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INCREASING CERVICAL CANCER SCREENING IN HIV POSITIVE WOMEN BY INTRODUCTION OF A PROVIDER PROMPTED ALGORITHM TOOL: A QUALITY IMPROVEMENT PROJECT

by

Aubri Bailey Hickman

A Capstone Project
Submitted to the Graduate School,
the College of Nursing
and the Department of Systems Leadership and Health Outcomes
at The University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

Approved by:

Dr. Melanie Gilmore, Committee Chair Dr. Marcus M. Gaut Dr. Sat Ananda Hayden

Dr. Melanie Gilmore
Committee Chair
Dr. Lachel Story
Dr. Karen S. Coats
Dean of the Graduate School

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ABSTRACT

Continuous quality improvement projects and appropriate documentation are an essential component to continue to receive Ryan White grant funding. Compliance with mandated aspects of quality improvement is an extremely important concept-specifically for a clinic setting that cares for the largest HIV positive population in the state of Mississippi. The Health Resources and Services Administration (HRSA) provides directives mandating that quality improvement projects should be applicable to areas of need and provide for outcomes that ensure quality care for HIV positive individuals (2016).

Initially, this clinic's rate of compliance with the HRSA Cervical Cancer

Screening Performance Measure was subpar to the last reported national average. Due to
the increased incidence of cervical dysplasia within the HIV positive female population,
cervical cancer screening was chosen for improvement focus. The purpose of this Doctor
of Nursing Practice (DNP) project was to increase the number of HIV positive women
referred for cervical cancer screening within the clinic setting. The overall aim of the
project was to increase cervical cancer screening within this vulnerable population.

Literature has indicated that provider-initiated referrals provide for increased adherence. A visible, provider-initiated algorithm was introduced for a period of three months. At the end of the project period, pre-and post-intervention referral rates were compared to determine project success and significance. Comparison of collected data confirmed a significant difference between pre- and post-intervention referrals.

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My deepest gratitude to Dr. Melanie Gilmore, my committee chair, for her patience and guidance throughout this project. I would also like to thank my other committee members, Drs. Marcus M. Gaut and Sat Ananda Hayden, for their help in completing this project. I also must acknowledge my DNP preceptor, Dr. Deborah Konkle-Parker, who allowed me this experience and mentored me along this journey.

I would also be amiss if I did not mention my medical director, Dr. Ben Brock, who exhibits the upmost confidence in my work and whose drive to improve the lives of HIV positive individuals has and will continue to make a significant impact on quality of life issues for HIV positive Mississippians.

DEDICATION

This project is dedicated to my family who has loved and supported me through every part of this journey. My mother, who I lost during the completion of this project, was the reason that I have continued this far in my educational journey. I strive every day to ensure she would continue to be proud of the student, provider, and person that I am. My husband, who absorbed a very heavy load so that I could see this project through to its completion, my three wonderful kids who did not always understand why mama had to do school work, and my sister-in-law and very best friend who took on the role of mother when my kids needed me, and I was not available. To all of them I say thank you, thank you, thank you, thank you-it is because of you that I have succeeded.

TABLE OF CONTENTS

ABSTRACTii
ACKNOWLEDGMENTSiii
DEDICATIONiv
LIST OF TABLESviii
LIST OF ILLUSTRATIONSix
LIST OF ABBREVIATIONSx
CHAPTER I - INTRODUCTION
Background and Significance
Review of Evidence
Cervical Dysplasia
Barriers to Screening6
Facilitators to Screening
Synthesis of Evidence
Needs Assessment
Problem Statement
Project Purpose
Theoretical Framework
DNP Essentials
Chapter One Summary

CHAPTER II – METHODS	18
Overview	18
Setting	18
Target Population	18
Outcomes of Interest and Evaluation Criteria	19
Outcome 1	20
Outcome 2	20
Contextual Elements	20
Baseline Referral Rate	21
Cervical Cancer Screening Performance Measure:	21
Provider Initiated Referral:	21
Same Day Appointment:	21
Design	21
Ethical Considerations	23
Chapter Two Summary	25
CHAPTER III - RESULTS	26
Chapter Three Summary	27
CHAPTER IV – DISCUSSION	28
Overview	28
Recommendations	29

Implications for Future Practice
Limitations
Dissemination
Conclusion
APPENDIX A – Literature Matrix
APPENDIX B – Provider Initiated Algorithm
APPENDIX C – Ryan White Data Tracking Sheet
APPENDIX D – Self-Certification Form for Determining Whether a Proposed Activity is
Research Involving Human Subjects
APPENDIX E – Letter of Support
APPENDIX F – USM IRB Approval55
REFERENCES 56

LIST OF TABLES

Table 1 Mean Comparison of Referral Rates	26
Table 2 Data Table: Monthly Provider Initiated Referrals	

LIST OF ILLUSTRATIONS

Figure 1. Timeline of Project Foundation	, Implementation, and Evaluation	27
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LIST OF ABBREVIATIONS

AIDS Acquired Immune Deficiency Syndrome

ASC-US Atypical Cells of Undetermined

Significance

CDC Centers for Disease Control and Prevention

CIN Cervical Intraepithelial Neoplasia

DNP Doctor of Nursing Practice

HHS U.S. Department of Health and Human

Services

HIV Human immunodeficiency virus

HPV Human papillomavirus

HRSA Human Resources and Services

Administration

HSIL High-grade Squamous Intraepithelial Lesion

LSIL Low-grade Squamous Intraepithelial Lesion

CHAPTER I - INTRODUCTION

HIV affects low-income minorities, specifically in the South, at an alarmingly disproportionate rate (Williams, Moneyham, Kempf, Chamot, & Scarinci, 2015). African American women have a disproportionately higher prevalence of both HIV infections and cervical cancer (Williams et al., 2015). Barriers to preventative care such as cervical cancer screening cited within minority populations are (a) lack of knowledge of resources, (b) denial, (c) fear, (d) competing obligations, and (e) embarrassment (Nonzee et al., 2015). Facilitators to care have been identified as (a) identification of an abnormality, (b) provider-initiated actions, (c) motivation from family and friends, and (d) patient empowerment through education (Nonzee et al., 2015).

The Ryan White Comprehensive AIDS Resources Emergency Act of 1990, mandates grant recipients to establish and maintain a clinical quality management programs ensuring patients provided services with grant funds have access to care that is consistent with the most recent Health and Human Service (HHS) Guidelines for treatment of Human Immuno-Deficiency (HIV) and prevention of opportunistic infections. Continuous quality improvement efforts are focused on areas that reflect the needs of people living with HIV (Health Resources and Service Administration [HRSA], 2016). Recommendations for clinical quality management programs include utilization of organized, structured processes to implement strategies to align care with current guidelines (HRSA, 2016).

Since the introduction of Highly Active Anti-Retroviral Therapy (HAART), the life expectancy of HIV positive individuals adhering to HAART therapy, closely resembles that of the HIV negative patient, effectively shifting HIV from a terminal

diagnosis to a chronic manageable condition (Cross et al., 2014; Simenson et al., 2014). Due to the increase in lifespan, more emphasis is now placed on preventive health measures (Cross et al., 2014; Koethe, Moore, & Wagner, 2008). One such preventative measure is cervical cancer screening.

Cervical intraepithelial neoplasia (CIN) and invasive cervical cancer (ICC) are increased within the HIV positive population (Aberg et al., 2014; Brogly et al., 2007; Denslow, Rositch, Firnhaber, Ting, & Smith, 2014). Women who are HIV positive have a rate of ICC that is four to five times higher than HIV negative women (Aberg et al., 2014; Brogly et al. 2007; Denslow et al., 2014). In 1993, due to the link between HIV and invasive cervical cancer, the Center for Disease Control and Prevention (CDC) categorized ICC as an Acquired Immuno-Deficiency Syndrome (AIDS) defining illness (National Institute of Health, 2011).

Despite this increased risk, cervical cancer screening remains suboptimal within the HIV positive female population (Baranoski, Horsburgh, Cupples, Ashcengrau, & Stier, 2011; Frazier et al., 2016), only 50-60% of HIV positive females report being screened at least once in the three-year period (Baranoski et al., 2011; Leece et al., 2010). Comparatively, the 2010 National Health Interview Survey reported the general female population cervical cancer screening rate to be 83% (CDC, 2012). HIV positive women also present for cervical cancer screening, diagnosis, and management at a later stage of the disease resulting in a negative impact on prognosis (Logan, Khambaty, D'Souza, & Menezes, 2010).

Background and Significance

Incidence of high-grade cervical intraepithelial lesions (CIN 2+) have been documented as having a median three-fold increase in HIV positive females and progression from a low-grade to a high-grade lesion is also significantly faster (Denslow et al., 2014). Due to these factors, commencement of cervical cancer screening is recommended to start within one year of initiating sexual activity but no later than 21 years of age even if the transmission was perinatal ("Panel on Opportunistic Infections," 2013). Follow up for atypical squamous cells of undetermined significance (ASC-US) and low-grade squamous intraepithelial lesions (LSIL) found on cervical cytology is also handled differently, requiring referral and follow-up with colposcopy ("Panel on Opportunistic Infections," 2013).

Globally, researchers have reported nearly all cases of cervical cancer and cervical dysplasia are attributable to infection with the human papilloma virus (HPV) with presence of the virus detected in 99.7% of cervical cancer cases (Frumovitz, 2017). Two specific strains of HPV, 16 and 18, are highly oncogenic and together they account for 70% of cases worldwide (World Health Organization [WHO], 2016). Approximately 80% of sexually active individuals are exposed to HPV within the first two years of initiating sexual activity.

Compared to HIV negative women who often clear the virus within two to twenty-fours months after infection, HIV positive women often have HPV infections that persist (WHO, 2016). Researchers have reported that between 25-44.9% of HIV infected women with normal cervical cytology were infected with oncogenic strains of HPV (Cubie, Seagar, Beattie, Monaghan, & Williams, 2000; Musa et al., 2013). On average

HPV infections take 5-10 years to progress to cervical cancer in the HIV infected female population as compared to 15-20 years in HIV negative females (WHO, 2016).

Review of Evidence

A review of the evidence was conducted in two parts. Initial search was focused on determining the significance of failing to perform recommended cervical cancer screening. After determination that cervical cancer screening was a significant aspect of care for the HIV positive female a secondary search was focused on specific barriers to screening and recommendations that would facilitate adherence to screening and improve quality of care for HIV positive women.

Databases searched included the Cumulative Index to Nursing and Allied Health Literature (CINAHL) with full text, Medline, and PubMed. The following key search terms were initially utilized for significance and background: *HIV*, *HPV*, *cervical cancer*, *screening, incidence, progression*, and *dysplasia*. An initial search limited to full text, English only with publication dates between 2012 and 2017 yielded 943 articles. After removal of duplicates 467 articles were available and after narrowing the search to only women in the United States 57 articles were left for review. Abstracts, titles, and publication dates were used to determine which articles would receive further review.

After review of evidence related to the significance and background of the problem, CINAHL with full text, Medline, and PubMed were again searched to include the following key search terms: *HIV*, *cervical cancer screening*, *pap smears*, *preventive health care*, *barriers*, and *facilitators*. An initial search limited to full text, English only with publication dates between 2012 and 2017 yielded 460 articles. After removal of duplicates 283 articles were available and after narrowing the search to only women in

the United States 92 articles were left for review. During this second phase of evidence review, abstracts, titles, and publication dates were again used as criteria to determine articles that received further review.

Review of available reference lists revealed another 20 previously published articles that were included for consideration. In total, there were 23 articles that were selected for inclusion due to strength and applicability to this quality improvement project. Articles chosen were related to (a) the increased incidence or prevalence of cervical dysplasia seen in the HIV positive population, (b) progression of cervical lesions, (c) identified facilitators and barriers to cervical cancer screening in HIV positive females, and (d) expert guidelines. A literature matrix is included with information from each of the chosen articles (see Appendix A).

Cervical Dysplasia

In a systematic global review conducted by Denslow and colleagues (2014), 15 studies met inclusion criteria to evaluate incidence of cervical dysplasia in HIV positive women; N=5882. The data extrapolated from these studies showed that per 100 life-years studied, incidence of any cervical lesion was between 4.9-21.1 cases for HIV infected females. Incidence of high-grade cervical lesions was between 0.4-8.8 cases per 100 life-years. There was a median three-fold increase of cervical lesions in HIV positive women when compared to HIV negative women (Denslow et al., 2014, p. 164).

In the same systematic global review conducted by Denslow and colleagues (2014), 11 studies were reviewed to measure progression of cervical lesions; N=1099. Data deduced from these studies indicated progression from a low- to high- grade lesion to range between 1.2-26.2 cases per 100 life-years for HIV positive women. HIV

positive women were also found to be twice as likely to have progression of cervical lesions when compared to HIV negative women (Denslow et al., 2014, p. 169).

Brogly and colleagues (2007) found the prevalence of atypical squamous cells of undetermined significance (ASC-US) or higher cervical abnormality found on first screening within the HIV positive, perinatally infected, female population was 29.7%, N=101. Of the 21 girls who underwent appropriate follow-up, 47.6% of cases either persisted or progressed to a more invasive lesion despite colposcopy, cryotherapy, excision, or a combination. Fourteen HIV positive, perinataly infected females did not undergo intervention and seven cases persisted or progressed to a more invasive lesions (Brogly et al., 2007).

In a retrospective cohort review of medical records of HIV positive women receiving care from January 1, 2002 to December 31, 2006 at an HIV clinic located in the Western United States, 69 women met inclusion criteria for chart review. Of the 69 women, 77.9% had at least one cervical screening during the study period (Rahangdale, Sarnquist, Yavari, Blumenthal, & Israelski, 2010). The collected cytology yielded 66.9% normal findings and 33.3% abnormal findings. Abnormalities identified were 50.9% ASC-US, 36.4% LSIL, 10.9% high-grade intraepithelial lesion (HSIL), and 1.8% atypical glandular cells of undetermined significance (Rahangdale et al., 2010). Only 62% of women who had an abnormality identified on cytology had documented follow up within 12 months (Rahangdale et al., 2010).

Barriers to Screening

Factors that have been associated with non-adherence to cervical cancer screening include (a) being in a racial minority, (b) lacking insurance coverage, and (c) not

receiving cervical cancer screening at the same location as primary HIV care (Frazier et al., 2016). Although lack of insurance coverage has been noted as a barrier to cervical cancer screening, having private insurance has also demonstrated decreased adherence rates (Simonsen et al., 2014). A retrospective cohort study of HIV positive women receiving care at an HIV clinic associated with the University of Utah reported a statistically significant correlation between having private health insurance coverage and not having had cervical cancer screening, p=0.025 (Simonsen et al., 2014). Researchers noted that this correlation could be related to the copay that women with private insurance are likely required to pay to receive services from an outside clinic (Simonsen et al., 2014).

Fletcher et al. (2014) found that notable barriers to cervical cancer screening in HIV positive females are (a) lack of education on the importance of screening, (b) lack of education that cervical cancer can be prevented with appropriate screening, and (c) difficulties with scheduling and remembering appointments for gynecological services. The barriers reported by Fletcher et al. (2014) were derived from interviews conducted as part of a qualitative focus group of 33 HIV positive females receiving care at a health center located in Houston, Texas. The women who participated in this study were predominantly African American, and had a median age of 51 years (Fletcher et al., 2014).

In a retrospective chart review of 200 randomly selected charts of HIV positive women receiving care in a health department setting, lack of insurance was found to be a statistically significant barrier to cervical cancer screening (Logan et al., 2010).

Researchers reported that 64.7% of women who did not receive a pap smear were

uninsured, p=0.0185 (Logan et al., 2010). The HIV positive women receiving care in this clinic were also found to be predominantly minorities—57.4% African American and 22.8% Hispanic (Logan et al., 2010). They were also found to be economically disadvantaged with a mean income of \$8,180 annually (Logan et al., 2010).

Andrasik, Rose, Pereira, and Antoni (2008) used Anderson's Behavioral Model of Health Services to identify barriers in 35 HIV positive African American women who had not received cervical cancer screening within the past five years. These researchers noted primary barriers to be (a) low self-esteem, (b) fear, (c) financial distress, and (d) lack of transportation. This study also highlighted the impact that psychological barriers have on HIV positive women when attempting to obtain cervical cancer screening services (Andrasik et al., 2008).

Another retrospective chart review of 148 HIV positive females receiving care at a clinic located in New Haven, Connecticut found that cervical cancer screening adherence rates were lowest among patients being cared for by infectious disease specialists (Koethe, Moore, & Wagner, 2008). The HIV positive females under the care of infectious disease specialists were found to have a 47% compliance rate of cervical cancer screening (Koethe et al., 2008). Comparatively, HIV positive women receiving HIV primary care from a generalist, not specialized in infectious disease were found to have a cervical cancer screening rate of 55% (Koethe et al., 2008).

Facilitators to Screening

Nonzee et al. (2015) conducted semi-structured interviews based on the Social-Ecological Model integrated with the Theory of Reasoned Action to determine factors that facilitated cervical and breast cancer screening within low-income, minority women. The participants were elicited from three health care facilities located in Chicago, Illinois. Adherence to recommended cervical cancer screening within the minority population studied were facilitated by provider-initiated actions such as: (a) education on importance of screening, (b) recommendation for appropriate screening intervals, and (c) referrals (Nonzee et al., 2015).

In a retrospective cohort study conducted by Baronski and Stier (2012), factors that contributed to appropriate follow-up after abnormal cervical cytology were found to be (a) higher education level of the patient, (b) high-grade cervical lesion identified, and (c) abnormality found by a nurse practitioner (NP) performing women's healthcare within the same clinic the patient was receiving HIV primary care. Time to follow up for abnormalities found by the HIV NP were significantly faster when compared to both infectious disease physicians at the same clinic and providers at the gynecological clinic (Baronski & Stier, 2012). Decreased time to follow-up is important because lapses of time greater than 6 months between abnormal findings on the index cytology and follow-up with colposcopy for histological evaluation have been cited as increasing negative health outcomes (Baranoski & Stier, 2012).

Fletcher et al., (2014) conducted focus groups using the Health Belief Model to determine themes associated with adherence to cervical cancer screening in HIV positive females. Facilitators were found to be: (a) awareness of increased risk of cervical cancer in HIV positive women, (b) awareness that cervical cancer could be prevented with appropriate screening, and (c) a trusting relationship with their HIV primary provider. Recommendations from this study included integration of cervical cancer screening into

HIV primary care and ensuring education concerning this screening was framed as a preventative measure (Fletcher et al., 2014).

Education about risk of cervical cancer as well as early detection producing more positive outcomes provided by the patient's primary HIV provider have been related to increased compliance (Cross et al., 2014). Barriers to appropriate cervical cancer screening for HIV positive women include lack of screening being performed by the patient's primary HIV caregiver as well as lack of coordination of HIV and women's healthcare at one location (Frazier et al., 2016). Due to the increased compliance of HIV positive women who receive cervical cancer screening at their primary HIV provider, integration of women's health services within this setting is a common theme to increase cervical cancer screening (Baronski & Stier, 2012; Frazier et al., 2016; Oster, Sullivan & Blair, 2009).

Synthesis of Evidence

Identification of facilitators and barriers through synthesis of literature was important to this project. The project structure accounted for specific aspects of barriers and facilitator within its design. The visual algorithm addressed these barriers by (a) prompting the provider to make the patient aware of the availability to receive the cervical cancer screening within the clinic setting, (b) addressing the importance of cervical cancer screening by educating the patient on the increased risk, (c) addressing patient fear by educating the patient on the ease of cervical cancer prevention and treatment with early and appropriate screening, (d) addressing competing obligations by offering the ability of a same day appointment or scheduling an appointment at the convenience of the patient, and (e) decreasing embarrassment by having a female NP

who is experienced in various aspects of women's health in vulnerable populations perform the screening.

A synthesis of the literature showed an elevated risk of cervical dysplasia in HIV positive women that is significantly increased when compared to HIV negative women (Brogly, 2007; Denslow et al., 2014; Rahangdale et al., 2010). Barriers to screening are many and have been cited as stemming from sociocultural factors as well as features that interfere with the structural and systematic process of referral for cervical cancer screening. Evidence supports integration of women's health services within the setting of HIV primary care (Baronski & Stier, 2012; Frazier et al., 2016; Oster et al., 2009).

Needs Assessment

Researchers have reported suboptimal rates of cervical cancer screening within the HIV positive population (Williams et al., 2015). Discrepancies have also been noted between self-report and documented evidence of cervical cancer screening. In a study conducted by Frazier and colleagues (2016), 78% of HIV positive females self-reported having a pap smear within the year proceeding the interview; however, researchers could find documented receipt of cervical cancer screening in only 45% of the respondents.

Lack of appropriate cervical cancer screening has been evidenced both nationally and at this clinic location. Per data reported from 126 clinics, located in various locations throughout the United States that receive Ryan White Part C and D funds the mean for the 2011 reporting year, for the cervical cancer screening measure was 60%, N=2793 (National Quality Center, 2013). This project location had an initial cervical cancer screening compliance rate of 32%, half of the 2011 reported national average.

Researchers report that providing women's health within the same clinical setting as HIV primary care greatly increases the likelihood of follow-up for preventative health maintenance, such as cervical cancer screening (Baronski & Stier, 2012; Frazier et al., 2016; Oster et al., 2009). The staffing matrix of this clinic includes: three full-time nurse practitioners, one part-time nurse practitioner, and four part-time physicians who provide HIV care to this population. The full-time providers have a patient load of approximately 450 patients, and the part-time providers have between 50-150 patients. This case load does not allow for the primary HIV provider to perform cervical cancer screening during clinic visits.

A chart review of every female who was actively receiving services within the clinic was performed to evaluate the status of cervical cancer screening. If the patient had a hysterectomy for non-malignant conditions, records were updated accordingly. Charts were also reviewed to identify women who may have had cervical cancer screening at an outside provider, such as a local health department or a private clinic.

If the patient received testing at a site affiliated with the clinic location, the cytology results would be available within the electronic medical record EPIC; however, this data does not directly transfer into the federal information system (CAREWare) that is used to report data to HRSA. To import the patient information, the data was extrapolated from EPIC and manually entered in to CAREWare. The retrieved data was then organized into an Excel sheet to be filtered, sorted, and validated.

Following informal discussions with the clinic providers concerning lack of cervical cancer screening, it was clear that this was not a health service the providers could integrate in to the clinic schedule. The constraints noted were (a) lack of time, (b)

competing priorities concerning patients' healthcare needs, and (c) forgetting to inquire about health maintenance history. Value stream mapping was conducted to determine specific strategies to facilitate cervical cancer screening within the clinic.

Historically, ambulatory referrals were placed within EPIC, for gynecological services, but only a small percentage of women followed up for these appointments. Approximately 80% of the clinic's female patients do not have health insurance and nearly all (95%) fall within 200% of the federal poverty level. These limited resources make procurement of the recommended cervical cancer screening unobtainable from a source outside of this clinic's setting. Researchers have reported that HIV positive females face additional barriers such as shame and stigma when attempting to receive women's health services from a provider other than their primary HIV provider (Andrasik et al., 2008; Baranoski, et al., 2011; Bynum et al., 2016; Cross et al., 2014; Fletcher et al., 2014; Frazier et al., 2016).

Since cervical cancer screening guidelines for HIV positive females are set by the CDC and monitored by HRSA as a standard of care, cervical cancer screening is financially supported by grant funding. By increasing referrals to an in-house provider for cervical cancer screening, the cost can be covered by grant funds for those patients that qualify, and if abnormalities are found, case managers are available to help the patient apply for a financial assistance program provided for through the academic medical center. This financial assistance allows the patient to receive appropriate follow-up at little to no cost depending on financial need.

Problem Statement

Cervical dysplasia, the precursor to cervical cancer is seen in 20-40 % of all HIV infected women and progression to invasive cervical cancer is largely preventable with appropriate cervical cancer screening (Cross et al., 2014). If cytology results within this clinic follows the previously documented trajectory, an estimated 111-222 women will present with cervical dysplasia. Ignoring this important health screening could lead to higher incidence of invasive cervical cancer. ICC without lymph node involvement results in radical hysterectomy. Cancer that has metastasized to pelvic or paraaortic lymph nodes results in a poor prognosis regardless of systemic chemotherapy treatment (Frumovitz, 2016). Receipt of a cancer diagnosis of any type can decreases quality of life and drastically impact healthcare costs.

Quality improvement initiatives focused on increasing cervical cancer screening of the HIV positive female population are integral to improving patient outcomes.

Compliance with guidelines set forth by HHS concerning appropriate care of the HIV positive female patient will ensure continued program funding and sustainability.

Continued quality improvement measures and program sustainability impact aggregate population health.

Project Purpose

This project's goal was to create a systematic process change that would increase provider-initiated referrals for HIV clinic-based cervical cancer screening. Achievement of this goal would support the overall aim of increasing the number of HIV positive women being appropriately screened for cervical cancer. The long-term goal to improve

population health would be achieved by the impact and sustainability of this quality improvement intervention.

Theoretical Framework

This project was built around Donabedian's Structure-Process-Outcomes Quality Improvement Model. Donabedian's Quality Improvement Model lays out three pathways: (a) structure, (b) process, and (c) outcome to evaluate health care (Donabedian, 1980). The structure of health care is constituted by both support provided for quality care and the environment in which the care is provided (Donabedian, 1982). Appropriate and available supplies, equipment, proficiency of healthcare personnel as well as barriers and facilitators to both access and care are all encompassed within structure (Donabedian, 1982). Process includes patient and provider interactions as well as the provider's technical proficiency. The process of providing health care that meets evidenced-based guidelines and practice standards is the measurement of quality of care (Hickey & Brosnan, 2012). Donabedian (1980) postulated that process was the primary object of study. The outcome is defined as a measurable change in patient care, effected by both structure and process (Donabedian, 1982).

DNP Essentials

There are eight essential elements applied to the Doctor of Nursing Practice (DNP) degree (American Association of Colleges of Nursing, 2006). The development of this quality improvement project encompasses all eight essentials as follows:

• Essential I, Scientific Underpinnings for Practice, was achieved by an extensive review of available evidence encompassing both quantitative

- and qualitative studies. Information was extrapolated and applied to this quality improvement project.
- Essential II, Organization and Systems Leadership for Quality
 Improvement and Systems Thinking, was achieved by examining the structure and process within the organization that could be improved upon to provide for more positive outcomes within the specified population.
- Essential III, Clinical Scholarship and Analytical Methods for Evidence-Based Practice, was met by extensive literature review and analysis of available evidence, including expert guidelines, current qualitative and quantitative studies, and historical research studies to apply to practice improvement.
- Essential IV, Information Systems/Technology and Patient Care
 Technology, utilized both facility information system-*EPIC*, as well as available federal information system-*CAREWare*.
- Essential V, Health Care Policy for Advocacy in Health Care, this
 essential was met because the results of this quality improvement project
 will increase the healthcare outcomes of HIV positive women by
 establishing a visible algorithm for providers to increase utilization of
 available recommended guidelines for cervical cancer screening.
- Essential VI, Interprofessional Collaboration for Improving Patient and Population Health Outcomes, this essential was met by collaboration with HIV care providers and other members of the healthcare team to establish

- a quality improvement project that would improve the health of a unique and vulnerable population.
- Essential VII, Clinical Prevention and Population Health for Improving
 the Nation's Health, met by constructing a quality improvement plan that
 could be used in other facilities caring for HIV-positive females that may
 be struggling with adherence to appropriate cervical cancer screening.
- Essential VIII, Advanced Nursing Practice, was met because it provides for collaboration between various healthcare providers to achieve common goals; collaboration being an essential element in advanced nursing practice.

Summary

Chapter one introduced the importance of cervical cancer screening in HIV positive women. This chapter also highlighted the need to increase cervical cancer screening within the location chosen for this DNP project. A thorough review of the evidence was performed to identify facilitators and barriers to cervical cancer screening that were then used as a framework to build a clinic specific intervention to increase referrals to an in-house provider.

CHAPTER II – METHODS

Overview

Rapid cycles of quality improvement are used within this clinic's quality program infrastructure. The data extrapolated from these rapid cycles was used to determine the best theoretical framework for this quality improvement project. Inconsistencies were found in both the structural and procedural methods of delivering cervical cancer screening services.

Structure within this quality improvement project pertained to the clinic environment and providers. The structure received some previous improvement outside of the scope of this project by integration of cervical cancer screening within the HIV clinic setting. Process was evidenced by the provision of provider-initiated referrals for cervical cancer screening. The measured outcome was the number of provider-initiated referrals.

Setting

The setting for this doctoral project was a large, urban, academic medical center, infectious disease clinic that receives Ryan White grant funding. There are over 1900 individual HIV positive patients receiving HIV primary care at this location. Over one-third of those patients are female, and roughly 80% of the female population still meet requirements for cervical cancer screening. The provider mix includes three full-time NPs, one part-time NP, and four part-time physicians specializing in infectious disease.

Target Population

The target population was HIV positive females receiving primary care at this clinic, N=749. The demographics of the women were 89.9% African American/Black

(n=674), economically disadvantaged, 95.1% (n=712) as evidenced by an annual income \leq 200% of the Federal Poverty Level, primarily uninsured, 80.1% (n=600), and between the ages of 18 and 60 years old, 90.1% (n=675). Targeted interest was placed on HIV positive women who still had a biological cervix or had undergone hysterectomy for malignant conditions, 74.1% (n=555).

Outcomes of Interest and Evaluation Criteria

The project had two targeted outcomes of interest that were measured to evaluate the impact of the project. The primary goal of the project was to increase the number of provider-initiated referrals for HIV positive females to receive cervical cancer screening provided by an in-house resource provider. To evaluate this goal the use of descriptive statistics was used to compare baseline referral rates for cervical cancer screening for the three-month period directly preceding the introduction of the intervention to the referral rate of the three-month period after introduction of the intervention.

The overall aim of the project was to increase the number of HIV positive female patients, receiving care at this clinic, who also received appropriate cervical cancer screening. This outcome was measured by the percentage of HIV positive female patients who received cervical cancer screening. In a previous article by Cross et al., (2014), the introduction of a multidisciplinary quality improvement intervention to increase cervical cancer screening increased the rates of HIV positive females appropriately screened by 22.3% over a one-year measurement period. The outcomes for this quality improvement initiative were evaluated at three-months. Comparison to achieved outcomes from Cross et al. (2014) any increase ≥ 6% would indicate a success

with this quality improvement project's overall aim of increasing cervical cancer screening rates of HIV positive females receiving care at this clinic.

Outcome 1

Outcome one was the primary project goal. The number of HIV positive females, receiving primary HIV care in a large, urban, academic medical center who received interdepartmental referrals was measured. Measurement of the referral rate was compared at baseline and the following three-months after introduction of a visible algorithm. Project success was determined by an increase in provider initiated cervical cancer screening referrals when compared to pre-intervention data.

Outcome 2

Outcome two was the project's overall aim which was to increase the number of HIV positive females who received appropriate cervical cancer screening. Increased cervical cancer screening would increase compliance with the HRSA performance measure. The HRSA cervical cancer screening measure would be calculated by the number of women receiving cervical cancer screening divided by the number who qualify for cervical cancer screening.

Contextual Elements

Donabedian (2003) defined the concept of *planned reconnaissance* as an action taken to reveal problems and opportunities for improvement. This portion of quality improvement is completed by routine surveillance by opinion surveys or performance monitoring. Assessment of quality of care could be divided into three approaches: (a) structure, (b) process, and (c) outcomes. Interpretations could not be made by any of

these approaches unless there was an encoded relationship amongst each piece (Donabedian, 2003).

Definition of several contextual elements are needed for project clarity and are as follows:

Baseline Referral Rate: Defined as the number of female patients who were provided cervical cancer screening by an action that was initiated by their HIV provider.

Cervical Cancer Screening Performance Measure: The percentage of women, over the age of 18, with a biological cervix or a hysterectomy due to malignant conditions, who have had cervical cancer screening within the past year, divided by the number of women, over the age of 18 who qualify for screening.

Provider Initiated Referral: Any referral for cervical cancer screening, notated on the Ryan White Data Tracking Sheet that was then entered into the CAREWare system by a Case Manager for the three-month period of October 24, 2017-January 23, 2018, regardless of appointment status.

Same Day Appointment: Any HIV positive female who required cervical cancer screening and requested a same-day appointment-regardless of referral source.

Design

After receipt of appropriate approvals, providers and staff were notified by e-mail that the previously discussed process for cervical cancer screening referrals had been implemented. This communication clarified the purpose of the algorithm and outlined the steps that providers should take to ensure the referral was handled properly. Specific steps to handling referrals was important for accurate data tracking to measure project outcomes.

The algorithm (see Appendix B) was laminated and placed in every clinic room directly by the computer where the provider sits to document each patient encounter. The algorithm outlined criteria that would qualify a patient for referral for cervical cancer screening and included talking points that the provider could use to introduce the importance of cervical cancer screening to the patient. Talking points included: (a) HIV positive females are at an increased risk of cervical dysplasia-including cervical cancer, (b) cervical cancer is a preventable cancer when appropriate screening is performed, (c) cervical cancer screening is available within the clinic setting, and (d) cervical cancer screening is a measure of care provided through grant funding for uninsured patients. The algorithm included a request that a release of information (ROI) be signed if the patient self-reported cervical cancer screening at an outside facility. Due to study reports of discrepancies between self-report and verifiable documentation of cervical cancer screening, self-report was not considered evidence of screening (Frazier et al., 2016; Howard, Argarwal, & Lytwyn, 2009).

The algorithm outlined appropriate candidates for cervical cancer screening referral. Key talking points were also included on the algorithm to help the provider educate the patient on the importance of cervical cancer screening. Once the patient agreed to be referred for cervical cancer screening, the provider checked the box on the Ryan White Data Tracking sheet (see Appendix C) indicating that the patient had been referred for cervical cancer screening. The Ryan White Data Tracking Sheets with the cervical cancer screening referral box checked where given to an identified case manager at the end of each day.

All case managers at this clinic are qualified to enter referrals into CAREWare and initiate provider requested referrals. For simplicity and accuracy during this project one identified case manager was chosen to handle aspects of data entry and appointment scheduling for cervical cancer screening referrals. This case manager is a registered nurse who also serves on the Continuous Quality Improvement Committee and is well versed in use of the CAREWare system and patient care-including referrals.

The case manager entered the referrals each day into CAREWare and routinely called patients to set up appointments for cervical cancer screening. Same day appointments were often available, and she also handled scheduling and facilitation of these appointments. Blinded reports concerning referrals as well as performance measure reports measuring the percentage of women appropriately screened was provided to the investigator by the case manager at the end of each measurement month and at project closure.

Ethical Considerations

Ethical considerations for this project were applicable to both the referring provider and the patient being referred. The providers were notified of the project and proposed intervention prior to implementation. All providers had previously agreed to a process change concerning referrals for cervical cancer screening, and all providers were made aware that the number of women being referred would be counted and reported for the purposes of this quality improvement project.

Assurance was provided that the identity of the referring provider would not be made available to this investigator and there would be no reprisal should they choose not to comply with the referral guidelines. If the provider chose not to refer based off the

methods outlined in this quality improvement project, there would also be no negative effect to the patient. The patient would still be offered and provided cervical cancer screening; however, the referral would not be included within the final project outcomes.

Ethical consideration was strongly enforced for the patient. The intervention was set up so that the referral would be entered into CAREWare and appointments set up by the case manager at the clinic, which is a duty of her position. This researcher received blinded reports, at the end of each month and at project end with information on total referrals placed. The report listed the date of referral for each individual patient and identified patient by an encrypted unique record number (eURN). This eURN is a number, generated by the CAREWare program, which includes the patient's initials, birthday, and elements of the social security number in no decipherable order.

Prior to project approval, the facility Institutional Review Board (IRB) was contacted to determine the appropriate ethical actions. This investigator was informed that due to the nature of the project only a Self-Certification Form for Determining Whether a Proposed Activity is Research Involving Human Subjects was needed (see Appendix D). Upon completion of the Self-Certification Form the investigator was instructed to maintain this document with project records.

A letter of support (see Appendix E) was obtained from the project director for this clinic's Ryan White Department. Both the Self-Certification Form and the support letter along with IRB application where sent for review by The University of Southern Mississippi's IRB and approval was granted, given Protocol #1710171702 (see Appendix F). No intervention was instituted until appropriate approvals were received.

Summary

Chapter two discussed this project's setting, target population, and outcomes of interest. The theoretical framework that was chosen to construct this project was also discussed. Contextual elements needed to successfully conduct this project were established and defined.

CHAPTER III - RESULTS

Comparison of means of pre- and post-intervention referral rates showed a significant increase after project implementation. On average, the provider-initiated referrals after introduction of the intervention (M=28, SE=2.082) were significantly higher than provider-initiated referrals measured at baseline (M=8, SE=1.732). The final percentage of HIV positive women appropriately screened for cervical cancer also saw a 23% increase over a three-month period; which was a fourfold increase of the improvement noted by Cross et al., (2014). The increase during the three-month period after project implementation was also significantly higher than the 15% increase noted during the six-month period prior to introduction of the intervention.

Table 1

Mean Comparison of Referral Rates

Measurement	N	М	SD	Std. Error Mean
Pre-Intervention	3	8	3	1.732
Post-Intervention	3	28	3.606	2.082

Table 2

Data Table: Monthly Provider Initiated Referrals

Month	Provider Initiated Referrals Received
July 22 nd -August 23 rd 2017	8
August 24 th -September 23 rd 2017	5

Table 2 (continued).

September 24 th -October 23 rd	11
2017 October 24 th -November 23 rd 2017	32
November 24 th -December 23 rd 2017	27
December 24 th – January 23 rd	25
2017-2018	23

Baseline Data 18.86%	Post Data Cleaning 32.07%	Pre-Intervention Data 47.03%	Post-Intervention Data 70.09%
•Record verification •Gynecological history review	 Value stream analysis Provider education Integrative care approach Active case-finding 	•Introduction of algorithm •Introduction of referral process	Completion of project Data review and analysis

Figure 1. Timeline of Project Foundation, Implementation, and Evaluation

Summary

Chapter three discussed the results of the project intervention. Data used to determine project success was provided including the mean of pre- and post-intervention measurements. Outcomes from previous quality improvement interventions was introduced for comparison.

CHAPTER IV – DISCUSSION

Overview

At the initiation of the project, the case manager thought it would be beneficial to place both release of information (ROI) sheets in each clinic room as well as the quality manager's business card. This provided a way for an ROI to be obtained by the provider without added inconvenience. The ROIs were turned in with the Ryan White Data Tracking sheet so that previous cytology results could be requested. If the provider referred the patient for cervical cancer screening, they could choose to provide the patient with a business card that could then be presented at check-out. For data tracking purposes, the provider would still check the referral box for cervical cancer screening. The front desk clerk was informed that if they received the quality manager's business card they were to schedule the patient for an appointment for cervical cancer screening. This process allowed for some patients to self-schedule for an appointment without the case manager having to handle setting up the appointment.

The algorithm prompted providers to request ROI documents for testing performed at outside clinics, and it is possible that this action may have provided an unexpected benefit on the increase of women appropriately screened, as it is appropriate to count screening performed at an outside clinic given the results have been reviewed and verified. It is also possible that having a specific provider who has clinic time devoted to performing cervical cancer screening has a positive impact on the number of women screened. This fact would correlate with the recommendation from available literature that women's health, such as cervical cancer screening, should be incorporated with primary HIV care (Baronski & Stier, 2012; Frazier et al., 2016; Oster et al., 2009).

Recommendations

The blinded nature of the data collection greatly reduced this investigator's ability to draw some conclusions. Infectious disease specialists have been noted as having the lowest percentage of performing cervical cancer screening when compared to providers of other disciplines (Koethe et al., 2008). Comparison of referral rates of the clinic providers would be a phenomenon of interest to determine if the impact of removing the time constraint of screening would increase their willingness to discuss the importance of this screening with patients. Should the data be unblinded later to identify the provider who initiated the referral, comparisons could be made between referral rates and provider type.

Recommendations for future investigation would also include retrospective chart review to determine how many women referred followed up and review of the cervical cytology outcome. This clinic would be an excellent location to conduct further scholarly inquiry on the incidence and progression of cervical dysplasia due to the high number of female, HIV positive patients. For women who were found to have cervical dysplasia and had appropriate follow-up, data could also be collected to discern the differences between the cervical cytology and the pathology. One study conducted by Curry, Sage, Vragovic, and Stier (2012) reported that 90 HIV positive women with minimally abnormal cervical cytology defined as ASC-US with HPV or LSIL received appropriate colposcopy and biopsy. Histological diagnosis included CIN2+ for 29 of these women. Further data concerning the variances in cytological screening when compared to diagnostic pathology for HIV positive women with cervical dysplasia would have a positive impact on the health outcomes for this vulnerable population.

Implications for Future Practice

Implications for future practice that can be extrapolated from this project include (a) continuing availability of a provider with dedicated time available to perform cervical cancer screening within the same clinic the patient is receiving HIV, (b) visible prompts such as the algorithm used in this project could be utilized for other aspects of health care that need improvement (i.e. mammography, colonoscopy, immunizations), and (c) education and emphasis should be placed on the importance of the patient-provider relationship that exists within the HIV care setting. Visual cues such as the intervention used in this project could increase integration of preventative health maintenance in similar clinics. An aging HIV positive population and difficulty accessing health care increase the need to integrate preventative health services within HIV specialty care.

Available literature has provided multiple articles that have statistically examined unique variables that may impede cervical cancer screening in HIV positive women. There is also well documented evidence of the negative impact on HIV positive women who fail to undergo cervical cancer screening. However, there was only one article (Cross et al., 2014) that addressed quality improvement interventions related to increasing cervical cancer screening within the HIV positive female cohort. Due to the importance of this preventative screening, it is vital that more quality improvement projects be both implemented and disseminated to facilitate structural and procedural changes within systems that will impact the long-term health outcomes of HIV positive women.

Limitations

This project, although effective at this location may not be reproducible in a clinic setting without a provider with appropriate time to provide cervical cancer screening.

Due to the aspect of the referrals being blinded to the investigator, it is possible that some women were referred inappropriately for cervical cancer screening. Inappropriate referrals would include HIV positive females who had a hysterectomy due to non-malignant purposes or who had already had appropriate screening within the past year. These women, although referred, would not increase the percentage associated with cervical cancer screening measure as they either (a) were not included in the denominator or (b) were already included in the numerator.

Dissemination

Dissemination included discussion of the project's outcome with both the investigator's preceptor and the clinic's medical director. Results were sent via e-mail to all clinic staff, along with words of appreciation and gratitude for their conscientious efforts to refer their patients for this important screening. Project overview and outcomes were also discussed with HRSA auditors during a recent on-site visit. This quality project will also be submitted for review for the March 23, 2018 meeting of the Mississippi Statewide Quality meeting, which is a quality improvement collaborative that focuses on improving care for HIV positive patients receiving care through Ryan White grant funded clinics. Plans for future dissemination include submission of a poster presentation concerning this quality improvement project during the 2018 National Ryan White Conference on HIV Care and Treatment, scheduled for December 11-14, 2018 in Washington D.C. This investigator also plans to submit this work to several HIV/AIDS

specific journals. Project data will be used as the groundwork for further scholarly inquiry related to this population. Possible inquiry includes a retrospective chart review of outcome data for concerning incidence of HPV in the presence of normal cervical cytology in the HIV positive female patient and incidence and progression of cervical dysplasia specific to this clinic's population.

Conclusion

In conclusion, this project was successful, and the intervention was found to produce significant increases in provider-initiated referrals. As previously noted, HIV affects women, specifically African American women at a disproportionate rate. There is sufficient evidence that HIV positive women have an increased risk of cervical cancer and multiple barriers to receiving cervical cancer screening, but there is minimal literature related to the improvement of cervical cancer screening adherence rates. This population would likely benefit from continued scholarly inquiry concerning cervical cancer screening improvement measure, including interventions that facilitate adherence.

Nurses with terminal, clinical degrees such as the Doctor of Nursing Practice are positioned to facilitate organizational changes that provide for positive impacts for population health. This quality improvement project has not only changed the referral process for HIV positive women but was built on a foundation that effectively transformed the clinic's structure as evidenced by integration of cervical cancer screening within the clinic. Changes instituted in both the structure and process allow for continued positive outcomes and sustainability.

APPENDIX A – Literature Matrix

Author/Year	Design/Sample/Setting	Findings	Recommendations
Aberg et al.	Guideline	HIV positive	Cervical cancer
(2014)		females have	screening should be
		increased	performed at
	Expert Opinion	incidence of	diagnosis and
		abnormal cervical	should continue
		cytology that is	through-out the
		10-11 times more	female's lifetime.
		common than	There is no
		HIV negative	recommendation to
		females	stop screening at
			age 65 as there is in
			HIV negative
			women. All
			cervical cytology
			that returns
			abnormal should be
			followed-up with
			colposcopy and
			directed biopsy.
			Consideration to
			increase screening
			intervals to every
			three years if the
			female is over age
			30 and cytology is
			normal and HPV
			co-testing returns
			negative.
Andrasik	Individual semi-	Researchers used	Barriers to
Rose	structured interviews	Anderson's	screening should be
Pereira	using a qualitative	Behavior Model	considered when
Antoni	instrument and open-	of Health Services	caring for
(2008)	ended question to	as a framework to	vulnerable
	elicit information.	identify barriers to	populations.
	Participants included	cervical cancer	Primary HIV
	African American,	screening.	providers should
	HIV positive, females		ensure that patients
	ages 18-49 with no	Davide ala - : 1/	are well educated
	pap in the last 5 years.	Psychological/	on the
		emotional barriers	benefits/risks of
	N=35	found were self-	undergoing cervical
	1N-33	esteem and fear.	cancer screening

		Economic and financial barriers were money to obtain screening and transportation.	and should proceed appropriately.
Horsburgh Cupples Aschengrau Stier (2011) Bo Oo M M wi es co	etrospective cohort andy of HIV positive fromen, ages 18-60, eceiving HIV care at an urban medical enter located in soston, MA between october 1, 2003 and farch 31, 2008. Multivariate analysis with generalized estimate equations for correlated data.	Risk factors of no pap in HIV positive females receiving HIV care. Subjects (n) only 53% of women engaged in HIV care had received a pap at any point during study duration.	The clinic setting had a nurse practitioner available on Monday, Tuesday, and Friday. The primary HIV provider could refer the patients for pap smears or the patient could self-refer. Review of documentation is more accurate to verify receipt of pap smears than relying on a patient's self-report alone. In 84 charts of women with no pap testing, 40.5% (34) had no documentation of an HIV provider ever inquiring about pap. Documentation of cervical dysplasia history was associated with decreased odds of not having a pap. CD4≤ 200cells/mm³

			increased odds of no pap.
Baranoski Stier (2012)	Retrospective cohort study was obtained by chart review of HIV + females receiving pap smears at their HIV providers office Evaluated time to colposcopy after identification of an abnormal pap smear using univariate and multivariate Cox proportional hazard modeling. N=177	Facilitators to decreased time to colposcopy were being married higher education HSIL on pap CD4≥500 NP HIV provider performing pap vs gynecological provider. Only 68% (120) of women who had abnormal cervical cytology followed up by 12 months.	Identification of barriers and follow up colposcopy are important and should continue to be studied. HIV + females are at an increased risk of invasive cervical cancer. Delays in follow-up over 6 months increase the likelihood of adverse events. HIV + females are less likely to have regression of cervical dysplasia.
Brogly et al. (2007)	Retrospective chart review of perinatally infected girls, ages 13 or over, enrolled in Protocol 219 C, who were sexually active and underwent screening for cervical cancer N=101	This study found that of the 174 girls known to be sexually active, only 101 had underwent pap testing. Of the 101 cases reviewed, 30 had abnormal cytology at baseline and only 21 of those females had appropriate follow-up. Despite follow-up and intervention, 10 cases progressed to more advanced squamous intraepithelial lesions.	This study found that 29.7% of perinatally HIV infected females (mean age=16.7 years) had abnormal cervical cytology on their initial pap smear. The recommendation is that HIV positive females should have regular cervical cancer screening within the first year of onset of sexual activity or age 21 regardless of mode of HIV transmission.

Bynum et al. (2016)	Questionnaire based study of HIV positive females, 18 years or older, receiving care at an AIDS service organization located in the South East United States. Used descriptive statistics to determine sociodemographic breakdown and	Questionnaire was designed to examine sociostructural determinants of cervical cancer screening. 64% of participants did not have a	Researchers reported that many abnormalities persisted despite interventions such as cryotherapy, excision or both. Many women noted that their HIV provider was the only provider that they received care from. Due to this fact it should be priority to provide women's health services such as cervical cancer screening within
	multivariable log regression to determine barriers.	personal health care provider other than their HIV provider.	the HIV primary setting.
	N=145	Barriers noted were (a) low access to health care, (b) no access to transportation, and (c) perceptions of stigma.	Factors such as transportation and perceptions of stigma should also be considered when determining what services to provide within the HIV care setting. Many women feel stigmatized when seeking care from health care providers who are not aware of their HIV status and feel uncomfortable disclosing.
			The HIV provider and patient

Cross et al. (2014)	Retrospective comparative study of pre-and post-intervention data after introduction of a quality improvement effort to increase Barriers to cervical cancer screening identified were training, preparedness, environment,	relationship is intimate and that can be utilized to provide screening within the HIV clinic setting. A multidisciplinary approach should be used to increase cervical cancer screening within the infectious disease clinic.	
	cervical cancer screening rates. Statistics use: Chi-Square Fisher's Exact Wilcoxon Rank-Sums N=422	equipment, provider incentives, patient factors, and time. Post-intervention the clinic saw a 43% increase in cervical cancer screening.	The gains can be sustained by interventions that are sustainable and relevant to the clinical environment. Increasing and maintaining cervical cancer screening rates should be a priority for the HIV provider. Patient barriers such as lack of education on the importance of screening for cervical cancer as well as provider specific barriers should be considered when attempting to increase cervical cancer screening rates.

Cubie	Prospective	23% of HIV	This study looked
Seagar	observational cohort	positive women	at the number of
Beattie	study of HIV positive	with normal	women who had
Monaghan	women.	cervical cytology	normal cervical
Williams		were infected with	cytology were co-
(2000)		high-risk strains	infected with high
	N=106	of HPV.	risk strains of
		70% of HIV	human papilloma-
		positive women	virus (HPV). HPV
		with ASC-US	co-infection
		cervical cytology	contributes to the
		were infected with	largest percentage
		high-risk strains	of cervical cancers.
		of HPV.	Due to this fact, HPV co-testing
		90% of HIV	should be provided
		positive women	when available and
		with cervical	appropriate.
		dysplasia greater	wppropries.
		than ASC-US	
		were infected with	
		high-risk strains	
		of HPV.	
Curry	Retrospective analysis	HIV positive	This study analyzed
Sage	of HIV positive	females have an	the difference in
Vragovic	females who had	increased rate of	HIV positive
Stier	minimally abnormal	underlying	women and HIV
(2012)	cervical cytology, who	Cervical Intra-	negative women
	also received	Epithelial	undergoing cervical
	recommended follow	Neoplasia (CIN)	biopsy after
	up colposcopy within	stage 2 or higher	identification of a
	a 6-month time. The	after minimally	minimally
	phenomenon of	abnormal cervical	abnormal index
	interest was the	cytology.	pap.
	number of women		
	who had CIN2+ confirmed with	655 HIV positive	It is not known if
	histology results after	women received a	the higher
	having cervical	pap during the	incidence of high-
	cytology of ASC-US	study period.	grade dysplasia in
	•	, , , , , , , , , , , , , , , , , , ,	
			women was due to
		146 (22%) had	increased
	N=146	ASC-US/LSIL on	progression from a
		index pap.	low-grade to a
	with HR HPV or LSIL. N=146	ASC-US/LSIL on	increased progression from a

		90 women underwent follow-up with colposcopy and biopsy. 29 (32%) had CIN2+.	high-grade lesion; however, HIV positive women were found to have a statistically significant increase in CIN2+ that was confirmed with histological samples, p =0.002, adjusted OR 2.17, 95%CI (1.33-3.62).
			Due to this difference it is of great importance that HIV positive receive recommended cervical cancer screening and appropriate follow-up when even minimally abnormal cytology is present.
Denslow Rositch Firnhaber Ting Smith (2014)	Incidence: Included 15 cohort studies with observational data including 5882 HIV positive women Progression: Included 11 cohort studies with data from 1099 HIV positive women	Cervical cancer caused by infections with HPV genotypes that cause cancer and HIV are strongly associated with increased prevalence, incidence, and persistence of HPV infection. Women with HIV have an incidence rate of cervical abnormality three-fold their negative	HIV-positive females have a higher incidence of cervical cancer and cervical dysplasia progresses faster in HIV-positive females than their non-infected counterparts. It would be advantageous to integrate women's health with HIV care.

Frazier et al. (2016)	TX between August 2012-November 2012 N=33 Cross-sectional analysis of weighted data retrieved from chart reviews of women who received care at specific sites. Logistic regression to	Facilitators included strong provider-patient relationships and knowledge of increased risk for cervical cancer. STI and cervical cancer screening are suboptimal in HIV + women. Factors that affect screening rates were age ≥50, not sexually active, no OBGYN provider,	Even in women receiving appropriate HIV care cervical cancer screening was found to be suboptimal. Integration of women's health-
	Participants were HIV positive females, receiving care at an HIV clinic in Houston,	cervical cancer is preventable, limited transportation, and systemic issues with scheduling.	providers about patient's barriers and facilitators should be used and cervical cancer screening should be
(2014)	Focus groups guided by the Health Belief Model	discomfort of both pap and follow up procedures, lack of awareness that	should include cancer screening.
Fletcher et al.	Qualitative focus groups	counterparts and HIV-positive women are twice as likely to have cervical lesions that progress in severity. The use of ART/HAART were not shown to be significantly linked to progression. Barriers include pain and	Holistic approaches to HIV/AIDS care

Howard Agarwal Lytwyn (2009)	N=2270 Systematic Review Meta-Analysis was used to compare accuracy of self-report preventative cancer screening to medical record. Articles Reviewed were 37	Analysis found that women over report preventative health screening such as pap smears and mammography.	testing for sexually transmitted infections with HIV care would provide improved outcomes. Strategies to strengthen engagement of HIV positive women to receive cervical cancer screening and testing for sexually transmitted infections should be deployed and are an important aspect of providing health care to HIV positive women. Self-report of cervical and breast cancer should be confirmed by medical records.
Koethe Moore Wagner (2008)	Retrospective cohort study that reviewed health record of HIV positive females receiving care at a clinic in New Haven, CT during the years 2001-2002.	When measuring frequency of health maintenance measures such as cervical cancer screening, lipid testing, influenza vaccine administration and mammography,	Women with HIV are found to more economically disadvantaged compared to HIV positive men and report greater obstacles to obtaining care.

rates of cervical cancer screening are lowest amon infectious diseas specialists (47% vs 55% for generalist).	
	Increasing treatment with HAART increases the HIV positive patient's life span, therefore integration of health maintenance resources should be considered in the primary HIV care setting.
	There is potential improvement to integrate women's health into HIV primary care and provide a source for in-house screening.
ohort Short Only 58% of participants had least one pap smear during a 3 year period of care. 2002 33% of the females who did undergo cervical cancer screening had an abnormal result	primary care
cancer screening had an abnorm	ng

			provider would likely be considered their primary care provider. HIV positive patients deserve the same type of routine care as their HIV negative counterparts, therefor these screenings should be integrated into HIV care.
Logan Khambaty D'Souza Menezes (2010)	Retrospective Chart Review Retrospective random chart review of 200 women receiving HIV care at a Florida Health Department between January 2000 and May 2006 N= 200	83 % of HIV positive women received a pap smear during the first year after diagnosis. Only 24.5% received a second pap smear to meet IDSA and CDC recommended screening. Insurance status was significantly related to receipt of cervical cancer screening as 64.7% of women who had not received a pap smear had no insurance coverage, p=0.0185.	Integration of HIV primary care and gynecological care would be beneficial to increased adherence of appropriate screening. Continuity and coordination of follow-up should be handled by the HIV positive patient's primary care provider, which often by definition is the HIV care provider. There should be a mechanism in place to ensure proper follow up for HIV positive women concerning cervical

			cancer screening and follow up.
Musa et al. (2013)	Cross-Sectional Study Bivariate and multivariate logistic regression N=89	44.9% of women with normal cervical cytology had detectable high-risk HPV 40/89.	Presence of high- risk strains of HPV should be evaluated in HIV positive women even with normal cervical cytology.
		Although immune compromised states have been noted to decrease clearance of HR HPV infections in HIV positive women, this study did not find a correlation between HPV presence and CD4 or viral load.	Recommendations for further research to determine if the presence of HR HPV in the presence of normal cervical cytology is a predictor of cervical dysplasia or cancer over time.
Nonzee et al. (2015)	Semi-structured qualitative interviews Semi-structured interviews with women recruited receiving follow-up care for breast or cervical cancer diagnosis at federally qualified health clinics and health departments N=138	Barriers to adherence noted were (a) lack of knowledge of resources, (b) denial or fear, (c) competing obligation and (d) embarrassment. Facilitators to care were (a) abnormality identification, (b) patient activation, (c) provider- initiated activation and (d) motivation from family and friends	Patient centered educational interventions are an important aspect of compliance to follow up in minority women. Development of interventions that address barriers to health care for vulnerable populations is critical to provide effective and equitable health care.

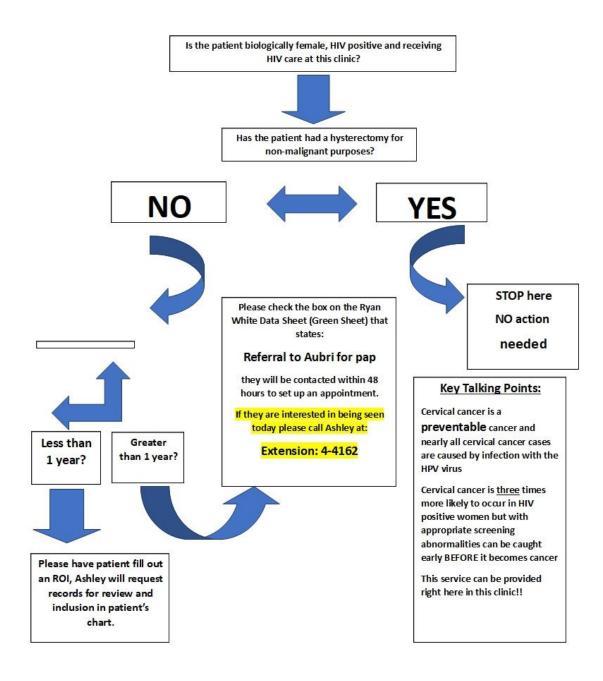
Oster Sullivan Blair (2009)	Retrospective qualitative data review Data was reviewed of HIV positive females interviewed in sites located in 18 states. Reasons for not getting annual pap smears was reviewed and logistic regression was used to draw conclusions N=2417	23% of women reported not receiving pap smears. Chance of not receiving appropriate screening increased with age, lower CD4 counts, and not receiving pap smear at primary HIV provider location.	Education to providers should be provided. Education to patients about screening recommendations and importance should be discussed with patients. Integration of HIV and gynecological care should be implemented if possible to increase adherence.
Panel on Opportunistic Infections in HIV- Infected Adults and Adolescents. (2013)	Guideline Expert opinion	HPV 16 alone accounts for 50% of cervical cancers within the general population. HPV 18 accounts for 10-15% and all other high-risk strains of HPV account for less than 5% each. HPV has an increased prevalence in women prior to age 30, therefore routine HPV cotesting should not be performed in this age group. HIV positive women who are sexually active and ages 21 and younger may have a higher rate of progression of	Cervical cancer screening should be started within one year of sexual activity, regardless of mode of transmission and continue throughout the patient's lifetime. HPV cotesting should be performed at baseline and repeated every three years if both cervical cytology and HPV are negative for women age 30 or older. If HPV co-testing is not performed then a cervical cytology should be performed every year until the patient has three consecutive results that are normal,

		1 1	,1 1 ₁
		abnormal cervical cytology than women in older age groups as well as HIV negative females.	then every three years is adequate. For women, less than 30 years of age cervical cytology should be performed annually, and HPV testing should only be ordered as a reflex for abnormal results. Follow up for ASC-US with positive HPV and LSIL (regardless of HPV results) requires colposcopy and appropriate follow-up. Normal cervical cytology with HPV 16 or 18 detected also require referral for follow-up with colposcopy.
Rahangdale et al. (2010)	Retrospective cohort study of medical records of HIV positive women receiving care at a county-based HIV clinic in San Mateo, CA from January 1, 2002-December 31, 2006. N=69	Out of the women who met inclusion criteria (receiving care for a continuous period of 12 months) 77.9% (53) received at least one cervical cancer screening during the study period. 59.5% (47) who had normal cervical cytology had a subsequent screening within 18 months of the first. 33.3% (23) women had one or	Due to increased incidence of cervical dysplasia and cervical cancer in HIV positive women, education and promotion of cervical cancer screening should be vigorously provided to women seeking care within a primary HIV clinic. Although women received some of the recommended screening, efforts

		more abnormal pap smears. Only 62% of women who had abnormal cervical cytology had follow up within one year.	should be made to ensure consistent appropriate screening.
Simonsen et al. (2014)	Retrospective cohort study of HIV positive women receiving care at the University of Utah's Infectious Disease Clinic during 2009	Cervical cancer screening was documented for 56.8% of HIV positive women.	Effective patient- provider communication improved quality of care.
	N=192	HIV negative women comparatively were documented at 74%.	Patients that receive care at Ryan White Funded clinics often do not have access to care outside of the
		One-third of the HIV positive women had no health insurance.	clinic. Therefore, efforts should be made to provide preventative health care, such as
		Women with private insurance are less likely to receive a pap smear (p=0.025).	cervical cancer screening within the clinic setting. Often women with
		This correlation could be due to copay required at outside clinics.	health insurance cannot afford copayments for preventative health care services at non-Ryan White facilities, making integration increasingly important.

			Efforts should be made to incorporate cancer screenings, STI testing, and safe-sex counseling from both a provider and a public health standpoint.
Williams et al. (2015).	Qualitative cohort study In-depth qualitative interviews based on the health belief model and the PEN-3 to ascertain why women do or not undergo routine cervical cancer screening N=20	Found multiple reasons women did not undergo cervical cancer screening such as (a) lack of knowledge of risk, (b) fear of negative diagnosis, or (c) embarrassment. Factors that increased compliance were education from provider and social support.	It was noted that lack of education was a significant theme noted in both women who had paps and those who had not. This fact makes it possible that provider-initiated referrals and suggestions for cervical cancer screening can have a significant impact. Development, implementation, and evaluation of health education interventions should be culturally sensitive.

APPENDIX B - Provider Initiated Algorithm



APPENDIX C – Ryan White Data Tracking Sheet

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APPENDIX D – Self-Certification Form for Determining Whether a Proposed Activity is

Research Involving Human Subjects

Self-Certification Form for Determining Whether a Proposed Activity is Research Involving Human Subjects

When to Use this Form:

- 1. If you need documentation for funding agencies, administrators, or collaborators
- 2. If you are unsure whether or not you need to submit your project to the IRB
- 3. If you are unsure if your project is research
- 4. If you are unsure if your research involves human subjects

This form is not an Exempt Certification or IRB review

Administrative Information

Exemptions are a type of IRB review. If your project meets the definition of human subjects research you must submit the project to the IRB for review.

Your Name	Aubri Hickman	Degree(s) +
Mailing Address	2050 Birdsong Road Vicksburg MS, 39183	Department Phone Email
Project/Study/Grant Title/Award#	Increasing Cervical Cancer S	Screening in HIV Positive Women by Introduction of a thm Tool: A Quality Improvement Project
1) Is your project "	research"?	
development, testing and eva	aluation, designed to devel institute research for purpo	systematic investigation, including research op or contribute to generalizable knowledge. Activities, ses of this policy, whether or not they are conducted or ch for other purposes.
Is your project a "systematic investigation"?	⊠.No	
investigation r		an activity that involves a prospective research plan that ther quantifative or qualitative, and data analysis to answer a
		os a prodetamined method for studying a specific topic answering poeffic hypothesis, or developing theory.
	interview (including those that	stigations include, but are not limited to, observational studies, are open-ended) or survey studies, group comparison studies, test- ion and interventional research.
Is the primary intent of the project for the purpose of	⊠ No □ Yes	
contributing to generalizable knowledge?	Investigations designed to dev- to draw general conclusions (i.	elop or contribute to generalizable knowledge are those designed e., knowledge guined from a study which may be applied to life study population), inform policy, or generalize findings.
		poralizable knowledge requires that the results (or conclusions) of
	the activity are intended to be a	extended beyond a single individual or an internal program

Examples of activities that are not considered research under the above definition:

- Quality Assurance/Improvement: Activities whose purposes are limited to: (a) implementing a
 practice to improve the quality of patient care and then (b) collecting patient or provider data regarding
 the implementation of the practice for clinical, practical, or administrative purposes. Planning to publish
 an account of a quality improvement or quality assurance project does not necessarily mean that the
 project fits the definition of research
- Case Reports: The external reporting (e.g., publication, poster or oral presentation) of an interesting
 clinical situation or medical condition of up to three patients. The patient information used in the report
 must have been originally collected solely for non-research purposes as the result of a clinical
 experience.
- Public Health Surveillance: A series of ongoing systematic activities, including collection, analysis, and interpretation of health-related data essential to planning, implementing, and evaluating public health practice closely integrated to the dissemination of data to those who need to know and linked to prevention and control.

If you answered **No** to both questions, you may stop here. You are not conducting research that needs to be reviewed by the IRB. A copy of this completed form should be maintained in your project file. Do not submit a copy of this form to the IRB.

If you answered Yes to one or both questions above, continue below.

Huma	oes your project involve "Human Subjects"? In Subject is defined under 45 CFR 46.102(f) as a living individual about whom an investigator acting research obtains:
1.	data through intervention or interaction with the individual, or
2.	identifiable private information.
	Does the project involve \No

nation.
.No
No. Yes "Private Information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving burnan subjects.
☐.No ☐ Yes (and answer two questions below)
Are the data/specimens coded such that they could not be re-identified without access to a link?
Is there a written agreement that prohibits No you and your staff access to the link? Yes

4.15.16, Version 3.5

If you answered **No** to all 3 questions in section 2, or **No** to the first two questions and **Yes** to the third question and both sub-parts, you are not conducting research that needs to be reviewed by the IRB. A copy of this completed form should be maintained in your project file. Do not submit a copy of this form to the IRB.

Any other combination of answers means that the proposed activity may be research that involves human subjects. You must submit an application to the IRB before starting your project. Visit the IRB's website,

Your Signature

Date Print Name Signature

4.15.16, Version 3.5

09/24/2017 Aubri Hickman, RN, MSN, FNP-C

I certify that the information above is true and accurate

APPENDIX E – Letter of Support



To Whom It May Concern:

Please accept this letter as my written support for Aubri Hickman's Doctoral Project, entitled: "Increasing Cervical Cancer Screening in HIV Positive Women by Introduction of a Provider Prompted Algorithm Tool: A Quality Improvement Project."



Please see attached IRB Self-Certification Form for Determining Whether a Proposed Activity is Research Involving Human Subjects. Due to the nature of the project there are no further actions needed from

Please feel free to contact me should you have any additional questions.

Sincerely,

Deborah Konkle-Parker, PhD, FNP, FAAN Professor, Division of Infectious Diseases

APPENDIX F - USM IRB Approval



INSTITUTIONAL REVIEW BOARD

118 College Drive #5147 | Hattiesburg, MS 39406-0001

Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional.review.board

NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- · The risks to subjects are minimized.
- · The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- · Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
 - If approved, the maximum period of approval is limited to twelve months.

 Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 1710171702

PROJECT TITLE: Increasing Cervical Cancer Screening in HIV Positive Women by Introduction of a

Provider Prompted Algorithm Tool: A Quality Improvement Project

PROJECT TYPE: New Project
RESEARCHER(S): Aubri Hickman
COLLEGE/DIVISION: College of Nursing

DEPARTMENT: Systems Leadership and Advanced Nursing Practice

FUNDING AGENCY/SPONSOR: N/A

IRB COMMITTEE ACTION: Exempt Review Approval PERIOD OF APPROVAL: 10/17/2017 to 10/16/2018

Lawrence A. Hosman, Ph.D. Institutional Review Board

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