screening test. As a patient's Prevention Care Manager, your job is to help women overcome their specific barriers and become up to date. This section lists the most commonly reported barriers, followed by an explanation of how to address and overcome each barrier, and a sample response.

The barriers are sorted into three categories: provider barriers, patient barriers, and practice barriers.

#### **Provider Barriers**

##### **Lack of physician recommendation**

Examples: "I didn't know I was overdue."

"My doctor hasn't told me to have this test."

- Convey the endorsement of the woman's primary care provider for needed screening.
- Mail provider recommendation letter and patient activation card to woman.
- If the patient has an upcoming appointment, call her prior to the appointment to remind her to bring the patient activation card to share with her physician.

Sample response: *"I know your doctor did not recommend the test, but your doctor is often busy when she sees you and has asked for my help in identifying patients who need to get this exam. The next time you see your doctor, please bring the patient activation card I'm going to mail to you so that she can schedule the Pap test that you need."*

#### **Patient Barriers**

##### **1. No knowledge of the test**

Examples: "I've never heard of the Pap smear before."

- Share information from fact sheets and brochures about Pap testing with women over the phone, and send the woman language-appropriate educational material in the mail.
- Explain the importance of the test and its role in cancer prevention.

Sample response: *"All tests help save lives by detecting cancer at an early stage. The Pap test is a test where your doctor or nurse takes a sample of cells from your cervix to see if they are normal. The test is important because if the cells are not normal then that could be an indication of cancer, and the faster cancer is caught the faster it can be treated and cured. Part of being healthy is getting screened for cervical cancer."*

##### **2. Misconceptions about the test**

Examples: "I thought it was only for people who are sexually active."

"I didn't know I needed to get a Pap test every year."

“I’m not having any problems down there, so I don’t need a Pap test.”

“No one in my family had cervical cancer, so I don’t need a Pap test.”

- Educate. Share information from fact sheets and brochures, and mail language-appropriate educational materials.
- Address the particular misconception held by the patient. For example, a woman might say that because she has not had sex in ten years, she does not need the Pap test. In this case, you would explain that regular Pap tests are recommended whether or not she is sexually active.
- Remember to remind women that even though they may not be having any problems “down there”, they are at increased risk of cervical disease and cervical cancer.

Sample responses: *Ms. Brown, whether you are having sex now or have not had sex in a long time, doesn’t matter. Cells can turn into cancer regardless of whether you are sexually active now or not. That is why it is important to get a Pap test regularly.*”

*Ms. Brown, women who are living with HIV are at greater risk of cervical cancer and other cervical diseases. That’s why it’s important that you are screened every year.*

### **3. No symptoms**

Examples: “I feel fine.”

“I am healthy; I do not need this test.”

- Educate. Share information from fact sheets and brochures, and mail language-appropriate educational materials.
- Inform the patient that the role of cancer screening is to find cancer *before* it makes a person feel sick, because the sooner it is found, the easier it is to treat.

Sample response: *“Ms. Brown, I’m glad you are feeling healthy, but part of STAYING healthy is getting regular Pap tests. A person can develop cancer without experiencing any pain or discomfort in the beginning stages.”*

### **4. No family history**

Examples: “No one in my family has/had cancer.”

“My family only gets hypertension, not cancer.”

- Educate. Share information from fact sheets and brochures, and mail language-appropriate educational materials.

Sample response: *“Having a family history of a particular cancer can increase your chances of developing that cancer, but it’s important to remember that ALL women, family history or not, may be at risk for developing cervical cancer. That’s why it’s important to get screened yearly.”*

### **5. Cost**

Examples: “I’m waiting for my Medicaid to be renewed and right now I don’t have insurance.”

“I can’t afford the bus fare to the doctor’s appointment.”

“I can’t afford to pay somebody to take me to the appointment.”

- Check with your local hospital system or health department for low or no-cost Pap screening program.
- Make sure your patients do not feel helpless or victimized because of their insurance status. Provide them with information about free services and when possible, schedule the appointments for them and follow up to make sure they are planning to attend. They will appreciate being remembered and they will feel empowered!

Sample Response: *“Ms. Brown, while you wait for your Medicaid to be renewed, you can take advantage of your health center’s sliding fee scale for those with no insurance. Also, your health center can refer you to free mammogram and Pap programs for uninsured women in your neighborhood.”*

## **6. Lack of family support**

Examples: “My husband won’t let me have this test.”

- Make sure the woman’s family is aware of the importance of preventive care.
- Provide language appropriate educational materials to share with family members.
- If support continues to be a problem, suggest that the spouse or family member come to the center to speak with the Prevention Care Manager, or offer to speak with them by phone.

Sample Response: *“Ms. Brown, your health should be of supreme importance to your family. To take care of your family, you have to take care of yourself.”*

## **7. No social support**

Examples: “There’s no one else to take care of my children/grandchildren.”

“I have no one to talk about things like this.”

“My friends don’t think I should get that test.”

- Make sure the woman’s family and friends are aware of the importance of preventive care. Ask her to share the educational material you have sent with friends and family members.
- Provide a supportive relationship, and provide answers to any questions she may have about the screening tests.

Sample Response: *“Ms. Brown, your health is of supreme importance to your family and friends. I am here to help you follow your doctor’s recommendations to take care of yourself.”*

## **8. Competing priorities**

Examples: “My husband is sick, and I need to take care of him.”

“My housing situation is taking up all of my time right now.”

“I’m too busy!”

“I missed my Pap appointment because I had to watch my grandchild, and nobody else could do it.”

“I’m recovering from knee surgery, and I am in a lot of pain.”

- Sometimes it’s difficult to concentrate on preventive care when other things in our lives “take over”, like being busy with grandchildren or mourning a family member. Let the patient know that you understand how it feels to be overwhelmed, and remind her that this screening takes relatively little time and if results are normal, only needs to be done once a year.
- Offer to call her back at a better time, perhaps in 2-3 weeks.

Sample response: *“Ms. Brown, I understand how challenging it can be to fit cancer screening into your busy life. But, in the middle of stressful times, it’s essential to stay healthy. When you are healthy, you are able to better deal with all of the other “priorities.”*

### **9. Worry about the test**

Examples: “The idea of the test makes me nervous.”

“I’m afraid that it will hurt.”

“I don’t like removing my clothes in front of strangers.”

“I feel so violated.”

- Offer support. Suggest that someone go with her to the appointment (family member, friend).
- Try to address the patient’s specific worry and don’t be pushy about scheduling the test. Give her time to think about it and send her educational materials.
- Let her know that it’s normal to be nervous and explain the exact procedure of the Pap test.

Sample response: *“Ms. Brown, many women are nervous about receiving a Pap. It is the doctor’s/nurse’s job to make the test as comfortable as possible.”*

### **10. Chronic condition**

Examples: “My diabetes/asthma/arthritis prevents me from getting the test.”

- Offer support. Let the patient know you understand how challenging it can be to fit cancer screening into her busy life. Acknowledge the difficulty of managing a chronic condition, but also remind the woman not to neglect her preventive health.
- If you call at a bad time or the patient is acutely ill, suggest calling back at another time, perhaps in 3-4 weeks.
- Enlist the help of the patient’s primary care physician if necessary.

Sample response: *“I know you have diabetes, Ms. Brown, and that it is difficult to manage. But it’s very important that you remember to take care of the other parts of your body. I know it’s easy to concentrate on one thing and forget other stuff. Maybe you can make a special appointment for a check-up with your primary care doctor where you can spend the appointment focusing on other needs, such as scheduling your Pap test.”*

## **Practice Barriers**

**Access barriers** (long waits for appointments, language barriers, and inconvenient hours)

Examples: “I can’t get an appointment.”

“I have to take three buses to get the doctor’s office.”

“The health department told me that there is a really long waiting list for Pap tests, so it may be a while before they can schedule me an appointment.”

- Share information with patient about locations, hours, payment methods, contact information, type of referral required, if any, and other relevant information about local cancer screening facilities.
- Speak to the patient’s physician or health center contact to make an appointment or place high risk patients (e.g. many years overdue, women with a family history) on an urgent screening list.
- Determine whether language is a barrier and explore options for translation with the assistance of a clinician or administrator with translation skills.

Adapted from Prevention Care Management: A Manual for Improving Breast, Cervical, and Colorectal Cancer Screening Rates for Women in Primary Care





**Public Health**  
Prevent. Promote. Protect.

## West Central Health District

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West Central Health District • Beverley A. Townsend, M.D., MBA, FAAFP, District Health Director  
Post Office Box 2299 • 2100 Comer Avenue • Columbus, Georgia 31902-2299 • Tel: (706)321-6300 • Fax: (706)321-6126

Date: \_\_\_\_\_

Dear Ms. \_\_\_\_\_,

Your medical record shows that you are overdue for your Pap test. The Pap test is an important screening test and should be performed once every year.

District Clinical Services is dedicated to providing you with the best possible health care. For this reason, I have asked \_\_\_\_\_, Prevention Care Manager, to help you receive this care.

Excellent health care includes prevention checkups to detect serious conditions early, when they can best be treated.

Because it is important that you get your Pap test, we would like you to speak to \_\_\_\_\_ as soon as possible. Please call her at \_\_\_\_\_ between the hours of \_\_\_\_\_ and \_\_\_\_\_ on \_\_\_\_\_ through \_\_\_\_\_.

If the Prevention Care Manager is not available, please leave a detailed message that includes your name and a working phone number where you can be reached.

We are looking forward to working together to help you get the best health care possible.

Sincerely,

Audrey W. Brown, MD

Appendix F  
Telephone Support Project – Cervical Cancer Screening  
**Appointment Reminder Cards**

District Clinical Services Prevention Care Manager Project

APPOINTMENT REMINDER CARD

Ms. \_\_\_\_\_

You are scheduled for a Pap Test!

Date: \_\_\_\_\_

Time: \_\_\_\_\_

Place: \_\_\_\_\_

District Clinical Services Prevention Care Manager Project

APPOINTMENT REMINDER CARD

Ms. \_\_\_\_\_

You are scheduled for a Pap Test!

Date: \_\_\_\_\_

Time: \_\_\_\_\_

Place: \_\_\_\_\_

Telephone Support Project – Cervical Cancer Screening  
**Patient Activation Card**

District Clinical Services Prevention Care Manager Project

**TAKE CONTROL OF YOUR HEALTH!**

Dr. \_\_\_\_\_,

I am overdue for my Pap test.

Please help me to get up to date for this test.

Thank you.

District Clinical Services Prevention Care Manager Project

**TAKE CONTROL OF YOUR HEALTH!**

Dr. \_\_\_\_\_,

I am overdue for my Pap test.

Please help me to get up to date for this test.

Thank you.