Evaluating a Quality Improvement Program for Cervical Cancer Screening Guideline Compliance

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Abstract

The unprecedented 2012 alignment of national cervical cancer screening recommendations indicates that the time is right for implementing strategies to improve screening guideline compliance in the primary care practice setting. The aim of this project was to evaluate a systematic quality improvement program for cervical cancer screening designed to improve compliance with national recommendations in an urban free clinic setting. The Theory of Diffusion of Innovations and the Awareness-to-Adherence Conceptual Model were integrated to provide a framework to improve program outcomes. With a focus on changing practice policies, the question guiding this study was: What are the outcomes of the implementation of a systematic, guideline-based quality improvement program for cervical cancer screening in terms of compliance with national clinical practice guidelines for screening in an urban free clinic setting? The provider- and workflow-based strategies implemented in the quality improvement program included 1) the addition of a clinical decision support system, 2) provider educational outreach, 3) patient reminder letters, and 4) the development of a procedures manual. An established quality measure guided the selection of the quality indicators, specifically patients screened according to evidence-based guidelines, patients who were not screened, and patients screened more frequently than recommended. A chi-square test of independence indicated that the proportions in each quality indicator category at baseline were significantly different from those at 12-months' post-programmatic implementation. The first quality indicator -- the number of patients screened according to guidelines – nearly doubled. Conversely, the number of unscreened patients as well as the number of patients screened more frequently than recommended significantly decreased.

Key words: cervical cancer screening, evidence-based guidelines, guideline compliance, quality improvement, implementation strategies, interventions

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Section I: Introduction

As recently as the 1940s, cervical cancer was the most common cause of cancer deaths among women in the United States (U.S.). Screening and early detection, in addition to more effective treatment methods, reduced the mortality rate from cervical cancer by 74% between 1955 and 1992 (American Cancer Society [ACS], 2013). From 2005 to 2009 the incidence rate in Virginia was 6.6 cases per 100,000 women compared to 8.1 cases in the United States (Virginia Department of Health [VDH], 2012). In 2012, the VDH reported 2.1 deaths per 100,000 women in Virginia from cervical cancer, with the U.S. slightly higher at 2.4 deaths per 100,000 women over the period from 2006 to 2010.

Although these incidence and mortality rates of cervical cancer are relatively low, it is important to note the strong link to socioeconomic, geographic, and racial disparities. Women who have low income and educational levels, those who have immigrated to the United States in the past 10 years, and those who are uninsured account for the majority of cervical cancer cases (National Center for Health Statistics, 2011). The Hispanic population represents the highest incidence rate and the Black population exhibits the highest mortality rate (U.S. Department of Health and Human Services [DHHS], Centers for Disease Control and Prevention [CDC], 2012).

Inadequate screening plays a role in these disparities as reflected in the significant difference in the cervical cancer screening rates for women with commercial insurance (80.8%) compared to those who are Medicaid-insured (66.0%) and uninsured (63.8%) (CDC, 2012; DHHS, Health Resources and Services Administration, 2011). The *Healthy People 2020* agenda acknowledges this problem in its goal "to achieve health equality and eliminate disparities" (DHHS, Office of Disease Prevention and Health Promotion, 2012). *Healthy People 2020* set an ambitious improvement target at 93.0 percent, using

the baseline of 84.5 percent of females in the U.S. aged 21 to 65 years who received cervical cancer screening.

In addition to inadequate screening, the literature clearly identifies the practice of screening many low-risk women for cervical cancer more frequently than recommended. This over-screening generates needless healthcare expenditures, patient inconvenience, and harm from false-positive results and unnecessary invasive procedures (U.S. Preventive Services Task Force, 2012). In fact, an estimated $4 billion are spent each year in the U.S. on diagnostic tests and treatment visits to address abnormal screening results that are unlikely to progress to cancer (Schiffman et al., 2011). Because addressing the problems of under- and over-screening are likely to both increase healthcare quality and reduce healthcare costs, cervical cancer screening provides a rich context for examining organizational processes regarding appropriate use in the clinical practice setting. Recent health policy initiatives incorporate systems strategies into primary care with the goal of improving the use and quality of cancer screening in the United States (Yabroff et al., 2011). Therefore, the aim of this project was to evaluate a systematic, guideline-based quality improvement program for cervical cancer screening designed to improve compliance with national recommendations for screening in an urban free clinic setting.

Background

Epidemiology. Cervical cancer is caused by carcinogenic types of human papillomavirus (HPV), with approximately 55% to 60% of the cases caused by HPV type 16, 10% to 15% by HPV type 18, and the remaining 25% to 35% caused by ten other HPV genotypes (Saslow et al., 2012). This causal link has led to the development of a new model for cervical carcinogenesis -- viral acquisition, viral persistence vs. clearance, precancerous lesion, and invasion -- with a typical time lapse of 15 to 20 years (Saslow et al., 2012). The goal of cervical cancer screening is to identify the few women with detectable persistence of an oncogenic type of HPV with

accompanying precancerous cervical neoplastic changes since the immune systems of most women (approximately 90%) spontaneously resolve HPV infections within one to two years after exposure. Therefore, the optimal screening strategy would maximize the benefits while at the same time minimize the potential harms.

Historical Perspective. Screening for cervical cancer has been routinely recommended since 1957 when the ACS endorsed annual screening. From this initial recommendation until 2000, cervical neoplastic changes were identified solely through the use of cervical cytologic testing also known as the Papanicolaou test (Pap test). With a sensitivity of 51% and specificity of 97% (Sawaya et al., 2003), results of Pap testing were commonly false-positive; because of this low sensitivity, annual screening was the recommended interval in order to achieve programmatic effectiveness. In the late 1990s, mounting evidence suggested a very low cervical cancer risk in women with three or more consecutive negative Pap tests which led to the development of the hypothesis that the screening interval could be extended with comparable outcomes. To test this hypothesis, a study of screening tests performed on 31,728 women 30 to 64 years of age between January 1991 and March 2000 estimated that the risk of cancer within three years in women with historically negative pap results was very low at approximately 3 in 100,000 (Sawaya et al., 2003). These results as well as those from other well-designed studies led to the addition of the option to extend the screening interval to three years for low-risk women in the ACS 2002 guidelines (Saslow et al., 2002).

Soon after this initial introduction of the extended screening interval, the U.S. Food and Drug Administration (FDA) in 2003 approved HPV DNA testing as an adjunct to cytologic testing (referred to hereafter as ‘cotesting’) for women ages 30 years and older (FDA, 2003). With the security of a greater than 99% negative predictive value, cotesting was found to increase the lead time for diagnosing women with high-grade lesions or cancer by ten or more

years thus permitting a longer interval between screenings (Saraiya et al., 2010; Saslow et al., 2012). As a result of this longer interval, fewer women will be referred for diagnostic and treatment procedures to address abnormalities that most likely would never have progressed to cancer thus reducing patient burden and anxiety related to more frequent screening (Jain et al., 2007).

Problem Defined

Most research on cancer screening in the U.S. to date has been focused on promoting the increased use of testing with few studies assessing appropriate use (Habbema, De Kok & Brown, 2012). Even with a ten-year history of recommendations for longer screening intervals, more intensive screening continues to be common practice in the U.S. Improved targeting of higher-risk patients accompanied by decreased overuse in lower-risk patients has the potential to increase efficiency and reduce healthcare costs which are of particular importance in the free clinic setting. The effective quality improvement program would, therefore, address the socioeconomic, geographic, and racial disparities that are linked to under-screening while at the same time decrease over-screening by reducing the use of low-value testing.

The *Healthy People 2020* benchmark provides guidance toward achieving this goal of appropriate use of cervical cancer screening: "to increase the proportion of women who receive cervical cancer screening <u>based on the most recent guidelines</u>" (underline added) (Objective C-15, DHHS, Office of Disease Prevention and Health Promotion, 2010). The variability in clinical practice guidelines from influential professional organizations over the past two decades has, however, caused much confusion regarding best cervical cancer detection practices (Han et al., 2011).

Fortunately, an increased understanding of the natural history of HPV infection and its role in the development of cervical cancer accompanied by improved testing has led to the alignment

Table 1

Summary of 2012 Revised Cervical Cancer Screening National Guidelines

Population	USPSTF	ACS, ASCCP, ASCP	ACOG
Younger than 21 years	Recommends against screening. Grade: D recommendation.	Women should not be screened regardless of the age of sexual initiation or other risk factors.	Women should not be screened regardless of the age of sexual initiation or other risk factors.
21–29 years of age	Recommends screening with cytology every 3 years. Grade: A recommendation.	Screening with cytology alone every 3 years is recommended.	Screening with cytology alone every 3 years is recommended.
30–65 years of age	Recommends screening with cytology every 3 years or for women who want to lengthen the screening interval, screening with a combination of cytology and HPV testing every 5 years. Grade: A recommendation.	Screening with cytology and HPV testing ("co-testing") every 5 years (preferred) or cytology alone every 3 years (acceptable) is recommended.	Screening with cytology and HPV testing ("co-testing") every 5 years (preferred) or cytology alone every 3 years (acceptable) is recommended.
Older than 65 years of age	Recommends against screening women who have had adequate prior screening and are not otherwise at high risk for cervical cancer. Grade: D recommendation.	Women with evidence of adequate negative prior screening and no history of CIN2+ within the last 20 years should not be screened. Screening should not be resumed for any reason, even if a woman reports having a new sexual partner.	Women with evidence of adequate negative prior screening and no history of CIN2+ within the last 20 years should not be screened. Screening should not be resumed for any reason, even if a woman reports having a new sexual partner.
After hysterectomy	Recommends against screening in women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (i.e, CIN 2 or 3) or cervical cancer. Grade: D recommendation	Women of any age following a hysterectomy with removal of the cervix who have no history of CIN2+ should not be screened for vaginal cancer. Evidence of adequate negative prior screening is not required. Screening should not be resumed for any reason, including if a woman reports having a new sexual partner.	Women of any age following a hysterectomy with removal of the cervix who have no history of CIN2+ should not be screened for vaginal cancer. Evidence of adequate negative prior screening is not required. Screening should not be resumed for any reason, including if a woman reports having a new sexual partner.
HPV vaccinated	Women who have been vaccinated should continue to be screened.	Recommended screening practices should not change on the basis of HPV vaccination status.	Recommended screening practices should not change on the basis of HPV vaccination status.

USPSTF - United States Preventive Services Task Force; ACS - American Cancer Society; ASCCP - American Society of Colposcopy and Cervical Pathology; ASCP - American Society of Clinical Pathologists; ACOG - American College of Obstetrics and Gynecologists

of recommendations regarding the timing of cervical cancer screening initiation, the conditions warranting discontinuation of screening, and the extension of the screening interval (Moyer, 2012). In 2012, revised guidelines were released (see Table 1) by the most influential national organizations perceived by U.S. primary care clinicians in a 2006-7 national survey (Han et al.,

2011). These include the U.S. Preventive Services Task Force (USPSTF), American Cancer Society (ACS), the American Congress of Obstetricians and Gynecologists (ACOG), the American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society of Clinical Pathology (ASCP)(ACOG, 2012; Moyer, 2012; Saslow et al., 2012). Unlike the conflicting cervical cancer screening guidelines of the past, these major national guidelines are now aligned allowing practice to move forward toward efficient and effective cervical cancer screening.

Despite recent guideline alignment, a large gap persists between what is known and what is consistently done 'in the real world', and the availability of evidence-based guidelines alone is insufficient to change practice. Application of theoretical frameworks and conceptual models will shed light on how best to begin to close this gap.

Theoretical Frameworks and Conceptual Models

Theory of Diffusion of Innovations (DOI). Individuals seldom adopt a new idea on impulse -- gaining an awareness of a new idea is a necessary first stage toward adoption. According to the theory of DOI, once awareness is generated, the second stage is being persuaded that the new idea is favorable. This need for persuasion explains why, although guidelines indirectly influence practice by creating provider awareness, they should not be expected to immediately persuade providers to adopt them (Rogers, 1995).

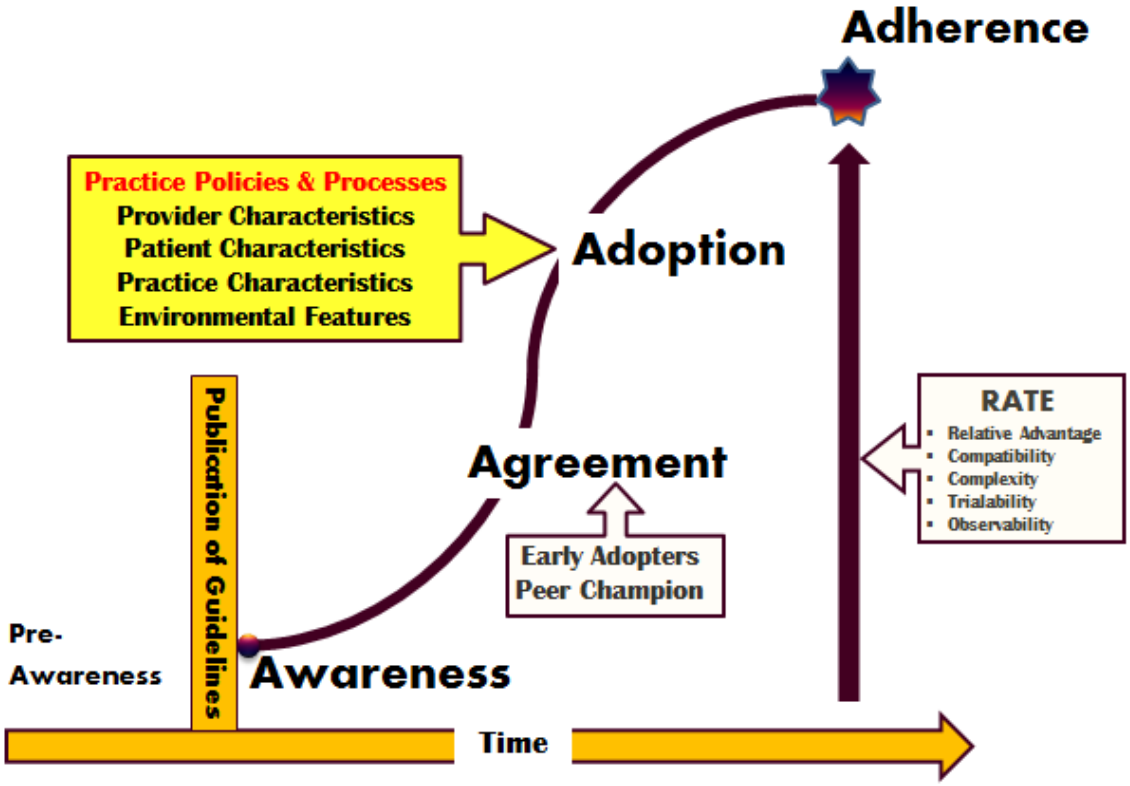
According to Rogers (1995), social constructs play a significant role in the adoption of an innovation. Providers are, therefore, often persuaded by early adopters who serve as peer champions. They are also persuaded by the degree to which they perceive a guideline to possess the attributes of innovation – relative advantage, compatibility, complexity, trialability, and observability. These attributes along with the engagement of peer champions should be considered when designing guideline implementation strategies.

Awareness-to-Adherence Conceptual Model. Building on these attributes identified as predictors of provider awareness and agreement, Pathman, Konrad, Freed, Freeman and Koch (1996) presented the awareness-to-adherence model as a template for explaining the process of guideline utilization. Developed to explain pediatric vaccine guideline adoption practices, Pathman et al. (1996) postulated that "there are sequential, cognitive, and behavioral steps [providers] make as they comply with a guideline." While not specifically noted, the awareness-to-adherence model parallels the transtheoretical model of behavior change. In the awareness-to-adherence model, providers, initially unaware of a specific guideline, progress through a series of four stages: first, they become aware of the guideline, then they intellectually agree with it, followed by the decision to adopt it for some patients, and finally follow the guideline at appropriate times for all patients (Pre-awareness → Awareness → Agreement → Adoption → Adherence). This model further identifies certain factors which facilitate or hinder movement along these steps including practice policies, provider, patient and practice characteristics, and environmental features.

Guideline Adoption Model. The addition of these factors to the theory of diffusion of innovations will paint a more accurate picture of the awareness-to-adherence process. Therefore, for purposes of this study, the guideline adoption model (Figure 1) was developed to integrate the awareness-to-adherence model with the theory of diffusion of innovations in order to better illustrate the influential factors on the stages over time. The effect development and implementation of ‘practice policies’ (highlighted in red) has on facilitating movement toward adherence to guidelines in the primary care setting is of particular interest for this study.

Figure 1

Guideline Adoption Model



(Adapted from Rogers, 1995 and Pathman, et al., 1996)

Research Question

With this focus on practice policies, the following question guided this study: What are the outcomes of the implementation of a systematic, guideline-based quality improvement program for cervical cancer screening in terms of compliance with national clinical practice guidelines for screening in an urban free clinic setting? To begin to answer this question, a review of the literature focused on provider adoption practices of cervical cancer screening guidelines is presented through application of the guideline adoption model.

Definition of Terms

The following terms are defined in context of how they are used in the study:

Cervical cancer - A typically slow-growing asymptomatic cancer that forms in tissues of the cervix (the organ connecting the uterus and vagina) the presence of which is identified through periodic cytologic testing and HPV-DNA testing (National Cancer Institute, 2013).

Pap test – A procedure in which cells are scraped from the cervix for examination under a microscope. It is used to detect cancer and changes that may lead to cancer (National Cancer Institute, 2013).

HPV DNA test – A molecular test that detects the presence of high risk cervical human papillomaviruses (National Cancer Institute, 2013).

Low-value testing – testing performed sooner than recommended (Mathias, Gossett & Baker, 2012).

Clinical practice guidelines - systematically developed statements to assist practitioner and patient decisions about appropriate screening for cervical cancer (Cabana et al., 1999). These statements contain recommendations that are based on evidence from a rigorous systematic review and synthesis of the published medical literature.

Quality improvement program - a program of related activities designed to achieve measurable improvement in processes and outcomes of care through interventions that target health care providers, organizational processes, and patients (DHHS, Centers for Medicare & Medicaid Services, 2003).

Implementation strategies – specific interventions that are deployed to provide the necessary information, knowledge, skills, incentives, and infrastructure for adherence (Flanagan, Ramanujam & Doebbeling, 2009).

Section II: Review of Literature

A decade has elapsed since the first recommendation was made to extend the screening interval for cervical cancer in low-risk women. Are providers of women's preventive care aware of this recommendation? If so, do they agree with it? To what extent are providers of women's preventive health care adopting cervical cancer screening guidelines and are they following them appropriately at all times?

To answer these questions, a search of MEDLINE, the Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature databases was performed to identify studies that report provider cervical cancer screening guideline adoption practices with a primary outcome of cervical cancer screening interval frequency. Search terms included *cervical cancer, screening practices, guideline adoption, screening interval, human papillomavirus, HPV, cotesting,* and *practice patterns*. An ancestral search was also performed to identify pertinent studies with unique titles which were not found using the search terms. The combined initial and ancestral searches resulted in 11 studies which used survey methodology, and five studies which analyzed providers' actual ordering practices for a total of 16 studies.

The following inclusion criteria were then applied: 1) unique articles published after 2002 (the first release of guidelines citing screening interval extension for low-risk women as an option) through 2012, and 2) articles which included reports of screening interval frequency by physician and non-physician providers. Exclusion criteria included non-English studies performed on non-U.S. subjects and those studies performed prior to 2002 which did not directly report screening interval frequency findings. After application of these criteria, seven studies (five survey studies and two retrospective observational studies examining provider ordering practices) remained (see Table 2). Findings from this review will be presented using the stages of the guideline adoption model.

Table 2

Summary of Literature Review Studies

Study	Purpose	Sample Size	Methodology	Findings	Limitations
Cross-Sectional Self-Report Studies					
2003 Noller, et al.	To document the current cervical cytology screening practices of Fellows of ACOG before the widespread implementation of the revised guidelines	N=651 of 1,008 questionnaires mailed December 2001 --n=599 ACOG fellows --n=409 group of Fellows who have regularly participated in past ACOG surveys	**Cross-sectional study** National survey Descriptive statistics used to evaluate the responses ---64.6% response rate -- random sample	Reported frequency: Vignette of low-risk woman with w/3 consec neg paps: Q1yr - 75%, Q3yr - **11.5%** Reasons: pt hx 72%, pt demand 58.5%, legal concerns 44.5%, "other" 22.8%, insurance reimbursement 12.5, lack of insurance 8.2%	--Self-reported practices may not reflect actual practice --Ob-Gyns only specialty surveyed
2005 Saint, Gildengorin & Sawaya	To determine the present cervical cancer screening practices of OBGYNs in the US subsequent to the 2002 publication of ACS guidelines	N=185 of 355 questionnaires mailed May/June 2003	**Cross-sectional study** --Random sample (randomization not described) of 40,000 US practicing OB/Gyns --Pilot tested for clarity --60% response rate	Reported frequency: 35yo w/3 consec neg paps: Q1yr 60.0%, Q≥3yr-**17.8%** 35yo w/3 consec neg paps - anxious desires q6mos screen: Q6mo 24.9%, Q1yr-68.6%, **Q≥3yr-1.6%** No data on use of human papillomavirus (HPV) cotesting	--Self-reported practices may not reflect actual practice --private practice/managed care Ob-Gyns only surveyed so questionable whether representative --Northeast under-represented
2007 Murphy & Schwarz	To assess current practices among nurse practitioners regarding screening for cervical cancer	N= 134 NP responses from 394 emailed invitations to participate with a pre-notice and reminder emails -sample of national population of NPs N=124 after exclusion criteria	**Cross-sectional study** Stratified random sample - questionnaire -38.6% response rate Saint questionnaire used (see above)	Reported frequency: --35yo w/3 consec neg paps: --Q1yr 31.5%, Q3yr 37.1% --35 yo w/3 consec neg paps - anxious desires q6mos screen --Q6mo-7.3%, Q1yr-69.4%, **Q≥3yr-11.3%** --No data on use of HPV cotesting --30% of NPs surveyed reported more frequent screening than was recommended	--Relatively low response rate --Self-reported practices may not reflect actual practice --Omitted data r/t cotesting
2008 Murphy, Schwarz, & Dyer	To examine the practices of certified nurse midwives in screening for cervical cancer	N=127 out of 264 questionnaires mailed to ACNM members September 2006	**Cross-sectional study** Randomized questionnaire Saint tool used (see above) 58% response rate	35yo w/3 consecutive negative paps: Q1yr 27.6%, Q≥3yr 39.4% 35yo w/3 consecutive negative paps - anxious desires q6mo screen Q6mo 10.2%, Q1yr-74.8%, Q≥3yr-7.1% No data on HPV use	--Self-reported practices may not reflect actual practice --Omitted data r/t cotesting

2009 Yabroff, et al.	To assess current primary care physicians' cervical cancer screening practices in the United States	N=1,212 out of 1948 questionnaires mailed to AMA physician members in 4 specialties: general practice, family practice, general internal medicine, & ob/gyn September 2006	**Cross-sectional study** using a stratified random sample - Questionnaire data tool Limitations: Physician self-report may reflect idealized rather than actual practice.	35yo w/3 consecutive negative paps: Q1yr 31.3%, Q3yr 33.1% Overall, 84.3% of MDs believe screening guidelines are influential to their practice	--Self-reported practices may not reflect actual practice --self-reports not validated through medical records review --cotesting was not studied

Retrospective Longitudinal Studies of Cervical Pathology Specimen Orders

2010 Thrall, et al.	To systematically monitor the follow-up cervical testing of women who had cytology interpreted as negative for intraepithelial lesion or malignancy (NILM) and HR-HPV cotesting to quantify these observations	N=2,719 tests from 2,686 unique female patients	**Retrospective longitudinal study** January 1, 2006 - July 31, 2008 --The computerized laboratory records for URMC were reviewed for the one-year period to find all pap tests interpreted as NILM with HPV cotesting. --F/U pap test, HPV test and biopsy results were also retrieved for this period --(deidentification prior to elimination of same year cotesting) --Rereview of all HR-HPV+ NILM pap tests was done as a quality assurance measure	Actual F/U Rates in NILM HR-/ HPV- women: 51.8% had another pap within 18 mos (13.4% of which had pap plus HR-HPV testing) These repeats led to 2 HG lesions - 0.007% Summary: Only about half of all women had follow-up consistent with published recommendations	--no way to account for women who followed up at a location that used a different laboratory --limited to ordering habits of one geographic area
2012 Tatsas, Phelan, Gravitt, Boitnott & Clark	To document the follow-up patterns and pathologic findings in a cohort of women undergoing testing as a part of routine clinical care To extend observation of trends in ordering practices for pap tests and associated HPV tests and to further assess temporal changes in cervical cancer screening practices based on specimens submitted to a laboratory	N=75,396 After exclusion criteria: N=3,081 pts with dual negative cotesting Total reviewed: 69,570 pap specimen records and 17,518 HPV test specimens from 50,392 unique patients submitted from 723 unique providers among 115 unique clinics in Baltimore MD	**Retrospective longitudinal study** --analysis of Pathology Data system data at Johns Hopkins Hospital Dept of Pathology --PDS data were deidentified to create a limited dataset of all SurePath liquid-based pap specimens from 1/1/08 to 6/30/10 for the analysis Monthly proportions by age group 18-29 or 30+ --screening interval extension was calculated by tracking all patients who received a dual negative cotest result in year 1 and recorded all repeat pap & HPV testing results during the remainder of study Joinpoint Regression --Program used to identify significant monthly chgs in slope of the trend	Screening interval extended: 3,081 patients had dual negative cotest in yr 1 785 (25.5%) had repeat testing over 2.5 period Of these 730/785 remained negative (93.0%) – no cases of carcinoma were detected on repeat testing	HPV testing is performed before the cytologic diagnosis is rendered - $$ --no way to account for women who followed up at a location that used a different laboratory --limited to ordering habits of one geographic area

Awareness

Results of a large, randomized, nationally representative study by Yabroff et al. (2009) provide insight into the level of provider awareness of guideline recommendations. They surveyed the responders with a specific question asking whether or not they believed any screening guideline was influential to their practice. An overwhelming majority (84.3%) of the survey responders consisting of obstetrician-gynecologists (Ob-Gyns)(N=333), internal medicine physicians (N=310), and family/general practice physicians (N=471) reported that guidelines were very influential, while Ob-Gyns reported that guidelines were influential at an even higher percentage of 89.1%. These results indicated that, in general, physician primary care providers of women's preventive services consider themselves to be aware of cervical cancer screening guidelines and find them to be very influential to their practice.

Agreement

Declaration of awareness of guidelines by providers may not necessarily mean they agree with them. Although the degree to which providers agree with the guidelines regarding extension of the screening interval was not directly assessed, a study by Saint, Gilgendorin and Sawaya (2005) included one question that indirectly reflected provider agreement:

> "*The American Cancer Society (ACS) has recommended that women over age 30 years may be primarily screened with cytology plus a cervical test for types of human papillomavirus (HPV) associated with cervical cancer. The ACS recommended that if both tests are negative, screening should not be performed again for 3 years. This strategy is an alternative to more frequent screening with cytology alone. If this strategy were made available to you, would you adopt this type of screening in your practice?"* (p. 418)

Only 33% (N=185) of the respondents indicated that they would adopt the extended interval despite the recommendation. According to Saraiya et al. (2010), because cervical cancer screening and annual well-woman visits have been historically linked, this low rate may be due to concern that patients will return less frequently for other preventive services. A study of women's reasons for annual examinations did not, however, find cervical cancer screening to be one of the top three reasons (Becker, Longacre & Harper, 2004). Therefore, it must be recognized that organizations may resist implementation of screening guidelines for other reasons such as the potential for lost revenue (Weiland et al., 2011).

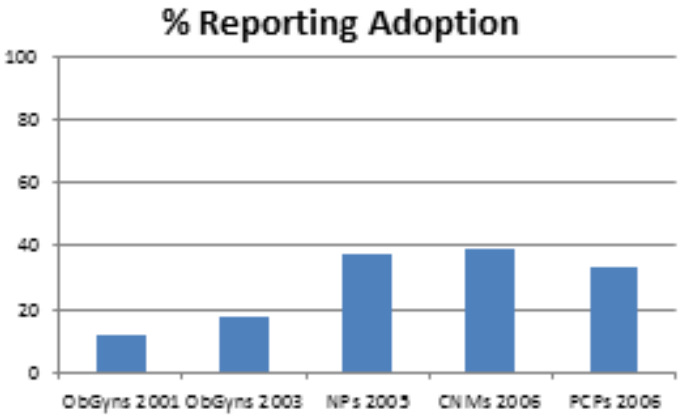
Adoption

A synthesis of the results of the seven studies also demonstrated a discrepancy between the cervical cancer screening guideline regarding extending the frequency interval in low-risk women and provider guideline adoption practices. These results are presented next as self-report (Murphy & Schwarz, 2007; Murphy, Schwarz & Dyer, 2008; Noller et al., 2003; Saint, Gildengorin, & Sawaya, 2005; & Yabroff et al., 2009) and actual practice (Tatsas, Phelan, Gravitt, Boitnott & Clark, 2012; Thrall et al., 2010).

Self-Report. Although an upward trend in the percentage of providers reporting they would recommend a three-year screening interval increased with time, providers have consistently resisted lengthening the screening interval in low-risk patients who have a history of negative screening (see Figure2). Legal concerns were found to be a contributing factor earlier in this over-screening phenomenon (Noller et al., 2003). The Noller et al. study also identified the lack of reimbursement constraints in the practice setting which would incentivize providers to consider the economic and potentially harmful effects of over-screening. Even more striking was the influence patient demand had on the choice of annual screening over extending the screening interval. Three studies that used identical surveys (Murphy & Schwarz, 2007;

Figure 2

Provider Self-Reported Adoption Rate of Extended Screening Frequency Interval



Noller et al. (2003); Saint, Gildengorin, & Sawaya (2005); Murphy & Schwarz (2007); Murphy, Schwarz & Dyer (2008); Yabroff et al. (2009)

Murphy, Schwarz & Dyer, 2008; Saint, Gildengorin, & Sawaya, 2005) provided data for determining the influence of patient request on provider behaviors. When anxiety in the low-risk patient was added to the vignette, a shift toward six-month and annual screening occurred with a subsequent decline in the two-year and three-year frequency interval recommendations. In contrast, Castle et al. (2009) reported that, after being properly educated, 91.6% of Kaiser Permanente Northern California members aged 30 years and older who participated in screening elected the cotesting option with its accompanying interval extension. These findings indicate that providing the reassurance that accompanies cotesting is sufficient to move the well-informed woman away from annual screening.

The need for education regarding extending the frequency interval does not reside with patients alone. Berkowitz and colleagues (2013) examined clinicians' reported behaviors after the endorsement of cotesting from 2006 to 2009 and found that providers do not fully understand the purpose of cotesting and are not accustomed to using the data appropriately in results management.

Actual Practice. While surveys and clinical vignettes have been shown to be valid and comprehensive tools for measuring clinical behavior, observation of actual test ordering patterns of specimens submitted to the laboratory for evaluation provides a different perspective on provider guideline adoption practices. Two studies of actual ordering practices included in this

review focused on HPV cotesting in women 30 years of age or older. Thrall et al. (2010) reported that, if the guidelines were strictly followed, none of the women with dual negative results should have had repeat testing within the ensuing three-year period. However, after only 18 months, 51.8% had repeat cytology testing. Also of particular interest is the extent to which HPV testing was inappropriately ordered. Many providers ordered HPV testing for women less than 30 years of age, and even more significant was the very large proportion of inappropriate repeat testing after appropriately-ordered HPV cotesting resulting in no identified cases of cervical cancer and only 2 high-grade lesions (0.0008%) in the almost 1,400 women sampled (Thrall et al., 2010).

The results of study by Tatsas, Phelan, Gravitt, Boitnott and Clark (2012) revealed excessive screening, albeit to a lesser extent. In this study, of the 3,081 patients who had dual negative results in year 1, 25.5% had repeat testing over the remaining 2.5 year study period with no cases of low- or high-grade intraepithelial lesions nor invasive carcinoma detected.

Adherence

Both the cross-sectional and retrospective longitudinal studies did not include interval-specific data on provider adherence practices. Murphy & Schwarz did report that, overall, 30% of NPs screened more frequently than was recommended. Along similar lines, Yabroff et al. (2009) reported that only 22.3% of the responders made guideline-consistent recommendations for all vignettes. These findings confirm the existence of a gap between the evidence and what is consistently done in ‘real world’ practice.

Summary

The findings from this review revealed high provider self-report of awareness of guidelines with low agreement and adoption of an extended screening interval despite a ten-year history of this recommendation in national guidelines. Although slight movement toward current guideline

adoption has occurred, there is strong evidence that barriers exist among a majority of providers who continue to screen annually for cervical cancer consistent with guidelines that have been in place since the 1980s. These low adoption rates are consistent with findings from reviews of provider guideline compliance (Cohen, Halvorson & Gosselink, 1994; Davis & Taylor-Vaisey, 1997). In a systematic review of guideline adoption practices, Davis and Taylor-Vaisey (1997) found guideline compliance barriers to include provider and patient knowledge deficits, the inertia of established practice, a paucity of cost containment incentives by payers and insurers, and a lack of organizational processes. These barriers extend beyond provider resistance and addressing them is essential to achieve improved guideline compliance.

Implications for Practice

Although historically the existence of multiple conflicting guidelines was a significant barrier to guideline compliance, an unprecedented alignment of national cervical cancer screening recommendations indicates that the time is right for implementing strategies to improve screening guideline compliance in the primary care practice setting. According to Grimshaw et al. (2001), targeting compliance barriers with active, multifaceted implementation strategies is more likely to be effective than passive, single strategies. Additionally, guideline compliance is dependent upon the extent to which provider- and workflow-focused strategies are implemented (Flanagan, Ramanujam & Doebbeling, 2009). Therefore, incorporating both types of strategies into the design of a quality improvement program has the potential to result in increased appropriate screening of current patients, improved use of clinic resources, expanded opportunities to provide wellness care to new patients, and engagement in clinic performance measurement moving forward.

Section III: Methodology

The question guiding this study was: What are the outcomes of the implementation of a systematic, guideline-based quality improvement program for cervical cancer screening in terms of compliance with national clinical practice guidelines for screening in an urban free clinic setting?

Study Design

This quality improvement project employed a descriptive comparison study design. Variables included in this study were prior screening tests performed, date of last screening, results of last screening test, provider recommendation for next screening and history of hysterectomy secondary to benign conditions. Baseline and 12 months post-implementation data collected on these variables provided the outcome measure, specifically the percentage of female patients receiving cervical cancer screening according to the adopted evidence-based office protocol.

Setting

The site of this quality improvement project was a safety net clinic in urban central Virginia which serves low-income uninsured men and women. Because safety net clinics are designed to narrow the health disparities gap, this clinic was an ideal setting to address inadequate screening for this vulnerable population.

Table 3

2011 Clinic Demographics

Gender:	Male	34%
	Female	66%
Age Range:	0-18	3%
	19-34	38%
	35-64	56%
	65+	3%
Race/Ethnicity:	Black	38%
	White	35%
	Hispanic	13%
Marital Status:	Single	63%
	Married	37%
Employment Status:	Employed	44%
	Unemployed	56%

(R. Bodemann, Director of Administration, Fan Free Clinic, personal communication, June 2012)

Demographics. The Clinic served 1,884 patients in 2011. Female patients represent 66% of the patient population seen at the Clinic. A breakdown of the demographic data on gender, age, race/ethnicity, and employment and marital status can be found in Table 3.

In order to qualify to receive care, uninsured patients must undergo an annual financial screening to determine whether they meet the requirements of uninsured status earning less than or equal to 200% of the federal poverty level prior to obtaining services. In 2011, 69% of the clinic patients earned less than 100% of the federal poverty level. Patients must also provide evidence of residence in one of the surrounding counties for at least three months. Permission-to-treat consent and personal data forms are offered in English and Spanish which are completed with the annual financial screening. HCA Healthcare subsidizes the cervical cancer screening tests for this not-for-profit free clinic. Both volunteer and employee providers perform approximately 50 cervical cancer screenings per month.

Sample

The sample for this study included all female patients determined to be financially-eligible during the study period. A query of the clinic database applying the parameters of the study timeframe of June 1, 2012 through June 1, 2013 identified 1,366 unique patient paper charts representing 1,846 total patient records during the study period.

Inclusion Criteria. Inclusion criteria for the study: female patients 21 years of age and older, financially-eligible as of June 1, 2012 or financially-eligible during the study period.

Exclusion Criteria. The exclusion criteria for the study were as follows:

- Female patients who were new to the clinic seeking care for the first time during the study period
- Female patients with a history of cervical cancer
- Female patients at baseline who were at higher risk for cervical cancer and ineligible for routine screening. These higher risk categories included a history of cervical intraepithelial neoplasia (CIN) II, III, cancer in-situ or cervical cancer, an abnormal Pap test within the past three years, a positive HPV test within the past 3 years without

evidence of a subsequent negative result, and a history of colposcopy without two consecutive negative Pap test results

- Female patients receiving non-screening Pap and HPV-DNA testing performed during the measurement period
- Female patients younger than 21 years of age at baseline
- Female patients older than 66 years of age at baseline

Two modifications to the exclusion criteria were necessary after proposal approval. First, new patients were initially included in the sample but exclusion of this group was necessary in order to perform the pre- and post-implementation statistical comparison. Second, patients with a history of hysterectomy secondary to benign conditions were initially excluded from the sample because screening is not recommended; however, this population must be included in order to calculate the percentage of over-screening using the selected quality measure.

Program Description

In order to accelerate quality improvement, organizations must have a clear direction, functional infrastructure, and commitment from leadership (DHHS, Health Resources and Services Administration, 2011). An advanced practice nurse (the author) provided the clear direction as the provider champion and project facilitator. A multidisciplinary quality improvement (QI) team provided the infrastructure for project implementation. The team -- consisting of the project facilitator, medical director, director of clinic operations, clinic outcomes coordinator, medical assistant, scheduling staff, information technology specialist and non-volunteer providers -- was educated on the aim and parameters of the QI program and was involved in developing, monitoring and refining the process. The clinic leadership committed to the project through the clinical protocol approval led by the project facilitator throughout April

and May 2012. Approval and adoption of the office protocol occurred on June 1, 2012 (see Figure 3).

Figure 3

Clinic Cervical Cancer Screening Protocol

Women younger than 21	• No cervical cancer screening regardless of sexual activity or other risk factors, unless the patient is immunocompromised (i.e., has HIV or a pre-existing invasive lesion on their cervix that is cancerous)
Women 21-29	• Cervical cancer screening every 3 years with cytology alone (accompanied by HPV DNA reflex testing as a diagnostic tool for AS-CUS)
Women 30-65	• Cervical cancer screening with a combination of cytology and HPV DNA testing every 5 years. If for any reason HPV DNA testing does not accompany cytology, recommend next screening in 3 years
Women older than 65	• Discontinue cervical cancer screening if adequate prior screening is documented (3 consecutive negative pap smears OR 1 negative pap smear accompanied by negative HPV DNA testing) and are not otherwise at high risk for cervical cancer (no history of CIN3+)
Women who have had a total hysterectomy with removal of the cervix	• No screening in the absence of a high-grade precancerous lesion (i.e., CIN 2 or 3) or cervical cancer. If unsure whether or not the cervix is intact based on patient report or past record, ascertain presence of cervix with a speculum and bimanual examination
HPV vaccinated women	• Women who have been vaccinated should continue to be screened following the protocol stated above until further evidence suggests otherwise
Effective 6/1/2012)	

Implementation Strategies. Upon approval and adoption of the revised clinic cervical cancer screening protocol, a six-month internal audit of the clinic database commenced to establish a baseline. Compliance with national guidelines and standards occurred when clinic staff implemented the following provider-, patient-, and workflow-focused strategies during the study period:

1. **Clinical Decision Support.** Findings from a recent systematic review of the use of clinical decision support systems identified four features as independent predictors of improved clinical practice: automatic provision of decision support as part of clinician workflow, provision of specific recommendations, provision of decision support at the time and location

of decision making, and computer based decision support (Kawamoto, Houlihan, Balas & Lobach, 2005). With these features in mind, first, the responsibility for interpretation of all screening results and determination of dates for next screening was transferred from multiple providers to a single, informed full-time provider. This procedural change provided the continuity and consistency that is inherently absent in a volunteer provider-based practice. A clinical decision support system was then created through the addition of database fields to the intake sheet with the single provider-generated dates of last screening and recommendation for the next screening. At the time of the visit, a provider may, at his or her discretion, review the chart to ensure agreement with the recommended date thus maintaining provider autonomy while at the same time reducing unnecessary variations and streamlining practice.

2. **Provider education.** Because active provider educational outreach is more effective than passively distributing guidelines (Grimshaw et al., 2001), individual provider educational outreach by the project facilitator was included as a provider-focused strategy. Serving as the peer champion/opinion leader for the newly-adopted office protocol, the project facilitator (author) met briefly with each of the seven providers who performed cervical cancer screening during the study period. The facilitator provided a summary table of the revised national guidelines, adopted office protocol, updated patient intake sheet, and project rationale for discussion.
3. **Patient reminder letters.** Based on two systematic reviews, the Community Preventive Services Task Force recommends the use of reminder letters to increase screening for cervical cancer on the basis of strong evidence of effectiveness when adapted to the target population (Community Preventive Services Task Force, 2012). However, the literature is mixed regarding the cost effectiveness of patient reminder letters. Mailing of one reminder

letter was found to be appropriate for most recommended care (Zhang &Fish, 2012). Therefore, upon completion of the internal audit, patients lacking current screening results, identified from a list from the database, received reminder letters in the mail. All patients for whom there was no record of up-to-date screening results in the clinic database received these letters mailed on February 20, 2013. The process of mailing reminder letters on a monthly basis to patients who are due for screening during the upcoming month began in April 2013.

4. **Procedures manual.** Because many factors impact whether or not a patient receives screening at any given visit (DHHS, Health Services and Resources Administration, 2011), a procedures manual (see Appendix A), including a clinical pathway algorithm with the accompanying supplemental "walkthrough" documentation, was developed with the assistance of the QI team. The manual and algorithm underwent revision as the process evolved throughout the study period. These implementation strategies represented one unified strategy with the goal of creating a synergistic effect on study outcomes and on the future improvement in and sustainability of guideline compliance.

Evaluation

Quality Measure. The quality measure (see Figure 4) by HealthPartners™ (Wehrle & Bussey, 2011), which measures average-risk asymptomatic women as "the percentage of women ages 21 years and older in the measurement year screened for cervical cancer in accordance with evidence-based standards," was selected for its ability to quantify both under- and over-screening. It was used to assess the degree to which cervical cancer screening services were delivered appropriately during the study period. Because the measure has been used to produce two clinical indicators reports, the measure demonstrated multiple-administration reliability. In

Figure 4

Study Quality Measure[±]

Inclusion Criteria	Exclusion Criteria
Denominator:	
All women ages 21 years and older at baseline (June 1, 2012) and at 12 months' post-implementation (June 1, 2013)	New patients enrolled during study period; women who have a history of any abnormal cervical cancer screening results, including cervical HPV, within the previous three years or with a history of cervical cancer
Numerator:	
The number of women from the denominator: **Screened in accordance with office protocol** **1** One screening Pap test in measurement year or within three years prior for women ages 21* to 29 and no history of hysterectomy for benign conditions. **2** One screening Pap test and one HPV DNA test in measurement year or within five years prior for women ages 30 to 65 and no history of hysterectomy secondary to benign conditions. **3** No screening Pap test in the measurement year of women ages 24 and older with history of hysterectomy secondary to benign conditions. **Under-screened according to office protocol** **4** No screening Pap test in measurement year or within three years prior for women ages 21* to 65 and no history of hysterectomy secondary to benign conditions. **5** Women with most recent screening result of "no endocervical cells" or "Unsatisfactory for evaluation" **Screened more frequently than recommended in office protocol** **6** Two or more screening Pap tests in measurement year or two years prior for women ages 21* to 29 and no history of hysterectomy secondary to benign conditions. **7** Two or more screening Pap tests and HPV DNA testing in measurement year or three years prior for women ages 30 to 65 and no history of hysterectomy secondary to benign conditions. **8** One or more Pap tests for women aged 21* and older with history of hysterectomy secondary to benign conditions.	All non-screening Pap and HPV-DNA testing performed during the measurement period.

*Included a 3-year look-back period.

± Adapted from NQMC - HealthPartners™ Quality Measure, Wehrle & Bussey, 2011)

addition, instructions for data collection were provided in the measure thus enhancing reproducibility.

The strengths of the selected measure include 1) the ability to evaluate both under- and over-screening (as previously indicated); 2) the age range of 21-65 which correlates with current guidelines, 3) the comparability of service type, and 4) the prior application of the measure to advanced practice nurses as professionals involved in the delivery of service (DHHS, Agency for Healthcare Research and Quality, 2012). Weaknesses of the selected quality measure include the fact that the measure is outdated despite a relatively recent report date of 2011 due to rapidly evolving guidelines for cervical cancer screening. Therefore, adaptations to the selected outcomes measure were necessary to accommodate the changes in the 2012 guidelines, which separated the sample into two age groups: 1) cytology performed every three years in women 21–65 years and 2) cytology/HPV co-testing performed every five years for women 30–65 years. These changes are in accordance with the proposed HEDIS 2014 changes (National Committee for Quality Assurance, 2013).

Quality indicators. The quality indicators for this study were selected using the HealthPartners™ quality measure and recommendations from the guidelines: 1) the percentage of female patients screened according to the office protocol, 2) the percentage of female patients under-screened according to the office protocol, and 3) the percentage of female patients screened more frequently than recommended in the office protocol.

Data Collection and Analysis

Institutional review board approval, received prior to the commencement of the study, was from the University of Virginia. All data were de-identified prior to statistical analysis. For purposes of this study, data collected from each patient chart (downloaded and stored in an Excel® spreadsheet) were on the quality measures found in Table 4. Coding of adherence to the protocol for each patient reflected the three quality indicators, *i.e.*, patients appropriately-screened, under-screened, and over-screened. Established female patients who lacked

documented cervical cancer screening results within the past three years fell into the under-screened category. To determine the frequency of over-screening, pre-implementation screening interval recommendations were compared with the protocol-recommended interval resulting in a revised next screening date. Finally, there was verification that each of the remaining patients fell into the appropriately screened category.

Table 4

Quality Measure Variables

- patient age
- gender (relevant in the case of transgender population)
- date and results of the pap test
- results of HPV DNA testing if performed,
- whether or not testing was performed for screening purposes
- code of the provider who performed the test
- code of the provider who originally reviewed the report
- original provider recommendation for next screening date in terms of time elapsed
- revised date for next screening of reports managed prior to implementation of the protocol

Descriptive statistics on the three quality indicators assessed the outcome of improvement efforts during the measurement period. Data analysis included a comparison of baseline and post-implementation percentages using the χ^2 test for significant differences in proportions of patients in each screening category due to large sample size (n=1,032). Cramér's V was used to describe the effect size of the χ^2 test, determining the degree of association between the screening categories and the two measurement time points (baseline and 12 months' post-implementation). The percentages were also compared to the *Healthy People 2020* target goal for cervical cancer screening as well as to surrounding city and county screening data in which the majority of the clinic patients reside. Statistical analyses were completed with IBM SPSS Statistics, Version 21.

Section IV: Results/Findings

A query of the clinic database applying the parameters of the study timeframe of June 1, 2012 through June 1, 2013 identified 1,366 unique patient charts representing 1,846 total patient records. The final sample consisted of 1,032 patient records after application of the exclusion criteria (see Figure 5) with patients aged 21-29 (n = 281) and aged 30-65 (n = 751) accounting for 27.2% and 72.8% of the baseline sample respectively. As presented in Table 5, the number of patients screened according to guidelines rose from 393 (38.1%) at baseline to 719 (69.7%) 12 months' post-implementation reflecting an increase of 31.6%. Conversely, the number of under-screened patients declined from 538 (52.1%) at baseline to 283 (27.4%) 12 months post-implementation reflecting a decrease of 24.7%. Likewise, the number of patients screened more frequently than recommended declined from 101 (9.8%) at baseline to 30 (2.9%) 12 months' post-implementation reflecting a decrease of 6.9%. A chi-square test of independence indicated that the proportions in each quality indicator category at baseline were significantly different from

Figure 5

Sample Flow Chart

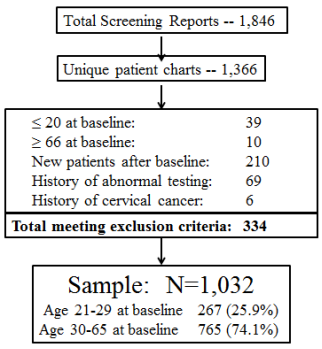


Table 5

Comparison of Screening Percentages for 3 Primary Quality Indicators

	Baseline (June 1, 2012) N = 1,032		**Post-implementation** (June 1, 2013) N = 1,032	
	Frequency	Percentage	Frequency	Percentage
Screened according to office protocol (Categories 1, 2 & 3)	393	38.1%	719	69.7%
Underscreened according to office protocol (Categories 4 & 5)	538	52.1%	283	27.4%
Screened more frequently than office protocol (Categories 6, 7 & 8)	101	9.8%	30	2.9%

Pearson χ^2 (2, N = 2,064) = 213.255, $p < .001$, Cramer's V = .321, $p < .001$

0 cells have expected count < 5. Minimum expected count 65.50

those at follow-up, χ^2 (2, N = 1,032) = 213.255, p < .001, Cramér's V = .321 reflecting a moderate association (Rea & Parker, 1992). The direction of percentage change was consistent for the three quality indicators across age groups with the 21-29 age-group having the highest percentage change. However, the calculation of the screening percentages by quality measure category revealed inconsistency in Categories 3, 5 and 8 (see Table 6). In Category 3, the percentage of women with a history of hysterectomy secondary to benign conditions not screened during the measurement year remained relatively unchanged (3.9% and 4.0% respectively). In Category 5, the percentage of women with the most recent result of "unsatisfactory" or "no endocervical cells" rose from 1.8% to 2.8%. Finally, in Category 8, the percentage of women with a history of hysterectomy secondary to benign conditions screened during the measurement year rose from 1.1% to 1.4%. Explanations for these inconsistencies will be provided at a later point.

Table 6

Comparison of Screening Percentages for 8 Quality Measure Categories

	Baseline (June 1, 2012) N = 1,032		**Post-implementation** (June 1, 2013) N = 1,032	
	n	**%**	**N**	**%**
Screened according to office protocol				
1 One screening Pap test in measurement year or within three years prior for women ages 21* to 29 and no history of hysterectomy secondary to benign conditions	85	8.2%	184	17.8%
2 One screening Pap test and one HPV DNA test in measurement year or within five years prior for women ages 30 to 65 and no history of hysterectomy secondary to benign conditions	268	26.0%	494	47.9%
3 No screening Pap test in the measurement year of women ages 21 and older with history of hysterectomy secondary to benign conditions	40	3.9%	41	4.0%
TOTAL	**393**	**38.1%**	**719**	**69.7%**
Not screened according to office protocol				
4 No screening Pap test in measurement year or within three years prior for women ages 21* to 65 and no history of hysterectomy secondary to benign conditions	519	50.3%	254	24.6%
5 Women with most recent screening result of "no endocervical cells" or "Unsatisfactory for evaluation"	19	1.8%	29	2.8%
TOTAL	**538**	**52.1%**	**283**	**27.4%**
Screened more frequently than office protocol				
6 Two or more screening Pap tests in measurement year or two years prior for women ages 21* to 29 and no history of hysterectomy secondary to benign conditions	28	2.7%	6	0.6%
7 Two or more screening Pap tests and HPV DNA testing in measurement year or three years prior for women ages 30 to 65 and no history of hysterectomy secondary to benign conditions	62	6.0%	10	1.0%
8 One or more Pap tests for women aged 21* and older with history of hysterectomy secondary to benign conditions	11	1.1%	14	1.4%
TOTAL	**101**	**9.8%**	**30**	**3.0%**

*Included 3-year look-back period.

Pearson χ^2 (7, N = 2,064) = 248.558, $p < .001$ Cramer's V = .347, $p < .001$

0 cells have expected count < 5. Minimum expected count 12.50

Section V: Discussion

The question guiding this study was: what are the outcomes of the implementation of a systematic, guideline-based quality improvement program for cervical cancer screening in terms of compliance with national clinical practice guidelines for screening in an urban free clinic setting? This discussion is organized around 1) theoretical application, 2) study outcomes, 3) study limitations, and 4) nursing implications.

Theoretical Application

The review of the literature on provider cervical cancer screening guideline compliance indicated that strategies beyond simple guideline distribution to providers are needed to limit unnecessary variations in practice. Expansion of the theory of DOI from provider compliance to practice compliance through the integration of the awareness-to-adherence model laid the foundation for the development of this multi-strategy initiative. This focus on practice compliance made it possible to implement improvement strategies which address select guideline adoption barriers identified by Davis and Taylor-Vaisey (1997), specifically provider knowledge deficits, practice inertia, paucity of cost containment incentives, and lack of organizational processes.

Study Outcomes

Overall, a chi-square test of independence indicated that the proportions in each quality indicator category at baseline were significantly different from those at 12-months' post-programmatic implementation. Through the combination of provider- and workflow-based implementation strategies, the number of patients appropriately screened nearly doubled from baseline (38.1% to 69.7%) using the selected quality measure. A previous provider-focused study, based on a representative sample and with a much higher baseline, found a 16.25%

improvement (73.95% to 90.20%) in women screened according to guidelines (Schwaiger, Aruda, LaCoursiere, Lynch & Rubin, 2013).

Conversely, the number of women screened more frequently than recommended in our study decreased from 9.8 to 2.9% reflecting marked improvement. Our results are consistent with those of a recent study identifying pediatric primary care provider educational outreach as the independent variable. Lozman, Belcher and Sloand (2013) also found a marked reduction (16.2% to 1.9%) in the number of sexually active adolescent females screened for cervical cancer which is in accordance with the 2012 guidelines. What separates our study from these other studies on provider-based strategies is that our study design reflects the evolution of guideline compliance research through the inclusion of workflow-based strategies.

Finally, the number of under-screened patients was nearly cut in half (from 52.1% to 24.7%) also reflecting marked improvement. Despite this substantial improvement from baseline, however, the post-implementation percentage of 69.7% for patients screened according to guidelines fell short of the *Healthy People 2020* baseline of 84.5% from 2008 data and the benchmark of 93%. In addition, the study post-implementation percentage is 16.4% below surrounding health districts (average of screening in Richmond City, Henrico and Chesterfield = 86.1%) and 14.5% below Virginia as a whole (84.2%) (VDH, 2012).

The presence of several determinants of health may have influenced the achievability of the improvement target. By its very nature, the free clinic population reflects a high vulnerability risk profile with the majority of clinic patients experiencing multiple risk factors (*i.e.*, low income, low education, and lack of health insurance). A clear dose-response relationship has been established regarding the disparity in the receipt of preventive services: as the number of risk factors increases, the receipt of preventive services declines (Shi & Stevens, 2005). The transient nature of this patient population with unstable insurance status, coupled with part-time

volunteer providers, makes continuity of care difficult. The low return of patients (32 of 282 or 11.3%) in response to the February and April reminder letters reflects this lack of continuity. Although recommending testing may lead to an increase in screening rates, making recommendations neither assures client adherence nor test completion. As previously noted, targeting compliance barriers with multifaceted implementation strategies, such as educating patients both verbally and in writing at the well-woman visit and/or addressing health literacy and language barriers, is more likely to be effective than mailing patient reminder letters as a single strategy (Grimshaw et al., 2001).

The inconsistencies regarding the screening of women with a history of hysterectomy secondary to benign conditions warrant further discussion. During the study period, select providers performed a pap test with a speculum examination (previously customary) on low-risk hysterectomized women instead of following the office protocol and simply verifying cervical absence. These pap tests performed in error prior to the discovery account for the relatively static percentage of hysterectomized women who had no screening during the measurement year (Category 3) as well as the rise in the percentage of hysterectomized women screened during the measurement year (Category 8). Subsequently, all women's health providers received updates on the correct procedure for these women.

The rise in the percentage of women with the most recent result of "unsatisfactory" or "no endocervical cells" (Category 5) also warrants further explanation. A rise in this category would be expected with an improvement in the screening tracking process after the chart audit. However, a clarification of the guidelines released during the study period required modification of the management of negative pap tests with absent or insufficient endocervical cells (Massad et al., 2013). Since 33 patients in the sample with these results no longer require intensive follow-up, they will in the future be considered "appropriately screened".

Limitations of Study Design

While the measurement of percentage was appropriate for this population, the application of the established quality measure precludes a number of analytical options. For example, although it was necessary to include only established patients for study comparison purposes, inclusion of the 210 new patients would have reflected an even higher percentage of patients (74.8% instead of 69.7%) screened according to the office protocol.

Because the study design required that the multi-faceted implementation strategies of this quality improvement program be treated as a unified strategy during analysis, another limitation of this study was its inability to link the outcomes to a specific intervention. Qualitative and long-term, prospective data collection is needed to further explore the influence of each intervention on guideline compliance.

Implications for Practice

Historically, efforts to address the barriers to cervical cancer screening guideline compliance have focused solely on changing provider behavior. A review of the literature on provider self-report and actual provider cervical cancer screening guideline adherence patterns clearly demonstrate that this narrow focus overlooks the complexities inherent in creating sustainable, evidence-based practice change. A multifaceted strategy that extends beyond changing provider behavior is needed. By combining Rogers' theory of diffusion of innovations with the Pathman et al. awarenesss-to-adherence model, the resulting guideline adoption model (Model) provided the framework to begin to disentangle the complexity of guideline compliance barriers. The unified strategy implemented in this study focused on one aspect of the Model – systematically changing practice policies and procedures with input from a quality improvement team.

On a broader scale, application of a systems approach is particularly timely with the movement toward Accountable Care Organizations (ACO) and Patient-Centered Medical Home (PCMH) models for primary care delivery. With encouragement from the Patient Protection and Affordable Care Act (PPACA) to improve health care quality and slow the growth of health care spending, primary care practices interested in obtaining ACO and/or PCMH recognition may find it helpful to consider incorporating into their overall quality improvement plan evidence-based provider-, patient-, and workflow-focused strategies similar to those implemented in this study.

From a public health perspective, the outcomes of this study demonstrate the need for quality improvement initiatives that target vulnerable populations who suffer disproportionately from chronic diseases. With cervical cancer screening as one of the preventive services covered by the PPACA, application of a similar multi-strategy initiative by for-profit and not-for-profit primary care practices alike has the potential to increase guideline compliance and ultimately reduce health disparities, improve quality, and decrease healthcare costs. Finally, as the Institute of Medicine's report *Future of Nursing: Leading Change, Advancing He*alth (Institute of Medicine, 2011) suggests, this quality improvement project exemplifies the leadership role that advanced practice nurses can play in improving the delivery of care and the broader health care system through the promotion of best prevention practices in the primary care setting.

Section VI: Manuscript

Evaluating a Quality Improvement Program for Cervical Cancer Screening Guideline Compliance

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Abstract

With a focus on changing practice policies, the question guiding this study was: what are the outcomes of the implementation of a systematic, guideline-based quality improvement program for cervical cancer screening in terms of compliance with national clinical practice guidelines for screening in an urban free clinic setting? The provider- and workflow-based strategies implemented in the quality improvement program included 1) the addition of a clinical decision support system, 2) provider educational outreach, 3) patient reminder letters, and 4) the development of a procedures manual. An established quality measure guided the selection of the quality indicators, specifically patients screened according to evidence-based guidelines, patients who were not screened, and patients screened more frequently than recommended. The findings from this study reflect marked improvements in all quality indicators.

Key words: cervical cancer screening, evidence-based guidelines, guideline compliance, quality improvement, implementation strategies, free clinic

Evaluating a Quality Improvement Program for Cervical Cancer Screening Guideline Compliance

Socioeconomic, geographic, and racial disparities influence the strong linkage between the incidence and mortality rates of cervical cancer and inadequate screening. In addition to inadequate screening, the literature clearly identifies the practice of screening many low-risk women for cervical cancer more frequently than recommended. This over-screening generates needless healthcare expenditures, patient inconvenience, and harm from false-positive results and unnecessary invasive procedures.[1] The effective quality improvement program would address the socioeconomic, geographic, and racial disparities that are linked to under-screening while at the same time decrease over-screening by reducing the use of low-value testing. Therefore, the following question guided this study: What are the outcomes of the implementation of a systematic, guideline-based quality improvement program for cervical cancer screening in terms of compliance with national clinical practice guidelines for screening in an urban free clinic setting?

Literature Review

A review of the literature provided an historical perspective on provider cervical cancer screening guideline adoption practices. A synthesis of the results revealed high provider self-report of awareness of guidelines. However, there was low agreement with and adoption of an extended screening interval despite a ten-year history of this recommendation in national guidelines. One reason for this low adoption rate may be the multiplicity of clinical practice guidelines from influential professional organizations over the past two decades. The variability of these guidelines caused much confusion regarding best cervical cancer detection practices[2]. More recently, there was an increased understanding of the natural history of HPV infection and its role in the development of cervical cancer. This understanding, accompanied by improved

testing, led to the alignment of national recommendations in 2012 regarding the timing of cervical cancer screening initiation, the conditions warranting discontinuation of screening, and the extension of the screening interval[3]. Although slight movement toward adoption of these current guidelines has occurred, a large gap continues to persist between what is known and what is consistently done 'in the real world', and there is strong evidence that the availability of evidence-based guidelines alone is insufficient to change practice[4]. In a systematic review of guideline adoption practices, Davis and Taylor-Vaisey[5] found that the barriers to guideline compliance included provider and patient knowledge deficits, the inertia of established practice, a paucity of cost containment incentives by payers and insurers, and a lack of organizational processes. These barriers extend beyond provider resistance and addressing them is essential to achieve improved guideline compliance.

According to Grimshaw et al.[6], targeting compliance barriers with active, multifaceted implementation strategies is more likely to be effective than passive, single strategies. Additionally, recent studies have revealed that guideline compliance is dependent upon the extent to which provider- and workflow-focused strategies are implemented[7]. Therefore, incorporating both types of strategies in the design of a quality improvement program has the potential to result in increased appropriate screening of current patients. In addition, expanded opportunities may exist to provide wellness care to new patients, to improve the use of clinic resources through elimination of excessive screening, and to engage in clinic performance measurement and clinic guideline compliance moving forward.

Methods

The site of this quality improvement project was a safety net clinic in urban central Virginia. Variables included in this descriptive comparison study were prior screening tests performed, date of last screening, results of last screening test, provider recommendation for next

screening, and history of hysterectomy secondary to benign conditions. Baseline and 12 months post-implementation data collected on these variables provided the outcome measure; specifically, the percentage of female patients receiving cervical cancer screening according to the adopted evidence-based office protocol.

[Insert Table 1 here]

The inclusion criteria for the study were female patients 21 years of age and older who were financially eligible as of June 1, 2012 or who became financially eligible during the study period. The exclusion criteria for the study were as follows:

1. Female patients who were new to the clinic seeking care for the first time during the study period;
2. Female patients with a history of cervical cancer;
3. Female patients at baseline who were at higher risk for cervical cancer and ineligible for routine screening. These higher risk categories included a history of CIN II, III, cancer in-situ or cervical cancer, an abnormal Pap test within the past three years, a positive HPV test within the past 3 years without evidence of a subsequent negative result, and a history of colposcopy without two consecutive negative Pap test results.
4. Female patients receiving non-screening Pap and HPV-DNA testing performed during the measurement period.
5. Female patients younger than 21 years of age and over 66 years of age.

Program Description

A multidisciplinary quality improvement (QI) team provided the functional infrastructure for project implementation. The team -- consisting of a project facilitator (author), medical director, director of clinic operations, clinic outcomes coordinator, medical assistants, scheduling staff, information technology specialist, and non-volunteer providers -- was educated on the aim

and parameters of the QI program and was involved in developing, monitoring and refining the process. The clinic leadership committed to the project through the clinical protocol approval process led by the project facilitator throughout April and May 2012. Approval and adoption of the office protocol occurred on June 1, 2012.

Upon approval and adoption of the revised clinic cervical cancer screening protocol, a six-month internal audit of the clinic database commenced to establish a baseline. Compliance with national guidelines and standards occurred when clinic staff implemented the following provider- and workflow-focused strategies during the study period:

1. **Clinical Decision Support**. Creation of a clinical decision support system included the addition of database fields to the intake sheet with the dates of last screening and recommendation for the next screening. An informed full-time provider, rather than multiple providers, took responsibility for interpreting all screening results and determining dates for next screening.
2. **Provider education.** The project facilitator (author) met briefly with each of the seven providers who performed cervical cancer screening during the study period. The facilitator provided a summary table of the revised national guidelines, adopted office protocol, updated patient intake sheet, and project rationale for discussion.
3. **Patient reminder letters.** Upon completion of the internal audit, patients lacking current screening results, identified from a list from the database, received reminder letters in the mail. All patients for whom there was no record of up-to-date screening results in the clinic database received these letters mailed on February 20, 2013. The process of mailing reminder letters on a monthly basis to patients who are due for screening during the upcoming month began in April 2013.

4. **Procedures manual.** Because many factors impact whether or not a patient receives screening at any given visit[8], a procedures manual, including a clinical pathway algorithm with the accompanying supplemental "walkthrough" documentation, was developed with the assistance of the QI team. The manual and algorithm underwent revision as the process evolved throughout the study period.

[Insert Figure 1 here]

These implementation strategies represented one unified strategy for purposes of outcomes measurement with the goal of creating a synergistic effect on study outcomes and on the future improvement in and sustainability of guideline compliance.

Outcomes Measure

The quality measure by HealthPartners™ [9] measuring average-risk asymptomatic women as "the percentage of women ages 21 years and older in the measurement year screened for cervical cancer in accordance with evidence-based standards" was selected for its ability to quantify both under- and over-screening. Adaptations to the measure were necessary to accommodate the changes in the 2012 guidelines.

[Insert Table 4 here]

The quality indicators selected for this study included a combination of the HealthPartners™ quality measure and the recommendations from the selected guideline. They used the calculation of the percentage of female patients 1) screened according to the office protocol, 2) under-screened according to the office protocol, and, 3) screened more frequently than recommended in the office protocol.

Data Collection

Institutional review board (IRB) approval, received prior to the commencement of the study, was from the University of Virginia. All data were de-identified prior to statistical

analysis. For purposes of this study, data collected from each patient chart, and then downloaded and stored in an Excel® spreadsheet, were on the following quality measures:

- patient age
- gender (relevant in the case of transgender population)
- the date and results of the pap test
- results of HPV DNA testing if performed,
- whether or not testing was performed for screening purposes
- the code of the provider who performed the test
- the code of the provider who originally reviewed the report
- the original provider recommendation for next screening date in terms of time elapsed, and
- the revised date for next screening of reports managed prior to implementation of the protocol.

Coding of adherence to the protocol for each patient reflected the three quality indicators, *i.e.*, patients appropriately screened, under-screened, and over-screened. Established female patients who lacked documented cervical cancer screening results within the past three years fell into the under-screened category. To determine the frequency of over-screening, pre-implementation screening interval recommendations were compared with the protocol-recommended interval resulting in a revised next screening date. Finally, there was verification that each of the remaining patients fell into the appropriately screened category.

Descriptive statistics on the three quality indicators assessed the outcome of improvement efforts during the measurement period. Statistical analyses were completed with IBM SPSS Statistics, Version 21.

Results

A query of the clinic database applying the parameters of the study timeframe of June 1, 2012 through June 1, 2013 identified 1,366 unique patient charts representing 1,846 total patient records. The final sample consisted of 1,032 patient records after application of the exclusion criteria with patients aged 21-29 (n = 281) and aged 30-65 (n = 751) accounting for 27.2% and 72.8% of the baseline sample respectively. As presented in Table 2, the number of patients screened according to guidelines rose from 393 (38.1%) at baseline to 719 (69.7%) 12 months' post-implementation reflecting an increase of 31.6%. Conversely, the number of unscreened patients declined from 538 (52.1%) at baseline to 283 (27.4%) 12 months post-implementation reflecting a decrease of 27.4%. Likewise, the number of patients screened more frequently than recommended declined from 101 (9.8%) at baseline to 30 (2.9%) 12 months post-implementation reflecting a decrease of 6.9%.

[Insert Table 2 here]

A Pearson's chi-square test of independence indicated that the proportions in each quality indicator category at baseline were significantly different from those at follow-up, χ^2 (2, N = 1,032) = 213.255, $p < .001$, Cramér's $V = .321$ reflecting a moderate association. The direction of percentage change was consistent for the three quality indicators across age groups, with the 21-29 age-group having the highest percentage change. However, the calculation of the screening percentages by quality measure category revealed inconsistency in Categories 3, 5 and 8 (Refer to Table 3). In Category 3, the percentage of women with a history of hysterectomy secondary to benign conditions who had no screening during the measurement year remained relatively unchanged (3.9% and 4.0% respectively). In Category 5, the percentage of women with the most recent result of "unsatisfactory" or "no endocervical cells" rose from 1.8% to

2.8%. Finally, in Category 8, the percentage of women with a history of hysterectomy secondary to benign conditions who were screening during the measurement year rose from 1.1% to 1.4%.

[Insert Table 3 here]

Discussion

Through the combination of provider- and workflow-based implementation strategies, the number of patients appropriately screened nearly doubled from baseline (38.1% to 69.7%) using the selected quality measure. A previous provider-based study, based on a representative sample and with a much higher baseline, found a 16.25% improvement (73.95% to 90.20%) in women screened according to guidelines.[10]

Conversely, the number of women screened more frequently than recommended in our study decreased from 9.8 to 2.9% reflecting marked improvement. Our results are consistent with those of a recent study identifying pediatric primary care provider educational outreach as the independent variable. Lozman, Belcher and Sloand[11] found a marked reduction (16.2% to 1.9%) in the number of sexually active adolescent females screened for cervical cancer, which is in accordance with the 2012 guidelines. What separates our study from these other studies on provider-based strategies is that our study design and results reflect the evolution of guideline compliance research through the inclusion of workflow-based strategies.

Finally, the number of under-screened patients was nearly cut in half (from 52.1% to 24.7%) also reflecting marked improvement. Despite this substantial improvement from baseline, however, the clinic fell short of achieving the 93% *Healthy People 2020* benchmark.[12] The presence of several determinants of health may have influenced the achievability of the improvement target. By its very nature, the free clinic population reflects a high vulnerability risk profile with the majority of clinic patients experiencing multiple risk factors (*i.e.*, low income, low education, and lack of health insurance). A clear dose-response relationship has

been established regarding the disparity in the receipt of preventive services: as the number of risk factors increase, the receipt of preventive services declines.[13] The transient nature of this patient population with unstable insurance status, coupled with part-time volunteer providers, makes continuity of care difficult. The low return of patients (32 of 282 or 11.3%) in response to the February and April reminder letters reflects this lack of continuity. Although recommending testing may lead to an increase in screening rates, making recommendations neither assures client adherence nor test completion. As previously noted, targeting compliance barriers with multifaceted implementation strategies, such as educating patients both verbally and in writing at the well-woman visit and/or addressing health literacy and language barriers, is more likely to be effective than mailing patient reminder letters as a single strategy (Grimshaw et al., 2001).

The inconsistencies regarding the screening of women with a history of hysterectomy secondary to benign conditions warrant further discussion. During the study period, select providers performed a pap test with a speculum examination (previously customary) on low-risk hysterectomized women instead of simply verifying cervical absence. These pap tests performed in error prior to the discovery account for the relatively static percentage of hysterectomized women who had no screening during the measurement year (Category 3) as well as the rise in the percentage of hysterectomized women screened during the measurement year (Category 8). Subsequently, all women's health providers received updates on the correct procedure for these women.

The rise in the percentage of women with the most recent result of "unsatisfactory" or "no endocervical cells" (Category 5) also warrants further explanation. A rise in this category would be due solely to an improvement in the screening tracking process after the chart audit. However, a clarification of the guidelines released during the study period required that providers modify the management of negative pap tests with absent or insufficient endocervical cells[14]. Since 33

patients in the sample with these results no longer require intensive follow-up, they will be considered "appropriately screened" in the future.

Study Limitations

While the measurement of percentage is appropriate for this population, the application of the established quality measure precludes a number of analytical options. For example, although it was necessary to include only established patients for study comparison purposes, inclusion of the 210 new patients would have reflected an even higher percentage of patients (74.8% instead of 69.7%) screened according to the office protocol.

Because the study design required that the multi-faceted implementation strategies of this quality improvement program be treated as a unified strategy during analysis, another limitation of this study was its inability to link the outcomes to a specific intervention. Qualitative and long-term, prospective data collection is needed to further explore the influence of each intervention of the unified strategy on guideline compliance.

Implications for Practice

Historically, efforts to address the barriers to cervical cancer screening guideline compliance have focused solely on changing provider behavior. This narrow focus overlooks the complexities inherent in creating sustainable, evidence-based practice change. Strategies that extend beyond changing provider behavior are needed to begin to disentangle the complexity of guideline compliance barriers. Application of a systems approach provided the structure and processes needed to maximize best use of clinic resources and improve population outcomes. On a broader scale, application of a systems approach is particularly timely with the movement toward Accountable Care Organizations (ACO) and Patient-Centered Medical Home (PCMH) models for primary care delivery. With encouragement from the Patient Protection and Affordable Care Act (PPACA) to improve health care quality and slow the growth of health care

spending, primary care practices interested in obtaining ACO and/or PCMH recognition may find it helpful to consider incorporating evidence-based provider-, patient-, and workflow-focused strategies similar to those implemented in this study.

From a public health perspective, the outcomes of this study demonstrate the need for quality improvement initiatives that target vulnerable populations who suffer disproportionately from chronic diseases. With cervical cancer screening as one of the preventive services covered by the PPACA, application of a similar multi-strategy initiative by for-profit and not-for-profit primary care practices alike has the potential to increase guideline compliance, and ultimately reduce health disparities, improve quality, and decrease healthcare costs.

Finally, as the Institute of Medicine's report *Future of Nursing: Leading Change, Advancing Health* (Institute of Medicine, 2011) suggests, this quality improvement project exemplifies the leadership role that advanced practice nurses can play in improving the delivery of care and the broader health care system through the promotion of best prevention practices in the primary care setting.

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Table 1

Clinic Cervical Cancer Screening Protocol

Women younger than 21	• No cervical cancer screening regardless of sexual activity or other risk factors, unless the patient is immunocompromised (i.e., has HIV or a pre-existing invasive lesion on their cervix that is cancerous)
Women 21-29	• Cervical cancer screening every 3 years with cytology alone (accompanied by HPV DNA reflex testing as a diagnostic tool for AS-CUS)
Women 30-65	• Cervical cancer screening with a combination of cytology and HPV DNA testing every 5 years. If for any reason HPV DNA testing does not accompany cytology, recommend next screening in 3 years
Women older than 65	• Discontinue cervical cancer screening if adequate prior screening is documented (3 consecutive negative pap smears OR 1 negative pap smear accompanied by negative HPV DNA testing) and are not otherwise at high risk for cervical cancer (no history of CIN3+)
Women who have had a total hysterectomy with removal of the cervix	• No screening in the absence of a high-grade precancerous lesion (i.e., CIN 2 or 3) or cervical cancer. If unsure whether or not the cervix is intact based on patient report or past record, ascertain presence of cervix with a speculum and bimanual examination
HPV vaccinated women	• Women who have been vaccinated should continue to be screened following the protocol stated above until further evidence suggests otherwise

Table 2

Comparison of Screening Percentages of 3 Primary Quality Indicators

	Baseline (June 1, 2012) N = 1,032		Post-implementation (June 1, 2013) N = 1,032	
	Frequency	%	Frequency	%
Screened according to office protocol (Categories 1, 2 & 3)	393	38.1%	719	69.7%
Underscreened according to office protocol (Categories 4 & 5)	538	52.1%	283	27.4%
Screened more frequently than office protocol (Categories 6, 7 & 8)	101	9.8%	30	2.9%

Pearson x^2 (2, N = 2,064) = 213.255, $p < .001$, Cramer's V = .321, $p < .001$

0 cells have expected count < 5. Minimum expected count 65.50

Table 3

Comparison of Screening Percentages for 8 Quality Measure Categories

	Baseline (June 1, 2012) N = 1,032		**Post-implementation** (June 1, 2013) N = 1,032	
	n	**%**	**n**	**%**
Screened according to office protocol				
1 One screening Pap test in measurement year or within three years prior for women ages 21* to 29 and no history of hysterectomy secondary to benign conditions	85	8.2%	184	17.8%
2 One screening Pap test and one HPV DNA test in measurement year or within five years prior for women ages 30 to 65 and no history of hysterectomy secondary to benign conditions	268	26.0%	494	47.9%
3 No screening Pap test in the measurement year of women ages 21 and older with history of hysterectomy secondary to benign conditions	40	3.9%	41	4.0%
TOTAL	**393**	**38.1%**	**719**	**69.7%**
Not screened according to office protocol				
4 No screening Pap test in measurement year or within three years prior for women ages 21* to 65 and no history of hysterectomy secondary to benign conditions	519	50.3%	254	24.6%
5 Women with most recent screening result of "no endocervical cells" or "Unsatisfactory for evaluation"	19	1.8%	29	2.8%
TOTAL	**538**	**52.1%**	**283**	**27.4%**
Screened more frequently than office protocol				
6 Two or more screening Pap tests in measurement year or two years prior for women ages 21* to 29 and no history of hysterectomy secondary to benign conditions	28	2.7%	6	0.6%
7 Two or more screening Pap tests and HPV DNA testing in measurement year or three years prior for women ages 30 to 65 and no history of hysterectomy secondary to benign conditions	62	6.0%	10	1.0%
8 One or more Pap tests for women aged 21* and older with history of hysterectomy secondary to benign conditions	11	1.1%	14	1.4%
TOTAL	**101**	**9.8%**	**30**	**3.0%**

*Included 3-year look-back period.

Pearson x^2 (7, N = 2,064) = 248.558, $p < .001$ Cramer's V = .347, $p < .001$

0 cells have expected count < 5. Minimum expected count 12.50

Table 4

Study Quality Measure[±]

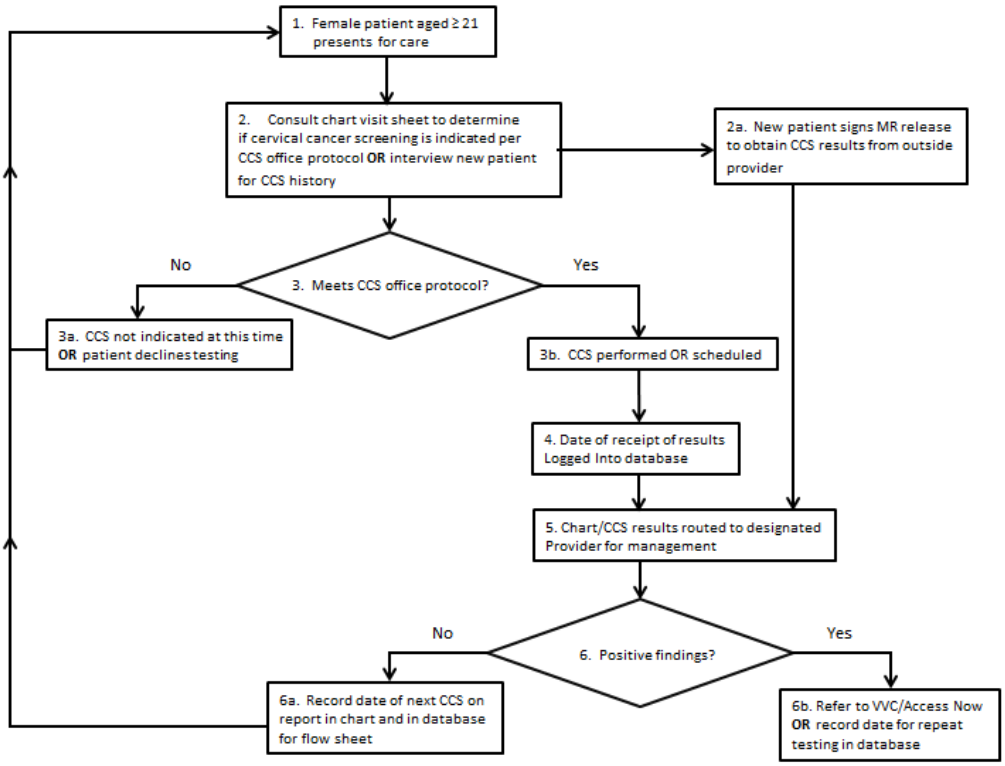
Inclusion Criteria	Exclusion Criteria
Denominator:	
All women ages 21 years and older at baseline (June 1, 2012) and at 12 months' post-implementation (June 1, 2013)	New patients enrolled during study period; women who have a history of any abnormal cervical cancer screening results, including cervical HPV, within the previous three years or with a history of cervical cancer
Numerator:	
The number of women from the denominator:	All non-screening Pap and HPV-DNA testing performed during the measurement period.
Screened in accordance with office protocol	
1 One screening Pap test in measurement year or within three years prior for women ages 21* to 29 and no history of hysterectomy secondary to benign conditions.	
2 One screening Pap test and one HPV DNA test in measurement year or within five years prior for women ages 30 to 65 and no history of hysterectomy secondary to benign conditions.	
3 No screening Pap test in the measurement year of women ages 24 and older with history of hysterectomy secondary to benign conditions.	
Under-screened according to office protocol	
4 No screening Pap test in measurement year or within three years prior for women ages 21* to 65 and no history of hysterectomy secondary to benign conditions.	
5 Women with most recent screening result of "no endocervical cells" or "Unsatisfactory for evaluation"	
Screened more frequently than recommended in office protocol	
6 Two or more screening Pap tests in measurement year or two years prior for women ages 21* to 29 and no history of hysterectomy secondary to benign conditions.	
7 Two or more screening Pap tests and HPV DNA testing in measurement year or three years prior for women ages 30 to 65 and no history of hysterectomy secondary to benign conditions.	
8 One or more Pap tests for women aged 21* and older with history of hysterectomy secondary to benign conditions.	

*Included a 3-year look-back period.

± Adapted from NQMC - HealthPartners™ Quality Measure, Wehrle & Bussey, 2011)

Figure 1

Cervical Cancer Screening Clinical Pathway



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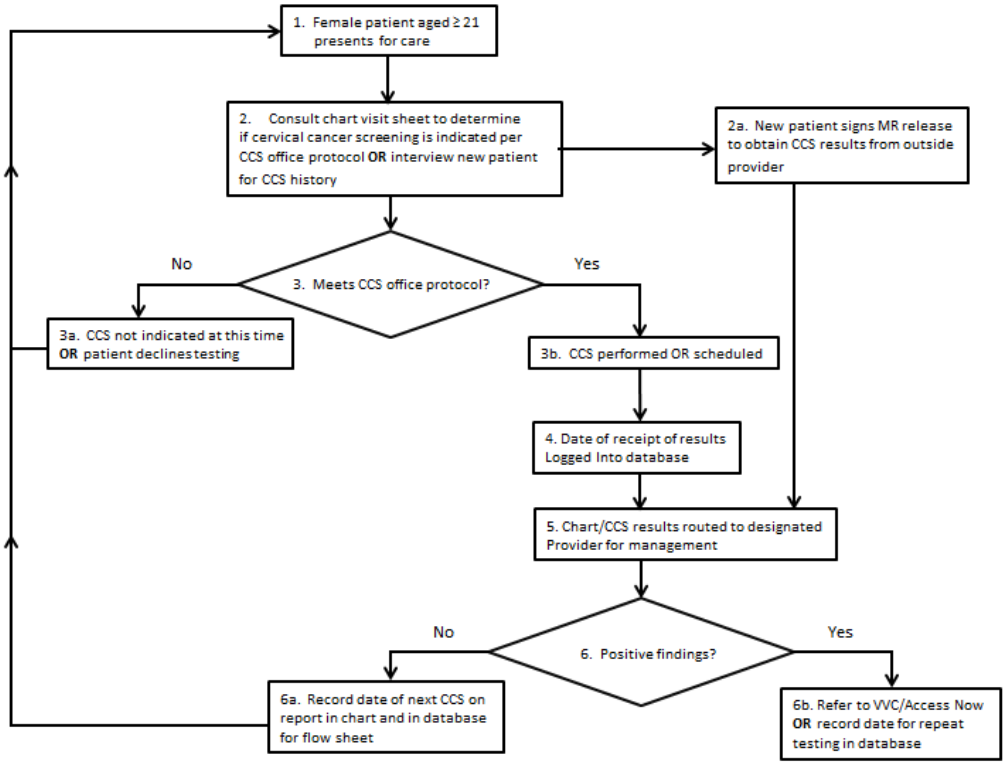
APPENDIX A

Cervical Cancer Screening Procedures Manual

Cervical Cancer Screening Clinical Pathway



Adapted from U.S. Department of Health & Human Services. Health Resources and Services Administration. (2011). Cervical Cancer Screening.

http://www.hrsa.gov/quality/toolbox/508pdfs/cervicalcancerscreening.pdf

Walkthrough of the Fan Free Clinic Cervical Cancer Screening Clinical Pathway

The steps illustrated in the schematic reflect the system for cervical cancer screening officially implemented at the Fan Free Clinic on June 1, 2012. Establishing a process to retrieve and review cytology results is important for tracking the number of completed screenings and a patient's adherence to recommended guidelines. Internal systems should clearly define who reviews the results of both positive and negative screenings. This pathway represents the steps needed to ensure that systematic guideline-based screening for cervical cancer systematically occurs for average risk female patients at the Clinic. These steps are pertinent to effective cervical cancer screening:

1. Data on natural history of HPV infection and the incidence of high-grade lesions and cervical cancer suggest that screening can safely be delayed until age 21.

2. Use of the approved office protocol has been tailored toward a standard of care according to best practices. The provider should consult the flow sheet for each patient visit to determine the recommended date of next cervical cancer screening OR interview a new patient for cervical cancer screening history. Female patients who are between 21 and 29 years of age should be offered cervical cytologic testing every three years until age 30. Female patients who are between the ages of 30 and 65 years of age should be offered cervical cytologic and HPV DNA testing at five-year intervals until age 65 in the presence of negative results. Discontinuation of cervical cancer screening in women over age 65 is recommended, provided women have had 3 consecutive negative Pap tests (one of which occurring in the past 5 years) and/or 2 consecutive negative HPV DNA tests (one of which occurring in the past 5 years).

2a. Because self-reported cervical cancer screening may result in an optimistically high screening rate, documentation in the medical record must include one of the following:

1. a copy of the lab report indicating the date the test was performed and its result;
2. a note from an outside provider documenting the name, date, and results of a test

The new patient should be requested to sign a Medical Records release form to obtain CCS results from an outside provider. Patients who are aged 21 years or older should be strongly encouraged to undergo cytologic screening.

3. If a patient does not meet cervical cancer screening guidelines, she is not screened but healthy behaviors to prevent cervical cancer should be reinforced. Guidelines are emphasized so the patient understands the benefits of cervical cancer screening and its risk factors.

3a. If cervical cancer screening is not indicated at this visit, the office visit should proceed without any additional action required. In addition, a patient may choose to decline screening even if strongly encouraged by the health care team. If she does decline, a note should be made in her chart and the database to document her decision.

3b. If it is determined that cervical cancer screening is indicated, the provider should 1) refer the patient to a Clinic women's health provider for her well-woman exam (preferred) OR 2) perform the screening at this visit, particularly if the appointment is a complete physical (including a clinical breast exam).

4. The date the screening is performed and the date results are received are logged into the database by the medical assistant.

5. Upon receipt of the results, the medical assistant will ensure the chart is pulled and matched with the results and then forwarded to the designated provider for management. This same procedure should be followed upon receipt of results from screening outside the clinic (Referring to 2a above).

6. Due to financial constraints, a "no-news-is-good-news" approach to negative screening results is used in the Clinic.

6a. Negative screening results should prompt interval screening recommendations per the adopted guidelines. The date for next screening should be documented on the screening results in the chart and in the database -- the cycle then repeats.

6b. If screening results are positive, management recommendations will include either 1) a referral to Access Now for additional diagnostic testing or treatment OR 2) a recommendation for repeat testing by the designated provider. The positive results, an explanation of these results, and recommended management according to ASCCP guidelines should be communicated personally to the patient in a culturally-sensitive manner via telephone call. If after 3 attempts personal telephone contact is not made, a letter will be sent to the patient advising her to contact the Clinic. A patient will return to routine screening upon successful management of a previously-abnormal result.

Ensuring that cervical cancer screening has been completed is essential for preventive care. Care teams should invite a conversation about any barriers – real or perceived – to completing the cervical cancer screening and work together with a patient to mitigate those barriers.

APPENDIX B

FAN FREE CLINIC

1010 North Thompson Street | Richmond, Virginia | 23230

804.358.6343 | www.fanfreeclinic.org

June 1, 2012

Attn: University of Virginia
Institutional Review Board

Re: Robin Hills -- Project on Cervical Cancer Screening Protocol Implementation

This letter serves to verify that the request by Robin Hills to conduct the project on Implementing the Cervical Cancer Screening Office Protocol adopted on this date, June 1st, 2012 at the Fan Free Clinic is approved.

Please contact me should you need any further information. My number is (804) 358-6343 extension 136.

Sincerely,

Catherine K. Wheeler

Catherine K. Wheeler
Director of Clinical Operations